Trial of validation of two devices for self-measurement of blood pressure according to the European Society of Hypertension International Protocol: the Citizen CH-432B and the Citizen CH-656C

Uwe V. Cotte\textsuperscript{a,\ast}, Verena H. Faltenbacher\textsuperscript{a,\ast}, Werner von Willich\textsuperscript{b} and Johannes R. Bogner\textsuperscript{a}

Objective Two devices for self-measurement of blood pressure, one at the upper arm (Citizen CH-432B) and one at the wrist (Citizen CH-656C), were evaluated according to the International Protocol of the European Society of Hypertension.

Design The International Protocol is divided into two phases: the first phase is performed on 15 selected participants with five participants in three different blood pressure ranges. If the devices passed this phase, 18 additional participants selected on the basis of the same criteria as in phase 1 were included.

Methods Two skilled observers performed the following blood pressure measurements: five measurements were performed with the mercury standard alternating with four measurements with each of the test devices per participant. The first measurement result from each device instrument was not included in the analysis. The difference between the blood pressure value given by the devices and that obtained by the two observers (mean of the two observers) was calculated for each pair of measurements and classified into three categories (within 5, 10 and 15 mmHg). The results were compared to the pass criteria established by the European Society of Hypertension. Afterwards the number of measurement differences falling within 5 mmHg was determined for each person. At least 22 of the 33 participants should have two of their three comparisons within 5 mmHg and there should be a maximum of three participants without a measurement difference within the 5 mmHg range.

Results Both tested devices passed the first phase of the validation process by exceeding the required number of comparisons falling within the 5, 10 and 15 mmHg error zones. Even the second phase confirmed the validation criteria with average differences between the device and the mercury sphygmomanometer of 0.7 ± 4.4 and −3.6 ± 4.0 mmHg for systolic blood pressure and diastolic blood pressure, respectively, for the Citizen CH-432B device and −0.7 ± 6.0 and −1.2 ± 4.5 mmHg for the Citizen CH-656C device. Phase 2 contains furthermore an individual analysis of the 33 participants, the requirements of which were also fulfilled by both devices.

Conclusion The Citizen CH-432B and the Citizen CH-656C devices pass the validation recommendations of the International Protocol. They can be recommended for clinical use.

Keywords: blood pressure, Citizen, International Protocol

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Introduction

A strong antihypertensive therapy is fundamental to avoid complications of arterial hypertension, in particular the long-term consequences such as coronary heart disease, stroke, renal failure and arterial occlusion [1,2]. In the treatment of hypertension, home blood pressure (home BP) measurement plays an important role. First of all, measuring BP at home improves patient’s compliance with antihypertensive therapy [3]. Furthermore, it eliminates the white coat effect, detects patients with resistant hypertension and patients with so-called out of office hypertension [4]. Self-monitoring has several advantages over clinic measurements, as it produces a more reproducible BP value that is devoid of placebo effects by allowing multiple readings averaged over time and by taking measurements in people’s usual environment [5]. Use of home BP measurement makes it possible to obtain multiple measurements over a long observation period under well-controlled conditions. It has been reported to be more reliable than casual (screening) BP measurement because it avoids observer bias and regression dilution [6].
As recent studies have shown, home BP measurement has a better correlation to target organ damage (microalbuminuria, left ventricle mass and intimamedia carotid thickness) of hypertension than clinic BP [7–9]. Regarding mortality, the Ohasama study indicated that also in general population’s home BP measurement has a stronger predictive power than screening BP measurements [6]. Even patients with risk factors for arterial hypertension such as genetic determination or renal diseases should think about controlling their BP themselves. In addition to medical benefits, home BP measurement also bears the advantage of cost-effectiveness. Self-monitoring at home is likely to reduce medical costs because the incidence of long-tail claims can be reduced [10].

To gain all the benefits from home BP measurement, it is important to have devices of high quality. During the last years more and more devices for home BP measurement were designed, therefore several validation protocols were developed to ensure accuracy and reliability [11–13]. Different devices are available for home BP measurement. The most popular devices are upper arm and wrist devices. Some patients prefer wrist devices, as they are normally easier to handle. They, however, also have the reputation sometimes to show inaccuracy in BP measurement. This study analyses the accuracy of two home BP devices, the Citizen CH-432B (upper arm) and the Citizen CH-656C (wrist), according to the International Protocol issued by the European Society of Hypertension (ESH) [11].

Methods
Device description
Citizen CH-432B
The Citizen CH-432B is an oscillometric device for upper arm measurements with a BP measurement range of 0–280 mmHg and heart rate range of 40–180 beats/min. A liquid crystal display shows the BP in turn with the pulse rate. Two possibilities of measuring BP exist: one is entirely automatic, whereas also a manual pressure setting is possible. The latter one is recommended if several people use the same unit or if a person with maximum BP of 170 mmHg or higher uses the device for the first time. The inflation is done automatically by an internal pump and the deflation works through an automatic air-release valve. The unit is powered by four ‘AA’ size batteries, which provide for about 200 measurements (manganese batteries) and 700 measurements (alkaline batteries), respectively. The unit’s weight is approximately 300 g. Its size is 129 mm(W) × 121.5 mm(D) × 55 mm(T). A soft cuff for an arm circumference of 22–32 cm is provided.

Citizen CH-656C
The measuring principle of the Citizen CH-656C is an oscillometric method with an internal pump for automatic inflation and an electromagnetic valve for deflation. It has a pressure measurement range from 0 to 280 mmHg and a heart rate range from 40 to 180 beats/min. The device is located on the left wrist with a soft cuff provided for wrist circumferences from 13.5 to 19.5 cm. The measured data (BP alternatively to pulse rate) are shown on a liquid crystal display and automatically stored into a memory (up to seven sets of results). The dimensions of the Citizen CH-656C are 67 mm(W) × 70 mm(D) × 29 mm(T) and it weighs approximately 100 g. Power sources are two ‘LR03’ size batteries, which conforms to ca. 400 measurements.

Study group
The study was approved by the institutional review board and informed consent was obtained from all participants. Individuals were selected via the outpatient clinic of an internist service at the University Hospital of Munich, Germany. Following the directions of the International Protocol, participants with a wide range of sex, age and BP values were selected. The study was divided into two phases. During the first phase, 15 persons (at least five men and five women) aged 30 years or older were selected. Most important for their selection was their BP, which had to correspond to one of three ranges (high, medium and low) for systolic blood pressure (SBP) and diastolic blood pressure (DBP) as shown in Table 1. SBP and DBP of each participant were categorized separately in one of the three ranges. At the end of the first phase five of the 15 participants should have SBP and DBP in each range. In the second phase another 18 participants were added, selected on the same criteria. By the end of all measurements, 11 of the 33 participants should have SBP and DBP in each range. The mean age of the 33 participants was 54.4 ± 13.4 years. Of the 33 participants included, 22 were men and 11 were women. The characteristics of the study group are shown in Table 2.

<table>
<thead>
<tr>
<th>SBP</th>
<th>DBP</th>
</tr>
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<tbody>
<tr>
<td>Low</td>
<td>90–129</td>
</tr>
<tr>
<td>Medium</td>
<td>130–160</td>
</tr>
<tr>
<td>High</td>
<td>161–180</td>
</tr>
</tbody>
</table>

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

Table 2 Characteristics of the participants (n=33)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean ± SD</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>54.4 ± 13.4</td>
<td>30–80</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>81.0 ± 11.4</td>
<td>60–100</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>176.0 ± 7.0</td>
<td>165–195</td>
</tr>
<tr>
<td>Wrist circumferences (cm)</td>
<td>17.6 ± 1.2</td>
<td>15–19.5</td>
</tr>
<tr>
<td>Arm circumferences (cm)</td>
<td>28.3 ± 2.4</td>
<td>24–32</td>
</tr>
<tr>
<td>Mean systolic pressure (mmHg) (BPA)</td>
<td>142.5 ± 24.1</td>
<td>103–180</td>
</tr>
<tr>
<td>Mean diastolic pressure (mmHg) (BPA)</td>
<td>90.7 ± 15.4</td>
<td>66–120</td>
</tr>
</tbody>
</table>

BPA, entry blood pressure.
Validation team
The validation of the devices was performed strictly according to the International Protocol issued by the ESH [11]. Two observers and one supervisor formed the validation team. The ESH demands an observer training to ensure that observers have adequate auditory and visual acuity. Therefore, the observers were trained by a web-based video tutorial, developed by a collaborative project between the British Hypertension Society and the British Medical Journal [14]. As independent observer a physicist participated in the study. A calibrated mercury sphygmomanometer was used for BP measurements of the reference values against which the two devices were validated. Before the study was conducted, all components in use were carefully checked to ensure valid measurements.

During the study, both observers performed the measurements simultaneously with a Y-tube stethoscope (Littmann Master Classic, 3M Health Care, St Paul, Minnesota, USA). The supervisor who had to check the correlations between the observer measurements also used the test devices. The observers were blinded to each other’s readings. If their measurements were more than 4 mmHg apart from each other, they had to be repeated. In phase 1, 15 participants in three different BP ranges were measured and evaluated according to the International Protocol. As both of the test devices passed the phase the validation procedure continued to phase 2.

Procedure
After introduction by the supervisor and explanation of the procedure, arm and wrist circumferences, age, weight and height of each participant were measured and documented. Only persons with an arm circumference of 22–32 cm and a wrist circumference of 13.5–19.5 cm were included in the study. These circumferences are according to the cuff sizes of the test devices. In the beginning, participants had to rest in sitting position for at least 10 min in a quiet room. Thereafter, the validation process started with a calibrated mercury sphygmomanometer. Measurements were taken simultaneously by two observers using a Y-tube stethoscope with an observer variability of no more than 4 mmHg. Sequential measurements comparing the test devices and the standard mercury sphygmomanometer were obtained in the following sequences:

1. BPA entry BP, taken by both observers simultaneously with the mercury standard. The mean of the two measurements was used to categorize the participant as low, medium or high BP candidate, separately for SBP and DBP (Table 1).
2. BPB device detection BP, taken by the supervisor. This BP was measured to allow the tested devices to determine the BP characteristics of the participant and was not included in the analysis.
3. BP1 observers 1 and 2 with the mercury standard.
4. BP2 supervisor with the test devices.
5. BP3 observers 1 and 2 with the mercury standard.
6. BP4 supervisor with the test devices.
7. BP5 observers 1 and 2 with the mercury standard.
8. BP6 supervisor with the test devices.
9. BP7 observers 1 and 2 with the mercury standard.

Measurements with the mercury standard and the Citizen CH-432B were made on the left arm at heart level. For measurements with the CH-656C device the wrist was positioned without flexion or hyperextension with the palm of the participant’s hand above in a relaxed arm position. The height of the wrist cuff was adjusted equal to the height of heart. Between the measurements at least 30 s and at most 60 s passed to prevent venous congestion and to avoid variability within the three sequential readings per participant.

Data analysis
For assessment of accuracy, only measurements BP1–BP7 were used. The mean of each pair of observer measurements was calculated and denoted as observer measurement BP1, BP3, BP5 and BP7. Each device measurement was flanked by two of these observer measurements, and one of these was selected as the comparative measurement.

1. The differences BP2–BP1, BP2–BP3, BP4–BP3, BP4–BP5, BP6–BP5 and BP6–BP7 were calculated.
2. The absolute values of the differences were calculated.
3. These were paired according to the device reading.
4. If the values in a pair were unequal, the observer measurement corresponding to the smaller difference was used.
5. If the values in a pair were equal, the first of the two observer measurements was used.

To measure the deviance of the test device measurement from the observer measurement, the calculated differences of the two values were classified according to three different error bands: whether they fall within 5, 10 or 15 mmHg. Upon completion of these steps, three device readings for SBP and DBP, respectively, have been obtained for each participant. Each of these six readings was assigned a single corresponding observer measurement, the difference between the two was calculated, and an error band of the difference was established as described.

Assessment of phase 1
Once data for five participants in each of the six BP ranges (three SBP ranges and three DBP ranges) had
been gathered (Table 1), recruitment was stopped and an interim-assessment of the devices was performed. This first assessment yielded 45 sets of measurements for both SBP and DBP.

1. The number of differences in each error band was determined.
2. A continue/fail grade was calculated according to Table 3a and 3b for both devices.
3. In case of failure of this phase, the validation would have stopped according to the protocol. Otherwise, the assessment proceeds with phase 2.

Assessment of phase 2

The second phase had to examine how accurate the devices were for individual measurements (phase 2.1) and for individual participants (phase 2.2) by determining the number of differences within the 5, 10 and 15 mmHg bands and controlling for their accuracy. After all BP ranges were filled, the assessment could be performed on a set of 99 measurements for both SBP and DBP.

1. The number of differences in each band as described above was determined.
2. A pass/fail grade for phase 2.1 was calculated according to Table 3a and 3b for the different devices.
3. For each of the 33 participants, the number of measurements falling within 5 mmHg was established.
4. A pass/fail recommendation for phase 2.2 was given according to Table 3a and 3b for both devices.
5. If the devices passed both phase 2.1 and phase 2.2, they passed the validation according to the International Protocol and therefore can be recommended for clinical use. In case of failure, clinical use is not recommended by the ESH [11].

Results

Citizen CH-432B

The classification BP measurements of the first tested device lay in the range 103–180 mmHg for SBP and 66–120 mmHg for DBP. Three ranges (low, medium and high) exist for each systolic and diastolic BP. Each group contained 11 participants, giving rise to 99 pairs of measurements, as shown in Table 1.

The top section of Table 3a shows the requirements for passing phase 1. Forty-five sets of measurements (three measurements × 15 participants) were available for analysis during the first phase of the validation process. The number of measurements differing from the mercury standard by ≤ 5, ≤ 10 and ≤ 15 mmHg are shown in Table 3a. As shown in Table 3a, the device fulfilled the requirements of phase 1.

The middle section of Table 3a shows the requirements for passing phase 2.1. In the second phase another 18 participants were recruited. After completing the measurements on all 33 participants, the data of 99 (three measurements × 33 participants) comparisons were analysed to determine the comparisons falling within the 5, 10 and 15 mmHg zone. As seen in Table 3a the device fulfilled the requirements of phase 2.1.

The bottom section of Table 3a shows the requirements for passing phase 2.2. The assessment of individual
measurements requires that at least 22 of the 33 participants had to have two of their three comparisons lying within 5 mmHg. For the evaluation of individual participant accuracy, at most three of the 33 participants are allowed a measurement deviation of more than 5 mmHg in all three comparisons. Measurements of the first device show that 31 participants had two of their three comparative values for SBP lying within 5 mmHg, whereas for DBP 26 participants fulfilled this pass criterion. Only one participant had values over 5 mmHg for all three comparative measurements. As shown in Table 3a, the device fulfilled the requirements of phase 2.2.

To sum up, these results conform to the requested criteria of the International Protocol for the primary and secondary phases. On this account the Citizen CH-432B device fulfils the validation criteria of the International Protocol and is therefore recommended for clinical use.

In addition, the difference between the device readings and observer readings and the mean BP from the device and from the two observers for all 99 points for SBP are shown in Fig. 1 and for DBP are shown in Fig. 2. The disagreement of the device was 0.7 ± 4.4 for SBP and −3.6 ± 4.0 mmHg for DBP.

**Citizen CH-656C**

The top section of Table 3b shows the requirements for passing phase 1. Forty-five sets of measurements (three measurements × 15 participants) were available for analysis in the first phase of the validation process. The number of measurements differing from the mercury standard by 5, 10 and 15 mmHg are shown in Table 3b. As shown in Table 3b, the device passed the requirements of phase 1.

The middle section of Table 3b shows the requirements for passing phase 2.1. In the second phase another 18 participants were recruited. After completing the measurements on all 33 participants, the data of 99 (three measurements × 33 participants) comparisons were analysed to determine the comparisons falling within the 5, 10 and 15 mmHg zone. As seen in Table 3b the device passes the requirements of phase 2.1.

The bottom section of Table 3b shows the requirements for passing phase 2.2. At least 22 of the 33 participants had to have two of their three comparisons lying within 5 mmHg. At most three of the 33 participants are allowed all three of their comparisons being larger than 5 mmHg. The second tested device shows that two of three comparative measurements of 27 participants for SBP and 28 participants for DBP, respectively, fell within the 5 mmHg range, and no participant had all three comparisons over 5 mmHg. As shown in Table 3b, the device fulfilled the requirements of phase 2.2.

Overall, these results conform to the requested criteria of the International Protocol for the primary and secondary phases. On this account the Citizen CH-656C device fulfils the validation criteria of the International Protocol. Clinical use is therefore recommended.

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**Fig. 1**

Plot for systolic blood pressure (SBP) (mean of observers’ and device readings) versus the difference between Citizen CH-432B and the mercury sphygmomanometer.
In addition, the difference between the device readings and observer readings and the mean BP from the device and from the two observers for all 99 points for SBP are shown in Fig. 3 and for DBP are shown in Fig. 4. The disagreement of the device was $-0.7 \pm 6.0$ for SBP and $-1.2 \pm 4.5$ mmHg for DBP.

**Discussion**

The Citizen CH-432B and Citizen CH-656C fulfilled the criteria for the validation demanded by the International Protocol for SBP and for DBP and are therefore recommended for clinical use. Even though this wrist device was accurate when tested according to the International Protocol in the validation setting, it may be inaccurate if the instructions are not strictly followed in the usual setting.

Home BP measurement is popular among patients. A growing public desire to know more about health and illness has increased the sales of devices [15]. These devices have to be validated to reassure patients of the reliability of these devices.
As a result of the increasing number of new devices on the free market the Association for the Advancement of Medical Instrumentation published in 1987 standards for electronic and aneroid sphygmomanometers [12], which included a protocol for the evaluation of the accuracy of devices. This was followed by the protocol of the British Hypertension Society [13]. Both protocols had the ambition to establish minimum standards of accuracy and performance and gave opportunity to compare one device with another. As the demanded conditions are difficult to fulfill, the Working Group on Blood Pressure Monitoring of the ESH [11] has published a simplified protocol to facilitate the evaluation process.

Our experience with the validation of these two devices shows that the recruitment of participants having high systolic (161–180 mmHg) and especially high diastolic (101–130 mmHg) BPs is the major factor that extends the time required for the validation.

Even with a period of at least 10 min to relax and to feel conditioned at the situation the BP of most participants decreased during the measurements.

Upper arm devices are still the most recommended devices for self-BP measurement because they are believed to be the most reliable devices. Wrist monitors are popular among patients, because measurements are obtained without the need to remove clothing. In addition, it is easier for elderly individuals to use wrist devices [5]. Several studies show that self-BP measurement at the wrist is at times inaccurate, particularly if the wrist is not positioned at heart level during measurement [15]. The measurements are also influenced by flexion and hyperextension of the wrist [15]. In comparison of the Citizen CH-656C and the Citizen CH-432B no significant differences in accuracy of the measurements could be detected. The Citizen CH-656C was used strictly accurate at heart level.

To avoid inaccurate measurements by patients using wrist devices at home it is necessary to advise patients and give them a proper training by a practitioner or skilled staff. Education of patients must encompass information about hypertension and cardiovascular risk, BP measurement procedures, advice on items of equipment and their proper use, protocols and interpretation of data. A patient’s proficiency must be checked before he or she should be considered competent at performing the procedure. Annual reevaluation is required [16]. Another study exists that underlined that the inaccuracy of wrist-cuff oscillometric BP devices is an arm position artefact. That study supports the use of wrist-cuff monitors for self/home use and underlines the need for a more precise definition for arm position when using all BP devices [17].

Acknowledgement
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