

Validation of four automatic devices for self-measurement of blood pressure according to the International Protocol of the European Society of Hypertension

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Background: Four electronic devices for self-measurement of brachial blood pressure (BP): the Omron M1 Plus, the Omron M6 Comfort, the Spengler KP7500 D, and the Microlife BP A100 Plus, were evaluated in four separate studies according to the International Protocol of the European Society of Hypertension (ESH).

Design: The International Validation Protocol is divided into 2 phases: the first phase is performed on 15 selected subjects (45 pairs of BP measurements); if the device passes this phase, 18 supplementary subjects are included (54 pairs of BP measurements) making a total number of 33 subjects (99 pairs of BP measurements) on which the final validation is performed.

Methods: The same methodology recommended by the ESH protocol was applied for the 4 studies. In each study and for each subject, 4 BP measurements were performed simultaneously by 2 trained observers using mercury sphygmomanometers alternately with 3 measurements by the tested device. The difference between the BP 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 BP differences were classified into 3 categories (≤ 5 , ≤ 10 , ≤ 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 for each subject the number of comparisons ≤ 5 mmHg. At least 22 of the 33 subjects should have 2 of their 3 comparisons ≤ 5 mmHg.

Results: All 4 tested devices passed the first and the second phase of the validation process. The average differences between the device and mercury sphygmomanometer readings were -1.4 ± 5.5 and -0.4 ± 4.8 mmHg for SBP and DBP respectively for the Omron M1 Plus device, -2.1 ± 7.4 and 0.1 ± 4.9 mmHg for SBP and DBP respectively for the Omron M6 Comfort device, -1.4 ± 8.6 and -0.1 ± 3.5 mmHg for SBP and DBP respectively for the Spengler KP7500 D device, and 1.6 ± 4.2 mmHg and 0.54 ± 2.8 mmHg for SBP and DBP respectively for the Microlife BP A100 Plus device. For all devices, readings differing by less than 5, 10, and 15 mmHg for SBP and DBP values fulfill the recommendation criteria of the International Protocol as well as the individual analysis.

Conclusions: Omron M1 Plus (HEM-4011C-E), Omron M6 Comfort (HEM 7000-E), Spengler KP7500 D, and Microlife BP A100 Plus devices fulfilled the validation recommendations of the International Protocol.

Keywords: Omron M1 Plus (HEM-4011C-E), Omron M6 Comfort (HEM-7000-E), Spengler KP7500 D and Microlife BP A100 Plus, validation, International Protocol, self-blood pressure measurement

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Introduction

Advantages of blood pressure (BP) self-measurement have been well documented (Pickering et al 1996; White 1998; O'Brien et al 2005). Indeed, self-BP measurement

(sBPM) not only provides valuable information for hypertension diagnosis but also on BP control of the treated patient, and it improves patient's compliance with antihypertensive therapy (Haynes et al 1976). 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 (Thijs et al 1998; Asmar et al 2000). Clinical indications of sBPM have been recently highlighted in several international scientific society recommendations (Asmar et al 2000; O'Brien et al 2005). Obviously, BP self-measurement is only practicable if the devices are accurate, user-friendly, and relatively inexpensive. Particular attention must be paid to ensure the accuracy of the used devices (O'Brien et al 1993a). 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, but only some have been validated (O'Brien et al 1993a, 1996; Foster et al 1994; Modesti et al 1996; Cordoba et al 1997; Bortolotto et al 1999; Naschitz et al 2000; Mattu et al 2001; White et al 2001; El Assaad et al 2002; Cuckson et al 2002; Golar et al 2002; Ploin et al 2002; El Assaad et al 2003; Alpert et al 2004; Nolly et al 2004; Verdecchia et al 2004; Stergiou et al 2006; Topouchian et al 2006) according to recognized protocols specifically designed for this purpose, such as the British Hypertension Society (BHS) protocol (O'Brien et al 1990, 1993b), the Association for the Advancement of Medical Instrumentation (AAMI) protocol (AAMI 1987, 1993) and the most recent International Protocol (O'Brien et al 2002) published by the European Society of Hypertension (ESH). In this study, 4 devices for self-measurement of BP were validated according to the ESH protocol in 4 separate studies (O'Brien et al 2002).

Methods

Devices

Omron M1 plus (HEM-4011C-E)

The Omron M1 Plus device records brachial BP oscillometrically with a BP measurement range of 0–299 mmHg and heart rate range of 40–180 beats/min. Systolic blood pressure (SBP), diastolic blood pressure (DBP), and heart rate are displayed on a liquid crystal digital (LCD) read-out. Inflation is manual by pumping the inflation bulb. Measurement starts automatically after having stopped inflating the arm cuff. Deflation is made by pressing the air release button to release the air in the arm cuff; this is an automatic pressure release valve. Standard cuff type adult for an arm circumferences ranging from 220 to 320 mm is provided.

Omron M6 comfort (HEM-7000-E)

The Omron M6 Comfort (HEM 7000-E) device records brachial BP oscillometrically with a BP measurement range of 0–299 mmHg and heart rate range of 40–180 beats/min. SBP, DBP, and heart rate are displayed on an LCD read-out. The inflation is performed using a fuzzy-logic electric pumping system and the deflation by an automatic pressure release valve. Standard cuff type adult for an arm circumference ranging from 220 to 420 mm is provided, which fits both standard and large arm circumferences (cuff dimensions: 152 × 600 mm; weight: 240 g).

Spengler KP7500D

The Spengler KP7500D device records brachial BP oscillometrically with a BP measurement range of 20–300 mmHg and heart rate range of 40–200 beats/min. SBP, DBP, and heart rate are displayed on an LCD read-out. Inflation is automatic by a micro rolling pump. Measurement starts automatically after having pressed and released the power button. Deflation is automatic by an automatic pressure release valve to release the air in the arm cuff. Standard adult cuff type for an arm circumference ranging from 220 to 320 mm is provided.

Microlife BP A100 plus

The Microlife BP A100 Plus device records brachial BP oscillometrically with a BP measurement range of 30–280 mmHg and heart rate range of 40–200 beats/min. SBP, DBP, and heart rate are displayed on an LCD read-out. Measurement starts automatically; deflation is also automatic by a constant air release solenoid valve. Standard adult cuff type for an arm circumference ranging from 220 to 320 mm is provided. Two other cuffs, small (arm circumference 170–220 mm), and extra large cuffs (320–420 mm) are optional.

Device validation

Each device was validated separately in specific populations and at different times. Therefore, each patient participated in only one study device validation. The devices were validated according to the ESH protocol. For each study, the manufacturer was asked to loan 2 or 3 devices with 2 different size cuffs (medium and large).

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

The validation team consisted of 3 persons experienced in BP measurement who also had received training based

on a CD-ROM (Groupe d'Evaluation et de Mesure de la Société Française d'Hypertension Artérielle 1998) 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 by the tested device.

Analysis according to the International Protocol consisted of 2 phases. In the first phase, 15 subjects (45 BP measurements) were recruited; devices passing this primary phase proceeded to the second phase, for which a further 18 subjects (54 BP measurements) were recruited. All the devices were validated at the same center, by the same observers but at different times and in different populations.

Subject selection

For each study, selection of subjects was done according to the recommendations of the International Protocol (Table 1). Four different populations were used in these 4 validation procedures. Arm circumferences were measured in each patient to ensure the use of an adequate cuff size; 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 subjects for the high diastolic and low systolic groups should be recruited first, then those with high systolic and low diastolic, and finally the remaining gaps should be filled. Thirty-three subjects with both SBP and DBP measurements corresponding to the requested BP ranges were selected to validate each of the four devices.

For the primary phase, 5 of the 15 subjects should have an SBP in each of the ranges. Similarly, 5 of the 15 subjects should have a DBP in each of the ranges. For the second phase, 11 of the 33 subjects (including the first 15 subjects) should have SBP and DBP in each of the ranges. There are 3 ranges for SBP and 3 for DBP, with 11 subjects in each range to provide 99 pairs of measurements. Final analysis is performed on the 99 paired measurements.

Procedure

BP measurements by the observers

The subjects were seated in a quiet room and BP measurements started after a 10-minute rest period. Arm circumference was measured and brachial BP cuff size was adapted to the circumference. All measurements were made on the left arm

at the heart level. BP was measured simultaneously (Y tube) with 2 calibrated mercury sphygmomanometers by the two observers alternately with the device undergoing validation. The observers were blinded to each other's readings.

Measurements were carried out in the following sequence for all 4 validation procedures:

BPA Entry BP, observers 1 and 2 each with independent mercury standard sphygmomanometer. The mean values were used to categorize the subject 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 subject 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.

Subject 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 between BP2-BP1, BP2-BP3, BP4-BP3, BP4-BP5, BP6-BP5, and BP6-BP7 were calculated.

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

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

- 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 2 observer measurements was used.

When this had been completed, there were 3 device readings for SBP and 3 for DBP for each subject. Each of these 6 readings had a single corresponding observer measurement, a difference between the two and a band for that difference categorized as follows: (0–5 mmHg, 6–10 mmHg, 11–15 mmHg, >15 mmHg).

Assessment

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

The number of differences in each zone was calculated and compared to the number required by the International Protocol and a continue/fail grade for first phase and pass/fail grade for second phase (phase 2.1) was determined. Also for the second phase, the number of measurements falling within 5 mmHg was determined for each of the 33 subjects and a pass/fail recommendation was determined according to the protocol (phase 2.2). For this phase at least 22 of the 33 subjects should have at least 2 of their 3 comparisons lying within 5 mmHg. And at most 3 of the 33 subjects can have all three of their comparison 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

Different populations were used in each of the validation procedures. The number of subjects screened for each device's study was: 43 pre-included subjects for the Omron M1 Plus, 52 for the Omron M6 Comfort, 46 for the Spengler KP7500 D, and 47 for the Microlife BP A100 Plus.

Omron M1 plus (HEM-4011C-E)

In the Omron M1 Plus study, mean age of the 33 subjects included was 58 ± 13 (21 men and 12 women), the arm circumference was 28 ± 4 (range: 19–38), and 26 standard cuffs, 6 large cuffs, and 1 small cuff were used (Table 2). The BP difference between the two observers was 0.95 ± 1.4 mmHg and 0.08 ± 0.84 mmHg for SBP and DBP respectively. The mean values of 99 measurements for SBP and DBP were respectively $136.5 \pm 20.9/89.6 \pm 16.4$ mmHg with the Omron M1 Plus (HEM-4011C-E) device and $137.9 \pm 22.1/90 \pm 16$ mmHg with the standard mercury sphygmomanometer. The mean and standard deviation of the difference between the device and the observers were -1.4 ± 5.5 and -0.4 ± 4.8 mmHg for SBP and DBP respectively.

In total, 45 measurements (3 measurements \times 15 subjects) were available for analysis in the first phase of the validation process, and 99 (3 measurements \times 33 subjects) in the second phase. The number of measurements differing from the mercury sphygmomanometer standard by 5, 10, and 15 mmHg or less are shown in Table 3. These results are in accordance with the requested criteria of the International Protocol for the primary and secondary phases. Thus the Omron M1 Plus device fulfills the validation criteria of the International Protocol.

The difference between the device readings and the mean BP of the device and the two observers for all 99 points for SBP and DBP are shown in Figure 1a and Figure 2a respectively.

Omron M6 comfort (HEM-7000-E)

In the Omron M6 Comfort (HEM-7000-E) study, mean age of the 33 subjects included was 52 ± 15 (19 men and 14 women), the arm circumference was 29 ± 4 (range: 19–34), so the standard cuff was used for all subjects (Table 2). The difference between the two observers was 0.36 ± 1.88 mmHg and 0.34 ± 1.14 mmHg for SBP and DBP respectively. The mean values of 99 measurements for SBP and DBP were respectively $133.8 \pm 24.2/85.2 \pm 13.9$ mmHg with the Omron M6 Comfort device and $135.9 \pm 22.7/85.2 \pm 13.8$ mmHg with

Table 2 Age, arm circumference distribution, and BP values for all four devices populations

	Omron M1 Plus	Omron M6 Comfort	Spengler KP7500D	Microlife BP A100 Plus
Age (years)	58 ± 13	52 ± 15	59 ± 13	57 ± 13
Arm circ. distribution (cm)	28 ± 4	29 ± 4	30 ± 4	29 ± 4
Arm circ. range (cm)	19–38	19–34	23–40	24–38
BP (SBP/DBP) (mmHg)	$136.5 \pm 20.9/89.6 \pm 16.4$	$133.8 \pm 24.2/85.2 \pm 13.9$	$138 \pm 20.2/83.6 \pm 17.0$	$141.9 \pm 24.5/84.5 \pm 16.4$

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

Table 3 Results of the OMRON M1 Plus (HEM-4011C-E) device

Phase 1		≤5 mmHg	≤10 mmHg	≤15 mmHg	Recomm.		
Required	One of	25	35	40			
Achieved	SBP	41	44	45	Continue		
	DBP	39	44	45	Continue		
Phase 2.1		≤5 mmHg	≤10 mmHg	≤15 mmHg	Recomm.	Mean diff.	SD
Required	Two of	65	80	95			
	All of	60	75	90			
Achieved	SBP	83	97	99	Pass	-1.4	5.5
	DBP	80	93	98	Pass	-0.4	4.8
Phase 2.2		2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg		Recomm.		
Required		≥22	≤3				
Achieved	SBP	29	0		Pass		
	DBP	27	1		Pass		

Abbreviations: SBP, systolic blood pressure; DBP, diastolic blood pressure; Recomm., recommendation; Mean diff., mean difference (mmHg); SD, standard deviation (mmHg).

the standard mercury sphygmomanometer. The mean and standard deviation of the difference between the device and the observers were -2.13 ± 7.37 and 0.09 ± 4.91 mmHg for SBP and DBP respectively.

In total, 45 measurements (3 measurements \times 15 subjects) were available for analysis in the first phase of the validation process, and 99 (3 measurements \times 33 subjects) in the second phase. The number of measurements differing from the mercury standard by 5, 10, and 15 mmHg or less are shown in Table 4. These results are in accordance with the requested criteria of the International Protocol for the primary and secondary phases. Thus the Omron M6 Comfort device fulfills the validation criteria of the International Protocol.

The difference between the device readings and the mean BP of the device and the two observers for all 99 points for SBP and DBP are shown in Figure 1b and Figure 2b respectively.

Spengler KP7500D

In the Spengler KP7500D study, mean age of the 33 subjects included was 59 ± 13 (21 men and 12 women), the arm circumference was 30 ± 4 (range: 23–40), and 29 standard cuffs and 4 large cuffs were used (Table 2). The difference between the two observers was 0.01 ± 2.01 mmHg and 0.1 ± 1.6 mmHg for SBP and DBP respectively. The mean values of 99 measurements for SBP and DBP were respectively $138 \pm 20.2/83.6 \pm 17.0$ mmHg with the Spengler KP7500D device and $139.4 \pm 21.9/83.7 \pm 16.3$ mmHg with the standard mercury sphygmomanometer. The mean and standard deviation of the difference between the device and the observers were -1.4 ± 8.6 and -0.1 ± 3.5 mmHg for SBP and DBP respectively.

In total, 45 measurements (3 measurements \times 15 subjects) were available for analysis in the first phase of the validation process, and 99 (3 measurements \times 33 subjects) in the second phase. The number of measurements differing from the mercury standard by 5, 10, and 15 mmHg or less are shown in Table 5. These results are in accordance with the requested criteria of the International Protocol for the primary and secondary phases. Thus the Spengler KP7500D device fulfills the validation criteria of the International Protocol.

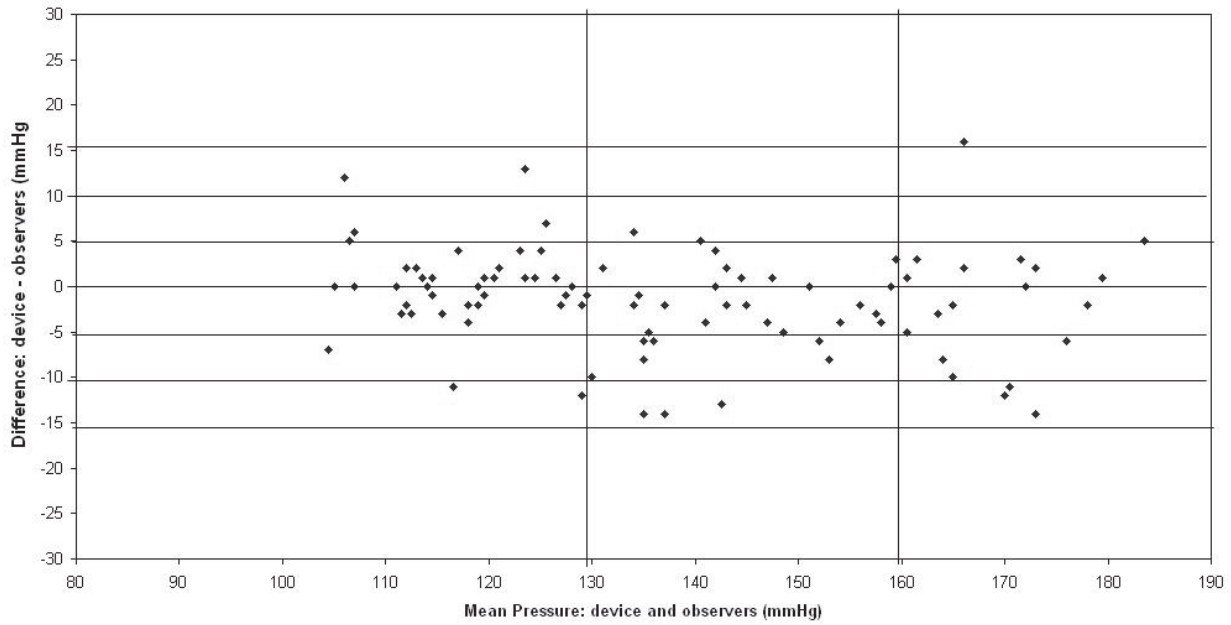
The difference between the device readings and the mean BP of the device and the two observers for all 99 points for SBP and DBP are shown in Figure 1c and Figure 2c respectively.

Microlife BP A100 plus

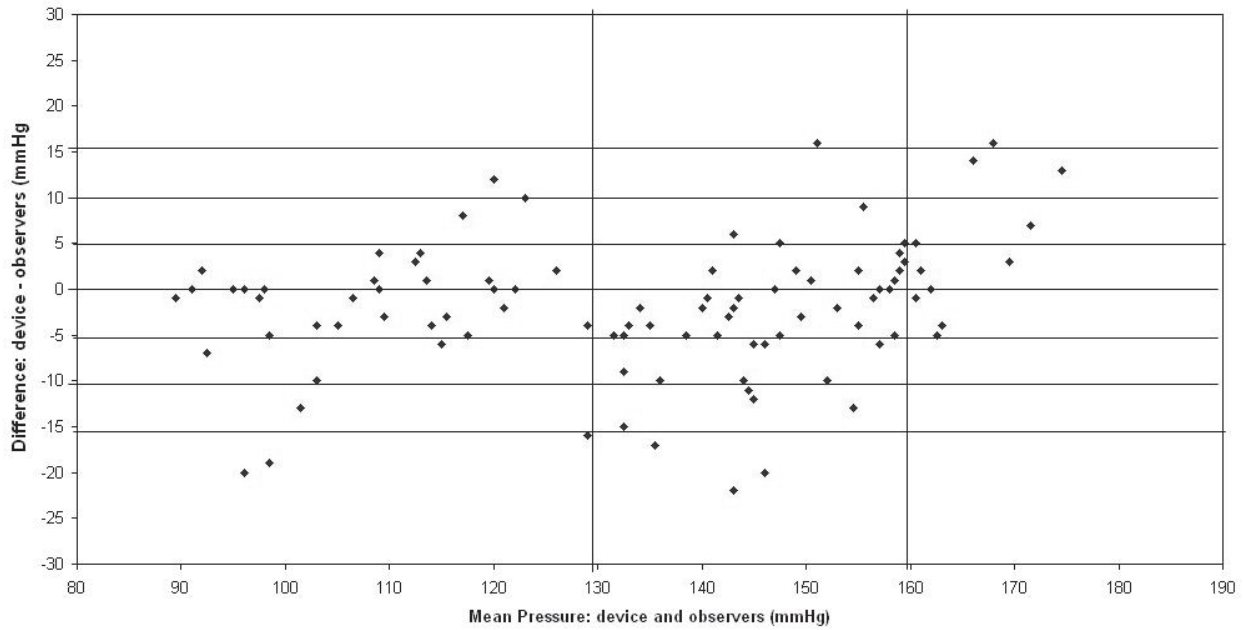
In the Microlife BP A100 Plus study, mean age of the 33 subjects included was 57 ± 13 (23 men and 10 women), the arm circumference was 29 ± 4 (range: 24–38), and 26 standard cuffs and 7 large cuffs were used (Table 2). The difference between the two observers was 0.067 ± 1.7 mmHg and 0.12 ± 0.98 mmHg for SBP and DBP respectively. The mean values of 99 measurements for SBP and DBP were respectively $141.9 \pm 24.5/84.5 \pm 16.4$ mmHg with the Microlife BP A100 Plus device and $140.3 \pm 24.7/83.9 \pm 17.35$ mmHg with the standard mercury sphygmomanometer. The mean and standard deviation of the difference between the device and the observers were 1.6 ± 4.2 and 0.54 ± 2.8 mmHg for SBP and DBP respectively.

In total, 45 measurements (3 measurements \times 15 subjects) were available for analysis in the first phase of the validation process, and 99 (3 measurements \times 33 subjects) in the second phase. The number of measurements differing from the mercury standard by 5, 10, and 15 mmHg or less, are shown in

a)
Plot of SBP difference between the test device and the mean of the 2 observers in 33 subjects (n=99)



b)
Plot of SBP difference between the test device and the mean of the 2 observers in 33 subjects (n=99)



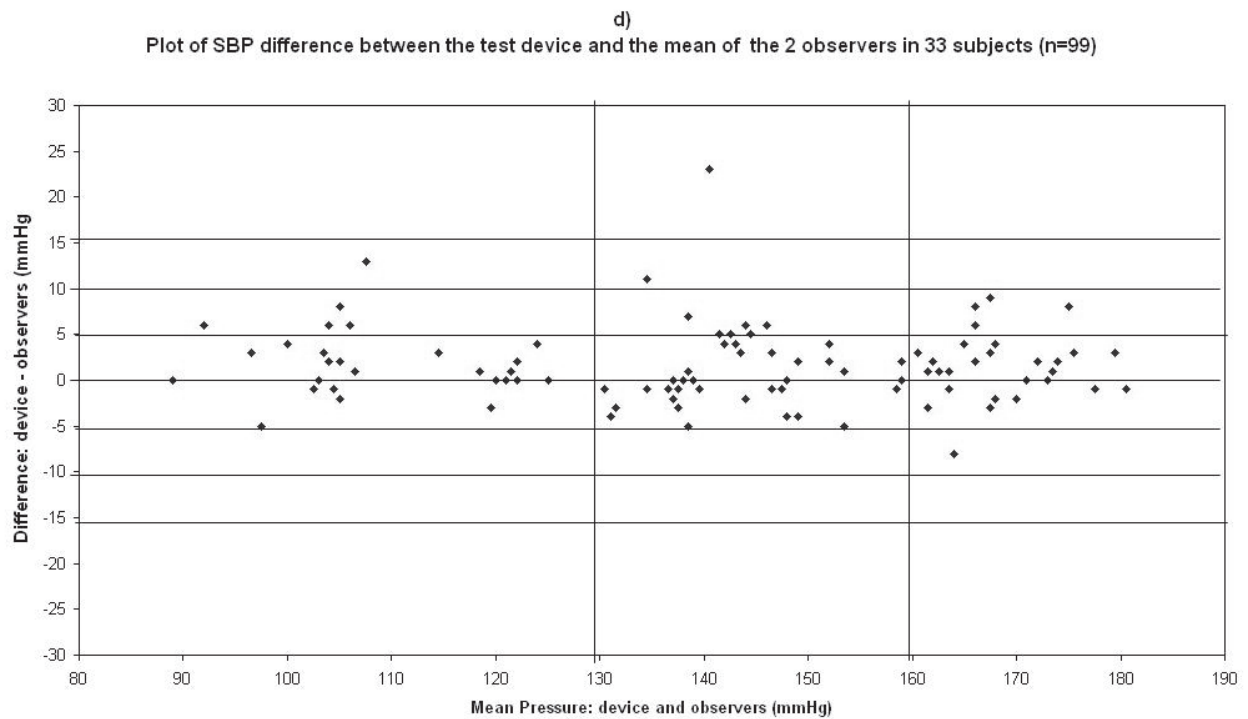
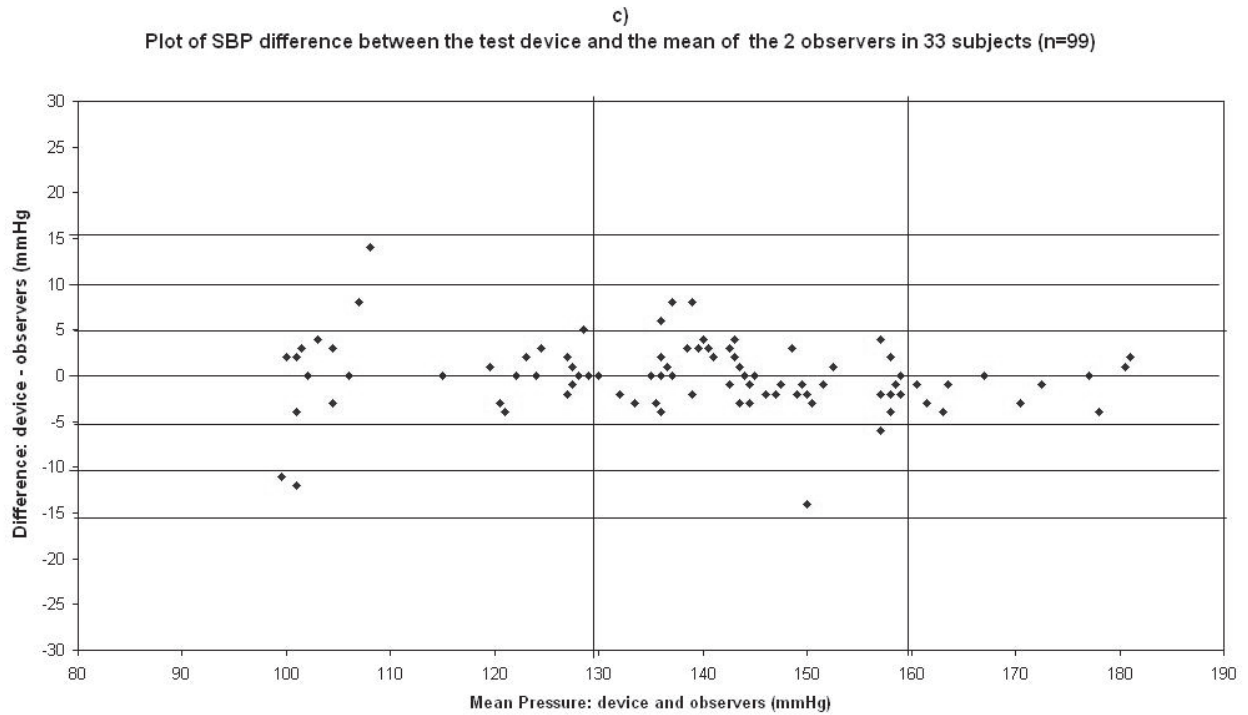
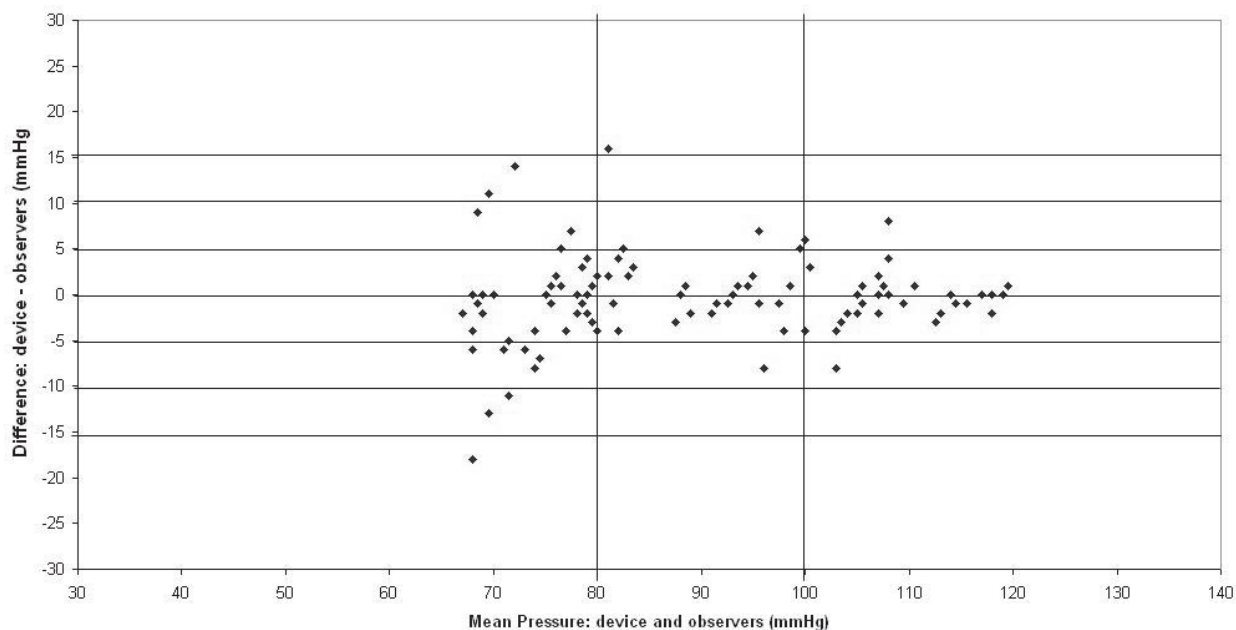
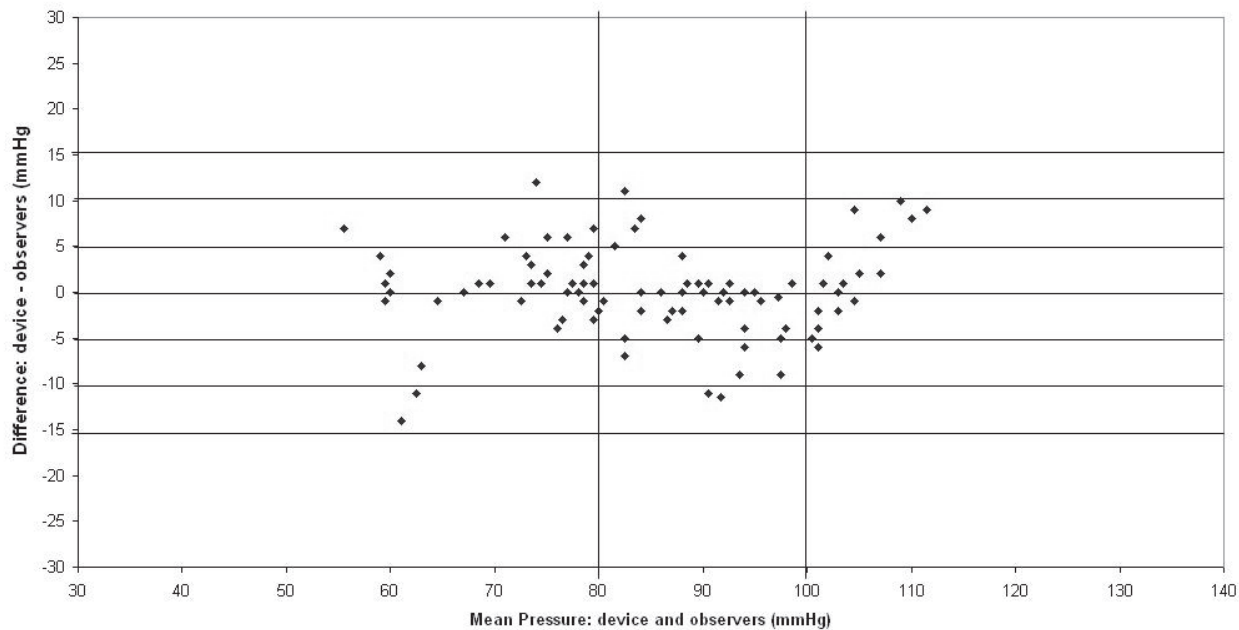


Figure 1 Plots for systolic blood pressure (SBP) difference between the test device readings and the mean of the two observer readings in 33 participants ($n = 99$) versus the mean of the devices and the mercury sphygmomanometer readings: (a) Omron M1 Plus (HEM 4011C-E), (b) Omron M6 Comfort (HEM-7000-E), (c) Spengler KP7500D, (d) Microlife BP A100 Plus.

a)
Plot of DBP difference between the test device and the mean of the 2 observers in 33 subjects (n=99)



b)
Plot of DBP difference between the test device and the mean of the 2 observers in 33 subjects (n=99)



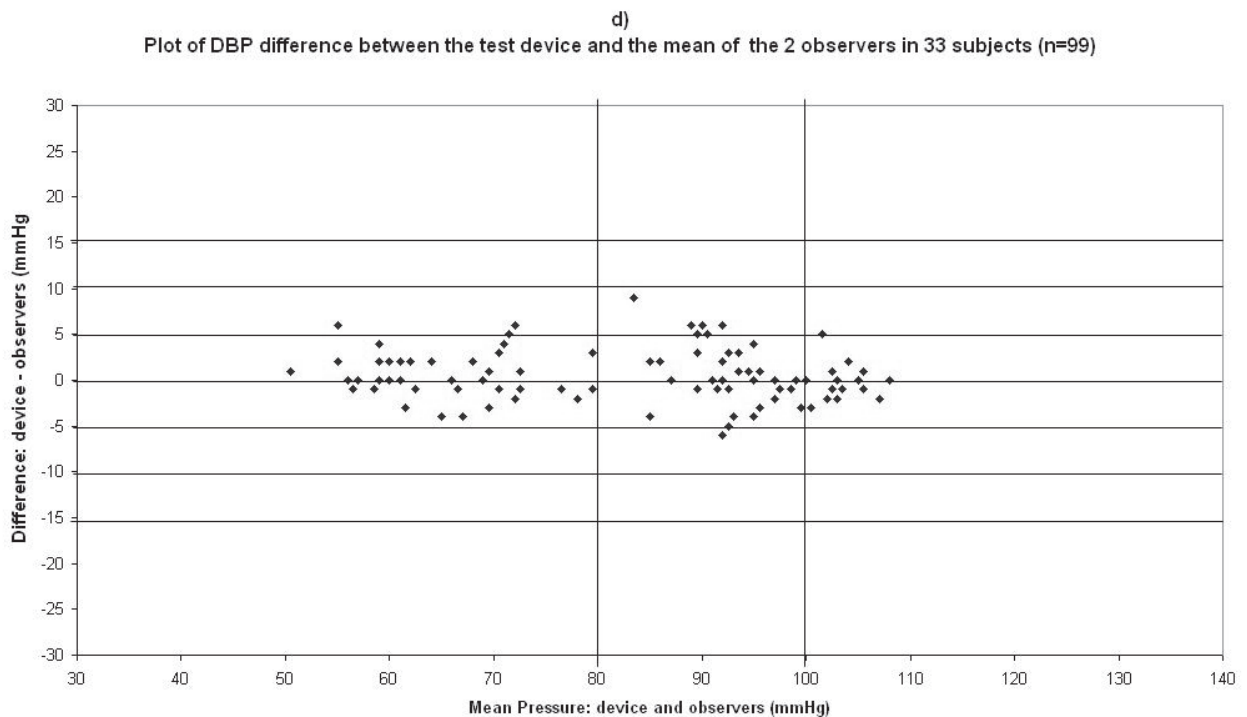
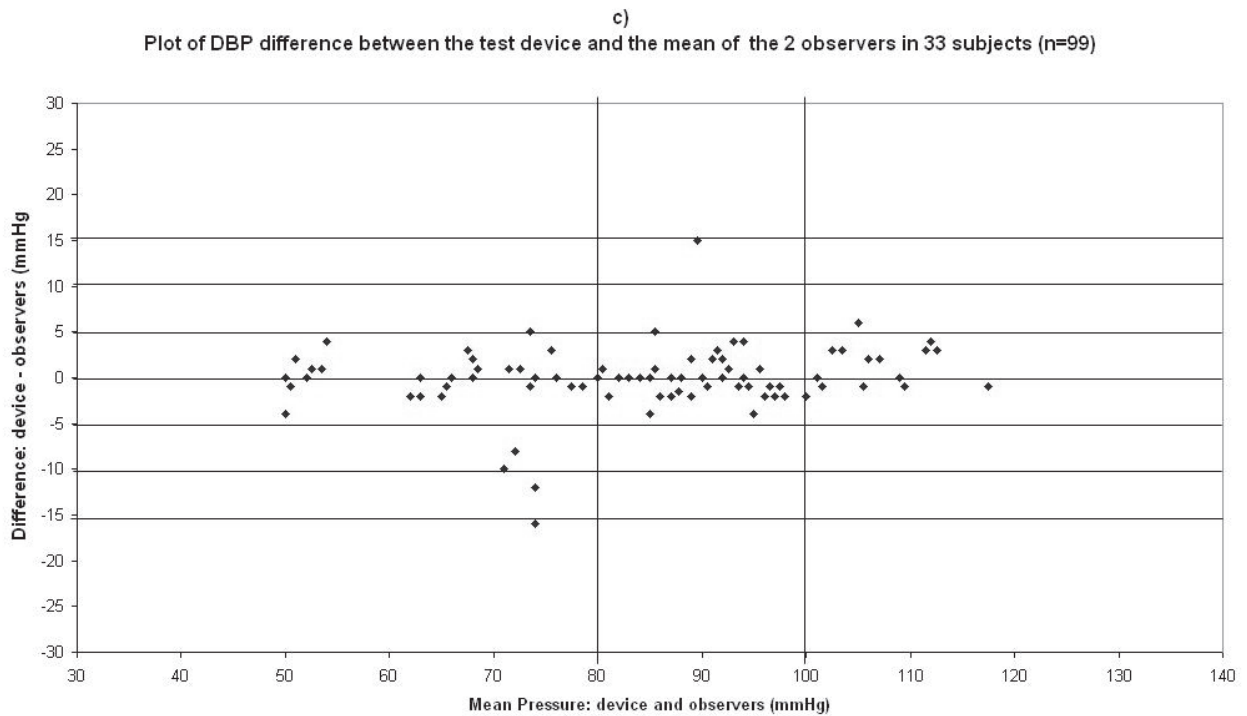


Figure 2 Plots for diastolic blood pressure (DBP) difference between the test device readings and the mean of the two observer readings in 33 participants (n = 99) versus the mean of the devices and the mercury sphygmomanometer readings: (a) Omron M1 Plus (HEM 4011C-E), (b) Omron M6 Comfort (HEM-7000-E), (c) Spengler KP7500D, (d) Microlife BPA100 Plus.

Table 4 Results of the OMRON M6 Comfort (HEM 7000-E) device

Phase I		≤5 mmHg	≤10 mmHg	≤15 mmHg	Recomm.		
Required	One of	25	35	40			
Achieved	SBP	32	37	40	Continue		
	DBP	38	43	45	Continue		
Phase 2.1		≤5 mmHg	≤10 mmHg	≤15 mmHg	Recomm.	Mean diff.	SD
Required	Two of	65	80	95			
	All of	60	75	90			
Achieved	SBP	67	81	90	Pass	-2.1	7.4
	DBP	73	93	99	Pass	0.1	4.9
Phase 2.2		2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg		Recomm.		
Required		≥22	≤3				
Achieved	SBP	25	3		Pass		
	DBP	25	3		Pass		

Abbreviations: SBP, systolic blood pressure; DBP, diastolic blood pressure; Recomm., recommendation; Mean diff., mean difference (mmHg); SD, standard deviation (mmHg).

Table 6. These results are in accordance with the requested criteria of the International Protocol for the primary and secondary phases. Thus the Microlife BP A100 Plus device fulfills the validation criteria of the International Protocol.

The difference between the device readings and the mean BP of the device and the two observers for all 99 points for SBP and DBP are shown in Figure 1d and Figure 2d respectively.

Discussion

The tested devices, Omron M1 Plus (HEM-4011C-E), Omron M6 Comfort (HEM-7000-E), Spengler KP7500D, and Microlife BP A100 Plus, fulfilled the validation criteria of the International Protocol for SBP and for DBP. The International Protocol recommendations (O'Brien et al 2002) have been published by the Working Group on Blood Pressure Monitoring of the ESH with the aim of simplifying the two main available guidelines, the BHS (O'Brien et al

1990, 1993b) and AAMI (AAMI 1987, 1993) 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 subjects 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 (O'Brien et al 2002). The main advantage of the International Protocol is that it requires fewer subjects, 33 instead of 85 with the two other protocols.

Our experience with the validation of these devices shows that the recruitment of subjects 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 subjects should commence by targeting those

Table 5 Results of the Spengler KP7500D device

Phase I		≤5 mmHg	≤10 mmHg	≤15 mmHg	Recomm.		
Required	One of	25	35	40			
Achieved	SBP	40	40	42	Continue		
	DBP	42	43	44	Continue		
Phase 2.1		≤5 mmHg	≤10 mmHg	≤15 mmHg	Recomm.	Mean diff.	SD
Required	Two of	65	80	95			
	All of	60	75	90			
Achieved	SBP	86	92	96	Pass	-1.4	8.6
	DBP	93	96	98	Pass	-0.1	3.5
Phase 2.2		2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg		Recomm.		
Required		≥22	≤3				
Achieved	SBP	29	1		Pass		
	DBP	31	1		Pass		

Abbreviations: SBP, systolic blood pressure; DBP, diastolic blood pressure; Recomm., recommendation; Mean diff., mean difference (mmHg); SD, standard deviation (mmHg).

Table 6 Results of the Microlife BP A100 Plus device

Phase 1		≤5 mmHg	≤10 mmHg	≤15 mmHg	Recomm.		
Required	One of	25	35	40			
Achieved	SBP	40	45	45	Continue		
	DBP	42	45	45	Continue		
Phase 2.1		≤5 mmHg	≤10 mmHg	≤15 mmHg	Recomm.	Mean diff.	SD
Required	Two of	65	80	95			
	All of	60	75	90			
Achieved	SBP	84	96	98	Pass	1.6	4.2
	DBP	91	99	99	Pass	0.54	2.8
Phase 2.2		2/3 ≤ 5mmHg	0/3 > 5 mmHg		Recomm.		
Required		≥22	≤3				
Achieved	SBP	30	2		Pass		
	DBP	33	0		Pass		

Abbreviations: SBP, systolic blood pressure; DBP, diastolic blood pressure; Recomm., recommendation; Mean diff., mean difference (mmHg); SD, standard deviation (mmHg).

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 limit 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 (O'Brien et al 2002) 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 (AAMI 1987, 1993) 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 (O'Brien et al 1990, 1993b) does not specify performing the validation in more than one site but recommends assessing the capability of a number of devices of the tested model to give consistent measurements. If substantial differences between instruments of the same device occur, further device validation is not appropriate. In this regard, Stergiou et al (2006) reported recently similar results for the Microlife BP A100 Plus device.

It is important to mention here that these validation studies were performed in the general population and that the observed results cannot be extrapolated to specific populations such as the elderly, the obese, and children. Specific validation studies are needed in specific populations.

This study shows that increased error at extremes of BP occurs in virtually all non-invasive devices, but the degree of error varies (White et al 2001; El Assaad et al 2002; Geddes et al 1982). It is, however, also important to recognize that this usually bears little clinical relevance since therapeutic decisions would not significantly differ (White et al 2001).

In conclusion, the tested devices, Omron M1 Plus (HEM-4011C-E), Omron M6 Comfort (HEM-7000-E), Spengler KP7500D, and Microlife BP A100 Plus have passed the

validation criteria of the International Protocol for validation of BP measuring devices.

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