



VALIDATED AUTOMATED BP DEVICES— ESSENTIAL TOOLS TO SAVE LIVES

Why automated devices

- Accurate and reproducible blood pressure (BP) measurement is the foundation for hypertension diagnosis and control.
- Leading health authorities, including the World Health Organization, recommend automated BP monitoring devices (BPMs) in primary care settings where most people seek treatment for their high BP.¹
- Automated BPMs are easier to operate than manual devices, so health workers with less experience and training can take accurate measurements and share in this task.

 Manual BP Devices Complex measurement process with significant opportunity for human error	 Automated BP Devices Simplified, expedited measurement process
<ul style="list-style-type: none"> ✗ Incorrect cuff pressure ✗ Health worker hand fatigue from pumping up the cuff repeatedly ✗ Incorrect deflation rate ✗ Difficulty hearing Korotkoff sounds in a busy, noisy clinic ✗ Misreading or misremembering BP measurement value on the meter or column ✗ Rounding the observed values (terminal digit preference) ✗ Miscalibration 	<ul style="list-style-type: none"> ✓ Cuff automatically inflates to correct pressure ✓ No health worker hand fatigue ✓ Cuff automatically deflates at the correct rate ✓ Listening is not required ✓ Digital display of values on an easy-to-read screen eliminates misinterpretation ✓ Values stay on the screen until the device is reset or turned off; no need to rely on health worker memory ✓ Does not require calibration

Why validated automated devices

- Validated automated BPMs provide more accurate and consistent BP measurements.
- Only using devices validated by an independent entity (not affiliated with the manufacturer) using an accepted validation protocol² can save lives. Even small errors in BP measurement can lead to incorrect diagnosis and undertreatment, leaving patients at risk for heart attacks and stroke, and premature death.



Current estimates indicate that 75–80% of automated BPMs marketed globally do not have evidence of being adequately clinically validated for accuracy.³



Where to find validated automated BP devices

Ideally, manufacturers should provide information on the validation status of every automated device they have on the market. It is important to note that not all products from a known manufacturer are validated for use in clinical settings, however, there are free online resources that administrators, physicians, and care teams can use to identify BPMDs that have been validated for clinical accuracy. These include:

- Medaval⁴ — This online resource lists devices, both validated and not validated, with their validation status.
- STRIDE BP website⁵
- ValidateBP.org⁶
- Regional Registries are maintained in the Hypertension Canada website,⁷ The British and Irish Hypertension Society website,⁸ American Medical Association etc.

Consequences of inaccurate BP measurement

Overestimation of blood pressure by even 10/5 mm Hg can falsely increase perceived hypertension prevalence (22% vs. 53%) and falsely decrease perceived hypertension control (21% vs. 4%).⁹

How to ensure accurate and consistent BP measurement

- Implement a policy to only use validated BP devices.
 - Gradually phase out unvalidated/manual devices in PHCs as budget allows.
- Insist on only using validated automated BP devices in donor-funded programs.
- Disseminate information on how providers and decision makers can find the validation status of devices.
- Request all suppliers to submit validation reports on devices they bring into the country.
- If there is interest, subsidize experts in local medical schools to build capacity in device validation, especially if some are manufactured locally.

REFERENCES

- 1 <https://www.who.int/publications/i/item/9789240002654>
- 2 These protocols include, the US Association for the Advancement of Medical Instrumentation (AAMI), British Hypertension Society (BHS), European Society of Hypertension-international protocol (ESH-IP), European Committee for Standardization, International Organization for Standardization (ISO), American National Standards Institute/AAMI/ISO, and AAMI/European Society of Hypertension (ESH)/ISO. The WHO discourages validation tests conducted by device manufacturers themselves or their affiliates to guard against biased reporting.
- 3 <https://www.nature.com/articles/s41371-022-00747-0>
- 4 <https://www.medaval.ie/>
- 5 <https://www.stridebp.org/bp-monitors>
- 6 <https://www.validatebp.org/>
- 7 www.hypertension.ca/bpdevices
- 8 www.bihsoc.org/bp-monitors
- 9 Lombardi, C. et al. Country experiences on the path to exclusive use of validated automated blood pressure measuring devices within the HEARTS in the Americas Initiative. *J Hum Hypertens* 37, 120–125 (2023). <https://doi.org/10.1038/s41371-022-00706-9>