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Blood Pressure Validation Listings: An Overview

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Validation Listings

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

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 Blood Pressure Devices					
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)

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Stride BP

STRIDE BP

JOINT INITIATIVE WITH

European Society of Hypertension

International Society of Hypertension

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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Validated blood pressure monitors

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Ambulatory

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Children

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Pregnancy

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Blood pressure monitors

Search

e.g. device model

Preferred devices rules

Population

Use

Manufacturer

Measurement site

Measurement method

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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

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General vs. Patient Specific Validation

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

Jennifer S. Ringrose,[1] Gina Polley,[1] Donna McLean,[2–4] Ann Thompson,[1,5] Fraulein Morales,[1] and Raj Padwal[1,4,6]

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 ≥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 ≥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 ± 11.0 years, mean arm circumference was 32.7 ± 3.7 cm, 54% were female and 78% had hypertension. Mean BPs were 125.7 ± 14.0/73.9 ± 10.4 mm Hg for home BP devices vs. 129.0 ± 14.7/72.9 ± 9.3 for auscultation (difference of −3.3 ± 7.3/0.9 ± 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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