Validation of a novel cuffless photoplethysmography-based wristband for measuring blood pressure according to the regulatory standard

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Background: Blood pressure is a key parameter in acute and chronic cardiovascular diseases (CVD) [1]. However, obtaining reliable and reproducible cuff blood pressure (BP) measurements is challenging. We demonstrate that a wristband-based PPG measurement in combination with a custom developed BP algorithm represents a possible alternative to cuff BP measurements.

Purpose: This study aimed to validate a novel cuffless photoplethysmography (PPG)-based non-invasive wristband for continuous BP monitoring in accordance with ISO 81060-2:2019.

Methods: The study compared PPG-guided BP algorithm predictions with subclavian arterial reference measurements taken during cardiac catheterization. Eligible patients were consecutively included, and eligibility was screened following ISO 81060-2:2019 requirements. Reference measurements were performed using a validated invasive BP monitoring device with a sampling rate of 100Hz. PPG signals were collected using six light emission diodes and two photodiodes at a sampling rate of 128Hz. Three sequential initialization measurements were taken using a validated blood pressure cuff before the cardiac catheterization exam. These measurements, along with approximately 100 additional features (PPG-derived and based on patient demographics), were used as input for the machine learning-based BP algorithm. Correlation, mean error, and standard deviation (SD) were determined for systolic and diastolic BP measurements between the BP algorithm predictions and invasive reference measurements.

Results: The study included 97 patients from whom 420 individual 30-second samples were obtained. The mean age, weight, and height of the analysed subjects were 67.1 (SD 11.1), 83.4 (SD 16.1), and 174.1 (SD 10.0), respectively. In 48 samples (11%), systolic BP was $\leq$100mmHg, while in 106 samples (25%), systolic BP was $\geq$160mmHg. Diastolic BP was $\leq$70 mmHg in 222 samples (53%) and $\geq$85 mmHg in 99 samples (24%). The BP algorithm predictions showed a high correlation with invasive reference measurements for systolic ($r = 0.985$) and diastolic ($r = 0.961$) BP measurements. The mean error of the BP algorithm predictions compared to the invasive reference measurements was $\pm$3.7 mmHg (SD 4.4 mmHg) and $\pm$2.5 mmHg (SD 3.7 mmHg) for systolic and diastolic BP, respectively. Results were similar within each gender and skin colour category (Fitzpatrick I-VI).

Conclusion: This study demonstrates that a wristband-based PPG measurement in combination with the developed BP algorithm can provide accurate continuous BP measurements across a wide range of BP distributions. Therefore, wristband BP monitoring may serve as a valid and less burdensome alternative to cuff BP measurements for both in-hospital and at-home BP monitoring. However, further research is necessary to evaluate the precision of the BP algorithm during movement and the stability of the predictions over time.
Systolic BP

**Correlation**

Correlation between PPG-wristband and reference for all subjects ($r = 0.985$, $n = 4/20$)

**Bland Altman**

Bland Altman analysis of PPG-wristband vs. reference for all subjects

Mean bias: 0.17 mmHg Systolic Blood pressure, LoA = [1.74, 8.4] mmHg Systolic Blood pressure

Diastolic BP

**Correlation**

Correlation between PPG-wristband and reference for all subjects ($r = 0.961$, $n = 42/20$)

**Bland Altman**

Bland Altman analysis of PPG-wristband vs. reference for all subjects

Mean bias: 0.2 mmHg Diastolic Blood pressure, LoA = [4.96, 7.37] mmHg Diastolic Blood pressure

figure of BP