

# An investigation of the individualized, two-point calibration method for cuffless blood pressure estimation using pulse arrival time: an historical perspective using the Casio BP-100 digital watch

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**Abstract—Background:** The use of wearable cuffless blood pressure (BP) devices is becoming commercially prevalent with little published validation information. Most devices rely, at least in part, on the relationship between pulse arrival time (PAT) and BP, a theoretical fundamental relationship that was first commercially exploited in 1993 with the release of the Casio BP-100 digital watch. **Objective:** This study explored the PAT method of BP estimation in a commercial device where it first began, the Casio BP-100 (Model No. 900) digital watch, which employs an individualized, two-point calibration method. Device accuracy was determined by comparison to a conventional cuff-based BP device measurements. **Methods:** Twenty participants (11 female, 9 male) had BP measured using both devices at rest, during a 5-minute isometric hand-grip exercise and at 1-minute post-exercise. **Results:** Due to bidirectional scatter of BP estimation by the BP-100 device, there was no significant difference between the reference device and the BP-100. The devices showed poor correlation for both systolic BP (SBP) ( $R=0.36$ ,  $p=0.13$ ) and diastolic BP (DBP) ( $R=0.044$ ,  $p=0.37$ ). However, on average the watch was able to provide correct directional changes in SBP but not DBP with exercise. **Conclusions:** Despite being an industry first, the Casio BP-100 watch employed a method that gives a great chance of accuracy: a two point, individualized calibration method – more detailed than calibration methods in more modern devices. The watch, on average across a cohort, provided some information on BP directional change but was uncorrelated with cuff-based BP measurement. If the utility of beat-by-beat BP estimation is to be utilized, limitations of this method need to be addressed.

## I. INTRODUCTION

Accurate blood pressure (BP) measurement and monitoring are essential for the diagnosis of hypertension, a major cardiovascular risk factor [1]. For well over 100 years, brachial, cuff-based techniques have been used for BP assessment, correlating sounds (auscultation) or oscillometric waveforms with pneumatic cuff pressure to arrive at an estimate of systolic BP (SBP) and diastolic BP (DBP). Although this is the most reliable non-invasive method of measuring BP, there are several limitations to these devices aside from the correlation of the sound or oscillometric events/calculations with invasive BP [2]. Physiologically, BP is dynamic and varies with each heartbeat. Conventional cuff-based devices can only provide a snapshot of a patient's BP profile, intermittent at best with measurements every 15 to 20 minutes using ambulatory BP devices. Recent studies have

demonstrated the utility of observing beat-to-beat BP [3], [4] supporting the concept of continuous BP estimation, as potentially achieved through cuffless approaches.

Such cuffless BP monitors are becoming commercially prevalent. The predominant technique used to estimate BP without a cuff exploits the theoretical and fundamental relationship between arterial stiffness and BP [5], [6]. The technique requires the pulse to be recorded at two sites and the transit time for the pulse to travel between those two sites measured. The method can be simplified in terms of equipment by using the R peak of the electrocardiogram (ECG) to signify the start of the pulse (ignoring confounding effects of the pre-ejection period) and a fiducial point on a distally acquired pulse (i.e. wrist or finger) to calculate the pulse arrival time (PAT). An increase in BP increases tension in the arterial wall, which can be measured as a decrease in pulse transit time and PAT due to an increase in wall stiffness [7]. If the relationship between change in BP and change in PAT is known (i.e. calibration), BP can be estimated from PAT. These devices have shown promising results in recent studies [8]–[11] displaying agreement to cuff-based BP assessment using mean values across a cohort. However, these studies ignore the need for individual accuracy in medical measurement [12], which is hidden by regression to the mean. Some devices make claims for validation using the European Society of Hypertension protocol [13], [14], ignoring that these guidelines are for cuff-based devices and not cuffless devices. The IEEE standard for cuffless device validation [15], [16] highlights that a BP *change* is required to validate these devices, else they are being validated at the point at which they are calibrated.

The basis of cuffless BP estimation has been used commercially as far back as 1993 with the release of the Casio BP-100 (Model No. 900, Figure 1). The watch uses a calibration technique that gives a greater chance of success than many current devices on the market in that the calibration uses *two points* of BP (many current devices use a single point and assume a calibration slope) and is *individualized*. Following on from the CASIO JP-100 that used finger photoplethysmography (PPG) to provide heart rate (HR) in a digital watch, the BP-100 added an ECG sensor. When coupled with the PPG this allows PAT calculation. The method of BP estimation is relatively unknown, but instruction manuals for the BP-100 and following model BP-120 suggest that from an individual two-point calibration (at rest and during exercise) using the watch and cuff-based BP measurement,

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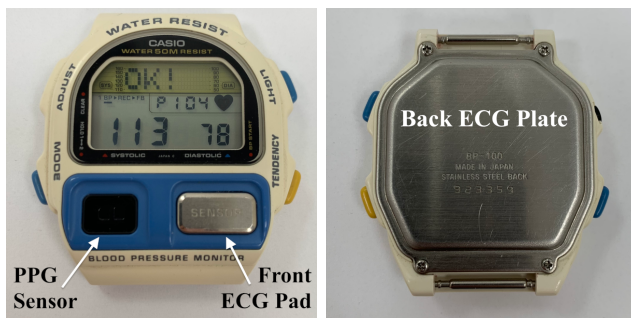


Fig. 1. The Casio BP-100 digital watch. The sensor on the bottom left (left image) is the PPG sensor (taken from the index finger on the non-watch wearing hand) and the metal pad on the bottom right is the contact point for the middle finger, which when coupled with the metal back plate (right image) on the wrist provides an ECG.

PAT is correlated with SBP. The method by which the watch estimates DBP is unknown but is likely similar in approach.

Despite using a technique that is likely more successful than more modern devices that either do not use an individualized approach or assume a calibration slope (single point calibration), the accuracy of the BP-100 has never been reported. This study reports on the Casio BP-100 accuracy as a flagship device both in historical significance as the first commercial cuffless BP device, and as a device employing a technique that is more likely to provide success than many of the modern day equivalents.

## II. METHODS

Participants aged between 21 to 50 years old were recruited, excluding only those that were pregnant or had sinus arrhythmias. Written, informed consent was acquired from each participant. The study was approved by the Macquarie University Human Research Ethics Committee.

Inter-arm BP difference was assessed by cuff BP readings during seated rest, three times on each arm using an automatic oscillometric device (Omron HEM-907) with one minute between each measurement.

### A. Calibration

Participants were first allowed to familiarize themselves with the watch fitted to the left wrist by using a demonstration feature. This helped the participants gauge the required finger pressure for successful measurement. The watch was then calibrated by entering a seated cuff-measured, resting BP (cuff fitted to the right arm), and a PAT measurement was made using the watch. The participant then performed an isometric hand-grip exercise by holding a force of 20% of their maximum grip strength for 5 minutes using a dynamometer (force transducer) using their left hand. Participants were instructed to breathe normally during this period to avoid performing a Valsalva maneuver. The second calibration point was obtained during the raised BP period of the final minute of exercise.

### B. Measurements

After 5 minutes of seated rest, resting cuff BP was taken along with a watch BP estimation within 30 seconds of

the cuff BP measurement. This was repeated three times. The participant then performed a second isometric hand-grip exercise identical to the first. BP measurements were taken by the cuff and watch at 1 minute, 3 minutes and 5 minutes into the exercise. One more measurement was taken by each device, 1-minute post-exercise.

When measurement errors occurred on either the watch or cuff, the measurement was repeated immediately. If errors persisted, the participant's hands were warmed to ensure the PPG sensor was working optimally. Calibration errors also occurred and were mitigated by remeasuring oscillometric BP and inputting the value into the watch.

### C. Statistical Analysis

Inter-arm BP differences were assessed by paired t-test. The watch and cuff BP were compared by paired t-test, Pearson's correlation and Bland-Altman representation [12]. Analysis of variance (ANOVA) was performed for the analysis of unequal samples when comparing BP estimates for each exercise state during the experiment. Analysis was performed using Microsoft Excel® Version 16.42. Data are presented as mean  $\pm$  standard error.

## III. RESULTS

Twenty participants were recruited (age  $26 \pm 9$  years, 11 (55%) female). Two participants were removed from the analysis due to the watch calibration being unsuccessful. There were no inter-arm BP differences (right to left SBP difference  $-1 \pm 6$  mmHg,  $p=0.54$ ; DBP difference  $0 \pm 6$  mmHg,  $p=0.92$ ). The isometric hand-grip exercise successfully increased BP for the two-point calibration (SBP from  $111 \pm 13$  to  $127 \pm 11$  mmHg,  $p < 0.001$ ; DBP from  $72 \pm 10$  to  $83 \pm 10$  mmHg,  $p < 0.001$ ). Data acquisition using the watch had a success rate of 60% when taking PAT measurements (40% of readings failed and needed to be retaken).

Comparing all SBP readings taken by the reference device and the watch, there was no significant difference ( $1 \pm 20$  mmHg;  $p=0.13$ ). Watch DBP also did not significantly differ from cuff readings when all measurements were grouped ( $1 \pm 20$  mmHg;  $p=0.37$ ). BP measurements taken by the watch and cuff-based device (Fig. 2) showed a poor correlation (SBP:  $R=0.36$ ,  $p=0.13$ ; DBP:  $R=0.044$ ,  $p=0.37$ ).

The direction of BP change with exercise and with exercise recovery provided by the Casio watch was correct for SBP but incorrect for DBP with the exception of rest to exercise recovery difference (Table I).

## IV. DISCUSSION

The results demonstrate, which Bland and Altman put forward in their landmark paper of 1986, that examining the statistical results across only the averages (e.g. t-tests and ANOVAs) can hide a spread of data, a spread which can render a measurement useless in the clinical setting [12]. For SBP estimated using the PAT method with a two-point calibration as employed in the Casio BP-100 watch, the directional changes on average are correct, and the differences in average magnitude of change are generally

TABLE I  
COMPARISON BETWEEN BASELINE AND EXERCISE INDUCED SBP AND DBP CHANGES.

		rest to exercise	<i>p</i>	exercise to exercise recovery	<i>p</i>	rest to exercise recovery	<i>p</i>
SBP (mmHg)	Cuff	9±3	0.0002	-5±3	0.03	-4±2	0.33
	Watch	15±6	0.0001	-9±6	0.10	-6±4	0.07
DBP (mmHg)	Cuff	9±2	0.0003	-6±2	0.14	-3±2	0.10
	Watch	0±4	0.40	10±4	0.04	-10±4	0.07

Cuff to watch difference (ANOVA) for SBP was  $p=0.516$ , and for DBP was  $p=0.14$ .

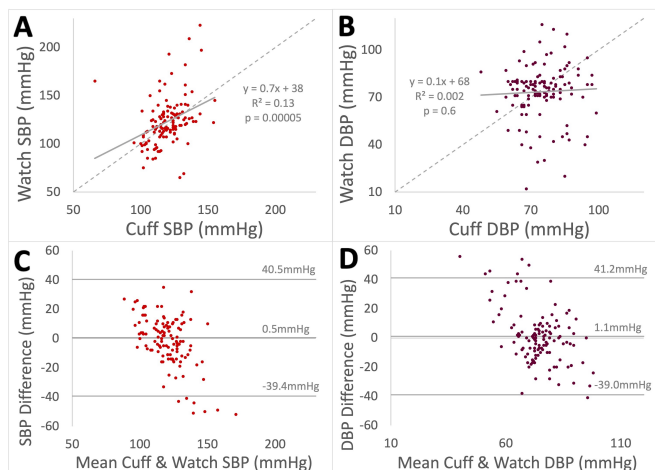


Fig. 2. Correlation and Bland-Altman plots comparing the cuffless Casio BP-100 watch to cuff-based BP measurements. Solid line in (A) and (B) is the line of regression and dashed line is the line of unit (theoretical perfect device agreement). Solid lines in (C) and (D) provide the mean device difference and 95% confidence interval. BP differences calculated as cuff BP - watch BP.

within a few mmHg of the cuff-based measurements (Table I). This study demonstrates comparable mean BP differences to previously validated PAT-based devices [13], [14], [17]. The difference between the Casio device and these studies is that these studies used devices that had a single point of calibration and assumed slope. Another study conducted in 2007 used tonometric measurements of the radial pulse wave to estimate BP also found similar mean differences in both SBP and DBP [18]. Presentation of the data in such a manner is favorable for the adoption of cuffless BP estimation and might provide some basis for the use of cuffless BP in population-based studies where this would be advantageous over cuff-based BP measurement approaches. The caveat here is that given the variability in accuracy, the sensitivity of cuffless, estimated BP would mean only very large BP differences between groups could plausibly be detected.

Inspection of the spread of the data through correlation statistics and Bland-Altman graphical representation (Figure 2) gives information on the utility of the BP estimation within the individual. The 95% confidence interval for the estimation of BP using the cuffless BP approach was over 80 mmHg for both SBP and DBP. With reference to the expected accuracy of devices as per validation guidelines [15], [16], for which this result is an order of magnitude

from, the variability means the result for an individual measurement is little better than a random guess within a physiologically reasonable range of BP.

There are potential clinical advantages of continuous BP estimation through cuffless approaches [3], [4] and the potential wider adoption of BP measurement in the community with a more convenient form of BP measurement could reduce undiagnosed hypertension. The Casio BP-100 was the start of the commercial cuffless BP space. Recent findings have shown that by using algorithms based on PAT and PPG intensity ratio [19], [20], as well as impedance plethysmography [21], the accuracy of BP estimation can be improved. In interpreting the Casio BP-100 results, the processing power of the device must be kept in mind and it is likely that the fiducial points of the ECG and PPG were found by a simple threshold method (though the exact method employed by the device is unknown) and better location of the R peak and PPG foot may lead to less variability. Broader fuzzy logic and machine learning techniques, though less fundamentally driven relationships in terms of a link to BP, may also provide increased accuracy. Within this work, the fundamental relationship between arterial stiffness and BP, and the individualization of the calibration term [6] as adopted in the BP-100 should not be discarded. Ganti et al. showed that a two-point calibration is advantageous compared to a single-point calibration [22], highlighting that a move toward generalization of the calibration term (or slope) is likely to decrease BP estimation accuracy.

The accuracy of this method of cuffless BP estimation relies on PAT changes being impacted by BP and BP alone. However, PAT consists of BP independent components including the left ventricular pre-ejection period [23], and the BP independent effects of HR [24] and sympathetic activity [9] on arterial stiffness. It is plausible to correct PAT for some of these BP independent factors and in so doing the accuracy of BP estimated from PAT may be increased.

In the current study, PAT was measured from the heart to the left wrist whilst cuff BP whilst measured in the right arm. Inter-arm BP differences would give a false BP difference, though there was no inter-arm BP difference observed in the participants of this study. The study was not suitably powered to investigate sex differences though given the relationship between arterial stiffness and BP underpinning the BP estimation technique, it is unlikely sex plays a role. Additionally, the study did not represent hypertensive or older individuals. This may play a role as that population would have greater

arterial stiffness and lower PAT. Whilst there is a standard for validation of cuffless BP devices [15], [16], given the results of this study the larger, standardised study approach will likely only reinforce that the CASIO BP-100 does not provide an accurate BP measurement. The study also suffered from a condition common in cuffless BP studies: the validation data repeated measurements at the BP points at which the calibration was made. It would be expected that this pre-disposes the study to show good agreement between estimation and cuff measurement. However, this was not the case, and poor agreement was shown. We attempted to address this limitation by also including BP measurements between the calibration points (measurements during the exercise challenge at 1 minute and 3 minutes), though a stronger method would be to use an alternative method (e.g. vasoactive drug administration) to move BP outside of the calibrated range.

## V. CONCLUSIONS

The Casio BP-100 digital watch was the first commercial device for cuffless BP measurement. It uses a technique that is stronger in basis than many modern cuffless BP devices. Averaged across the studied sample, the cuffless approach is within agreement with cuff-based measurement. The variability of this accuracy, however, means it has limited utility in indicating an individual's BP at any single point in time. Correction for confounders including left ventricular pre-ejection period, HR and sympathetic activity, alongside use of other BP correlates in autoregressive models might provide an avenue for the increased accuracy required for cuffless BP estimation to be useful in the clinical, exercise science and community environment.

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