Hypertension

AHA SCIENTIFIC STATEMENT

Cuffless Devices for the Measurement of Blood Pressure: A Scientific Statement From the American Heart Association

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ABSTRACT: Conventional cuff-based blood pressure (BP) monitoring has several limitations, including patient discomfort with arm cuff inflation, inconvenience, and limited frequency of readings. Cuffless BP devices, which are increasingly available for purchase on the international market, have the potential to remove barriers to BP measurement in both research and clinical care. However, there are unanswered questions on whether, how, and in what settings these devices may be appropriate for use. Gaps include the need to understand whether the somewhat distinctive and often enormous volume of readings obtained by these devices have meaningful relationships with clinical outcomes and are appropriate for determining actionable interventions. Furthermore, international standards for determining the accuracy of some, but not yet all, of these devices only recently became available and do not provide a full assessment of the typical use of the devices. Thus, the devices on the market have not yet been adequately vetted for accuracy and efficacy. Several of these devices, however, have been cleared by the US Food and Drug Administration and are being used clinically. Moreover, many patients use cuffless devices for BP self-monitoring, often without disclosing this information to health care professionals. This scientific statement provides an overview of the existing literature on cuffless BP monitoring technologies and their potential future applications, and stresses the importance of understanding the gaps that need to be filled before these devices can be used clinically, recognizing that currently available devices may be inappropriate for clinical use.

Key Words: AHA Scientific Statements ■ ambulatory blood pressure monitoring ■ blood pressure ■ blood pressure determination ■ hypertension ■ photoplethysmography ■ pulse wave analysis ■ tonometry

Over the past decade, there has been a significant increase in the number and type of new devices on the market that are claimed to estimate blood pressure (BP).[1] Many of these devices are designed to address the limitations of conventional arm cuff–based BP measurement by increasing comfort, allowing for continuous passive monitoring or spot manual checking, facilitating electronic storage of data, and increasing accessibility. With these rapid technologic advances, industry, consumers, and clinicians have struggled to keep up with methods of testing device accuracy, understanding the nuances of how different devices operate and what they are designed to estimate (BP or change in BP), and interpreting the massive influx of BP data, none of which has been correlated with clinical outcomes. Many devices that have received Food and Drug Administration (FDA) 510(k) clearance are being used in clinical and home settings despite inappropriate testing with traditional cuff-based protocols and questionable claims of equivalence to existing (eg, cuffed) devices.[2] Accordingly, the 2025 American Heart Association/American College of Cardiology Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults recommends against the use of cuffless BP devices for the diagnosis or management of hypertension until these devices demonstrate greater precision and reliability.[3]

In this scientific statement, we provide an overview of cuffless technologies and their potential future utility,

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while highlighting the notable limitations that need to be addressed before these devices can be considered for clinical decision-making.

MECHANISMS OF CUFFLESS BP MEASUREMENT

The technology, methods, and outputs of cuffless devices for estimating BP noninvasively vary substantially.[4–6] They provide either continuous, beat-to-beat estimations using intracardiac cycle data or intermittent BP estimations, spaced >30 seconds apart, using data from multiple heartbeats. These estimates can be made either with or without additional biologic information input from the user (eg, demographic or anthropometric characteristics, previous BP measured by cuff device). The incorporation of these user-derived inputs into these devices, frequently referred to as device calibration, must be repeated at varying intervals to maintain the stated level of accuracy.[7]

Many of the technologies do not require an inflatable cuff as the sensor but instead rely on cardiac or pulsatility sensors placed on ≥1 locations (eg, chest and wrist) to measure pulse waveforms (see the Figure for examples of these sensors). Machine learning is then applied to translate waveform features into BP estimations with pulse wave analysis or determination of pulse transit time (PTT) or pulse arrival time (PAT). These estimations could be meant to indicate changes in BP between 2 different time points, or, with additional inputs such as periodic BP measurements with a cuff device or demographic and anthropometric measurements, are meant to provide BP estimation in millimeters of mercury.

One popular sensor is a tonometry (force) sensor that measures net arterial force waves by applying pressure on the radial or another superficial artery. Whereas tonometry waveforms can be reliable, the force sensor must be positioned directly over the artery, which is difficult for most people to do, and applied with a certain amount of pressure, making comfortable measurement challenging.

The most common sensor used to measure pulsatility waveforms is a photoplethysmography (PPG) sensor. PPG, which measures the intensity of light that is either transmitted through or reflected back from an illuminated tissue to a photoreceptor, computes blood volume oscillations. Photon absorption is affected by the amount of melanin in the skin; thus, PPG may yield different results across varying skin tones.[8,9] PPG waveform quality is also compromised with cold temperatures due to vasoconstriction, increased skin thickness caused by obesity, and smaller vessels due to increased vessel stiffness.[10] PPG waveform fidelity tends to be lowest at the popular back-of-the-wrist measurement site and highest at the digital arteries of the fingers. Blood volume oscillation amplitude and shape are also sensitive to the required contact pressure of the PPG sensor on the skin.[10,11]

The PAT—a popular waveform feature of BP estimation—is the elapsed time from when the electrical activity of the heart is detected and a peripheral pulse is measured. Measurement of PAT requires 2 sensors: an ECG to identify when the electrical activity of the heart is first detected (usually the R wave) and a distal sensor

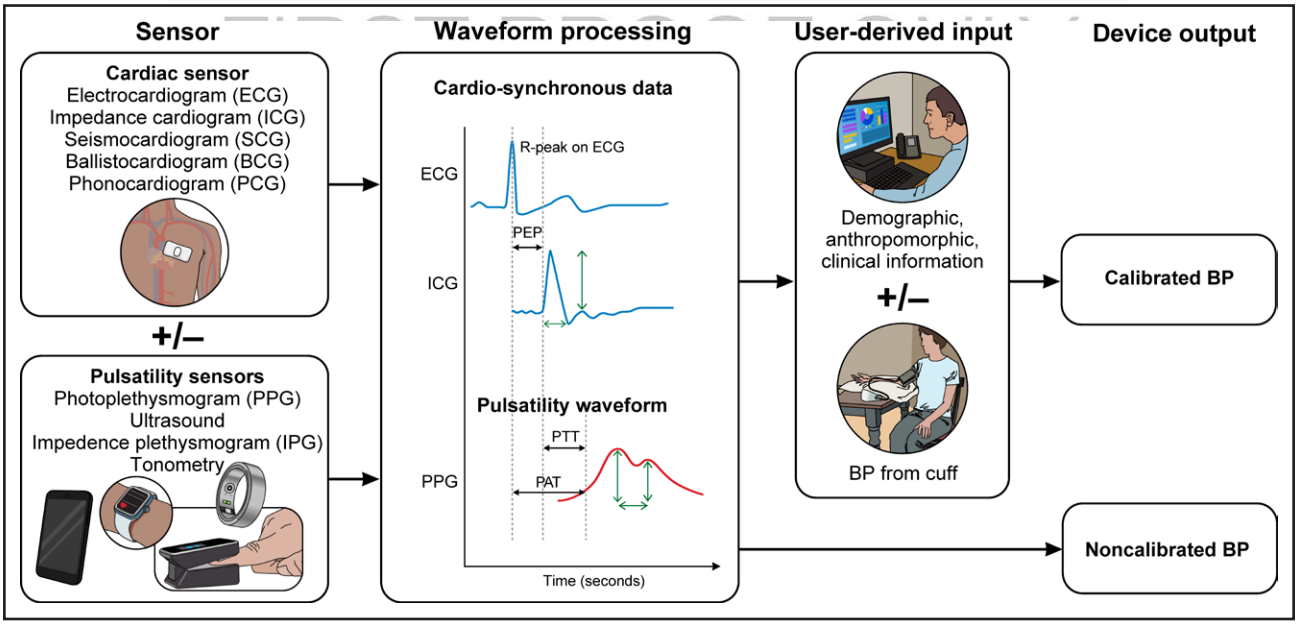

Figure. Mechanisms of cuffless blood pressure measurement.
This figure illustrates several technologies used in cuffless blood pressure (BP) measurement and proposes a framework for cuffless device classification based on sensor type, waveform processing approach, presence or absence of user-derived input, and corresponding device output. The green open arrows represent examples of features that can be used to compute BP. PAT indicates pulse arrival time; PEP, preejection period; and PTT, pulse transit time.

(eg, tonometry or PPG sensor placed at the wrist or finger) to detect when the blood that is ejected from the heart reaches the periphery. Embedded in the PAT is the preejection period, which is the time between the electrical activity and blood being ejected from the left ventricle. The PTT, which is detected from proximal and distal pulsatility waveforms, is the actual time of pulse propagation, reflecting the time from when the blood is ejected from the left ventricle to when it reaches a distal arterial site. Therefore, PAT is the sum of the preejection period and PTT. This detail is important to consider because the preejection period can be highly variable depending on an individual's stress and activity level, position, age, hydration status, and use of vasoactive drugs.[12] Furthermore, typical PTTs through small vessels are not only inversely related to BP but are also affected by smooth muscle contraction.[10] Therefore, most devices that rely on PAT for BP estimation may be susceptible to error due to contamination by the preejection period and smooth muscle contraction, both of which can change independently of BP.[13,14]

Because none of the measured waveforms measures BP directly, many devices need an initial and repeated (eg, daily, weekly, monthly) cuff calibration to yield BP values in millimeters of mercury. Without this calibration, the output is not meant to be interpreted as absolute BP in millimeters of mercury but is instead only able to communicate BP changes. The "cuff-calibrated" devices may come with an automatic cuff device or may require the user to purchase a separate cuff device for this purpose (which may or may not include education on measurement technique and adequate validation). Other devices use demographic inputs, such as age, sex, body mass index, and race, which are known to correlate with BP, for calibration. Some cuff-calibrated devices may also use demographic and anthropometric inputs to compute BP. Cuff-calibrated devices estimate BP in millimeters of mercury on the basis of the intraindividual BP changes detected relative to the cuff BP level at calibration, whereas demographic-calibrated devices measure inter- and intraindividual BP changes relative to the average BP level of individuals from the same demographic population. Therefore, whereas cuffless devices may display a reading that appears as an absolute BP, users must understand that the waveforms they measure actually only serve to track BP changes relative to the calibration BP level.

Cuffless devices often apply machine learning, which has helped solve numerous problems in other fields, to measure BP. However, there are physiologic reasons to doubt that the measured waveforms contain the necessary BP information for machine learning to extract. For example, blood volume oscillation amplitude does not consistently change with BP variations due to profound smooth muscle contraction of the small vessels.[10] Although most cuffless devices do not disclose details of their machine learning algorithm, one manufacturer reported that its device can extract PTT by analyzing a single PPG waveform from cutaneous vessels.[15] Even if the PTT could be extracted reliably without another sensor to inform when the blood leaves the heart, it would likewise be confounded by smooth muscle contraction.

The indications for use vary substantially between devices.[4,5] Some devices are intended to monitor hospitalized patients; others are intended to monitor outpatients. Some are meant to be used during usual activities for ambulatory BP monitoring (ABPM). Sensor placement and stability are important considerations for these devices. Many signals require immobility for acquisition and the hydrostatic effects of gravity on BP may make estimation challenging with sensors not placed at the heart level. Several FDA-cleared cuffless devices are available in the United States for BP monitoring using various measurement methods for a range of clinical applications.[2,16,17]

THEORETICAL APPLICATIONS OF CUFFLESS BP MEASUREMENT

Research

Cuffless technologies have received considerable attention for their ability to measure BP in settings and times that are not feasible with typical cuff-based approaches. Both office and home cuff-based devices are intended to measure BP with the individual in a rested, seated position. Even ABPM, which includes measurements in a broader range of contexts and body positions, requires a stationary state at the time of measurement to avoid motion artifact. In contrast, cuffless devices could offer the potential for measurement in higher-activity states. This could allow for unprecedented capture of BP at times not amenable to typical measurement approaches, with implications for the identification and study of novel contributors to hypertensive injury and mechanisms precipitating cardiovascular events. Coupled with modern machine learning analytic techniques, these more complete and detailed BP data have the potential to identify novel hypertensive phenotypes that could be targeted with interventions.

Another important potential advantage of cuffless devices is the ability to measure BP at night without disturbing sleep. Nocturnal hypertension has been repeatedly shown to be one of the most prognostic hypertension phenotypes captured with ABPM, partly due to its association with salt sensitivity and sleep apnea. However, sleep disruption is a well-recognized cause for inadequate ABPM studies and low participation rates in research cohorts.[18] Moreover, studies of sleep and BP can be affected by cuff compression during ABPM, which may disrupt sleep. Cuffless devices have the potential to remove this barrier to overnight BP

measurement, allowing for thorough capture of sleep-time BP and early morning pathologic states, such as "morning surge."

Beyond more detailed phenotyping, continuous monitoring may also have the added benefit of providing instantaneous feedback on environmental triggers and behaviors that abruptly increase or lower BP. This could theoretically inform greater precision in future hypertension treatments and behavioral interventions that may reduce BP lability and its associated organ injury.

These devices have useful potential applications for adults who may not have valid options for traditional cuff-based BP measurement. There are limited cuff-based devices validated for BP measurement among adults with obesity, children, and in specific populations (eg, pregnant women, people with arrhythmia).[19–22] Other situations that limit options for BP measurement (eg, arteriovenous fistula) could also be overcome by cuffless technologies, and measurement error from miscuffing could be avoided.[23] These technologies hold promise for overcoming barriers to the study and clinical care of a broad range of patients, recognizing that potential benefits are theoretical and not supported by empirical evidence.

Inpatient or Perioperative Setting

BP measurement with a cuff-based, oscillometric device is considered a standard vital sign in the inpatient setting and is generally measured every 4 to 6 hours in the United States and every 8 to 12 hours in Western Europe.[24,25] In the operating room, oscillometric, cuff-based measurement is the exclusive form of BP measurement in 85% of cases.[26] Among inpatients, cuff-based measurement is a frequent source of sleep disturbance, which may contribute to delirium, prolonged illness, and impaired recovery.[27,28] In inpatient and perioperative settings, there is often a need for highly frequent or continuous BP monitoring, which historically could only be performed intrusively or invasively. Some work has been done to understand the impact of noninvasive continuous BP monitoring devices on clinical decisions, typically using error grid analyses. Three large-scale comparisons of volume-clamp devices (a well-established approach using a finger cuff for noninvasive continuous BP estimation) with arterial catheterization in surgical patients suggested that inaccuracies in noninvasive continuous measurements led to unnecessary treatments, resulting in moderate, non–life-threatening outcomes, in 0.1% to 3% of cases.[29–31] Cuffless devices therefore could overcome the need for invasive or intrusive BP measurement in many patients.

Underresourced Adult Communities

Cuffless BP devices have the potential to increase access and overcome barriers to BP screening, particularly for underresourced communities. Individuals from these communities—including people from rural areas, with low income, or from underrepresented racial or ethnic groups—often have a higher prevalence of hypertension and uncontrolled BP than their counterparts and face barriers to accessing health care services, including regular BP monitoring and confirmation of office BP with ABPM.[32–34]

One of the primary barriers to BP screening in underresourced communities is a lack of health care facilities and trained physicians.[35] Cuffless devices, which are often portable and convenient and can be incorporated into everyday objects (eg, watches, smartphones), can be deployed in homes, in community centers, among lay community health workers, and by individuals themselves.[4,5,36] This accessibility eliminates the need for individuals to travel long distances to receive basic health screenings, making it easier for residents of rural areas, or areas with shortages of health care professionals, to monitor their out-of-office BP regularly.

Cost is a major barrier hindering access to health care and traditional BP monitoring methods for individuals from underresourced populations, many of whom may be uninsured or underinsured. Cuffless BP devices could theoretically reduce costs, particularly when integrated into wearable or mobile devices that consumers purchase for multiple uses.[36] However, because of the limitations of cuffless devices, including the need for calibration with additional purchased devices and insufficient accuracy, cost-effectiveness remains speculative.

Cuffless BP devices offer promise for expanding BP measurement in underresourced communities, but they rely heavily on technology, including sensors, algorithms, and data transmissions, which may not always function optimally in resource-limited settings or areas with poor connectivity. Underresourced communities may lack access to adequately validated oscillometric cuff-based BP devices with which to calibrate cuffless BP devices, as well as training and education on the accuracy of cuffless devices and how to use them correctly, potentially leading to errors in measurement and interpretation.[36] Widespread use of cuffless BP devices in all populations requires a multifaceted approach to address limitations, including ongoing research to improve the accuracy, reliability, and ease of use of cuffless devices; targeted training programs to ensure proper usage and interpretation; and initiatives to ensure affordability and accessibility.

Children and Adolescents

Standard cuff-based BP measurements are challenging in children. These challenges can be physiologic, related to their smaller arms, elastic arteries with different waveforms, large differences between peripheral and central BP, and difficult-to-detect Korotkoff sounds.[19] Oscillometric cuff-based BP devices are commonly used in clinical practice, but few have been validated for use in children, and even fewer validated devices are available

for out-of-office measurement.[19,20] Pediatric hypertension guidelines recommend ABPM for all children with elevated readings to confirm hypertension. This can be particularly challenging in children and adolescents due to tolerability and hesitancy related to social stressors (eg, wearing a medical device in a school setting). Many of the barriers encountered in low-resource settings regarding access are amplified in pediatric settings, because ABPM pick-up and drop-off requires a parent or guardian to take time off work and other household responsibilities.[19]

Cuffless BP devices have the potential to address some of the pitfalls of conventional BP measurement techniques in children. The technology offers a way to measure BP without the obtrusive cuff inflation, which can lead to measurement error and falsely elevated BP. This can be especially useful with ABPM, because traditional devices have been reported as poorly tolerated and associated with sleep disturbance in children.[37] Among the few studies examining the use of cuffless BP devices in children,[38,39] some correlation was found between cuffless and standard BP measurements, but wide intrasubject variability (up 20 mm Hg) was also observed. As with standard BP devices, attention must be paid to customizing cuffless devices for pediatric use. Validation within the pediatric population using a protocol appropriate for cuffless devices will be necessary before widespread adoption.

CUFFLESS DEVICE VALIDATION

Clinical validation refers to standardized, in-human accuracy testing of a novel device compared with a reference device. Clinical validation testing of conventional BP measurement devices aims to ensure that devices provide accurate BP measurements across the breadth of arm sizes, BP values, ages, and sexes for their intended use. For this purpose, the International Organization for Standardization (ISO) publishes international validation standards for BP measurement devices with a cuff, with an addendum to the most recent iteration from 2018 published in 2024 (ISO 81060-2:2018 and ISO 81060-2:2018/A2:2024).[40,41]

FDA clearance of cuffless devices does not mean they will prove accurate enough for clinical use. Although the FDA reviews data on device performance, formal clinical validation testing that adheres to an established protocol is not required for a BP measurement device to receive FDA clearance[42]; thus, regulatory clearance is not synonymous with measurement accuracy. Nearly 80% of cuff-based devices available in the global marketplace have never published the results of formal validation testing for accuracy according to an established protocol.[43] For cuffless devices, this percentage is much higher, due to the lack of validation standards until recently (or at all).[40,44,45]

Whereas arm cuff–based validation protocols have been available for decades, protocols to test the accuracy of cuffless devices are only now starting to become available (Table 1). An ISO validation protocol for noninvasive cuffless or cuff devices that provide continuous (beat-to-beat) measurements was published in 2022.[44] An ISO protocol to address accuracy testing of cuffless devices providing intermittent measurements (spot or repeated measurements >30 seconds apart) is not yet available. This has led several manufacturers to test their cuffless devices according to validation protocols designed for traditional cuff-based devices or according to non-ISO standards. These approaches, although laudable, do not adequately address specific characteristics of cuffless technologies, including their reliance on distinctive, indirect estimation methods and use in varied contexts, which differ substantially from the principles and conditions underlying cuff-based protocols.[43]

One of the first standards to guide measurement-based validation testing of cuffless BP devices was first published in 2014 by the Institute of Electrical and Electronics Engineers (IEEE; Standard for Wearable Cuffless Blood Pressure Measuring Devices [1708-2014]).[46] This standard was later amended in 2019 and is used by the FDA to evaluate novel cuffless BP technologies that provide intermittent measurements.[45] The IEEE standard relies on auscultation as the reference standard and recommends validation testing immediately after calibration, in distinct body positions, after inducing BP changes, and before recalibration.[2,45,46]

In 2022, the ISO 81060-3 validation protocol for continuous cuffless or cuff devices was published.[44] Unlike the IEEE standard, this protocol focuses on devices intended for use in operating room and intensive care settings. Because continuous devices provide beat-to-beat monitoring, the ISO 81060-3 adopted intra-arterial monitoring as the reference standard. Similar to the IEEE standard, ISO 81060-3 includes testing after calibration, in distinct body positions, after induced BP changes, and before recalibration. Given the clinical settings intended for these devices (nonambulatory) and requirement of invasive arterial BP measurements for validation, this protocol cannot be easily translated to intermittent cuffless BP devices intended to be used during activities of daily living.

The ISO recently convened an international working group to draft a validation protocol intended for accuracy testing of a wide range of intermittent cuffless device types (ISO 81060-7). This new protocol will address the aspects of technology and intermittent cuffless BP measurement devices that are not covered by the ISO standard for continuous devices (ISO 81060-3), as well as the limitations of current cuffless validation protocols that were highlighted by the European Society of Hypertension in 2023.[47] Consistent with previous ISO guidelines, this protocol will likely not focus on safety or clinical

Table 1. Differences in Recent Validation Protocols for Cuffed and Cuffless Blood Pressure Measurement Devices

Protocol features	Cuffed oscillometric devices for seated measurements (ISO 81060-2:2018)[40]	Cuffed oscillometric ambulatory BP monitors (ISO 81060-2:2018)[40]	Continuous cuff or cuffless devices (ISO 81060-3:2022)[44]	Cuffless devices (IEEE 1708a-2019)[45]
Participants, n	85	35	≥30*	85
Paired BP measurements, n	255	105	≥278*	255
Special populations (if passed in general population)	Pregnant individuals, N=45; children 3–12 y, N=35; neonates, N=18	Each special population is studied separately	Each special population is studied separately	Additional testing required for certain populations (ie, pregnant, >50 y of age, with arrhythmia, on vasoactive therapy)
Reference approach and device	Auscultation with a mercury or aneroid device that complies with ISO 81060-1	Auscultation with a mercury or aneroid device that complies with ISO 81060-1	Intra-arterial line	Auscultation with a mercury device
Setting	Seated at rest using standardized measurements	Dynamic exercise on a bicycle to increase heart rate to at least 15% above resting heart rate	Resting, after inducing a change in BP, testing over the device's established reinitialization period (period of time between need for recalibration) if applicable	Seated at rest using standardized measurements, supine, and standing; after inducing a change in BP; after a period of time to determine maintained calibration within the device's specifications; during ambulatory conditions
Pass criteria, mm Hg†	≤5±8	≤5±8	≤6±10	≤7
Limitations	Few validation studies performed in special populations	Few validation studies performed in special populations	Invasive monitoring required; applicable only to hospital environment	No guidance on how to induce BP changes; no requirement for testing in ambulatory conditions

IEEE indicates Institute of Electrical and Electronics Engineers; and ISO, International Standard Organization.
*Depends on intraclass correlation coefficient.
†Allowable blood pressure (BP) differences for devices providing absolute BP values. Values are mean±SD or mean absolute difference.

use cases (eg, the ability of devices to measure blood pressure while the individual is asleep or in response to drug treatment), but rather awake testing, in a controlled laboratory environment, comparing accuracy and precision with auscultation. Absence of these clinical test results may represent a formidable limitation for clinicians hoping to replace conventional BP measurement approaches with these devices.

The heterogeneity of cuffless BP measurement devices necessitates tailored validation protocols according to their function and calibration.[48] For example, the IEEE standard is intended to test the accuracy of both continuous and intermittent cuffless BP devices using manual auscultation as a reference.[45] Given the variability of BP in each cardiac cycle, using an auscultatory reference for continuous measurements could lead to incorrect conclusions regarding a device's accuracy. The BP comparisons for these, often ambulatory, devices are made in static conditions immediately after cuff calibration, which does not reflect typical use conditions (eg, during activity; hours, days, or weeks after initial calibration). Induction of BP changes ±30 mm Hg is recommended and performed before cuff recalibration; however, there is a lack of specific protocols provided to induce BP changes, which is a crucially important step that requires reproducibility and applicability for all device types. With many devices providing measurements throughout the day, guidance regarding how to test overnight measurements and perform other testing in research centers is needed.

Many cuffless BP measurement devices are automated and positioned at the wrist or hand, making them highly susceptible to error due to hydrostatic pressure effects, exacerbated by malpositioning or movement. Because some devices require periodic cuff calibration to provide accurate absolute BP values, validation protocols do not address stability over time (ie, current protocols only test the accuracy of the device immediately after calibration). The performance of devices using PPG sensors may be influenced by skin color.[8] Therefore, the European Society of Hypertension writing group acknowledges that cuffless devices require more complex validation protocols. The European Society of Hypertension suggests 6 validation tests to address some of the unique characteristics of cuffless devices: static tests (ie, at rest), device position tests (ie, in at least 1 other position), treatment tests (ie, 1–4 weeks after initiating a new antihypertensive therapy), awake/asleep tests (eg, using ABPM for overnight BP measurement), exercise tests, and recalibration tests (ie, right before the device is recommended to undergo recalibration).[46] The complexity of these protocols may hinder their practicality in assessing device accuracy, and the need for separate protocols for children and pregnant women adds to their limitations. The absence of environmental standards (eg, ambient temperature) also poses challenges in evaluating device performance.

Table 2. Important Remaining Gaps Before Cuffless BP Devices Will Be Appropriate for Clinical Decision-Making

Standardized accuracy assessment
Develop an international protocol for cuffless intermittent BP devices
Develop a protocol to validate these cuffless devices, including a full range of skin tones for devices using PPG and in special populations (eg, pregnant, older, or pediatric individuals; people with arrhythmia)
Clinical applicability across use conditions
Perform clinical accuracy assessment that addresses:
Change in BP after administering BP-lowering medication
Change in BP in response to physiologic stimuli (eg, cold pressor test, isometric handgrip) across populations with differing autonomic regulation (eg, due to age, sex, clinical comorbidities)
Full recommended use period and settings
Multiple different positions, postures
Daily activities, if intended for this use
Exercise, if intended for this use
Sleep, if intended for this use
Calibration requirements
Assess influence and feasibility of the calibration step (eg, potential for cuff-based device–derived and user-derived inaccuracies)
Demonstrate stability of calibration over time
Clinical utility
Determine the relationship of the large volume of cuffless BP data in typical use settings with clinical outcomes
Evaluate the need for new thresholds or other approaches to interpreting the large volume of cuffless BP data
Test the actionability of abnormal readings (ie, feasibility, safety, and effectiveness of treating) in settings or situations not previously measured
Assess the effect of individual algorithms (eg, with smoothing, differences across user risk factors) and technologies across devices on prognostic capability and actionability of data
Compare output with standard, established measurements for BP monitoring, including ambulatory BP monitoring and standardized office BP assessment with validated devices
Data communication and interpretability
Ensure device output makes it clear to the end user what data are being communicated (eg, absolute BP, change in BP)
Provide indications for use that are clear to both clinicians and users
Require greater transparency from manufacturers on algorithmic inputs and logic to support independent verification and clinical interpretability
Ethical and regulatory oversight
Address data ownership, privacy, and patient consent related to continuous personal health data collection
Ensure secure data storage, appropriate data sharing protocols, and protection against misuse
Person- and system-level considerations
Address acceptability and feasibility of use in different patient populations
Determine cost-effectiveness

BP indicates blood pressure; and PPG, photoplethysmography.

CRUCIAL GAPS IN INTERPRETING DEVICE OUTPUTS FROM CUFFLESS BP DEVICES

Given the exponential growth of consumer wearable devices, clinicians will likely be presented with large amounts of out-of-office cardiovascular measurement data. Studies of cuffless BP devices have demonstrated poor performance (eg, accuracy not significantly better than that of a baseline model, which estimates BP using only cuff BP for calibration or demographic and anthropometric inputs) in tracking exercise-induced BP changes, sleep-time BP changes, antihypertensive treatment–induced BP changes, BP changes associated with activities of daily living, and during 24-hour continuous BP monitoring.[49–53] Despite FDA clearance or possibly passing future ISO validation protocols, clinical performance must be considered before these devices can be accepted for clinical decision-making (Table 2).

Comprehensive protocols to test for accuracy across an array of devices intended for use across a range of conditions and people are lacking. These concerns may not be addressed by ISO and IEEE validation procedures alone. Future protocols need to allow manufacturers to reliably ensure that devices perform as expected across skin tone, age, activity level, and pregnancy status and within individuals over time. Many devices rely on extra inputs, such as cuff-based BP measurements. For these technologies to be optimally implemented, the influence and feasibility of this calibration step needs to be carefully examined; cuffless BP device accuracy is highly dependent on the accuracy of the cuff-based device used for calibration, user skill in obtaining cuff-based measurement, and periodic recalibration. Research linking cuffless device data with outcomes is emerging but not yet robust enough to inform clinical decision-making.

CONCLUSION AND FUTURE DIRECTIONS

Cuffless BP devices have incredible potential to change the landscape of cardiovascular disease prevention and treatment. With the advent of technologies to capture BP data in varied settings, over day(s) to weeks, in products that are affordable and accessible to most individuals, we are entering a new era of health care. Being able to measure BP continuously and passively with wearable devices and obtain intermittent BPs throughout the day with devices embedded in everyday items (eg, smartphones, watches) will allow large numbers of people to self-monitor their BP, overcoming contemporary barriers to cardiovascular health promotion, such as lack of access to health care. However, major limitations must be addressed before individuals can fully benefit from these new technologies. There is a need for standardized validation protocols that evaluate accuracy across diverse technologies, contexts of use, and populations. Technical barriers to obtaining reliable BP estimation must be resolved to ensure results are actionable. The extensive volume of data these devices generate, especially in settings not traditionally used for BP monitoring, must be linked to meaningful clinical outcomes. Furthermore, data privacy, ownership, and consent must be addressed

(Table 2). Until these issues are resolved, using these devices to guide treatment could lead to inappropriate care and may pose safety risks to patients.

ARTICLE INFORMATION

The American Heart Association makes every effort to avoid any actual or potential conflicts of interest that may arise as a result of an outside relationship or a personal, professional, or business interest of a member of the writing panel. Specifically, all members of the writing group are required to complete and submit a Disclosure Questionnaire showing all such relationships that might be perceived as real or potential conflicts of interest.

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Robert H. Thiele	University of Virginia	NIH (R-21 [NIBIB])†	None	CMS 2024: Philips North America LLC; honoraria*; compensation for serving as faculty or as a speaker for a medical education program*; CMS 2023: Philips Electronics North America Corp; compensation for serving as faculty or as a speaker for a medical education program*	Adams & Reese, LLP*; Harris Creech*	Hoplite Healthcare, LLC*	Philips Medical*; CMS 2023: Philips Electronics North America Corp; consulting fee*; Edwards Lifesciences Corp, consulting fee*; consulting fees*	None
Eugene Yang	University of Washington Medical Center	Microsoft Research (grant to support research on new BP measurement technologies)†	None	None	None	None	American College of Cardiology†; Idorsia†; Sky Labs*; Genentech, Inc, consulting fee†	None

This table represents the relationships of writing group members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all members of the writing group are required to complete and submit. A relationship is considered to be "significant" if (a) the person receives ≥$5000 during any 12-month period, or ≥5% of the person's gross income; or (b) the person owns ≥5% of the voting stock or share of the entity, or owns ≥$5000 of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

*Modest.

†Significant.

Reviewer Disclosures

Reviewer	Employment	Research grant	Other research support	Speakers' bureau/ honoraria	Expert witness	Ownership interest	Consultant/ advisory board	Other
Michael S. Brian	Plymouth State University	None	None	None	None	None	None	None
Remi Goupil	Hôpital du Sacre-Coeur de Montreal (Canada)	None	None	None	None	None	None	None
Jiun-Ruey Hu	Yale School of Medicine	None	None	None	None	None	None	None
Daichi Shimbo	Columbia University Irving Medical Center	None	None	None	None	None	None	None
Wanpen Vongpatanasin	University of Texas Southwestern Medical Center	None	None	None	None	None	None	None

This table represents the relationships of reviewers that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all reviewers are required to complete and submit. A relationship is considered to be "significant" if (a) the person receives ≥$5000 during any 12-month period, or ≥5% of the person's gross income; or (b) the person owns ≥5% of the voting stock or share of the entity, or owns ≥$5000 of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

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