

Frequently Asked Questions

What is the US Blood Pressure Validated Device Listing (VDL™)?

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

What does it mean for a device to be validated for clinical accuracy?

To be validated for clinical accuracy, a device must demonstrate that it meets the AMA’s established criteria for clinical accuracy. The “Validated Device Listing Criteria” (VDL Criteria) was developed by the AMA in consultation with hypertension and measurement experts, and requires (1) active Food & Drug Administration (FDA) 510k clearance, (2) independent third-party testing following an international accepted protocol, and (3) cuff sizes appropriate for the general population. If a BP device manufacturer wants to determine if their BP device meets the VDL Criteria, it must provide documentation to the Independent Review Committee for that assessment.

Why is the AMA championing this VDL?

Until now, U.S. physicians have not had access to the information necessary to select accurate automated BP devices for their practices or properly make recommendations of home BP devices for their patients.

In November 2017, the American College of Cardiology (ACC), the American Heart Association (AHA) and other organizations published hypertension guidelines that emphasized the importance of ensuring that (1) BP measurement devices used for self-monitoring are validated with an internationally accepted protocol and (2) the results have been published in a peer-reviewed journal. (<http://hyper.ahajournals.org/content/guidelines2017>)

What role does NORC play in the VDL?

The National Opinion Research Center at the University of Chicago (NORC) is an objective, non-partisan research institution that delivers reliable data and rigorous analysis to guide critical programmatic, business, and policy decisions.

The AMA contracted with NORC as an independent third party to manage the VDL manufacturer submission and review process, including secure hosting and maintenance of the Submission Portal. NORC is the sole contact point between manufacturers and the VDL Independent Review Committee.

Who determines which devices are included on the list?

An essential part of the VDL initiative is the Independent Review Committee which reviews BP device manufacturer submissions to determine if a device meets the VDL Criteria. Individuals on the Committee must have expertise in internationally recognized validation testing protocols, as demonstrated by: (1) publication history on topics related to BP device testing, international validation protocols, BP measurement and clinical impact; (2) prior experience conducting clinical testing on BP devices or similar medical devices; and (3) prior experience reviewing documentation in certification, standards development, clinical trials, and similar capacity.

The AMA and NORC do not have representatives on the Independent Review Committee.

What does the submission process for manufacturers consist of?

Manufacturers can submit documentation for review electronically at any time through a Submission Portal. The Portal provides manufacturers with step-by-step instructions to ensure the successful submission of each device to be reviewed. Visit validatebp.org for more information.

Each submission is analyzed for accuracy and thoroughness before being assigned to two (2) reviewers on the Independent Review Committee. Each reviewer will make a determination based on the VDL Criteria, after which the Committee will convene to approve the determinations and final listing. NORC has been contracted as an independent third party to manage the submission and review process, including secure hosting and maintenance of the Submission Portal. NORC will also serve as the sole point of contact for manufacturer communications. The AMA has no role in the data submission process, nor in the BP device review and approval process.

Does this list mean the AMA endorses any of these devices?

No, inclusion on the VDL does not constitute an expressed or implied endorsement of BP devices by the AMA. Inclusion on the VDL also does not constitute a recommendation, promotion, or endorsement of the BP device manufacturer corporation, its policies, its services, or its products by the AMA and any affiliated or partner organizations.

Manufacturers and any of their distribution partners are prohibited from using the AMA name and logo in the marketing or promotion of any VDL-listed product.

How trustworthy is this list?

The devices on the VDL have passed a strict review process to be considered validated for clinical accuracy. The manufacturers currently on the list represent some of the largest manufacturers based on BP devices sold in the U.S.

What does this mean for payors who cover BP devices for members?

We encourage health plans to cover evidence-based services and validated devices that are essential for prevention and management of cardiovascular disease.

How does the AMA process differ from the FDA process to approve blood pressure devices?

The FDA reviews and clears non-invasive BP devices prior to sale in the U.S. market; however, the process for receiving FDA clearance does not require testing to demonstrate that a home BP device is validated for clinical accuracy. The AMA convened with the FDA on the VDL Criteria, and the FDA understands the AMA's desire to provide increased guidance to physicians and care teams on BP devices.

An active FDA 510k clearance is required as part of the VDL Criteria to be eligible for the VDL. Additionally, documentation from validation testing following an accepted protocol is reviewed by the Independent Review Committee. Only devices that have been reviewed by the Independent Review Committee and determined to meet the VDL Criteria are listed on the VDL.

What types of BP devices made the VDL?

Current guidelines recommend ambulatory BP and automated upper arm devices for use at home or in the community, and automated BP devices for use in the clinic setting. Wrist cuff devices may be necessary for certain patients where an upper arm device cannot be used. These device types are included in the VDL, and we encourage manufacturers of these BP devices to submit applications for their devices. The VDL Criteria outlines the devices eligible for review at this time.

What about other types of devices besides upper arm?

Current clinical guidelines do not support the use of finger devices for clinical decision making for the vast majority of patients, so these devices are not being included in the VDL. An Advisory Group will convene to discuss research, application of new technologies, and other emerging topics and how they could apply to the VDL in the future.

Do you provide BP devices to the public?

No, we do not sell or distribute any blood pressure devices. If you need to obtain a validated blood pressure device, check your local retailer or pharmacy, or contact your local health department or insurance company for options that may be available to you.

I recently bought a BP device that isn't on the list. Will it be added?

The current list only includes specific device models that were submitted by the manufacturer, reviewed by the Independent Review Committee and meet the VDL Criteria. All manufacturers are encouraged to review the VDL Criteria and submit the required documentation for consideration.

How often are devices added to the list?

The list of devices is updated after the Independent Review Committee completes reviews of manufacturer submissions. Manufacturers can submit devices for review at any time.

Blood pressure measurement devices included on the US Blood Pressure Validated Device Listing (VDL™) have been tested and verified to be clinically accurate through an independent review process. [Learn more at validatebp.org](https://www.validatebp.org).