

Validation of two automatic devices for self-measurement of blood pressure according to the International Protocol of the European Society of Hypertension: the Omron M6 (HEM-7001-E) and the Omron R7 (HEM 637-IT)

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Background Two electronic devices for self-measurement of blood pressure – a brachial monitor, the Omron M6, and a wrist monitor, the Omron R7 – were evaluated in two separate studies according to the International Protocol of the European Society of Hypertension.

Design The International Validation Protocol is divided into two phases: the first phase is performed on 15 selected participants (45 pairs of blood pressure measurements); if the device passes this phase, 18 supplementary participants are included (54 pairs of blood pressure measurements) making a total number of 33 participants (99 pairs of blood pressure measurements) on whom the final validation is performed.

Methods The same methodology recommended by the European Society of Hypertension protocol was applied for both studies. In each study and for each participant, four blood pressure measurements were taken simultaneously by two trained observers using mercury sphygmomanometers alternately with three measurements taken by the tested device. The difference between the blood pressure value given by the device and that obtained by the two observers (mean of the two observers) was calculated for each measure. The 99 pairs of blood pressure differences were classified into three categories (≤ 5 , ≤ 10 and ≤ 15 mmHg). The number of differences in each category was compared with the number required by the International Protocol. An individual analysis was then done to determine the number of comparisons ≤ 5 mmHg for each participant. At least 22 of the 33 participants should have two of their three comparisons ≤ 5 mmHg.

Introduction

The advantages of blood pressure (BP) self-measurement have been well documented [1–3]. Indeed, self-measurement of BP provides valuable information not only for hypertension diagnosis but also for BP control of the treated patient, and it improves a patient's compliance with antihypertensive therapy [4]. Therefore, it is appropriate to encourage the widespread use of self-recorded BP as an important adjunct to the clinical care of some patients with hypertension [5,6]. Clinical indications of self-measurement of BP have been recently

Results In both studies, the two tested devices passed the first and the second phases of the validation process. The average differences between the device and mercury sphygmomanometer readings were 0.8 ± 2.7 and -1.9 ± 3.3 mmHg for systolic and diastolic blood pressure, respectively, for the Omron M6 device, and 0.2 ± 4.2 and 0.2 ± 2.9 mmHg for systolic and diastolic blood pressure, respectively, for the Omron R7 device. For both devices, readings differing by less than 5, 10 and 15 mmHg for systolic and diastolic blood pressure values fulfill the recommendation criteria of the International Protocol as well as the individual analysis.

Conclusions The Omron M6 (HEM-7001-E) and the Omron R7 (HEM 637-IT) devices fulfilled the validation recommendations of the International Protocol. *Blood Press Monit* 11:165–171 © 2006 Lippincott Williams & Wilkins.

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highlighted in several international scientific society recommendations [3,6]. Obviously, BP self-measurement is only practically useful if the devices are accurate, user-friendly and relatively inexpensive. Particular attention must be paid to ensure the accuracy of the used devices [7]. Ideally, recommended devices should have been submitted to independent clinical validation procedures. During recent years, various automated devices for self-measurement of BP have been fabricated; only some of them have been validated [7–23] according to recognized protocols specifically designed for this purpose, such as

the British Hypertension Society (BHS) protocol [24,25], the Association for the Advancement of Medical Instrumentation (AAMI) protocol [26,27] and the most recent International Protocol [22,28] published by the European Society of Hypertension (ESH). In this study, accuracy of two devices for self-measurement of BP was assessed according to the ESH protocol in two separate studies [28].

Methods

Omron M6 (HEM-7001-E)

The Omron M6 (HEM-7001-E) Omron, Kyoto, Japan device records brachial BP oscillometrically with a BP measurement range of 0–299 mmHg and heart rate range of 40–180 beat/min. Systolic blood pressure (SBP), diastolic blood pressure (DBP) and heart rate are displayed on a liquid crystal digital display. The inflation is performed using a fuzzy logic electric pumping system and the deflation by an automatic pressure release valve. Standard cuff type adult (140 mm × 480 mm), for an arm circumference of 22–32 cm, is provided. Two other cuffs, small (arm circumference 17–22 cm) and extra large (arm circumference 32–42 cm), are optional.

Omron R7 (HEM 637-IT)

For the Omron R7 (HEM 637-IT) Omron, Kyoto, Japan device records BP oscillometrically with a BP measurement range of 0–299 mmHg and heart rate range of 40–180 beat/min. SBP, DBP and heart rate are displayed on a liquid crystal digital display. The inflation is performed using a fuzzy logic electric pumping system and the deflation by an automatic pressure release valve. Standard cuff applicable to a 13.5–21.5 cm wrist circumference is provided.

Device validation

Validation studies for both the Omron M6 and the Omron R7 were assessed separately in two different populations and at different times. The evaluation of both devices was done according to the ESH protocol. For each study, the manufacturer was asked to loan three devices with three different brachial cuff sizes (small, medium and large).

Factors affecting accuracy of measurements were described by the manufacturers of both devices according to the requirements of the International Protocol and were taken into consideration during the validation procedure.

The validation team consisted of three persons experienced in BP measurement who have in addition followed a training on the basis of a CD-ROM [29] specifically developed by the French Society of Hypertension for the certification of observers involved in clinical studies. Two of the three observers simultaneously measured BP using a standard mercury sphygmomanometer, the components

of which had been carefully checked before the study, and the third observer was the supervisor who checked the values obtained by the two observers and measured the BP using the tested device.

Analysis according to the International Protocol consisted of two phases. In the first phase, 15 participants (45 BP measurements) were recruited; devices passing this primary phase proceeded to the secondary phase, for which a further 18 participants (54 BP measurements) were recruited. Both devices were validated at the same center, by the same observers but at different times and with different populations.

Participant selection

For each study, selection of participants was done according to the recommendations of the International Protocol (Table 1). Two different populations were used in the validation procedure. Arm circumferences were measured in each patient and adequate cuff sizes were used; arm circumferences were distributed by chance according to the ESH protocol. In order to fulfill the BP criteria ranges and to optimize recruitment, it is recommended that participants for the high diastolic and low systolic groups should be recruited first and then those for the high systolic and low diastolic groups. Finally, the remaining gaps should be filled. Only 33 participants with both SBP and DBP measurements were selected to validate each of the two devices.

For the primary phase, five of the 15 participants should have an SBP in each of the ranges. Similarly, five of the 15 participants should have a DBP in each of the ranges. For the secondary phase, 11 of the 33 participants (including the first 15 participants) should have SBP and DBP in each of the ranges. Three ranges for SBP and three for DBP exist, with 11 participants in each range, to provide 99 pairs of measurements. The final analysis is carried out on the 99 paired measurements.

Procedure

Blood pressure measurements by the observers

The participants were seated in a quiet room and BP measurements were started after a 10-min rest period. Arm circumference and wrist were measured and brachial BP cuff type was adapted to the circumference. All measurements were made on the left arm at heart level. BP was measured simultaneously (Y tube) with two calibrated mercury sphygmomanometers, by the two observers, alternately with the automatic device. The

Table 1 BP ranges for entry BP

	SBP (mmHg)	DBP (mmHg)
Low	90–129	40–79
Medium	130–160	80–100
High	161–180	101–130

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

observers were blinded to each other's readings. BP measurements were taken on the left arm for the Omron M6 and on the left wrist for the Omron R7.

Measurement sequence

BPA Entry BP, observers 1 and 2 each with independent mercury standard sphygmomanometers. The mean values were used to categorize the participant into a low, medium or high range separately for SBP and DBP (Table 1).

BPB Device detection BP, observer 3. This BP was measured to allow the tested device to determine the BP characteristics of the participant and was not included in the analysis.

BP1 Observers 1 and 2 with the mercury standard.

BP2 Supervisor with the tested device.

BP3 Observers 1 and 2 with the mercury standard.

BP4 Supervisor with the tested device.

BP5 Observers 1 and 2 with the mercury standard.

BP6 Supervisor with the tested device.

BP7 Observers 1 and 2 with the mercury standard.

Accuracy criteria

The concept of the International Protocol is to classify the differences between the device tested and control measurements according to whether these differences lie within 5, 10 or 15 mmHg. Differences are always calculated by subtracting the tested observer measurement from the device measurement. Differences were classified separately in this way for both SBP and DBP.

Participant measurements

For assessment of accuracy, only measurements BP1 to BP7 were used. The mean of each pair of observer measurements was calculated; this was denoted as observer measurement BP1, BP3, BP5 or BP7. Each device measurement was flanked by two of these observer measurements, and one of these was selected as the comparative measurement as follows:

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.

When this was completed, there were three device readings for SBP and three for DBP for each participant. Each of these six readings had a single corresponding observer measurement, a difference between the two and

a band for that difference categorized as 0–5, 6–10, 11–15 and > 15 mmHg).

Assessment

After all the BP ranges had been filled (Table 1), there were 45 sets of measurements for both SBP and DBP for the first phase (15 participants) and 99 sets for the second phase (33 participants).

The number of differences in each zone was calculated and compared with the number required by the International Protocol and a continue/fail grade for first phase and pass/fail grade for the second phase (phase 2.1) were determined. In addition, for the second phase, the number of measurements falling within 5 mmHg was determined for each of the 33 participants and a pass/fail recommendation was determined according to the protocol (phase 2.2). For this phase, at least 22 of the 33 participants should have at least two of their three comparisons lying within 5 mmHg, and at most three of the 33 participants can have all three of their comparisons over 5 mmHg apart.

To pass the validation and to be recommended for clinical use, a device must pass both phase 2.1 and phase 2.2. If it does not, it fails and is not recommended for clinical use.

Results

Two different populations were used in the validation procedure. About 41 participants were screened for the Omron M6 study and 35 participants for the Omron R7 study.

Omron M6 (HEM-7001-E)

In the Omron M6 study, mean age of the 33 participants included was 57 ± 13 years (18 men and 15 women), the arm circumference was 30 ± 4 cm (range: 23–42), and 26 standard cuffs and seven large cuffs were used (Table 2). The difference between the two observers was -0.1 ± 2.0 and 0.4 ± 1.5 mmHg for SBP and DBP, respectively. The mean values of 99 measurements for SBP and DBP were 141 ± 22 and 84 ± 16 mmHg, respectively, with the Omron M6 (HEM-7001-E) device and 140 ± 23 and 86 ± 16 mmHg, respectively, with the standard mercury sphygmomanometer. The mean and standard deviation of the difference were 0.8 ± 2.7 and -1.9 ± 3.3 mmHg for SBP and DBP, respectively.

Table 2 Age, arm circumference distribution and BP values for the two device populations

	Omron M6	Omron R7
Age (years)	57 ± 13	53 ± 15
Arm circumference distribution (cm)	30 ± 4	30 ± 2
Arm circumference range (cm)	23–42	26–32
BP (SBP/DBP) (mmHg)	$141 \pm 22/86 \pm 16$	$141 \pm 24/86 \pm 14$

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

In total, 45 measurements (3 measurements \times 15 participants) were available for analysis in the first phase of the validation process, and 99 (3 measurements \times 33 participants) in the second phase for each of the two devices. The number of measurements differing from the mercury standard by 5, 10 and 15 mmHg or less is shown in Table 3. These results are in concordance with the requested criteria of the International Protocol for the primary and secondary phases. Thus, the Omron M6 device fulfills the validation criteria of the International Protocol.

The difference between the device readings and the mean BP of device and the two observers for all 99 points for SBP and DBP are shown in Fig. 1.

Omron R7 (HEM 637-IT)

In the Omron R7 (HEM 637-IT) study, mean age of the 33 participants included was 53 ± 15 years (19 men and 14 women), the arm circumference was 30 ± 2 cm (range: 26–32 cm) and 33 standard cuffs were used (Table 2). The difference between the two observers was -0.2 ± 1.4 and 0.3 ± 1.5 mmHg for SBP and DBP, respectively. The mean values of 99 measurements for SBP and DBP were 141 ± 23 and 86 ± 13 mmHg, respectively, with the Omron R7 device and 141 ± 24 and 86 ± 14 mmHg, respectively, with the standard mercury sphygmomanometer. The mean and standard deviation of the difference were 0.2 ± 4.2 and 0.2 ± 2.9 mmHg for SBP and DBP, respectively.

In total, 45 measurements (3 measurements \times 15 participants) were available for analysis in the first phase of the validation process, and 99 (3 measurements \times 33 participants) in the second phase for each of the two devices. The number of measurements differing from the mercury standard by 5, 10 and 15 mmHg or less is shown in Table 4. These results are in concordance with the requested criteria of the International Protocol for the primary and secondary phases. Thus, the Omron R7 device fulfills the validation criteria of the International Protocol.

The difference between the device readings and the mean BP of device and the two observers for all 99 points for SBP and DBP are displayed in Fig. 2.

Table 3 Results of the Omron M6 (HEM-7001-E) device

Phase	Required	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Recommendation	Mean difference	SD	
Phase 1	One of	25	35	40	Continue			
		SBP	35	43				45
		DBP	36	41				44
Phase 2.1	Two of	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Recommendation			
		65	80	95				
		All of	60	75				90
		SBP	83	97				99
DBP	84	95	98	Pass	-1.9	3.8		
Phase 2.2	Required	$2/3 \leq 5$ mmHg	$0/3 > 5$ mmHg		Recommendation			
		≥ 22	≤ 3	≥ 22				
		SBP	30	0				30
		DBP	29	2				29

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

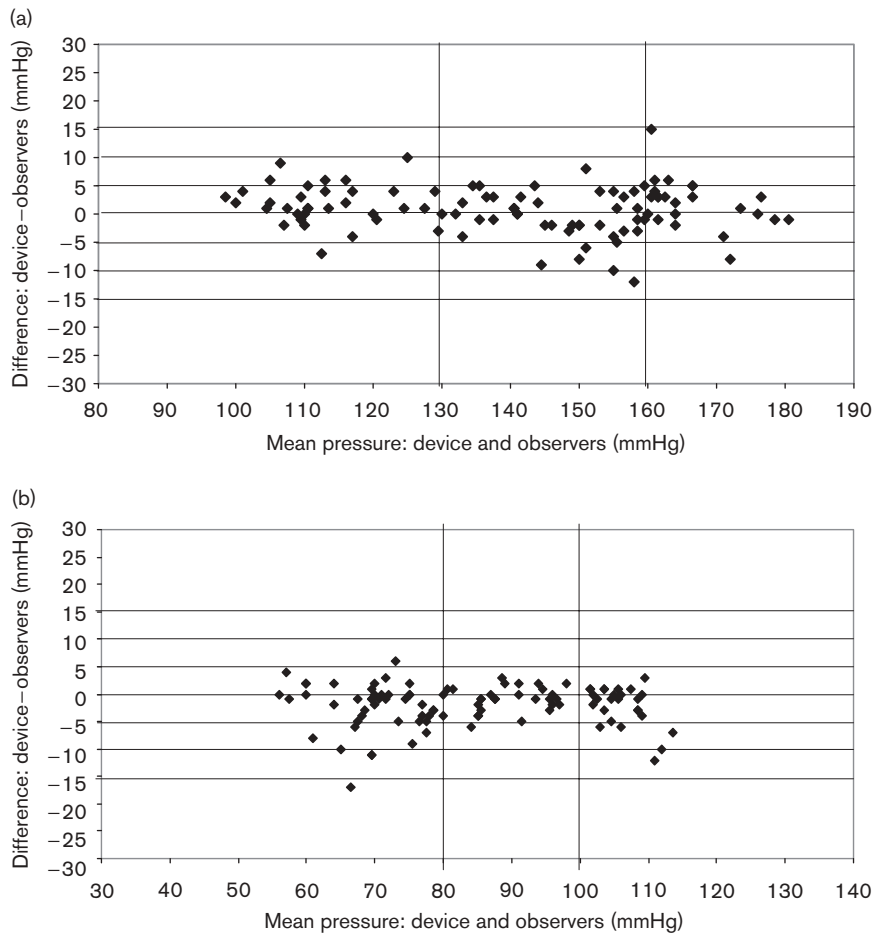
Discussion

The tested devices, Omron M6 (HEM-7001-E) and Omron R7 (HEM 637-IT), fulfilled the validation criteria of the International Protocol for SBP and DBP. The International Protocol recommendations [28] have been published by the Working Group on Blood Pressure Monitoring of the ESH, aiming to simplify the two main available guidelines, the BHS [24,25] and AAMI [26,27] protocols, without sacrificing their integrity. These two validation protocols have many similarities but experience has demonstrated that the conditions they recommend are sometimes extremely difficult to fulfill especially because of the large number of participants who have to be recruited and the ranges of BP required. It has been demonstrated by the ESH Working Group that validation studies can be performed in such a way as to satisfy the criteria of the much more complicated earlier protocols [28]. The main advantage of the International Protocol is that it requires a lower number of participants, 33 instead of 85 with the two further protocols.

Our experience with the validation of these two devices shows that the recruitment of participants having low SBP (90–129 mmHg) and especially high DBP (101–130 mmHg) is the major factor that extends the time required for the validation, although the International Protocol recommends that recruitment of participants should commence by targeting those likely to have pressures in the low-systolic and high-diastolic ranges so that it will be easy to complete the recruitment with the remaining ranges.

Another point that remains a limitation of the present study is that the results are based on only one device and the validation was done in only one center; however, the International Protocol [28] does not specify the number of devices to be tested or the number of study sites recommended to enhance the heterogeneity of the study population. The AAMI protocol [26,27] recommends more than one study site without specifying the number and without noting the number of devices used for the validation. On the other hand, the BHS protocol [24,25] does not specify performing the validation in more than one site but recommends assessing the capability of a

Fig. 1



Omron M6 (HEM-7001-E) device: plots for (a) systolic blood pressure (SBP) and (b) diastolic blood pressure (DBP) (means of observer and device readings) versus the difference between the Omron M6 device and the mercury sphygmomanometer.

Table 4 Results of the Omron R7 (HEM 637-IT) device

Phase	Requirement	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Recommendation	Mean difference	SD
Phase 1	Required	One of	25	35	40	Continue Continue	
		SBP	35	40	45		
		DBP	39	44	45		
Phase 2.1	Two of	≤ 5 mmHg	65	80	95	Pass Pass	0.2 0.2
		All of	60	75	90		
		SBP	75	90	98		
		DBP	88	98	99		
Phase 2.2	Required	2/3 ≤ 5 mmHg	0/3 > 5 mmHg		Recommendation		
		≥ 22	≤ 3	≥ 22			
		SBP	28	1			
	DBP	31	1	31			

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

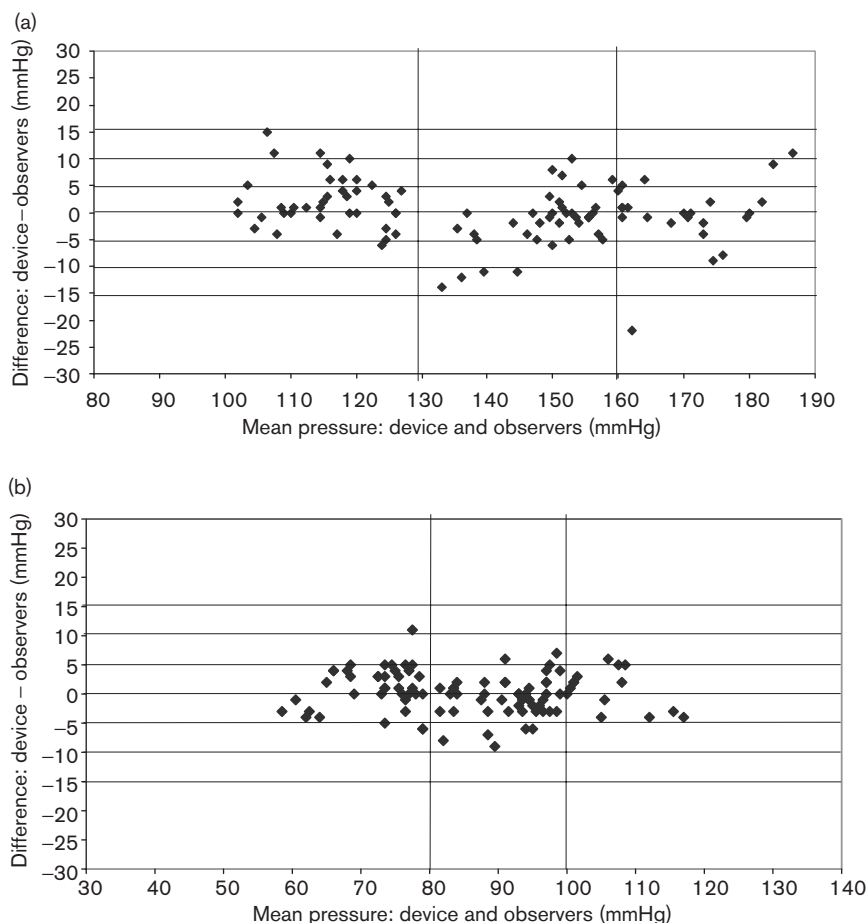
number of devices of the tested model to give consistent measurements, and if substantial differences between instruments of the same device occur, further device validation is not appropriate.

It is important to mention here that these validations were performed in the general population and that the

observed results cannot be extrapolated to specific populations such as the elderly, the obese, children, etc. Specific validation studies are needed in specific populations.

This analysis shows that with the Omron M6 (HEM-7001-E) and the Omron R7 (HEM 637-IT) the device-observer

Fig. 2



Omron R7 (HEM 637-IT) device: plots for (a) systolic blood pressure (SBP) and (b) diastolic blood pressure (DBP) (means of observer and device readings) versus the difference between the Omron HEM 637-IT device and the mercury sphygmomanometer.

limits of agreement widened with SBP rather than with DBP. This difference seems to be more important at higher SBP. With regard to DBP, the difference is more obvious at lower rather than at higher DBP. The increased error at extremes of BP occurs in virtually all non-invasive devices, but the degree of error varies [15,16,30]. It is, however, also important to recognize that this usually bears little clinical relevance as therapeutic decisions would not differ significantly [15].

In conclusion, both tested devices, Omron M6 (HEM-7001-E) and Omron R7 (HEM 637-IT), have passed the validation criteria of the International Protocol for validation of BP measuring devices.

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