Validated Device Listing (VDL™) Criteria

US Blood Pressure Validated Device Listing (VDL™) - the first U.S. list of blood pressure (BP) measurement devices developed to assist physicians and patients in identifying BP devices that have been validated for clinical accuracy.

BP devices listed on the VDL have met the VDL Criteria detailed below as determined through independent review. Visit ValidateBP.org to view the current VDL and to get information on the independent review process.

Each blood pressure measurement device must be cleared by the Food and Drug Administration (FDA) and be marketed in the United States under an FDA 510(k) number. Each device must further demonstrate clinical accuracy, determined on the specific make and model, in accordance with the standards published by the Association for the Advancement of Medical Instrumentation (AAMI), the ANSI/AAMI/ISO standard, the British Hypertension Society (BHS) protocol requirements, or the most recent ISO universal protocol for its intended population as outlined in the device's FDA 510(k) clearance documentation.

Part I. The following BP device types are being addressed:

1. Automated professional office devices for clinical evaluation of BP
2. Automated professional ambulatory (ABPM) devices for the clinical evaluation of BP
3. Automated upper arm devices for patient self-measurement of BP (SMBP). SMBP devices must include (or offer for sale) a cuff or cuffs that accommodate a minimum arm circumference range of 22 – 42 cm, as measured at the midpoint of the upper arm.[1]
4. Automated wrist devices for patient self-measurement of BP, using a cuff

Notes:

- *Devices that are used to collect blood pressure readings from the finger are not being addressed at this time.*
- *Wearable devices using emerging optical or pressure sensor technologies to provide blood pressure readings are not being addressed at this time.*

[1] Leading experts within AAMI/ISO agree that this is a reasonable minimal expectation of devices intended for sale to, or use by, the general public

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Part II. The following criteria must be met for each device model:

A. Active FDA 510(k) pre-market clearance with documentation to include 510(k) clearance letter and summary or statement.

AND

B. Documentation of validation testing for clinical accuracy per ***one*** of the following internationally accepted protocols:

   i. ISO 81060-2:2018
   ii. ANSI/AAMI/ISO 81060-2: 2013
   iii. ANSI/AAMI/ISO 81060-2: 2009
   iv. ANSI/AAMI SP10: 2002
   v. BHS Revised Protocol: 1993

The following represents the types of documentation that should be made available, in order of preference and credibility of testing methodology and results:

a. **Peer reviewed publication.** Electronic version, full citation, or DOI number must be provided to access the publication.

b. **Independent third-party validation testing by a qualified entity.** Qualified third parties include academic institutions or credible research organizations with in-depth knowledge of the specific protocols and study requirements.

Notes:

- *ESH International Protocol (IP) 2002 and ESH International Protocol (IP-2) 2010 are excluded.*[2]
- *"Substantial equivalence", as defined by the FDA and used for 510(k) clearance, is not sufficient to meet the criteria for clinical accuracy.*
- *Validation testing conducted by the manufacturer is insufficient unless also independently verified.*

[2]It has been determined, and agreed upon, by leading authorities within AAMI, ISO, and ESH, that the ESH/International Protocols of 2002 and 2010 are of insufficient statistical power to determine device clinical validity, and further that the protocols fail to account for subject arm size differences and the impact of those variables on system validity.

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Part III. Equivalent model variants:

Manufacturers may apply for "equivalent model variant" listing for models within the same device family (e.g. Model #100A, 100B, 100C), as follows:

The manufacturer must supply a signed, notarized affidavit listing each equivalent model claimed, and attesting that each model variant claimed has no differences from the clinically validated model that would impact BP values or accuracy. This includes confirmation of no differences in:

1. BP Algorithm
2. BP Module Software
3. Cuff Design, Sizes, or Material
4. Inflation/Deflation Mechanism or Method
5. Any other feature that would impact collection of waveform data or calculation of BP result

Note:

- *Organizations that use Original Equipment Manufacturer (OEM) blood pressure devices or components must disclose or attest to how the blood pressure components are used to meet this criterion. Both the OEM manufacturer and the reseller must supply a signed, notarized affidavit to be reviewed.*