

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 oscillometric devices for self-measurement of blood pressure (SBPM) were evaluated according to the European Society of Hypertension (ESH) international protocol and its 2010 revision in four separate studies. The Omron® M2, Omron M3, and Omron M6 measure blood pressure (BP) at the brachial level, while the Omron R2 measures BP at the wrist level.

Methods: The international protocol requires a total number of 33 subjects in which the validation is performed. The Omron M2 and Omron R2 were validated in 2009 according to the ESH international protocol, while the Omron M3 and Omron M6 were validated in 2010–2011 according to the 2010 ESH international protocol revision. The protocol procedures were followed precisely.

Results: All four tested devices passed the validation process. The mean differences between the device and mercury readings were 2.7 ± 5.0 and -1.4 ± 3.2 mmHg for systolic and diastolic BP, respectively, using the Omron M2 device, and 1.7 ± 3.2 and -0.9 ± 2.6 mmHg using the Omron M3, 1.6 ± 2.9 and -0.9 ± 2.5 mmHg using the Omron M6, and -1.1 ± 4.8 and -0.9 ± 4.3 mmHg using the Omron R2.

Conclusion: Readings from the Omron M2, Omron M3, Omron M6, and Omron R2, differing by less than 5, 10, and 15 mmHg, fulfill the ESH international protocol and its 2010 revision requirements. Therefore, each of these four devices can be used by patients for SBPM.

Keywords: Omron R2, M2, M3, M6, blood pressure measurement, validation, international protocol, European Society of Hypertension

Introduction

The advantages of blood pressure (BP) self-measurement have been well documented.^{1,2} Indeed, self-BP measurement (SBPM) not only provides valuable information for diagnosis of hypertension but also for BP control in the treated patient, and improves patient compliance with antihypertensive therapy.¹⁻³ Therefore, it is appropriate to encourage widespread use of SBPM as an important adjunct to the clinical care of patients with hypertension.² Clinical indications for SBPM have recently been highlighted in several guidelines and consensus conferences.¹⁻⁶ Obviously, SBPM is only practicably useful if the devices are user-friendly and accurate. Recommended devices for SBPM should be submitted to independent validation procedures. Currently, only a few of the devices available on the market have been validated and are recommended for patient use.⁷ Validation has to be performed according to recognized protocols specifically designed for this purpose, such as the British Hypertension Society protocol,⁸ the Association for the Advancement of Medical Instrumentation protocol,⁹ and the

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international protocol published by the European Society of Hypertension (ESH).^{10,11} In this study, four devices for SBPM were validated according to the international protocol in four separate studies.

Methods and materials

Devices

Omron M2

The Omron® M2 (HEM-7117-E) device records brachial BP using the oscillometric method with a pressure range of 0–299 mmHg and pulse rate range of 40–180 beats/minute. Systolic BP, diastolic BP, and pulse rate are displayed on a liquid crystal digital (LCD) screen. The device can detect and display a symbol on the LCD screen if an irregular heart beat defined by a heart beat rhythm that varies by more than 25% from the average heart beat rhythm is detected while the unit is measuring the systolic and diastolic BP. It includes memory for 21 measurements. The unit weighs approximately 260 g without batteries. Four AAA batteries are needed with an approximate capacity of 300 measurements. The standard cuff included is applicable to arm circumferences ranging from 22 to 32 cm; a large cuff is also available for arm circumferences of 32–42 cm.

Omron M3

The Omron M3 (HEM-7200-E) device records brachial BP using the oscillometric method with a pressure range of 0–299 mmHg and pulse rate range of 40–180 beats/minute. Inflation is performed using a fuzzy-logic electric pumping system and deflation by an automatic pressure release valve. At the end of each measurement, systolic BP, diastolic BP, and pulse rate are displayed on a LCD screen. The device can detect and display a symbol on the LCD screen if an irregular heart beat defined by a heart beat rhythm that varies by more than 25% from the average heart beat rhythm is detected while the unit is measuring the systolic and diastolic BP. The monitor automatically stores results for up to 60 sets. It can also calculate an average reading based on measurements from the last three readings taken within 10 minutes. The unit weighs approximately 340 g without batteries. Four AA alkaline batteries are needed with an approximate capacity for 1500 measurements. Two sizes of cuffs, ie, standard and large, are available. The standard cuff is adapted to an arm circumference of 22–32 cm and the large cuff to an arm circumference of 32–42 cm.

Omron M6

The Omron M6 (HEM-7211-E) device records brachial BP using the oscillometric method with a pressure range of

0–299 mmHg and pulse rate range of 40–180 beats/minute. Inflation is performed using a fuzzy-logic electric pumping system and deflation by an automatic pressure release valve. At the end of each measurement, systolic BP, diastolic BP, and pulse rate are displayed on a LCD screen. The device can detect and display a symbol on the LCD screen if an irregular heart beat defined by a heart beat rhythm that varies by more than 25% from the average heart beat rhythm detected while the unit is measuring the systolic and diastolic BP. The monitor automatically stores results for up to 90 sets. It 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 for 1500 measurements. Three sizes of cuffs, ie, small, standard, and large, are available. The standard cuff is adapted to an arm circumference of 22–32 cm, the small cuff to an arm circumference of 17–22 cm, and the large cuff to an arm circumference of 32–42 cm.

Omron R2

The Omron R2 (HEM-6113-E) device is an automatic oscillometric device for SBPM, measuring radial BP at the wrist level. This device uses automatic inflation by pump and automatic rapid deflation. It measures a BP range of 1–299 mmHg and a pulse rate range of 40–180 beats/minute, and values are displayed on a LCD screen. The unit includes memory for 30 measurements. It weighs approximately 117 g without batteries. Two AAA alkaline batteries are needed with an approximate capacity for 300 measurements. The device can be used for wrist circumferences of 13.5–21.5 cm.

BP measurements

For each study, the manufacturer was asked to provide three complete devices, declared by the manufacturer as standard production models. Before the validation study per se, a familiarization period of about one week took place in an outpatient clinic. During this period, the investigators familiarized themselves with use of the tested device. Each validation study was performed using one device chosen randomly by the investigator from the three provided by the manufacturer.

The validation team for each study consisted of three persons experienced in BP measurement. Investigators underwent training on the basis of a CD-ROM specifically developed by the French Society of Hypertension for the certification of observers involved in clinical studies. Two of the three observers measured BP using a teaching stethoscope for simultaneous

measurements (Y tube, Littmann, Schaumburg, IL) and two standard mercury sphygmomanometers, the components of which had been carefully checked before the study. 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. In one study (of the Omron M6), the second observer was also the supervisor (JT).

Patient population

The four validation studies were performed in the general population. According to the international protocol, a total of 33 participants who fulfilled the age, gender, and entry BP requirements (age ≥ 25 years, at least 10 men and 10 women, 11 participants with entry BP within each of the ranges 90–129 mmHg, 130–160 mmHg, and 161–180 for systolic BP and 40–79 mmHg, 80–100 mmHg, and 101–130 mmHg for diastolic BP). Arm circumference is distributed by chance. In order to optimize recruitment, it was recommended that subjects for the high diastolic BP and low systolic BP groups should be recruited first, then those with high systolic BP and low diastolic BP, and finally the remaining gaps should be filled. In these four studies, subjects were preselected in order to avoid a high number of subjects being excluded because of their BP range.

Procedure

Subjects were seated in a quiet room and BP measurements started after a 10-minute rest period. Arm circumference was measured and the cuff size was adapted. All measurements were performed in the left arm at the heart level. BP was measured simultaneously by the two observers alternately with the automatic device as mentioned earlier. Nine consecutive measurements were carried out according to the procedure described in detail elsewhere.¹⁰ The validation studies of the Omron R2 and the Omron M2 were performed during the last quarter of 2009 according to the first version of the international protocol;¹⁰ those for the Omron M3 and the Omron M6 were performed at the end of 2010 and 2011 according to the 2010 international protocol revision. In each of the four studies, the ESH International protocol and its revision 2010 were followed precisely.

Data analysis

Differences between the tested device and control measurements were classified according to whether they were within 5, 10, or 15 mmHg. Differences were calculated by subtracting the observer measurement from the device measurement; they were classified separately in this way for

both systolic BP and diastolic BP. The number of differences in each zone was calculated and compared with the number required by the international protocol and its 2010 revision. Details of the analysis procedure have already been published elsewhere.^{10,11}

Results

Omron M2

This study included 33 subjects (20 men and 13 women) with a mean age of 58 ± 11 (range 37–80) years, and a mean arm circumference of 28 ± 4 (range 20–34) cm. A standard size cuff was used in 30 subjects and a large cuff in three subjects. At entry, the mean BP values were, respectively, 142 ± 23 (range 101–180) mmHg for systolic BP and 86 ± 18 (range 53–110) mmHg for diastolic BP. The difference between the two observers was 0.1 ± 2.1 mmHg and 0.3 ± 2.1 mmHg for systolic BP and diastolic BP, respectively. The mean differences between the observers and the tested device were 2.7 ± 5.0 and -1.4 ± 3.2 mmHg for systolic BP and diastolic BP, respectively.

The numbers of measurements differing from the mercury standard by 5, 10, and 15 mmHg or less are shown in Table 1. The difference between the device readings and the mean BP of the device and the two observers for all 99 points of systolic BP and diastolic BP are displayed in Figure 1. These results are in agreement with the international protocol requirements for the primary and secondary phases. Thus, the Omron M2 device fulfills the validation criteria of the international protocol.

Omron M3

This study included 33 subjects (16 men and 17 women) with a mean age of 60 ± 11 (range 31–78) years and a mean arm circumference of 29 ± 3 (range 25–36) cm. A standard size cuff was used in 29 subjects and a large cuff in four subjects. At entry, the mean BP values were, respectively, 142 ± 25 (range 90–179) mmHg for systolic BP and 85 ± 18 (range 50–119) mmHg for diastolic BP. The difference between the two observers was 0.1 ± 0.8 and -0.2 ± 1.0 mmHg for systolic BP and diastolic BP, respectively. The mean differences between the observers and the tested device were 1.7 ± 3.2 and -0.9 ± 2.6 mmHg for systolic BP and diastolic BP, respectively.

The numbers of measurements differing from the mercury standard by 5, 10, and 15 mmHg or less are shown in Table 2. The difference between the device readings and the mean BP of the device and the two observers for all 99 points of systolic BP and diastolic BP are displayed in Figure 2.

Table 1 Results for the Omron M2 device according to the ESH international protocol

Phase 1		≤5 mmHg	≤10 mmHg	≤15 mmHg	Recommendation		
Required	One of	25	35	40			
Achieved	SBP	23	38	42	Continue		
	DBP	40	45	45	Continue		
Phase 2.1		≤5 mmHg	≤10 mmHg	≤15 mmHg	Recommendation	Mean difference (mmHg)	SD
Required	Two of	65	80	95			
	All of	60	75	90			
Achieved	SBP	73	92	96	Pass	2.7	5.0
	DBP	88	99	99	Pass	−1.4	3.2
Phase 2.2		2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg	Recommendation			
Required		≥22	≤3				
Achieved	SBP	25	3	Pass			
	DBP	31	0	Pass			

Abbreviations: ESH, European Society for Hypertension; SD, standard deviation (mmHg); SBP, systolic blood pressure; DBP, diastolic blood pressure.

These results are in concordance with the 2010 international protocol revision requirements. Thus, the Omron M3 device fulfills the validation criteria of the 2010 ESH international protocol revision.

Omron M6

This study included 33 subjects (15 men and 18 women) with a mean age of 60 ± 13 (range 25–79) years and a mean arm circumference of 29 ± 3 (range 25–36) cm. A standard size cuff was used in 32 subjects and a large cuff in one subject. At entry, the mean BP values were, respectively, 144 ± 25 (range 96–180) mmHg for systolic BP and 86 ± 18 (range 50–119) mmHg for diastolic BP. The difference between the two observers was 0.2 ± 1.1 and -0.1 ± 1.1 mmHg for systolic BP and diastolic BP, respectively. The mean differences between the observers and the tested device were 1.6 ± 2.9 and -0.9 ± 2.5 mmHg for systolic BP and diastolic BP, respectively.

The numbers of measurements differing from the mercury standard by 5, 10, and 15 mmHg or less are shown in Table 3. The difference between the device readings and the mean BP of the device and the two observers for all 99 points of systolic BP and diastolic BP are displayed in Figure 3. These results are in concordance with the 2010 international protocol revision requirements. Thus, the Omron M6 device fulfills the validation criteria of the 2010 ESH international protocol revision.

Omron R2

This study included 33 subjects (19 men and 14 women) with a mean age of 58 ± 11 (range 37–80) years and a mean wrist circumference of 18 ± 2 (range 14–22) cm. A standard brachial size cuff was used in 31 subjects and a large cuff in two subjects. At entry, the mean BP values were,

respectively, 142 ± 24 (range 101–179) mmHg for systolic BP and 86 ± 18 (range 53–111) mmHg for diastolic BP. The difference between the two observers was 0.3 ± 2.2 and 0.3 ± 1.8 mmHg for systolic BP and diastolic BP, respectively. The mean differences between the observers and the tested device were -1.1 ± 4.8 and -0.9 ± 4.3 mmHg for systolic BP and diastolic BP, respectively.

The numbers of measurements differing from the mercury standard by 5, 10, and 15 mmHg or less are shown in Table 4. The difference between the device readings and the mean BP of the device and the two observers for all 99 points of systolic BP and diastolic BP are displayed in Figure 4. These results are in concordance with the requested criteria of the international protocol for the primary and secondary phases. Thus, the Omron R2 device fulfills the validation criteria of the international protocol.

Discussion

This study provides information on the accuracy of four devices for SBPM measurement. The Omron M2, Omron M3, and Omron M6 measure BP at the brachial level, whereas the Omron R2 measures radial BP at the wrist level. The results show that all four devices met the validation requirements of the ESH international protocol and its 2010 revision, provided that they are used by well trained observers and considering the factors affecting measurement accuracy as described by the manufacturers. The Omron M2 and R2 were validated according to the international protocol version 2002 because these studies were performed during the last quarter of 2009, whereas the Omron M3 and Omron M6 were validated according to the 2010 international protocol revision because these two studies were performed after its publication during 2010 and 2011.

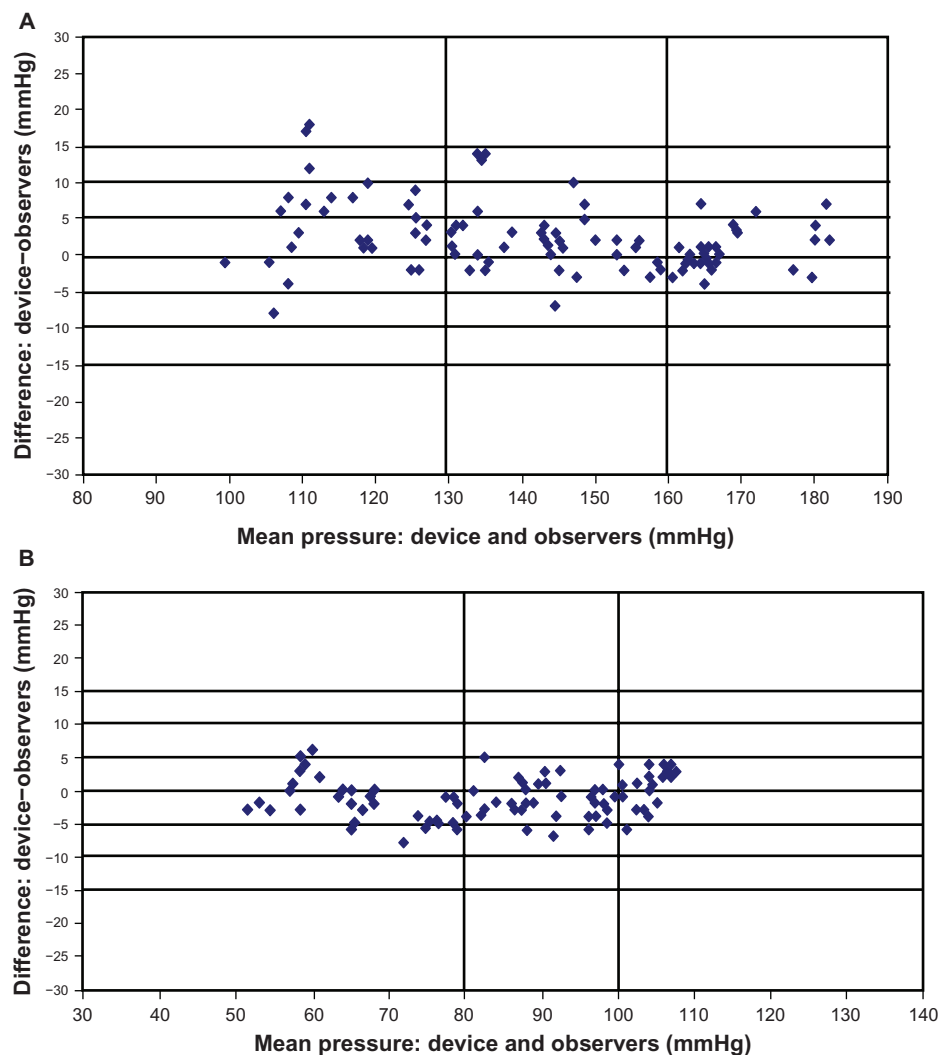


Figure 1 Plots of systolic (**A**) and diastolic (**B**) blood pressure differences between the Omron M2 readings and the mean of two observer readings in 33 participants ($n = 99$).

The four present validation studies were performed by well trained observers, who used the tested devices as recommended by the manufacturers and considered the factors affecting measurement accuracy. The latter is particularly important for the wrist BP device. BP measurements at the

wrist level are prone to a number of errors, most of them related to how the patient uses the device. The wrist cuff has to be wrapped in a correct way and measurements performed in the correct posture, ie, the arm held across the chest, the wrist at the heart level, the arm relaxed without

Table 2 Results for the Omron M3 device according to the ESH international protocol revision 2010

Part 1		≤5 mmHg	≤10 mmHg	≤15 mmHg	Grade 1	Mean difference	SD
Required	Two of	73	87	96			
	All of	65	81	93			
Achieved	SBP	86	99	99	Pass	1.7	3.2
	DBP	94	99	99	Pass	−0.9	2.6
Part 2		2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg		Grade 2		Grade 3
Required		≥24	≤3				
Achieved	SBP	31	0		Pass		Pass
	DBP	33	0		Pass		Pass
Part 3		PASS					

Abbreviations: ESH, European Society for Hypertension; SD, standard deviation (mmHg); SDP, systolic blood pressure; DBP, diastolic blood pressure.

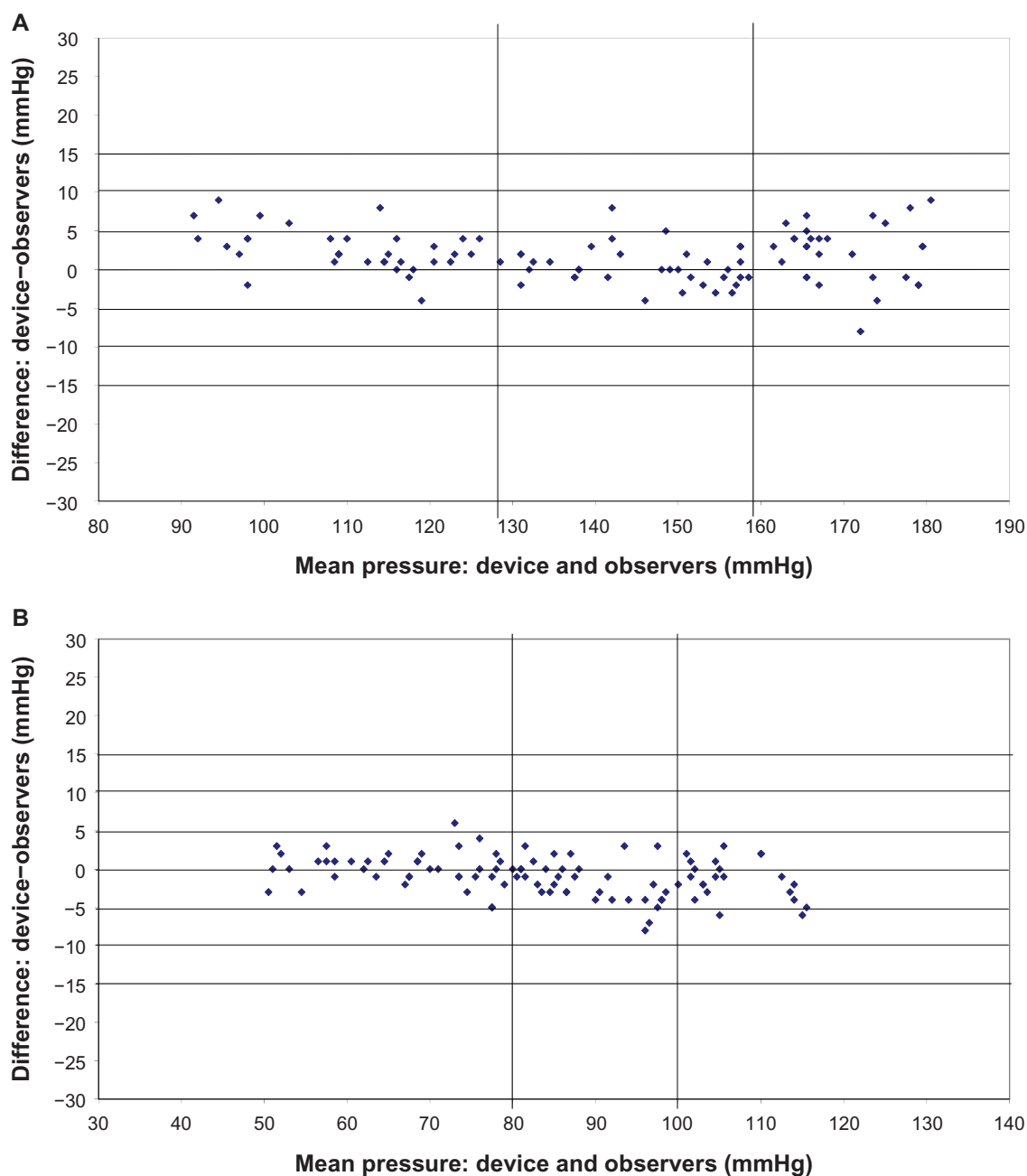


Figure 2 Plots of systolic (A) and diastolic (B) blood pressure differences between the Omron M3 readings and mean of the two observer readings in 33 participants (n = 99).

Table 3 Results for the Omron M6 device according to the ESH international protocol revision 2010

Part 1		≤5 mmHg	≤10 mmHg	≤15 mmHg	Grade 1	Mean difference	SD
Required	Two of	73	87	96			
	All of	65	81	93			
Achieved	SBP	89	99	99	Pass	1.6	2.9
	DBP	96	99	99	Pass	−0.9	2.5
Part 2		2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg		Grade 2		Grade 3
Required		≥24	≤3				
Achieved	SBP	32	0		Pass		Pass
	DBP	33	0		Pass		Pass
Part 3							PASS

Abbreviations: ESH, European Society for Hypertension; SD, standard deviation (mmHg); SBP, systolic blood pressure; DBP, diastolic blood pressure.

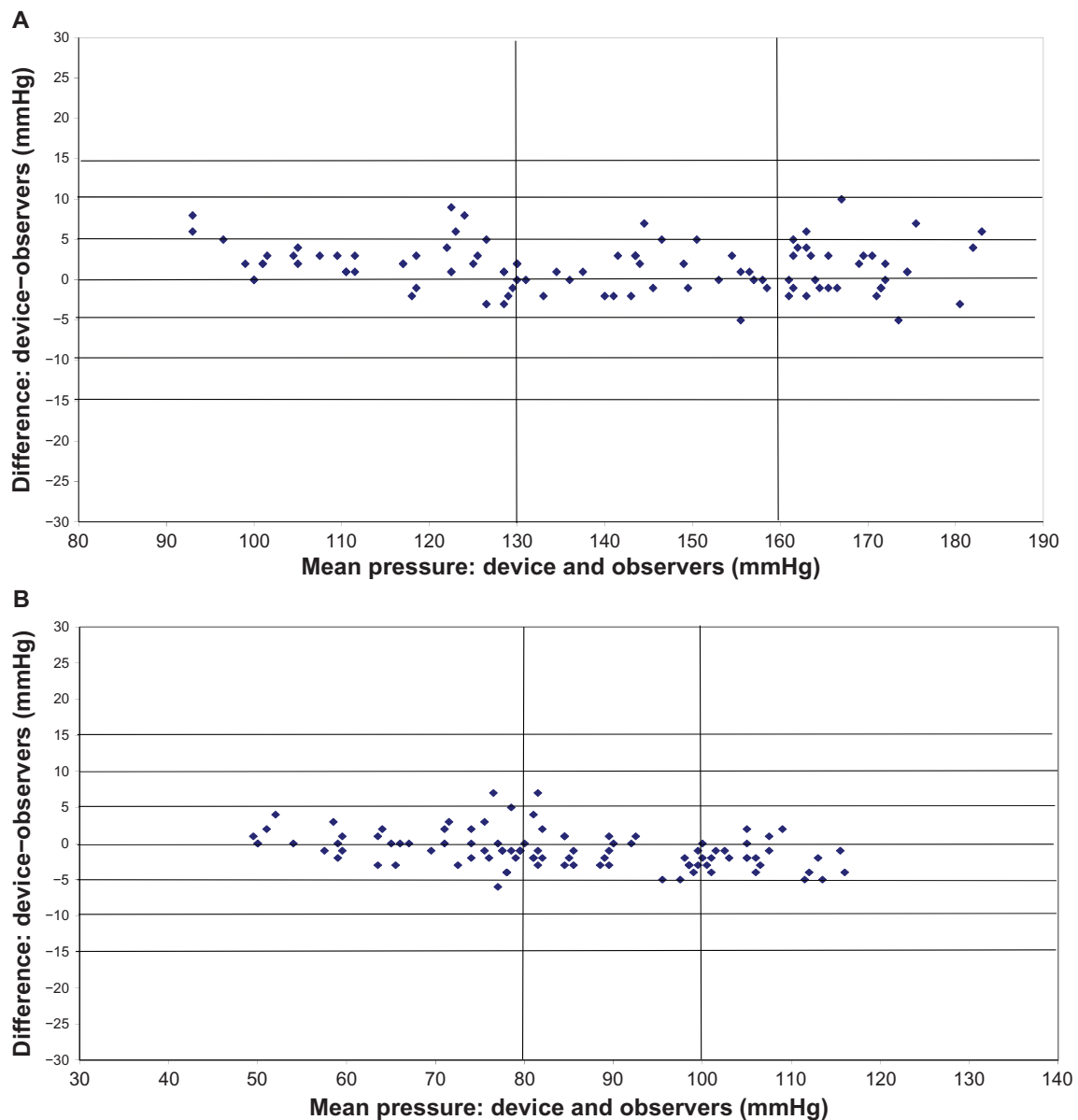


Figure 3 Plots of systolic (**A**) and diastolic (**B**) blood pressure differences between the Omron M6 readings and the mean of two observer readings in 33 participants (n = 99).

Table 4 Results of the Omron R2 device according to the ESH international protocol

Phase I		≤5 mmHg	≤10 mmHg	≤15 mmHg	Recommendation		
Required	One of	25	35	40			
Achieved	SBP	38	41	45	Continue		
	DBP	37	44	45	Continue		
Phase 2.1		≤5 mmHg	≤10 mmHg	≤15 mmHg	Recommendation	Mean difference	SD
Required	Two of	65	80	95			
	All of	60	75	90			
Achieved	SBP	81	92	99	Pass	-1.1	4.8
	DBP	82	94	99	Pass	-0.9	4.3
Phase 2.2		2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg	Recommendation			
Required		≥22	≤3				
Achieved	SBP	29	2	Pass			
	DBP	29	3	Pass			

Abbreviations: ESH, European Society for Hypertension; SD, standard deviation (mmHg); SBP, systolic blood pressure; DBP, diastolic blood pressure.

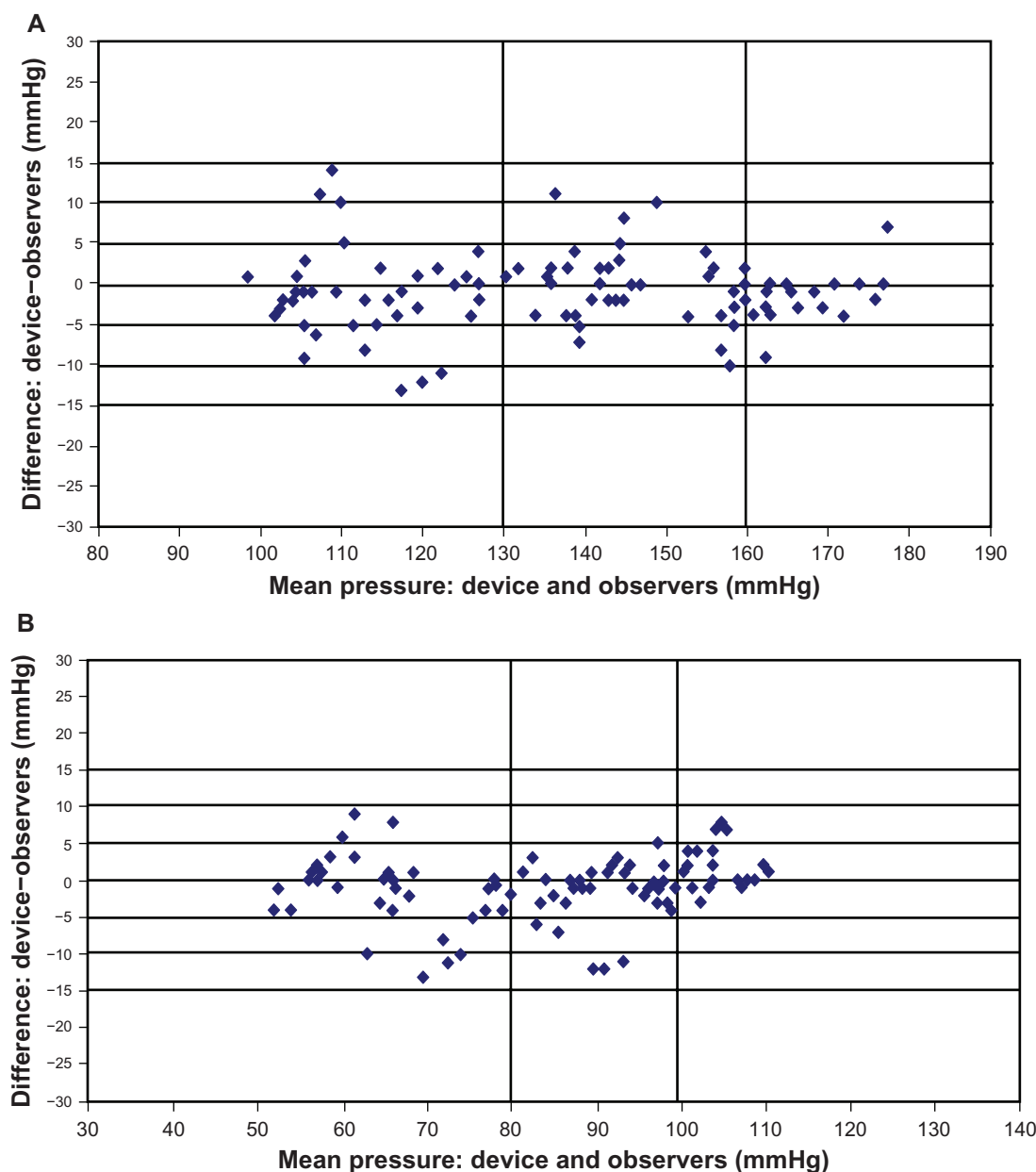


Figure 4 Plots of systolic (**A**) and diastolic (**B**) blood pressure differences between the OmronR2 readings and the mean of two observer readings in 33 participants ($n = 99$).

excessive extension or flexion and without a clenched fist. In practice, these recommendations are usually not fully followed, so experts prefer to use a device measuring BP at the brachial level.

In this study, validation was performed according to the international protocol. This protocol was published in 2002 by the ESH¹⁰ aiming to simplify the other two available protocols, ie, the British Hypertension Society⁸ and Association for the Advancement of Medical Instrumentation⁹ protocols, without compromising their integrity. The main advantage of this protocol is that it requires a smaller number of subjects

($n = 33$) than the 85 required for the two other protocols. However, this protocol had some limitations. First, the population required in the international protocol is confined to adults >30 years (>25 years in the 2010 revision) with specifications in terms of age, gender, BP level, and arm circumference. Because this selected population is only a part of the large heterogeneous population affected by hypertension, extrapolation of results to other specific populations may be hazardous and risky. Specific validation studies are needed if the devices are to be used by specific populations, eg, pregnant women, the elderly, the obese, children,

or patients with specific conditions, such as arrhythmia. Second, the number of validation studies needed to confirm device accuracy is an important issue. The international protocol does not specify the number of devices or study sites recommended to optimize accuracy of measurements. 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 Association for the Advancement of Medical Instrumentation protocol recommends more than one study but does not specify the number of studies or devices. Therefore, because none of the four tested devices in the present study went through prior validation, it would be important to undertake at least one further study in a specific population before recommending their widespread use in the clinic.

Conclusion

The results of the present study show that the four tested devices, ie, the Omron M2, Omron M3, and Omron M6 which measure BP at the brachial level (arm) and the Omron R2 which measures the BP at the radial level (wrist) meet the requirements of the ESH international protocol and its 2010 revision in a general population. Therefore, any of these four devices can be used by patients for SBPM if used correctly according to the manufacturer recommendations. Because of certain limitations of the international protocol, it would be desirable to corroborate the present results by other studies performed in both the general population and in selected patient populations.

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Disclosure

The authors report no conflicts of interest in this work. The study was sponsored by Omron Healthcare Europe.

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