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ORIGINAL RESEARCH

Accuracy of the Combei BP880W Wrist Device for Self-Blood Pressure Measurements in General Population According to the International Organization for Standardization Universal Standard (ISO 81060-2:2018/AMD 1:2020) Protocol

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Background: Scientific societies universally recommend evaluating the accuracy of electronic devices designed for blood pressure (BP) measurement using established validation protocols.

Objective: This study aimed to assess the accuracy of the Combei BP880W wrist device for BP measurement in the general population, according to the ISO 81060–2:2018/AMD 1:2020 Universal Standard.

Methods: The Combei BP880W is an oscillometric device designed to measure BP at the wrist. This study adhered to the ISO 81060–2:2018/AMD 1:2020 protocol and employed the same-arm sequential BP measurement method. A total of 85 participants, meeting protocol-specified age, gender, BP, and cuff distribution criteria, were included. The accuracy analysis utilized Criterion 1 (differences and standard deviations between reference and test device measurements) and Criterion 2 (intra-individual standard deviation of BP differences).

Results: Eighty-five participants were included. Mean BP differences between the simultaneous observer measurements were −0.2 ± 1.9 mmHg for systolic BP (SBP) and 0.1 ± 1.9 mmHg for diastolic BP (DBP). For Criterion 1, the mean difference ± standard deviation (SD) between the reference and test device measurements were −2.7 ± 5.9 mmHg (SBP) and −2.0 ± 3.9 mmHg (DBP), meeting the required threshold (≤ 5 ± 8 mmHg). For Criterion 2, intra-individual SDs were 4.6 mmHg (SBP) and 3.4 mmHg (DBP), both below the respective limits (≤ 6.39 mmHg for SBP and ≤ 6.65 mmHg for DBP).

Conclusion: The Combei BP880W wrist device meets the accuracy requirements of the ISO 81060–2:2018/AMD 1:2020 protocol, supporting its use for home BP monitoring in the general population.

Keywords: blood pressure measurements, accuracy, validation, home blood pressure, oscillometric, wrist, Combei

Introduction

Blood pressure (BP) measurement represents the most frequently performed medical procedure in clinical practice, serving as a cornerstone for the assessment of cardiovascular health. Typically, BP is measured in clinical settings by healthcare professionals to evaluate BP levels and their implications for conditions such as hypertension and associated comorbidities.[1,2] Additionally, individuals may measure their BP independently to monitor cardiovascular status, or patients may engage in home BP monitoring (HBPM) for the management of hypertension, as recommended by clinical guidelines.[3] Accurate BP measurement is crucial to avoid errors that may lead to significant clinical consequences, including misclassification of hypertension status and inappropriate treatment decisions, whether under- or overtreatment.[4,5]

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To ensure the reliability of BP measurement devices, scientific and regulatory authorities mandate that these devices undergo rigorous clinical validation using standardized protocols in experienced centers.[1,2,5] Multiple protocols have been developed to evaluate the accuracy of BP measurement devices.[6–8] In 2018, a consensus was achieved among the American Advancement of Medical Instrumentation (AAMI), the European Society of Hypertension (ESH), and the International Organization for Standardization (ISO) to consolidate these efforts into a unified validation protocol: the AAMI/ESH/ISO Universal Standard (ISO 81060–2:2018).[9–12] This protocol was subsequently updated with an amendment in 2020 (ISO 81060–2:2018/AMD 1:2020) and is now regarded as the gold standard for BP device validation.[12] Most international health institutions recommend adherence to this standard, and devices that successfully meet its criteria are listed as "recommended" on selected professional websites.[13]

Previously, we published in this journal the validation of another device from the same manufacturer,[14] the Combei BP118A, which measures BP at upper arm level;[14] to date, the Combei BP880W, which measures BP at wrist level, has never been assessed. This study aims to evaluate the accuracy of the Combei BP880W wrist BP monitor, designed for home use, in the general population according to the Universal Standard (ISO 81060–2:2018/AMD 1:2020);[10–12] the findings will provide essential evidence regarding its suitability for home BP monitoring.

Methods

Study Design

This prospective, non-interventional, and non-randomized study evaluated the accuracy of a Type IIa medical device, the Combei BP880W, and was approved by the ethics committee of the Institute of Cardiology, Yerevan, Armenia. The study adhered to the Universal Standard (ISO 81060–2:2018/AMD 1:2020) and complied with the principles of the Declaration of Helsinki, the International Council for Harmonization (ICH), and the Good Clinical Practice (GCP) guidelines. All procedures for performing and reporting the validation study followed the recommendations outlined in the ISO standard.

Study Population

The ISO 81060–2:2018/AMD 1:2020 protocol mandates a minimum of 85 participants, each undergoing three pairs of BP measurements, resulting in at least 255 BP measurement pairs using both the reference sphygmomanometer and the test device. The study population was selected to ensure compliance with the ISO protocol's requirements regarding gender distribution, BP ranges, and arm and wrist circumference distributions.

Participants were included if they were aged ≥ 12 years, had wrist circumferences between 12.5 cm and 21.5 cm (as specified in the instructions for use of the Combei BP880W device), and were either untreated or undergoing treatment for hypertension. Exclusion criteria included arrhythmias, poor-quality Korotkoff sounds, inability to provide informed consent or understand study procedures, and the presence of open wounds or damaged skin on the arms or wrists. Written informed consent was obtained from all participants before study enrollment.

Test Device

The COMBEI BP880W (MDD) device is manufactured by COMBEI Technology Co, LTD company. This is a new generation digital automatic device for home BP measurement at the wrist level (Figure 1). The BP 880 W monitor uses automatic internal inflation pump and constant automatic deflation system; it measures BP and pulse rate during deflation, hence the name "MDD" (Measurement During Deflation). The monitor uses 2 size "AAA" alkaline batteries; it 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 with integrated time/date. The device automatically stores each of the last 120 measurement values. By pressing the "MEMORY" button, an average value of the last 3 measurements as well as the last measurement (MR1) and the further last 120 measurements (MR2, MR3., MR120) can be displayed one after the other. The device can be used by 2 distinct users. The device uses a single cuff covering wrist circumferences from 12.5 to 21.5 cm. For this study, three BP880W (MDD) devices were provided by Combei Technology, one of which was randomly selected to conduct this study and used according to the manufacturer's instructions.

Figure 1 The Combei BP880W wrist device.

Blood Pressure Measurements

The validation study was conducted by a supervisor and two observers, all of whom were trained in accurate BP measurement techniques. The observers measured BP using two parallel-connected mercury sphygmomanometers (KDM®, Germany) and a Y-connected teaching stethoscope (3M™ Littmann®, United States). Observers were blinded to each other's measurements, and their results were cross verified by the supervisor to ensure inter-observer agreement within ±4 mmHg for both SBP and DBP; otherwise, the measurement was repeated.

Arm circumferences were measured to ensure appropriate cuff sizing for the reference method, and wrist circumferences were measured to confirm compatibility with the test device. For the reference (mercury) BP measurement, the cuff-size being used was adequate for the subject (the cuff length reached 75–100% and its width 37–50% of the arm circumference). BP measurements were performed after participants rested for at least five minutes, with the left arm supported at heart level. Measurements followed the "same-arm, sequential measurements" protocol described in ISO 81060–2:2018/AMD 1:2020.

A total of nine sequential BP measurements were taken per participant: five with the reference mercury sphygmomanometers (R0, R1, R2, R3, R4) and four with the test device (T0, T1, T2, T3). Measurements were conducted at one-minute intervals, starting with the mercury sphygmomanometer. The initial readings (R0 and T0) were excluded from the analysis.

Statistical Analysis

Statistical analysis was performed using software developed by the International Society of Vascular Health (ISVH®).[14] Each reference BP measurement was calculated as the mean of the two simultaneous readings from the observers. Test device measurements were compared to the mean of the preceding and subsequent reference measurements (eg, T1 was compared to the mean of R1 and R2).

Differences were calculated by subtracting the reference measurements from the test device measurements. The mean and standard deviation (SD) of these differences were computed and compared to Criterion 1 of ISO 81060–2:2018/AMD 1:2020, which specifies a mean difference of ≤5.0 mmHg and an SD of ≤8.0 mmHg. Criterion 2, addressing within-subject variation, was also evaluated.[10–12]

Bland-Altman scatterplots were used to illustrate the differences between test device and reference BP measurements against their mean values. Additional Bland-Altman plots assessed differences in SBP and DBP stratified by wrist circumference. Population distributions by gender, BP values, and arm circumference were analyzed to confirm compliance with protocol requirements.[10–12]

Results

Study Population

A total of 86 individuals from the Preventive Cardiology Department of the Institute of Cardiology were initially assessed for inclusion in the study. Of these, 85 subjects met the eligibility criteria and were included in the analysis, while one participant was excluded due to the presence of arrhythmia. The clinical characteristics of the study population are summarized in Table 1, demonstrating compliance with the ISO 81060–2:2018/AMD 1:2020 validation protocol requirements in terms of age and gender distribution.[10–12]

BP Measurements

The distribution of BP levels obtained using the reference method is presented in Table 2. The results confirmed adherence to the protocol requirements for BP distribution as follows:

- For SBP readings: ≥ 5% readings must be ≤ 100 mmHg, ≥ 5% readings must be ≥ 160 mmHg and ≥ 20% readings ≥ 140 mmHg.

- For DBP readings: ≥ 5% readings must be ≤ 60 mmHg, ≥ 5% readings must be ≥ 100 mmHg and ≥ 20% readings ≥ 85 mmHg.

The inter-observer agreement between simultaneous BP measurements by the two observers showed mean differences of –0.2 ± 1.9 mmHg for SBP and 0.1 ± 1.9 mmHg for DBP, with a range of –4 to 4 mmHg, indicating high concordance between measurements.

Table 1 Characteristics of the Study Participants (n=85)

	Mean ± SD	Range
Age (years)	46.4 ± 19.5	13–87
Gender (male/female)	32/53	–
Arm circumference (cm)	29.8 ± 4.9	21–41
Wrist Circumference (cm)	17.6 ± 2.5	13–21.5
Entry SBP R0 (mm Hg)	123.9 ± 22.4	87–186
Entry DBP R0 (mm Hg)	76.9 ± 13.9	58–124

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

Table 2 Distribution in Percentages of Reference Blood Pressure Measurements

SBP	≤100 mmHg	≥160 mmHg	≥140 mmHg
%	19.12%	6.47%	21.18%
DBP	≤60 mmHg	≥100 mmHg	≥85 mmHg
%	12.94%	5.59%	22.94%

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

Table 3 Validation Results - Comparison Between Reference and the Test Device Blood Pressure Measurements

	Pass requirement	SBP	DBP
Criterion 1 (255 BP pairs)			
Mean BP difference (mm Hg)	≤5	− 2.7	−2.0
SD (mm Hg)	≤8	5.9	3.9
		Pass	Pass
Criterion 2 (85 Subjects)			
SD (mm Hg, SBP/DBP)	≤ 6.39/6.65	4.6	3.4
		Pass	Pass
Result		**Pass**	

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

Table 4 Blood Pressure Differences According to the Wrist Circumference

Subjects/Wrist Circumference	Participants n (%)	Mean SBP Difference ±SD (mmHg)	Mean DBP Difference ±SD (mmHg)
≥ 34 subjects ≥ 17 cm	51 (60)	−2.9 ± 6.7	−1.8 ± 3.9
≥ 34 subjects < 17 cm	34 (40)	−2.42 ± 4.6	−2.21 ± 3.8
≥ 17 subjects ≥ 19.25 cm	26 (31)	−2.83 ± 7.2	−1.35 ± 4.1
≥ 17 subjects ≤ 14.75 cm	17 (20)	−2.23 ± 4.1	−2.14 ± 3.2
≥ 9 subjects ≥ 20.37 cm	15 (18)	−3.43 ± 7.7	−2.04 ± 3.0
≥ 9 subjects ≤ 13.62 cm	10 (12)	−2.75 ± 4.5	−3.37 ± 2.9

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

Accuracy Analysis

The accuracy analysis results are summarized in Table 3 and Table 4.

Criterion 1: Population-Level Accuracy. The mean differences between the tested device and reference BP values were: SBP: –2.7 ± 5.9 mmHg and DBP: –2.0 ± 3.9 mmHg. These values satisfy the ISO 81060–2:2018/AMD 1:2020 Criterion 1, which requires that the mean difference between test and reference BP values be ≤ 5.0 mmHg with a standard deviation (SD) ≤ 8.0 mmHg.

Criterion 2: Individual-Level Accuracy. For individual subjects, the SD of the mean BP differences across 85 participants was: SBP: 4.6 mmHg and DBP: 3.4 mmHg. These results meet the Criterion 2 thresholds of ≤ 6.39 mmHg for SBP and ≤ 6.65 mmHg for DBP, as defined by the ISO 81060–2:2018/AMD 1:2020 standard.

The tested device successfully fulfilled both Criterion 1 and Criterion 2, confirming compliance with the ISO protocol and validating the accuracy of the device.

Influence of Wrist Circumference

The accuracy of the tested device in relation to wrist circumference is detailed in Table 4. The wrist circumference distribution was consistent with the protocol requirements:

≥ 20% of subjects in each quarter of the cuff range (12.5–21.5 cm)

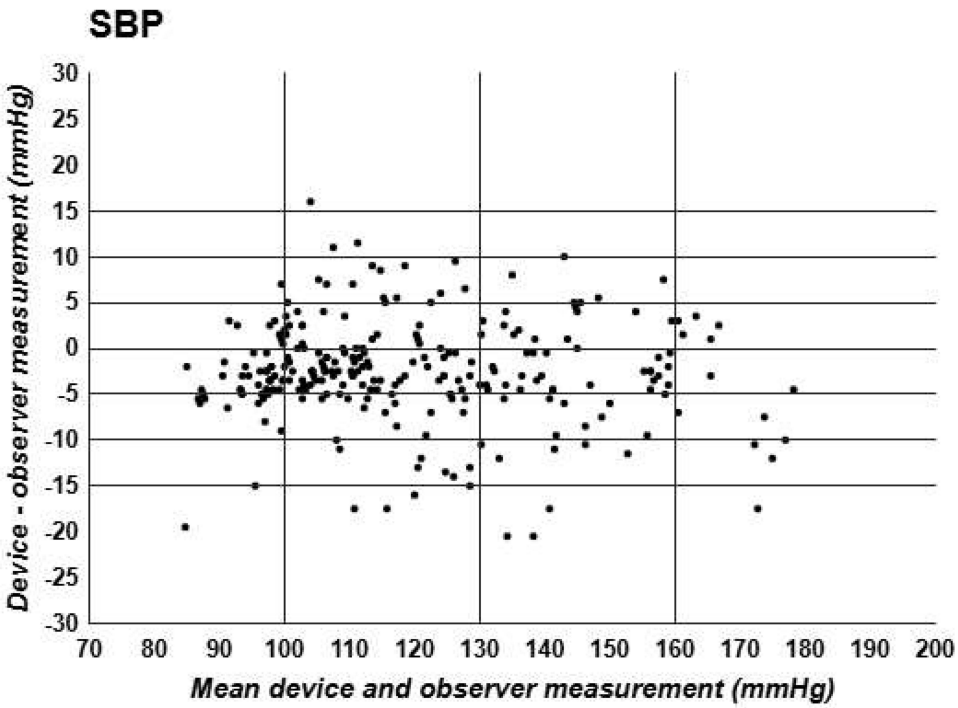
≥ 10% of subjects in both the highest and lowest octiles of wrist circumference

BP differences (test device minus reference) stratified by wrist circumference are presented in Table 4 for both SBP and DBP, showing no systematic bias across the range of wrist sizes.

Bland-Altman Scatter Plots

Standardized Bland-Altman scatter plots were used to evaluate the agreement between test and reference BP measurements:

A- Systolic blood pressure



B- Diastolic Blood Pressure

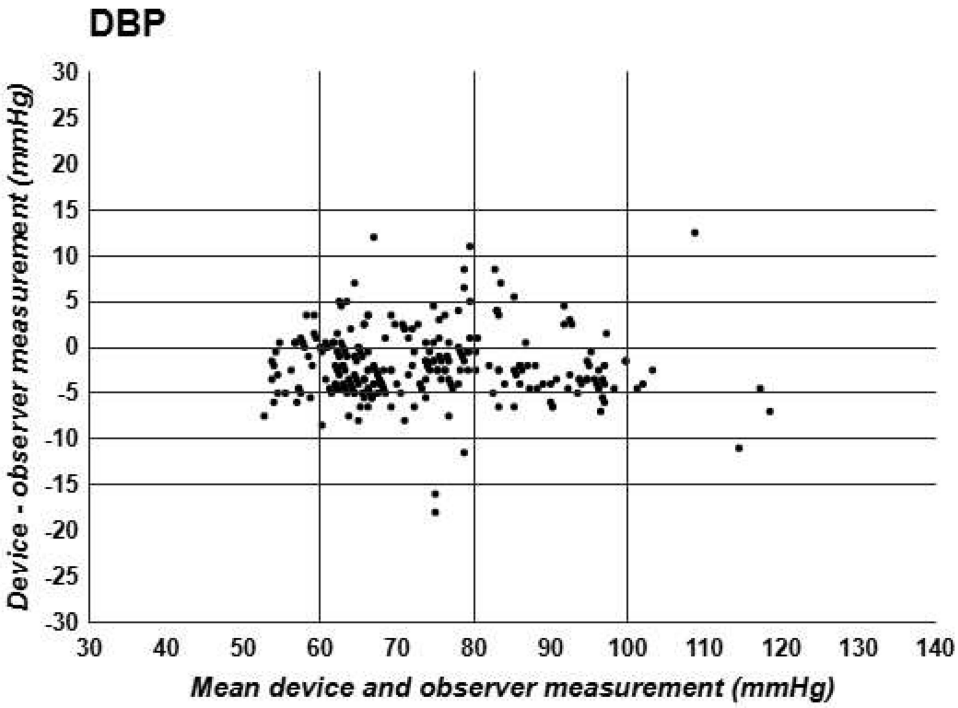
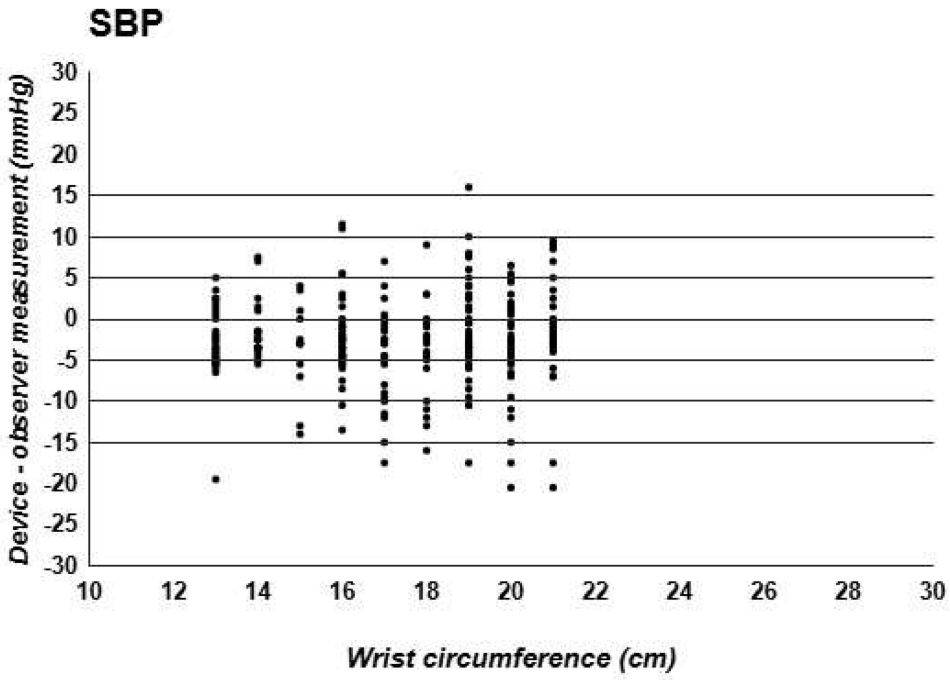


Figure 2 Standardized Bland-Altman scatter plots of test-reference BP differences against their mean values. Panel (**A**) SBP = systolic blood pressure; Panel (**B**) DBP = diastolic blood pressure.

Figure 2 depicts the differences against mean values for SBP (Panel A) and DBP (Panel B), demonstrating uniform scatter and no significant proportional bias.

A- Systolic Blood Pressure



B- Diastolic Blood Pressure

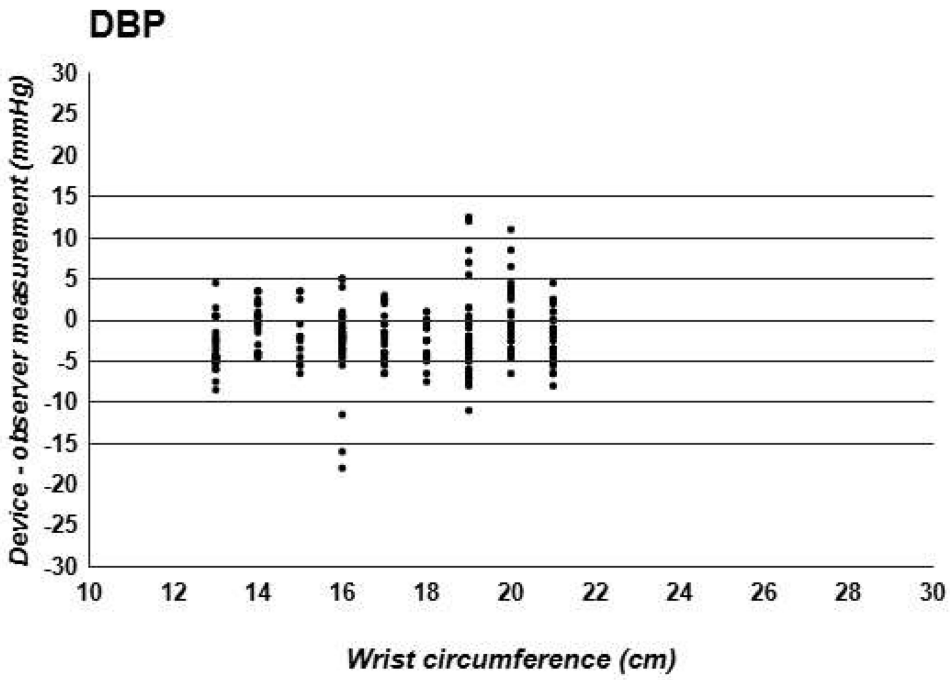


Figure 3 Scatter plots showing the differences between test-reference BP values according to the wrist circumferences. Panel (**A**) SBP = systolic blood pressure; Panel (**B**) DBP = diastolic blood pressure.

Figure 3 illustrates the relationship between BP differences and wrist circumference for SBP (Panel A) and DBP (Panel B). The plots confirm consistent performance of the test device across the full range of wrist circumferences.

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Overall, the tested device, Combei BP880W, demonstrated compliance with all requirements of the ISO 81060–2:2018/AMD 1:2020 protocol, achieving satisfactory accuracy for both SBP and DBP measurements. These findings indicate that the device is qualified as "PASSED" and suitable for home use.

Discussion

Previously, we published in this journal the validation of another device from the same manufacturer, the Combei BP118A, which measures BP at upper arm level.[14] The present study is the first clinical validation study of the Combei BP880W (MDD) wrist blood pressure (BP) monitor, developed by Combei Technology & Co., for BP measurement in the general population. The results indicate that the device meets the accuracy requirements outlined in the ISO 81060–2:2018/AMD 1:2020 Universal Protocol, successfully fulfilling both Criterion 1 (population-level accuracy) and Criterion 2 (individual-level accuracy).[10–12] This assessment is critical for ensuring reliable BP measurements prior to recommending such devices for home-based BP monitoring.

Accurate BP measurement is essential for the diagnosis and management of hypertension and other cardiovascular conditions. The clinical guidelines universally recommend the use of validated BP monitors to avoid diagnostic and therapeutic errors.[1–4] Both healthcare professionals and consumers are urged to verify the validation status of BP devices through professional websites that list approved monitors.[10–13] The findings of this study, therefore, support the inclusion of Combei BP880 W (MDD) on such recommendation lists.

Strengths and Considerations

Advantages of Oscillometric BP Monitors

Oscillometric BP monitors, such as the Combei BP880W (MDD), offer several advantages over traditional auscultatory methods, including ease of use, reduced operator dependence, and applicability in diverse settings. These benefits contribute to their growing adoption in clinical and home environments. However, concerns persist regarding inter-individual variability associated with oscillometric measurements. Certain individuals may exhibit increased variability in repeated BP measurements compared to the auscultatory method. This variability underscores the need to verify device accuracy not only at the population level, as performed in this study, but also at the individual level, particularly when devices are used for long-term self-monitoring.

Compliance with BP Measurement Conditions

BP measurement can be affected by many causes of error, including those related to the observer and the conditions under which the equipment is used. Wrist devices are more sensitive to such errors than those measuring BP at arm level. In particular, BP measurement at wrist level can be particularly affected by the wrist position in reference to the heart and the position of the hand (flexion/extension) in reference to the axis of the forearm. To overcome these errors, some devices include a "position-sensor" to alert the user to poor wrist position and allow measurement only when the position is deemed acceptable. In this regard, each manufacturer provides detailed instructions on the conditions for measuring BP using its own device. Some recommend using a forearm support, while others recommend placing the hand on the contralateral shoulder, with the elbow resting on a table. In this study, we used the Combei BP880W device with the wrist at heart level, strictly adhering to the manufacturer's instructions to avoid any an allegation of misuse.

Special Populations

While this study exclusively evaluated the device in the general adult population, the ISO 81060–2:2018/AMD 1:2020 protocol emphasizes the importance of validating BP monitors in specific populations, such as pregnant women, children, and individuals with arrhythmias. Extrapolation of the current findings to these populations would be inappropriate and speculative. Future studies are needed to assess the device's accuracy and performance in these special populations, given their unique physiological conditions that may influence BP measurement.

Number of Validation Studies

The ISO 81060–2:2018/AMD 1:2020 Universal Protocol does not mandate a minimum number of validation studies for a device to be considered accurate. In theory, a single study demonstrating compliance with the ISO criteria could suffice for device approval. However, additional independent studies would strengthen the evidence base, offering a more comprehensive evaluation of the device's reliability and performance across various settings and populations. The current study provides a robust initial assessment, but replication of these findings in different cohorts would enhance confidence in the device's accuracy.

Implications for Practice

The successful validation of the Combei BP880W (MDD) device supports its use for BP measurement in the general population. Its compliance with international standards ensures it can be considered a reliable tool for home-based self-monitoring. This is particularly relevant given the increasing emphasis on out-of-office BP monitoring in hypertension management, which has been shown to improve diagnostic accuracy and therapeutic decision-making.

Limitations

Several limitations of this study should be acknowledged:

Population Scope: The validation was restricted to the general population, limiting its applicability to special subgroups.

Single Validation Study: Although the study adhered strictly to the ISO protocol, additional studies are needed to confirm these findings in diverse populations and settings.

Device-Specific Validation: The findings pertain specifically to the Combei BP880W (MDD) device and cannot be generalized to other wrist BP monitors without similar validation.

Conclusion

This study demonstrates that the Combei BP880W (MDD) wrist BP monitor satisfies the accuracy requirements of the ISO 81060–2:2018/AMD 1:2020 Universal Protocol. These findings highlight the importance of rigorous clinical validation in ensuring the reliability of BP monitors for home use. Further research is encouraged to evaluate the device in special populations and through independent validation studies to expand the evidence base supporting its use.

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Disclosure

All authors conducted validation studies for various manufacturers; they received honorarium for this validation study. The study, including its design, conduct, analysis, and reporting, was performed completely independently from the manufacturer Combei technology. The authors report no other conflicts of interest in this work.

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