



Cuff-less, AI-PPG
Blood Pressure Monitoring
Technology from Valencell

January 2020



Hypertension management is a significant public health issue

CDC: Hypertension was a primary or contributing cause of death for > 410,000 Americans in 2014 [1]

CDC: 1/3rd of American adults have hypertension, and only 1/2 know they have the disease [1]

WHO: Over 1B people globally have “uncontrolled hypertension”. The “silent killer” is estimated to cause ~7.5M deaths/year worldwide (roughly 12.8% of all deaths) [2]

HHS: Combining prevention with regular BP monitoring can improve health and reduce risk of heart attack or stroke [3]

Few households own a BP monitor and comply with regular monitoring due to difficulties with properly using a BP cuff [4-8]

[1] CDC: <https://www.cdc.gov/bloodpressure/index.htm>

[2] WHO: https://www.who.int/gho/ncd/risk_factors/blood_pressure_prevalence_text/en/

[3] Your Guide to Lowering Blood Pressure. U.S. Department of Health & Human Services, NIH Publication No. 03-5232 May 2003. https://www.nhlbi.nih.gov/files/docs/public/heart/hbp_low.pdf

[4] Tolonen H, Koponen P, Naka A, et al. Challenges in standardization of blood pressure measurement at the population level. BMC Med Res Methodol. 2015; 15:33.

[5] Wagner S, Toftegaard TS, Bertelsen OW. Challenges in Blood Pressure Self-Measurement. Int J Telemed Appl. 2012; 2012: 437350.

[6] de Greeff A, Lorde I, Wilton A, et al. Calibration accuracy of hospital-based non-invasive blood pressure measuring devices. Journal of Human Hypertension volume. 2010; 24: 58–63.

[7] Home Blood Pressure Monitors Inaccurate? Up to a Third May Give Imprecise Blood Pressure. <https://www.webmd.com/hypertension-high-blood-pressure/news/20030516/home-blood-pressure-monitors-inaccurate#1>

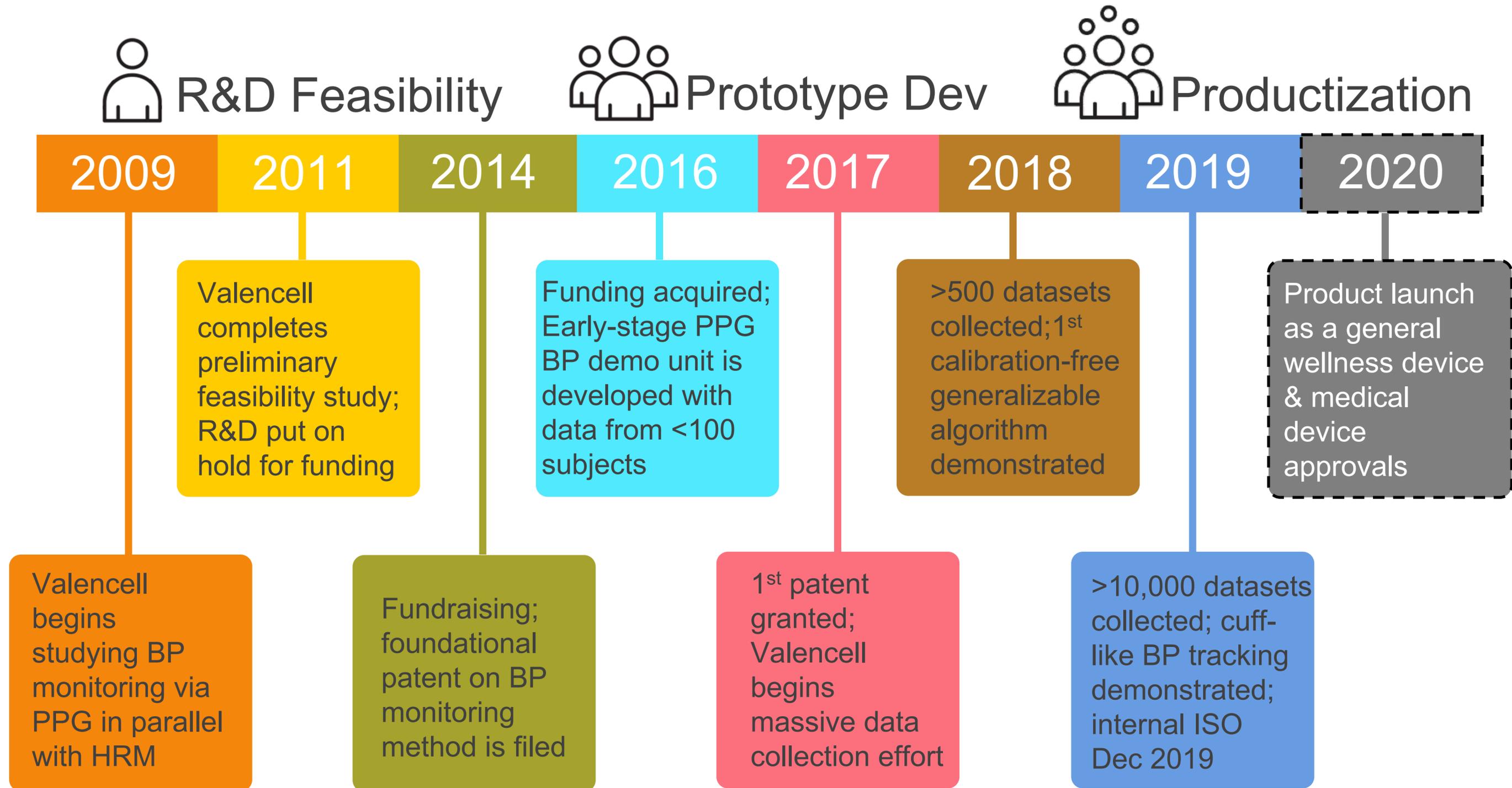
[8] How can I get my OMRON blood pressure monitor re-calibrated? <https://www.omron-healthcare.com/eu/category/blood-pressure-monitors>

[9] Chung E, Chen G, et al. Front Med. 2013 Mar;7(1):91-101. doi: 10.1007/s11684-013-0239-5..

Valencell cuff-less BP monitoring technology summary

- Valencell has developed a calibration-free, reflection-mode PPG-based cuff-less blood pressure monitoring technology for use at the ear (primarily for use in earbuds and hearing aids); no such solution has ever existed in the marketplace
- The combined HW/SW solution combines the new BE5.0 sensor module with advanced embedded Valencell software operating on a low-power microprocessor
- The solution does NOT require calibration of any kind; only 3 input parameters are required: a PPG signal, a motion signal, and static biometrics (height, weight, age, and gender)
- The technology enables in-session BP measurements with the subject at rest (as with a BP cuff), with cuff-like performance
- Valencell's solution has been developed using raw PPG and BP data from >15,000 datasets of ~5000 subjects in a free-living environment; approximately 25% of subjects were on BP medications, enabling a diverse monitoring solution
- The solution has been validated in a qualified test dataset of >600 measures from >130 subjects, collected via 3 trained nurses not employed by Valencell, using the ISO 81060-2:2018 protocol
- This qualified test dataset is a true “test dataset” – it was never used to train Valencell's BP model, providing an unbiased validation
- The final report has shown that Valencell's BP solution can meet the ISO standard for accuracy: 5 ± 8 mmHg with respect to the manual cuff readings
- The technology is now integrated into an evaluation kit for prospects to evaluate independently

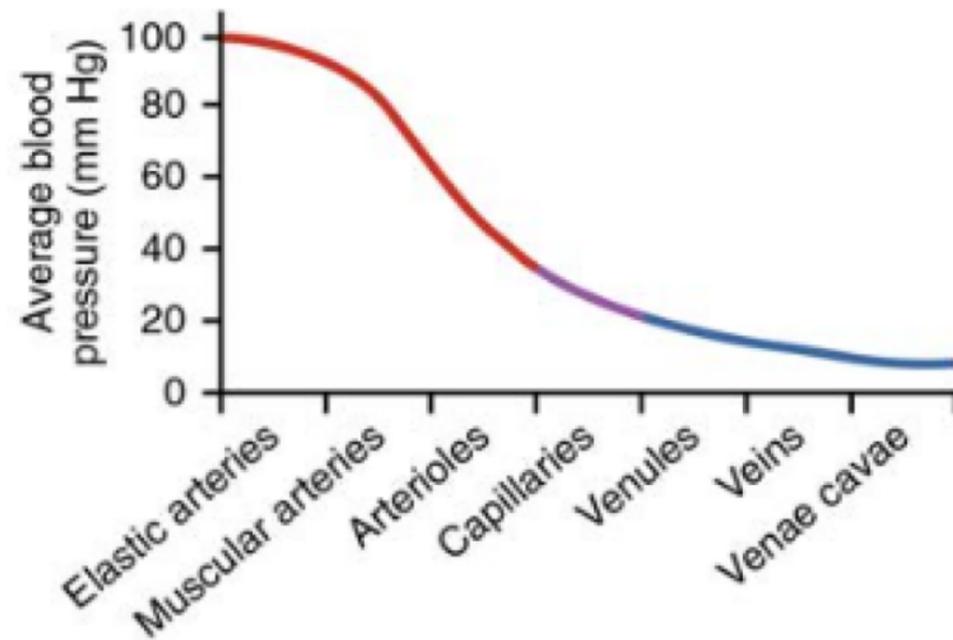
History of Valencell BP development



The ear is one of the best locations on the body for accurately measuring blood pressure via PPG

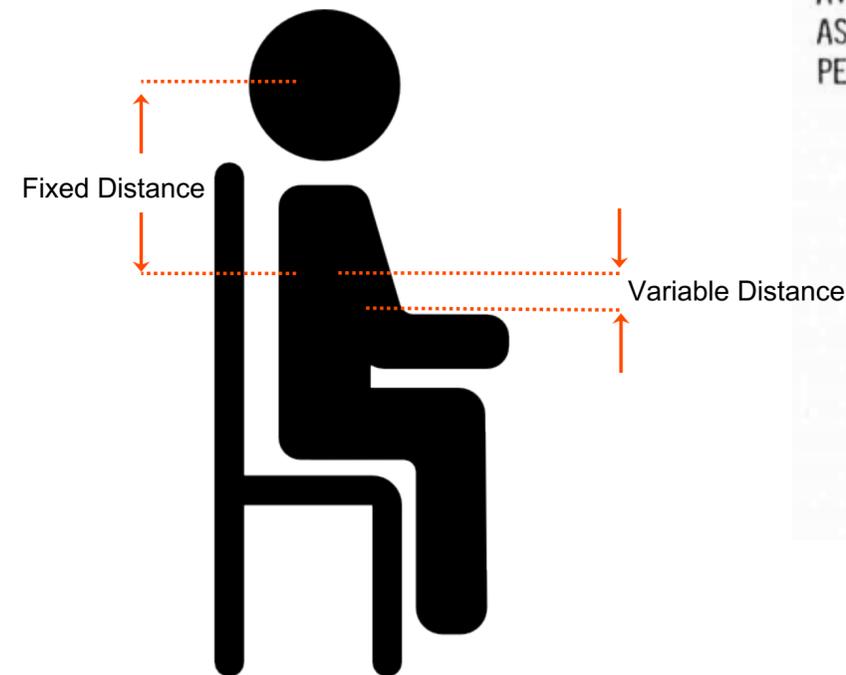
1) Optimal vascular structure

The ear region comprises a high density of arterioles, which have the highest blood pressure content when compared with capillaries, venules, and veins [1]



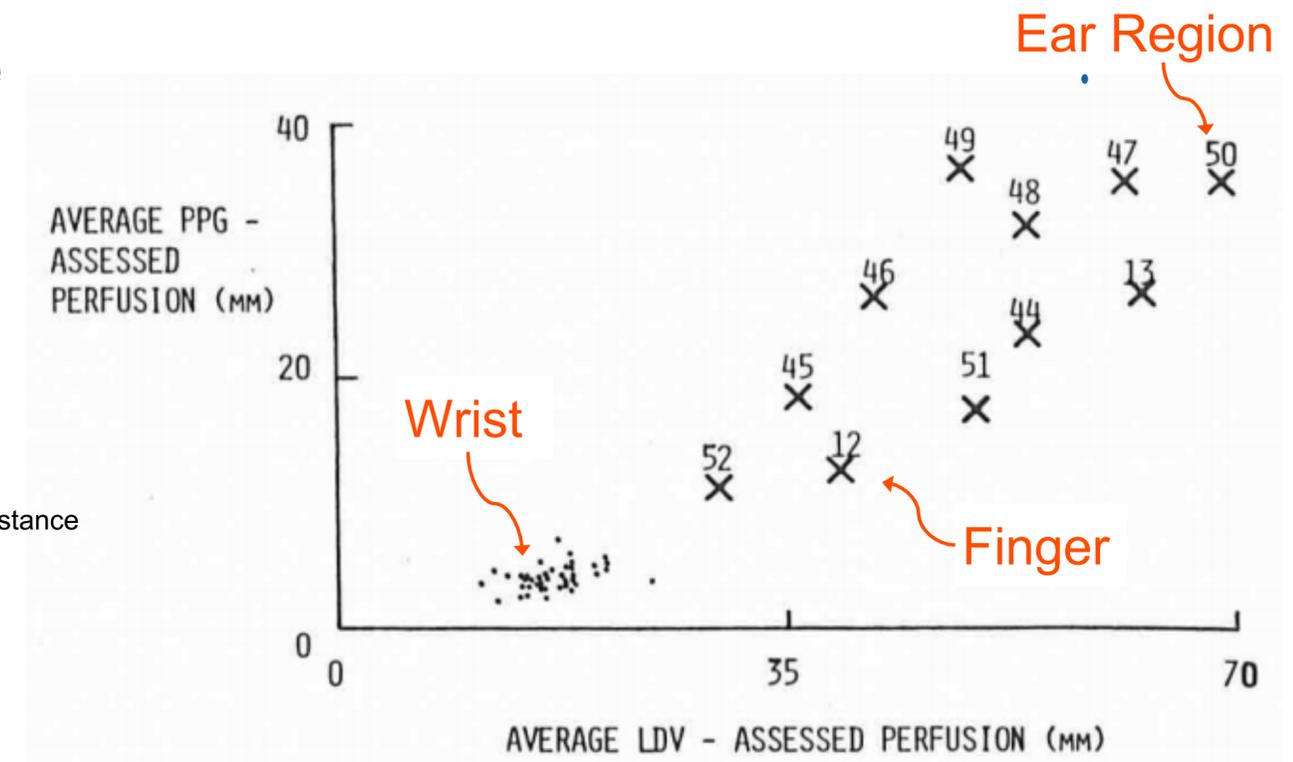
2) Fixed distance from heart

Having a fixed distance from the heart, the ear location is free of the arm positioning errors inherent to brachial cuffs [2]



3) Highest blood perfusion

The ear region has the highest blood perfusion when compared with the wrists and other distal body locations [3]



[1] <https://courses.lumenlearning.com/ap2/>

[2] 9. Netea RT, Lenders JW, Smits P, Thien T. Arm position is important for blood pressure measurement. *J Hum Hypertens*. 1999;13(2):105-109.

[3] Tur et al, *Basal Perfusion of the Cutaneous Microcirculation: Measurements as a Function of Anatomical Position*, *The Journal of Investigate Dermatology*, 81:442-466, 1983.

Valencell's approach comprises machine learning applied to >15,000 of datasets from ~5000 subjects

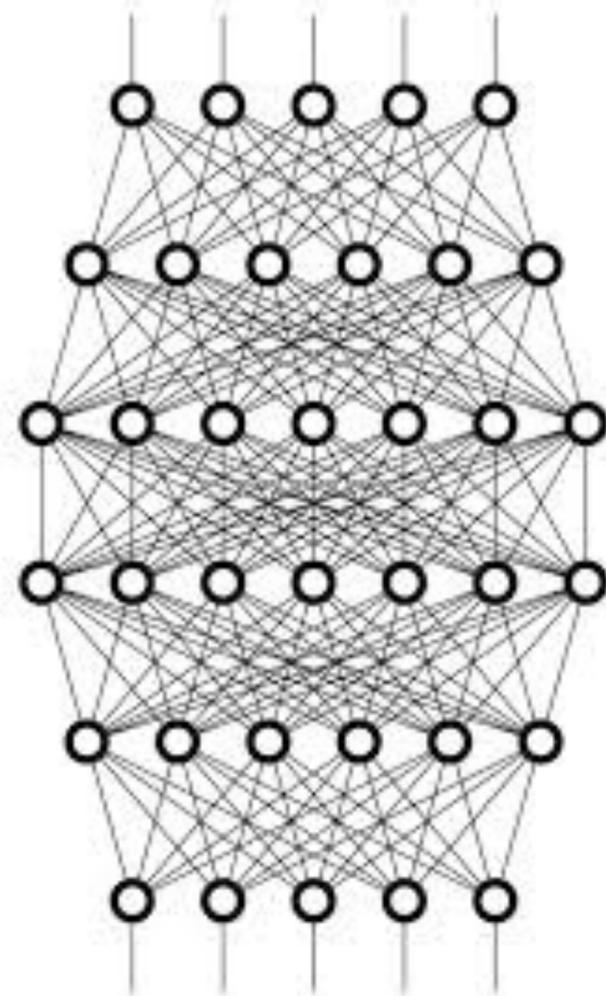
1) Massive data collection

Thousands of training datasets collected in the US, Vietnam, & 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 protocol



4) Embedded solution

Integrating model into Valencell's PerformTek® biometric operating system



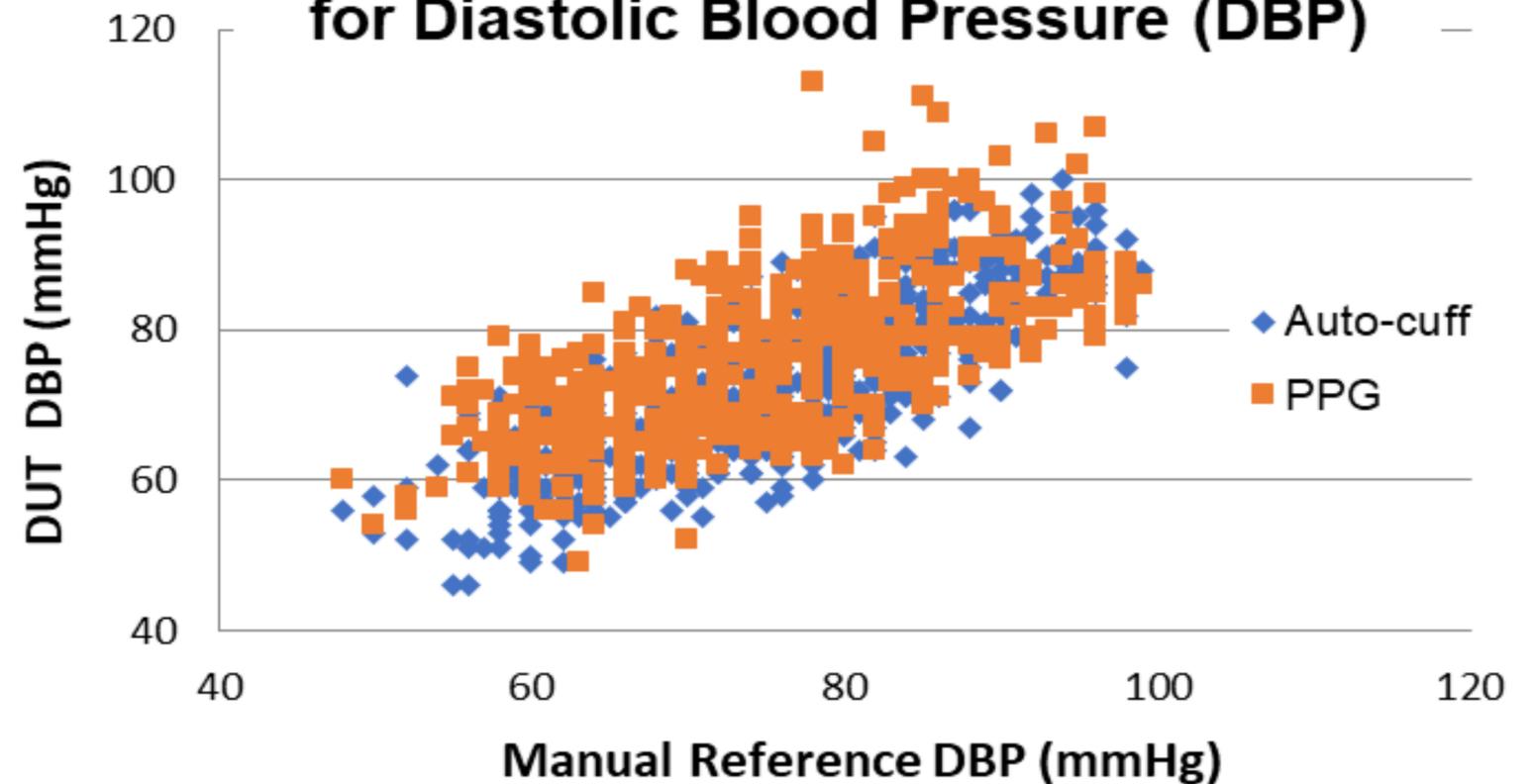
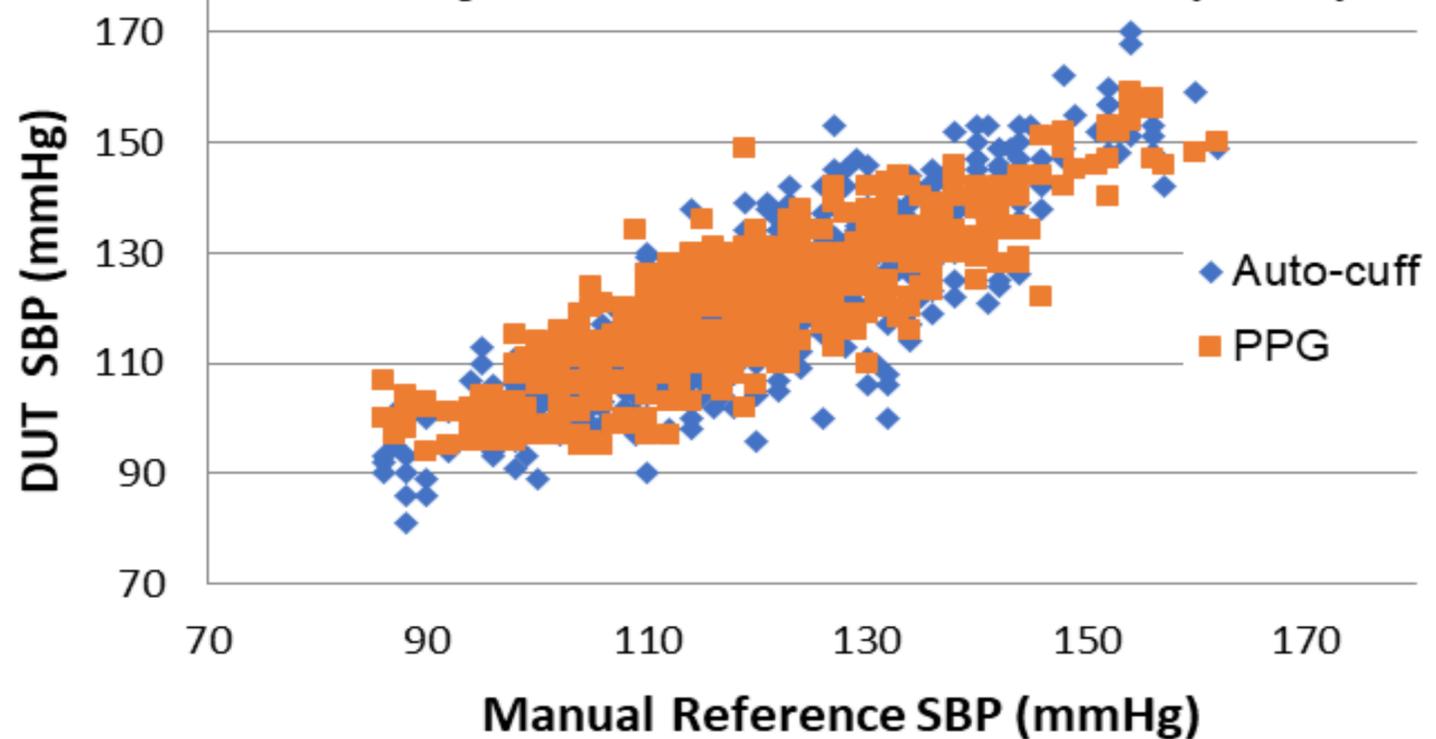
Valencell's BP monitoring technology shows cuff-like accuracy in a test dataset that was never used to build the BP algorithm (654 measurements from 147 subjects)

Systolic

Diastolic

Auto-cuff & PPG vs. Manual Reference for Systolic Blood Pressure (SBP)

Auto-cuff & PPG vs. Manual Reference for Diastolic Blood Pressure (DBP)



| | |
|-----------------|--------------------|
| Ear PPG Error | 1.7 ± 7.7 mmHg |
| Auto Cuff Error | 0.9 ± 8.0 mmHg |

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

| | |
|-----------------|---------------------|
| Ear PPG Error | -1.1 ± 8.0 mmHg |
| Auto Cuff Error | -2.3 ± 6.8 mmHg |

Valencell's ear PPG solution can categorize hypertension equivalently to an automated BP cuff

| | PPG | Auto-cuff |
|--------------------|------------|------------------|
| Accuracy | 89% | 88% |
| Precision | 73% | 69% |
| Sensitivity | 77% | 75% |
| Specificity | 93% | 92% |

All SBP measurements ≥ 130 mmHg were classified as hypertensive

Accuracy – The ability to differentiate hypertension and non-hypertension correctly

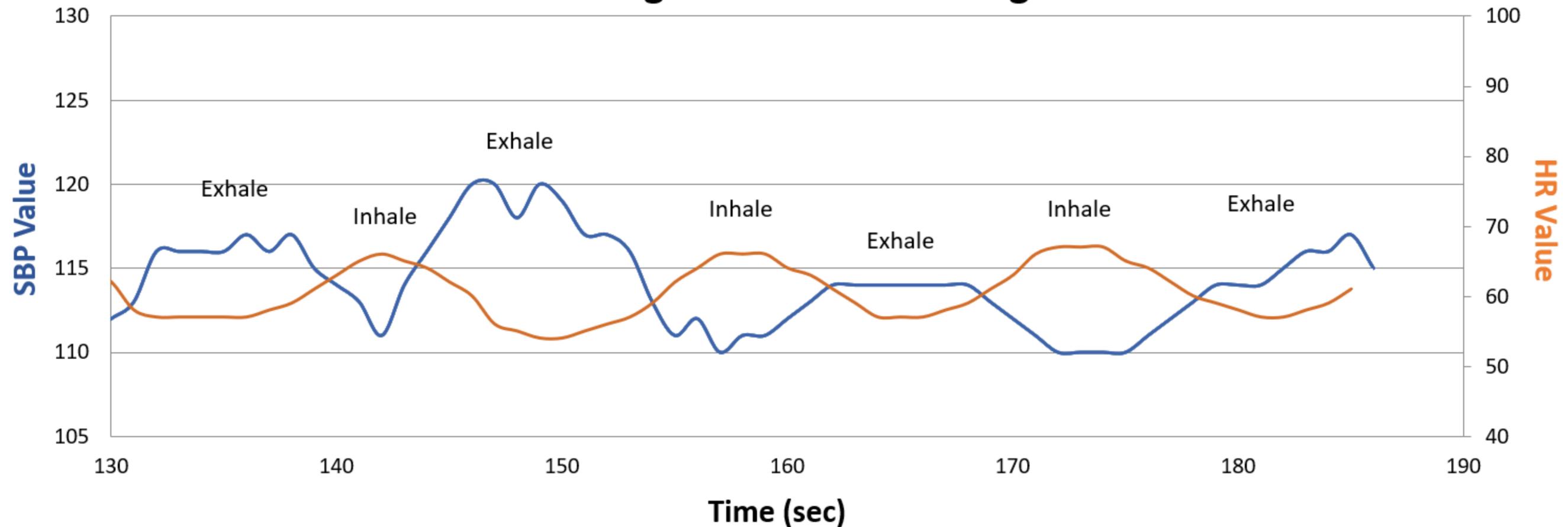
Precision – Confidence that hypertension was determined correctly

Sensitivity – The ability to determine the hypertension cases correctly

Specificity – The ability to determine the non-hypertension cases correctly

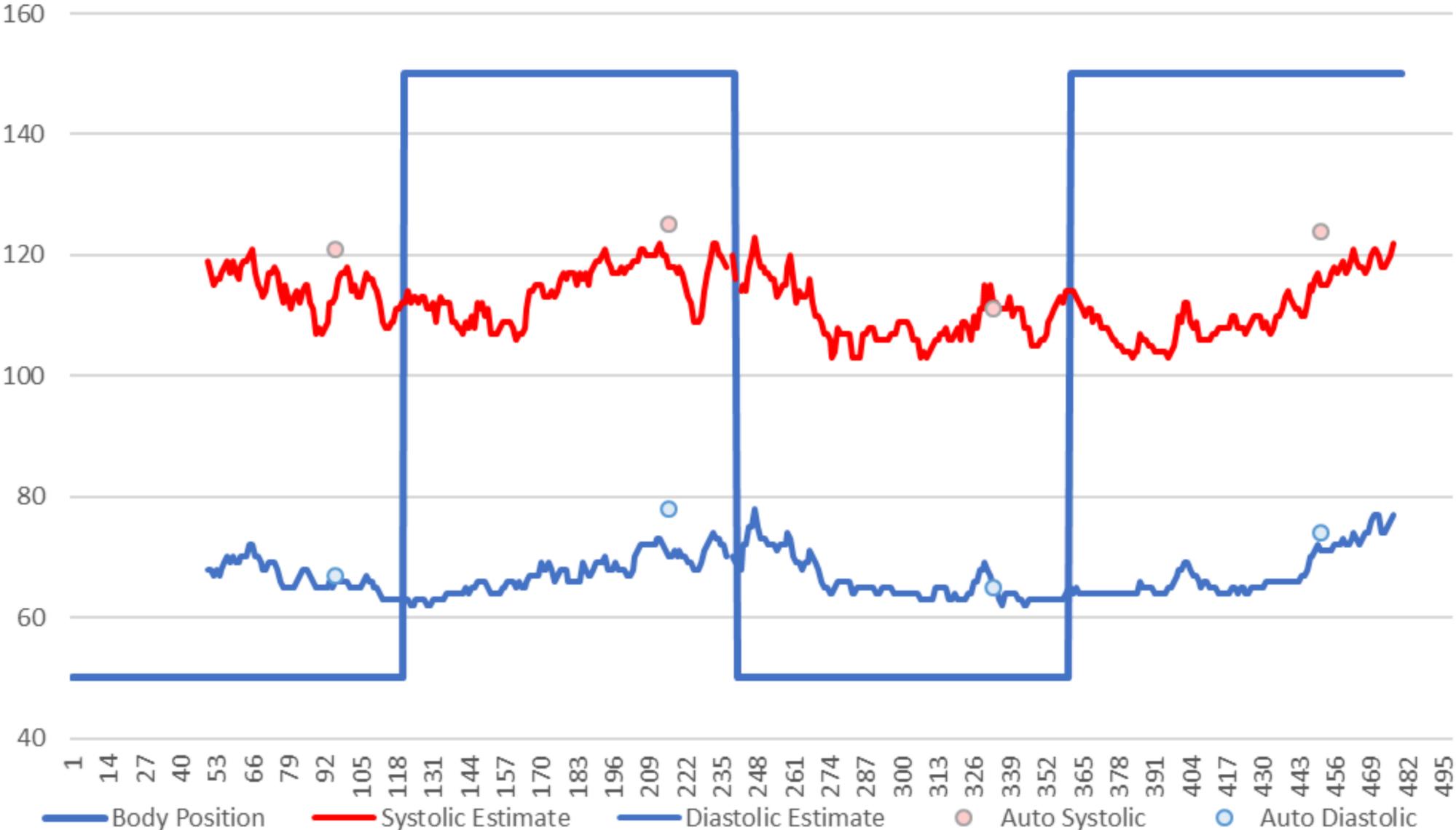
Feasibility has been demonstrated for “continuous” BP monitoring

Systolic BP & HR measured by Valencell BP Eval Kit during controlled breathing



Data collected from controlled breathing studies shows the expected 180° out-of-phase relationship between systolic blood pressure and heart rate, with a resolution better than 5 mmHg

Feasibility has been demonstrated for “continuous” tracking via stress-induced BP modulation



Preliminary testing of isostatic exercise protocols, designed to raise and lower BP by 20 mmHg, has shown that Valencell’s BP monitoring solution is capable of continuous tracking

Cuff-less Blood Pressure Evaluation Kit

Valencell's Evaluation Kit for the cuff-less, calibration-free blood pressure technology includes the following:

Hardware

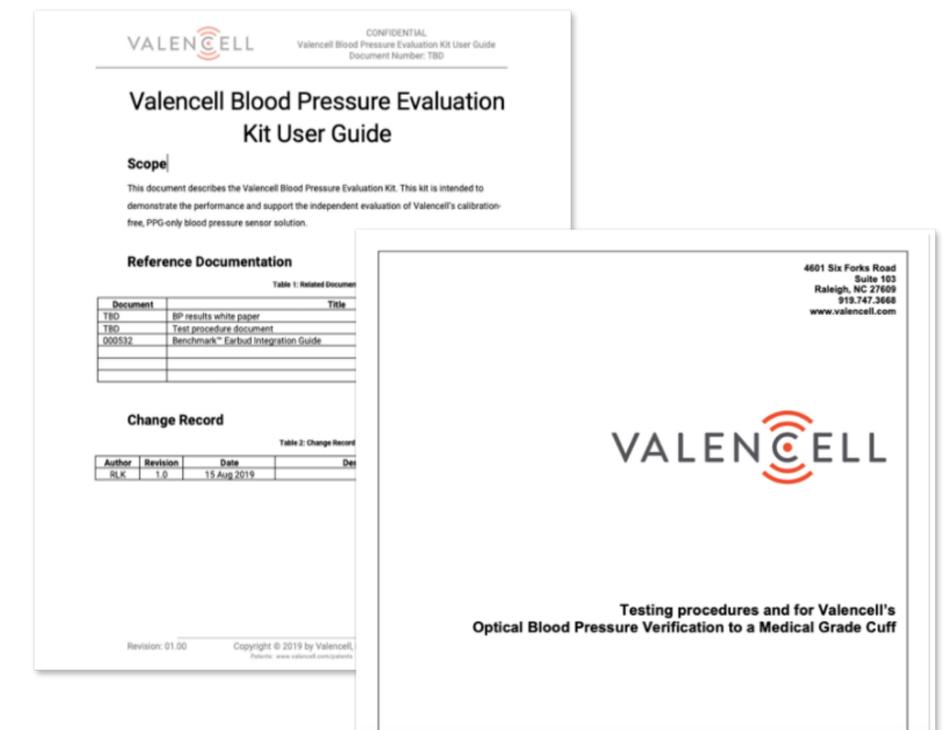
- Wired earbud with embedded PPG-sensor
- USB development board
- Low-power MCU board
- PC or Mac (provided by evaluating team)

Software

- Blood pressure firmware embedded in MCU board
- All of Valencell's biometrics are delivered on the same MCU
- Mobile data collection app

Documentation

- Quick start guide
- Demonstration videos - hardware & software set-up and use; data collection videos
- Test procedures and validation white papers



Summary

- Valencell's calibration-free PPG BP monitoring solution demonstrates cuff-like performance without the cuff
- Following the data collection guidelines of the ISO 81060-2:2018 protocol, the ear PPG BP solution demonstrated an accuracy within the required error limit of 5 ± 8 mmHg
- The current solution is ready for commercialization in the consumer market as a general wellness product, and regulatory efforts are underway to enable medical-grade solutions
- Though not designed for continuous monitoring, successful continuous monitoring has been demonstrated
- BE5.0 Eval Kits with BP capability will be available for customer evaluation on Feb 2nd, 2020



Thank You!

www.valencell.com
info@valencell.com
+1-919-747-3668