

Validation of the OMRON M7 (HEM-780-E) blood pressure measuring device in a population requiring large cuff use according to the International Protocol of the European Society of Hypertension

Ramzi N. El Feghali, Jirar A. Topouchian, Bruno M. Pannier, Hiba A. El Assaad and Roland G. Asmar

Background A high percentage of hypertensive patients present an arm circumference of over 32 cm; the use of a large cuff is therefore recommended. Validation studies are usually performed in the general population using a standard-size cuff. The aim of this study was to assess the accuracy of the Omron M7 device in a population with an arm circumference ranging from 32 to 42 cm.

Design A validation study was performed according to the International Protocol of the European Society of Hypertension. This protocol is divided into two phases: the first phase is performed on 15 selected participants (45 pairs of blood-pressure measurements); if the device passes this phase, 18 supplementary participants are included (54 pairs of blood-pressure measurements), making a total number of 33 participants (99 pairs of blood-pressure measurements), on whom the analysis is performed.

Methods For each participant, four blood-pressure measurements were performed simultaneously by two trained observers, using mercury sphygmomanometers fitted with a Y tube; the measurements alternated with three by the test device. The difference between the blood-pressure value given by the device and that obtained by the two observers (mean of the two observations) was calculated for each measure. The 99 pairs of blood-pressure differences were classified into three categories (≤ 5 , ≤ 10 and ≤ 15 mmHg). The number of differences in each category was

compared with the number required by the European Society of Hypertension protocol.

Results The Omron M7 device passed the first and the second phases of the validation process. The average differences between the two observers were 1.5 ± 3.2 and -0.5 ± 2.2 mmHg for systolic blood pressure and diastolic blood pressure, and those between the device and the mercury sphygmomanometer were -1.6 ± 6.7 for systolic blood pressure and -0.12 ± 4.0 mmHg for diastolic blood pressure. Readings that differ by less than 5, 10 and 15 mmHg for systolic blood-pressure and diastolic blood-pressure values fulfill the recommendation criteria of the European Society of Hypertension protocol.

Conclusions The Omron M7 (HEM-780-E) device fulfilled the validation criteria of the international protocol in a population with an arm circumference ranging from 32 to 42 cm. *Blood Press Monit* 12:173–178 © 2007 Lippincott Williams & Wilkins.

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The CardioVascular Institute, Paris, France

Correspondence to Professor Roland G. Asmar, MD, The CardioVascular Institute, 2 rue du Docteur Blanche, 75016 Paris, France
Tel: +33 1 55 74 66 66; fax: +33 1 55 74 66 65;
e-mail: icv@icv.org

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Introduction

Several studies have shown the importance of self blood pressure measurements (SBPM) for the management of hypertension [1–3]. After the publication of the first international consensus conference on SBPM in 1999, the use of SBPM took shape and became more popular in both clinics and research. The advantages of SBPM have therefore been highlighted and well documented. Indeed, SBPM provides valuable information not only for hypertension diagnosis but also for the control of the blood pressure (BP) of the treated patient; further, it improves the patient's compliance with antihypertensive

therapy [4]. Moreover, SBPM has been shown to be a valuable tool in pharmacological and therapeutical trials. On the basis of this strong evidence, guidelines on hypertension management [3,5] clearly state the benefits of SBPM and encourage its widespread use as an important adjunct to the clinical care of hypertension patients [5,6].

There is an increasing number of automated BP monitors available on the market, and SBPM is useful only if it is performed according to guidelines and if the devices used are accurate [7]. Recommended devices should have

been subjected to independent clinical validation procedures [8–12]. However, although there are now an estimated 100 or more automated devices on the French market, not all have been validated for accuracy according to one of the recognized protocols specifically designed for this purpose, such as the British Hypertension Society (BHS) protocol [13], the Association for the Advancement of Medical Instrumentation (AAMI) protocol [14] and the most recent International Protocol [15] published by the European Society of Hypertension (ESH).

These three protocols look at accuracy in adult men and women in the general population with arm circumference distributed either by chance for the BHS and the ESH protocols, or by including 10% of patients with arm circumference < 25 cm and 10% > 35 cm for the AAMI protocol. Therefore, the accuracy of the results observed in the general population cannot be extrapolated to a specific population, such as a population in which the use of a large cuff is needed to obtain accurate BP measurements [16]. Taking these technical aspects, and the prevalence of some specific populations into consideration, it is important to assess the accuracy of automated BP devices not only in the general population but also in specific populations.

The aim of this study is to validate the Omron M7 automatic oscillometric BP device according to the international protocol of the ESH [15] in a population that requires a large cuff.

Methods

The tested device

Three Omron M7 devices were provided by the manufacturer. One of them was randomly selected to be used in this study. The Omron M7 is an electronic device for SBPM at the arm level, using the oscillometric method. Inflation is automatic (fuzzy-logic control) by electric pump. Deflation is automatic by pressure-release valve. The unit weighs approximately 400 g (without batteries). The device has a digital liquid crystal display screen that shows the measured BP and pulse rate in addition to date and time. The unit measures pressures from 0 to 299 mmHg and pulse from 40 to 180 beats/min. Ninety measurements, with date and time, can be stored in its memory. The included cuff HEM-CUFF-P is applicable to arm circumferences ranging from 220 to 420 mm, and has the following dimensions: 150 mm (width) × 582 (length).

Device validation

The study validation protocol was in accordance with the international protocol of the ESH with one modification: all the included patients had to present an arm circumference of between 32 and 42 cm. The validation team consisted of three persons: two observers trained in

accurate BP measurement and a supervisor. The two observers had completed a training session according to the training program of the French Society of Hypertension [17]. The measurements made by the two observers were checked throughout the evaluation period by the supervisor to make sure that the difference between the two was no more than 4 mmHg for SBP and DBP values. If the difference was greater, the measurements were repeated.

Two standard mercury sphygmomanometers, the components of which had been carefully checked before the study, were used by the two observers as the reference standard. Measurements to the nearest 2 mmHg were taken simultaneously by the two observers. The measurements were taken on the left arm, which was supported at heart level. Measurements by the OMRON M7 device were taken on the left arm supported at heart level, as recommended by the manufacturer. The arm circumference was measured to check the inclusion criterion: patients with arm circumference between 32 and 42 cm.

In all, nine sequential same-arm measurements using the test instrument and the standard mercury sphygmomanometer were recorded according to the international protocol.

Participants' selection

Patients were recruited from the population of outpatients attending the CardioVascular Institute in Paris for routine primary or secondary cardiovascular prevention. Participants excluded were those with atrial fibrillation, frequent extra systoles, intolerance for repeated arm compressions or who became anxious during the course of the measurements, and those with arm circumference < 32 or > 42 cm. Participants were selected according to the BP ranges recommended by the international protocol (Table 1). To fulfill the BP criteria ranges and 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 and, finally, the remaining gaps should be filled. Thirty-three participants with both SBP and DBP measurements were selected to validate the device.

The ESH international protocol consists of two phases. In the first phase, 15 participants (45 pairs of BP

Table 1 Blood pressure categories recommended by the international validation protocol

	Systolic BP (mmHg)	Diastolic BP (mmHg)
Low	90–129	40–79
Medium	130–160	80–100
High	161–180	101–130

BP, blood pressure.

measurements) are recruited; devices passing this primary phase proceed to the secondary phase, for which 18 participants (54 pairs of BP measurements) are recruited. Final analysis is performed on 99 paired measurements.

Procedure

BP measurements by the observers were as follows. The participants were seated in a quiet room and BP measurements started after a 10-min rest period. Arm circumference was measured and had to be between 32 and 42 cm to fulfill the inclusion criterion. All measurements were made on the left arm at the heart level. BP was measured simultaneously (Y tube) using two calibrated mercury sphygmomanometers by the two observers; these measurements altered with those made by the supervisor, who used the automatic device. The observers were blinded to each other's readings. As the inflatable bladder was connected to the two columns of mercury in the observers booths and to the Omron M7 device in a Y position, both the columns of mercury fell simultaneously for each of the blinded observers, who wrote down their measurements. BP measurements were performed on the left arm for the Omron M7. The Omron-specific cuff (HEM-CUFF-P) was used for both device and mercury sphygmomanometer BP measurements.

Measurements were carried out in the following sequence:

BPA entry BP, observers 1 and 2, each with an independent standard mercury sphygmomanometer. The mean values were used to categorize the participants into low, medium or high ranges, 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 participant 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 tested device 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.

Individual 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 comparable 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 had been completed, there were three device readings for SBP and three for DBP for each participant. Each of these six readings had a single corresponding observer measurement, a difference between the two and a band for that difference categorized as follows: 0–5, 6–10, 11–15, > 15 mmHg.

Assessment

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

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 a pass/fail grade for the second phase (phase 2.1) were determined. Also, for the second phase, the number of measurements falling within 5 mmHg was determined for each of the 33 participants and a pass/fail recommendation was determined according to the protocol (phase 2.2). For this phase, at least 22 of the 33 participants had to have at least two of their three comparisons lying within 5 mmHg. At most, three of the 33 participants could have all three of their comparisons over 5 mmHg apart.

To pass the validation and to be recommended for clinical use, a device had to pass both phase 2.1 and phase 2.2. If it did not, it failed and would not be recommended for clinical use.

Results

Participants

Recruitment to the study continued until all the specified BP categories were filled, giving a total of 33 participants. A total of 45 participants were screened to achieve this; 12 participants were excluded because the

relevant BP category was already full. The mean age of the 33 participants, of whom 18 were men and 15 women, was 48 ± 11 years. The mean arm circumference was 36 ± 3 cm with a ranging from 32 to 42 cm; so the cuff 'HEM-CUFF-P' was used for all participants.

Observer agreement

For all measurements, the differences between the two observers were 1.5 ± 3.2 and -0.5 ± 2.2 mmHg for SBP and DBP, respectively. The international protocol specifies that measurements made simultaneously by two observers must be checked by the validation supervisor. If both SBP and DBP values are no more than 4 mmHg apart, the mean values of the two observer measurements are used; otherwise measurement must be repeated.

Observer-device agreement

Mean BP values, obtained using a standard mercury sphygmomanometer, were, respectively, 138.5 ± 21.6 and 87.1 ± 13.7 mmHg for SBP and DBP. Mean BP values obtained using the Omron M7 device were 136.9 ± 21.7 and 86.9 ± 14.3 mmHg for SBP and DBP, respectively. The mean differences between the Omron M7 and the mercury sphygmomanometer were -1.6 ± 6.7 and -0.12 ± 4.0 mmHg for SBP and DBP, respectively.

In total, 45 pairs of measurements (three pairs of measurements $\times$ 15 participants) were available for analysis in the first phase of the validation process, and 99 pairs of measurements (three pairs of measurements $\times$ 33 participants) in the second phase for both Omron M7 and the mercury sphygmomanometer. The number of measurements differing from the mercury standard by 5, 10 and

15 mmHg or less is shown in Table 2. These results are in concordance with the requisite criteria of the international protocol for the primary and secondary phases. Thus the Omron M7 device fulfills the validation criteria of the international protocol. The difference between the device readings and the mean BP readings of the two observers for all measurement pairs of SBP and DBP are displayed in Fig. 1.

Discussion

The Omron M7 (HEM-780-E) device is an electronic device for SBPM using the oscillometric method at heart level. The original aspect of this device is that it includes a specific cuff (HEM-CUFF-P), which, according to the manufacturer, is applicable to arm circumferences ranging from 22 to 42 cm. The results of this study show that the Omron M7 device, with its appropriate cuff, fulfilled the validation criteria of the international protocol for SBP and DBP in a specific population with arm circumferences ranging from 32 to 42 cm, in which the use of an especially large cuff is usually recommended

In this study, validation has been performed according to the international protocol. The international protocol recommendations [15] have been published by the Working Group on Blood Pressure Monitoring of the ESH, which aimed to simplify the other two available protocols, the BHS [13] and AAMI [14], 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 participants who have to be recruited and

Table 2 Results of the Omron M7 device validation according to the international protocol

Phase 1: Number of comparisons falling within the 5, 10 and 15 mmHg error bands

Phase 1	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Recommendation
Required				
One of	25	35	40	
Achieved				
SBP	24	37	41	Continue
DBP	37	45	45	Continue

Phase 2.1: Number of comparisons falling within the 5, 10 and 15 mmHg error bands, mean difference (mmHg) and standard deviation (mmHg):

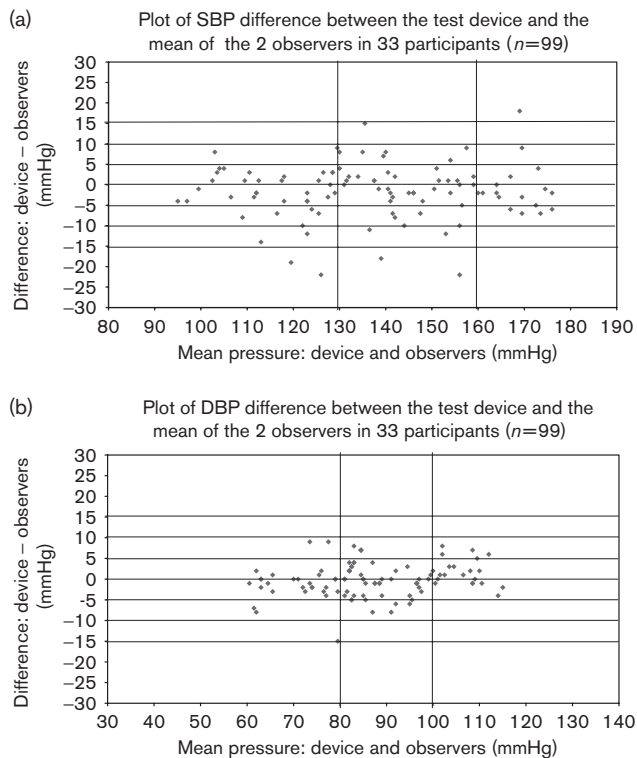
Phase 2.1	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Recommendation	Mean diff.	SD
Required						
Two of	65	80	95			
All of	60	75	90			
Achieved						
SBP	66	89	94	Pass	-1.6	6.7
DBP	82	98	99	Pass	-0.12	4.0

Phase 2.2: Number of comparisons per participant falling within 5 mmHg

Phase 2.2	2/3 ≤ 5 mmHg	0/3 ≤ 10 mmHg	Recommendation
Required	≥ 22	≤ 3	
Achieved			
SBP	22	3	Pass
DBP	29	1	Pass

The device passes for systolic and diastolic BP.

BP, blood pressure; DBP, diastolic blood pressure; SBP, systolic blood pressure.

Fig. 1

OMRON M7 (HEM-780-E) device. Plots for systolic (a) and diastolic (b) blood pressure differences between the test-device readings and the mean of the two observer readings in 33 participants ($n=99$) versus the difference between the OMRON M7 device and the mercury sphygmomanometer readings. (a) Plot of SBP difference between the test device and the mean of the two observers in 33 participants ($n=99$). (b) Plot of DBP difference between the test device and the mean of the two observers in 33 participants ($n=99$). DBP, diastolic blood pressure; SBP, systolic blood pressure.

because of 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 [15]. The main advantage of the international protocol is that it requires fewer participants: 33 instead of 85 with the two earlier protocols. It is important to mention here that statistical analysis in the international protocol is carried on the 99 paired measurements.

The total number of recruited participants ($n = 45$) was about 35% more than the requisite number ($n = 33$). This reflected the need to continue unproductive recruitment to find patients in all the BP categories. All participants in this study had regular heartbeats. Our experience with the validation of this device shows that the recruitment of participants with low SBP (90–129 mmHg) and especially high DBP (101–130 mmHg) is the major factor that extends the time required for validation, although the international protocol recommends that recruitment of participants should begin by targeting those likely to

have pressures in the low-systolic and high-diastolic ranges, so that it becomes easy to complete the recruitment in the remaining ranges.

A limitation of this study is that the results are based on only one device and the validation was done at only one center; however the international protocol [15] 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 [14] recommends more than one study site, without specifying the number and without noting the number of devices used for the validation. However, the BHS protocol [13] does not specify validation in more than one site but recommends assessing the capabilities of a number of devices of the tested model to give consistent measurements, and if substantial differences between instruments of the same device occur, further device validation would not be appropriate.

It is important to mention here that this validation was performed in a specific population and that the observed results cannot be extrapolated to the general population or to other specific populations, such as the elderly or children. Specific validation studies are needed and will be done in other centers. For this specific validation, we used the international protocol with only one modification: all the included patients must have presented an arm circumference of 32–42 cm. In fact, the aim of this study was to assess the accuracy of the Omron M7 (HEM-780-E) with its cuff, in a population that had been recommended to use a large cuff. According to guidelines, a large cuff is to be used in patients with arm circumference ≥ 32 cm. As the upper limit of the Omron cuff is 42 cm, the criterion range was 32–42 cm. In this study, validation of the Omron M7 device was performed using the Omron-specific cuff (HEM-CUFF-P) for both device and mercury sphygmomanometer BP measurements. In fact, use of the same cuff allowed us to assess the accuracy of the Omron device *per se* versus the mercury sphygmomanometer. Replacing the Omron cuff by a standard cuff for the mercury sphygmomanometer BP measurements can cause confusion over the validation specifications for devices and cuffs. As the purpose of this study was to assess the accuracy of the Omron device, for the reasons mentioned above, the use of a unique cuff was necessary. Therefore, if the accuracy of the Omron cuff is questionable, this has to be assessed in a specific study comparing the Omron cuff with a standard cuff, with both being connected to the same mercury sphygmomanometer.

In conclusion, the Omron M7 (HEM-780-E) device has passed the validation criteria of the international protocol of the ESH in a population with an arm-circumference range of 32–42 cm.

Acknowledgement

Potential conflicts of interest: None.

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