


Accuracy of the COMBEI BP118A Device for Self-Blood Pressure Measurements in General Population – Validation According to the Association for the Advancement of Medical Instrumentation/European Society of Hypertension/International Organization for Standardization Universal Standard

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Background: Electronic devices for blood pressure (BP) measurements must undergo independent clinical validation as recommended by various authorities and scientific societies.

Objective: To assess the accuracy of the Combei BP118A device in the general population according to the Universal Standard Validation Protocol.

Methods: The new-developed Combei BP118A device measures BP at the brachial level using the oscillometric method. The study was performed according to the “AAMI/ESH/ISO Universal Standard (ISO 81060–2:2018) protocol”. Subjects (n = 88) were recruited to fulfill the age, gender, BP and cuff distribution criteria according to the protocol requirements using the same arm sequential BP measurement method. Differences between observers’ mercury sphygmomanometer reference measurements and device BP values (test versus reference) and their standard deviation (SD) were calculated.

Results: Ninety-one subjects were selected, 88 of whom were included. The mean BP differences between the simultaneous observers’ reference measurements were -0.2 ± 1.7 mmHg for systolic BP (SBP) and -0.2 ± 1.7 mmHg for diastolic BP (DBP). For validation criterion 1, the mean difference \pm SD between the reference and device BP values were 3.6 ± 5.5 mmHg for SBP and 1.4 ± 4.5 mmHg for DBP. For criterion 2, the SD of the mean BP differences between the test device and reference BP per subject was $5/4.1$ mmHg for SBP/DBP ($\leq 5.9/6.8$). These results fulfilled the protocol requirements.

Conclusion: The Combei BP118A oscillometric device for home BP measurement fulfilled all of the requirements of the AAMI/ESH/ISO Universal Standard (ISO 81060–2:2018) in general population and consequently can be recommended for home BP measurements.

Keywords: blood pressure measurement, accuracy, validation, home blood pressure, oscillometric, Combei

Introduction

Blood pressure (BP) measurement is one of the most performed acts in medical practice. It is performed either to assess cardiovascular hemodynamics or to detect, diagnose or monitor hypertension. An accurate measurement of BP is thus crucial since wrong values and misclassification can incur serious clinical consequences. Whomever is performing the BP measurement,

whether practitioner, nurse, pharmacist, patient, etc., the latter's major concern must be the reliability of the BP device and the accuracy of the observed BP values.¹ Several automatic electronic devices for BP measurement, based principally on the oscillometric method, have been developed.¹ These devices must undergo clinical validation as recommended by several authorities/scientific societies.² In the past, different protocols were used to assess the accuracy of BP measuring devices. Recently, members of the Advancement of Medical Instrumentation (AAMI), the European Society of Hypertension (ESH) and the International Organization for Standardization (ISO) committees reached a consensus on an optimal validation standard, the AAMI/ESH/ISO Universal Standard (ISO 81060–2:2018) which is now considered as the standard protocol for the validation of non-invasive blood pressure measuring devices.³ Elsewhere, such independent clinical validation and its publication is needed to allow new BP devices to be listed as “recommended” in professional websites.⁴ Therefore, for each newly developed BP device, it is highly recommended to proceed to its specific clinical validation study clarifying the accuracy of its BP measurements according to the established standard. The aim of this study was to assess the accuracy of the Combei BP118A automatic upper-arm BP monitor for home BP measurement in the general population, according to the AAMI/ESH/ISO Universal Standard (ISO 81060–2:2018).³

Methods

Ethical Aspects

This study using a medical device (Type IIA) was approved by the ethics committee of the Cardiovascular Institute “Dedinje” Heroja Milana Tepića 1, Belgrade Serbia. Written informed consent was obtained from all included subjects. The study was performed according to the declaration of Helsinki and ICH good clinical practice.

Study Design

This is a prospective non-interventional, non-randomized study using a medical Type II A device. The study was performed according to the AAMI/ESH/ISO Universal Standard (ISO 81060–2:2018). Details of this validation protocol have been published previously.³ The recommendations for performing and reporting validation studies according to this validation standard were strictly followed.

Study Population

The required sample size is defined by the AAMI/ESH/ISO validation protocol. A minimum of 85 subjects must be included and analyzed, usually with 3 pairs of BP measurements per subject and a minimum of 255 pairs of BP measurements using the reference sphygmomanometer and the tested device should be obtained. Inclusion criteria were treated or untreated patients, age > 12 years, arm circumference between 22 cm and 42 cm, the latter being in accordance with the instructions for use of the Combei BP118A device. Exclusion criteria were arrhythmia, poor quality of Korotkoff sounds, and patient unable to give consent or properly understand protocol information.

Procedures and BP Measurements

Tested Device

The COMBEI BP118A (Figure 1) is a new recently developed device manufactured by COMBEI Technology Co, LTD company (Shenzhen China). This is a new generation of digital automatic device for home BP measurement at the brachial level. The monitor uses an electric inflation pump and constant automatic deflation system. The monitor operates on 4 “AA” alkaline batteries, and measures BP using the oscillometric method with a pressure range of 30–280 and pulse rate range of 40–199 beats/min. Systolic BP (SBP), diastolic BP (DBP) and pulse rate are displayed on a digital display. The device includes 2 memory sets of 120 measurements each (SBP, DBP and pulse rate), which allows the device to be used by 2 distinct users. The device uses a single cuff covering arm circumferences from 22 to 42 cm. Further technical details are described in its User Manual.

For the present study, 3 Combei BP118A BP monitors were provided by COMBEI Technology, one of which was randomly chosen to conduct the study and used according to the manufacturer's recommendations.



Figure 1 The COMBEI BP118A device.

Reference Blood Pressure Measurements – Mercury Sphygmomanometer

The validation team consisted of three investigators, namely two observers and one supervisor trained in accurate BP measurements. BP was measured by the two observers blinded to each other's result using: 2 parallel connected mercury sphygmomanometers (ALPK2 300 V - Tokyo- Japan), calibrated prior to study initiation, and a “Y” connected teaching stethoscope (3M™ Littmann®, United States), after which BP was measured by the supervisor using the tested device. Agreement between the 2 observers was verified by the supervisor to ensure that the difference between their measurements was < 4 mmHg for SBP and DBP. In case of disagreement between the 2 observers, additional pairs of measurements were performed with a maximum of 8 pairs of BP determinations after which the subject was excluded. Korotkoff sound (K5) was used for reference diastolic BP.

The circumference of the arm was measured to ensure that the reference cuff-size being used was adequate for the subject. Three cuffs with inflatable bladder dimensions 9×18 cm, 12×24 cm and 15×32 cm respectively were used such that the length reached 75–100% of the participant's midarm circumference and the width at 37–50%.

Procedure of BP Measurements and Data Collection

The validation procedure began with the patient seated comfortably and relaxed for at least 5 minutes, the back and the arm supported with the middle of the upper arm at heart level, legs uncrossed and feet flat on the floor. BP measurements were performed according to the “same arm, sequential measurements” method on the left arm supported at heart level as described in the AAMI/ESH/ISO Universal Standard.³ Measurements by the tested device were performed on the same arm supported at the heart level as recommended by the manufacturer. As required, nine consecutive BP measurements were carried out in each subject using the mercury sphygmomanometers (5 times: R0, R1, R2, R3, R4,) and the tested devices (4 times: T0, T1, T2, T3). All nine-sequential same-arm measurements were recorded at 1-minute intervals starting with the standard mercury sphygmomanometer. The first auscultatory and first device measurements represent the recruitment pressures (R0 and T0) and were not used in the accuracy assessment of the test device.

Statistical Analysis

Data were analyzed and presented according to the validation protocol requirements.³ Statistical analysis was performed using specific analysis software established by the International Society of Vascular Health (ISVH). Each reference BP

measurements (R1, R2, R3, R4) represented the mean of the simultaneous readings of the two observers. Each of the test device measurements was compared against the mean of the previous and next reference BP readings (eg, T1 versus the mean of R1-R2). Differences were calculated by subtracting the reference BP measurements from the test device measurements. The mean BP differences and their SD were calculated, ie, criterion 1 (protocol requirements $< 5 \pm 8$ mmHg), criterion 2 being the SD of mean BP differences per subject as defined by the AAMI/ESH/ISO Universal Standard (ISO 81060–2:2018). The same criteria were used for SBP and DBP measurements. Standardized Bland-Altman scatter plots were used to illustrate device - observer differences versus mean device and observer values for all pairs of comparison. More specifically, the BP differences between the reference measurements and the tested device were calculated according to arm circumference and presented in a Bland-Altman scatter plot. The distribution of the population was calculated according to age, gender, BP values and arm circumference as recommended by the protocol.

Results

Study Population

In the present study, 91 subjects from the cardiology and cardiovascular research departments of the “Dedinje” Cardiovascular Institute were selected, 88 of whom were recruited and analyzed; 3 subjects were excluded due poor Korotkoff sounds. The clinical characteristics of the participants are summarized in Table 1. The results showed that their characteristics are in accordance with the requirements of the validation protocol.

BP Measurements

Table 2 depicts the distribution of BP levels measured using the reference method, the results of which were in accordance with the protocol requirements, namely:

For SBP readings: $\geq 5\%$ readings must be ≤ 100 mmHg, $\geq 5\%$ readings must be ≥ 160 mmHg and $\geq 20\%$ readings ≥ 140 mmHg. For DBP readings: $\geq 5\%$ readings must be ≤ 60 mmHg, $\geq 5\%$ readings must be ≥ 100 mmHg and $\geq 20\%$ readings ≥ 85 mmHg.

The mean BP differences between the simultaneous observers' measurements were $-0.2 \pm 2.7/-0.2 \pm 2.7$ mmHg (systolic/diastolic, range -4 to 4 mmHg). The validation analysis is shown in Table 3. For criterion 1, the mean differences between the tested device and reference BP values (tested device minus reference BP values) were 3.6 ± 5.5 mmHg for SBP and 1.4 ± 4.5 mmHg for DBP. For criterion 2 (for individual subjects), the SD of 88 mean BP differences (test minus reference BP per subject) must be within a threshold defined by the mean test-reference BP difference and calculated to be $\leq 5.89/6.8$ for SBP/DBP.^{2,3} Results showed that SD was 5.0 mmHg for SBP and 4.1 mmHg for DBP (Table 3), thereby confirming that the tested

Table 1 Characteristics of Study Participants (n=88)

	Mean \pm SD	Range
Age (years)	53.4 \pm 15.3	19–82
Gender (male/female)	50/38	–
Arm circumference (cm)	31.7 \pm 5.5	22–41.5
Entry SBP R0 (mmHg)	141.0 \pm 21.6	97–200
Entry DBP R0 (mmHg)	83.4 \pm 12.9	56–110

Abbreviations: DBP, diastolic blood pressure; SBP, systolic blood pressure.

Table 2 Distribution of Reference BP Measurements (R1-R4)

SBP	≤ 100 mmHg	≥ 160 mmHg	≥ 140 mmHg
	7.39% (26)	14.49% (51)	43.75% (154)
DBP	≤ 60 mmHg 8.24% (29)	≥ 100 mmHg 10.51% (37)	≥ 85 mmHg 36.93% (130)

Note: Values are expressed as percentages and (absolute values).

Abbreviations: DBP, diastolic blood pressure; SBP, systolic blood pressure.

Table 3 Validation Study Results

	Pass Requirement	SBP	DBP
Criterion 1 (264 BP pairs)			
Mean BP difference (mmHg)	≤5	3.6	1.4
SD (mmHg)	≤8	5.5	4.5
		Pass	Pass
Criterion 2 (88 Subjects)			
SD (mmHg, SBP/DBP)	≤5.89/6.8	5	4.1
		Pass	Pass
Result		Pass	

Abbreviations: DBP, diastolic blood pressure; SBP, systolic blood pressure; SD, standard deviation.

device fulfilled the requirements of the (AAMI/ESH/ISO) - (ISO 81060–2:2018) Universal protocol for both criteria 1 and 2 and thus qualified as having successfully “PASSED” the validation.

Assessment of the accuracy of the tested device according to arm circumference is shown in Table 4. The distribution of the arm circumference was in accordance with the requirements of the Universal Validation protocol, namely: ≥ 40% of the subjects must have an arm circumference within the upper half of the specified range of use of the cuff, ≥ 40% within the lower half, ≥ 20% within the higher quarter, ≥ 20% within the lower quarter, ≥ 10% within the higher octal, and ≥ 10% within the lower octal of the specified range of use of the cuff (22–42 cm). The differences between BP values (test device minus reference) according to arm circumference are shown in Table 4 for both SBP and DBP.

Standardized Bland-Altman scatter plots of the test-reference BP differences against their mean are shown in Figure 2 for SBP (panel A) and DBP (panel B). The Bland-Altman scatter plots showing the relationship between Test-Reference BP differences according to arm circumference are further illustrated in Figure 3 for SBP (panel A) and DBP (panel B).

Discussion

This is the first study assessing the accuracy of the newly developed COMBEI BP118A device from COMBEI Technology Co, for BP measurement. The results of the study showed that the Combei BP118A device successfully fulfilled criteria 1 and 2 required by the (AAMI/ESH/ISO) – (ISO 81060–2:2018) Universal Validation protocol.

Certain points related to tested devices, or the validation protocol warrant additional consideration.

Oscillometric Devices

Despite the advantages of automatic oscillometric devices, there are several persistent concerns with these devices, including 1) the accuracy of BP measurements: this is of concern in the general population and of even greater concern in special populations;⁴ 2) the inter-individual variability of oscillometric BP measurements: in some patients, the oscillometric methods may show high variability and/or substantial difference in comparison to the auscultatory method. It is

Table 4 BP Differences According to Arm Circumference

Arm Circumference	Participants n(%)	Mean SBP Difference ±SD (mmHg)	Mean DBP Difference ±SD (mmHg)
≥ 36 subjects ≥ 32 cm	43(49)	3.28±5.8	1.38±3.9
≥ 36 subjects < 32 cm	45(51)	4±5.2	1.43±4.9
≥ 18 subjects ≥ 37 cm	19(22)	3.04±3.6	1.32±3.4
≥ 18 subjects ≤ 27 cm	20(23)	3.15±4.2	1.6±4.3
≥ 9 subjects ≥ 39.5 cm	11(13)	4.38±3.5	2.36±3.7
≥ 9 subjects ≤ 24.5 cm	10(11)	2.4±3.4	2.33±4.3

Abbreviations: DBP, diastolic blood pressure; SBP, systolic blood pressure; SD, standard deviation.

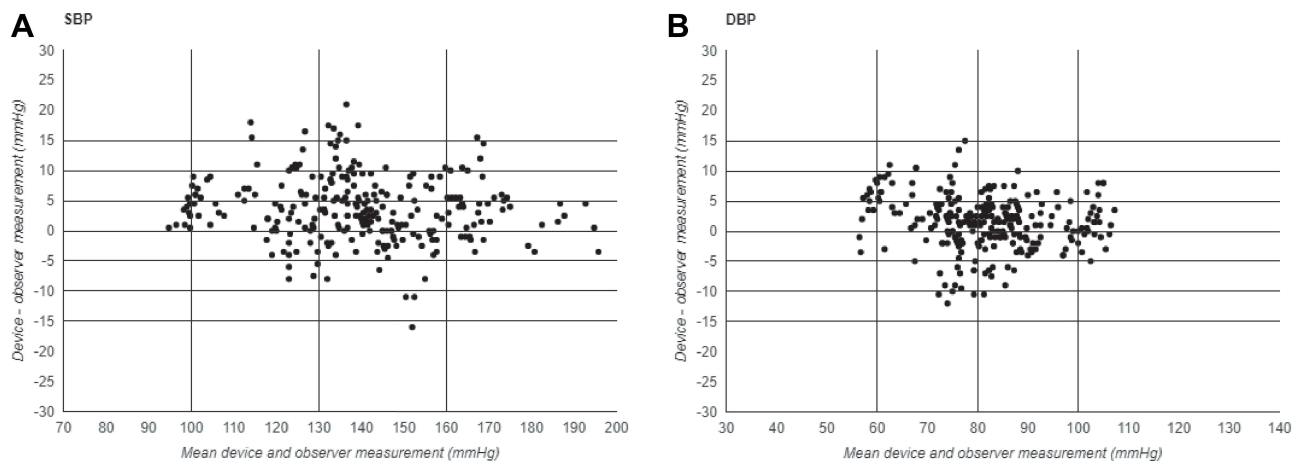


Figure 2 (A, B) Standardized Bland-Altman scatter plots of Test-Reference BP differences against their mean values.

Abbreviations: SBP, systolic blood pressure; DBP, diastolic blood pressure.

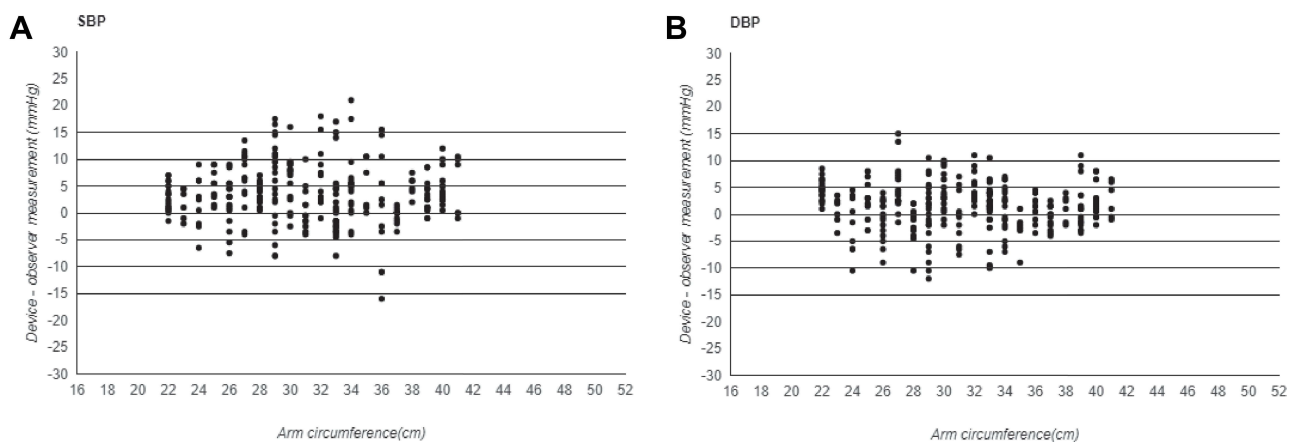


Figure 3 (A, B) Bland-Altman scatter plots showing the differences between Test - Reference BP according to arm circumference.

Abbreviations: SBP, systolic blood pressure; DBP, diastolic blood pressure.

therefore recommended to verify the accuracy of any automatic oscillometric BP measurement at the individual level before its clinical application.¹

Special Populations

The AAMI/ESH/ISO Universal Standard (ISO 81060–2:2018)³ recommends clinical validation of automatic devices for BP measurements in the general population but also in other special populations. In the present study, the Combei BP118A was validated in the general population, hence the results presented herein cannot be extrapolated to other more specific populations since such extrapolation would be speculative and arbitrary.

Validation Protocol

This study is the first validation study of the Combei BP118A device performed according to the latest “Universal” standard. Nevertheless, this standard does not specify the number of validation studies needed to approve a device’s accuracy. Due to the questionable reproducibility of validation studies, some experts agree that a device should be validated separately in at least two different centers (2 studies). For instance, one clinical validation, if successful, would

seemingly be sufficient to approve the device and consider its registration on the list of “approved” devices of several institutions and scientific societies.⁴

Conclusion

The Combei BP118A from Combei Technology Co., an automatic oscillometric upper-arm BP monitor for home BP measurement, fulfils the accuracy validation requirements of the AAMI/ESH/ISO Universal Standard (ISO 81060–2:2018) for both SBP and DBP measurements in the general population with 22–42 cm arm circumference. These results are crucial to ensure the accuracy of its BP measurement before its use by patients for home BP monitoring. Consequently, this device can be recommended for home BP measurements.

Acknowledgments

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Disclosure

All authors conducted validation studies for various manufacturers, they received honorarium for this validation study. Prof. Dr. Nebojsa Tasić reports personal fees from ISVH, during the conduct of the study. Dr Jirar Topouchian reports personal fees from FMRI, during the conduct of the study. Prof. Dr. Roland Asmar reports personal fees from COMBEI Co, during the conduct of the study. The authors report no other conflicts of interest in this work.

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