Cuffless Blood Pressure Monitoring: Precision is Maintained four Months after Calibration

M. Proença, C. Aguet, G. Bonnier, K. Adam, D. Ferrario, M. Lemay

Frequent and accurate blood pressure (BP) monitoring is essential for effective hypertension management. Automated cuff-based devices are poorly suited for frequent and long-term monitoring. Alternatives based on photoplethysmography (PPG) and pulse wave analysis (PWA) offer promising potential, but require calibration. Limiting the number of re-calibrations is crucial for their practical usability. In this study, we tackle this Achilles' heel and demonstrate that CSEM's cuffless BP monitoring algorithm remains within ISO 81060-2 limits over a four-month period after calibration.

Persistently high blood pressure (BP), or hypertension, affecting approximately one third of the adult population, significantly increases the risk of developing cardiovascular diseases. Accurate and frequent BP monitoring is crucial to identify atypical BP fluctuations, especially in treated patients, for effective therapy management and reduction of long-term cardiovascular risk. While automated cuff-based devices are widely used both in clinical and home/ambulatory settings, they suffer from limitations such as discomfort, unsuitability for frequent monitoring, and occasional inaccuracies. These drawbacks contribute to the widespread underdiagnosis of hypertension.

Solutions based on photoplethysmography (PPG) and pulse wave analysis (PWA) offer promising and convenient alternatives, particularly due to their unobtrusive nature. Absolute BP values can be obtained after a calibration with a reference device. However, the need for frequent re-calibrations in case of sensitivity to peripheral effects strongly affects their practical usability, and inevitably raises concerns about long-term trending ability for hypertension management. Leveraging PWA features that reflect central rather than peripheral phenomena can help mitigate the problem. This observation was at the root of the development of CSEM's patented PPG-based PWA algorithm[1]. We have previously validated its short-term trending ability during general anesthesia induction[2], and its ability to track circadian fluctuations in 24-h ambulatory BP monitoring settings[3]. In the present study, our aim was to demonstrate its long-term post-calibration stability, over weeks and months.

To that end, recording sessions were performed on 11 participants (6 female, age: 36.8 ± 10.7 years, body-mass index: 23.0 ± 3.1 kg/m², Fitzpatrick skin type: 2.1 ± 0.5, treated hypertension: 1, smoker: 1), at irregular intervals of one or several days, depending on their availability, over a period of 123 days, with an average of 30 recording sessions per participant. All subjects provided written informed consent. During each recording session, the subjects were sitting, forearms, elbows and back supported, legs uncrossed and feet flat on the floor and asked to relax and not to talk. PPG sensors were attached at their right upper arm and fingertip, while an oscillometric upper arm BP monitor (Omron M6 Comfort) was installed at their left upper arm. After a resting period of at least 8 minutes, PPG data acquisition was started, and five BP measurements were acquired with the cuff-based monitor. After PPG data processing via CSEM's BP algorithm, five cuff-PPG BP pairs were obtained. As oscillometric cuffs are not accepted BP references, the five cuff measurements were then averaged to produce one single representative cuff BP value, and the same was done for the five PPG BP values. In ~60% of sessions, a BP change was induced after the five measurements through isometric exercise (leg extension). Two additional cuff-PPG BP pairs (leg extension measurements) were acquired during the exercise. The induced BP change was calculated as the average of the leg extension measurements minus the average of the baseline measurements.

CSEM's PPG-based algorithm calibration procedure − a simple offset correction − can be performed in post-processing. Thus, the one-month stability of the calibration can easily be evaluated by calibrating the PPG-based BP on a given session and evaluating the agreement between the cuff-based and PPG-based BP on a session occurring one month later. It is therefore possible to evaluate the stability of the calibration for various time intervals by combining different pairs of sessions in each subject, depending on the time elapsed between them. All thus-assessed cuff-PPG differences of all subjects were grouped according to their respective time intervals, and the accuracy (bias) and precision (standard deviation (SD)) were assessed for each time interval group for both systolic (SBP) and diastolic BP (DBP).

While evaluating post-calibration stability, it is essential to also verify sensitivity to actual BP changes. We thus pooled all exercise-induced BP changes of all subjects and evaluated their agreement (bias ± SD) against their corresponding cuff-based changes. The concordance rate (CR) on large changes (>15/10 mmHg on SBP/DBP, respectively) was also assessed.

Figure 1 show the post-calibration bias and SD of CSEM's BP. Both SBP and DBP remain within the ISO 81060-2 limits (bias within ±5 mmHg, SD ≤ 8 mmHg) at all times, for both fingertip and upper arm PPG. No significant correlation (at the 5% level) with time was found, suggesting no deterioration of the stability over time. Regarding BP changes, all agreements were within ISO 81060-2 limits as well, and CR = 100% in all cases.

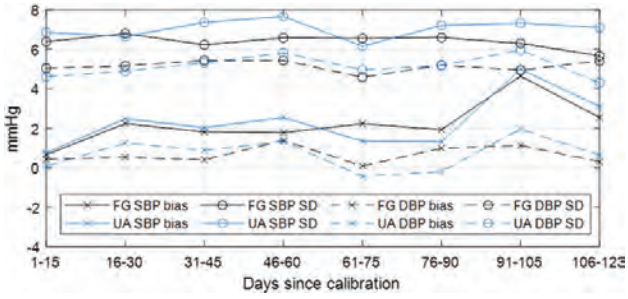

Figure 1: Accuracy (bias) and precision (SD) of CSEM's cuffless systolic (SBP) and diastolic BP (DBP) as a function of the time elapsed since calibration using fingertip (FG) or upper arm (UA) PPG data.

This study demonstrates that CSEM's cuffless BP algorithm is stable for four months after calibration. Clinical studies for further evaluating its long-term stability and trending ability in hypertensive patients are currently ongoing.

[1] M. Proença, *et al*., WO 2016138965 A1, 9th of September 2016

[2] Y. Ghamri, *et al*., Anesth Analg, 130(5):1222-1233, 2020

[3] M. Proença, *et al*., Sci Rep, 13:6149, 2023