Validation of the Aktiia blood pressure cuff for clinical use according to the ANSI/AAMI/ISO 81060-2:2013 protocol

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Objective **Assess the accuracy and precision of the Aktiia initialization oscillometric upper-arm cuff device (Aktiia SA, Neuchâtel, Switzerland) for home blood pressure (BP) monitoring in the general population according to the American National Standards Institute / Association for the Advancement of Medical Instrumentation/International Organization for Standardization (ANSI/AAMI/ISO) 81060-2:2013 standard.**

Methods **Three trained observers validated BP measurements performed using the Aktiia cuff versus BP measurements performed using a standard mercury sphygmomanometer. Two ISO 81060-2 criteria were used to validate the Aktiia cuff. Criterion 1 evaluated, for both SBP and DBP, whether the mean error between BP readings performed by the Aktiia cuff and auscultation was ≤±5 mmHg, and whether the SD of the error was ≤8 mmHg. Criterion 2 assessed whether, for the SBP and DBP of each individual subject, the SD of the averaged paired determinations per subject of the Aktiia cuff and of the auscultation met the criteria listed in the table of Averaged Subject Data Acceptance.**

Results **Mean differences between the Aktiia cuff and the standard mercury sphygmomanometer (criterion 1) were 1.3 ± 7.11 mmHg for SBP and −0.2 ± 5.46 mmHg for DBP. The SD of the averaged paired differences per subject (criterion 2) was 6.55 mmHg for SBP and 5.15 mmHg for DBP.**

Conclusion **Aktiia initialization cuff complies with the requirements of the ANSI/AAMI/ISO guidelines and can be safely recommended for BP measurements in the adult population.** ***Blood Press Monit*** **28: 109–112 Copyright © 2023 The Author(s). Published by Wolters Kluwer Health, Inc.**

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Introduction

Hypertension is a major cause of preventable death in the world [1–3]. Blood pressure (BP) measurement is recommended for diagnostics and long-term hypertension management [1–3]. Accordingly, the validation of BP measurement devices is critical to support accurate hypertension diagnostic and medication titration [4,5]. Currently, many BP devices are commercialized prior to validation, which hinders adequate hypertension management and consumers' access to validated BP devices [6,7].

Aktiia SA (Neuchâtel, Switzerland) has developed a Conformité Européenne-marked, non-invasive, cuffless BP monitor (Fig. 1). The Aktiia monitor requires a once-a-month initialization procedure that recalibrates measurements using BP readings performed by the Aktiia cuff (Fig. 1a). Although the Aktiia monitor has been thoroughly investigated in previous studies [8–13] and the Aktiia cuff has been fully validated according to the International Organization for Standardization (ISO) 81060-2 protocol, the publication of the results for the Aktiia cuff validation is still pending [5].

In the present work, we sought to validate the Aktiia cuff for upper-arm BP measurements in accordance with the American National Standards Institute / Association for the Advancement of Medical Instrumentation / International Organization for Standardization (ANSI/AAMI/ISO) 81060-2:2013 protocol [5].

Methods

The Aktiia cuff

The Aktiia cuff is manufactured by Guangdong Transtek Medical Electronics Co., Ltd (Zhongshan, China). Transtek was responsible for data collection and protocol implementation during the study. The Aktiia cuff is designed for BP measurements at the upper arm. It is provided with a USB cable to recharge its internal

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Fig. 1

Illustration of the Aktiia monitor with (a) the Aktiia cuff, (b) the Aktiia bracelet and (c) the associated smartphone application to visualize SBP and DBP.

battery and is equipped with Bluetooth technology that supports communication with the Aktiia smartphone application. The Aktiia cuff performs BP measurements in the range of 0–299 mmHg, and heart rate (HR) within 40–199 bpm. It is a one-size-fits-all cuff, which can be adjusted around the user's arm (arm circumference between 22 and 42 cm).

Study population

The Aktiia cuff was tested on 99 subjects following the ANSI/AAMI/ISO protocol, 2013. All subjects were volunteers recruited at Zhongshan's City People Hospital (Zhongshan, China). Subjects with any two reference SBP values that differ by more than 12 mmHg or any two reference DBP values that differ by more than 8 mmHg were excluded from the study (14 subjects excluded). The demographic and clinical characteristics of the study population included in this study (85 subjects) are shown in Table 1.

Table 1 Demographic and clinical characteristics of the study population (*N*=85)

Age, years	43.2±17.2 [18–77]
Prevalence of	
The elderly (>60 years)	36%
Obesity (BMI≥30 kg/m^2)	48%
Male/female	38/47 [45%/55%]
Arm circumference, cm	32.8±5.4 [22–42]
Arm circumference, cuff specified range	
Lower half	41.2%
Upper half	58.8%
Lower quarter	22.4%
Upper quarter	22.4%
Lower octal	5.9%
Upper octal	9.4%
SBP, mmHg	126.6±16.0 [84–162]
≤100	5.9%
≥140	20.0%
≥160	5.5%
DBP, mmHg	79.2±12.3 [53–120]
≤60	6.7%
≥85	29.0%
≥100	5.1%

Numbers represented as $(\mu \pm \sigma)$ [range].

This study was approved by the Zhongshan People's Hospital Ethics Committee with written informed consent obtained from each subject.

Study protocol

Study subjects were seated in a quiet room at a comfortable temperature and instructed not to move or speak during the procedure. Subjects were requested to place their feet flat on the floor. The arm circumference of each subject was measured before the start of the procedure. BP measurements started at least 5 min after the participants were seated. All BP measurements were performed on the participants' left arm at the heart level. Accordingly, the Aktiia cuff was placed on the subjects' left arm at heart level, and the double stethoscope was placed on the inner part of the elbow joint for recording Korotkoff sounds.

Blood pressure measurements validation

BP measurements were conducted by three observers experienced in BP measurement. BP measurements were conducted following the same-limb sequential procedure described in the ISO 81060-2:2013 protocol [5], with alternating measurements performed with the Aktiia cuff and a mercury sphygmomanometer. Simultaneous auscultatory measurements were performed by two observers blinded from each other using a double stethoscope (T piece) via the Korotkoff method. The third observer recorded the device readings and supervised the BP readings made by the first two observers.

Data analysis

Data analyses were performed as delineated in the ANSI/AAMI/ISO protocol. Auscultation BP measurements were computed as the average between the readings performed by the two observers before and after each device reading. The Aktiia cuff performed automated BP readings by oscillometry. The two criteria for ISO 81060-2 validation were investigated [5].

Statistical analysis

The results of the comparisons are expressed as mean ± SD ($\mu \pm \sigma$).

Bland–Altman plots were created to highlight individual-level measurements. Additionally, regions of interest (ROIs) within ±5 mmHg, ±10 mmHg and ±15 mmHg were included to assess levels of agreement [14].

Additionally, results extending the ISO 81060-2 requirements are shown in the Supplementary materials, Supplemental digital content 1, *http://links.lww.com/BPMJ/A186*.

Results

Table 2 and Fig. 2 summarize the results for criteria 1 and 2 of ISO 81060-2. For criterion 1, the bias and SD ($\mu \pm \sigma$) found between Aktiia cuff and reference double-auscultation for SBP were 1.3 ± 7.11. For DBP, the bias and SD were −0.2 ± 5.46. For criterion 2, the SD of the averaged paired differences per subject was 6.55 mmHg for SBP and 5.15 mmHg for DBP – also within the limits delineated by ISO 81060-2.

Additionally, the two modalities resulted in SBP agreements of 53%, 86% and 96% within the ±5 mmHg, ±10 mmHg and the ±15 mmHg ROIs, respectively (Fig. 2). Similarly, the two modalities resulted in DBP agreements of 69%, 95% and 99% within the ±5/±10/±15 mmHg ROIs, respectively.

Discussion

In the present study, we investigate the accuracy of the Aktiia initialization oscillometric upper-arm cuff device for home BP monitoring in the general population according to the ANSI/AAMI/ISO 81060-2:2013 standard.

Our study demonstrates that the accuracy of SBP and DBP values measured by the Aktiia cuff satisfying the criteria defined by ISO 81060-2:2013 [5]. The tested oscillometric device fulfils the same requirements as any validated upper-arm device available on the market. Consequently, the Aktiia cuff is validated according to international standards and is thus recommended for use in clinical practice.

Cuffless blood pressure monitors

The Aktiia cuff will be integrated into the Aktiia System and will be used to initialize Aktiia's cuffless BP monitor, allowing users to perform on-demand readings. The Aktiia cuffless monitor comprises a small bracelet (Fig. 1b) that contains optical sensors to collect photoplethysmography signals acquired on the user's wrist. Pulse wave analysis is applied to the photoplethysmography signals to estimate SBP, DBP and HR, which are displayed in a smartphone application (Fig. 1c). This over-the-counter fully automated device is ideal for long-term continual BP monitoring in daily conditions.

Cuffless BP devices offer a new perspective and strategy for continual BP monitoring. The validation of the Aktiia cuff in the sitting position is a first step towards this paradigm change in the management of hypertension.

Limitations

The present validation was performed in early 2019 following the recommendations of the ISO 81060-2:2013 standard that was applicable then, and its data supported the immediate commercialization of the Aktiia System across Europe. In November of the same year, a new version of the ISO 81060-2 was released (EN ISO 81060-2:2019). The Aktiia cuff also complies with the procedures described by this new version of the standard, except for the lower and upper octal arm circumferences found in the present cohort (Table 1). The presented results, however, support that the Aktiia Initialization cuff can be safely recommended for BP measurements in the adult population.

The Aktiia cuff is produced and tested by Guangdong Transtek Medical Electronics, which might lead to potential conflicts of interest. We believe, however, that the results shown in the present work are representative since Transtek implemented all methods in accordance with the guidelines described in the ISO 81060-2 standard. Additionally, all data collected during the validation study have been recorded and stored and can be accessed upon request for further verification.

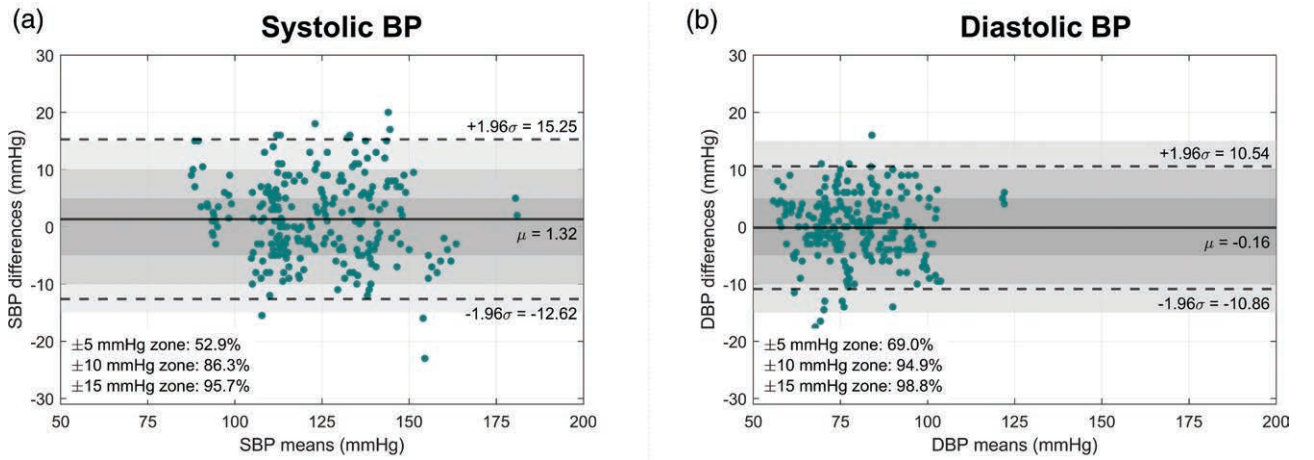
Conclusion

In the present work, we validated the Aktiia cuff for upper-arm BP measurements following the ANSI/AAMI/ISO 81060-2:2013 protocol. Our results show that the Aktiia cuff complies with the requirements of the ANSI/AAMI/ISO guidelines and can be safely recommended for BP measurements in the adult population. This is of paramount importance for an accurate once-a-month initialization procedure that recalibrates measurements using the Aktiia cuffless monitor. Therefore, the Aktiia monitor can be effectively used for non-invasive, self-triggered,

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

	Criterion 1				Criterion 2		
	Mean error	ISO target	SD	ISO target	SD of averaged differences per subject	ISO target	Result
SBP (mmHg)	1.3	≤±5.0	7.11	≤8.00	6.55	≤6.82	Pass
DBP (mmHg)	−0.2	≤±5.0	5.46	≤8.00	5.15	≤6.95	Pass

Fig. 2



Bland–Altman plots comparing (a) SBP and (b) DBP measurements performed by the Aktiia cuff and the reference double-auscultation. ROIs within ±5 mmHg, ±10 mmHg and ±15 mmHg are highlighted in dark grey and light grey, respectively. The percentage of agreement for each region is shown on the bottom left of the Bland–Altman plots. The solid black line denotes the average mean of differences, while the dotted lines denote the limits of agreement (±1.96σ). ROIs, regions of interest.

intermittent SBP and DBP monitoring in adult patients when the user is sitting and the device is calibrated.

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Conflicts of interest

The Aktiia cuff is produced (and tested) by Guangdong Transtek Medical Electronics. B.S.A. serves as a consultant for Aktiia SA. For the remaining authors, there are no conflicts of interest.

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