REFLECTION-MODE PHOTOPLETHYSMOGRAPHY FINGER SENSORS ENABLE ACCURATE TRACKING OF BLOOD PRESSURE TRENDS IN SMARTPHONES WITHOUT REQUIRING A USER CALIBRATION

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BACKGROUND

Daily self-monitoring of blood pressure (BP) is widely recognized as a cost-effective method to identify and manage hypertension in conjunction with physician-prescribed interventions. However, few American households own a BP monitor and even less comply with daily monitoring, in part due to annoyances associated with porting and properly donning a BP cuff. The purpose of this study was to demonstrate the accuracy of a cuff-less BP monitoring technology, based upon photoplethysmography (PPG), embedded within a finger sensor that can be integrated within a smartphone, smartwatch, kiosk, and finger-clip.

METHODS

A training dataset was collected from BP measurements on 4072 participants in 3 sequential readings: a manual auscultatory reading, an automated oscillometric cuff reading, and at least one PPG reading from a commercial PPG sensor configured to monitor reflection-mode PPG from the finger (Figs 1 & 2). With the manual readings serving as "ground truth", a machine learning model for finger-PPG BP (FPBP) was trained to predict both systolic and diastolic BP based solely on finger-PPG sensor data. An unbiased accuracy assessment of the trained FPBP model was generated by statistical analysis of the model's BP predictions for a test dataset (Fig. 3) of 82 participants, collected via the ISO 81060-2:2018 standard. This test dataset comprised data from participants who were not used in training the FPBP model, providing a true unbiased assessment.

RESULTS

When compared with the manual auscultatory blood pressure readings, the accuracy of the FPBP model was found to be within 0 ± 7.9 mmHg and 0.4 ± 7.4 mmHg for systolic blood pressure (SBP) and diastolic blood pressure (DBP) respectively. Similarly, the accuracy of the oscillometric cuff (auto-cuff) was found to be within -1.9 ± 8.0 mmHg and 2.3 ± 6.5 mmHg for SBP and DBP, respectively.

CONCLUSION

Although the FPBP solution demonstrated slightly less precision than that of an oscillometric cuff for DBP, the accuracy for both SBP and DBP was found to be sufficiently cuff-like and suitable for accurately predicting longitudinal BP trends and for assessing hypertension status (Fig. 4).

A smart, calibration-free PPG-based finger sensor **can accurately monitor BP** in smartphones, smartwatches, kiosks, and finger-clips **without the need for a cuff**

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DISCUSSION

The ultimate purpose of this R&D program was to develop and validate the world's first commercially viable cuff-less, calibration-free, all-PPG BP monitoring solution that could ultimately: 1) provide demonstrable public health value, 2) provide cuff-like accuracy in a general population, and 3) be integrated within existing popular consumer form-factors. Both objectives were achieved. Moreover, it was found that the FPBP solution was able to categorize hypertension status with cuff-like accuracy (Fig. 4).

FIG 1 - METHODS

1) Massive data collection
Thousands of training datasets collected in the US, China, Vietnam, & the Philippines

2) BP model development
PPG-based model development utilizing machine learning tools

3) Proving generalization
Model applied to a test dataset collected via ISO 81060-2:2018 protocol

4) Embedded solution
Software integrated within Valencell's PerformTek® biometric operating system

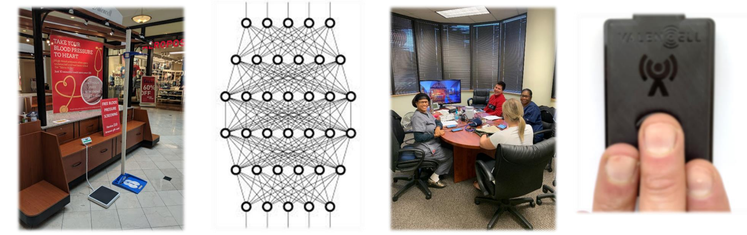


Fig. 1: Valencell developed and validated a novel machine learning model, based on PPG datasets collected from thousands of unique participants, to estimate BP via finger PPG.

FIG 2 – TRAINING DATASET

# of Unique Tests:	7,889	
# or Unique Participants:	4,072	
Gender:	Count	Percentage
Female	2,284	56%
Male	1,795	44%
Smoker:	Count	Percentage
No	3,729	91%
Yes	350	9%
BP Medication(s):	Count	Percentage
No	3,042	75%
Yes	1,037	25%

	Mean ± SD	**Range**	**Units**
Age	45 ± 19	18 - 100	Years
BMI	27 ± 6	10 - 60	N/A
Systolic BP	123 ± 20	80 - 220	mmHg
Diastolic BP	75 ± 12	32 - 134	mmHg

FIG 3 – TEST DATASET

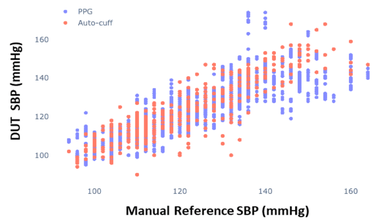
Total # of Measures	347
Total # of Participants	82
Percent on BP Medication	27%
Percent Male/Female	45% / 55%
Number of SBP ≤ 100	21
Number of SBP ≥ 160	5
Number of SBP ≥ 140	53
Number of DBP ≤ 60	38
Number of DBP ≥ 100	12
Number of DBP ≥ 85	74

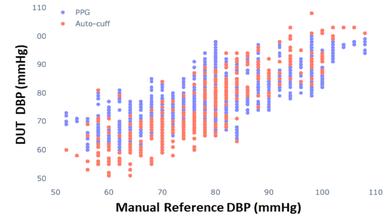
FIG 4 – HYPERTENSION STATUS

	Finger PPG	**Auto-cuff**
Accuracy (SBP ≥ 130 mmHg)	90%	89%
Precision (SBP ≥ 130 mmHg)	90%	89%
Sensitivity (SBP ≥ 130 mmHg)	90%	88%
SBP Error ≤ 10 mmHg	83%	76%
DBP Error ≤ 10 mmHg	82%	83%

Fig. 4: The FPBP solution can accurately assess hypertension status (SBP ≥ 130 mmHg).

FIG 5 – RESULTS





Finger PPG Error	0.0 ± 7.9 mmHg
Auto Cuff Error	-1.9 ± 8.0 mmHg

***Note**: In the ISO testing protocol, manual auscultatory readings are considered to be "ground truth"

Finger PPG Error	0.4 ± 7.4 mmHg
Auto Cuff Error	2.3 ± 6.5 mmHg

DISCLOSURE INFORMATION

*All authors are employed by Valencell, Inc.: valencell.com/patents