FINAL PUBLISHABLE REPORT

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Internal Funded Partners: 1. CMI, Czech Republic 2. BEV PTP, Austria 3. GUM, Poland 4. IMBiH, Bosnia and Herzegovina 5. IPQ, Portugal 6. NSAI, Ireland 7. PTB, Germany 8. SMU, Slovakia	External Funded Partners: 9. UL, Slovenia	Unfunded Partners:
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1 Overview

This project aimed to improve the reliability and accuracy of blood pressure (BP) measurements by developing an advanced oscillometric signal generator (aOSG) and by establishing new calibration procedures and services for blood pressure metrology. Meeting the technical objectives made in-depth accuracy assessment of sphygmomanometers easier, faster and it improved traceability chain for blood pressure measurements. Furthermore, the project established a competence centre for blood pressure metrology and created a network in this field consisting of NMIs, DIs, surveillance bodies and medical professionals. The competence centre and implementation of smart specialisation concept for blood pressure, representing the capacity building objectives, makes metrology for advanced blood pressure measurement accessible to a broader range of interested parties and provides support for blood pressure metrology even beyond the project lifetime.

2 Need

Hypertension affects almost half of the European population and is responsible for 13 % of all non-accidental deaths. Hypertension increases the probability of stroke, heart attack and kidney diseases, causing over 22 % of all heart attacks. Reliable and accurate BP measurements using sphygmomanometers (SMs) are indispensable in the diagnostic and treatment of hypertension as its detection is very sensitive to measurement errors. Studies show that even small deviations can have critical consequences.

While the European legislation requires lengthy and costly clinical trials before a new sphygmomanometer enters the market, such trials are not performed on every manufactured device, but on single, well-maintained specimens. In addition, despite the fact that periodical verifications of medical devices in use are recommended by the European Society of Hypertension, most EU countries ignore this recommendation. Only few countries adopt mandatory periodical checks for SMs in operation. Currently these checks are only performed at static pressure and check the accuracy of the pressure sensor. The algorithm used for the determination of the systolic and diastolic pressure is ignored and consequently the accuracy of the measurands themselves is never examined.

The challenges in the area of BP measurements are exacerbated by an insufficient metrology infrastructure at NMI level, where blood pressure metrology is considered of secondary importance to pressure metrology. Consequently, instead of establishing urgently needed true traceability for dynamic oscillometric instruments, only the surrogate of static pressure measurements is verified.

To rectify this situation, a new standard for suitable blood pressure measurements, capable of generating BP signals indistinguishable from real-life human signals was needed. As there were no aOSG on the market, this had to be developed and tested. As there were no procedures for testing sphygmomanometers with such a device available, corresponding procedures had to be defined as well. Using aOSGs for SM testing would solve the problem on the device level but the aOSGs must also be adequately calibrated. To exploit the full potential, the complete traceability chain for aOSGs had to be established as well.

3 Objectives

The overall aim of the project was to develop sustainable metrological research capabilities to provide traceability for blood pressure measurement in Europe. This included the development of a new advanced blood pressure oscillometric signal generator and investigation of its possible role as an absolute blood pressure standard to carry out checks of the performance of sphygmomanometers.

The specific objectives were:

1. **To develop an advanced oscillometric signal generator device** with the capability of accurately reproducing pre-recorded real-life oscillometric blood pressure pulses.
2. **To define the necessary requirements and test procedures** for the newly developed advanced oscillometric signal generator to become a reference standard to establish traceability for automated sphygmomanometers.
3. **To develop a procedure for the periodic recalibration of the newly developed advanced oscillometric signal generator** at the NMI level, including defining acceptable uncertainty limits of ±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 regarding blood pressure measuring devices 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**. To establish a single joint research capacity and 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 internal partner, to develop an individual strategy for the long-term operation and transnational use of this joint research capacity, and for the access to its calibration and testing services from their respective countries. The individual strategies would be discussed within the consortium, to ensure that a coordinated and optimised approach to the development of traceability in this field is developed which is suitable for Europe as a whole.

4 Results

To develop an advanced oscillometric signal generator device

The main aim of the project was to develop an oscillometric signal generator (aOSG) capable of accurately, precisely and repeatably re-generating human oscillometric signals in order to ensure an in-depth testing of automated sphygmomanometers.

The aOSG is an advanced type of blood pressure simulator. Blood pressure simulators are devices generating artificial blood pressure oscillations in the pneumatic system of an automated sphygmomanometers in order to test the automated sphygmomanometers. While there is number of commercial simulators available on the market, these are mostly employed for the quick and basic testing of automated sphygmomanometers as they are limited in the options offered and they always generate idealised signals which to some degree differ from real-life oscillometric signals. In contrast, the developed aOSG is able to accurately recreate pre-recorded real-life oscillometric signals. The oscillometric signals that are send to the tested sphygmomanometer are synthetised from real-life signals stored in a database used by the aOSG.

The design and manufacturing of the device as well as the development of the accompanying software were carried out by PTB. The technical and metrological specifications for the aOSG were defined early in the project. The needed components for the device were identified based on literature research and prior experience in order to ensure a reliable performance of the device, while the requirements for the software concentrated on ensuring the complex processing of the recorded data while keeping the user interface friendly.

Key hardware components of the developed aOSG consist of pneumatic chamber with a diaphragm that generates small pneumatic oscillations. Movement of the diaphragm is controlled by a servomotor connected by lever system.

Unlike its commercial counterparts, the aOSG uses pre-recorded real-life oscillometric signals. For the purposes of the project, the consortium was authorised to use database from the Newcastle University. The database contains approximately 1300 signals from 600 patients which were collected 20 years ago from patients attending the Freeman Hospital in Newcastle.

To be used in testing of a sphygmomanometer with the aOSG, the oscillometric signals have to processed in several steps. First the signal was recorded and the value of blood pressure they represent was determined by two observers. To be used by the simulator, the raw data have to be processed to obtain the simulated signal to be output by the simulator.

First, the arterial pressure oscillations are separated from the baseline pressure and the resulting oscillations are displayed as a function of the baseline pressure. Next step involves the segmentation of the oscillations into single oscillation periods and the corresponding cuff pressure range. The individual segments are then stored in a new database directly on the computer controlling the simulator together with the corresponding baseline pressure. During the testing of a sphygmomanometer, the software of the developed aOSG selects the segment corresponding to the measured baseline pressure of the sphygmomanometer.

In the final step, the simulated signal will be applied to the tested sphygmomanometer. In order to test an automated sphygmomanometer using the aOSG, the latter is linked to the pneumatic system of the automated sphygmomanometer to be tested as well as to a computer which is used to operate the aOSG via a non-

commercial software (developed by PTB as well). The cuff is wrapped around a rigid metal cylinder instead of a human limb.

Once a measurement is started, the cuff pressure is controlled by the tested sphygmomanometer. Using the software, the aOSG measures the momentary cuff pressure at any time during the deflation, seeks the best-fitting pressure oscillation from the new database based on the corresponding pressure, and replicates it, i.e., generates a pressure oscillation which is superimposed to the cuff pressure. This process is reiterated until a minimum baseline pressure is reached. The obtained pressure oscillations are then stitched, and the signal is detected by the sphygmomanometer and evaluated according to its internal (and generally unknown) algorithm. The resulting blood-pressure indication of the sphygmomanometer then can be compared to the reference value in the simulator database.

Upon its development, the performance of the aOSG was tested by PTB using a protocol inspired by the requirements in ISO/TS 81060-5. This set-up was used to investigate the repeatability of the oscillation amplitude as well as the repeatability of the oscillations shape.

Within the scope of this work, eleven representative signals were selected from the Newcastle University database of human oscillometric signals and compared with the pulses generated by the aOSG.

First, the repeatability of oscillation amplitudes of the simulated signals was studied. To perform the proposed test, the signals generated by the aOSG at applied constant pressures were recorded for at least 60 s for different simulator settings. To investigate the repeatability of the amplitude of the oscillations, the standard deviation of 10 peak-to-peak amplitudes of the generated oscillations for each parameter combination required by the TS was then calculated. For all investigated signals, the calculated standard deviation was well below the 0.05 mmHg limit imposed by the technical specification, indicating a very good repeatability of the oscillation amplitudes simulated by the developed aOSG.

Furthermore, the repeatability of the shape of the simulated oscillations was examined. In that scope, the data generated for the examination of the repeatability of the oscillation amplitudes were considered and the squared correlation coefficient R^2 was determined. -

The squared correlation coefficient for the evaluated signals lies between 0.977 - 0.996. While the values are very close to the limit of 0.998 imposed by the technical specification, they are all lower than required. These results were discussed with the developer of the technical specification (member of the ISO/TC 121/SC 3/ JWG 7) and it was agreed that since the required limit of 0.998 was based on theoretical considerations, it is possible that the requirements of the technical specification are too strict. Therefore, additional practical experiments including commercial and non-commercial simulators are needed to establish a realistic value. The consortium considers the possibility of designing additional experiments in this scope and, if required, proposing a revision of the ISO/TS 81060-5. This task will be assumed by the working group on advanced blood pressure metrology established in another work package of the project.

The results of these initial tests prove a good compliance of the aOSG with the repeatability requirements required by ISO/TS 81060-5 and are an indicator of the consistency of the generated oscillometric signals by the developed aOSG.

Following the development and investigation of properties performed by PTB, the aOSG was sent for further investigation to project partners, UL and then CMI. The aOSG, its performance and experience with sphygmomanometer testing using the aOSG were presented to participants of stakeholder workshops in September 2021 and September 2022. Particularly clinicians present at these events welcomed the developments of the project and underlined the importance of having access to trustworthy test devices designed to ensure a correct performance of BP measuring devices. Furthermore, the topic of oscillometric blood pressure simulators with focus on aOSG and progress and results were presented at several conferences and during meetings of standards development organisation and metrology committees.

With excellent performance of the aOSG and good results of testing, all defined criteria were achieved and thus this project objective was fully met.

To define the necessary requirements and test procedures

Devices using the automated oscillometric method represent the vast majority of electronic devices entering the market today, as they do not require skilled observers, avoid the "white-coat effect", can be used for long-term and home monitoring, and allow for fully automated BP monitoring on intensive care units. However, the relationship between oscillometric pulses and systolic and diastolic BP values is complex and a correct, in-depth verification of such devices, particularly after they enter the market does not currently occur. The algorithms used to estimate BP values are based on empirical data, gained from clinical studies by each manufacturer separately. There is no standard procedure or algorithm and the proprietary internal software of automated sphygmomanometers (SMs) is not disclosed, neither to the public nor to regulatory bodies or test houses. And although commonly used, oscillometric sphygmomanometers are known to occasionally indicate inaccurate values due to algorithmic and software issues, the current state of the art only requires the verification of the static pressure indicated by the devices (the verification of the proper functioning of the pressure sensor), a verification of the software is ignored.

For the developed advanced oscillometric signal generator to be used for in-depth performance checks of oscillometric sphygmomanometers, test procedures for such testing of sphygmomanometers as well as technical and metrological requirements had to be developed.

These were developed to amend the insufficient static pressure testing and will allow the evaluation of the performance of the entire components of the sphygmomanometer rather than just the pressure sensor.

The test procedures and requirements are based on harmonised standard EN ISO 81060-2 and define simulated clinical trial and repeatability tests. The test procedure for accuracy checks, simulated clinical trial, defines testing with sample of at least oscillometric 85 signals representing people with various blood pressure ranges. The procedure defines two options for testing; an accelerated test and a comprehensive test, The difference is in number of measurements, where the accelerated test requires each of the used test signal to used once, the comprehensive test requires three repetitions for each signal and therefore mimics the procedure in the standard EN ISO 81060-2. The accuracy requirements for sphygmomanometer to successfully pass the test are the same as in the EN ISO 81060-2, i.e. maximum average error in both systolic and diastolic pressure to be ±5.0 mmHg or less and standard deviation of systolic and diastolic pressure not to be greater than 8 mmHg.

The test procedure defines the reproducibility test as well, this consists of at least ten repeated measurements with the same oscillometric signal. In order to pass this test successfully, the average error of the tested sphygmomanometer has to be below ±2.5 mmHg.

The development of the test procedure was led by work-package leader, CMI with inputs and support from UL, PTB, SMU, NSAI and GUM.

The applicability was of the procedures was evaluated by practical tests, i.e. testing of sphygmomanometers.

In second quarter of 2022 these procedures were used during an example of early uptake, testing of sphygmomanometers as part of consumer test for Czech newspaper Mladá Fronta Dnes. The testing with aOSG and a sample of 85 signals fulfilling the criteria of EN ISO 81060-2 compared results of 11 sphygmomanometers available on the market. It also confirmed the applicability of the aOSG and developed test procedures.

With this objective successfully achieved, the procedures published as one of project deliverables and an excellent performance of the aOSG, the practical implication can be faster and easier in-depth testing of sphygmomanometers, easier clinical trials and faster development. Here, the aOSG could substitute some hard-to-be found or ethically sensitive human test subjects or make repeated testing easier.

To develop a procedure for the periodic recalibration of the newly developed advanced oscillometric signal generator

Introduction of the aOSG for the in-depth checks of SMs accuracy brought the need for valid traceability of the aOSG itself. Until recently, the only option for traceability of aOSG and similar devices was a static pressure calibration, although the devices measure and generate time-dependent, highly variable, i.e. dynamic pressure.

This objective with respective work package was developed by UL with support from IMBiH, CMI, SMU, PTB and GUM.

Developed calibration procedure for the advanced oscillometric signal generator comprises of two parts, static and dynamic calibrations. The static calibration is based on existing procedure described in calibration guide CG 17 published by Euramet. Since this is a standard procedure for most NMIs, the static calibration was not a challenging part of this objective.

The opposite is true for the dynamic calibration. Although there were significant developments if for dynamic pressures in recent years, these usually focused on measurements suitable for internal combustion engines, turbines, i.e. on high amplitude and milliseconds long pressure pulses. To provide valid traceability for aOSG and similar devices, the metrological challenges are related to measurement and evaluation of low amplitude, low frequency pressure pulses superimposed on semi-static pressure.

Prior this project a valid calibration of such a aOSG was not possible at NMI level, hence the development of suitable dynamic calibration procedures was one of the necessary steps to allow the aOSG to work as intended. Following thorough literature survey on available solutions for dynamic pressure with emphasis on range of the oscillometric signals and BP applications, the consortium continued research on the dynamic pressure traceability. The main goal of this objective was to reach an uncertainty of measurement of ±1.5 mmHg at most in dynamic calibration.

Project partners investigated two alternative dynamic pressure traceability paths; classical fast pressure sampling measurement and novel acoustic measurement. While the calibration via acoustic path was considered a research study, the fast pressure measurement was decided to be used within the project.

Precision pressure transducer (Druck UNIK 5000) with fast response connected to fast sampling data acquisition system was used as the main component. Manufacturer declares the ability to measure signals up to 3.5 kHz. Based on this, the project partners assume that this sensor will serve well for the purposes of oscillometric signal measurement, where the main constituent has frequency of heartbeat, close to 1 Hz. Calibration and measurement performed both by UL and CMI confirmed very low uncertainty of this device when measuring static pressures. Repeated measurements helped to establish requirements for calibration interval and to estimate the long-term stability of the pressure sensor and its influence on the uncertainty budget. Calibration procedure for dynamic mode was based on ISO/TS 81060-5 and comprises of evaluation of oscillometric pulses amplitude and shape stability.

Oscillometric pressure pulse amplitude stability shall be determined by analysing 10 consecutive pressure pulses, generated at specific static pressures. Pressure pulse shape stability shall be calculated as a correlation of shapes of 10 consecutive pressure pulses, generated at specific static pressures.

Amplitude stability of the generated pressure pulses shall be tested by generating the same pressure pulses repeatedly and calculating the repeatability of the pulse amplitude. Simulator shall be set to a certain subject and tests at static pressures performed. Pressure pulse shape stability shall be calculated as a correlation of averaged shapes at different times of recording. Use the averaged shape of 10 repeated oscillations in the first 15 s of the recording and the averaged shape of 10 repeated oscillations in the last 15 s of the recording to determine the squared correlation coefficient R^2.

Based on the developed procedure (with both static and dynamic part included), the contributing factors for uncertainty model were identified, quantified and model was created. The project had initially rather ambitious goal of reaching ± 1.5 mmHg uncertainty of measurement.

Calculation based on measurement result proved, that this goal was met with the expanded uncertainty reaching the value of just ±0.78 mmHg (k = 2).

Concept for smart specialisation in the field of traceable blood pressure measurements

Until recently, European national metrology institutes (NMIs) didn't endeavour to implement the smart specialisation concept in medical metrology. As a result, many NMIs are equally underdeveloped in this specific field of metrology. This has resulted in a significant lack of harmonisation at European level and an insufficient metrology infrastructure for blood pressure measurement and research at NMI level. There has also been a lack of motivation or drivers for certain regions and states to invest in the development of this critical field of measurement.

The feasibility of smart specialisation concept in the medical metrology was initially validated in the EMPIR project 16RPT03 inTENSE which focused on intra-ocular pressure metrology (namely capacity building and strengthening, new measurands and international cooperation). Following the steps taken in the project inTENSE, project adOSSIG implemented the smart specialisation concept in blood pressure metrology.

The smart specialisation concept is foundation for a long-term partnership, beyond the end of this project. It allows the involved NMIs and DIs to optimally utilise the limited national capacities in a smart division of labour and resources. Upon the implementation of the smart specialisation concept, many NMIs can focus their limited resources and capacities on other, and for them more important or profitable, fields while still being able to utilise the network and expertise of other NMI's with expertise and resources in the area of BP instruments calibration and verification.

This allows NMIs/DIs to stay active in the field even if they do not have the experience, capacity or resources to do so at a full scale, e.g. an NMI which has the experience and equipment to calibrate pressure sensors but not the medical knowhow required for advanced BP metrology, can keep the first part of the business and outsource the second part to the competence centre established by the project.

Implementation of the smart specialisation concept proceeded in several steps.

First, a centre of excellence for blood pressure measurement (competence centre) was created. The competence centre was established with the scope of ensuring the harmonisation of the metrological requirements at European level, by offering countries the possibility to work together, develop common requirements and provide all interested parties with access to an advanced level of expertise in the field of medical devices.

The centre serves as a hub of future network for medical devices with measuring function metrology and consists of both, a physical and a virtual section.

The physical section is represented by the centre of competence, having its headquarters at the location of CMI in Czech Republic, with virtual network created in order to support the competence centre. The competence centre for blood pressure metrology is organised as part of a laboratory at the site of CMI and offers the expertise, the equipment and the resources to provide the traceability to aOSG and similar devices, traceability services to NMIs, DIs, academia, testing labs, and stakeholders in the field who request this type of service, training and knowledge transfer for NMIs/DIs or other interested parties, e.g. by temporarily hosting other metrologists as trainees or as external experts, by organising workshops and comparisons, etc.

Laboratory established at CMI to provide traceability to aOSG and similar devices used existing infrastructure of existing CMI's primary laboratory of pressure and expanded its capabilities based on development within WP3. To provide traceability for aOSG, same pressure sensor as above (Druck UNIK 5000) was used. The device was metrologically characterised, its long term stability estimated and recalibration interval defined.

Last but not least, the developed aOSG is located at the competence centre as well. Access to the aOSG can be granted to project partners, NMIs, WG on blood pressure metrology and other parties under conditions stated in deliverable 8.

The project partners established the Working Group on Advanced Blood Pressure Metrology to support the competence centre. This group is a division of the virtual network for Medical Devices with Measuring Functions (MDMF) and focuses exclusively on blood pressure metrology. The working group includes the project consortium as a core and flexible members with expertise and interest in specific topics. The network will encompass medical devices with medical functions and develop strategies for the competence centre by prioritizing MDMF, ensuring harmonized traceability for MDMF, and fostering smooth cooperation with stakeholders. Over time, both the Working Group on Blood Pressure Metrology and the MDMF network will expand, primarily in European countries, while international collaborations will also be considered and valued.

This project objective of SSC in the field of traceable blood pressure measurements was fully met.

5 Impact

This project brought together the most relevant international metrological and medical institutions, producers of sphygmomanometers and market surveillance bodies; which made the project known and accessible to the wider community. The consortium approached more than 50 potential stakeholders. Positive responses were received from 33 institutions from 11 countries and 3 continents. The institutions that expressed their interest in project were continuously updated on the latest development within the project.

Majority of stakeholders, medical experts, notified body and NMI representatives attended both stakeholder workshops organised in 2021 and 2022 where the project, its objectives and progress were presented. In particular, the interaction with stakeholders from the clinical sector was highly valuable.

In addition to the presentation of the project at the annual conference of the Czech society for hypertension, the partners presented the project and its objectives and results at four more scientific conferences. Presentations were given at 30th International Electrotechnical and Computer Science Conference ERK 2021, 9th Congress of Alps Adria Acoustics and XXIII IMEKO World Congress where two presentations were given and a presentation was given at Joint IMEKO TC11 & TC24 hybrid conference 2022. Papers from XXIII IMEKO World Congress were subsequently published in peer-revied journal Measurement: Sensors.

Impact on industrial and other user communities

The development of the aOSG and corresponding advanced calibration procedures will allow easier and more affordable in-depth performance checks of automated sphygmomanometers. This will ease the development process of SMs for new and small manufacturers, offering them a chance to access the market at lower costs and thus encouraging the innovation.

The research and competence centre for blood pressure metrology established by the project creates a well-developed metrological infrastructure with advanced calibration services and will provide manufacturers with clear guidance, and hence legal certainty on how requirements can be met. Physicians and medical staff will be able to rely on the existing traceability chain, trust the measurement results are correct and methods are validated. Patients in clinics, practitioner offices, and home-care settings will have more confidence in the measured BP values, as the improved infrastructure will allow surveillance bodies and other legal entities to ensure adequate quality of the devices available on the market.

Impact on the metrology and scientific communities

Main impact on the metrology and scientific communities is achieved through knowledge and know-how concentration in one place. Until recently, all European countries and their NMIs had to face challenges of blood pressure traceability and specifics on their own, which ultimately led to many equally undeveloped NMIs facing similar problems.

The project has started correcting the situation in several steps. Early in the project, the network of interested organisations has been created by connecting the project consortium with stakeholders and organisations interested in reliable and traceable blood pressure measurements consisting of NMIs, DIs, surveillance bodies and medical professionals. This led to establishment of the Working Group on advanced blood pressure metrology which was established in the second half of the project. The group will meet regularly, even beyond the project lifetime, and work on different priority topics in the field of blood pressure metrology. The first tasks of the working group is the development of two drafts for two newly proposed and accepted OIML publications; the draft for the future OIML Recommendation on the requirements for the evaluation of non-invasive blood pressure simulators used for the testing of automated non-invasive sphygmomanometers and the draft for a new OIML guide for the evaluation of automated sphygmomanometers using oscillometric signal generators able to generate real-life oscillometric signals. While the draft of the OIML Recommendation was developed by the end of the project, its finalisation and development of draft of the OIML Guide remain to be done beyond the project-lifetime.

Simultaneously, project partners have started investigation on traceability for oscillometric blood pressure generators. During the initial stages of the project development, the partners estimated that the final uncertainty of measurement of the dynamic oscillometric pressure pulses could be ± 1.5 mmHg. The calibration procedures, selected test equipment and the developed uncertainty model allowed a much lower uncertainty of measurement of ± 0.78 mmHg to be reached. The establishment of dynamic pressure traceability allowed for the calibration laboratory at CMI to be established. This laboratory will serve as the physical part of the competence centre which will provide traceability for aOSG and similar devices and expertise on BP measurements to all interested parties.

By implementing the smart specialisation concept, providing traceability, creating a working group in this field and integrating interested organisation into one network and finally, by concentrating knowledge and know-how on one place, this project makes metrology for advanced blood pressure measurements accessible to a broader range of countries. This can be important to many smaller NMIs, particularly emerging NMIs and DIs, who are lacking the capabilities or the resources to provide the complete traceability chain for BP measurements. With the implementation of SSC and help of the competence centre they will be able to serve their national customers with less demanding metrological services, while relying on the competence centre for the higher-level ones.

Impact on relevant standards

The project is actively participating in key blood pressure monitoring equipment and pressure related

standardisation committees as well as international and European legal metrology organisations (e.g. ISO/TC 121/ SC3/ JWG 7, OIML TC 18 and IMEKO TC 16). This participation builds on links already established by the consortium, which is highly influential in national and international metrology and standardisation committees and will be used to facilitate greater awareness of the benefits of the project.

In the period September 2019 – March 2020, PTB was strongly involved in the revision of the OIML Recommendations *OIML R 16-1 Non-invasive non automated sphygmomanometers* and *OIML R 16-2 Non-invasive automated sphygmomanometers*. R 16-2 includes details regarding testing procedures for the verification of automated sphygmomanometers using patient simulators. The two Recommendations are in the committee draft stages and awaiting the balloting results.

As the main proposer of the *ISO TS 81060-5:2020 Non-invasive sphygmomanometers - Part 5: Requirements for the repeatability and reproducibility of NIBP simulators for testing of automated non-invasive sphygmomanometers,* PTB was highly involved in the development of this new technical specification. The TS was published in February 2020. The TS was relevant for the establishment of traceability chain for aOSG in WP3.

To ensure a world-wide dissemination of the guidelines for the evaluation of automated sphygmomanometers developed during the project, the consortium successfully applied in 2021 for two projects within OIML. First project is a new OIML Guide for the evaluation of automated sphygmomanometers using oscillometric signal generators able to generate real-life oscillometric signals. The second project is a new OIML Recommendation covering the requirements for the evaluation of non-invasive blood pressure (commercial and non-commercial) simulators used for the testing of automated non-invasive sphygmomanometers. The work is being conducted by the Working Group on blood pressure within the OIML SC1 "*Blood pressure instruments*" of the TC18 "*Medical measuring instruments*". By the end of the project the draft of the OIML Recommendation was developed, however its finalisation as well the development of draft of the OIML Guide remain to be done beyond the project-lifetime. In the longer term, the outcomes may contribute to the revision of different normative documents (e.g. IEC 80601-2-30, ISO TS 81060-5:2020).

Longer-term economic, social and environmental impacts

The European healthcare industry will primarily benefit from this project in the long term. The prevalence of hypertension is approx. 25 % in EU's adult population. Thus, the importance of accurate and reliable blood pressure measurements is obvious. At the end of the project, an aOSG exists with uncertainty of better than ±1.5 mmHg and a dynamic traceability chain was established. Although this doesn't improve the accuracy of the sphygmomanometers per se, it will allow cheaper complex in-depth testing of sphygmomanometers; either existing or in development. It can thus be expected that the accuracy of a sphygmomanometer can be maintained without significant deterioration over the whole production and lifetime cycle of the device; a guarantee which cannot possibly be given today. Cautiously, assuming that for only 1 % of the patient misdiagnoses can be avoided in the future, the direct benefits of the project can be quantified as:

- 2 million EU citizens who will be spared a false positive or false negative diagnosis,
- 370 M€ per year which will be saved for the EU healthcare systems by avoiding the costs for unnecessary medication of healthy subjects and the even higher costs for undetected and untreated hypertension (estimated from 196 B€/a total costs for cardiovascular diseases in the EU in 2009, 53 % of which are treatment costs, and a ~36 % share for hypertension treatment).

6 List of publications

Gregor Geršak, Markus Schiebl, Michał Nawotka, Ehlimana Jugo, Maria do Céu Ferreira, Alan Duffy, Dana Maria Rosu, Peter Pavlásek, Václav Sedlák, Dominik Pražák, Physiology-based patient simulator for blood pressure meter testing, *Measurement: Sensors*, Volume 18, 2021, 100260, ISSN 2665-9174, https://doi.org/10.1016/j.measen.2021.100260.

Václav Sedlák, Dominik Pražák, Markus Schiebl, Michał Nawotka, Ehlimana Jugo, Maria do Céu Ferreira, Alan Duffy, Dana Maria Rosu, Peter Pavlásek, Gregor Geršak, Smart specialisation concept in metrology for blood and intraocular pressure measurements, *Measurement: Sensors*, Volume 18, 2021, 100283, ISSN 2665-9174, https://doi.org/10.1016/j.measen.2021.100283.

This list is also available here: https://www.euramet.org/repository/research-publications-repository-link/