

HE RTS IN THE AMERICAS





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Blood Pressure Validation Listings: An Overview

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Validation Listings

IN THE AMERICAS

These are lists of devices that have passed validation testing. They used by consumers, providers, manufacturers, and regulators to recognize which devices are valid.

- 1. National registries
 - 1. Hypertension Canada (<u>https://hypertension.ca/hypertension-and-you/managing-hypertension/measuring-blood-pressure/devices/</u>)
 - 2. British and Irish Society of Hypertension (<u>https://bihsoc.org/bp-monitors/</u>)
 - 3. United States Validated Device Listing (VDL) (<u>www.validatebp.org</u>)
 - 4. German (<u>https://www.hochdruckliga.de/messgeraete-mit-pruefsiegel.html</u>)
 - 5. Japanese listing (Japanese only)
- 2. General: STRIDE BP (<u>www.stridebp.org/index.php</u>)
- 3. Dableducational (www.dableducational.org)
- 4. Medeval (<u>https://medaval.ie/</u>)





Hypertension Canada

Blood pressure monitors recommended by Hypertension Canada will have the following on the box and/or in material supplied with the device:



Blood pressure measurement devices improve technological advances. Likewise, the standards for validating these devices as accurate are also improving. Various standards exist globally to gauge the accuracy of blood pressure measurement devices. Those with a Gold rating meet the highest and most current international standards, and those with the Silver ratings meet the highest international standards available prior to their most recent updates. Both Gold and Silver levels are accepted as accurate).





Hypertension Canada

Recommended Devices

Brand	Model Name and Number	Photo	Device Type	Recommendation Level	Cuff Sizes available
		Ambulatory Bl	ood Pressure Devices	5	
A&D Medical	Ambulatory Blood Pressure Monitor TM 2430		Ambulatory Blood Pressure Monitor	Gold	Small cuff for left arm (15-22cm, 5.9-8.6 inches) Adult cuff for left arm (20-31cm, 7.9-12 inches) Large cuff for left arm (28-36cm, 11- 14 inches) Adult cuff for right arm (20-31cm, 7.9-12 inches)







STRIDE BP is an international scientific non-profit organization founded by hypertension experts with the mission of improving the accuracy of blood pressure measurement.

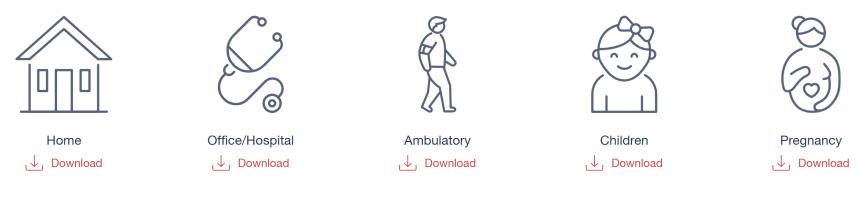
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Stride BP

Validated blood pressure monitors



Blood pressure monitors

Search	e.g. devi	ce model							Preferred devices rules
Populati	on	\checkmark	Use	\checkmark	Manufacturer	\checkmark	Measurement site	\sim	Measurement metho&
				Pan Ameria Health Organizati World Heal	an D A				



Essential Components of the US Validated Device List

Criteria
A validation study performed according to one of the following 85-subject protocols*
ANSI/AAMI/ISO 81060-2:2013
AAMI/ISO 81060-2:2009
ANSI/AAMI SP10:2002
BHS Revised Protocol 1993
One of the following methods of summarizing validation data (listed in order of preference)

Peer-reviewed publication

Independent third-party validation testing by a qualified entity. These may include academic institutions or credible research entities with expertise in BP measurement and knowledge of validation protocols and validation study requirements.





Considerations for Starting a National Registry

- 1. Multiple devices on available on the market.
 - a. Validated versus unvalidated.
 - b. Price differences.
 - c. Guidance for providers and consumers.
- 2. National professional hypertension society.
- 3. National expertise in assessing validation studies.
- 4. Need to generate revenue.





Differences Between Listings

- 1. Differences in protocols that are accepted
- 2. Derivative devices
- 3. Private versus professional society
- 4. Multiple versus single validations
- 5. Published versus unpublished validations





General vs. Patient Specific Validation

An Assessment of the Accuracy of Home Blood Pressure Monitors When Used in Device Owners

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OBJECTIVE

To examine the accuracy of home blood pressure (BP) devices, on their owners, compared to auscultatory reference standard BP measurements.

METHODS

Eighty-five consecutive consenting subjects \geq 18 years of age, who owned an oscillometric home BP device (wrist or upper-arm device), with BP levels between 80–220/50–120 mm Hg, and with arm circumferences between 25–43 cm were studied. Pregnancy and atrial fibrillation were exclusion criteria. Device measurements from each subject's home BP device were compared to simultaneous 2-observer auscultation using a mercury sphygmomanometer. Between-group mean comparisons were conducted using paired *t*-tests. The proportion of patients with device-to-auscultatory differences of \geq 5, 10, and 15 mm Hg were tabulated and predictors of systolic and diastolic BP differences were identified using linear regression.

RESULTS

Mean age was 66.4 \pm 11.0 years, mean arm circumference was 32.7 \pm 3.7 cm, 54% were female and 78% had hypertension. Mean

BPs were $125.7 \pm 14.0/73.9 \pm 10.4$ mm Hg for home BP devices vs. $129.0 \pm 14.7/72.9 \pm 9.3$ for auscultation (difference of $-3.3 \pm 7.3/0.9 \pm 6.1$; *P* values <0.0001 for systolic and 0.17 for diastolic). The proportion of devices with systolic or diastolic BP differences from auscultation of ≥ 5 , 10, and 15 mm Hg was 69%, 29%, and 7%, respectively. Increasing arm circumference was a statistically significant predictor of higher systolic (parameter estimate 0.61 per cm increase; *P* value 0.004) and diastolic (0.38; 0.03) BP.

CONCLUSIONS

Although mean differences from 2-observer auscultation were acceptable, when tested on their owners, most home BP devices were not accurate to within 5 mm Hg. Ensuring acceptable accuracy of the device-owner pairing should be prioritized.

Keywords: auscultatory; blood pressure; blood pressure measurement; home blood pressure; hypertension; oscillometry; validation.

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Thank you!

