Validation of the Omron HEM-907 device for blood pressure measurement

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Background The aim of this study was to validate the Omron HEM-907 blood pressure (BP) measuring device according to the international validation protocol.

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 more subjects are selected making a total number of 33 subjects on which the final validation is performed.

Methods For each subject, BP measurements were performed simultaneously by two trained observers using mercury sphygmomanometers alternately with the Omron HEM-907 device. In all, 99 measurements were obtained for comparison. 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.

Results The difference between the two observers was -1 ± 2 mmHg for the systolic BP (SBP) and for the diastolic BP (DBP). The Omron HEM-907 passed the first phase of the validation process. For the second phase, the average differences between the device and mercury sphygmomanometer readings were -1 ± 7 and -5 ± 6 mmHg for SBP and DBP respectively. Readings for the HEM-907 device differed by less than 5 mmHg for 61 of the systolic readings and 52 of the diastolic readings; by less than 10 mmHg for 85 of the systolic readings and 85 of the diastolic readings; and by less than 15 mmHg for 94 of the systolic readings and 96 of the diastolic readings.

Conclusions The Omron HEM-907 device passes the two phases of the international validation protocol. *Blood Press Monit* **7:** 237–241 © 2002 Lippincott Williams & Wilkins.

Blood Pressure Monitoring 2002, **7:**237–241

Keywords: Omron HEM-907, blood pressure measuring device, validation, international protocol

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Sponsorship: Supported in part by Omron Japan.

Potential conflicts of interest: None

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Received 12 December 2001 **Revised** 22 April 2002
Accepted 26 April 2002

Introduction

Banning the use of mercury in clinical practice because of its toxicity may lead to the total replacement of mercury sphygmomanometers by automatic blood pressure (BP) measuring devices in the near future. Prior to marketing, these devices should be assessed for safety, accuracy, and reliability [1]. In 1987, the Association for the Advancement of Medical Instrumentation (AAMI) [2] published a standard for electronic or automated sphygmomanometers that included a protocol for the evaluation of the accuracy of devices and in 1990 the protocol of the British Hypertension Society (BHS) [3] was published. These protocols, which differed in details, had a common objective, the standardization of validation of BP measuring devices [4]. Both protocols [5,6] have since been revised. Recently, a suggestion was made that it would seem timely, therefore, for the AAMI and the BHS to join together in producing a revised common protocol for the validation of BP measuring devices that might be acceptable as an international protocol. A proposal for the international validation protocol has been established during the session 'Devices and Validation' of the First Consensus Conference on Self Blood Pressure Measurement [1,7]. The aim of our study was to validate the Omron HEM-907 device according to the proposed published international validation protocol [1,7].

Methods

The tested device

The Omron HEM-907 device records BP oscillometrically with an electrostatic capacity semi-conductor pressure sensor in the range 0–299 mmHg and heart rates in the range 30–199 beats/min. Systolic blood pressure (SBP), diastolic blood pressure (DBP) and heart rate are displayed on a digital display. The inflation is by an automatic pumping system and the deflation is by means of an automatic pressure-releasing electromagnetic control valve. Error codes (from 1 to 9) indicate when the device is malfunctioning or being used inappropriately. The unit is powered by an AC adapter (230 VAC, 50 Hz, output DC

8 V 500 mA). The unit's weight is approximately 910 g (32 oz) and it measures 139 mm (5 1/2″) × 203 mm (8″) × 131 mm (5 1/6″) (width, height and depth, respectively). A cuff/bladder set M (applicable arm circumference: 22–32 cm or 8 2/3″–12 3/5″) is provided. Two other cuff/bladder sets, L (arm circumference 32–42 cm or 12 3/5″–16 1/2″) and set S (arm circumference 17–22 cm or 6 2/3″–8 2/3″) are optional.

Device validation

Observer training was achieved prior to the validation process. Two physicians (observer 1 and observer 2) were trained and certified on the basis of a CD-ROM [8] specifically developed by the French Society of Hypertension for the certification of observers involved in clinical studies.

The validation of the Omron HEM-907 was performed according to the international protocol [1,7]. In a first step, validation was performed by the two observers on a group of 15 subjects, five subjects in each of the BP categories defined by the international guidelines [1,7]; then inclusion was carried out until 33 subjects in total had been included, with 11 subjects being in each BP category (for SBP: < 130, in the 130–160 range, and > 160 mmHg; for DBP: < 80, in the 80–100 range, and > 100 mmHg). According to the guidelines [1,7], a device failing the first phase of validation is eliminated from further testing.

The subjects were seated in a quiet room and BP measurements started after a 5–10 min rest. All measurements were made on the left arm with a cuff adapted to the arm circumference. 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: BP1, mercury; BP2, device; BP3, mercury; BP4, device; BP5, mercury; BP6, device; and BP7, mercury. All pressures were recorded with the patient seated, with the arm being at heart level. For each subject, the device measurements BP2, BP4, and BP6 were first compared to the mean of the two observer measurements BP1, BP3, and BP5 respectively to form a set and then to observer measurements BP3, BP5, and BP7 respectively to form a second set. In total, 45 pairs of measurements were available for analysis for the primary phase and 99 pairs for the secondary phase of the international protocol.

Accuracy criteria

For each set and each observer, the number of test-instrument measurements differing from the mercury sphygmomanometer by 5, 10, and 15 mmHg or less were calculated separately for SBP and DBP. The three pairs from the set whose comparisons were more favourable to the device were retained. The number of differences in each class was compared to the number required by the international protocol. Table 1 shows the international protocol evaluation criteria. The difference (device–observer), for SBP and DBP separately (using the data on which the final grade is based), was plotted against the mean of the device pressure and the mean observer pressure, using all 99 points [9].

In order to obtain 33 subjects to fulfil the inclusion criteria of the international protocol, 96 subjects in total were pre-included in the study. Also, 52 additional subjects (the first 52) out of the remaining 63, were selected on the basis of the BHS criteria in order to perform the analysis according to the AAMI [6] and BHS [5] guidelines; however analysis according to BP categories as recommended in the BHS protocol [5] was not performed since the number of patients required in each BP category was not achieved (Table 2).

Table 1 **The international protocol evaluation criteria for devices using sequential same-arm measurement**

		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg
Phase 1	At least one of	20	30	35
Phase 2	At least two of	50	75	90
	All of	45	70	85

Table 2 **BP ranges of the subjects according to the BHS categorization criteria**

SBP (mmHg)	< 90	90–129	130–160	161–180	> 180
BHS (*n*)	8	20	20	20	8
Omron study (*n*)	0	32	37	12	4
DBP (mmHg)	< 60	60–79	80–100	101–110	> 110
BHS (*n*)	8	20	20	20	8
Omron study (*n*)	1	27	46	7	4

SBP, systolic blood pressure; DBP, diastolic blood pressure; *n*, number of subjects.

Statistical analysis was performed using the NCSS® software (Number Cruncher Statistical Systems, Kaysville, Utah, USA).

Results

The mean age of the 33 subjects was 51.1 ± 13.9 years (19 men and 14 women). The difference between the two observers was −1 ± 2 mmHg for the SBP and for the DBP. The 99 measurements were 139 ± 27/84 ± 16 mmHg with the Omron HEM-907 device and 140 ± 27/89 ± 15 mmHg with the standard mercury sphygmomanometer.

In total, 45 (3 × 15) sets of measurements were available for analysis in the first phase of the validation process, and 99 (3 × 33) 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 3. These results are in concordance with the requested criteria of the international protocol for the primary and secondary phases. Thus the Omron HEM-907 device fulfils the validation criteria of the international protocol.

The difference between the device readings and observer readings and the mean BP of the device and the two observers for all 99 points for SBP and DBP are displayed in Figure 1. The standard deviation tends to increase with the level of BP. This tendency seems more marked for SBP than for DBP.

According to BHS 93 the grade is A for SBP and B for DBP (Table 4). The device also passes the validation criteria of the AAMI (Table 4).

Discussion

The Omron HEM-907 device fulfils the validation criteria of the international protocol for SBP and for DBP. The International recommendations [1,7] have been published as a proposed draft aiming to simplify the two main available guidelines, the BHS protocol, and the AAMI protocol. These two validation protocols have many similarities but there are some important differences [1,10]. It has been demonstrated in practice that validation studies can be performed in such a way as to satisfy the criteria of both protocols [1,7]. The main advantages of the international protocol are that it requires a lower number of subjects, simplifies the procedure, without affecting the accuracy of the validation [1,7]. To our knowledge, this is the first study to be published following the published proposal of the international protocol.

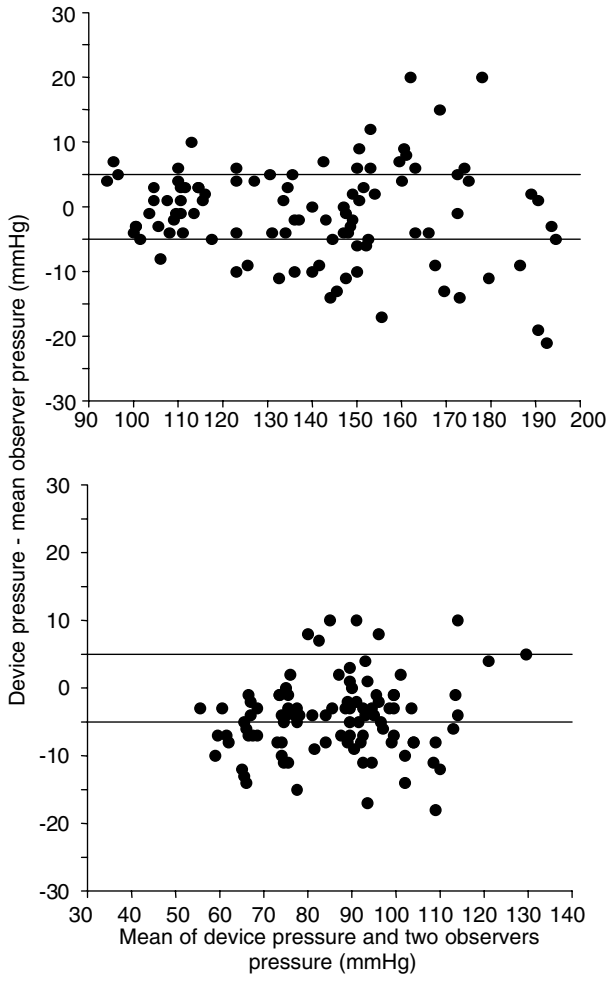
The Omron HEM-907 has been previously validated according to the AAMI validation protocol [11]. The present study confirms that the international protocol on 33 subjects does not substantially alter the results but greatly simplifies the process of validation. This analysis shows that with the Omron HEM-907, the device–observer limits of agreement widened at higher SBP values. The same conclusion was reached with the AAMI validation protocol but after analysis on 100 subjects [11].

Table 3 Number of measurements differing by 5, 10, and 15 mmHg from the mercury standard, and mean ± SD of the differences between the device and the mercury standard (Phase I: 15 subjects, 45 measurements and Phase II: 33 subjects, 99 measurements

	Mean ± SD (mmHg)	Differences between Omron device and mercury sphygmomanometer			Mean ± SD of differences (mmHg)
		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	
Phase I					
BP1 BP3 BP5					
SBP	143 ± 26	24	35	38	−3 ± 9
DBP	89 ± 15	26	39	43	−4 ± 6
BP3 BP5 BP7					
SBP	140 ± 25	27	39	44	−1 ± 7
DBP	89 ± 14	26	40	43	−4 ± 7
Final Grading					
SBP	140 ± 25	27	39	44	−1 ± 7
DBP	89 ± 14	26	40	43	−4 ± 7
Phase II					
BP1 BP3 BP5					
SBP	142 ± 28	53	76	89	−3 ± 8
DBP	89 ± 16	52	83	96	−5 ± 5
BP3 BP5 BP7					
SBP	140 ± 27	61	85	94	−1 ± 7
DBP	89 ± 15	52	85	96	−5 ± 6
Final Grading					
SBP	140 ± 27	61	85	94	−1 ± 7
DBP	89 ± 15	52	85	96	−5 ± 6

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

Fig. 1



Plot of pressure difference (mmHg) between the mean of the two observers and the Omron HEM-907 device and the mean pressure (mmHg) for the mean of the two observers and the Omron HEM-907 device in 33 subjects ($n = 99$). The upper panel corresponds to the systolic blood pressure readings whereas the lower panel shows the values for diastolic blood pressure. Reference lines, 0, ± 5, ± 10 and ± 15 mmHg difference.

The increased error at extremes of BP occurs in virtually all non-invasive devices, but the degree of error varies [11,12]. It is, however, also important to recognize that this usually bears little clinical relevance since therapeutic decisions would not significantly differ at, for example, a SBP of 190 mmHg versus one of 200 mmHg [11].

One limit of the present study is that these results are based on only one device and the validation was done in only one centre, however the international protocol 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 [6] recommends more than one study site without specifying the number of study sites and without noting the number of devices to validate, whereas the BHS protocol [5] does not make any recommendations regarding the number of study sites but does recommend that the capability of a number of devices of the model being tested are assessed in order to give consistent measurements, and if any substantial differences between instruments of the same device occur, then further device validation is not appropriate.

Conclusion

In conclusion, the Omron HEM-907 BP measuring device has passed the validation criteria of the published proposal of the international protocol for the validation of BP measuring devices and can be used for BP measurement.

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Table 4 British Hypertension Society (BHS) grading and Association for the Advancement of Medical Instrumentation (AAMI) criteria for the Omron HEM-907 device (85 subjects, 255 measurements)

	BHS				AAMI	
	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade	Mean $\pm$ SD (mmHg)	Grade
Final grading						
SBP	62%	87%	95%	A	0 ± 7	Pass
DBP	58%	90%	98%	B	-4 ± 5	Pass
Observer comparison						
SBP	100%	100%	100%		-1 ± 2	
DBP	100%	100%	100%		-1 ± 2	

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

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