JAMA Cardiology | Review

Cuffless Blood Pressure Measurement Devices—International Perspectives on Accuracy and Clinical Use
A Narrative Review

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IMPORTANCE Hypertension is a primary modifiable risk factor for cardiovascular death and disability. Accurate blood pressure (BP) measurement is essential for the diagnosis and treatment of hypertension. Conventional BP measurement with cuff devices is recommended but difficult for patients to perform due to inconvenience, discomfort, and challenges with appropriate cuff sizing and measurement protocols. The emergence of cuffless BP devices provides an opportunity to address many of these problems, including inconvenience, patient comfort, positional requirements, and continuous measurement.

OBSERVATIONS Cuffless BP measurement devices are appealing to patients and clinicians, but validation of these technologies is essential before they can be deployed for clinical use. Key issues that remain include accuracy with risk of undertreatment or overtreatment, equitable access for low- and middle-income countries and minoritized populations, data privacy concerns, and how the devices will be deployed in clinical practice.

CONCLUSIONS Clinicians and patients should only use validated BP cuff devices until cuffless BP measurement devices are appropriately tested and validated.

JAMA Cardiol. doi:10.1001/jamacardio.2025.0662
Published online April 23, 2025.

Supplemental content

CME at jamacmelookup.com

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High blood pressure (BP) is the leading modifiable risk factor for disability and premature cardiovascular deaths and is strongly linked to ischemic heart disease and stroke deaths.[1] The global burden of hypertension, estimated at 1.3 billion in 2019,[2] is projected to exceed 1.6 billion by 2025.[3] Hypertension affects half of US adults, and only 1 in 4 have their BP controlled.[4] There is a critical need to improve ways to measure BP and increase BP control rates, as standard approaches have not substantially improved the care of patients with hypertension.[5]

There has been a rapid proliferation of consumer wearable devices (CWDs) that can provide health and fitness metrics.[6] Although early CWDs focused on activity and fitness tracking, heart rate, or oxygen saturation level, newer devices use technologies such as optical photoplethysmography (PPG) with or without machine-learned algorithms to identify abnormal heart rhythms and estimate BP. Advances in mobile technologies have created a receptive environment for CWDs as a platform for health care services.[7] The global market for wearable health care devices is expected to reach $46 billion by 2025, including $2.25 billion by 2023 for cuffless BP monitoring technologies.[8]

Cuffless BP measurement devices offer advantages over validated cuffed devices, including greater comfort and convenience, BP measurement without upper arm sizing or positioning, and continuous BP measurements over extended periods.[9] Cuffless devices may also be less expensive,[10] improving consumer access, especially in low- and middle-income countries (LMICs), where cost may be a determinant.

Although the availability of cuffless BP measurement devices has increased, validation of device readings for accuracy has not been addressed. This review from US and international experts provides clinicians with an understanding of the state of cuffless BP devices, including an overview of the devices, validation protocols, patient and clinician perspectives, and major barriers to implementation.

Discussions/Observations

Overview of Cuffless BP Devices on the Market

The exponential growth in innovative technologies to measure BP without a cuff is evident from patent registrations of cuffless BP technologies worldwide (eFigure in the Supplement). With the challenges of conventional cuff-based methods and recent advancements in body signal sensors, artificial intelligence (AI), data science, machine learning (ML), and mobile phone technologies, the time is right to reinvent the most frequent patient measurement taken in clinical practice.

Wrist-worn watch-type[11] devices (**Figure 1**) are what many consider to be cuffless devices, but companies are thinking outside the box, with many innovative approaches under development,[12] including mobile phone technologies (estimating BP from transdermal optical processing[13] or oscillometric finger pressing[14]), chest patches,[15] wearable ultrasound patches,[16] temporary graphene electronic tattoos,[17] glasses,[18] rings,[19] and even a toilet seat.[20]

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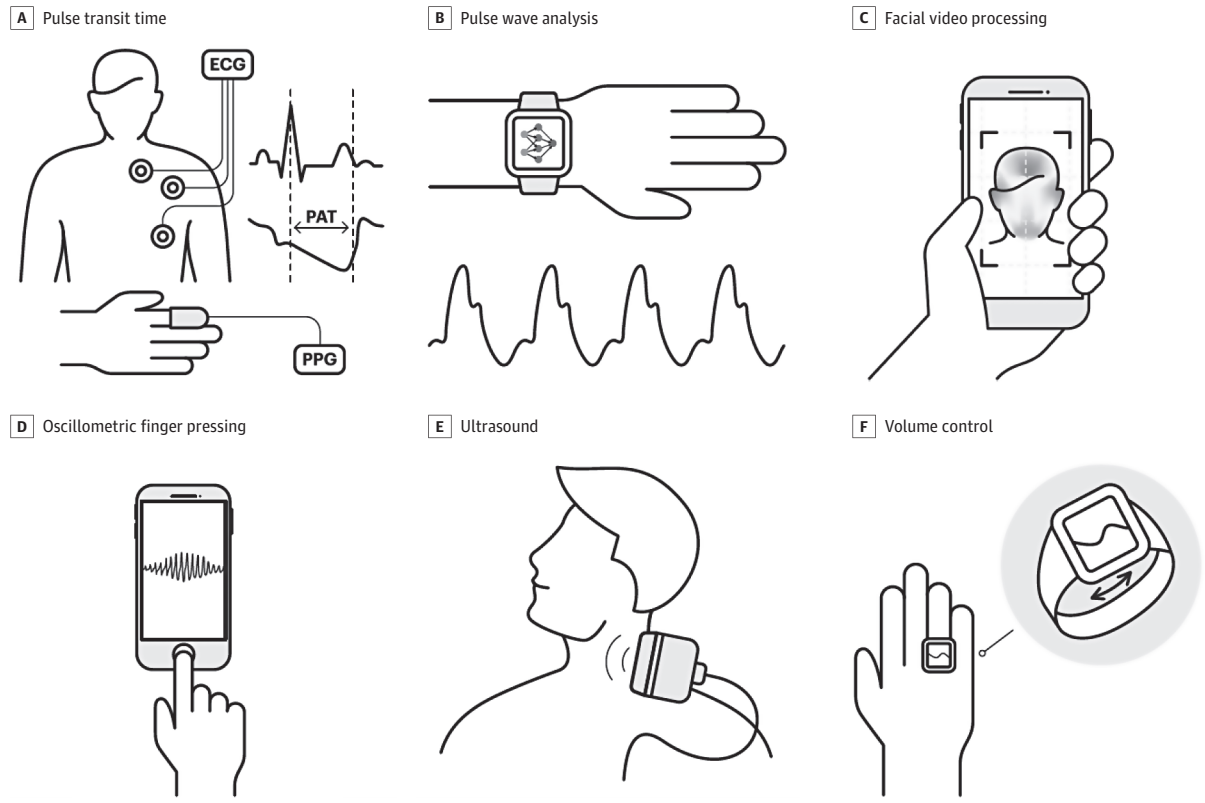
Figure 1. Examples of Cuffless Blood Pressure Measurement Technologies



ECG indicates electrocardiogram; PPG, photoplethysmography. Permission to reprint obtained from Wolters Kluwer Health.

A challenge in determining how accurate and useful these devices would be in clinical practice is the use of heterogeneous technologies.[21] These devices rely on obtaining a specific type of measurement that correlates with BP and converting this reading into millimeters of mercury units. The vast majority of the currently available cuffless BP devices use principles based on pulse wave analysis (PWA) with PPG and electrocardiography (ECG) and require individual user calibration with classic cuff BP measurement and/or biometric data.[11-20] Other devices use pulse transit time (PTT), facial video processing, arterial tonometry, thoracic bioimpedance, phonocardiography, or ballistocardiography (Figure 1).[11-21]

Most cuffless BP devices use PPG via a light sensor, which measures an optically obtained, pulsatile hemodynamic waveform to assess blood volume changes in the microvasculature. ML algorithms extract features from the waveform to estimate BP values. As mentioned previously, these devices typically require periodic calibration with a standard cuff BP measurement with or without demographic data from the individual user and, thus, track changes in BP relative to the calibrated measurement, rather than measure absolute BP values. Some devices obtain ECG waveforms to extract PTT and pulse arrival time (Figure 1). Tonometric cuffless BP devices use a tonometry sensor to obtain a net force oscillation waveform from the radial artery. Other technologies, such as oscillometric finger pressing, ultrasound, and volume control, have also been investigated. Remote PPG uses advanced camera technology to capture optical signals from the skin of the face to obtain pulsatile waveforms from a distance, allowing contactless PWA (Figure 1).

In contrast, cuff-based BP devices measure BP by sphygmomanometry. Many devices use PPG waveforms (with or without an electrocardiogram signal) from the wrist or finger. Although PPG waveforms have challenges, such as vascular age dependence and poor correlation with BP, PPG has potential due to BP-related information captured in the waveform.[22] Advances in AI to extract BP-specific features from PPG signals, such as artificial and convolutional neural networks, may improve BP estimation algorithms.[19]

Devices typically require initial calibration with a BP measurement taken by a conventional arm cuff device, with or without demographic information such as age, sex, weight, and height. Recently developed technologies, such as oscillometric finger pressing and ultrasound, do not require calibration. Yet, it is still unclear whether these new technologies are valid and will ultimately make it to market.

Notwithstanding challenges to ensuring accurate cuffless BP measurement, a plethora of devices are available for purchase.[10] Until recently, proving the accuracy of cuffless devices was challenging for manufacturers due to a lack of specific validation protocols. Cuffless devices have different accuracy issues than cuff devices and, therefore, require different and more complex validation standards, including measurements obtained from different positions and after inducing BP changes.

Several devices have obtained regulatory clearance from the US Food and Drug Administration (FDA; BioBeat [Biobeat], Nanowear

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Table 1. Validation Protocols for Cuffless Blood Pressure (BP) Measuring Devices[a]

Device information	IEEE 1708-2014[32] & 1708a-2019[33]	ISO Standard 81060-3:2022[31]	ESH Recommendations 2023[27]
Device type	Wearable	Continuous	Intermittent
Sample size	≥85	30-120, Depending on intraclass correlation for each BP parameter	85-175, Depending on device type
Reference	Manual auscultatory	Intra-arterial	Manual auscultatory; 24-h oscillometric
Validation procedure			
Immediately after calibration	Yes	Yes	Some device types
Different device positions	Yes	Yes	Some device types
After BP change	Yes, acute (not specified)	Yes, acute (in-hospital care)	Some device types Short-term (exercise); longer-term (pre-post treatment; awake/asleep)
Before recalibration	Yes	Yes	Some device types
Test/reference BP measurements	Simultaneous or sequential	Simultaneous	Sequential (24-h BP simultaneous)
Pass criteria (BP difference)	≤7 mm Hg	≤6 ± 10 mm Hg	≤5 ± 8 mm Hg

Abbreviations: IEEE, Institute of Electrical and Electronics Engineers; ISO, International Organization for Standardization; ESH, European Society of Hypertension.

[a] Modified from reference.[27]

[Nanowear Inc], LiveOne [LiveMetric], Visi [Sotera Wireless], Caretaker [Caretaker Medical], BPro [Healthstats International]), CE mark in the European Union (Aktiia [Aktiia], Samsung Galaxy [Samsung Electronics]), or reimbursement for 24-hour ambulatory monitoring (CART BP [Sky Labs]). Although some companies have published studies demonstrating device accuracy, they generally compare their devices to intra-arterial or sitting BP, which are not appropriate for validation. Although manufacturers claim their devices are accurate,[11,23-25] independent researchers have generally not reached similar conclusions.[26-28] External validation of these devices is critically important, especially since cuffless technologies are continuously evolving.

The US FDA uses a 510(k) clearance mechanism to determine whether a device is equivalent to one that is already commercially distributed. This mechanism is not an approval or attestation of device validity. As of 2022, the FDA has accepted 510(k) documentation for 4 cuffless devices. ViSi (Sotera Wireless), cleared in 2012, estimates BP by ECG and PPG (wrist). Caretaker (Caretaker Medical), cleared in 2017, estimates BP by PWA (finger). BPro (Med Tach Inc), cleared in 2018, estimates BP by applanation tonometry (wrist). Biobeat (Biobeat Technologies), cleared in 2019, estimates BP by PPG (wrist, chest). All of these devices rely on calibration with a cuff-based, brachial BP measurement.[29]

There is a substantial need for convenient modalities that accurately measure BP outside of health care settings, but novel approaches have limitations that should not be ignored, including technical aspects such as skin tone (relevant for PPG); the need to frequently calibrate the device; the inability to track BP during sleep,[26] exercise, or when taking BP-lowering medications[27]; multiple artifacts; and missing data. Clinician concerns include skepticism about accuracy, interpretation, and whether the data are safe and useful for clinical decision-making.

Validation of Cuffless BP Measuring Devices

In 2018, the Association for the Advancement of Medical Instrumentation (AAMI), the European Society of Hypertension (ESH), and the International Organization for Standardization (ISO) developed an AAMI/ESH/ISO Universal Standard (ISO 81060-2:2018) for the validation of automated cuff BP-measuring devices using the auscultatory measurement as reference.[30] This standard, designed for cuff BP devices, is inappropriate for cuffless devices, as the latter have different measurement principles and specific accuracy issues.[26,29,31-34] First, for validating continuous cuffless devices (BP reading output every ≤30 seconds),[32,35] the auscultatory method cannot be applied as a reference.[21,32] Second, most intermittent cuffless devices (output every >30 seconds or after user initiation)[32,35] require calibration (using cuff BP measurement or demographic information), which renders them as BP tracking rather than measuring[21,32] because they assess BP fluctuations rather than absolute levels.[21,32] Thus, validation procedures involving BP changes are crucial for calibrated cuffless devices.[32] Additional issues associated with wearable devices include the effect of hydrostatic pressure and the instability of accuracy between recalibration sessions, requiring additional validation procedures.[32] These procedures are not included in the AAMI/ESH/ISO Universal Standard,[30,32] which may be only appropriate for cuffless devices that do not require calibration.[21,32,33]

Validation protocols for cuffless devices have been published by the Institute of Electrical and Electronics Engineers (IEEE),[36,37] the ISO,[35] and the ESH Working Group on Blood Pressure Monitoring and Cardiovascular Variability[32] (**Table 1**).[27,31-33] The 2014 IEEE standard[36,37] was the first to address key validation issues of cuffless BP devices and the need to assess BP changes. This standard did not provide specific instructions on how to induce BP changes, and its wide application was impractical, mainly due to difficulties with induction of acute BP decline in the clinical setting.[21,32] The 2022 ISO standard for continuous cuffless BP devices (ISO 81060-3:2022) incorporated intra-arterial measurement as a reference.[35] Continuous BP devices are useful in critical care (anesthesia, intensive care) to track short-term BP fluctuations[21,32] but are not used for the diagnosis or management of hypertension.[21,32] In 2023, ESH published recommendations with pragmatic validation procedures for cuffless BP-measuring devices that can be performed in many research centers to test the large number of cuffless devices on the market.[32] These recommendations are intended for intermittent cuffless devices, which are useful for hypertension diagnosis and management.[21,32] Six validation tests are recommended

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in different combinations to tailor the validation procedure for each cuffless device type depending on its design, features, and intended use.[32] A new ISO task group is developing a new standard for intermittent cuffless measurement type devices (ISO Standard 81060-7).

Because ESH recommendations for cuffless devices were only recently published, industry and independent evaluators have had limited time to perform specific validation tests. Studies that have been published on key aspects, such as the ability to track BP over 24 hours, highlight potential challenges in tracking nighttime dipping (eg, Aktiia [Aktiia US], BioBeat [Biobeat Technologies US], CART BP [Sky Labs], Samsung Galaxy [Samsung Electronics][25,27,28,38]). Although 1 report[39] found that the SOMNOtouch device (SOMNOmedics GmbH) demonstrated good precision in 24-hour BP monitoring for children and adolescents, another study[40] found that the device was unable to accurately track BP changes after calibration in adults. To improve our understanding of clinical usefulness, more studies based on the ESH recommendations are needed, in particular, the ability of cuffless devices to track BP changes in response to BP lowering medication.

The accuracy of all devices providing BP measurements is critical, irrespective of whether they are used by clinicians or patients. Cuffless BP devices must have the same accuracy level as cuff BP devices deployed in medical settings or they should not be used at all. There is an urgent need to develop a universal validation standard, as with the AAMI/ESH/ISO Universal Standard (ISO 81060-2: 2018) for cuff BP devices.[30] Unfortunately, testing the accuracy of a cuffless device is more complex and expensive than for cuff devices. Although this is a challenge for the industry, regulatory agencies should not approve technologies with unproven accuracy.

Patient Perspectives

Home BP monitoring (HBPM) is recommended by BP guidelines. However, validated cuff devices can pose significant challenges for patients: only 3% of patients correctly measured their BP, whereas 60% made 3 or more errors, the most common being incorrect cuff placement (76%).[41] Incorrect cuff sizing may result in as much as a 20-mm Hg measurement error.[42] Major barriers to cuff BP measurement include inconvenience, lack of time or motivation, as well as patient discomfort and anxiety as well as incorrect sizing and placement, leading to significant errors (**Table 2**). A recent study found that patients prefer cuffless devices to conventional 24-hour monitoring or HBPM using cuff BP devices.[43]

Patient perspectives are important in adopting new technologies such as cuffless BP devices.[44] Self-monitoring facilitated by these technologies empowers and increases engagement by patients in their health care.[45] Empowerment experienced by patients with technology-enabled care enhanced their ability to participate in decision-making, achieve control, learn about their health, and experience less frustration with technology.[45]

Patient privacy is key for wearable technology adoption, but many are hesitant to share health data. A survey found that primary care patients were more comfortable sharing data with physicians than third parties, with older adults and those with lower health literacy less comfortable.[46] Practices should promote awareness, address privacy concerns, and offer education, especially for older patients and those with health literacy limitations.

Despite the potential benefits of wearable devices in health care, patient acceptance is paramount. A recent study[47] found that only 20% of participants believed that the benefits of technology outweigh the potential dangers, including concerns about AI replacing human intelligence, hacking risks, and data misuse.

Table 2. Patient Profiles Where Cuffless Blood Pressure (BP) Measurement Devices May Be Clinically Useful

Patient profiles	Conditions where cuffless BP devices may be useful
Uncertain diagnosis with cuff BP	• White coat hypertension • Masked hypertension • Borderline BP values • Increased BP variability • Alerting reaction to BP cuff inflation
Uncertain accuracy with cuff BP	• Large arm circumference (>42 cm) • Very small arm circumference (<20 cm) • Significant arrhythmia (eg, atrial fibrillation or frequent PVCs) • Poor sleep affecting standard nighttime BP readings
Hospitalized patients requiring close BP monitoring	• Acute or severe medical conditions (eg, sepsis, gastrointestinal bleeding) • Perioperative/postoperative patients
High-risk patients requiring close BP monitoring	• Postmyocardial infarction or stroke • Congestive heart failure • Hypertensive emergency • High total cardiovascular risk • Hypertensive disorders of pregnancy • Frail patients
Apparently healthy adults	• Hypertension screening via smartphones or smartwatches • General health monitoring with cuffless BP technology

Abbreviation: PVC, premature ventricular complex.

An important consideration in cuffless BP device validation is the digital divide, which describes the growing chasm between groups with unequal access to digital technologies such as computers, smartphones and CWDs. Availability of cuffless BP devices may be challenging for people in LMICs, where socioeconomic barriers may limit their successful uptake.[48] Lack of digital literacy can impede equitable deployment of these technologies and may isolate populations with low digital literacy.[49] Although at-risk populations may benefit from CWDs to improve their cardiovascular health,[50] several barriers limit wearable device efficacy, including lack of non-English resources[51] and limited culturally diverse mobile health interventions.[50]

Clinician Perspectives

Clinical guidelines recommend out-of-office BP monitoring as part of the routine diagnosis and treatment of hypertension.[52-56] The convenience and comfort of cuffless BP devices make them promising tools for facilitating out-of-office BP monitoring. In one of the few studies of clinician attitudes toward cuffless BP devices, those who had used them expressed optimism about their benefits.[57] Yet, many clinician barriers to out-of-office BP monitoring[58] may go unaddressed or may even be exacerbated by cuffless BP devices (**Table 3**).

Clinicians have concerns about the ability of patients to correctly follow out-of-office BP monitoring protocols with cuff devices.[59] If accurate readings from cuffless devices are less operator dependent, clinicians may recommend their use. Yet, as highlighted previously, most cuffless technologies require intermittent calibration, often with cuff devices, to account for calibration drift over time.[60] This measurement complexity will negatively influence clinicians' attitudes toward cuffless devices.

One barrier to HBPM uptake is concerns about the responsibility of managing a large volume of BP readings. This worry will only

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Table 3. Clinician Perspectives on Potential Benefits and Barriers to Adopting Cuffless Blood Pressure (BP) Devices Compared With Cuff Devices

Theme	Potential benefits	Potential barriers
Accuracy	• Reduces spurious elevated BP readings caused by measurement-related anxiety	• Complex calibration protocols may affect data accuracy • Accuracy concerns in individuals with dark skin tone, obesity, peripheral artery disease, or pregnancy
Anxiety	• Passive data collection minimizes measurement-related anxiety	• Patients may become preoccupied by BP levels
Comfort and convenience	• Cuffless devices offer increased comfort and portability	• Periodic use of a cuff BP device required for calibration
Data	• Provides a greater volume of BP data for clinical decision-making	• Clinicians may experience data overload • Limited device platform interoperability with EHR may restrict accessibility.
Ecological validity	• Captures out-of-office BP data across multiple settings, including during sleep and work	• Limited guidance on how to interpret continuous BP data
Equity	• Improves accessibility of out-of-office BP monitoring	• Cost and lack of insurance coverage may create disparities
Personalization	• Enables integration with other mobile health data for tailored treatment	• Limited evidence on using continuous BP data for treatment decisions

Abbreviation: EHR, electronic health record.

be intensified by cuffless devices, which have the potential to generate a much higher number of BP readings than cuff devices.[61] Without careful design of secure cloud-based systems that store, aggregate, and control the sharing of cuffless BP device data, clinicians will be less likely to adopt these devices into their practices. Of note, companies have been developing secure data storage systems for standard cuff devices with wireless capabilities. Evidence-based summaries with clinical implications, analogous to time in range or time above/below range for continuous glucose monitoring, are needed to promote use by clinicians.

Insufficient reimbursement is another barrier to greater adoption of out-of-office BP monitoring in the US.[62] It will be essential to create appropriate reimbursement models for clinicians managing patients with frequent readings from cuffless BP devices, with safeguards in place to ensure that billing codes are not misused.[63] Billing codes for remote monitoring with home BP devices exist in some countries (*Current Procedural Terminology* codes 99453, 99454, 99457, 99458, 99091 in the US). Documentation requirements and out-of-pocket costs to patients, particularly those already self-monitoring using cuff devices without charge, may limit their uptake.[64] Value-based pricing and reimbursement for achieving hypertension control metrics could incentivize adoption, but high-quality evidence demonstrating improved quality metrics will be needed.[65]

Health equity is another concern with cuffless devices. Out-of-pocket costs already limit the adoption of HBPM devices in lower-income populations.[66] Low purchasing power in LMICs has further limited clinician investment in out-of-office BP monitoring use. At present, FDA-cleared devices are mostly available in high-income settings and costs range from $300 to $700 per device (eg, Aktiia [Aktiia US], approximate cost = $280). Cuffless BP devices will likely need to be paired with smartphones or tablets that can wirelessly connect data to the cloud. Thus, unequal access to the technologies required for wireless devices may discourage use by clinicians.

Perhaps the most important concern regarding cuffless BP devices relates to potential misuse by clinicians. Recent studies have documented that 75% to 80% of home BP devices and 100% of the studied cuffless devices available for consumer purchase were not validated for accuracy.[10,67] Many clinicians lack awareness of validation issues with existing BP devices.[68] In the US, there is a poor understanding of the difference between FDA clearance, which only indicates safety and equivalence with similar consumer devices, and FDA validation, which refers to passing an exacting validation protocol demonstrating accuracy.[69] Hypertension experts have been raising the alarm regarding unvalidated BP devices, including cuffless BP devices, and the need for new policies and regulations to decrease their use.[70]

Barriers to Cuffless BP Device Use

Cuffless BP devices have the potential to revolutionize the way BP is monitored and managed, providing valuable data for individuals and health care professionals. However, several barriers associated with these devices hinder widespread adoption and effective use (Table 3).

Most cuffless BP devices use PPG sensors to track blood flow and detect BP changes. These sensors are sensitive to variations in skin tone or local blood flow, potentially leading to measurement inaccuracies. People with darker skin tones may experience less accurate results than those with lighter skin tones.[71] Reduced accuracy can be observed in patients with obesity, aortic regurgitation, atrial fibrillation, peripheral arterial disease, diabetes, heart failure, end-stage kidney disease, neurological disorders such as essential tremors, or blood clotting disorders.[72,73] Cuffless devices are not recommended during pregnancy because hormonal changes may affect vascular tone.[72,73]

As previously highlighted, many cuffless PPG-based BP measurement devices require precise calibration. The user must be taught how to accurately perform calibration to avoid errors introduced during the calibration process.[74] Some individuals, especially older patients, may have difficulty learning how to calibrate devices, leading to inaccurate BP estimation. A recent study of a cuffless BP monitoring device found that self-calibration performed by participants resulted in significant fluctuations in measured systolic BP values, up to 10 mm Hg in hypertensive individuals.[38] These findings suggest that precise calibration of the device performed by a health care professional might be preferred to individual calibration, yet this would be difficult to apply routinely in clinical practice.

Cuffless BP devices generate substantial data that need to be transmitted, stored, and securely analyzed. There are significant challenges to establishing a seamless architecture to manage data flow from devices to the cloud and integrating it into electronic health record (EHR) systems. Interoperability issues between different device platforms and EHRs will also hinder data exchange. The lack of a standardized infrastructure may result in data-sharing delays, which might affect timely diagnosis and treatment decisions. Furthermore, wearable BP devices collect sensitive health data, making it crucial for health care professionals and device manufacturers to implement robust data protection measures and comply with relevant privacy regulations.

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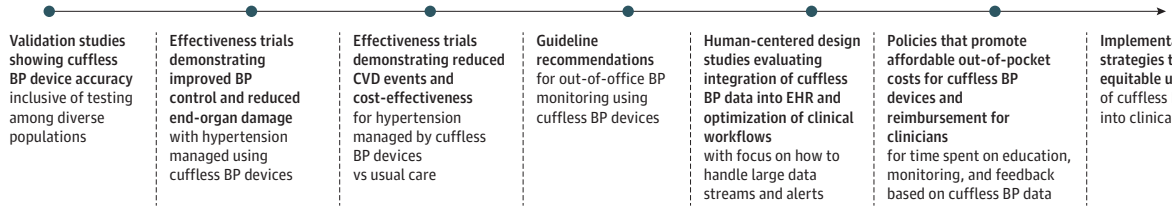
Figure 2. Roadmap to Establishing Cuffless Blood Pressure (BP) Devices as Tools for Improving Hypertension Control



CVD indicates cardiovascular disease; EHR, electronic health record.

Future Directions

Although there are exciting new developments in cuffless BP devices, several important, inadequately addressed issues remain (**Figure 2**). The efficacy and cost-effectiveness of cuffless BP devices in preventing cardiovascular events, compared with traditional cuff-based devices or usual care, have not yet been established in clinical trials. A cluster-randomized trial may be more suitable than an individually randomized trial, as it allows for easier implementation of the intervention at the clinic or community practice level.

The technology underlying cuffless BP devices is proprietary; therefore, how these devices derive BP from the variables they measure is nebulous. Device manufacturers should report how their devices estimate BP. This would allow clinicians to understand the limitations of each device and aid in their decision-making regarding which patients may be most appropriate for their use.

The role of cuffless devices in out-of-office BP monitoring needs to be clearly defined. It is unclear whether cuffless BP devices should be classified as ambulatory BP-monitoring (ABPM) or HBPM devices, or a third category.[60] The 2017 American College of Cardiology/American Heart Association High BP guideline,[75] 2020 International Society of Hypertension Global Hypertension Practice Guidelines,[76] 2023 ESH guideline,[77] and 2024 European Society of Cardiology BP guideline[78] all recommend BP thresholds that should be applied to define high out-of-office BP. These thresholds are based on studies that included traditional ABPM and HBPM monitoring devices with an upper arm cuff. It is unclear whether the same BP thresholds should be applied to cuffless BP devices. To our knowledge, there are no studies with clinical outcomes to relate office and cuffless device BP measurements with cardiovascular morbidity and mortality.

It is also unclear whether cuffless BP devices should become the primary method for out-of-office BP monitoring for everyone or reserved for individuals from specific subgroups, eg, those with an upper arm size larger than the manufacturer's recommended arm circumference range.

Despite the potential benefits of cuffless BP devices, minimal data have been published comparing these devices with traditional ABPM or HBPM devices. If these devices are not superior in terms of convenience, tolerability, and long-term adherence, then the use case for these devices is not evident.

Finally, there are limited data regarding the reproducibility of cuffless BP devices over days, weeks, or months. A cuffless BP device, even when accurate, must provide reliable BP estimates to be useful in clinical practice and must be designed to have longer periods of use without the need for recalibration to offer advantages over current out-of-office BP monitoring devices. Clinicians should only recommend validated BP measurement devices from resources like STRIDE BP (stridebp.org) and the Validated Device Listing (validatebp.org).

Conclusions

Cuffless BP devices for improving BP measurement have a long road ahead before they are ready for clinical use. It is important to call attention to accuracy issues and regulatory needs before these devices are widely adopted in clinical practice. It may take years to establish the evidence base for precision treatment using cuffless BP device data. Assuming data supporting the accuracy of cuffless BP devices improves over time, this technology may provide a new avenue to achieve better BP control for patients.

ARTICLE INFORMATION

Accepted for Publication: February 24, 2025.

Published Online: April 23, 2025. doi:10.1001/jamacardio.2025.0662

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Author Contributions: Dr Yang had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Dr Shimbo is considered the senior author.
Concept and design: Yang, Schutte, Stergiou, Commodore-Mensah, Kronish, Shimbo.
Acquisition, analysis, or interpretation of data: Yang, Schutte, Wyss, Odili, Lee.
Drafting of the manuscript: All authors.
Critical review of the manuscript for important intellectual content: Yang, Schutte, Stergiou, Kronish.
Statistical analysis: Yang.
Administrative, technical, or material support: Yang, Wyss, Lee, Shimbo.
Supervision: Yang, Schutte, Odili.

Conflict of Interest Disclosures: Dr Yang reported receiving advisory board fees from Sky Labs, Mineralys, and Idorsia and grants from Microsoft to perform research on new blood pressure measurement technologies outside the submitted

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work. Dr Schutte reported receiving speaker/advisory board fees from Aktiia, Sky Labs, and Omron outside the submitted work. Dr Stergiou reported receiving consulting fees from Sonion, Sky Labs, and Livemetric outside the submitted work. Dr Kronish reported receiving grants from National Institutes of Health, serving as section editor of *Current Cardiology Reports*, and serving as data safety monitoring board chair from University of Pittsburgh outside the submitted work. No other disclosures were reported.

Additional Contributions: We thank Nar Ramkissoon, MPH (American Medical Association), Matt McReynolds, MPH (American Medical Association), and the American Medical Association's Validated Device Listing Advisory Group for supporting this review, and Lori O'Keefe, BS, for providing editorial support. Beyond usual salary, no one received financial compensation for their contribution.

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