

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



COORDINATOR

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Encouraging innovation in the sphygmomanometer market

Hypertension affects about 44 % of Europe's population, and is a factor in around 22 % of all heart attacks. Treatment relies on early detection, that depends on accurate blood pressure measurements using sphygmomanometers (SM). European directives require clinical trials prior to market entry for these instruments, involving costly tests on human subjects and allowing average errors of no more than ± 5 mmHg. In practice, accuracy relies on the effectiveness of manufacturers' quality assurance practices. It's also limited by calibrations that apply static pressures rather than more realistic dynamic pressures, as produced by oscillometric signal generators (aOSG).

The project will develop an aOSG enabling SM devices to be calibrated to accuracies better than ± 1.5 mmHg and establish SI traceability. This would remove the need for human subjects in clinical trials, lower development costs and empower monitoring bodies to ensure market quality. If just 1 % of patient misdiagnoses were avoided, 2 million EU citizens would be spared false positive or false negative diagnoses and EU healthcare systems could save roughly €370 M a year.

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