

Validation of three automatic devices for self-measurement of blood pressure according to the International Protocol: The Omron M3 Intellisense (HEM-7051-E), the Omron M2 Compact (HEM 7102-E), and the Omron R3-I Plus (HEM 6022-E)

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Objective Three oscillometric devices for the self blood pressure measurement were evaluated according to the International Protocol of the European Society of Hypertension in three separate studies. The Omron M3 Intellisense and the Omron M2 Compact measures blood pressure (BP) at the brachial level; the Omron R3-I Plus measures BP at the wrist level.

Methods The International Protocol is divided into two phases and includes a total number of 33 participants on whom the validation is performed. In each study, and for each participant, four BP measurements were taken simultaneously by two observers using mercury sphygmomanometers alternately with three measurements with the tested device. The difference between the observers and the device BP values was calculated for each measurement. The 99 pairs of BP differences were classified into three categories (≤ 5 , ≤ 10 , ≤ 15 mmHg).

Results All three tested devices passed the first and second phase of the validation process. The mean differences between the device and mercury readings were 1.9 ± 3.0 and -1.0 ± 2.3 mmHg for systolic and diastolic BP,

respectively, for the Omron M3 Intellisense device, 2.5 ± 5.4 and -2.3 ± 3.6 mmHg for the Omron M2 Compact device, and 1.4 ± 4.5 and 0.8 ± 4.6 mmHg for the Omron R3-I Plus device.

Conclusion Readings of the Omron M3 Intellisense, the Omron M2 Compact and the Omron R3-I Plus, differing by less than 5, 10, and 15 mmHg fulfill the International Protocol requirements and therefore can be used by patients for self blood pressure measurement. *Blood Press Monit* 15:49–54 © 2010 Wolters Kluwer Health | Lippincott Williams & Wilkins.

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Introduction

Advantages of blood pressure (BP) self-measurement have been well documented [1,2]. 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 the patient's compliance with antihypertensive therapy [1–3]. Therefore, it is appropriate to encourage the widespread use of SBPM as an important adjunct to the clinical care of patients with hypertension [2]. Clinical indications of the SBPM have been recently highlighted in several guidelines and consensus conferences [1–6]. Obviously, SBPM is only practically useful if the devices are user-friendly and accurate. Recommended devices for SBPM should be submitted to independent validation procedures.

Previous presentation: Part of this study was presented at the European Society of Hypertension meeting (abstract Omron M3 Intellisense).

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Currently, only a few of the available devices 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 (AAMI) protocol [9], and the International Protocol [10] published by the European Society of Hypertension. In this study, three devices for SBPM were validated according to the International Protocol in three separate studies.

Methods

Devices

Omron M3 Intellisense (HEM-7051-E)

The Omron M3 Intellisense device (Omron healthcare, Kyoto, Japan) records brachial BP using the oscillometric

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method with a pressure range of 0–299 mmHg and pulse rate range of 40–180 beats/min. Systolic BP (SBP), diastolic BP (DBP), and pulse rate are displayed on a liquid crystal digital (LCD) screen. For comfortable controlled inflation without the need for pressure presetting or reinflation the device uses its advance 'IntelliSense' technology. Deflation is automatic by pressure release valve. The unit weighs approximately 340 g without batteries. The standard cuff that is 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 M2 Compact (HEM-7102-E)

The Omron M2 Compact device (Omron healthcare) records brachial BP using the oscillometric method with a pressure range of 0–299 mmHg and pulse rate range of 40–180 beats/min. It includes memory for 14 measurements. Inflation is performed using a fuzzy-logic electric pumping system and deflation is by an automatic pressure release valve. At the end of each measurement, SBP, DBP, and pulse rate are displayed on a LCD screen. The unit weighs approximately 350 g without batteries. Two sizes of cuffs, 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 R3-I Plus (HEM-6022-E)

The Omron R3-I Plus device (Omron healthcare) is an automatic oscillometric device for SBPM, measuring radial BP at the wrist level. This device uses the 'Intellisense technology', which measures BP during the inflation period with personalized inflation level; deflation is fast and complete. Therefore, BP measurement is quicker and more comfortable for the patient. This device can be used for wrist circumferences ranging from 13.5 to 21.5 cm; it measures BP in a range from 0 to 299 mmHg and pulse rate from 40 to 180 beats/min; values are displayed on a LCD screen. It includes memory for 60 measurements. The unit weighs approximately 140 g without batteries.

Blood pressure 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 1 week took place in an outpatient clinic. During this period, the investigators familiarized themselves with the use of the tested device.

The validation team of each study consisted of three persons experienced in BP measurement. The investigators followed 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 have measured BP using a teaching stethoscope for simultaneous

measurements (Y tube) and two standard mercury sphygmomanometers, the components of which have 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 from each other's readings.

Population

According to the International Protocol, in phase 1 a total of 15 treated or untreated participants are included who fulfill the age, sex, and entry BP range requirements (age ≥ 30 years, at least five men and five women, five participants with entry BP within each of the ranges 90–129, 130–160 mmHg and 161–180 for SBP and 40–79, 80–100 and 101–130 mmHg for DBP). Arm circumference is distributed by chance. If analysis of these data is successful, additional participants are recruited until a total of 33 participants fulfill the age, sex, and entry BP requirements for phase 2 (age ≥ 30 years, at least 10 men and 10 women, 11 participants with entry BP within each of the BP ranges for SBP and DBP). To optimize recruitment it is recommended that participants for the high diastolic and low systolic groups should be recruited first, then those with high systolic and low diastolic, finally the remaining gaps should be filled. In these three studies, the participants were preselected to limit the high number of excluded participants, mainly because of their BP ranges.

Procedure

The participants were seated in a quiet room and BP measurements were started after a 10 min rest period. Arm circumference was measured and cuff size was adapted. 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. Nine consecutive measurements were made according to the procedure described in detail elsewhere [10].

Analysis

Differences between the tested device and control measurements were classified according to whether they lay 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 SBP and DBP. 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 the first phase and pass/fail grade for the second phase was determined. Details of the analysis procedure have been published elsewhere [10].

Results

Omron M3 Intellisense (HEM-7051-E)

This study included 33 participants (16 men and 17 women) with a mean age of 52 ± 11 years (range: 31–75),

their mean arm circumference was 29 ± 2 cm (range: 24–33). A standard size cuff was used in 28 participants and large cuff in five participants. At entry, the mean BP

values were, respectively, 144 ± 25 (range: 100–179) for SBP and 88 ± 18 (range: 50–120) mmHg for DBP. The difference between the two observers was 0.70 ± 1.80 and 0.58 ± 1.40 mmHg for SBP and DBP, respectively. The mean differences between the observers and the tested device were 1.9 ± 3.0 and -1.0 ± 2.3 mmHg for SBP and DBP, respectively.

Table 1 Results of the Omron M3 Intellisense (HEM-7051-E) device

Phase 1	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Recomm.		
Required						
One of	25	35	40			
Achieved						
SBP	39	45	45	Continue		
DBP	43	45	45	Continue		
Phase 2.1					Mean diff.	SD
Required						
Two of	65	80	95			
All of	60	75	90			
Achieved						
SBP	86	98	99	Pass	1.9	3.0
DBP	96	99	99	Pass	-1.0	2.3
Phase 2.2	$2/3 \leq 5$ mmHg	$0/3 \leq 5$ mmHg				
Required	≥ 22	≤ 3				
Achieved						
SBP	31	0		Pass		
DBP	32	0		Pass		

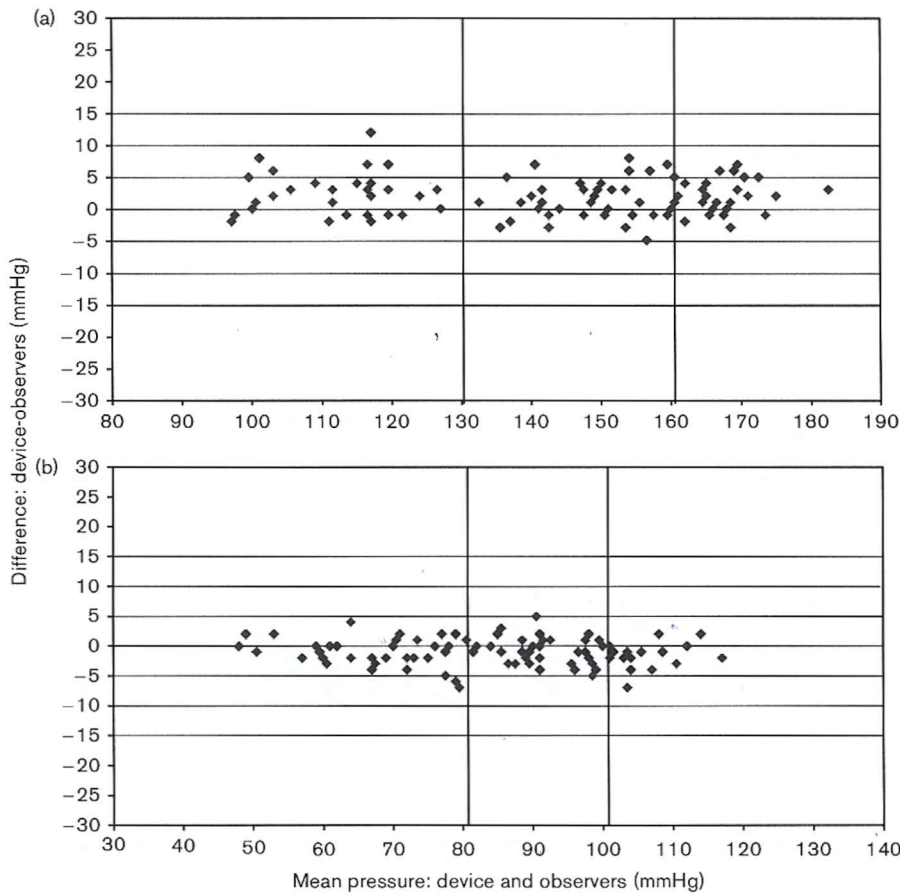
DBP, diastolic blood pressure; Mean diff., mean difference (mmHg); Recomm., recommendation; SBP, systolic blood pressure; SD, standard deviation (mmHg).

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 device and the two observers for all 99 points for SBP and DBP are displayed in Fig. 1. These results are in agreement with the International Protocol requirements for the primary and secondary phases. Thus the Omron M3 Intellisense device fulfills the validation criteria of the International Protocol.

Omron M2 Compact (HEM 7102-E)

This study included 33 participants (20 men and 13 women) with a mean age of 57 ± 13 years (range: 30–80), their mean arm circumference was 28 ± 4 cm (range: 21–38).

Fig. 1



Plots of blood pressure difference between the Omron M3 Intellisense readings and the mean of the two observer readings in 33 participants ($n=99$). Systolic (a) and diastolic (b).

A standard size cuff was used in 29 participants and large cuff in four participants. At entry, the mean BP values were, respectively, 143 ± 26 (range: 95–180) for SBP and 84 ± 19 mmHg (range: 44–114) for DBP. The difference

between the two observers was 0.4 ± 2.0 and 0.2 ± 2.0 mmHg for SBP and DBP respectively. The mean differences between the observers and the tested device were 2.5 ± 5.4 and -2.3 ± 3.6 mmHg for SBP and DBP respectively.

Table 2 Results of the Omron M2 Compact (HEM 7102-E) device

Phase 1	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Recomm.		
Required						
One of	25	35	40			
Achieved						
SBP	27	38	45	Continue		
DBP	37	42	45	Continue		
Phase 2.1					Mean diff.	SD
Required						
Two of	65	80	95			
All of	60	75	90			
Achieved						
SBP	69	89	98	Pass	2.5	5.4
DBP	81	95	99	Pass	-2.3	3.6
Phase 2.2	$2/3 \leq 5$ mmHg	$0/3 \leq 5$ mmHg				
Required	≥ 22	≤ 3				
Achieved						
SBP	24	2		Pass		
DBP	28	1		Pass		

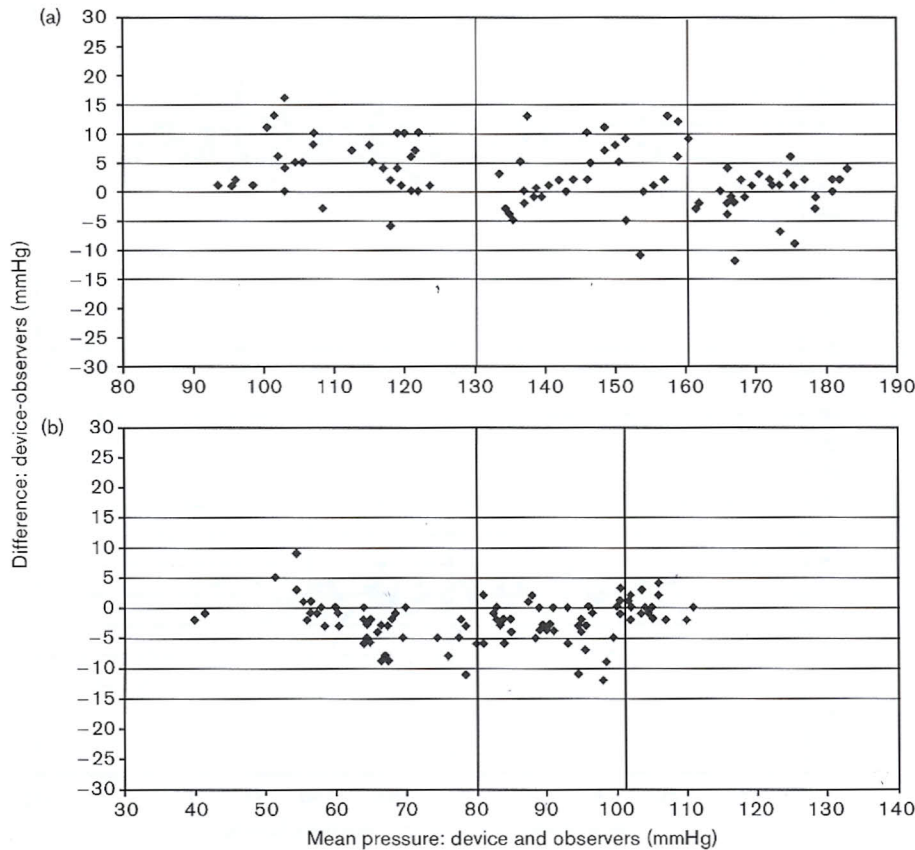
DBP, diastolic blood pressure; Mean diff., mean difference (mmHg); Recomm., recommendation; SBP, systolic blood pressure; SD, standard deviation (mmHg).

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 device and the two observers for all 99 points for SBP and DBP are displayed in Fig. 2. These results are in concordance with the International Protocol requirements. Thus Omron M2 Compact device fulfills the validation criteria of the International Protocol.

Omron R3-I Plus (HEM 6022-E)

This study included 33 participants (18 men and 15 women) with a mean age of 57 ± 12 years (range: 30–78), their mean wrist circumference was 18 ± 2 cm (range: 14–22). A standard brachial size cuff was used in 30 participants and large cuff in three participants. At entry, the mean BP values were, respectively, 143 ± 26 mmHg

Fig. 2



Plots of blood pressure difference between the Omron M2 Compact readings and the mean of the two observer readings in 33 participants ($n=99$). Systolic (a) and diastolic (b).

(range: 97–180) for SBP and 86 ± 18 mmHg (range: 47–114) for DBP. The difference between the two observers was -0.4 ± 2.2 and 0.1 ± 1.9 mmHg for SBP and DBP

respectively. The mean differences between the observers and the tested device were 1.4 ± 4.5 and 0.8 ± 4.6 mmHg for SBP and DBP respectively.

Table 3 Results of the Omron R3-I Plus (HEM 6022-E) device

Phase 1	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Recomm.		
Required						
One of	25	35	40			
Achieved						
SBP	34	45	45	Continue		
DBP	36	43	45	Continue		
Phase 2.1					Mean diff.	SD
Required						
Two of	65	80	95			
All of	60	75	90			
Achieved						
SBP	78	95	99	Pass	1.4	4.5
DBP	80	96	98	Pass	0.8	4.6
Phase 2.2	$2/3 \leq 5$ mmHg	$0/3 \leq 5$ mmHg				
Required	≥ 22	≤ 3				
Achieved						
SBP	27	2		Pass		
DBP	27	2		Pass		

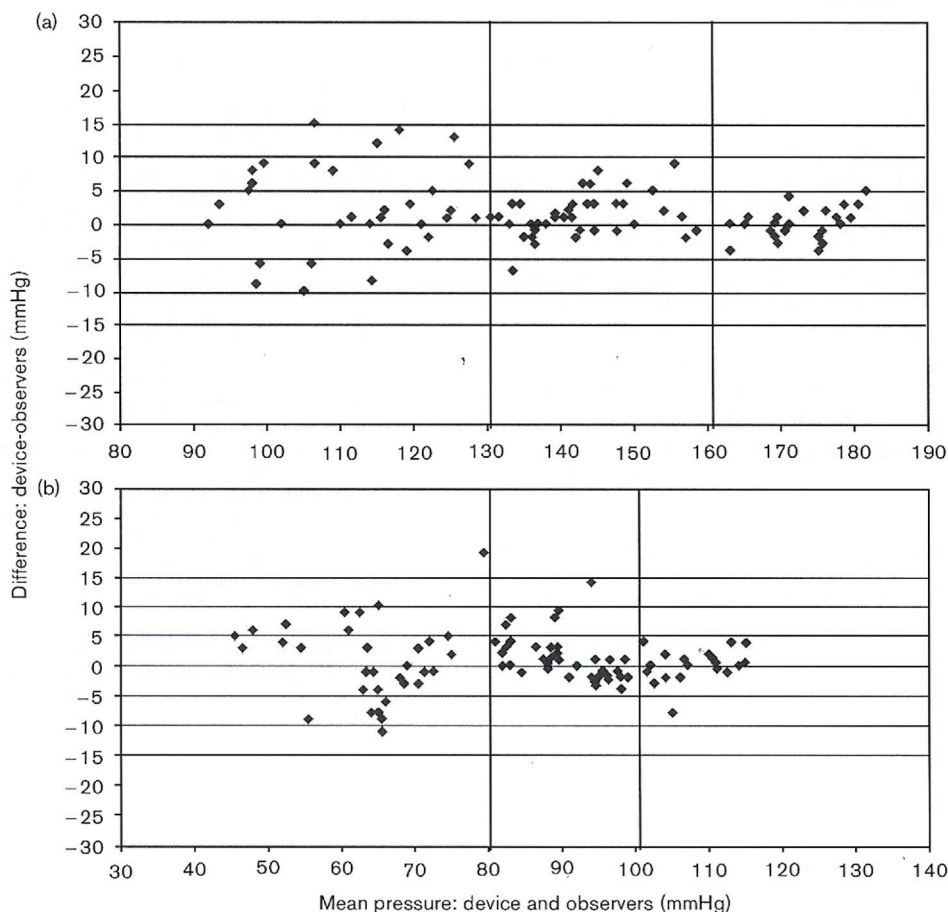
DBP, diastolic blood pressure; Mean diff., mean difference (mmHg); Recomm., recommendation; SBP, systolic blood pressure; SD, standard deviation (mmHg).

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's readings and the mean BP of the device and the two observers for all 99 points are displayed in Fig. 3 for SBP and DBP. These results are in concordance with the requested criteria of the International Protocol for the primary and secondary phases. Thus the Omron R3-I Plus device fulfills the validation criteria of the International Protocol.

Discussion

This study provides information on the accuracy of three devices for SBPM measurements. The Omron M3 Intellisense and the Omron M2 Compact measures BP at the brachial level whereas the Omron R3-I Plus measures radial BP at the wrist level. The results showed that all three devices passed the validation requirements of

Fig. 3



Plots of blood pressure difference between the Omron R3-I Plus readings and the mean of the two observer readings in 33 participants ($n=99$). Systolic (a) and diastolic (b).

the International Protocol provided that they were used by well trained observers and respected the factors affecting the measurements of accuracy described by the manufacturers. The latest is most important, principally for the wrist BP device. In fact, BP measurements at the wrist level may be affected by a number of errors, most of them related to the patient and their way of using the device. The wrist cuff has to be wrapped in the correct way and measurements taken in the correct posture: arm held across the chest, wrist at heart level, the arm relaxed without excessive extension, neither flexion and without clenched fist. In practice, these recommendations are usually not fully followed; therefore experts prefer the use of device measuring BP at the brachial level. Before the widespread use of these three devices, some comments have to be addressed.

In this study, validation was performed according to the International Protocol. This protocol has been published by the European Society of Hypertension [10] aiming to simplify the two other available protocols, the British Hypertension Society [8] and AAMI [9] without sacrificing their integrity. The main advantage of this protocol is that it requires a smaller number of participants, 33 instead of 85 with the two other protocols. However, this protocol has some limitations. (i) The population requested in the International Protocol is confined to adults more than 30 years of age with specifications in terms of age, sex, BP level, arm circumference, etc. as such a selective population is only a part of the large heterogeneous population affected by hypertension; the extrapolation of the results to other specific populations may be hazardous and risky. Specific validation studies are needed if the devices will be used by specific populations, such as pregnant women, elderly, obese, children, etc; or with specific conditions such as arrhythmia. (ii) The number of validation studies requested to approve device accuracy is an important issue. The International Protocol does not specify the number of devices or study sites recommended to enhance the accuracy requirements. Experts agree that it would be important to have at least two validation studies conducted in different centers and with various populations. In this regard, the AAMI protocol recommends more than one study but without specifying the number of studies or devices. Therefore, as none of the three tested devices in this study went through earlier

validation, it would be important to achieve at least a second study in a specific population before recommending their widespread use in clinic.

Conclusion

The results of this study show that the three tested devices, The Omron M3 Intellisense, the Omron M2 Compact and the Omron R3-I Plus meet the requirements of the International Protocol in a general population and can be used by patients for SBPM. On account of certain limitations of the International Protocol, it would be desirable to corroborate these results by other studies carried out in general or specific populations.

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