

Validation of four devices: Omron M6 Comfort, Omron HEM-7420, Withings BP-800, and Polygreen KP-7670 for home blood pressure measurement according to the European Society of Hypertension International Protocol

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Background: Four oscillometric devices, including the Omron M6 Comfort, Omron HEM-7420, Withings BP-800, and Polygreen KP-7670, designed for self-blood pressure measurement (SBPM) were evaluated according to the European Society of Hypertension (ESH) International Protocol Revision 2010 in four separate studies.

Methods: The four devices measure brachial blood pressure (BP) using the oscillometric method. The Withings BP-800 has to be connected to an Apple® iOS device such as an iPhone®, iPad®, or iPod®. The ESH International Protocol Revision 2010 includes a total number of 33 subjects. The difference between observer and device BP values was calculated for each measure. Ninety-nine pairs of BP differences were classified into three categories (≤ 5 mmHg, ≤ 10 mmHg, ≤ 15 mmHg). The protocol procedures were followed precisely in each of the four studies.

Results: All four tested devices passed the validation process. The mean differences between the device and mercury readings were: -1.8 ± 5.1 mmHg and -0.4 ± 2.8 mmHg for systolic and diastolic BP, respectively, using the Omron M6 Comfort device; 2.5 ± 4.6 mmHg and -1.2 ± 4.3 mmHg for the Omron HEM-7420 device; -0.2 ± 5.0 mmHg and 0.4 ± 4.2 mmHg for the Withings BP-800 device; and 3.0 ± 5.3 mmHg and 0.3 ± 5.2 mmHg for the Polygreen KP-7670 device.

Conclusion: Omron M6 Comfort, Omron HEM-7420, Withings BP-800, and Polygreen KP-7670 readings differing by less than 5 mmHg, 10 mmHg, and 15 mmHg fulfill the ESH International Protocol Revision 2010 requirements, and therefore are suitable for use by patients for SBPM, if used correctly.

Keywords: Omron M6 Comfort, Omron HEM-7420, Withings BP-800, Polygreen KP-7670, self-blood pressure measurement, validation, European Society of Hypertension International Protocol Revision

Introduction

All national and international guidelines for management of hypertension agree that accurate blood pressure (BP) measurement is the *sine qua non* for successful management of the condition.^{1,2} Whereas most of the guidelines mention that office BP measurement is the gold standard method, they agree that this method has to be performed in a number of situations outside the medical environment.³⁻⁵ In this regard, the advantages of self-BP measurement (SBPM) have been well documented.^{4,5} Indeed, SBPM

provides not only valuable information for diagnosis of hypertension but also for BP control in the treated patient, and improves patient compliance with antihypertensive therapy.^{4,5} Therefore, it is appropriate to encourage the widespread use of SBPM as an important adjunct to the clinical care of patients with hypertension.⁴ The clinical indications for SBPM have recently been highlighted in several guidelines and consensus conferences.^{1,4,6}

Obviously, SBPM is only practicably useful if devices are user-friendly, adapted to patient conditions, and accurate. Considerable efforts have been made by manufacturers to improve the quality of devices, which have become automatic and more robust. One of the remaining weak points of devices that measure brachial BP is cuff characteristics.⁵⁻⁸ In order to facilitate the use and dissemination of SBPM to more subjects with a wide variety of arm circumference, some manufacturers have started using the concept of a single-sized cuff. It is obvious that this type of device, like others, needs to go through independent validation procedures, as recommended by scientific societies. Such validation has to be performed according to recognized protocols specifically designed for this purpose, such as the British Hypertension Society protocol,⁹ the Association for the Advancement of Medical Instrumentation/International Standards Organization (AAMI/ISO) protocol,¹⁰ or the International Protocol^{11,12} published by the European Society of Hypertension (ESH), the latter currently being the most popular.

This paper presents the results of four validation studies for SBPM devices performed according to the ESH International Protocol, ie, the Polygreen KP-7670, which uses multiple cuffs, and three others that use a single-sized cuff, ie, the Omron M6 Comfort, the Omron HEM-7420, and Withings BP-800 (the latter designed specifically for Apple® iOS devices).¹² All four devices use the oscillometric method to determine systolic and diastolic BP.

Materials and methods

Devices tested

Omron M6 Comfort

The Omron M6 Comfort (HEM-7221-E) monitor was randomly selected and provided by the manufacturer (Omron Healthcare, Kyoto, Japan). It is a digital automatic device for home BP measurement at the arm level. The monitor uses a Fuzzy-logic inflation system controlled by an electric pump and an automatic pressure release valve for deflation. It records BP using the oscillometric method with a pressure range of 0–299 mmHg and a pulse rate range of 40–180 beats per minute. Systolic BP, diastolic BP, and pulse rate

are displayed on a liquid crystal digital screen. The device can display a symbol on the liquid crystal digital screen if it detects an irregular heartbeat, defined by a heart rhythm that varies by more than 25% from the average heart rhythm detected while the unit is measuring BP. It includes memory for 90 measurements and can also calculate an average reading based on measurements from the last three readings taken within 10 minutes. The unit weighs approximately 380 g without batteries. Four AA alkaline batteries are needed, with an approximate capacity of 1,000 measurements. The single cuff included is made of semirigid nylon/polyester with dimensions of 152 × 600 mm, weighs approximately 240 g, and is applicable for arm circumferences ranging from 22 cm to 42 cm. A specific error message is given if the cuff is not applied correctly.

Omron HEM-7420

The Omron HEM-7420 monitor was randomly selected and provided by the manufacturer (Omron Healthcare). It is a digital automatic device for home BP measurement at the arm level. The monitor uses a Fuzzy-logic inflation system controlled by an electric pump and automatic pressure release valve for deflation. It records BP using the oscillometric method with a pressure range of 0–299 mmHg and a pulse rate range of 40–180 beats per minute. Systolic BP, diastolic BP, and pulse rate are displayed on a liquid crystal digital screen. The device includes memory for 90 measurements and can also calculate an average reading based on the measurements from the last three readings taken within 10 minutes. It can also store the measurement values for two users and calculate morning, evening, daily, and weekly average values. The unit weighs approximately 430 g without batteries. Four AA alkaline batteries are needed, with an approximate capacity of 300 measurements. The single cuff included is an easy-fit nylon/polyester cuff with dimensions of 120 × 530 mm, weighs approximately 130 g, and can be used for arm circumferences ranging from 17 cm to 36 cm.

Withings BP-800

The Withings BP-800 device was provided by the manufacturer (Withings, Paris, France). It is an automatic device for home BP measurement at the arm level. The device is specifically designed to be connected to an Apple iOS and fits an iPhone®, iPad®, or iPod®. A specific Withings BP-800 free application that can be downloaded from the App® store is needed to operate the device. Inflation is automatic to 30 mmHg over the systolic BP, at 15 mmHg per second, by an electric pump fitted on the cuff. Deflation is linear at

6 mmHg per second by an actively controlled pressure release valve. The unit records BP using the oscillometric method with a pressure range of 0–285 mmHg and a pulse rate range of 40–180 beats per minute. Systolic BP, diastolic BP, and pulse rate are displayed on the screen of the iOS device. The Withings BP-800 application allows one or three consecutive BP measurements, and can calculate average values and display recording graphs. Recordings can be forwarded by email or synchronized with other health records. The unit weighs approximately 600 g without batteries. Four AAA batteries are needed, with an approximate capacity of 300 measurements. Moreover, the Apple device should have sufficient battery charge. The single cuff included is made of easy-fit Lycra with dimensions of 150 × 600 mm and can be used for arm circumferences ranging from 22 cm to 42 cm.

Polygreen KP-7670

The Polygreen KP-7670 monitor was randomly selected and provided by the manufacturer (Polygreen K-Jump, Taipei, Taiwan). It is a digital automatic device for home BP measurement at the arm level. The monitor uses a microrolling pump for inflation and an electrical solenoid valve for deflation. It records BP using the oscillometric method with a pressure range of 20–300 mmHg and a pulse rate range of 40–200 beats per minute. Systolic BP, diastolic BP, and pulse rate are displayed on a large liquid crystal digital screen. The device includes memory for 100 measurements, and can store measurement values for five users. The unit weighs approximately 480 g with batteries. Four AA alkaline batteries are needed, with an approximate capacity of 250 measurements. A standard-sized cuff made of nylon/polyester is included and can be used for arm circumferences ranging from 22 cm to 32 cm. Optional small and large cuffs can be applied. The small cuff is used for an arm circumference of 17–22 cm and the large cuff for an arm circumference of 32–42 cm.

Blood pressure measurements

Before the validation study per se, a familiarization period of about one week took place in an outpatient clinic. During this period, the investigators involved in each study familiarized themselves with the use of the test devices.

Each device validation study was assessed in specific populations, separately from the other device validations. Therefore, each patient participated in only one study device validation. Evaluation of the devices was done according to the ESH International Protocol Revision 2010. For each study, the manufacturer was asked to provide three devices confirmed to be standard production models. Omron and

Polygreen sent three devices from each model, and Withings BP-800 sent three devices including an iPod with the necessary software. 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 for each study consisted of three persons experienced in BP measurement. In addition, all investigators completed training on the basis of a CD-ROM specifically developed by the French Society of Hypertension for certification of observers involved in clinical studies.¹³ Two of the three observers measured BP using a Littman® teaching stethoscope (3M, St Paul, MN, USA) for simultaneous measurements (Y tube) and two standard mercury sphygmomanometers (Rudolf Riester GmbH, Jungingen, Germany), the components of which had been carefully checked before the study (Dupont Medical, Pantin, France); the third observer was the supervisor who checked the agreement of BP values obtained by the two observers, who were blinded to each other's readings. The supervisor also measured BP using the tested automatic devices. Three cuffs were used for the standard mercury sphygmomanometer measurements: a small cuff for an arm circumference of 17–22 cm, a standard cuff for an arm circumference of 22–32 cm, and a large cuff for an arm circumference of 32–42 cm.

Population

The four validation studies were performed in the general population. According to the ESH International Protocol Revision 2010, a total of 33 participants fulfilling the age, gender, and entry BP requirements (age ≥25 years, at least ten men and ten women, 11 participants with entry BP in each of the ranges 90–129 mmHg, 130–160 mmHg, and 161–180 mmHg for systolic BP and 40–79 mmHg, 80–100 mmHg, and 101–130 mmHg for diastolic BP) were included in each study. In order 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. In these four studies, subjects were preselected from outpatient clinics. The Omron and Polygreen studies were performed at the Lebanese University-affiliated hospitals (Mount-Lebanon, Lebanese Hospital Geitawi), and the Withings study was performed at the Hôtel Dieu Hospital, Paris, France.

Procedure

Subjects were seated in a quiet room and BP measurements were started after a 10-minute rest period. Arm circumference was

Table 1 Clinical characteristics of subjects included in each study

	Omron M6 Comfort	Omron HEM-7420	Withings BP-800	Polygreen KP-7670
Total subjects screened (n)	47	47	42	49
M/F	16/17	17/16	18/15	19/14
Age (years)	59±14	56±16	55±14	47±14
Arm circumference (cm)	31±4	31±3	30±4	29±4
Hypertension treatment (n)	26	25	26	17
Initial mercury sphygmomanometer				
SBP	142±21 (98–171)	145±20 (106–179)	147±25 (95–179)	146±27 (94–180)
DBP	88±15 (56–111)	90±17 (59–118)	88±17 (50–118)	89±17 (58–118)

Notes: Omron M6 Comfort and HEM-7420 (Omron Healthcare, Kyoto, Japan); Withings BP-800 (Withings, Paris, France); Polygreen KP-7670 (Polygreen K-Jump, Taipei, Taiwan).

Abbreviations: DBP, diastolic blood pressure; SBP, systolic blood pressure; M, male; F, female.

measured and the cuff type was adapted for the mercury sphygmomanometer measurements. All measurements were made on the left arm at the heart level. BP was measured simultaneously by the two observers alternately with the automatic device as mentioned above. Patients with arrhythmia were excluded. Nine consecutive BP measurements were carried out according to the International Protocol, which was strictly followed.¹² Verbal informed consent was obtained from all patients.

Analysis

Differences between the tested device and control measurements were classified according to whether their values lay within 5 mmHg, 10 mmHg, or 15 mmHg. Differences were calculated by subtracting the observer measurement from

the device measurement, and were classified separately in this way for both systolic and diastolic BP. The number of differences in each zone was calculated and compared with the number required by the ESH International Protocol Revision 2010. Details of the analysis procedure have been published elsewhere.¹² Briefly, the data were expressed as the mean ± standard deviation, and minimum and maximum values along with ranges were calculated. Bland and Altman plots were used to show the deviations, and linear correlation coefficients were calculated to analyze the differences according to age, BP level, and arm circumference.

Results

Omron M6 Comfort

The clinical characteristics of the 33 included subjects are shown in Table 1. For the mercury sphygmomanometer, the standard-sized cuff was used in 22 subjects and a large-sized cuff in eleven subjects. The difference between the two observers was 0.0±2.0 mmHg and -0.2±1.9 mmHg for systolic BP and diastolic BP, respectively (-4 to +4 mmHg). The mean differences between the observers and the tested device were -1.8±5.1 mmHg and -0.4±2.8 mmHg for systolic BP and diastolic BP, respectively.

The numbers of measurements differing from the mercury standard by 5 mmHg, 10 mmHg, and 15 mmHg or less are shown in Table 2. The differences between the device readings and the mean BP of the device and two observers for all 99 points of systolic BP and diastolic BP are shown in Figure 1. These results are in concordance with the requested criteria of the International Protocol. Thus, the Omron M6 Comfort device fulfills

Table 2 Results of the Omron M6 Comfort (HEM 7221-E) (Omron Healthcare, Kyoto, Japan) device according to the European Society of Hypertension International Protocol Revision 2010

	≤5 mmHg	≤10 mmHg	≤15 mmHg	Grade I	Mean difference	SD
Part 1						
Required						
Two of	73	87	96			
All of	65	81	93			
Achieved						
SBP	78	91	98	Pass	-1.8	5.1
DBP	94	99	99	Pass	-0.4	2.8
Part 2	2/3 ≤5 mmHg	0/3 ≤5 mmHg		Grade 2		Grade 3
Required	≥24	≤3				
Achieved						
SBP	28	1		Pass		Pass
DBP	33	0		Pass		Pass
Part 3						Pass

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

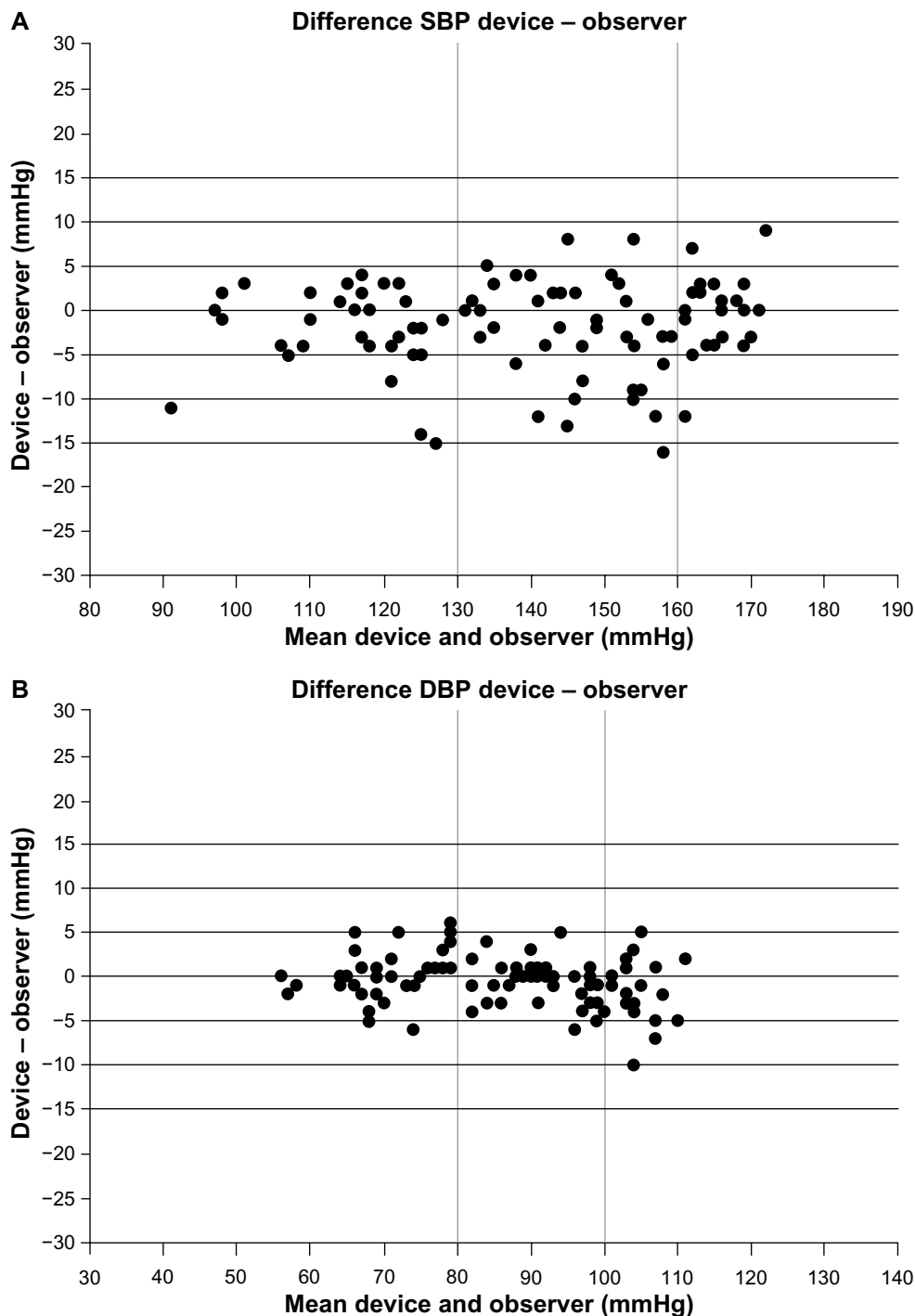


Figure 1 Plots showing difference in blood pressure between the Omron M6 Comfort (HEM-7221-E) (Omron Healthcare, Kyoto, Japan) readings and the mean of two observer readings in 33 participants (n=99). **(A)** SBP and **(B)** DBP. Points in bold are multiple (superimposition).

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

the validation criteria of the ESH International Protocol Revision 2010.

Omron HEM-7420

This study included 33 subjects (17 men and 16 women), whose clinical characteristics are shown in Table 1. For the

mercury sphygmomanometer, the standard-sized cuff was used in 20 subjects and a large-sized cuff in 13 subjects. The difference between the two observers was 0.1 ± 1.6 mmHg and -0.2 ± 1.6 mmHg for systolic BP and diastolic BP, respectively (-4 to $+4$ mmHg). The mean difference between the observers and the tested device was 2.5 ± 4.6 mmHg

and -1.2 ± 4.3 mmHg for systolic BP and diastolic BP, respectively.

The numbers of measurements differing from the mercury standard by 5 mmHg, 10 mmHg, and 15 mmHg or less are shown in Table 3. The differences between the device readings and the mean BP of device and the two observers for all 99 points of systolic BP and diastolic BP are shown in Figure 2. These results are in concordance with the requested criteria of the International Protocol. Thus, the Omron HEM-7420 device fulfills the validation criteria of the ESH International Protocol Revision 2010.

Withings BP-800

This study included 33 subjects, whose clinical characteristics are shown in Table 1. A standard-sized cuff was used in 25 subjects and a large-sized cuff in eight subjects. The difference between the two observers was 0.2 ± 2.1 mmHg and -0.7 ± 2.3 mmHg for systolic BP and diastolic BP, respectively (-4 to $+4$ mmHg). The mean difference between the observers and the tested device was -0.2 ± 5.0 mmHg and 0.4 ± 4.2 mmHg for systolic BP and diastolic BP, respectively.

Numbers of measurements differing from the mercury standard by 5 mmHg, 10 mmHg, and 15 mmHg or less are shown in Table 4. The differences between the device readings and the mean BP of the device and the two observers on all 99 points for systolic BP and diastolic BP are shown in Figure 3. These results are in concordance with the requested criteria of the International Protocol. Thus, the Withings BP-800 device fulfills the validation criteria of the ESH International Protocol Revision 2010.

Polygreen KP-7670

This study included 33 subjects, whose clinical characteristics are shown in Table 1. The standard-sized cuff was used in 29 subjects and a large-sized cuff in four subjects. The difference between the two observers was -0.4 ± 2.0 mmHg and 0.1 ± 2.3 mmHg for systolic BP and diastolic BP, respectively (-4 to $+4$ mmHg). The mean difference between the observers and the tested device was 3.0 ± 5.3 and 0.3 ± 5.2 mmHg for systolic BP and diastolic BP, respectively.

The numbers of measurements differing from the mercury standard by 5 mmHg, 10 mmHg, and 15 mmHg or less are shown in Table 5. Differences between the device readings and the mean BP of the device and the two observers for all 99 points for systolic BP and diastolic BP are shown in Figure 4. These results are in concordance with the requested criteria of the International Protocol. Thus, the Polygreen KP-7670 device fulfills the validation criteria of the ESH International Protocol Revision 2010.

Discussion

This study provides information on the accuracy of four devices designed for SBPM. Each of these devices measures BP using a specific algorithm and dedicated cuff in terms of dimensions and characteristics. The Omron M6 Comfort uses a specific cuff (152×600 mm) for arm circumferences of 22–42 cm; the Omron HEM-7420 uses a specific cuff (120×530 mm) for arm circumferences of 17–36 cm, with a special bladder structure. The Withings BP-800 uses a specific cuff (150×600 mm) for arm circumferences of 22–42 cm, and the Polygreen KP-7670 uses a range of cuffs. In this study, all four devices passed the validation requirements of the ESH International Protocol Revision 2010.

Table 3 Results of the OMRON HEM-7420 device (Omron Healthcare, Kyoto, Japan) according to the European Society of Hypertension International Protocol Revision 2010

	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade 1	Mean difference	SD
Part 1						
Required						
Two of	73	87	96			
All of	65	81	93			
Achieved						
SBP	78	92	99	Pass	2.5	4.6
DBP	81	95	99	Pass	-1.2	4.3
Part 2	$2/3 \leq 5$ mmHg	$0/3 \leq 5$ mmHg		Grade 2		Grade 3
Required	≥ 24	≤ 3				
Achieved						
SBP	26	0		Pass		Pass
DBP	29	0		Pass		Pass
Part 3						Pass

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

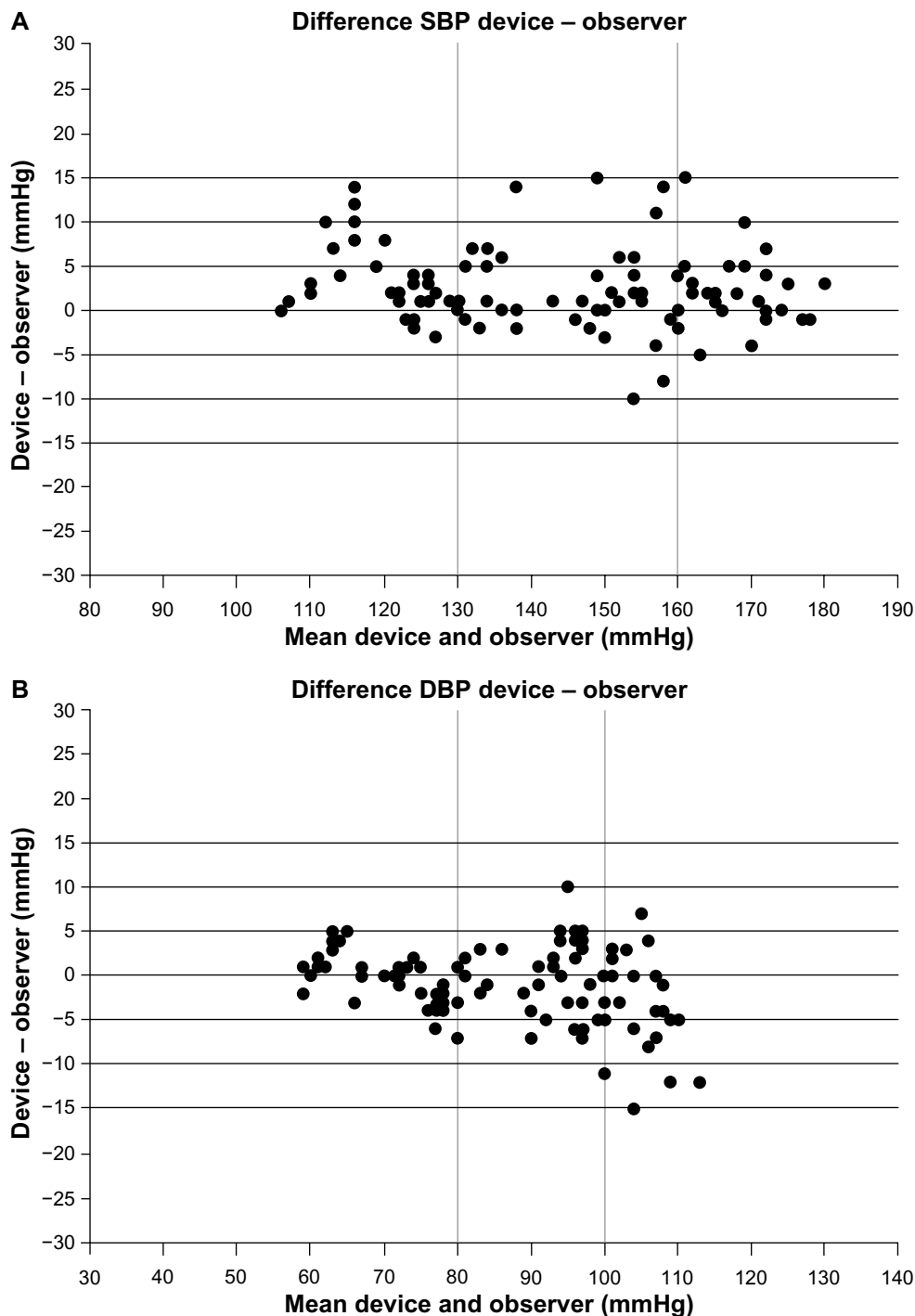


Figure 2 Plots showing difference in blood pressure between the Omron HEM-7420 (Omron Healthcare, Kyoto, Japan) readings and the mean of the two observer readings in 33 participants ($n=99$). **(A)** SBP and **(B)** DBP. Points in bold are multiple (superimposition).

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

Before their widespread application in the clinic, some important points related to both the validation protocol and the devices need to be discussed.

Considerable effort has been made by manufacturers to improve the quality of SBPM devices; however, the cuff characteristics of devices measuring brachial BP remains a point

of weakness which considerably limits their dissemination and correct use in a large part of the population. In fact, miscuffing is a frequent and serious source of errors. To overcome miscuffing, several approaches have been used over recent years but none has been ideal. The most popular are listed as follows:

Table 4 Results of the Withings BP-800 device (Withings, Paris, France) according to the European Society of Hypertension International Protocol Revision 2010

	≤5 mmHg	≤10 mmHg	≤15 mmHg	Grade I	Mean difference	SD
Part 1						
Required						
Two of	73	87	96			
All of	65	81	93			
Achieved						
SBP	78	96	98	Pass	-0.2	5.0
DBP	77	98	99	Pass	0.4	4.2
Part 2						
	2/3 ≤5 mmHg	0/3 ≤5 mmHg		Grade 2		Grade 3
Required						
	≥24	≤3				
Achieved						
SBP	26	3		Pass		Pass
DBP	27	1		Pass		Pass
Part 3						
						Pass

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

- use of a range of cuffs, with three or four different cuff sizes having been recommended according to arm circumference by several national and international bodies; this solution remains the gold standard used for BP measurements in the clinic;⁵⁻⁷
- a cuff containing three different sizes of inflatable bladders designed to allow choice of the most suitable bladder for the corresponding arm circumference; this cuff has the disadvantage of being difficult to use in the clinic in some patients because of its oversize for small and standard arm circumferences;
- the “adjustable” cuff, by means of a clamping mechanism on an inflatable bladder, is able to be used on most adult arms, but experience with this cuff has been very limited;
- a “single” cuff for the majority of arms; use of a cuff containing a bladder measuring 35 × 12 cm which would encircle the majority of adult arms has been suggested, but this needs to be validated.⁷

From the other side, to date, most SBPM devices are supplied with only one standard cuff for arms of 22–32 cm, with the possibility to purchase other optional cuffs. To facilitate use of SBPM by more subjects with a wide variety of arm circumferences, some manufacturers have started using the concept of a single universal cuff size. Despite the fact that the devices use a specific algorithm and dedicated cuff, this approach is critical because:

- a single-sized cuff may continue to induce miscuffing errors, mainly overcuffing of lean arms;
- it can be important commercially as a marketing issue, but not at the individual level;
- it has been argued that this can be interesting if the device has to be used by more than one person needing different

cuff sizes, but this is not usually the case for SBPM performed by one person;

- finally, for a given individual, use of one adapted cuff, small, medium, or large, is appropriate and limits miscuffing errors.

In this independent validation study, comparison of BP measurements obtained using single-sized cuff devices (Omron and Withings) with those obtained using a mercury sphygmomanometer with a range of cuffs showed acceptable accuracy for SBPM. These results are in accordance with those of other validation studies testing the accuracy of the “easy wrap” cuff and the impact of size and form of the cuff.^{14,15}

Study limitations

This validation was performed according to the ESH International Protocol Revision 2010.¹² This is the most popular protocol and simplifies the two other main available protocols, ie, those published by the British Hypertension Society⁹ and the AAMI/ISO,¹⁰ without sacrificing their integrity. The main advantage of this protocol is that it requires fewer subjects (33, instead of the 85 needed with the other two protocols). However, this protocol has some disadvantages and limitations. First, the population required in the International Protocol is confined to adults >25 years with some specifications in terms of age, gender, and BP level. Since such a selected population does not represent the whole population, extrapolation of the results to other populations with different characteristics may be hazardous and risky. Second, the International Protocol does not require inclusion of subjects according to their arm circumference; this can result from inclusion of only subjects with a standard arm circumference.

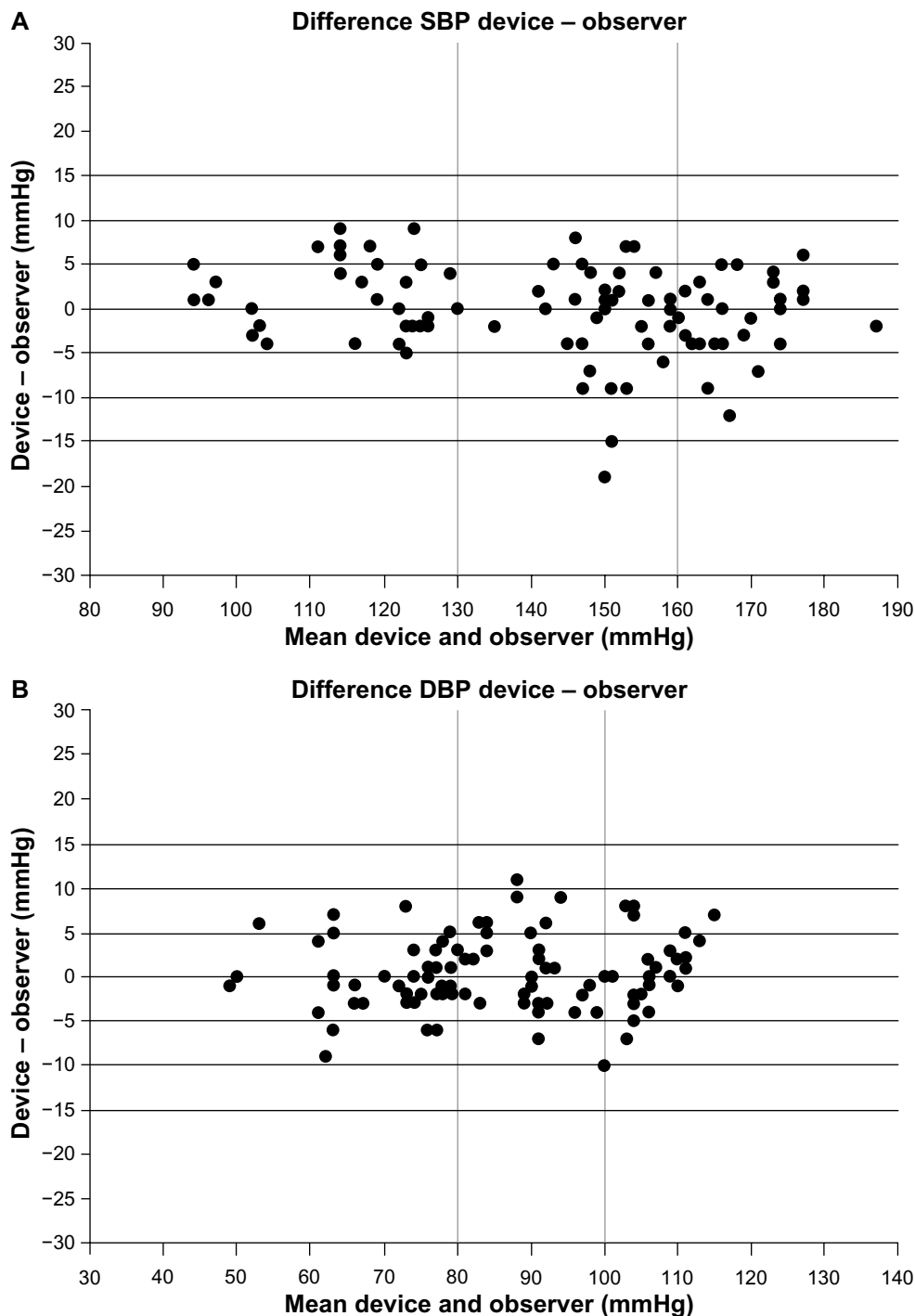


Figure 3 Plots showing difference in blood pressure between the Withings BP-800 (Withings, Paris, France) readings and the mean of the two observer readings in 33 participants (n=99). **(A)** SBP and **(B)** DBP. Points in bold are multiple (superimposition).

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

In this regard, the AAMI/ISO protocol recommends that a sphygmomanometer intended for use with a single cuff size should include at least 40% of the subjects with arm circumference which lies within the upper half of the specified range of use of the cuff and at least 40% within the lower half of the

specified range of use of the cuff. Moreover, at least 20% of the subjects should have an arm circumference which lies within the upper quarter of the specified range for use of the cuff and at least 20% within the lower quarter. Despite the absence of such recommendations in the International Protocol, our

Table 5 Results of the Polygreen KP-7670 device (Polygreen K-Jump, Taipei, Taiwan) according to European Society of Hypertension International Protocol Revision 2010

	≤5 mmHg	≤10 mmHg	≤15 mmHg	Grade 1	Mean difference	SD
Part 1						
Required						
Two of	73	87	96			
All of	65	81	93			
Achieved						
SBP	68	87	98	Pass	3.0	5.3
DBP	71	93	99	Pass	0.3	5.2
Part 2	2/3 ≤5 mmHg	0/3 ≤5 mmHg		Grade 2		Grade 3
Required	≥24	≤3				
Achieved						
SBP	25	3		Pass		Pass
DBP	24	2		Pass		Pass
Part 3						Pass

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

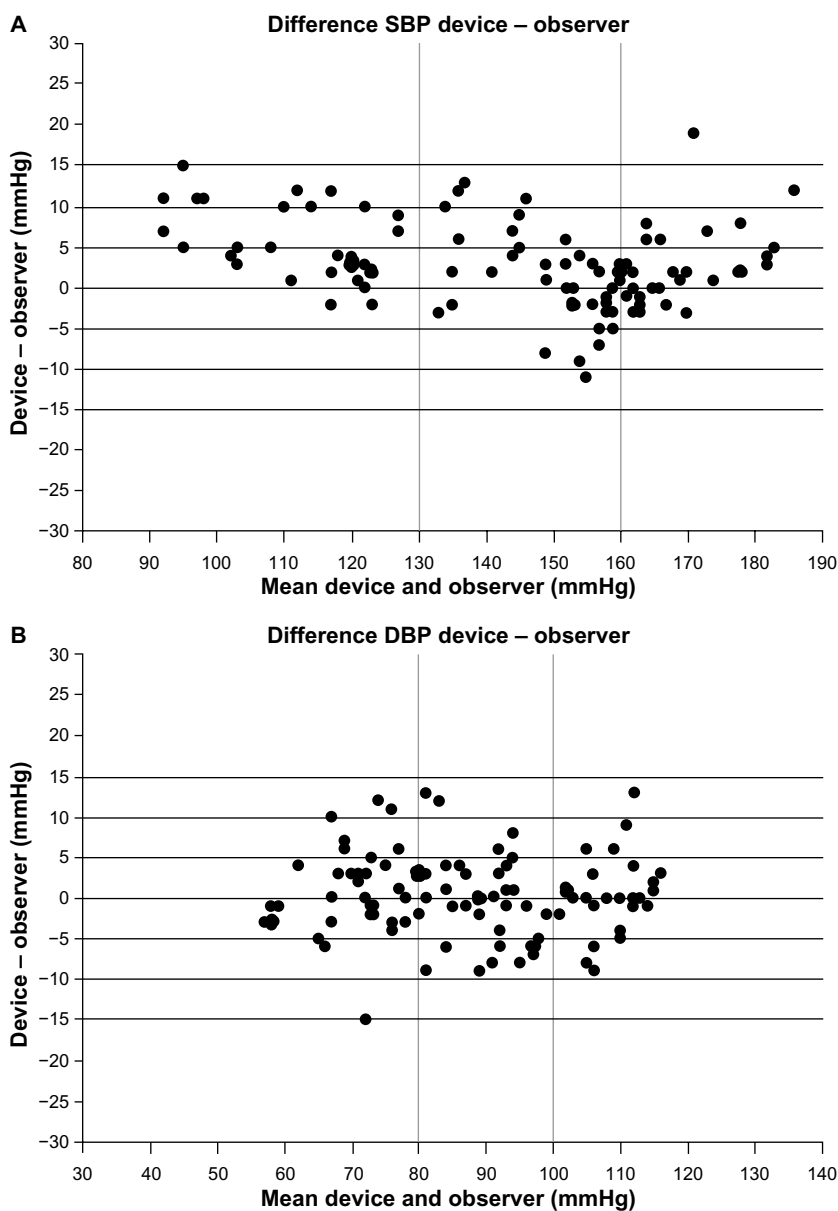


Figure 4 Plots showing difference in blood pressure between the Polygreen KP-7670 (Polygreen K-Jump, Taipei, Taiwan) readings and the mean of the two observer readings in 33 participants (n=99). **(A)** SBP and **(B)** DBP. Points in bold are multiple (superimposition).

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

studies included approximately 25% of subjects with a large arm circumference ≥ 32 cm (Omron M6 Comfort, n=11; Omron HEM-7420, n=13; Withings BP-800, n=8). Taking into consideration this limitation, it will be important to corroborate our results in specific populations selected on the basis of arm circumference. Third, the number of validation studies requested to approve device accuracy is an important issue. The International Protocol does not specify a number of devices or studies needed to enhance the accuracy requirements. Experts agree that it would be important to have at least two validation studies conducted in different centers and various populations. In this regard, the AAMI¹⁰ recommends more than one study site, but does not specify a number of studies or devices. Therefore, since none of the four devices tested in the present study went through prior validation, it is important that further studies be performed by experts in specific populations before recommending their widespread use in the population.

Further, the present studies were performed by well-trained observers who used the tested devices as recommended by the manufacturers and considered factors affecting measurement accuracy. The latest is of most important principally because BP measurements may be affected by number of errors, most of them related to the patient and the way of using the device such as arm position, movements, and cuff use. The cuff has to be wrapped in a correct way and the measurements performed with a correct posture, ie, the arm at the heart level and relaxed. In practice, these recommendations are usually not fully followed, so clinicians recommending SBPM should emphasize compliance with the user manual in order to obtain BP measurements of good quality.

Conclusion

The results of the present study show that the four tested devices meet the requirements of the ESH International Protocol Revision 2010 in a general population and thus can be used by patients for SBPM. Because of certain limitations of the International Protocol, it would be desirable to corroborate the present results in other studies performed in general or specific populations.

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Disclosure

The authors report no conflicts of interest in this work.

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