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RESEARCH ARTICLE

Autonomous Calibration of Blood Pressure Dependent Data Using Second-Order Blood Pressure Variation for a Future Mobile Diagnostic: Requirements for a Calibration

MARTIN DEUTGES AND HOLGER REDTEL
Redtel, 19348 Perleberg, Germany
Corresponding author: Martin Deutges (m.deutges@redtel.de)

ABSTRACT Currently, blood pressure assessment is on the verge of shifting from classical cuff-based measurements to continuous estimation using smart devices based on the absorption and reflection characteristics of light in tissue. This type of blood pressure estimation has been known for a long time and depends on calibration with conventional blood pressure measurement systems. Products from well-known manufacturers in this market already perform calibration with automatic cuffs using an oscillometric estimation. The main aim is to show that classical oscillometric blood pressure estimation is not suitable for calibration, which allows a burden-free and continuous estimation by today's approaches. This study identifies the reason and also the solution for this in the second-order blood pressure variation. The current approach to oscillometric estimation of blood pressure has an uncorrectable systematic error of the order of the second-order blood pressure variation. Therefore the current method has too much error to be used as a basis for calibration to allow continuous estimation of blood pressure based on another vital parameter. It is shown that when using a measurement of the second-order blood pressure variation as basis for such calibration this problem can be solved.

INDEX TERMS Blood pressure, calibration, cuff pressure simulation, oscillometric blood pressure measurement, photoplethysmography (PPG), pulse transit time (PTT), respiration, second-order blood pressure variation, systematic error, Traube wave.

I. INTRODUCTION

Regular monitoring of blood pressure in the context of a disease is common nowadays. Blood pressure measurement is so well established that even unaffected people recognize its usefulness, for example in assessing their physical fitness. Because everyone can potentially gain some insight from blood pressure measurement, there is a market for it.

Many products from well-known manufacturers are available on the market and therefore blood pressure measurement is a solved problem in the minds of many people and they rely on it blindly. It is feared that a trend has begun similar to other potentially dangerous products such as cosmetics or dietary supplements, where words such as "patented," "FDA approved," or "official supplier" are used to convince customers [1].

In 2022 the market value for cuff-based blood pressure measurement devices was estimated to be worth 1.77 billion

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USD [2]. These devices provide a reliable measurement only under controlled conditions.

This is not the case for new users who want to take measurements during physical activity, for example. Therefore, new products in the form of smartwatches are being launched on the market, promising mobile blood pressure measurement [3], [4], [5], [6], [7], [8], [9], [10].

Often, these products have questionable measurement quality [11], [12], [13].

A reliable and mobile solution for estimating blood pressure using a measurement based on the properties of light would be a milestone in monitoring diseases.

Current devices measuring blood pressure dependent data for example the pulse wave velocity or the shape of the pulse, which is used for estimating the blood pressure using a mathematical model or even machine learning methods. Devices that claim to be accurate do have a calibration procedure with a reference device. The current state of research is indeed that such calibration is necessary due to the individual nature of factors influencing the blood pressure. The field of existing solutions is diverse and there are various calibration methods. However, there is no compelling proof that these methods can be used to reliably track blood pressure [10], [14].

To address the problem of calibration, this study investigates the reasons why current calibration methods, based on a single measurement with a cuff, cannot work reliably and what the requirements for calibration are.

Due to the enormous amount of work in this area, the reader is directed to the key references that underline the need for a detailed investigation of calibration itself, which form the basis for the investigation methods in this study, and which can lead to the solution of the calibration problem (see Table 1).

A. WHAT IS CALIBRATION

For a light-based measurement to be used to estimate blood pressure, the input data must be calibrated to a reference system [13], [14], [18], [21]. This calibration is different for each person and physical condition [21]. Therefore, calibration must be performed at regular intervals [10], [22], [23].

Mathematically speaking, calibration is finding a functional relationship between input data and target output. The basis for this is a model that describes the influence of the blood pressure on the input data [23]. In the simplest case the goal of calibration is to find a linear equation that maps input data to a target value:

$$p(x) = m \cdot x + b \tag{1}$$

The target value $p(x)$ in this case is the blood pressure and x is the input, for example a vital parameter such as pulse wave velocity [18]. The parameters m and b must be estimated by the calibration using at least two value pairs of input data and reference-target data.

To estimate the magnitude of a blood pressure change at least two points are required. It is also necessary to perform a separate calibration for systole and diastole, and these calibrations cannot be based on the (exact) same input data, because the resulting estimates of systole and diastole would be correlated. For example the degree of correlation between systole and diastole is an indicator of arterial health [24].

A calibration procedure must therefore record two different pairs of input data and reference values for systole and diastole, and the recordings of these two pairs have to be under different physical conditions, otherwise it would be not possible to obtain a linear equation.

In particular, the independence of systole and diastole regarding different input values for those estimations was not taken into account [18], [23]. A calibration was used which took one value of the pulse wave velocity to estimate two values, i.e. systole and diastole. Therefore, the estimations for systole and diastole cannot be independent of each other. Physical exercise typically results in an increase in systolic blood pressure, but in healthy, athletic individuals, there is little to no change in the diastolic blood pressure [25], [26]. A change in the diastolic value in this case may indicate the presence of a cardiac disease [27], [28].

B. CALIBRATION IN APPLICATIONS

It is worth noting that products on the market do not perform a calibration [29], [30], [31], or they may use only one reference measurement for calibration [30], [31]. However, some products do record multiple reference values [4], [5], [14] without altering the physical situation. Therefore, these systems are incapable to estimate the magnitude of a blood pressure change.

Currently, there are no devices on the market that can demonstrate a working calibration. This is due to the fact that basic mathematical requirements are not met. Specifically a linear equation must be defined by at least two points.

The reason for this is that currently there are no devices that allow for easy calibration to record measurements in two different physical states [14].

The fundamental approach for a calibration has been known for a long time. Already in 1998, Barschdorff and Erig [18] presented a calibration method that uses both relaxed and stressed conditions. This method solves the task of calibration, but this method cannot be used in everyday life. Additionally, it is only applicable to physically healthy individuals.

C. SOLUTION OF THE CALIBRATION QUESTION

The foundation for a user-friendly calibration has been established since the early days of medical blood pressure history. As early as 1733 Hales observed the second-order blood pressure variation [20], which was later described in detail by Traube [32] and classified as Traube waves [33].

The second-order blood pressure variation is a regular change in the blood pressure values systole, diastole, and

TABLE 1. Summary of key related works in blood pressure (bp) measurement and calibration.

Author(s) and reference	*Year*	*Methodology*	*Key findings*	*Relevance to current study*
Mukkamala *et al.* [10]	2022	Review	State of cuffless bp estimation methods	Mukkamala *et al.* shows the diversity of estimation methods and the lack of a sufficient calibration methods. This shows the requirement of a rigorous analysis of the calibration itself is required.
ISO 81060-3 [15]	2019	Standard	Requirements and approval test for continuous bp measuring devices	A calibration method is required for a device to meet this standard.
Babbs *et al.* [16]	2012	Mathematical modelling	A automatic pre test for evaluation an oscillographic algorithm and a oscillographic algorithm	Babbs *et al.* provides a model for simulation of air pressure in a cuff used by this study.
Chandrasekhar *et al.* [17]	2019	Review and mathematical modelling	A thorough parametric analysis of oscillographic algorithms.	Base for the oscillographic algorithm used in this study.
Barschdorff *et al.* [18]	1998	bp estimation from bp-dependent data	A linear model for estimating the bp from pulse wave velocity using a model of calibration with two physical states of the body as reference.	This model allows to determine the requirements for a calibration.
Mukadam2023 [19]	2023	Intravenous bp measurements	The usage of single point result for bp related diagnosis must be reevaluated.	This study shows the magnitude of variation in systolic and diastolic pressure due to respiration.
Hales1733 [20]	1733	Experiments on animals	Blood pressure can be measured and it is dynamic.	First publication which mentions the second-order blood pressure variation.

mean arterial pressure(MAP) [19], [34]. For the purpose of this study only the blood pressure values systole and diastole were investigated.

This variation is believed to be caused by respiration [19], [33], [34], [35], [36]. According to the literature, the magnitude of this variation is as follows (Δ systole / Δ diastole):

$$\begin{array}{lcll} 14.5 \pm 2.5 & / & 13 \pm 3 & \text{mmHg [19]} \\ 6.6 - 10 & / & - & \text{mmHg [35]} \\ 2.7 - 4.4 & / & 1.2 - 1.6 & \text{mmHg [37]} \\ 14 \pm 5 & / & 8 \pm 3 & \text{mmHg [38]} \end{array}$$

During normal respiration, there are variations in intrathoracic pressure, which is the pressure in the chest cavity. The diaphragm contracts during inhalation, causing the chest cavity expand and intrathoracic pressure to decrease. This decrease in pressure leads to an increase in blood flow into the chest vessels and a decrease in blood flow returning to the heart. As a result, blood pressure tends to decrease slightly on inhalation.

During exhalation, the diaphragm relaxes and the chest cavity becomes smaller, causing an increase in intrathoracic pressure. As a result blood flow into the chest vessels decrease while the blood flow returning to the heart increases. Therefore, blood pressure tends to increase slightly on exhalation [39].

Similar to respiratory sinus arrhythmia (RSA) [40], knowledge of blood pressure variability is a measure of an individual's health and fitness and can indicate illnesses [39], [41], [42]. A high amplitude of second-order blood pressure variations typically indicates a healthy and responsive cardiovascular system. This means that blood vessels can efficiently dilate and constrict in response to changes in respiration, helping to maintain stable blood flow [39], [43]. A high amplitude of blood pressure variations during respiration is often associated with good cardiovascular fitness and exercise capacity [43].

In the context of blood pressure measurement, the second-order blood pressure variation is considered a negative influence because it affects the estimation of blood pressure using an automated blood pressure cuff [44]. When estimating with an automatic cuff, special algorithms are typically used to filter out this phenomenon [45]. Understanding this phenomenon is key to better calibration.

In order to create a broad understanding of the requirements for calibration, the aims of this study are:

1) The relationship between second-order blood pressure variation and the results of automated measurements using an oscillometric method.
2) The discussion of the expression of second-order blood pressure variation in conventional measurements and the conditions required for a measuring device to measure it accurately for calibration purposes.
3) The demonstration that current calibration methods, including officially validated ones, for continuous measurement systems based, for example, on a photoplethysmography (PPG) measurement (e.g. [4], [5], [7]) are inadequate.
4) Furthermore, this study will demonstrate that the second-order blood pressure variation should not be understood as measurement uncertainty, but as the key for solving the ‘‘calibration’’ problem.

II. PRESENTATION OF THE PROBLEM OF SECOND-ORDER BLOOD PRESSURE VARIATIONS IN CONVENTIONAL MEASUREMENTS

In a conventional automatic blood pressure measurement based on the oscillometric method [17], [46], a cuff is used to compress either the upper arm or the forearm. The pressure is typically first increased above the expected systolic pressure and then reduced linearly [46], [47]. However, in recent years, the opposite approach, i.e. measurement during pressure increase, has become more popular due to its faster measurement and reduced stress on the user [48], [49].

A. THE OSCILLOMETRIC BLOOD PRESSURE ESTIMATION

A measurement is taken by recording the air pressure in the cuff with fine resolution when the air pressure in the cuff is been changed. Fig. 2 compares measured values from a real measurement with a simulation of such a measurement (according to [16]). Additionally, the steps involved in evaluating a measurement are illustrated.

The cuff pressure curve initially shows a linear progression, originating from high air pressure in the cuff, Fig. 2a/a2. Fluctuations in the cuff pressure curve can be observed when the air pressure of the cuff reaches the systole range. These fluctuations are caused by variations in blood pressure within the arteries under the cuff, which are generated by factors such as the heartbeat or respiration. The fluctuations increase with the reduction of the cuff pressure until they reach a maximum between systole and diastole, and than disappear with further reduction below diastole, Fig. 2b/b2.

The fluctuations’ magnitude is determined by examining the cuff pressure signal, typically filtered with a high-pass filter, for local minima and maxima (Fig. 2c/c2) [46]. The pressure fluctuation between a local minimum and the subsequent maximum is the desired magnitude at a given time.

The course of the magnitudes with the cuff pressure is used to estimate systole and diastole. Ideally, this curve should consist of only one peak. Typically, either the turning points or a relative height are searched for [50]. However, the exact process is manufacturer-related and is usually not disclosed [16]. The air pressure in the cuff is output as systolic or diastolic pressure at the identified points.

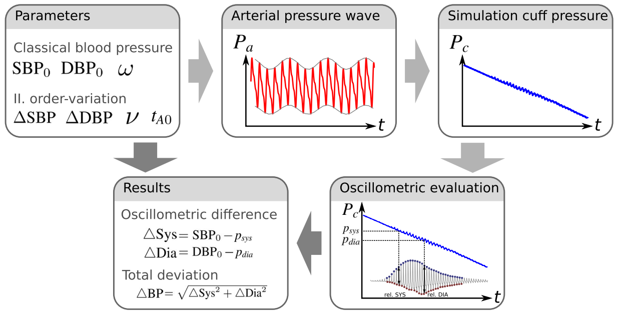

FIGURE 1. **One purpose of this study is to investigate the systematic error of current used oscillometric evaluation methods regarding the second-order blood pressure variation due to respiration. Therefore a set of input parameters describing (classical) blood pressure (systole/diastole pulse: $\mathrm{SBP}_0/\mathrm{DBP}_0$ ω) and a set describing respiration (influence of respiration on systole/diastole, frequency and phase shift: $\triangle\mathrm{SBP}/\triangle\mathrm{DBP}$, ν and t_{A0}) has been variated. In a first step of the simulation the arterial pressure wave P_a is constructed (see (4), (5), and (3)). In a second step the model of Babbs [16] is applied, which gives the air pressure curve inside a cuff P_c. The third step is the evaluation of P_c with a simple oscillometric method (refer to Fig. 2 and [17]) which results in a estimation of the blood pressure (p_{sys} / p_{dia}). For further discussion a measure of difference between the input parameter and the estimated blood pressure values are used.**

B. THE PROBLEM OF OSCILLOMETRIC BLOOD PRESSURE ESTIMATION

The problem with this approach is that it assumes different boundary conditions. These include taking measurements at rest and neglecting the influence of respiration. A list of other influencing factors is presented in [51].

However, it is important to note that the user’s rest [52] and respiration [53] cannot be neglected as influences. A measurement taken at rest represents a measurement that is unrealistic and interrupts the normal life of a user. In the area of patient transport, the requirement for rest cannot be met [52], [54]. This is why the approach taken by today’s smartwatches is crucial in solving this problem. The approach involves using a very short blood pressure estimations. Blood pressure can be estimated using PPG during short periods of rest in everyday life, but it must be calibrated with another blood pressure measurement method [10], [14], [30]. Respiration is usually considered as a disturbance, and technical implementations aim to remove its influence using special algorithms and filtering [17].

C. SIMULATION OF OSCILLOMETRIC AIR PRESSURE CURVES

To illustrate this problem, we simulate respiration in blood pressure based on the work of Babbs [16]. Babbs introduced a model of the pressure propagation from the arteries beneath a cuff into the cuff. The model describes the relationship between the blood pressure curve in the arteries and the air pressure in the cuff.

In this study the description of the model is limited to the modification done to include the respiration, for a full and exact description of the model the reader is referred to the works of Babbs [16] and the implementation in the supplementary material. An Overview of the major steps required for the simulation is given in a block diagram in Fig. 1. The related results of the simulations are given in Fig. 3 - 5.

A pressure curve, similar to those obtained in real experiments, will be produced, see Fig. 2. The purpose of Babbs's model is to provide a base for testing of different methods of oscillometric blood pressure assessment.

The presented simulations aim to demonstrate the general systematic errors of the oscillometric evaluation.

The procedure is similar to Babbs, but it expands the blood pressure wave P_a within the artery to include the influence of respiration, see (2) and (3), as shown at the bottom of the next page.

Respiration is represented by a sine wave oscillating around the set values of mean systolic (SBP_0) and diastolic blood pressure (DBP_0):

$$\begin{aligned} &\mathrm{SBP}(t, \nu, \Delta\mathrm{SBP}, t_{A0}) \\ &\quad = \mathrm{SBP}_0 + 0.5 \cdot \Delta\mathrm{SBP} \cdot \sin(\nu \cdot (t - t_{A0})) \qquad (4) \\ &\mathrm{DBP}(t, \nu, \Delta\mathrm{DBP}, t_{A0}) \\ &\quad = \mathrm{DBP}_0 + 0.5 \cdot \Delta\mathrm{DBP} \cdot \sin(\nu \cdot (t - t_{A0})) \qquad (5) \end{aligned}$$

D. DESCRIPTION OF THE SIMULATIONS PERFORMED

Fig. 2 shows a simulation of a blood pressure curve without the influence of respiration and its effect on the air pressure in a cuff. Fig. 5 shows a second simulation with strong respiration and with different start phases of the respiratory cycle. The evaluation results do not correspond to the setting of the mean blood pressure values for systole and diastole set in the simulation. Furthermore, the determination of systole is unclear in some settings.

In order to be able to analyze the simulated air pressure curves in a cuff, a minimal algorithm for classical oscillometric evaluation has been used, based on fixed thresholds for the magnitude of the fluctuations. The implementation is included in the supplementary material.

The algorithm presented here is in no way suitable for everyday use and can only be used because the simulated cuff pressure waves are not noisy and idealized.

Fig. 3 shows a comparison of the results of this algorithm with the setting of the simulation. The default blood pressure was varied between (systole/diastole) 80/40 to 200/150 mmHg, with the pulse also varying between 30 and 200 bpm for each blood pressure setting. Blood pressures with a pulse pressure of less than 20 mmHg or greater than 100 mmHg were not considered. The specific implementation of the algorithm check can be found in the supplementary material.

The influence of the respiratory amplitude is shown in the Fig. 4. The deviation of the classical oscillometric method from the simulation setting is shown as a function of the setting of the mean values of systole and diastole and the phase of the respiratory cycle at the start of the simulation. A second-order blood pressure variation of (systole/diastole) 10/8 mmHg at a pulse of 60 bpm with a respiratory rate of $5 \cdot 1/min$. was used as a fixed parameter. It can be seen that the deviation can increase up to the (systolic) value of the amplitude of the blood pressure variation during the respiratory cycle and does not follow a predictable course.

Analogous to the previous consideration, the influence of the phase of the respiratory cycle, given as the difference in the time of maximum inhalation at the start time of the simulation, or in the figurative sense at the start of a measurement is shown in Fig. 5. The deviation of the classical oscillometric method from the simulation setting is shown as a function of the time difference of the maximum inhalation at the start of the simulation. The phase was varied throughout an entire cycle. A mean blood pressure of 120/80 to 60 with a fixed respiratory amplitude of (ΔSBD / ΔDBD) of 10/8 mmHg at a respiratory rate of $5 \cdot 1/min$ was used as a fixed parameter.

III. DISCUSSION

A. METHODOLOGY DESCRIPTION

By simulating the air pressure inside a cuff for oscillometric estimation of blood pressure, the systematic error due to the negligence of respiration was analyzed. For this purpose, a computer model by Babbs [16] was used, which simulates the air pressure inside the cuff on the basis of the arterial blood pressure below the cuff. This model was extended to include the influence of respiration on the arterial blood pressure.

The presented computer model therefore has the following initial parameters: systole, diastole, blood pressure curve in the artery below the cuff, amplitude of the change in systole and diastole within the respiratory cycle, respiratory frequency, and phase or time differences of respiration at the beginning of the simulation.

A simple algorithm for oscillometric evaluation of the cuff pressure curve was used to evaluate the simulation. Details of such algorithms can be found, for example, in [17]. The algorithm used is based on fixed empirical values for the estimation of systole and diastole from the relative magnitude of the fluctuations on the cuff pressure curve (see Fig. 2).

The limitation of the algorithm is that it only works on the (relatively) smooth values of the simulation, using moderate settings for pulse rate (> 40 bpm) and pulse pressure (< 80 mmHg), and has no strategies for dealing with noise, arrhythmias or the like, nor does it have a strategy for ambiguous databases. It is precisely this limitation that highlights the source of errors in the algorithms used today. One source of error that has been specifically investigated in this paper is the influence of respiration on the estimation of blood pressure using oscillometric methods. Fig. 3 shows that under ideal conditions, i.e. without the influence of respiration, this simple algorithm can reproduce the simulation settings for systole and diastole with a deviation of ±5 mmHg and thus meets the typical approval criteria for oscillometric methods [55].

B. DESCRIPTION OF THE SIMULATION RESULTS

When respiration is activated, the algorithm used reveals perceived weaknesses. Fig. 4 shows the deviation of the oscillometric evaluation from the simulation setting in systole and diastole. The point of this figure is: firstly, that respiration leads to a deviation in the estimation of the values of systole or diastole up to the amplitude of the second-order blood pressure variation and secondly, that the deviation is not predictable because there is no linear relationship between the deviation and the "target value." A non-linear mapping for example a look-up table based on the Fig. 4 cannot be used in a real measurement due to the circumstances (noise of the measured values, correct handling). The deviation is also determined by the respiratory phase at the beginning of the simulation.

It is precisely this dependence of the deviation on the respiratory phase that leads to the problem of non-repeatability of the measurement in a real measurement. This corresponds to the observation of most users: that three blood pressure measurements results in three different blood pressure values.

Another source of error is shown in Fig. 5. Subfigure (c) shows the deviation for the variation of the respiratory phase. It is noticeable that there is an area where the evaluation of the systole becomes ambiguous and two possible values for the systole can be determined (the isolated dots indicate further ambiguities). This is because the fluctuations in the cuff pressure curve are also influenced by respiration. If there is a change in respiration from exhalation to inhalation or vice versa at the point at which the fluctuations correspond to the empirical relative values, the influence can reduce the fluctuations and there are two points where the criterion for a blood pressure value is met. It should be noted that this phenomenon of ambiguity can be observed with the pressure reduction rate of 3· mmHg given here. This rate is typically used for such measurements [47].

The probability of this phenomenon decreases with increasing pressure reduction rate. At lower rates, not only the probability increases, but also ambiguity occurs and more than two values can be determined for one blood pressure value, see supplementary material.

C. DEALING WITH THE DEVIATION/MARKET CONDITION

The way to deal with these sources of error in today's algorithms is to apply a low-pass filter on the values of the fluctuations in the cuff pressure curve [17]. This means that blood pressure peaks are in principle averaged out and cannot be detected, but such peaks are the cause of acute heart disease [56]. On the positive side, however, a high variability of blood pressure is an indicator of good physical condition and fitness [39], [41], [42].

Current techniques may be well suited to monitoring the state of health in conjunction with treatment [57]. However, its use today is not only limited to accompanying treatment, in particular the regular monitoring of

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$$P_a(\mathrm{SBP}, \mathrm{DBP}, t, \omega) = \mathrm{DBP} + 0.5 \cdot \mathrm{PP} + 0.36 \cdot \mathrm{PP}\left[\sin \omega t + \frac{1}{2}\sin 2\omega t + \frac{1}{4}\sin 3\omega t\right] \tag{2}$$

$$\rightarrow$$

$$P_a(\mathrm{SBP}(t, \nu, \Delta\mathrm{SBP}, t_{A0}), \mathrm{DBP}(t, \nu, \Delta\mathrm{DBP}, t_{A0}), t, \omega) = \mathrm{DBP}(\ldots) + 0.5 \cdot \mathrm{PP}(\ldots) + 0.36 \cdot \mathrm{PP}(\ldots)\left[\sin \omega t + \frac{1}{2}\sin 2\omega t + \frac{1}{4}\sin 3\omega t\right] \tag{3}$$

Parameter	Meaning
P_a	Progression of the pressure in the arteries beneath the cuff.
P_c	Progression of the pressure in the cuff.
SBP / DBP	Simulated arterial blood pressure value, see (4) and (5).
t	Time
ω	Frequency of the heart beat $= 2\pi\,\mathrm{BPM}/60$ with BPM the heart beat in $1/min$.
PP	Pulse pressure = SBP − DBP
ν	Respiratory frequency $= 2\pi\,\mathrm{APM}/60$ with APM the number of respiratory cycles in $1/min$.
ΔSBP / ΔDBP	Magnitude of the variation of the systolic/diastolic value during a respiratory cycle.
t_{A0}	Phase of the respiratory cycle given as the time difference between inhalation and simulation start.
p_{sys} / p_{dia}	Blood pressure value estimated by the used oscillometric algorithm.
△Sys / △Dia	$= \mathrm{SBP}_0 - p_{sys}$ / $= \mathrm{DBP}_0 - p_{dia}$ derivation between simulation setting and estimation of the blood pressure.
△BP	$= \sqrt{\triangle\mathrm{Sys}^2 + \triangle\mathrm{Dia}^2}$ total derivation between simulation setting and estimation of the blood pressure.

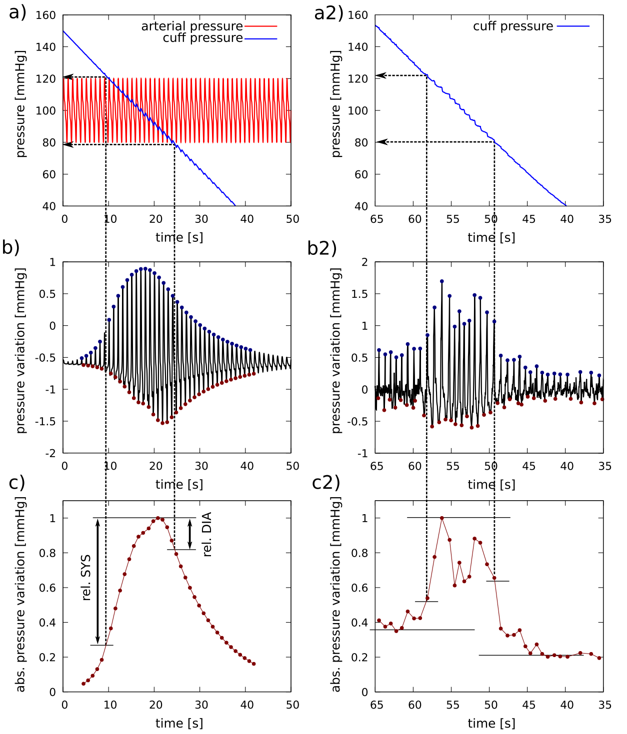

FIGURE 2. **Classical evaluation of cuff pressure using the oscillometric method to obtain systole and diastole. The comparison shows a simulation and a real measurement (real measurement measured with increasing pressure) with comparable parameters (120/80 to 60). During a measurement (a, a2), the air pressure in the cuff is recorded as a function of time. The cuff pressure shows a linear decrease over time, but upon closer inspection, fluctuations can be observed. These fluctuations originate from the pressure within the arteries below the cuff.**
To separates the fluctuations from the general pressure curve, a high-pass filter is used (b, b2). The magnitude of these fluctuations is then determined (c, c2). Points are now sought within the magnitude curve where the systole or diastole has an empirical proportion of the maximum magnitude. Time points are found. The cuff pressure at these times is reported as systole and diastole respectively.

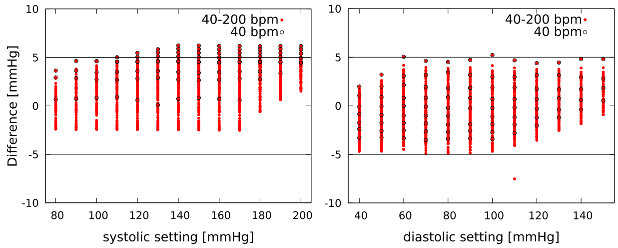

FIGURE 3. **Quality of the simple algorithm for evaluating cuff pressure values for estimating systole and diastole. Bland-Altman plots of the deviation between algorithm and simulation specifications are shown. The comparison for systole is shown on the left and the comparison for diastole is shown on the right. The simulations were evaluated without respiration with the specification of systole and diastole in the range of 80/40 to 200/150 mmHg in the pulse range 30-200 bpm (30 bpm not shown). It can be seen that the simple algorithm reproduces the default values of the simulation with an accuracy of ±5 mmHg, which corresponds to the typical requirements of a type approval [55]. However, certain points differ. These points relate to extreme settings for pulse pressures of 80 mmHg and above or low pulse rates of 40 bpm (marked points). Therefore, a pulse rate of 40 bpm was excluded from further investigation.**

a patient by a doctor, but blood pressure measurement has become a ubiquitous measurement. In particular, new smartwatches that promise to measure blood pressure are

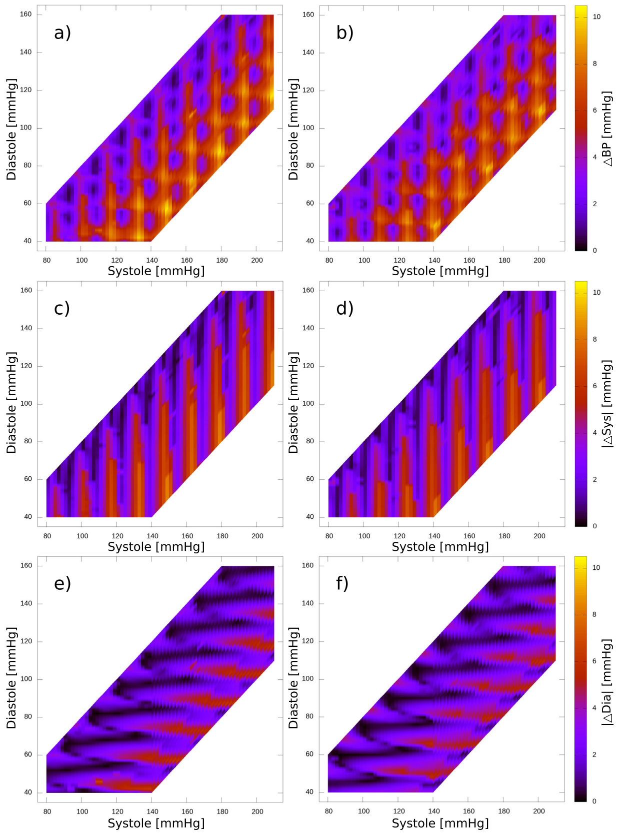

FIGURE 4. **Systematic measurement error of the oscillometric method due to the influence of respiration as a function of the simulation setting of diastole and systole. The other simulation parameters are a second-order blood pressure variation (systole/diastole) 10/8 mmHg, a respiratory rate of $5 \cdot 1/min$. and an initial cuff pressure of 230 mmHg. (a, c, e) show the error when the simulation is started for exhalation and (b, d, f) when it is started for inhalation. (a) and (b) show the total derivation, determined by the L2norm of the derivation between simulation setting and oscillometric evaluation ($\Delta Sys/\Delta Dia$, the derivation in systole/diastole): $\Delta BP = \sqrt{\Delta Sys^2 + \Delta Dia^2}$. Figures (c) and (d) show the absolute deviation of the systole and e and f the absolute deviation of the diastole. The point of these graphs is that the systematic error is in the order of the second-order blood pressure variation and that the initial conditions (phase of respiration) are crucial for the specific deviation. For a real measurement, this means that a classical oscillometric evaluation cannot measure more accurately than the blood pressure variation.**

launched almost daily [2], [4], [5]. Devices that claim to provide a professional measurement perform a calibration with a blood pressure cuff before what is usually a repeated or even continuous measurement, with the user taking the measurements at rest and under normal circumstances [4], [5]. In the author's opinion, such calibration is not possible with the algorithms currently used for oscillometric evaluation. As a result, healthy people are declared to be sick and, even worse, sick people are declared to be healthy.

D. BLOOD PRESSURE ESTIMATION BASED ON A BURDEN-FREE MEASUREMENT OF BLOOD PRESSURE-DEPENDENT TREND DATA

The correlation between the pulse wave transit time (PTT) [18] or the pulse wave contour [10], [23] and blood pressure is

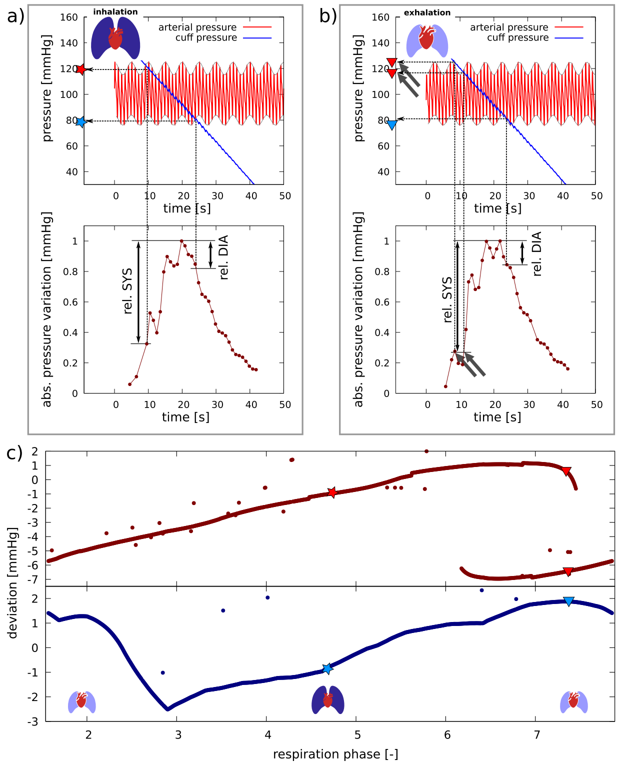

FIGURE 5. **Comparison of possible situations for oscillometric blood pressure measurement in relation to the respiratory phase. Figures (a) and (b) show the oscillometric evaluation of a cuff pressure curve, analogous to Fig. 2. In both cases, the same parameters were used for the simulation: mean blood pressure 120/80 to 60; respiratory rate 5 · 1/*min*.; second-order blood pressure variation 10/8 mmHg; pressure reduction rate 3 mmHg/s. The only difference is the start of the simulation in relation to the respiratory cycle. In (a), the start of inhalation or maximum exhalation was chosen for the respiratory phase, (b) shows the situation at maximum inhalation. Section (c) shows the deviation of the estimated systole and diastole from the setting of the mean systole and diastole of the simulation (△Sys/△Dia). The outcomes from (a) are marked with stars and the outcomes from (b) are marked with triangles. Note that for (b), the evaluation is no longer clear (arrows) and there are two possible outcomes for systole.**

well established. However, other vital data also exhibit at least a temporary correlation with blood pressure [23]. To estimate blood pressure based on these vital data a mathematical model is typically used or machine learning is employed [10], [23]. Both approaches require individual parameter determination for each user as part of a calibration process. The parameters vary between users and only apply to an individual as long as their physical situation remains similar.

To determine the required level of accuracy, it is recommended to examine the Barschdorff and Erig [18] method in greater detail. Barschdorff stated that PTT (t_{RP}) is determined from the times of the R wave of the ECG signal and the time of the next local minima in the PPG signal of a subject. t_{RP} can be mapped to the blood pressure values p_{sys} or p_{dia} using (6).

$$p_{sys} = m_{sys}\frac{1}{t_{RP}} + b_{sys} \quad \text{and} \quad p_{dia} = m_{dia}\frac{1}{t_{RP}} + b_{dia} \tag{6}$$

To provide an idea of the magnitude of the values involved, Barschdorff offers example pairs of calibration values (systolic value at transit time: $[p, t_{RP}]$) for a calibration (using transit time at the finger):

$$\begin{aligned}[p, t_{RP}]_1 &= [130\,mmHg, 0.20\,s] \quad \text{and}\\ [p, t_{RP}]_2 &= [187\,mmHg, 0.14\,s]\\ \Rightarrow p_{sys}(t_{RP}) &= 23.940\frac{1}{t_{RP}} + 16.000\end{aligned} \tag{7}$$

These values were determined before and shortly after physical exertion and used to determine the free parameters m_{sys} and b_{sys}. This type of calibration is not suitable for daily calibration or for patients who cannot withstand such physical stress.

Firstly, it is necessary to analyze the required level of accuracy for the calibration value pairs when measuring changes in blood pressure due to physical exertion or second-order blood pressure variations.

The suitable measurement range for continuous monitoring is specified to be 50-200 mmHg which should be estimated with an accuracy of ±1 mmHg. Blood pressure values outside this range are extremely critical, but a diagnosis in these areas is clear and does not require a blood pressure estimate with 1 mmHg accuracy. To achieve a continuous measurement that is comparable to the invasive blood pressure measurement, the total error must not exceed ±5 mmHg [15], [55]. Therefore, the accuracy of ±1 mmHg was chosen to account for systematic errors caused by sensor technology resolution and other errors that may occur during a real measurement that will contribute to the overall error.

Barschdorff's exemplary measured values allow for an estimation of the accuracy order for the PTT t_{RP}: a difference of 57 mmHg and a range of 60 ms is given. Therefore, the measurement accuracy for a blood pressure estimate with ±1 mmHg must be within the range of 1 ms. To obtain an accurate estimate the calibration (6) is setup as a function of the pairs of calibration values:

$$p(t_{RP})_{p1,t_{RP,1},p2,t_{RP,2}} = m_{p1,t_{RP,1},p2,t_{RP,2}}\frac{1}{t_{RP}} + b_{p1,t_{RP,1},p2,t_{RP,2}} \tag{8}$$

with

$$m_{p1,t_{RP,1},p2,t_{RP,2}} = \frac{p1 - p1}{1/t_{RP,1} - 1/t_{RP,2}} \tag{9}$$

$$b_{p1,t_{RP,1},p2,t_{RP,2}} = p1 - m_{p1,t_{RP,1},p2,t_{RP,2}}/t_{RP,1} \tag{10}$$

The straight line through the two pairs of calibration values (or linear fit for more than two pairs of values) gives the values for m and b. The difference between $p(t_{RP})$ and $p'(t_{RP})$ results in the deviation of the blood pressure estimate due to the measurement uncertainty of a parameter. Here, $p'(t_{RP})$ equals $p(t_{RP})$, except for the choice of a value of a pair of calibration values, for example $t_{RP,2}$ is varied. This results in the exact value for Barschdorff's example: 0.6 ms, with the deviation in the entire estimated measuring range corresponding to the deviation criterion.

The procedure for utilizing second-order blood pressure variation is similar. On the plot of (7), two blood pressure values are chosen to correspond to typical inhalation and exhalation values, for example, 130 mmHg and 120 mmHg. The difference between $p(t_{RP})$ and $p'(t_{RP})$ is then determined, ensuring that the deviation in the estimated range of blood pressure values is below ±1 mmHg. For a second-order variation in systolic blood pressure between 120 mmHg and 130 mmHg, a resolution of 0.2 ms is required. For a second-order variation in systolic blood pressure between 120 mmHg and 121 mmHg, a resolution of 0.03 ms is required.

To achieve a maximum deviation of 1 mmHg in blood pressure estimation, the following conditions based on the calibration range(CR) are summarized. The resolution of the PTT results to:

Barschdorff	(CR: 60 mmHg):	0.60 ms
strong respiration	(CR: 10 mmHg):	0.20 ms
shallow respiration	(CR: 1 mmHg):	0.03 ms

The following strict conditions apply for a variation of the reference calibration blood pressure value:

Barschdorff	(CR: 60 mmHg):	0.420 mmHg
strong respiration	(CR: 10 mmHg):	0.120 mmHg
shallow respiration	(CR: 1 mmHg):	0.016 mmHg

Today's technology allows for resolution of the PTT to be achieved using current sensors. For instance, the GH3220 sensor from Goodix [58] has a resolution of 2 kHz for the simultaneous measurement of ECG and PPG signals. However, "simple" peak detection is not enough, the peaks must be approximated with an ideal peak shape in order to obtain a higher temporal resolution with respect to the PTT [50].

To accurately measure continuous blood pressure using current oscillometric methods, calibration must involve a significant change in blood pressure, as proposed by Barschdorff.

E. REQUIREMENTS FOR A CALIBRATION DEVICE THAT ENABLES THE ESTIMATION OF CONTINUOUS BLOOD PRESSURE VALUES

The task of a calibration device is to determine reference blood pressure values at specified or defined times and to transmit them to another measuring device.

This enables the other measuring device to continuously determine a blood pressure value for each measurement of a vital parameter, preferably determined for each heartbeat.

The results of the previous section place high requirement on a calibration system in terms of resolution in pressure. Current sensor and cuff technology will not meet this requirements. However, using oversampling future oscillometric algorithm, which can measure multiple blood pressure values during the respiratory cycle may come available.

The measuring device must have an accuracy requirement of no more than ±5 mmHg in the measuring range of 50-200 mmHg, as determined by the deviation from invasive blood pressure measurement.

The systolic and diastolic blood pressure values must be calibrated separately.

This results in the following requirements for a calibration device:

- accuracy < ±1 mmHg
- (short-term) continuous systolic and diastolic values
- The time of the measured values needs to be determined

IV. CONCLUSION

The presented simulation demonstrates that the oscillometric evaluation of a cuff pressure curve using current methods results in a systematic error in the order of the second-order blood pressure variation.

On the contrary, the oscillometric measurement contains the information of the second-order blood pressure variation. Therefore, there is no substantial objection to evaluating the oscillometric measurement in a way that allows for calibration.

Regarding the requirements for calibrating blood pressure estimation, the Barschdorff method [18] is the only one that can currently borderline meet the standard for calibration [15] under high physical stress through current oscillometric methods.

Any future oscillometric evaluations will also not meet the high requirements under real conditions for calibration during respiration, unless the blood pressure is continuously determined during the calibration. This will allow for an appropriate resolution to be achieved through oversampling with several calibration pairs within the respiratory cycle.

In an upcoming publication by the authors and described already in a patent [59] a new method for oscillometric evaluation of the cuff pressure curve is proposed. The method outputs a pair of systolic/diastolic values and continuously determines a pair of blood pressure values for each heartbeat during the time of the pressure change in a cuff.

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MARTIN DEUTGES received the B.S., M.S., and Ph.D. degrees in material physics from Universität Göttingen, Germany, in 2010, 2013, and 2016, respectively. After graduation, he joined Redtel as a System Developer. His research interest includes tackling the challenging problems that exist in the measurement of vital data in mobile solutions.

HOLGER REDTEL has been self-employed, since 1990, and has 16 years of experience in research and development of medical diagnostic methods. During this time, he supported several companies and start-ups as a Founder, a Business Partner, and a Consultant. He has established various partnerships with research institutes and universities. This led to several patent applications worldwide.

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