

Evaluation of two devices for self-measurement of blood pressure according to the international protocol: the Omron M5-I and the Omron 705IT

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Background Two devices for self-measurement of blood pressure at the brachial artery—the Omron M5-I and the Omron 705IT—were evaluated according to the international protocol of the European Society of Hypertension.

Design The international validation protocol is divided into two phases: the first phase is performed on 15 selected subjects and if the device passes this phase, 18 supplementary subjects are included making a total number of 33 subjects on which the final validation is performed.

Methods For each subject, four blood pressure (BP) measurements were performed simultaneously by two trained observers using mercury sphygmomanometers alternately with three 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 differences were classified into categories (≤ 5 , ≤ 10 , ≤ 15 mmHg). The number of differences in each category was compared to 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 two of their three comparisons ≤ 5 mmHg.

Results The two tested devices passed the first phase of the validation process. For the second phase, the average differences between the device and mercury sphygmomanometer readings were -0.9 ± 5.8 and -0.8 ± 4.8 mmHg for systolic blood pressure (SBP) and diastolic blood pressure (DBP) respectively for the Omron M5-I device and -0.2 ± 4.5 and -2.0 ± 4.8 mmHg for the Omron 705IT device. Readings for the two devices differing by less than 5, 10 and 15 mmHg for systolic and diastolic values fulfil the recommendation criteria of the international protocol as well as the individual analysis.

Conclusions The Omron M5-I and the Omron 705IT devices pass the validation recommendations of the international protocol. *Blood Press Monit* 8:127–133 © 2003 Lippincott Williams & Wilkins.

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Introduction

Advantages of blood pressure (BP) self-measurement have been well documented [1–3]. Indeed, BP self-measurement not only provides valuable information on BP control of the treated patient, but also improves patient's compliance with anti-hypertensive therapy [4]. Therefore, it is appropriate to encourage the widespread use of self-recorded BP as an important adjunct to the clinical care of some patients with hypertension [5,6]. Obviously, BP self-measurement is only practicably useful if the devices are accurate, user-friendly, and relatively inexpensive. Particular attention must be paid to ensure the accuracy of the devices used. Ideally, recommended devices should have been subjected to standard validation procedures. During recent years various automated devices for self-measurement of BP have been fabricated. Some devices for measuring BP have been validated [7–16] according to protocols specifically designed for

this purpose, such as the British Hypertension Society (BHS) protocol [17,18], the Association for the Advancement of Medical Instrumentation (AAMI) protocol [19,20] and the most recent international protocol [21] published by the European Society of Hypertension. In this study, two devices for self-measurement of BP were validated according to the international protocol [21].

Methods

Omron M5-I

The Omron M5-I device records BP oscillometrically with a BP measurement range of 40–280 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) display. The inflation is by an automatic pumping system and the deflation is by an automatic pressure release valve. The unit is powered by four alkaline batteries 1.5V (type

LR6) which provide for about 300 measurements or by an AC/DC adapter (optional, 6V = 4W). The unit's weight is approximately 600 g with batteries and it measures 115 mm × 177 mm × 72 mm (width, height and depth, respectively). A standard cuff type M (140 mm × 480 mm) for an arm circumference 22–32 cm is provided. Two other cuffs, small (arm circumference 15–22 cm) and extra large (arm circumference 32–42 cm) are optional.

Omron 705IT

For the Omron 705IT device, BP is recorded by oscillometry, the cuff is inflated automatically by an electric pump system and deflated by an active electronic control valve system. Blood pressure and pulse ranges of measurement are 0–299 mmHg and 40–180 beats/min respectively. Approximated main unit weight and dimensions are 480 g including batteries and 115 mm × 177 mm × 71 mm respectively. The cuff is provided in standard size (140 mm × 480 mm) applicable to arm circumference 22–32 cm. A large cuff that fits arms 32–42 cm in circumference and a small cuff for arms 17–22 cm are optional accessories. Standard cuff dimensions are approximately 140 mm × 480 mm. The unit is powered by four 'AA' batteries for approximately 300 uses or an AC adapter (optional). The time, date, BP and heart rate are displayed on a LCD display. Data can be stored and printed or transferred to a PC.

Device validation

The evaluation of the two devices was done according to the most recent validation protocol, the international protocol [21], published by the European Society of Hypertension in 2002. The validation team consisted of three persons experienced in BP measurement that have in addition followed training on the basis of a CD-ROM [22] 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 standard mercury sphygmomanometer, the components of which were 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 with the test device. Analysis according to the international protocol consisted of two phases. In the first phase, 15 subjects were recruited; devices passing this primary phase proceeded to the secondary phase, for which a further 18 subjects were recruited.

Subject selection

Selection of subjects was done according to the recommendations of the international protocol (Table 1). For the primary phase, five of the 15 subjects should have a systolic blood pressure (SBP) in each of the ranges (Table 1). Similarly, five of the 15 subjects should have a diastolic blood pressure (DBP) in each of the ranges (Table 1). For the secondary phase, 11 of the 33 subjects

Table 1 Blood pressure (BP) ranges for entry BP

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

SBP, systolic blood pressure; DBP, diastolic blood pressure

(including the first 15 subjects) should have SBP and DBP in each of the ranges (Table 1). There are three ranges for SBP and three for DBP, with 11 subjects in each range to provide 99 pairs of measurements.

Procedure

The subjects were seated in a quiet room and BP measurements started after a 10–15 min rest period. Arm circumference was measured and cuff type was adapted to the circumference. All measurements were made on the left arm at the heart level. Blood pressure was measured simultaneously (Y tube) with two calibrated mercury sphygmomanometers by the two observers alternately with the automatic device. The observers were blinded to each other's readings. Measurements were carried out in the following sequence:

- *BPA* Entry BP, taken by both observers with the mercury standard. 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 test device.
- *BP3* Observers 1 and 2 with the mercury standard.
- *BP4* Supervisor with the test device.
- *BP5* Observers 1 and 2 with the mercury standard.
- *BP6* Supervisor with the test device.
- *BP7* Observers 1 and 2 with the mercury standard.

Accuracy criteria

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

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

Table 2 Results of the Omron M5-I device

Phase 1		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Recomm.		
Required	One of	25	35	40			
Achieved	SBP	35	43	45	Continue		
	DBP	39	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	68	92	98	Pass	-0.9	5.8
	DBP	83	95	98	Pass	-0.8	4.8
Phase 2.2		2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg		Recomm.		
Required		≥ 22	≤ 3				
Achieved	SBP	25	1		Pass		
	DBP	29	1		Pass		

Recomm., recommendation; Mean diff., mean difference (mmHg); SD, standard deviation (mmHg).

device measurement was flanked by two of these observer measurements, and one of these was selected as the comparative measurement as follows:

1. The differences BP2–BP1, BP2–BP3, BP4–BP3, BP4–BP5, BP6–BP5 and BP6–BP7 were calculated.
2. The absolute values of the differences were calculated.
3. These were paired according to the device reading.
4. If the values in a pair were unequal, the observer measurement corresponding to the smaller difference was used.
5. If the values in a pair were equal, the first of the two observer measurements was used.

When this has been completed, there were three device readings for SBP and three for DBP for each subject. Each of these six readings had a single corresponding observer measurement, a difference between the two and a band for that difference as described.

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

Results

Omron M5-I

The mean age of the 33 subjects was 52 ± 14 years (17 men and 16 women). The difference between the two

observers was 0.3 ± 1.6 and -0.2 ± 1.4 mmHg for SBP and DBP, respectively. The 99 measurements were $138 \pm 22/86 \pm 14$ mmHg with the Omron M5-I device and $145 \pm 23/89 \pm 15$ mmHg with the standard mercury sphygmomanometer. The mean and standard deviation of the difference were -0.9 ± 5.8 and -0.8 ± 4.8 for SBP and DBP, respectively.

In total, 45 sets of measurements (three measurements \times 15 subjects) were available for analysis in the first phase of the validation process, and 99 (three 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 2. These results are in concordance with the requested criteria of the international protocol for the primary and secondary phases. Thus the Omron M5-I device fulfils the validation criteria of the international protocol.

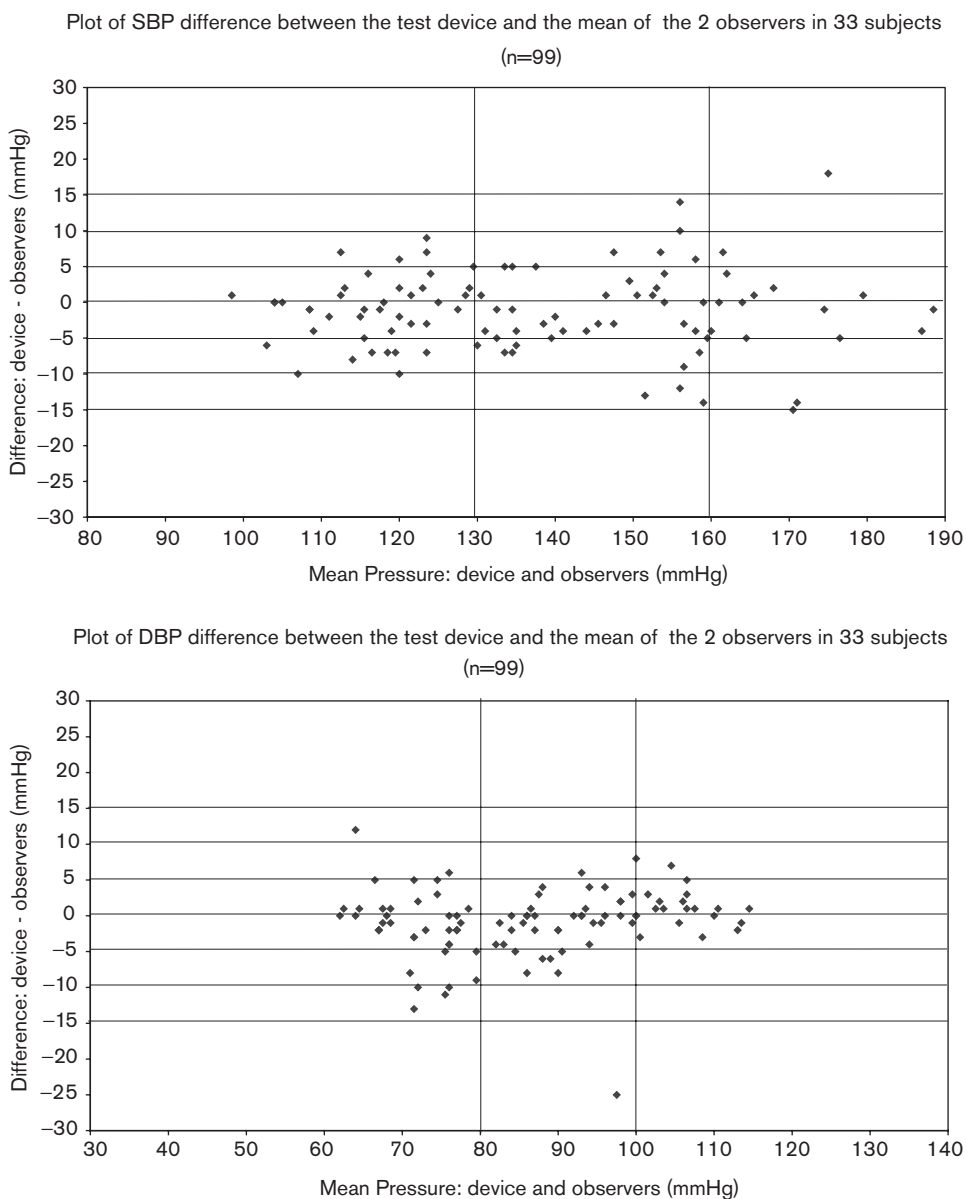
The difference between the device readings and observer readings and the mean BP from the device and from the two observers for all 99 points for SBP and DBP are displayed in Figure 1.

Omron 705IT

The mean age of the 33 subjects was 54 ± 13 years (18 men and 15 women). The difference between the two observers was 0.8 ± 1.5 and 0.1 ± 1.4 mmHg for SBP and DBP, respectively. The 99 measurements were $139 \pm 23/84 \pm 15$ mmHg with the Omron 705IT device and $141 \pm 26/88 \pm 16$ mmHg with the standard mercury sphygmomanometer. The mean and standard deviation of the difference were -0.2 ± 4.5 and -2.0 ± 4.8 for SBP and DBP, respectively.

In total, 45 sets of measurements (three measurements \times 15 subjects) were available for analysis in the first phase of the validation process, and 99 (three measurements \times 33 subjects) in the second phase. The number of measurements differing from the mercury

Fig. 1



Plots for systolic blood pressure (SBP) and diastolic blood pressure (DBP) (means of observer and device readings) versus the difference between the Omron M5-I device and the mercury sphygmomanometer.

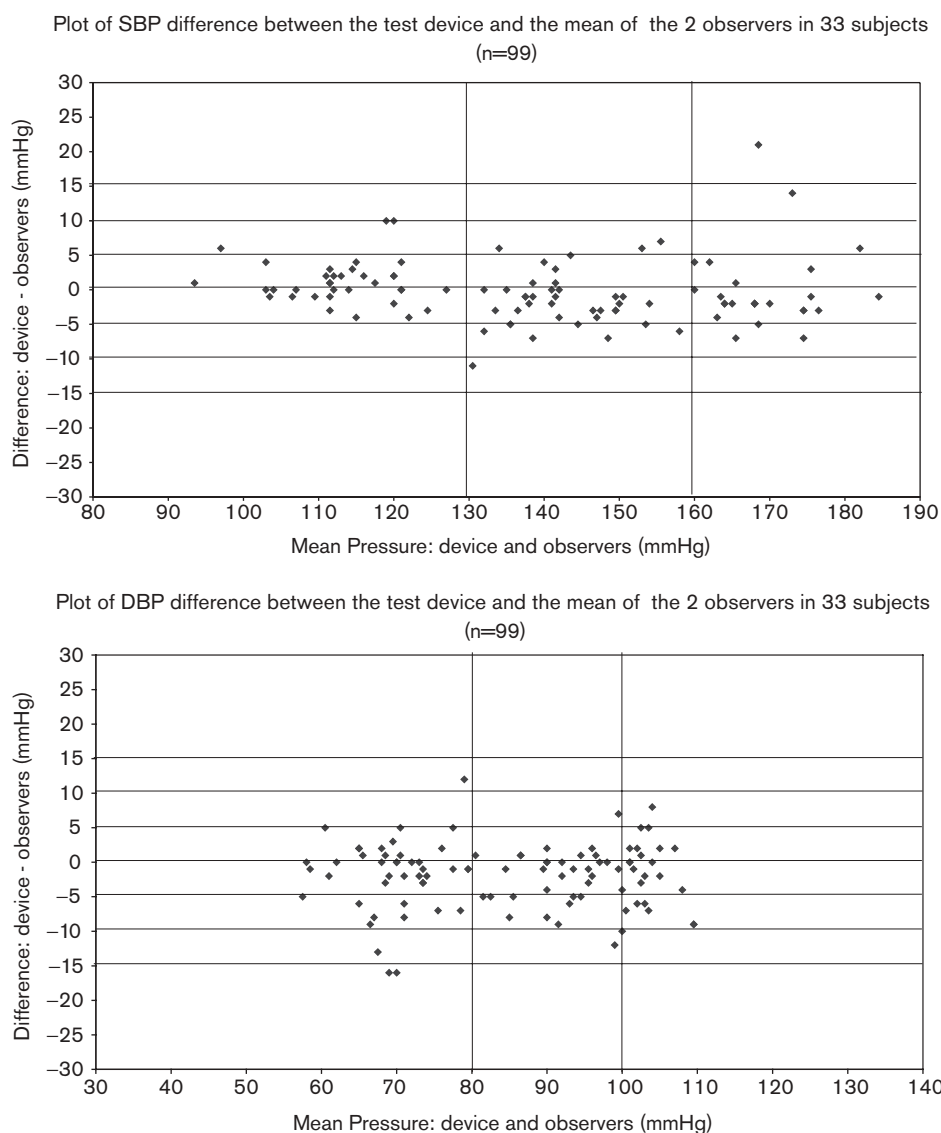
standard by 5, 10 and 15 mmHg or less, are shown in Table 3. These results are in concordance with the requested criteria of the international protocol for the primary and secondary phases. Thus the Omron 705IT device fulfils the validation criteria of the international protocol.

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

Discussion

The Omron M5-I and Omron 705IT fulfilled the validation criteria of the international protocol for SBP and for DBP. The international protocol recommendations [21] have been published in 2002 by the Working Group on Blood Pressure Monitoring of the European Society of Hypertension (ESH) aimed at simplifying the two main available guidelines, the BHS (17,18) and AAMI (19,20) protocols without sacrificing their integrity. These two validation protocols have many similarities but experience has demonstrated that the conditions they

Fig. 2



Plots for systolic blood pressure (SBP) and diastolic blood pressure (DBP) (means of observer and device readings) versus the difference between the Omron 705-IT device and the mercury sphygmomanometer.

recommend are sometimes extremely difficult to fulfil 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 these much more complicated earlier protocols [21]. The main advantage of the international protocol is that it requires a lower number of subjects, 33 instead of 85 with the two further protocols.

Our experience with the validation of these two devices shows that the recruitment of subjects having low systolic

(90–129 mmHg) and especially high diastolic (101–130 mmHg) blood pressures 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 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.

One other limitation to the present study is that the results are based on only one device and the validation was done in only one centre; however the international protocol [21] does not specify the number of devices to

Table 3 Results of the Omron 705IT device

Phase 1		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Recomm.		
Required	One of	25	35	40			
Achieved	SBP	38	43	44	Continue		
	DBP	31	42	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	96	98	Pass	-0.2	4.5
	DBP	74	94	97	Pass	-2.0	4.8
Phase 2.2		2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg		Recomm.		
Required		≥ 22	≤ 3				
Achieved	SBP	31	0		Pass		
	DBP	26	3		Pass		

Recomm., recommendation; Mean diff., mean difference (mmHg); SD, standard deviation (mmHg).

be tested or the number of study sites recommended to enhance the heterogeneity of the study population. The AAMI protocol [19,20] recommends more than one study site without specifying the number and without noting the number of devices required for validation, whereas the BHS protocol [17,18] does not specify any particular number of sites, but recommends using more than one of the model being tested to give consistent measurements, and if substantial differences between instruments of the same device occur, further device validation is not appropriate.

This analysis shows that with the Omron M5-I and the Omron 705IT, the device-observer limits of agreement widened with SBP rather than with DBP. This difference seems to be more important at higher SBP. Concerning DBP the difference is more obvious at lower rather than at higher DBP. The increased error at extremes of BP occurs in virtually all non-invasive devices, but the degree of error varies [15,16,23]. It is, however, also important to recognize that this usually bears little clinical relevance since therapeutic decisions would not significantly differ [15].

In conclusion, the two tested devices – the Omron M5-I and Omron 705IT – passed the validation criteria of the international protocol for validation of BP measuring devices.

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