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## Cuffless blood pressure measuring devices: Review and Statement by the European Society of Hypertension Working Group on Blood Pressure Monitoring and Cardiovascular Variability --Manuscript Draft--

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<b>Abstract:</b>	<p>Background</p> <p>Many cuffless blood pressure (BP) measuring devices are currently on the market claiming that they provide accurate BP measurements. These technologies have considerable potential to improve the awareness, treatment, and management of hypertension. However, recent guidelines by the European Society of Hypertension do not recommend cuffless devices for the diagnosis and management of hypertension.</p> <p>Objective</p> <p>This statement by the European Society of Hypertension Working Group on BP Monitoring and Cardiovascular Variability presents the types of cuffless BP technologies, issues in their validation, and recommendations for clinical practice.</p> <p>Statements</p> <p>Cuffless BP monitors constitute a wide and heterogeneous group of novel technologies and devices with different intended uses. Cuffless BP devices have specific accuracy issues, which render the established validation protocols for cuff BP devices inadequate for their validation. In 2014 the Institute of Electrical and Electronics Engineers published a standard for the validation of cuffless BP devices, and the International Organization for Standardization is currently developing another standard. The validation of cuffless devices should address issues related to the need of individual cuff calibration, the stability of measurements post calibration, the ability to track BP changes, and the implementation of machine learning technology. Clinical field investigations may also be considered and issues regarding the clinical implementation of cuffless BP readings should be investigated.</p> <p>Conclusion</p> <p>Cuffless BP devices have considerable potential for changing the diagnosis and management of hypertension. However, fundamental questions regarding their accuracy, performance and implementation need to be carefully addressed before they can be recommended for clinical use.</p>

To  
Prof. Anthony Heagerty  
Editor-in-Chief, *Journal of Hypertension*

Dear Professor Heagerty,

We are pleased to upload to the *Journal of Hypertension* website an *Official Statement* by the ***European Society of Hypertension Working Group on Blood Pressure Monitoring and Cardiovascular Variability*** entitled “***Cuffless blood pressure measuring devices: Review and Statement***”.

Many cuffless BP measuring devices are currently on the market claiming that they provide accurate BP measurements. Experts, doctors, patients, and the public, are all keen to use them, yet they are not aware of the special issues of these technologies regarding their accuracy and implementation.

This ESH Consensus Statement aims to present the different types of cuffless BP technologies, their potential uses, issues in evaluating and validating their accuracy, and recommendations for clinical practice.

Since an international panel of 24 experts worked to develop this statement and reach consensus on cuffless BP monitors, we believe minimal review is needed. Moreover, we would like to kindly request to publish this statement with open access, as it is important to be read by many healthcare professionals who should be informed about the current status of cuffless BP monitors.

All authors have read and approved the submission of the manuscript. This manuscript has not been published and is not being considered for publication elsewhere, in whole or in part, in any language.

We are looking forward to your response.

Best wishes and thanks,

George Stergiou

Chairman, European Society of Hypertension  
Working Group on BP Monitoring and  
Cardiovascular Variability

Reinhold Kreutz

President, European Society of Hypertension

## **CONDENSED ABSTRACT**

Many cuffless blood pressure (BP) measuring devices are currently on the market claiming that they provide accurate measurements. Cuffless BP monitors constitute a wide and heterogeneous group of novel technologies and devices with different intended uses. However, fundamental questions remain regarding their performance, accuracy, and implementation, and at present they should not be used for the evaluation of individuals with suspected or treated hypertension. This statement by the European Society of Hypertension Working Group on BP Monitoring and Cardiovascular Variability aims to inform healthcare professionals about the types of cuffless BP technologies, and issues with their accuracy and validation.

**Cuffless blood pressure measuring devices:**  
**Review and Statement by the European Society of Hypertension Working Group**  
**on Blood Pressure Monitoring and Cardiovascular Variability**

**Short title:** Cuffless blood pressure measurement

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## **Sources of Funding**

None

## **Conflicts of Interest**

GSS, GP, KK, JW, EOB, PP: Conducted validation studies for various manufacturers of blood pressure measurement technologies and advised manufacturers on device and software development. RM: Holds NIH grants and patents on cuffless blood pressure measurement. Some of the patents have been licensed or optioned to Digitouch Health and Samsung Advanced Institute of Technology. AA, KGK, AK: Contributed to validation studies by various manufacturers of blood pressure measurement technologies. SM: Former convenor of the ISO/IEC JWG Non-invasive Sphygmomanometer. AM: Principal Investigator in blood pressure measurement research funded by the UK Engineering and

Physical Sciences Research Council. AES, RA, GW: Contributed to validation studies by manufacturers of blood pressure measurement technologies and received speaker honoraria from device manufacturers. JES: Served as a consultant on blood pressure device validation for HEARTS in the Americas. Conducted independent validation studies of central blood pressure devices. Principal investigator of a National Health and Medical Research Council partnership grant (S0026615) on cardiovascular disease risk assessment which includes a medical technology company that manufactures a central blood pressure monitor. RJM: BP monitors for research from Omron. His institution (Oxford University) receives fees from his telemonitoring work from Omron and Sensyne. KA, TO: Received research grant from Omron Healthcare. AS, GH, MM, TN, RK: None.

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## ABSTRACT

**Background:** Many cuffless blood pressure (BP) measuring devices are currently on the market claiming that they provide accurate BP measurements. These technologies have considerable potential to improve the awareness, treatment, and management of hypertension. However, recent guidelines by the European Society of Hypertension do not recommend cuffless devices for the diagnosis and management of hypertension.

**Objective:** This statement by the European Society of Hypertension Working Group on BP Monitoring and Cardiovascular Variability presents the types of cuffless BP technologies, issues in their validation, and recommendations for clinical practice.

**Statements:** Cuffless BP monitors constitute a wide and heterogeneous group of novel technologies and devices with different intended uses. Cuffless BP devices have specific accuracy issues, which render the established validation protocols for cuff BP devices inadequate for their validation. In 2014 the Institute of Electrical and Electronics Engineers published a standard for the validation of cuffless BP devices, and the International Organization for Standardization is currently developing another standard. The validation of cuffless devices should address issues related to the need of individual cuff calibration, the stability of measurements post calibration, the ability to track BP changes, and the implementation of machine learning technology. Clinical field investigations may also be considered and issues regarding the clinical implementation of cuffless BP readings should be investigated.

**Conclusion:** Cuffless BP devices have considerable potential for changing the diagnosis and management of hypertension. However, fundamental questions regarding their

accuracy, performance and implementation need to be carefully addressed before they can be recommended for clinical use.

## **KEYWORDS**

Accuracy; calibration; continuous; cuffless blood pressure measurement; cuffless blood pressure monitoring; photoplethysmography; technology; smartwatch; validation; wearable

## **1. Introduction**

In 1733 Stephen Hales first measured arterial blood pressure (BP) and observed its dynamic variation by inserting a glass tube into an artery of a horse [1]. Development of several sphygmographs followed, which estimated BP non-invasively and recorded the continuous arterial oscillations [1]. The invention of the sphygmomanometer by Siegfried Ritter von Basch (1880), the invention of the pneumatic cuff by Scipione Riva-Rocci (1896), and the discovery of the Korotkoff sounds by Nicolai Sergeivich Korotkoff (1905) have been the milestones in establishing the manual auscultatory BP measurement which led to the evolution of clinical hypertension [1]. Nevertheless, this major achievement contained an inherent limitation, because since then the dynamic behavior of the arterial pressure waves has been largely ignored, and focus put on snapshot BP measurement. Eventually, the automated cuff oscillometric BP technology was invented, which was developed to simplify the auscultatory BP measurement.

In the last century, BP has been routinely assessed in clinical practice as a vital sign and as a strong modifiable risk factor for cardiovascular disease. All the evidence showing that hypertension is the major global risk factor of morbidity and death and demonstrating the benefits of treatment induced BP lowering, has been based on upper-arm cuff BP measurement [2]. Thus, upper-arm cuff BP measurement is recommended for office, home, and ambulatory BP measurement in clinical practice [2], and is the reference for assessing novel BP measurement technologies [3]. However, the cuff-BP method has two important limitations. First, as mentioned above, it provides only intermittent BP measurements in

static conditions, thus being unable to detect and record the rapid and dynamic BP changes in response to physical and mental challenges of daily life. Second, the use of a cuff introduces errors related to its size, shape, and positioning, and the compression of the limb during inflation may alert the user and induce anxiety and discomfort during daily activities and sleep. These factors may affect the level of measured BP [4]. An additional important issue is that automated arm cuff devices may not be readily available and not easily accessible especially in low resource settings.

Aiming to provide a solution to the above issues, several approaches have recently been developed that use cuffless technologies to estimate BP based on sensors, signal processing and algorithms embedded in wearable devices, smartphones, pocket devices, or other types of devices [5-7]. The promise of cuffless wearable BP devices is to record BP comfortably and continuously with minimal user intervention. First, they may detect rapid BP changes during routine daily activities and sleep. Second, they avoid the use of a cuff and its related issues and can record BP with the user unaware of the measurement since there is no cuff inflation. Thus, cuffless BP devices could provide detailed and unbiased information regarding circadian BP patterns and variability. In addition, by avoiding cuff inflation, cuffless devices may be especially useful for evaluating BP at work and during night-time, without sleep disturbance. Cuffless devices may also be useful for continuous BP monitoring in intensive care units or during anaesthesia, and also in patients with arrhythmias, hypotension/syncope and other transient conditions affecting BP levels and variability. On the other hand, wearable BP monitors may report transient excessively

raised BP values during daily life activities, which are likely to be harmless if they last for a short time, but may cause anxiety and even unnecessary clinic or emergency visits.

Cuffless BP measurement technologies embedded in wearable devices and smartphones may improve the awareness and early treatment of hypertension in the general population. They may also facilitate self-monitoring of BP by patients with hypertension, thereby improving adherence to treatment and long-term BP control [7]. Many cuffless BP devices that use different technologies and have different intended uses are now available on the market, claiming that they provide accurate BP measurements [5-11]. Given the challenging potential of novel cuffless BP measuring approaches, some researchers, doctors, patients, and members of the public, are eager to use them, despite little understanding of their limitations and special issues in assessing their accuracy. The hope that cuffless BP devices might be superior to conventional cuff BP devices and may ultimately replace them is encouraging developments in technology and bioengineering. As a result, many cuffless devices are already available, but this is being driven primarily by financial rather than scientific interest.

This Consensus Statement by the European Society of Hypertension (ESH) Working Group on BP Monitoring and Cardiovascular Variability aims to (i) present the different types of cuffless BP technologies, (ii) describe their potential uses, (iii) discuss issues in evaluating and validating their accuracy, and (iv) provide recommendations for clinical practice and future perspectives. An international panel of 24 experts worked in small writing groups to prepare draft sections of the statement, which was then reviewed by the experts with the

aim of reaching consensus on all aspects of the current status of cuffless BP technologies regarding their potential use in clinical hypertension.

## **2. Scientific Patents, Publications, and Market for Cuffless Blood Pressure Devices**

The global market for wearable healthcare devices is projected to increase at a compound annual growth rate of ~20%, climbing from a market value of USD 18.4 billion in 2020 to USD ~46 billion in 2025. Similar upward growth is anticipated in the global market for cuffless BP monitoring technologies, which is projected to reach USD 2.25 billion by 2023 [8].

Several factors influence the rising popularity of wearable devices, including comfort, the growing adoption of mobile platforms and preference towards home-based healthcare [9,10]. Consumers seeking to purchase cuffless BP technologies may be provided with an extensive collection of choices, with many devices often accompanied by unsubstantiated claims about performance. A recent study of the Australian online marketplace reported that there were 532 unique cuffless wearable devices purporting to measure BP available for consumer purchase, yet none of these devices demonstrated their accuracy using adequate validation protocols [11]. The median cost of cuffless BP devices was less than half that of upper arm cuff BP devices [11], which probably influences the consumers choices. However, for devices requiring periodic calibration using a cuff oscillometric device, the cost of the latter should also be considered.

The staggering increase in interest and activity in cuffless BP monitoring over the past two decades is also indicated by the number of relevant patents, publications and citations since 2000 (**Figure 1**). The initial surge occurred in 2005 with 29 patents registered that year, increasing from 1 patent in 2004, and the upward trajectory in scientific publications and interest in the form of citations followed suit.

Until February 2022 a total of 323 scientific publications on cuffless BP measurement were found on PubMed, but this number is anticipated to rapidly escalate. The scientific literature comprises an array of publications ranging from technical papers, to reviews and scientific statements.

The majority of publications focus on new technologies to estimate BP without a cuff, incorporating machine learning [12], deep learning [13], neural networks [14,15], ballistocardiogram gating and wave localization [16], flexible wearable pressure sensors [17], and ECG monitoring with photoplethysmography [18]. There are at least 17 reviews covering for example, ‘learning and non-learning algorithms’ [19], automated detection of hypertension using physiological signals [20], possibilities for artificial intelligence in managing hypertension [21], single [22] and multi-site photoplethysmography technologies to monitor BP [23]. Several papers claim to be ‘validation studies’ but too often no appropriate protocol for cuffless BP devices was used [7]. Some studies compared cuffless BP measurement to classical oscillometric or auscultatory methods and reported that values differ significantly [24-26], some report mixed results [27], and others report acceptable

agreement [28-31]. The protocols used in these studies vary substantially in terms of the number of participants (from 14 to 86), the measurement conditions (static sitting or ambulatory), the comparator measures (intra-arterial BP, office BP, ambulatory BP, daytime BP, night BP, dipping pattern), statistical methods (Bland-Altman comparisons, intraclass correlation coefficients), with some using the ISO 81060-2 standard or other established validation protocols for cuff-BP devices [7,28,30-43].

Some organizations have also published position statements for cuffless BP devices. The Korean Society of Hypertension in their paper “Smartphone/smartwatch-based cuffless blood pressure measurement” [44] encourages cuffless devices to improve awareness in the younger population, but cautions that there is limited evidence on accuracy. The ‘2021 European Society of Hypertension Practice Guidelines for office and out-of-office BP measurement’ and the ‘Lancet Commission on Hypertension group on the global improvement of accuracy standards for devices that measure BP’ both state that cuffless BP devices should not be used for diagnostic or treatment decisions, until they are adequately validated using a standard specifically developed for such devices [2,45].

### **3. Cuffless Blood Pressure Technologies**

Cuffless BP technologies are categorized as requiring individual user cuff calibration or not (**Table 1**). Those requiring user calibration need each individual user to firstly take a self-measurement of BP using a classic upper-arm cuff-BP device, which is entered into the



monitor before use. This calibration procedure is usually repeated periodically (e.g., every day, few weeks, or months). Some cuffless devices are calibrated by entering simple demographic data (e.g., age, sex, and body size) which are well-known to correlate with BP, yet these are less reliable. Other technologies do not require either type of calibration by each individual user but, as described below, user calibrated technologies are generally more convenient to use (e.g., user is unaware of the measurement) once calibration is performed.

### ***3.1. Technologies requiring user cuff calibration***

These technologies involve obtaining one or more variables that correlate with BP and mapping or calibrating the variable(s) to mmHg units. They have been investigated extensively and include pulse transit time (PTT), pulse wave analysis (PWA), or facial video processing (**Table 1, Figure 2A-C**). Some devices based on PTT or PWA and requiring periodic cuff BP calibrations have some regulatory approval and are already available on the market [31,46-48], yet they are not currently recommended for clinical use [2]. These devices estimate BP changes from the initial cuff calibration BP. It remains unclear to what extent their readings depend on the calibration BP and whether they can reliably track BP changes after calibration [7]. There may also be issues with the accuracy of calibration, which may not be done properly by users.

#### ***3.1.1. Pulse transit time (PTT)***

PTT is detected as the time delay between proximal and distal arterial waveforms and may be the only calibrated technology with a generally accepted theory. Based on the intrinsic

BP-dependency of arterial stiffness and fluid dynamic principles, PTT along the elastic aorta is inversely related to diastolic BP for time periods in which arterial stiffening with aging is not a potentially confounding factor (e.g., several months) [49]. However, in practice, easier-to-measure surrogates, such as the time delay between ECG and finger photoplethysmography (PPG) waveforms (“finger pulse arrival time (PAT)”), are used. The finger PAT surrogate tracks systolic BP better than diastolic BP, but can change independently of either BP via pre-ejection period variations and smooth muscle contraction mediated by varying sympathetic nervous activity and local mechanisms in the distal arm arteries [49].

### 3.1.2. Pulse wave analysis (PWA)

PWA extracts BP-related features from an arterial waveform. It requires only a single sensor but has little theoretical basis. For example, PWA is most often applied to a PPG waveform from an extremity artery, but the amplitude of this blood volume oscillation waveform does not consistently change with BP due to profound smooth muscle contraction (i.e., BP can rise with increasing or decreasing PPG peak-to-peak amplitude) [50]. It has also been shown that the PPG waveform changes with age from below 30 to above 50 years [51]. Nevertheless, PWA is gaining attention due to the possibility that BP information is somehow embedded in the waveform shape [50] together with the popularity of machine learning.

### 3.1.3. Facial video processing

Facial video processing extracts pulse waveform features from the facial skin in a video stream and may uniquely allow BP to be measured passively with a common device (e.g., each time someone uses her/his smartphone [52]). The noncontact pulse waveform acquisition is usually based on PPG, and features of PPG waveforms from multiple skin regions-of-interest including facial PTTs can be extracted [35]. However, just attaining sufficient waveform quality is a major obstacle due to the minute changes in light intensity with each cardiac pulsation, especially in individuals with dark skin. Moreover, as the facial vasculature is very sensitive to vasomotion, the relationship with cuff BP and its changes is questionable.

### ***3.2. Technologies not requiring user cuff calibration***

These technologies are in earlier research stages than those requiring user cuff calibration; hence, a body of evidence is lacking, and they may or may not make it to market. They include “oscillometric finger pressing”, ultrasound, and “volume control” (**Table 1, Figure 2D-F**).

#### ***3.2.1. Oscillometric finger pressing***

Oscillometric finger pressing extends the automatic cuff principle for BP monitoring via widely available smartphones [53,54]. The user presses their fingertip against a sensor-unit on the phone to steadily increase the external pressure on the underlying artery, while the sensor-unit measures the resulting variable-amplitude PPG waveform and applied pressure. The phone visually guides the finger actuation and computes BP from the measurements

like a conventional brachial cuff-based monitor. However, this technology requires user action.

### 3.2.2. Ultrasound

Ultrasound may be the only technology in this group for measuring BP without involving variable pressure application. One version can measure the cross-sectional area and blood velocity of the carotid (or another) artery and compute pulse pressure from the ultrasonic measurements based on fluid dynamic principles [55,56]. While central pulse pressure may benefit cardiovascular risk stratification [57], ultrasound generally requires operator interaction and is less convenient than cuff-based monitors.

### 3.2.3. Volume control

Volume control may currently be the only technology in this group for continuous BP monitoring. This recent technology extends the longstanding cuff-based volume clamping principle for BP monitoring via a finger-worn ring [58]. A servo-controlled actuator continually applies external pressure to the finger to clamp the average of PPG-measured blood volume over a cardiac cycle to its unloaded level to measure mean BP. Since only slow actuation is required to track mean BP changes, the ring may potentially be small and cuffless but would still cause finger numbness with long-term use.

## ***3.3. Intended uses of the technologies***

From the clinical point of view, it is important to consider the different intended uses of cuffless BP monitors, which influence their design (implemented technology and user interface) and probably the required validation procedure and accuracy standards (**Table 2**). Cuffless BP devices may have different “intended uses”, such as (i) screening for hypertension in healthy people, (ii) diagnosis of hypertension and long-term follow-up of treated patients, and (iii) professional short-term continuous BP monitoring in hospitalized patients (e.g., during anaesthesia, or in intensive care). In the first two cases, BP is evaluated as a risk factor for cardiovascular disease and BP profiles are needed to decide whether the average BP level is optimal, borderline, or elevated. If the device is to be used as described in the third case, BP is being evaluated as a vital sign and fast changes need to be followed to ensure hemodynamic stability. Regarding the measurement accuracy, for devices intended to diagnose hypertension it is reasonable to demand the established accuracy standards for cuff devices in medical use. However, for screening purposes a slightly inferior accuracy might be acceptable [59]. Also, for fast BP changes in intensive care and during anaesthesia, small BP changes (e.g., <10 mmHg) are probably clinically unimportant and less tight criteria might be considered.

### ***3.4. Summary of cuffless BP technologies***

**Table 1** summarizes the different cuffless BP technologies, while **Figure 2** illustrates examples of these cuffless BP technologies. The technologies requiring user cuff calibration currently on the market are mainly based on PWA or PTT and come in varying forms (**Figure 2A-B**). The “intended use” for each monitor must be read with care, as

accurate measurement may only be possible in limited circumstances (e.g. only if the user remains still). Technologies not requiring user calibration present challenging technological proposals; facial video processing, oscillometric finger pressing, ultrasound, and volume control are still in early research stages and may or may not make it to market (**Figure 2C-F**). **Table 2** summarizes the different intended uses of the technologies. See recent reviews for further details [6,59-66].

## **4. Measurement accuracy issues - Data presentation issues**

### **4.1. Measurement accuracy issues**

As mentioned above, cuffless BP monitors constitute a wide and heterogeneous group of novel technologies and devices, which provide either continuous or intermittent measurements [7]. These devices appear to have specific accuracy issues, which are not present with the conventional cuff devices. These may be related to the need of individual user cuff calibration and thus the unique importance of tracking BP changes in an individual, the stability of measurements post calibration, or the implementation of machine learning technology [7].

#### **4.1.1. Calibration and blood pressure changes**

The majority of cuffless BP monitors require initial and periodic calibration for the individual user, using a conventional upper-arm cuff BP monitor [7]. Then a proprietary

algorithm is employed to track BP changes relative to the calibration BP. Thus, these are essentially BP ‘tracking’ rather than ‘measuring’ devices, and the primary concern is whether these devices can accurately track physiological BP fluctuations. A testing procedure is therefore necessary to verify whether the cuffless device can accurately track BP changes.

The Association for the Advancement of Medical Instrumentation/European Society of Hypertension/International Organization for Standardization (AAMI/ESH/ISO) Universal Standard (ISO 81060-2:2018) which was developed for validating cuff BP devices [67] does not include a procedure to track BP changes, as this is not an issue with such devices. In addition, the Universal Standard is designed to ensure BP stability during validation, by excluding cases with differences between the reference BP measurements  $>12/8$  mmHg (systolic/diastolic) [67]. Thus, when using the Universal Standard to validate a cuffless device immediately post calibration, if the cuffless device after calibration always displays the calibration BP value, it will probably pass the validation requirements. This was confirmed using the dataset of two recent validation studies of upper-arm cuff oscillometric devices, by replacing all the BP measurements of the test device (T1, T2, T3) with the initial reference (cuff) BP measurement (R0) (*G Stergiou, K Kyriakoulis, Unpublished data 2021*). The mean $\pm$ SD of the BP errors (test minus reference BP - Criterion 1 for validation) was  $\leq 5\pm 8$  mmHg (pass) without an actual measurement, but simply by always reporting the same initial reference BP value (R0). Thus, all the established validation protocols for cuff BP devices are inappropriate for cuffless devices requiring calibration.

#### 4.1.2. Stability

Manufacturers of cuffless devices requiring user cuff calibration, recommend periodic recalibration (e.g., after a few weeks). A retest of accuracy (static validation session) immediately before the recommended recalibration time (stability test) is necessary to ensure that the measurement accuracy is retained between calibrations.

#### 4.1.3. Machine learning

Machine learning technology uses parameters known to correlate with BP levels (age, sex, body height, weight, etc.) in addition to the hemodynamic component (actual cuffless measurement) to predict BP values [7]. Thus, the BP reading displayed by the cuffless device is based on two components, i.e., a patient demographics component and the measured hemodynamic component. To what extent the displayed BP reading is influenced by each component is often unknown. It is important to assess the cuffless device performance without the hemodynamic component (“baseline device”), as an algorithm generating BP values solely based on the individual’s demographic parameters. A recent simulation study showed that the correlation between cuffless and reference BP measurements was superior when the former were predicted by demographic inputs alone (eg, age, sex), rather than when the hemodynamic measurement component was also considered [7].

### **4.2. Data presentation issues**



Since there is no widely agreed protocol for validating cuffless devices, relevant studies have not used a standard way for reporting and presenting data documenting the measurement accuracy. Most studies provide tables with the criteria of the AAMI/ESH/ISO Universal Standard [67], which as mentioned above is inadequate for many cuffless devices. However, data presentation and figures are important for demonstrating the performance of BP devices [7].

Several studies, particularly for devices requiring user cuff calibration, provide scatterplots of cuffless vs reference BP demonstrating their high correlation. In these studies, the BP measurements were usually pooled over all individuals' BP values. This will typically yield strong overall correlation (**Figure 3A**), while intraindividual correlation may be close to zero (**Figure 3B**) [7]. A scatter plot of the cuffless-calibration BP difference vs. the reference-calibration BP difference would indicate whether the cuffless BP change follows the reference BP change relative to the calibration BP for each individual [7]. A four quadrant plot of the directions of test and reference BP changes is also informative [68].

Bland-Altman scatterplots have been widely used to assess the agreement between test and reference BP devices [69]. In the case of cuffless BP monitors a Bland-Altman scatterplot of BP measurements generated by a baseline device (i.e., based on calibration BP or demographics without any measured hemodynamic component as defined above) could result in some surprising results. In a recent simulation study, Bland-Altman plots indicated better agreement when the hemodynamic component was eliminated [7]. This suggests that an additional side-by-side Bland-Altman plot of baseline cuffless vs reference BP could

demonstrate the impact and thus the value and accuracy of the actual hemodynamic measurement component of each device, which may mainly affect the precision (SD of error) rather than the bias (mean of error) of the device (**Figure 4**).

## **5. Validation Protocols**

In the last three decades several organizations, such as the AAMI, the British Hypertension Society, the ESH Working Group on BP Monitoring, and the ISO, have developed protocols for clinical validation of BP measuring devices [3]. In 2018, AAMI, ESH, and ISO developed a single standard (AAMI/ESH/ISO) for universal use [67]. All these protocols have been developed for evaluating the accuracy of automatic cuff BP devices using manual auscultatory BP measurement as reference [3,67]. However, as mentioned above for cuffless BP measuring technologies, several accuracy issues have emerged which are specific to such devices [7]. Thus, a new validation standard developed to address the special issues of cuffless devices is necessary [7]. Unfortunately, as mentioned above, several cuffless BP monitors claim accuracy based on studies using validation protocols for cuff BP devices [3,7,28,30-43,67], which is inadequate and misleading.

In 2014 the Institute of Electrical and Electronics Engineers (IEEE) published the first specific official standard for cuffless wearable BP devices [70] with an amendment published in 2019 [71]. This protocol presented for the first time fundamental issues in

validating cuffless devices and proposed procedures for overcoming each one of them (**Table 3**). However, there were practical difficulties in using this standard which rendered its wide application impractical [72]. Moreover, this standard uses as reference the manual auscultatory BP measurement method, which is suitable for the validation of intermittent but not for continuous cuffless BP monitors [70,71]. ISO is currently developing a new standard for continuous automated measurement type non-invasive sphygmomanometers defined as devices estimating BP from each cardiac cycle and providing a continual series of BP parameters with an output period which is not considerably larger than 30 seconds (ISO 81060-3) [73]. The main features of the upcoming ISO standard, which in principle are in line with those of the IEEE [70,71] are presented in **Table 3**.

The ISO 81060-3 draft standard is a major initiative for the proper evaluation of cuffless devices. However, there are several issues of concern. First, it is too complex and appears difficult to apply in many research centres interested in performing validation studies, which is necessary for dealing with the fast-growing market of cuffless devices. Second, it is intended for continuous cuffless devices which are useful during anaesthesia or intensive care for short-term BP monitoring as a vital sign to evaluate the patients' hemodynamic stability. However, for clinical hypertension (screening, diagnosis, and management) fast BP changes are irrelevant and cuffless wearable devices allowing long-term monitoring are needed for assessing intermittent BP at work, at home, and during other activities including sleep. Third, the use of intraarterial BP as the reference method is problematic. It is reasonable for evaluating continuous BP monitors but not for devices used in hypertension management in clinical practice, as invasive techniques are difficult to apply in large scale

(unethical unless there is clinical indication and therefore findings may not be generalizable) and intraarterial brachial BP differs from auscultatory BP (the latter giving lower systolic and higher diastolic BP) [74]. Because the classification of BP and the goals of antihypertensive therapy are based on cuff BP measurements, manual auscultatory BP should be the reference method in validating intermittent cuffless wearable devices [3,67].

The process for individual user calibration using a classic self-taken upper-arm cuff-BP measurement may introduce a baseline error to the cuffless BP device, due to the continuous variation of BP, common errors with fitting of the cuff and arm and body positioning, and the inherent accuracy level of the cuff device.

Tracking of BP changes is a new challenge in validation studies and the most crucial part (also the most problematic) in the validation of cuffless devices requiring user cuff calibration. It involves increasing and decreasing BP via different physiologic mechanisms and can be achieved using physical exercise (handgrip, bicycle, legs up-down, etc), cold pressor test, slow breathing, mental arithmetic test, Valsalva manoeuvre, neck chamber technique, or BP affecting drugs such as nitroglycerin. Inducing BP changes in the laboratory setting raises safety issues in some patients and individual BP responses may be unpredictable. The IEEE and ISO standards do not specify the interventions for changing BP, although they require the evaluation of the test device ability to accurately track BP changes [70,71,73]. This is more important for intermittent devices (IEEE standard), and less so for continuous ones (ISO standard), as the latter are tested versus intraarterial BP in

patients who may be hemodynamically unstable due to disease or interventions inducing considerable BP changes.

Inducing BP changes in the laboratory is an interventional procedure, which presents a new challenge to validation studies, as it requires more resources, is more costly, and may have risk issues for some patients. To date, such a procedure has not been defined, and there may be inadequate evidence on the expected BP change by different interventions and the interindividual variability in the BP change [75]. The protocol for such interventions in the laboratory setting should be standardised to ensure its safety and reproducibility and facilitate comparison among studies.

Clinical field investigations for tracking BP changes should also be considered. First, standard validation sessions might be repeated without recalibration a few days or weeks after a change in antihypertensive drug treatment. Second, cuffless wearable devices can be synchronized and applied simultaneously with gold standard 24-hour ambulatory BP monitoring using a validated upper-arm cuff oscillometric device. These approaches for pragmatic evaluation of accuracy can indicate whether the cuffless device is able to track BP changes not artificially induced in the laboratory, but by BP lowering drugs and during usual daily activities of each individual, including sleep [24,66,76].

Another issue of wearable devices is whether their performance is affected in different body postures (e.g., lying, sitting, standing, or at different distance of the hand from heart level (for wrist/finger wearables)). The effect of these postures on BP measurement

accuracy should be investigated. In addition, for cuffless technologies based on distal arterial waveform extraction, temperature variation or other factors inducing vasoconstriction or vasodilation may result in profound changes in the waveform [53,58,59,61,63]. Last, cuffless devices not requiring cuff calibration in each individual user may seemingly be validated using the Universal Standard for cuff BP devices [67], yet this is still unclear given the special issues of cuffless measurements (e.g., patient demographics component of the measurement), and additional factors which may influence the performance of different cuffless BP technologies [7].

In conclusion, the clinical validation of cuffless BP devices is different and more complex than that for cuff devices and developing a universal standard for validating such devices is a difficult task. Standards developed for cuff BP devices are notoriously inadequate for cuffless devices. The main elements of proper validation of intermittent cuffless wearable devices requiring cuff calibration which can be useful in clinical hypertension evaluation are summarised in **Table 4**. All devices providing BP readings, intended either for screening (healthy people) or for long-term monitoring (people with hypertension), must fulfil reasonable accuracy standards, as both underestimation and overestimation of BP can have serious health consequences for the users.

## **6. Future perspectives**

Rapidly developing future trends in cuffless BP devices present formidable challenges in health applications, particularly for noninvasive and unobtrusive monitoring of BP. Cuffless wearable techniques are being proposed as the “future of BP monitoring”, and considerable effort is emerging in providing guidance for scientists and clinicians [66]. However, notwithstanding the considerable technical progress and some good agreement with conventional cuff-based BP measurement mainly in static laboratory conditions [48], the clinical adoption has been slow, due to unproven reliability of cuffless BP measurement. To seriously consider its potential implementation in clinical medicine and hypertension management, the question of “trusting the measurement” in the individual patient will be the most important issue to be addressed by future developments in technology, validation procedures, regulatory standards, and clinical assessment.

An important requirement for future development and clinical acceptability will be the standardization of validation procedures, specifically in reliable tracking of BP changes in the short and long term. Studies reporting validation of cuffless devices according to professional standards often used inappropriate standards intended only for cuff sphygmomanometers [7,28,30-43], including for recent regulatory approval [34,77]. Standards used for cuffless devices currently specify static tests [71] with dynamic ranges yet to be fully developed. However, standardizing specific procedures to elicit BP changes presents a significant challenge to achieve relevant physiological pressure ranges with safe and repeatable interventions. In addition, the intervention itself (e.g. cold pressor, handgrip, exercise) could affect the actual signal being measured (e.g. PPG), as the BP response is not uniform across individuals and interventions [78]. Attempts have been made to mitigate

some of these issues by using postural changes to elicit BP changes [79], although the BP range would still be limited.

Even when the abovementioned accuracy issues are fully resolved, cuffless wearable devices present a new method for BP evaluation which may not be directly comparable with any of those that have been well investigated and are currently recommended for hypertension diagnosis and management in clinical practice (i.e., office, ambulatory, and home BP measurements). Thus, for example, the normalcy thresholds for average cuffless BP values will need to be verified. Moreover, other clinical aspects, such as the reproducibility of such measurements and their clinical validation with respect to the ability to reflect organ damage need to be investigated and will probably differ across the spectrum of cuffless BP technologies. Eventually, cuffless BP devices must prove that they offer benefits to healthy people and patients with hypertension on top of those provided by the currently recommended methods.

## **7. Conclusions – Statements and Recommendations**

The concluding consensus statements and recommendations are as follows:

- Cuffless BP measurement is a fast-growing and very promising field with considerable potential for improving hypertension awareness, management, and control.



- Cuffless BP monitors use a variety of different novel technologies, often require individual user cuff calibration, and have different intended uses.
- Cuffless BP technologies have specific accuracy issues, which are different and more complex than those of the cuff BP devices, and the data should be presented in informative ways.
- There is an urgent need to develop an internationally accepted accuracy standard, which is specific for the validation of cuffless BP devices.
- The clinical usefulness of cuffless BP devices must also be proven in healthy people and those with suspected or diagnosed hypertension when applied together or instead of the currently recommended BP measurement methods.
- Until the above research questions are properly addressed, cuffless BP devices should not be used for the evaluation or management of hypertension in clinical practice.

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## Legends to Figures

### Figure 1.

Patents, publications, and citations on cuffless blood pressure since 2000 (search criteria "cuffless" OR "cuff-less" AND "blood pressure" OR "BP"). *Sources: [www.scopus.com](http://www.scopus.com); <https://pubmed.ncbi.nlm.nih.gov>; <https://app.dimensions.ai>, Exported 3 Feb. 2022.*

### Figure 2.

Example illustrations of cuffless blood pressure technologies on the market (A, B), or in early research stage (C, D, E, F).

### Figure 3.

Cuffless vs reference blood pressure scatter plot showing (A) strong overall correlation and (B) no intraindividual correlation.

### Figure 4.

Bland-Altman scatterplots of cuffless vs. reference blood pressure by including or excluding the hemodynamic measurement component of the cuffless monitor. Data from a recent simulation study (Modified from [7]).

## **ABBREVIATIONS**

AAMI	Association for the Advancement of Medical Instrumentation
BP	blood pressure
ESH	European Society of Hypertension
IEEE	Institute of Electrical and Electronics Engineers
ISO	International Organization for Standardization
PAT	pulse arrival time
PPG	photoplethysmography
PTT	pulse transit time
PWA	pulse wave analysis
SD	standard deviation

**Table 1.**

Summary of cuffless blood pressure technologies.

Category	Method	Advantages		Disadvantages		Evidence
<b>Requiring user cuff calibration</b>  <i>(Estimate BP changes)</i>	PTT [A]	Continuous; without user action; not disturbing	Supporting  theory	Calibration  via periodic cuff BP measurement or by demographic	2  measurement  sites	Many published  studies
	PWA [B]		Single  sensor		Little theory (may not work well in many individuals)	Regulatory- approved, cuff- calibrated, contact monitors
	Facial video processing  [C]		Widely available device (smartphone)	data input	Insufficient waveform quality	Little published data on intra-individual BP change tracking
<b>Not requiring user cuff calibration</b>  <i>(Estimate BP values)</i>	Oscillometric finger pressing  [D]	Calibration not needed; solid theory (could work in many individuals)	Potential  widely available device (smartphone)	User action		Few  published  studies
	Ultrasound [E]		Central PP measurement	Difficult probe placement  (operator required)		
	Volume control [F]		Continuous	Disturbing  (finger numbness)		

PTT, pulse transit time; PWA, pulse wave analysis; PP, pulse pressure; [A-F], see Figure 2. Adapted from [6].

Table 2.

Features of different intended uses of cuffless blood pressure technologies.

Intended use	Clinical index (Clinical assessment)	Blood pressure measurement	Reference measurement
Hypertension screening (Apparently healthy people)	Cardiovascular risk factor (Hypertension)	Occasional	Manual auscultatory
Hypertension diagnosis - Long-term follow-up (Patients)	Cardiovascular risk factor (Hypertension)	Regular	Manual auscultatory
Intensive care - Anaesthesia (Professional)	Vital sign (Hemodynamic condition)	Continuous	Intra-arterial



**Table 3.**

Main features of standards specifically developed for the validation of cuffless blood pressure measuring devices by the Institute of Electrical and Electronics Engineers (IEEE) [70,71] and the International Organization for Standardization (ISO) [73].

	<b>IEEE 1708-2014 &amp; 1708a-2019</b>	<b>ISO 81060-3 (Under development-2022)</b>
<b>Intended use</b>	Cuffless wearable BP devices	Cuffless continuous BP devices
<b>Number of subjects</b>	$\geq 85$	30-120 depending on intraclass correlation for each BP parameter
<b>Reference method</b>	Manual auscultatory	Intraarterial
<b>Validation phases</b>		
<i>A. Test immediately post calibration</i>	Yes	Yes
<i>B. Test after BP change</i>	Specific requirements for BP change	Specific requirements for BP change
<i>C. Test before re- calibration</i>	Yes	Yes
<b>Procedure for inducing BP changes</b>	Not specified	Not specified (subjects may already be hemodynamically unstable)
<b>BP measurement sequence</b>	Simultaneous or sequential	Simultaneous
<b>Pass requirements (mean error limit)</b>	$\leq 6$ mmHg (for BP changes $\leq 7$ mmHg)	$\leq 6$ mmHg (SD $\leq 10$ mmHg)

**Table 4.**

Key elements for validation studies of intermittent cuffless wearable blood pressure measuring devices requiring user cuff calibration.

- Reference method: manual auscultatory measurement
- Validation phases:
  - a. Immediately post calibration
  - b. After inducing different blood pressure changes
  - c. In different body postures (lying, sitting, standing)
  - d. Immediately before recommended re-calibration

Figure 1

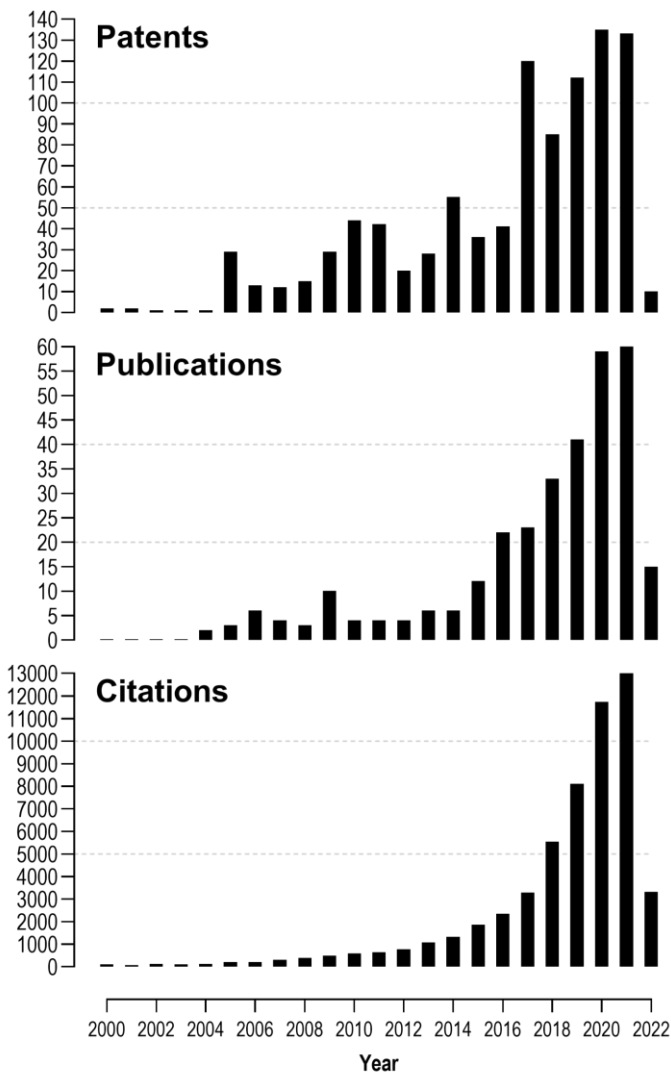
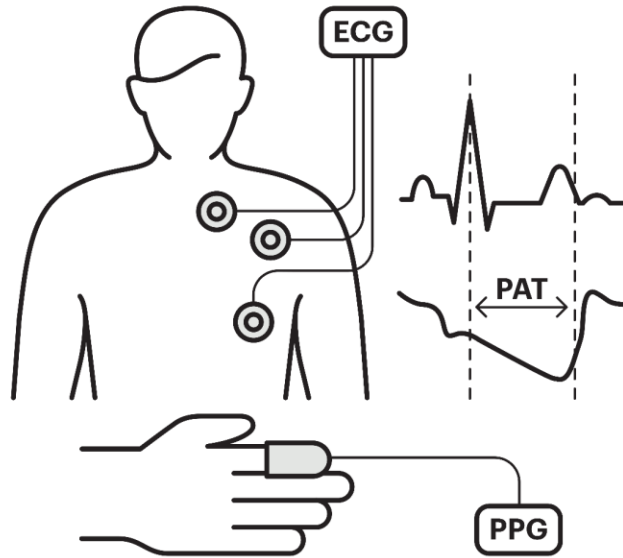
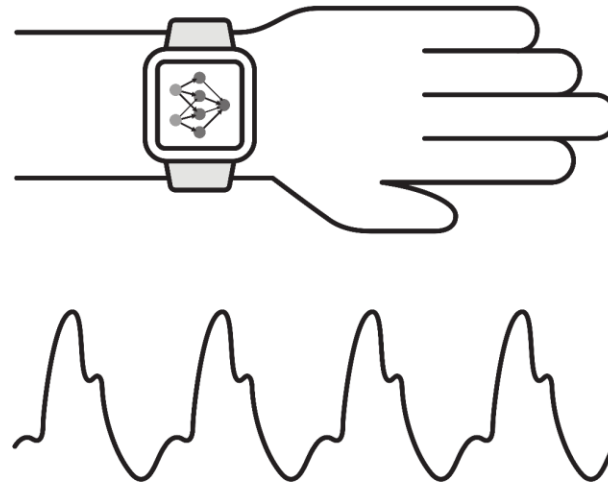


Figure 2

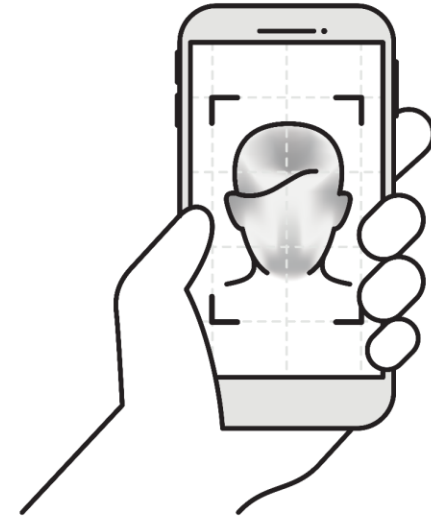
**A.** Pulse transit time



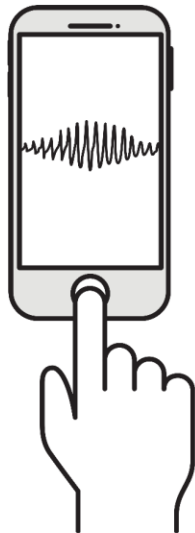
**B.** Pulse wave analysis



**C.** Facial video processing



**D.** Oscillometric finger pressing



**E.** Ultrasound



**F.** Volume control

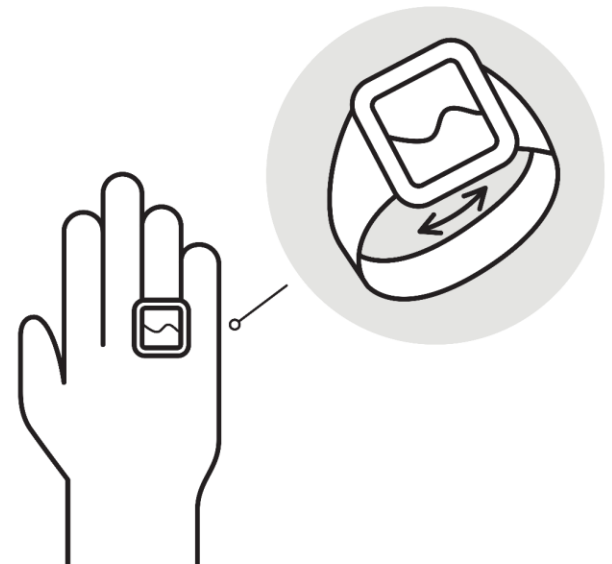


Figure 3

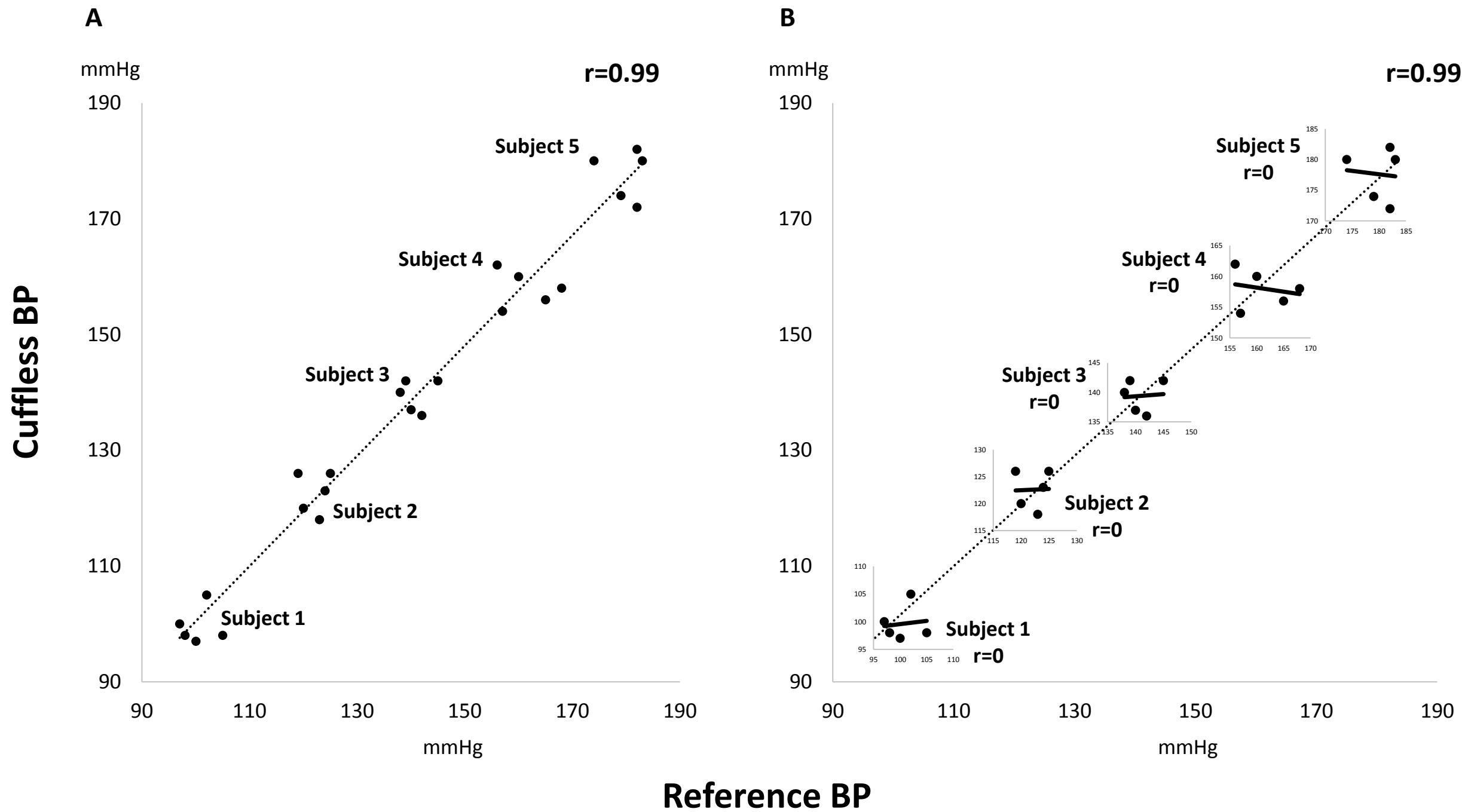
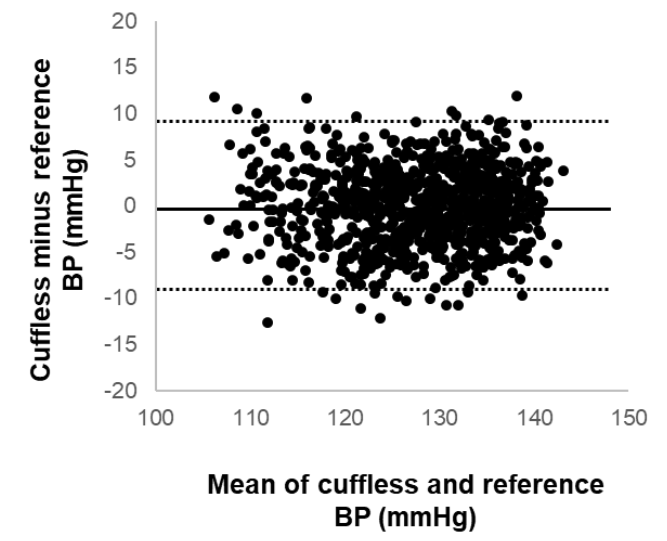
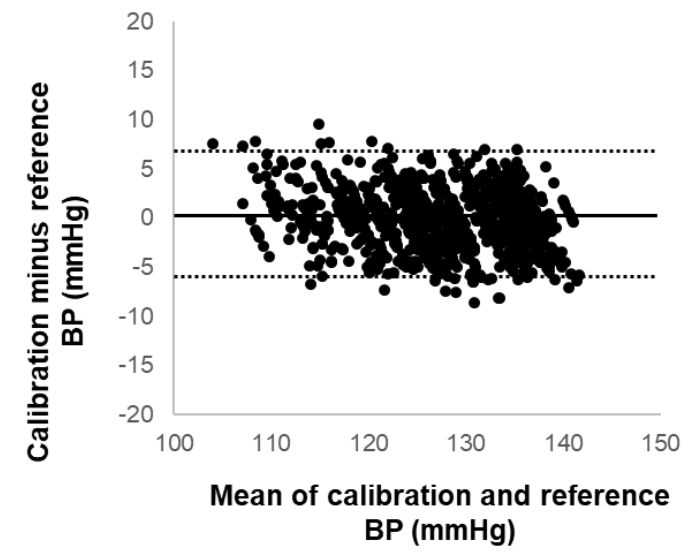


Figure 4

**Baseline/Naive Device  
(without hemodynamic measurement)**

**Cuffless Device  
(with hemodynamic measurement)**

**Cuff-calibrated**



**Demographic-calibrated**

