Frequently Asked Questions

Why use clinically validated upper arm cuff automated blood pressure measuring devices?

RESOLVE TO SAVE LIVES

SEA HEARTS

World Health Organization
South-East Asia Region

What are the different types of blood pressure measuring devices?

- Blood pressure (BP) measuring devices can be either **manual** (mercury or aneroid), or **automated** (automated or semi-automated**)**.
- Automated BP measuring devices is a device that estimates BP after automatic inflation and deflation of the cuff and displays the values on an electronic display. The semi-automated BP measuring device requires manual inflation and deflation of the cuff.
- Compared to manual devices, automated BP measuring devices are user-friendly, making it easy to train users, allowing for BP measurement by different categories of health care workers, facilitating the use at primary health care level.

Manual / analogue		Electronic / automated	
Mercury sphygmomanometer	Aneroid sphygmomanometer	Semi-automated, cuff	Automated, cuff
			 

What is validation of an automated BP measuring devices?

Validation is the process by which an automated blood pressure measuring device is demonstrated to produce accurate, safe, and clinically reliable measurements. Before a BP measuring device can be considered validated, it must successfully complete **two essential stages: technical (design) validation and clinical validation**. Both stages are necessary and complementary.

Step 1- Technical (design) validation

- Technical validation confirms that the device is appropriately designed and manufactured according to required technical, safety, and performance specifications. This stage assesses elements such as pressure sensors, cuff design, measurement algorithms, electrical safety, electromagnetic compatibility, and overall device reliability.
- Technical validation is typically conducted in accredited laboratories and assessed against international standards developed by organizations such as the *International Organization for Standardization (ISO)* and the *International Electrotechnical Commission (IEC).*
- Successful completion of technical validation demonstrates that the device is suitable to proceed to clinical testing and regulatory review.

Step 2- Clinical validation

- Clinical validation evaluates the accuracy of a specific BP device model in human subjects. It involves rigorous testing using internationally recognized and publicly available protocols, such as ISO 81060-2.
- Device measurements are compared with a reference standard under controlled conditions. Clinical validation studies are conducted by independent organizations such as an academic institution or accredited testing laboratory, and not by the manufacturer.
- Protocols require testing in a predefined number of participants representing specified ranges of age, sex, arm circumference, and blood pressure.
- Validation is conducted once per device model and demonstrates that the automated BP device can measure blood pressure accurately and reliably in real clinical settings.
- As an example, STRIDE BP provides an independently curated list of blood pressure measuring devices that have successfully completed clinical validation according to recognized international protocols. This resource supports policymakers, clinicians, and procurement agencies in identifying validated devices for use in health systems.

Validation is performed once for each model and confirms that the device can accurately measure blood pressure in real patients.

What are the advantages of using validated automated BP measuring devices?

- Simplified measuring process
  - ◊ eliminate errors related to hearing deficits, incorrect initial inflation pressure, and rapid cuff deflation.
  - ◊ reduce the subjectivity of measurement by minimizing observer errors and terminal digit preference.
- Ease of use and scalable
  - ◊ easy to operate and train on, enabling task sharing among a wide range of allied health staff, and suitable at the primary health care level.
- Improved accuracy and reliability
  - ◊ ensure accurate readings, minimize manual errors, and provide consistent values making the measurement process easier.
  - ◊ support effective management of hypertension at the primary healthcare level.

- Enhance patient safety
  - ◊ mitigate risks to patients due to misdiagnosis and improper treatment that can result from inaccurate BP readings

- Accurate BP measurement is the foundation for hypertension control.
- Incorrect readings can lead to misdiagnosis, inappropriate treatment, and uncontrolled hypertension.
- **75–80% of automated BP devices marketed globally are NOT clinically vali dated—even some from reputed brands**

What do WHO and other global health organizations recommend?

- WHO HEARTS Technical Package: Use validated automated BP devices in primary care.
- Resolve to Save Lives: Advocate for procurement policies requiring automated validated devices.
- International Hypertension Societies: Strong recommendation for automated validated devices in all settings.

Who develop the validation protocols?

Validation protocols have been developed by several independent international bodies them including the ones listed below.

- ◊ Association for the Advancement of Medical Instrumentation (AAMI)
- ◊ American National Standards Institute (ANSI)
- ◊ International Organization for Standardization (ISO)
- ◊ British Hypertension Society (BHS)
- ◊ European Society of Hypertension (ESH)

In 2018, a **"single universal standard - ISO 81060-2:2018"** was developed. It consolidates previous guidelines and includes additional specifications for special populations, such as children and pregnant women.

How can one identify validated devices?

- Check device validation status using trusted online registries**:**
  - ◊ STRIDE BP: www.stridebp.org
  - ◊ MEDAVAL: http://medaval.ie/
  - ◊ DABL Educational Trust: www.dableducational.org
  - ◊ Validate BP: www.validatebp.org
- Look for ISO/AAMI/ESH certification in product documentation

What are the common barriers and potential solutions for adoption of clinically validated automated BP measuring devices in the WHO South-East Asia Region?

Common barriers	Potential solutions
Limited awareness among clinicians, program managers & policymakers	• Sensitize and train users and decision makers • Disseminate information on how to check validation status • Advocate for national guidelines on validated devices • Gradually phase out manual and non-validated devices as budgets allow
Market dominance of non-validated devices	• Include validation as a requirement when calling for tenders for procurement of automated BP measuring devices • Promote exclusive use of automated validated devices.
Lack of easy identifiers or certification marks	• Refer to trusted online registries to check validation status • Mandate a logo or hologram (backed by certifying agency)
Higher upfront costs or limited suppliers	• Use pooled procurement • Engage local distributors • Build local capacity in device validation

References

- International Organization for Standardization. (2018). ISO 81060-2:2018: Non-invasive sphygmomanometers — Part 2: Clinical investigation of intermittent automated measurement type. ISO. https://www.iso.org/standard/73339.html
- Association for the Advancement of Medical Instrumentation, European Society of Hypertension, & International Organization for Standardization. (2018). A universal standard for validation of blood pressure measuring devices (AAMI/ESH/ISO). https://www.jstor.org/stable/resrep30115.17
- World Health Organization. (2020). WHO technical specifications for automated non-invasive blood pressure measuring devices with cuff. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO https://www.who.int/publications/i/item/9789240002654
- World Health Organization. Technical specifications for pre-market assessment of blood pressure measuring device with cuff, automated and semi-automated. Geneva: World Health Organization; 2023. Licence: CC BY-NC-SA 3.0 IGO. https://www.who.int/publications/i/item/9789240077348
- World Health Organization. (2021). HEARTS: Technical package for cardiovascular disease management in primary health care. WHO. https://www.who.int/publications/i/item/WHO-NMH-NVI-19-8
- Resolve to Save Lives. (2023). Validated automated BP devices—Essential tools to save lives. https://resolvetosavelives.org/wp-content/uploads/2023/05/640_CVH_Automated-Digital-BP-Device_Fact-Sheet_0324_Rev-A_v4.pdf
- Pan American Health Organization. (n.d.). HEARTS in the Americas: Blood pressure measurement. https://www.paho.org/en/hearts-americas/hearts-americas-blood-pressure-measurement
- STRIDE BP. (n.d.). Principles for device listing. https://www.stridebp.org/about-us/principles-for-device-listing/
- Medaval. (n.d.). Medaval validated device registry. https://medaval.ie/
- Dabl Educational Trust. (n.d.). Information on validated blood pressure devices. http://www.dableducational.org/
- Validate BP (American Medical Association). (n.d.). Validated Device Listing (VDL). https://www.validatebp.org/
- Sharman, J. E., Ordunez, P., Brady, T., Parati, G., Stergiou, G., et al. (2023). The urgency to regulate validation of automated blood pressure measuring devices. Journal of Human Hypertension. https://www.nature.com/articles/s41371-022-00747-0.pdf
- Picone, D. S., Campbell, N. R. C., Schutte, A. E., et al. (2022). Validation status of blood pressure measuring devices sold globally. JAMA, 327(7), 680–681. https://jamanetwork.com/journals/jama/fullarticle/2789043

World Health Organization

South-East Asia Region