

## Letter to the Editor:

### Cuffless Devices for the Measurement of Blood Pressure: A Scientific Statement From the American Heart Association

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\*Modest.

†Significant.

For more than two decades, ISO JWG 7, an international group of clinicians, manufacturers, and researchers have joined forces to develop consensus standards for the verification of blood pressure monitors.

The work of JWG 7 builds on the first standard for automated cuffed blood pressure monitors, published in 1987 by AAMI (1). Since 2009, the AAMI SP10 standard has been integrated into the ISO 81060-2 standard and has undergone numerous revisions and consolidations, resulting in the most recent ISO 81060-2 edition issued in 2018, which is undergoing a new revision at the time of this publication (2). In 2022, the members of JWG 7 also released the first version of the ISO 81060-3 standard (3), which specifies new clinical protocols for the verification of continuous blood pressure monitors, and this standard is also undergoing revision at the time of this publication. The scope, structure, and methodological principles of these two standards, ISO 81060-2 and ISO 81060-3, therefore rely on those of AAMI SP10. For almost four decades, these clinical trial protocols, conducted in “a controlled laboratory environment”, have supported the basic verification of automated blood pressure monitors, which have further demonstrated their ability to provide useful clinical information in real-world settings across a very wide range of healthcare situations.

In 2025, JWG 7 publicly announced that the group is working on a new standard for the verification of cuffless blood pressure monitors, ISO 81060-7 (4). As with the other standards in the ISO 81060 suite, ISO 81060-7 will rely on the scope, structure, and methodological principles of AAMI SP10, while being adapted and reinforced to describe the design of clinical research studies intended to verify the performance of cuffless blood pressure monitors.

In this article (5), the authors state: “Consistent with previous ISO guidelines, this protocol will likely not focus on safety or clinical use cases (eg, the ability of devices to measure blood pressure while the individual is asleep or in response to drug treatment), but rather awake testing, in a controlled laboratory environment, comparing accuracy and precision with auscultation.” While the

details of the standard cannot yet be publicly disclosed, in accordance with ISO confidentiality rules, we wish to confirm that ISO 81060-7 is expected to follow the same scope, structure, and methodological principles as the entire ISO 81060 suite, which is standardized to guide manufacturers, clinicians, and regulatory bodies in assessing the performance of the rapidly growing number of cuffless blood pressure monitors. The last four decades of experience with this design of clinical research protocols for the verification of blood pressure monitors, following these principles, have brought to market tens of millions of blood pressure devices with an unquestionably positive benefit–risk ratio.

As an international working group, and in accordance with ISO governing rules, ISO JWG 7 welcomes the participation of the authors of this article in the ongoing efforts to improve the verification of blood pressure devices.

### References:

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3. International Organization for Standardization ISO 81060-3:2022 Non-invasive sphygmomanometers Part 3: Clinical investigation of continuous automated measurement type
4. International Organization for Standardization ISO/CD 81060-7:2025 Non-invasive sphygmomanometers Part 7: Clinical performance verification of intermittent or repeated intermittent cuffless measurement type
5. Cohen JB, Byfield RL, Hardy ST, Juraschek SP, Houston Miller N, Mukkamala R, Picone DS, Thiele RH, Yang E, Brady TM; American Heart Association Council on Hypertension; Council on Cardiovascular and Stroke Nursing; Council on Cardiovascular Surgery and Anesthesia; and Council on Clinical Cardiology. Cuffless Devices for the Measurement of Blood Pressure: A Scientific Statement From the American Heart Association. *Hypertension*. 2025 Dec 11