How to identify validated blood pressure monitors

STRIDE BP lists validated BPMs, and identifies preferred devices for home and office use[10,11]

Validated

To be listed as validated by STRIDE BP, a device must either:[10]

- Have a published validation study
- Be demonstrated to have equivalent measurement functions to an already validated device

Preferred

STRIDE BP may identify a device as preferred if it meets these criteria:[10,11]

- Upper-arm cuff device
- At least one STRIDE BP approved validation study†
- Automated storage of multiple readings, or mobile, PC, or internet connectivity enabling data transfer‡

How are blood pressure monitors validated?

- New devices are validated by comparing their measurements to those of reference devices using protocols set out by professional societies
- A universal protocol has been developed by the US Association for the Advancement of Medical Instrumentation (AAMI), ESH, and the International Organization for Standardization (ISO)[12]
- STRIDE BP will list a device if the results of such a validation study are published as a full paper[10,11]

† Published in the last 10 years and using a recent validation protocol (AAMI/ESH/ISO 2018; ANSI/AAMI/ISO 2013 or 2009; ESH-IP 2010).
‡ This criterion only applies to devices for home use.

Key messages

- The ESH has recently updated their guidelines for the management of arterial hypertension, with greater emphasis on the use of clinically validated devices[1]
- Home BP monitoring with validated devices leads to better blood pressure control, whereas the use of non-validated devices with inaccurate measurements can lead to misdiagnosis[7]

All OMRON devices are clinically validated and listed by STRIDE BP[13,14]

- OMRON ensures that every model of their BPMs meets the highest standards of precision and reliability[13]
- OMRON has 84 validated upper-arm devices listed on STRIDE BP[2]

OMRON M7 is clinically validated[15,16] and is a STRIDE BP preferred device[2]

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2023 Updated Guidelines

Arterial Hypertension by the European Society of Hypertension (ESH)

Recommend clinically validated blood pressure monitors for accurate results

What has changed for blood pressure measurements?[1]

- Opportunistic screening for all adults
- Regular measurements for those >40 years or at high risk

- Screening of all children <3 years old
- Screening of children >3 years old with risk factors for high blood pressure (BP) including congenital heart disease, chronic kidney disease, solid organ transplantation, treatment with BP increasing drugs, or history of preterm birth

- Only properly validated devices should be used to ensure measurements are accurate
- Automatic electronic, upper-arm cuff devices are recommended for both office and out-of-office use
- Devices with automated storage and connectivity are preferred
- Support for telehealth technologies and nocturnal BP measurements are encouraged

Home BP monitoring is recommended for:[1]

- Providing better reproducibility and prognostic value
- Support the identification of white-coat or masked hypertension
- Improving BP control through long-term follow-up of treated hypertension
- Novel home devices could provide an alternative to ambulatory blood pressure measurement (ABPM) to measure blood pressure values during sleep to detect elevated or non-dipping blood pressure

The ESH recommends that healthcare professionals, patients, and the public should check STRIDE BP for listing of accurate devices[1]

Lists of devices validated for home, office/hospital, or ambulatory use, in addition to those validated for use in children or pregnant women can be found at www.stridebp.org

STRIDE BP currently approves 390 of the >4000 devices on the market[2]

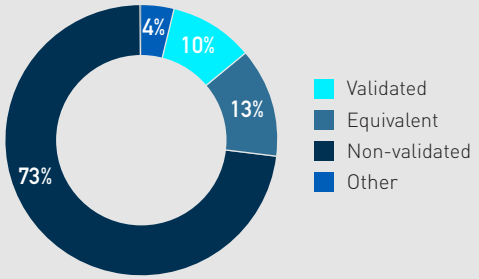
Upgraded recommendation New recommendation

Abbreviations: AAMI, US Association for Advancement of Medical Instrumentation; BP, blood pressure; BPM, blood pressure monitor; DBP, diastolic blood pressure; ESH, European Society of Hypertension; ISO, International Organization for Standardization; PC, personal computer; SBP, systolic blood pressure.

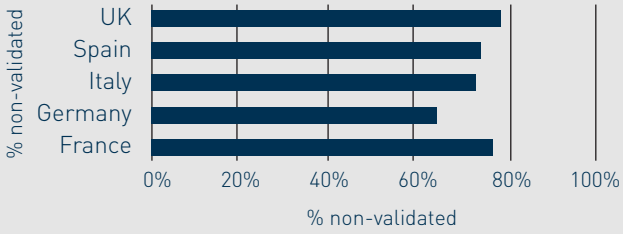
References: 1. Mancia G, et al. J Hypertens. 2023 June 21. 2. https://stridebp.org/index.php. Accessed 11/10/2023. 3. Stergiou GS, et al. J Clin Hypertens (Greenwich). 2018 Jul;20(7):1096-9. 4. Picone DS, et al. Hypertension. 2020 Jun;75(6):1593-9. 5. Picone DS, et al. JAMA. 2022 Feb 15;327(7):680-1. 6. Picone DS, et al. JAMA. 2023 May 2;329(17):1514-6. 7. Stergiou GS, et al. J Hypertens. 2021 Jul 1;39(7):1293-302. 8. Sakhuja S, et al. J Clin Hypertens (Greenwich). 2022 Mar;24(3):263-70. 9. Fan WG, et al. J Clin Hypertens (Greenwich). 2020 Feb;22(2):150-6. 10. https://stridebp.org/about-us/principles-for-device-listing. Accessed 11/10/2023. 11. Stergiou GS, et al. J Clin Hypertens (Greenwich). 2019 Nov;21(11):1616-22. 12. Stergiou GS, et al. J Hypertens. 2018 Mar;36(3):472-8. 13. https://healthcare.omron.com/healthcare-solutions/cardiovascular-health/clinical-validations. Accessed 18/10/23. 14. https://healthcare.omron.com/innovations/clinical-research-supporting-literature/cardiology/27/clinical-validation-of-medical-devices. Accessed 18/10/2023. 15. Takahashi H, et al. Vasc Health Risk Manag. 2015 Jan 9; 11:49-53. 16. Topouchian J, et al. Vasc Health Risk Manag. 2018 14:189-197.

Although clinical validation for accuracy is recommended by guidelines, it is not mandatory prior to bringing a blood pressure monitor (BPM) to market[3,4]

Globally, less than a quarter of upper-arm devices are validated or equivalent to a validated device[5]



Most devices in European countries are not clinically validated[6]



Non-validated devices may provide inaccurate measurements, leading to misdiagnosis and mistreatment[7]

A 5/3.5 mmHg overestimation of systolic/diastolic blood pressure (SBP/DBP) could result in a:

39%

increase in the number of people diagnosed with **high BP**[8]

Even a **2/1 mmHg overestimation** of SBP/DBP could result in a:

6%

increase in the number of people diagnosed with **hypertension**[9]