

Blood pressure from the optical Aktiia Bracelet: a 1-month validation study using an extended ISO81060-2 protocol adapted for a cuffless wrist device

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Objective The objective of this study (NCT04027777) was to assess the accuracy and precision of the Aktiia Bracelet, a CE-marked noninvasive optical blood pressure (BP) monitor worn at the wrist, over a period of 1 month.

Methods In this study, participants aged between 21 and 65 years were recruited. The clinical investigation extended the ISO81060-2:2013 standard to the specificities of cuffless devices. Each BP assessment consisted of the simultaneous recording of optical signals with Aktiia Bracelet and double-blinded auscultation by two trained observers in the standard sitting position. The algorithms of Aktiia Bracelet further processed the recorded optical signals to perform a signal quality check and to calculate uncalibrated estimates of systolic BP (SBP) and diastolic BP (DBP). These estimates were transformed into mmHg using a subject-dependent calibration parameter, which was calculated using the first two available reference measurements per subject.

Results Eighty-six participants were included in the analysis. The mean and SD of the differences between Aktiia Bracelet estimates and the reference (ISO81060-2 criterion 1) were 0.46 ± 7.75 mmHg for SBP and

0.39 ± 6.86 mmHg for DBP. The SD of the averaged paired difference per subject (ISO81060-2 criterion 2) were 3.9 mmHg for SBP and 3.6 mmHg for DBP.

Conclusion After initialization and during 1 month, the overall accuracy of Aktiia Bracelet satisfied validation criteria 1 and 2 of ISO81060-2 in the sitting position. The Aktiia Bracelet can be recommended for BP measurement in the adult population. *Blood Press Monit* 26: 305–311 Copyright © 2021 The Author(s). Published by Wolters Kluwer Health, Inc.

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Introduction

Blood pressure (BP) measurement is essential in the diagnosis and management of hypertension. As such, validation of BP measurement devices is of paramount importance in order to ensure accurate measurements [1]. To date, unvalidated devices dominate the online market, raising questions about adequate hypertension and cardiovascular management worldwide [2]. This lack of validation is specifically true for wrist-band wearables for which no specific recognized validation protocol exists so far. Nevertheless, cuffless measurement solutions have emerged recently with the associate hope of better hypertension management through BP telemonitoring [3]. These devices may increase convenience and patient empowerment in their disease management [4].

Aktiia SA has developed a noninvasive cuffless BP monitor (Fig. 1) that is intended to measure optical photo-plethysmographic (PPG) signals on the wrist and to calculate systolic BP (SBP) and diastolic BP (DBP) values using pulse wave analysis technique. The Aktiia Bracelet requires an initialization procedure to be performed once per month. So far, the accuracy and the precision of the algorithm of Aktiia Bracelet has already been tested against reference invasive BP measurement in a clinical study conducted in the intensive care setting, and the stability of the initialization procedure has been assessed over several weeks in a pilot study in the ambulatory setting [5,6]. However, a pivotal study combining both precision, accuracy and stability has not been published yet. The objective of the study (NCT04027777) was to assess the accuracy and precision of the Aktiia Bracelet in an outpatient setting against double-blinded auscultation over 1 month. As no recognized validation standard that fully covers clinical investigations for cuffless devices exists so far [7], we designed a protocol that was based on the procedures and data analysis of the ISO81060-2:2013

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Fig. 1



Aktiia Bracelet and the associated smartphone application to visualize SBP and DBP.

[8] protocol to which we added additional aspects to address device-specific challenges. Indeed, we retained the measurement conditions and the nature of the reference measurements, the number of patients, the total number of measurements, the study population stratification, the data analysis and the pass/fail criteria of ISO81060-2:2013, on top of which we added multiple assessments over a period of 1 month to address the

calibration stability. In addition, we added extra inclusion criteria to ensure that the participants' phenotypes covered the entire spectrum of both skin pigmentation (according to Fitzpatrick scale) and wrist hair follicles density (according to Schuckmann scale) of the device intended population (Fig. 2) [9,10,11].

Methods

The study was approved by the local Ethics Committee (<http://www.cer-vd.ch/>) and Swissmedic (Swiss Agency for Therapeutic Products). All study participants signed an informed consent form prior to study procedures. The study was conducted according to the current version of the World Medical Association Declaration of Helsinki, ICH-GCP guidelines and ISO 14155. No adverse event was reported during this clinical investigation.

Study population

The study was conducted in Lausanne University Hospital (CHUV) in Lausanne, Switzerland. Participants from the Lausanne University Hospital, the University of Lausanne, and patients from the outpatient clinic of hypertension were recruited in this clinical investigation. A representative cohort of male and female patients ($N = 86$) aged between 21 and 65 years old and presenting different skin pigmentation and different hair follicle densities were included in the analysis (Table 1). The cohort covered all BP categories ranging from hypotensive to hypertensive. The participants with the following conditions were excluded: diabetes, tachycardia, atrial fibrillation, renal dysfunction, hyper- or hypothyroidism, upper arm arteriovenous fistula, upper arm amputation, arm and wrist circumferences larger than 64 and 22 cm, respectively, interarm SBP and DBP higher than 15 and 10 mmHg, respectively, arm trembling or shivering and arm paralysis.

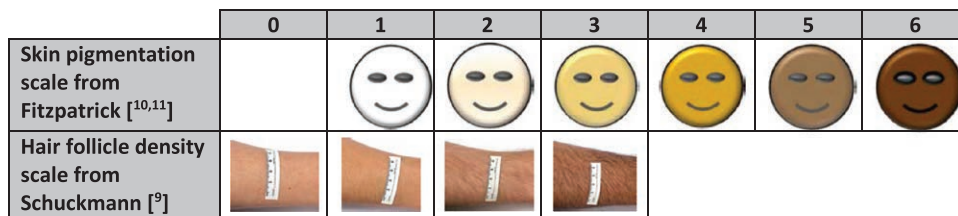
Study protocol

The following experimental set-up only describes the part of the study protocol (NCT04027777) in which participants were studied in the sitting and relaxed position. The complete study (NCT04027777) also includes BP measurements in other body positions and hemodynamic conditions.

Experimental set-up

The study consisted of an initial visit on day 1, followed by three successive visits on days 9 ± 3 , 18 ± 3 and 29 ± 3 . These three additional visits, compared to the ISO81060-2:2013 standard, were added to evaluate the performances and claims of stability of the device (i.e. Aktiia Bracelet shall be initialized at least every 4 weeks). At each visit, the participants were equipped with Aktiia Bracelet on the right wrist, which was placed at the level of the heart to remove any confounding effect related to hydrostatic pressure differences. A cuff of appropriate size was positioned on participant's left upper arm at

Fig. 2



Skin pigmentation scale and hair follicle density scale used during the clinical investigation to cover the phenotypes of the device intended population.

Table 1 Demographic and clinical characteristics of the 86 patients included in the analysis for the sitting position

	Distribution and categories	Comment
Age	38 ± 13 years (range 21–63 years)	Represents device intended population
Sex	Women: 43 Men: 43	Fulfill requirements of ISO81060-2:2013
BMI	24.0 ± 4.7 kg/m ² (range 18–41 kg/m ²)	–
Arm circumference	28.1 ± 3.8 cm (range 22–44 cm)	Represents device intended population
SBP category	122 ± 20 mmHg (range 89–180 mmHg) Categories according to ISO81060-2:2013: ≤100 mm Hg (target 5%): 14% (N = 12) ≥140 mm Hg (target 20%): 14% (N = 12) ≥160 mm Hg (target 5%): 11% (N = 9)	Fulfill requirements of ISO81060-2:2013, except for category ≥140 mm Hg.
DBP category	75 ± 14 mmHg (range 46–107) Categories according to ISO81060-2:2013: ≤60 mm Hg (target 5%): 14% (N = 12) ≥85 mm Hg (target 20%): 21% (N = 18) ≥100 mm Hg (target 5%): 7% (N = 6)	Fulfill requirements of ISO81060-2:2013
Skin category	Fitzpatrick skin pigmentation scale (Fig. 2): 1–2: 62% (N = 53) 3–4: 20% (N = 17) 5–6: 18% (N = 16)	Represents device intended population
Forearm hair category	Schuckmann hair follicle density scale (Fig. 2): 0–2: 80% (N = 69) 3: 20% (N = 17)	Represents device intended population

heart level. Study participants were comfortably seated with their backs and arms supported, legs uncrossed and feet flat on the floor.

A dual-head stethoscope, allowing simultaneous measurement for two independent blinded observers, and a mercury-free validated hybrid sphygmomanometer (UM-101A, A&D Company, Ltd., Toshima Ku, Tokyo, Japan), calibrated before the study, were used for the auscultatory reference measurement of BP [12,13]. Investigators collecting the signals from the Aktiia Bracelet were blinded to the double-auscultatory

readings of BP and to the outcome of the data quality control system of the device.

Measurement procedures

At each visit, BP assessments were performed after a 5-min rest. Three BP assessments were performed on visit 1, and one BP assessment was performed on visits 2, 3 and 4. The first twenty patients had only two BP assessments performed on visit 1 (instead of three in the amended protocol), and for two patients, five assessments were performed on visit 1 and three assessments were performed on visits 2, 3 and 4. The amendments to the initial protocol were duly notified and approved by the local Ethics Committee and Swissmedic.

A BP assessment consisted of a simultaneous recording of optical signals with Aktiia Bracelet and a BP measurement by double-auscultation. A validated team of two experienced observers independently recorded K1, and K5 Korotkoff sounds for SBP and DBP and wrote down each measurement in a separate sheet. If the difference between two observers was above 4 mmHg, the supervisor considered the measurement as invalid and the procedure was repeated. Throughout the study, 1.9% of the reference measurements were repeated, and for the retained measurements, the mean difference and the SD between the two observers were 1.7 ± 1.5 mmHg for SBP and 1.4 ± 1.7 mmHg for DBP.

For the data synchronization purposes, the optical signals at each assessment were labeled twice by the investigators: once the cuff of the sphygmomanometer was fully inflated (label 1) and after the last audible Korotkoff sound (label 2). The raw optical signal recording was stopped before the next assessment.

Data processing

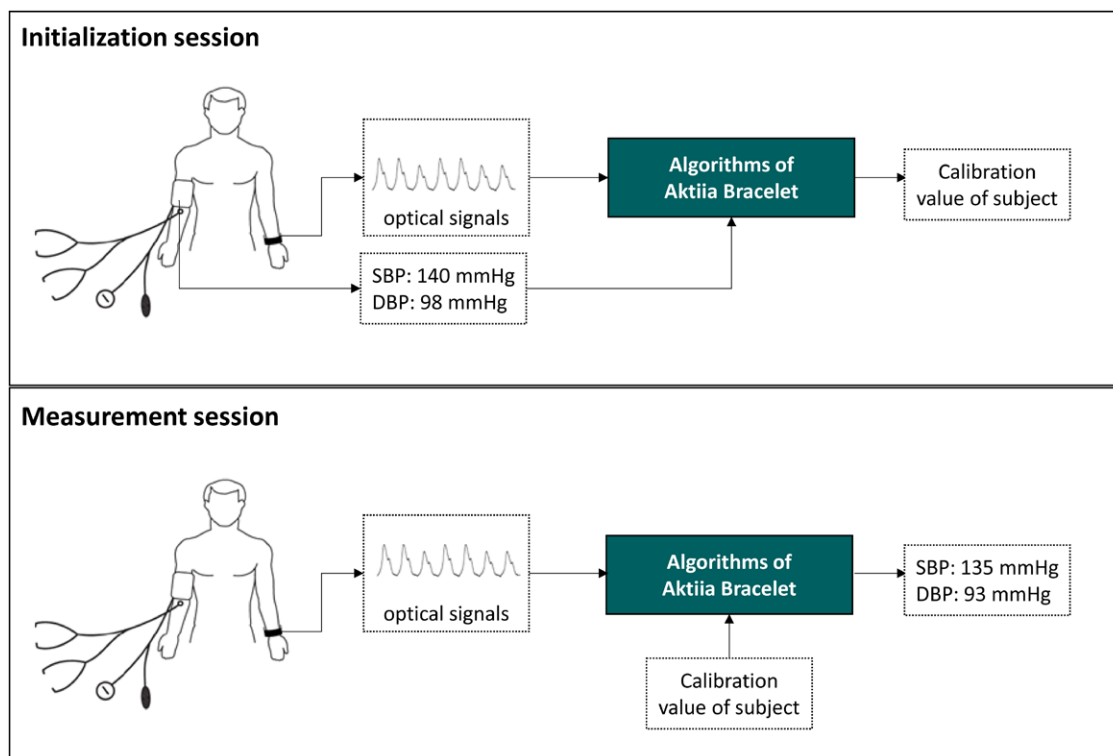
Double-blinded auscultation

The auscultation reference measurements were computed as an average value between two observers.

Uncalibrated blood pressure determinations from the optical signals

Auscultation reference measurements and the optical data recorded with the Aktiia Bracelet were synchronized,

Fig. 3



Aktiia Bracelet requires an initialization procedure to be performed once per month. This procedure allows to calculate a subject-dependent calibration. During a measurement session, SBP and DBP estimates are calculated by the Aktiia algorithms by analyzing the optical signals and applying the subject-dependent calibration.

and a portion of the signal around label 2 was collected. Depending on the nature of the assessment, the optical data window was at a maximum 90 s long, including a maximum 60 s portion before the label and 30 s portion after the label.

These PPG signal windows were retrospectively processed by the optical data quality control system of the pulse wave analysis algorithm, using a sliding window of 30 s with an overlap of 5 s. The data quality control system of Aktiia Bracelet has already been described in a previous publication [5] and is aimed at discarding optical signals that are either corrupted by motion artifacts or do not contain the physiological features required by the pulse wave analysis algorithms to successfully calculate BP estimates. Following that, the 30 s windows identified as reliable by the data quality control system were further analyzed by the algorithm of Aktiia Bracelet. The uncalibrated BP values (in arbitrary units) were computed from the outputs of algorithm on those windows. For some assessments, no reliable optical data windows were found, and these assessments were thus not eligible to be processed by algorithm, and no uncalibrated BP determinations were calculated.

Initialization procedure and calibration

Initialization procedure: for each subject, the first two available assessments of uncalibrated determinations from Aktiia Bracelet, together with their associated reference measurements, were used to initialize Aktiia Bracelet (calculation of a subject-specific offset for SBP and an offset for DBP).

Calibration procedure: for each subject, uncalibrated determinations of BP in arbitrary units were transformed into calibrated determinations in mmHg by applying the SBP and DBP offsets calculated during the initialization procedure.

The schematic representation of the initialization and calibration procedures is shown in Fig. 3.

Statistics

For validation of the ISO 81060-2:2013 criterion 1, the mean error and the SD of the error were computed for SBP and DBP. For validation of criterion 2 of the ISO 81060-2:2013, the SD of the averaged differences per subject were computed for SBP and DBP.

The number of absolute BP differences within 5, 10 and 15 mmHg were also calculated as recommended by the

ESH-IP protocol [14]. Bland–Altman plots assessing the agreement between double-blinded auscultation and Aktiia Bracelet were performed. Statistically significant differences in the performances of the Aktiia Bracelet when compared across subcohorts of patients were assessed by means of *t* tests. Were considered as relevant subcohort of patients differences in skin pigmentation: pale skin (Fitzpatrick 1–3) vs. dark skin (Fitzpatrick 4–5), and differences in hair follicles density: nonhairy wrist (Schuckmann 0–1) vs. hairy wrist (Schuckmann 2–3).

Deviations from ISO81060-2

Some of the methods implemented during the study required deviations or extensions from the procedures described in ISO81060-2:2013. For the sake of clearness, the most relevant deviations and extensions are listed here.

First, none of the clinical investigation methods described in the standard (same arm simultaneous method, same arm sequential method or opposite limb simultaneous method) could be realistically implemented in our experimental protocol because either they required a measurement time that exceeded the duration of the stability

period of some study interventions (not reported in the present analysis) or they required the introduction of lateral differences compensation (not applicable for the device under test). Note that because two initial auscultation reference measurements were used to initialize Aktiia Bracelet, the lateral difference as defined by the standard can be considered as zero. The implemented study procedures were thus inspired by the opposite limb simultaneous method of ISO81060-2:2013, adapting it in a most-realistic manner to fulfill the dynamic experimental constraints of the complete clinical investigation protocol (NCT04027777), which also includes body position other than sitting.

Second, as depicted in Table 1, the requirement of 20% of readings shall have SBP ≥ 140 mmHg was not fulfilled by the study cohort. This deviation results from a multi-factorial recruitment process that was implemented for the study involving, in addition to the inclusion criteria of ISO 81060-2:2013, constraints on skin pigmentation, wrist hair follicle density and age distribution. Yet, the inclusion was performed so that different BP phenotypes could be sufficiently represented in the cohort, leading to 24% of the patients presenting either SBP ≥ 140 mmHg or DBP ≥ 100 mmHg (hypertensive phenotype), and 24% of the patients presenting either SBP ≤ 100 mmHg or DBP ≤ 60 mmHg (hypotensive phenotype).

Table 2 Mean and SD of the differences between reference and the Aktiia Bracelet

	Criterion 1 ^a	Criterion 2 ^b
Systolic blood pressure (mmHg)	0.46 ± 7.75 mmHg	3.9 mmHg
Diastolic blood pressure (mmHg)	0.39 ± 6.86 mmHg	3.6 mmHg

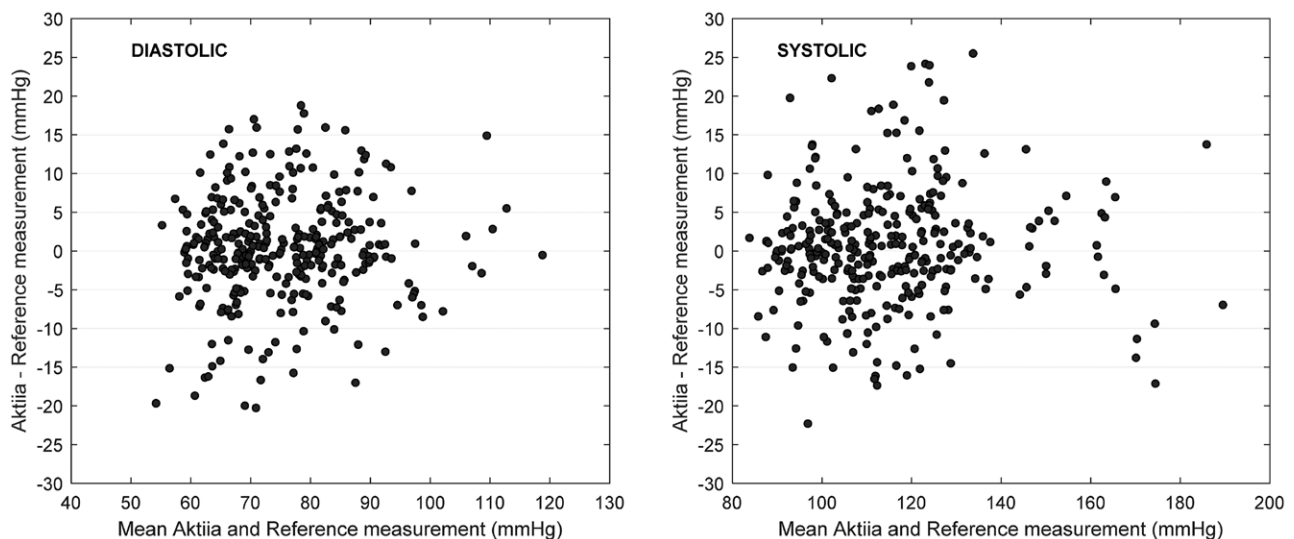
^aPassing if SBP and DBP: $\leq 5 \pm 8$ mmHg.

^bPassing if ≤ 6.91 mmHg for SBP, and < 6.93 for DBP.

Results

Over a total of 439 available measurements from the reference and the optical device, 327 were retained by the data quality control system of the algorithm of Aktiia Bracelet (acceptance rate of 75%). For the retained pairs,

Fig. 4



Bland–Altman plot comparing Aktiia Bracelet blood pressure estimates to reference double-auscultation performances for DBP and SBP.

the mean SBP and DBP differences between the Aktiia Bracelet and the reference method and the SD of the difference were $\leq 5 \pm 8$ mmHg and thus fulfilled criterion 1 of the ISO81060-2:2013 (Table 2). Analysis of criterion 2 for SBP and DBP fulfilled the requirements of the ISO81060-2:2013 protocol (≤ 6.91 mmHg for SBP and ≤ 6.93 for DBP) and are shown in Table 2.

The standardized Bland–Altman plot of all systolic and diastolic measures is shown in Fig. 4. The majority of the absolute differences between the Aktiia Bracelet and the reference method were lower than 5 mmHg (Table 3). No significant differences were found in the performances of Aktiia Bracelet when compared across subcohorts of patients as defined by characteristics such as skin pigmentation or wrist hair follicle density (Table 4).

At the end of the fourth visit (patient release), none of the 86 patients reported any discomfort related to the use of the Aktiia Bracelet to measure BP.

Discussion

Accurate measurement of BP is essential in the diagnosis and the management of hypertension, and universally recognized standards are enforceable to validate that a device is accurate [7].

Our study demonstrates that the accuracy and the precision of the SBP and DBP values provided by Aktiia Bracelet satisfy the requirements of criterion 1 and criterion 2 of ISO81060-2:2013. In addition, our implemented investigation protocol goes beyond the requirements of this standard, and we believe that this is a necessary step for the validation of optical BP monitors such as the Aktiia Bracelet. Indeed, the ISO81060-2:2013 standard explicitly describes methods to implement clinical investigations for BP monitors that use a cuff. We believe that the requirements of the standard are not sufficient to demonstrate the clinical performance of BP monitors relying on optical measurements and that a thorough validation shall, in

addition, address the challenges of (1) the stability of the calibration process and (2) the influence of different skin types in the optical signals [15]. Accordingly, the first challenge that we deemed important to specifically address was whether the calibration stability of the Aktiia Bracelet successfully allowed to obtain accurate BP measurements over the period of 1 month, as announced by the user manual of the device. Although preliminary data existed, it was important to verify this hypothesis in a larger and more heterogeneous cohort of patients during four visits over a period of 1 month [6]. The second challenge that we deemed important to address was whether the quality of the optical signals recorded by Aktiia Bracelet would compromise the reliability of the pulse wave analysis algorithms in patients with darker skin pigmentation (due to the increased absorption of the light), as well as in patients with increased hair follicle density (due to the introduction of an optical barrier). To the best of our knowledge, no other wearable BP monitor has disclosed results in this direction. Our results show that even with around 40% of the participants with high skin pigmentation (Fitzpatrick ≥ 3) and 20% with denser hair on the forearm (Schuckmann ≥ 2), the Aktiia Bracelet is able to fulfill the accuracy and precision requirements of ISO 81060-2:2013.

Home blood pressure monitoring (HBPM) and 24 h ambulatory blood pressure monitoring (ABPM) are known to be better predictors of cardiovascular events and are specifically recommended by the most recent international guidelines [16]. Unfortunately, accurate out-of-office BP measurements still require today the use of automated inflation cuffs, either for ABPM or HBPM procedures. The inflation of the cuff during the measurement is known to trigger an increase in BP, sometimes called cuff-inflation hypertension, especially at the arm in hypertensive patients [17]. Optical solutions, such as the Aktiia Bracelet, hold the clear advantage of providing increased comfort to the user due to the absence of need to inflate a cuff to perform a measurement, leading to a potential increase in patient compliance and adherence to monitoring campaigns and programs for control of BP. Optical and cuffless devices also open a new perspective in the way and frequency that 24 h ABPM measurements are performed today. The validation of Aktiia Bracelet in the sitting position is the first step toward this direction. Further validation of the accuracy of the device in other body positions than sitting will be required to promote the use of the device for 24 h monitoring.

Table 3 Percentage of absolute blood pressure differences between reference and the Aktiia Bracelet within 5, 10 and 15 mmHg

	≤ 5 mmHg (%)	≤ 10 mmHg (%)	≤ 15 mmHg (%)
Systolic blood pressure (mmHg)	58.7	83.2	92.3
Diastolic blood pressure (mmHg)	59.0	83.5	94.5

Table 4 Performances of the Aktiia Bracelet compared across subcohorts of patients

Differences Aktiia–reference	Skin pigmentation			Hair follicles density		
	Pale	Dark	<i>P</i> value ^a	Nonhairy	Hairy	<i>P</i> value ^a
Systolic blood pressure (mmHg)	0.4 \pm 8.0	0.5 \pm 5.7	0.97	0.3 \pm 7.7	0.9 \pm 7.9	0.60
Diastolic blood pressure (mmHg)	0.2 \pm 6.8	1.4 \pm 6.9	0.26	0.3 \pm 6.7	0.7 \pm 7.2	0.72

^a*P* value of a two-sample *t* test between performances of two subcohorts.

Conclusion

This study is the first to validate a cuffless bracelet for the measurement of BP in an outpatient setting over a period of one month in an extended cohort of adult participants. Aktiia Bracelet can be safely and effectively used for noninvasive, self-triggered, intermittent SBP and DBP monitoring in adult patients when the user is sitting, and the device is calibrated. In addition, Aktiia Bracelet can be safely and effectively used over a period of 1 month between calibration procedures.

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Conflicts of interest

G.W. serves as a consultant for Aktiia SA. For remaining authors, there are no conflicts of interest.

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