Validation of the Omron M7 (HEM-780-E) oscillometric blood pressure monitoring device according to the British Hypertension Society protocol

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Background **The Omron M7 (HEM-780-E) is an automated oscillometric upper arm blood pressure monitor for the professional and home use markets. The aim of this study was to validate the accuracy of this device according to the British Hypertension Society (BHS) and the Association for the Advancement of Medical Instrumentation (AAMI) SP10 validation criteria.**

Methods **Participants were recruited until a total of 85 were obtained that filled the blood pressure ranges specified by the BHS protocol. Recruitment to the study was from the general medical and specialist clinics and from the staff at Guy's and St Thomas' Hospital in London, UK. Nine sequential same-arm blood pressure readings were taken from each participant by two trained observers, alternating between a mercury reference sphygmomanometer and the Omron M7 (HEM-780-E). The differences between the reference and test device readings, for both systolic and diastolic pressures, were compared with BHS and AAMI criteria to determine the outcome of the study.**

Results **The Omron M7 (HEM-780-E) is graded 'A' for systolic and 'A' for diastolic blood pressures according to the BHS criteria. The mean (standard deviation) of the difference between the observer and the device measurements was 0.75 ± 6.5) mmHg for systolic and 1.33 ± 5 mmHg for diastolic pressures. The device, therefore, also satisfies the AAMI SP10 standard for the study population, which requires differences of < ± 5 (8) mmHg.**

Conclusion **The Omron M7 (HEM-780-E) achieved an 'A/A' performance classification under the BHS criteria and passed the AAMI requirements for the study population. It can be recommended for professional and home-use in this population.** ***Blood Press Monit*** **13:49–54 © 2008 Wolters Kluwer Health | Lippincott Williams & Wilkins.**

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Introduction

Blood pressure (BP) measurement by auscultation with trained observers operating a mercury sphygmomanometer, remains the recognized reference method against which the new generation of electronic automated BP monitors are validated [1–3]. This approach is becoming increasingly time consuming, as effective use of antihypertensive drugs continues to reduce the number of available participants from the UK adult population that can be recruited to the high BP categories required by the validation protocols [4]. The importance of rapid validation of new automated BP monitors, however, is greater than ever as the variety of models continues to increase and regulators tighten requirements to ensure only accurate devices are used [5,6]. The most recent advice from the Department of Health, for example, is that the National Health Service (NHS) and other healthcare authorities should purchase only those devices for which there is evidence of compliance with specified performance criteria from properly conducted clinical trials [7]. The clinical trial reported here has compared the Omron M7 (HEM-780-E) with the reference method following the British Hypertension Society (BHS) protocol. Some of the issues that affect the quality and speed of these studies are considered.

The Omron M7 (HEM-780-E) is manufactured by Omron Healthcare Corporation (Kyoto, Japan) and is an automated oscillometric upper arm BP monitor for the professional and home-use markets. In common with the Association for the Advancement of Medical Instrumentation (AAMI) protocol [3], the BHS protocol [1] requires that validation is performed by comparing reference and test results from 85 participants in a wide range of BP categories. These requirements make the BHS and AAMI protocols particularly difficult and time-consuming to complete, but also give them greater statistical power than the European Society of Hypertension protocol [2], which requires just 33 participants.

Methods

The tested device

The Omron M7 (HEM-780-E) is an electronic oscillometric device with a capacitative pressure sensor designed to measure pressure in the range 0–299 mmHg and pulse rates in the range 40–180 beats/min. The specified accuracy for the pressure scale is ± 3 mmHg. The device has a memory for 90 measurements. Systolic and diastolic blood pressures (SBP and DBP) are displayed, along with pulse rate on a digital readout. Inflation is by an automatic pumping system and deflation is controlled by an automatic pressure release valve.

The unit can be powered by an AC adaptor or four 1.5-V alkaline batteries (type LR6 AA). It weighs 400 g with batteries and measures $16.5 \times 7.3 \times 11.0\,cm^3$ (width, height and depth, respectively). A 'Universal' cuff (Omron Comfort Cuff, Omron Healthcare Corporation, Kyoto, Japan), recommended for measurements on arm circumferences in the range 22–42 cm, was provided for this study. This cuff, of dimensions $15.0 \times 58.2\,cm^2$ (width and length, respectively), is specifically designed for use in combination with the Omron M7 (HEM-780-E) to allow a more rapid measurement sequence. It has an internal bladder of 29 cm length and is intended to be easy to fit in the correct position with a conveniently shorter width than a normal large sized cuff. The device is claimed by the manufacturer to have the same measurement algorithm as the newer Omron M6 Comfort (HEM-7000-E) and Omron M10-IT (HEM-7080IT-E), which have some additional features.

Study design

Two previously accepted modifications of the BHS protocol were made [8,9]. First, the testing in the low SBP range was restricted such that 28 participants were recruited, eight with an SBP ≤ 100 mmHg and 20 participants in the range 101–129 mmHg instead of eight participants with an SBP of less than 90 mmHg and 20 participants with SBP in the range 90–129 mmHg. Second, a semiautomated static pressure calibration of the device was made, as opposed to the manual dynamic pressure calibration approach described in the BHS protocol. This semiautomated approach has the advantage of reducing any observer bias.

Before-use calibration

Three identical new Omron M7 (HEM-780-E) test devices were donated by the manufacturer for the study. The pressure scales of these three test devices were calibrated on receipt using a previously described semiautomated static pressure calibration [9]. Thirty different static pressures, taken from tabulated random values of pressures specified in the BHS protocol, were applied automatically to the test device in sequence at 30-s intervals using an accurately calibrated pressure actuator. The corresponding pressure readings from the digital scale of the Omron M7 (HEM-780-E), operated in manual mode, were recorded by an observer who was blinded from the remotely applied pressure values. All 30 control and test measurement pairs were within 3 mmHg for each of the three devices. Although this is a static rather than dynamic test of the calibration, it serves to ensure that the test monitor is adequately calibrated before embarking on the time-consuming clinical phase. The dynamic calibration of the test device is, in any case, specifically tested in the clinical phase by comparison with readings from the falling mercury column of the reference sphygmomanometer.

In-use field assessment and after-use calibration

The three test devices were then placed in hospital clinics and the static calibration repeated after each had undergone at least 400 inflations. Again, all 30 control and test measurements remained within 3 mmHg on all devices. One device was arbitrarily selected for inclusion in the subsequent clinical phase of the validation.

Static device validation

Trial management system and recruitment

The study was conducted under the research governance framework of the UK Department of Health [10]. This framework sets out good practice standards in the domains of ethics, science, information, health and safety, finance and intellectual property. Ethics approval was obtained and recruitment was completed in 27 months. Participants were considered to have been recruited to the trial if they provided signed consent. Recruitment was *ad hoc* from the population of patients attending routine outpatient clinics in a large teaching hospital and from staff responding to an advertisement posted on the hospital intranet. The criteria for exclusion from the study were pregnancy, arrhythmia, atrial fibrillation, frequent extra systoles and sufficiently weak Korotkoff sounds that acceptable auscultation was impossible.

Observer training and assessment

The study team consisted of a medically qualified expert who provided clinical oversight, along with two clinical scientists and a technician, who recruited patients and acted as observers, undertaking the clinical intercomparison between the automated and mercury reference devices. All team members were full-time hospital staff and undertook the validation as part of their designated duties. A healthcare assistant was employed to act as an additional observer when required. All those involved as observers were trained using the CD-ROM tutorial detailed on the British Hypertension Society web site [11].

Data collection

The participants were seated in a warm, quiet room close to the clinic. Measurements started after consent was obtained, allowing at least 5-min rest, during part of

which participants were asked their age, height and weight for the record. The arm circumference was also measured and recorded. All pressures were measured with the patient seated with the upper arm at heart level.

Sequential same-arm measurements of SBP and DBP were independently recorded by two trained observers simultaneously using two Accoson Dekamet Mk3 mercury sphygmomanometers (A C Cossor & Son Ltd, London, UK) and the Omron M7 test device. Care was taken to ensure that observers were blinded to each other's readings. This was achieved by positioning the reference devices so that each observer could view only the scale of their own device and by ensuring they completed separate forms for recording the results.

For participants with arm circumferences less than 36 cm, the same 'Universal' cuff (Omron Comfort Cuff) was used with both the Omron M7 (HEM-780-E) and reference mercury sphygmomanometer, as this cuff complies with the BHS protocol requirement that the bladder (29 cm length) encompasses at least 80% of the arm circumference in this range. For participants with an arm circumference in the range 36–42 cm, same-arm sequential measurements were obtained using the 'Universal' cuff with the Omron M7 (HEM-780-E) and a large cuff, having a bladder length of 34 cm, with the reference sphygmomanometer.

Measurements were carried out and recorded in the protocol-specified sequence, with more than 30-s intervals between measurements to minimize venous congestion, but less than 1 min to minimize variability in BP:

BPA mercury (entry value used to categorize participants);
BPB device (to check the automated device, not included in the analysis);
BP1 mercury (observers 1 and 2);
BP2 device (test device);
BP3 mercury (observers 1 and 2);
BP4 device (test device);
BP5 mercury (observers 1 and 2);
BP6 device (test device);
BP7 mercury (observers 1 and 2).

Participants were allocated into BP categories on the basis of measurement BPA, which was discarded subsequently. Measurement BPB was also discarded and served only to confirm that the automated test device was capable of registering a reading. The measurements BP1–BP7 were retained for the analysis.

Data analysis

The data analysis is described in the BHS protocol [1]. In summary, the forward and backward differences between the device and the observer measurements are calculated (in mmHg) in each case. The resulting pairs of forward and backward device–observer differences are

BP2–BP1, BP4–BP3, BP6–BP5
BP2–BP3, BP4–BP5, BP6–BP7.

The three device–observer difference values most favourable to the device (i.e. the set with the smallest values, ignoring the sign) are selected for the analysis, generating 255 difference values for the complete study of 85 participants. This analysis is done separately for both SBP and DBP.

The differences derived from this procedure are then categorized, again ignoring the sign, to determine the percentage with values ≤ 5, ≤ 10 and ≤ 15 mmHg. The protocol specifies the minimum percentage for the test device to achieve an 'A', 'B', 'C' or 'D' rating. The percentage in all three categories should be equal to, or exceed, the specified minimum percentage. An 'A' rating, for example, requires at least 60% of device–observer difference values to be in the ≤ 5 mmHg error category, at least 85% in the ≤ 10 mmHg category and at least 95% to be in the ≤ 15 mmHg category. This analysis is done separately for each observer and for both SBP and DBP. The final grade for each SBP and DBP is the better of the grades obtained by the two observers.

Results

Participants

Recruitment continued until all protocol-specified categories of BP were filled, requiring 132 participants. Forty-seven of these were excluded leaving the required 85 participants for the analysis, an attrition rate of 36%.

The mean age of the 85 participants included in the study was 49.5 ± 15.2 years (range 24–88 years), of which 41 were men and 44 were women. The mean arm circumference was 30.2 ± 3.6 cm with a range of 23.5–39.5 cm.

Observer agreement

The BHS protocol specifies that at least 80% of measurements by the observers should be within 5 mmHg of each other, and 95% within 10 mmHg. The agreement between observers was well within these limits and results are presented in Table 1.

Observer–device agreement

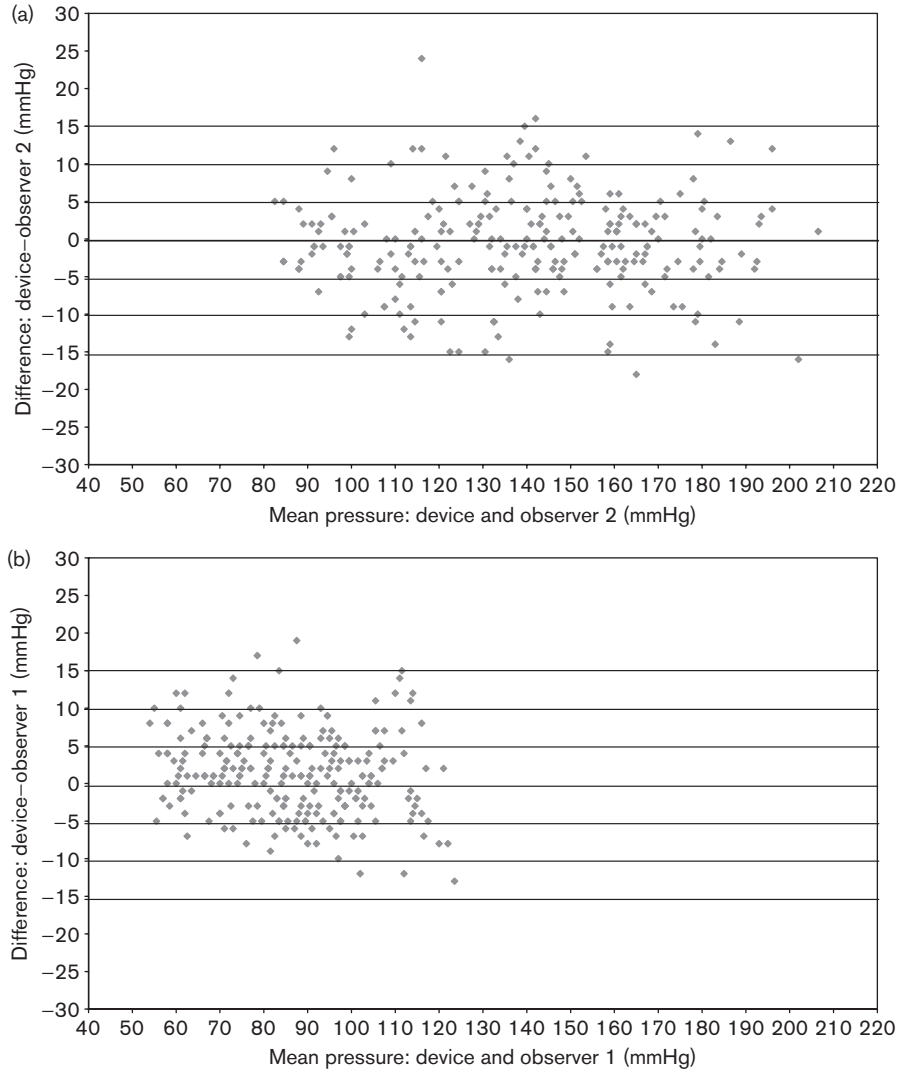
The overall result of the validation for both observers is shown in Table 1. The mean and standard deviation of the device–observer differences are -0.75 ± 6.5 mmHg for SBP (observer 2) and 1.33 ± 5.5 mmHg for DBP (observer 1). The data set, therefore, satisfies the AAMI standard [3] requirement that SBP and DBP device–observer differences be less than 5 ± 8 mmHg.

Table 1 Grading criteria, mean and mean differences for test device and an analysis for overall pressure levels for both observers

		Differences between standard and test device (mmHg)				
	Grade	≤ 5 (%)	≤ 10 (%)	≤ 15 (%)	Mean ± SD (mmHg)	Mean ± SD of differences (mmHg)
Observer 1						
SBP	A	66	89	98	139.5 ± 29.2	−0.17 ± 6.4
DBP	A	70	94	99	85.3 ± 17.3	1.33 ± 5.5
Observer 2						
SBP	A	69	86	98	140.1 ± 29.2	−0.75 ± 6.5
DBP	A	69	95	100	85.9 ± 17.6	0.56 ± 5.6
Final grade						
SBP	A	69	86	98	140.1 ± 29.2	−0.75 ± 6.5
DBP	A	70	94	99	85.3 ± 17.3	1.33 ± 5.5
Observer comparison						
SBP		96.5	100	100		
DBP		98.8	100	100		

Pressure range: SBP 80–228 mmHg; DBP 50–130 mmHg. On the basis of 255 difference values per observer for SBP and DBP. DBP, diastolic blood pressure; SBP, systolic blood pressure.

Fig. 1



(a) Plot of the pressure difference between the better observer and the test device, and the mean pressure for the test device and that observer, in 85 participants for diastolic pressure (the number of data points is 255). (b) Plot of the pressure difference between the better observer and the test device, and the mean pressure for the test device and that observer, in 85 participants for systolic pressure (the number of data points is 255).

Table 2 Grading criteria for test device at high, medium and low pressure levels for the better observer

		Differences between standard and test device (mmHg)			
	Grade	≤ 5 (%)	≤ 10 (%)	≤ 15 (%)	*N*
Low pressure range (<130/80 mmHg)					
SBP	A	69	90	98	84
DBP	A	70	94	99	99
Medium pressure range (130–160/80–100 mmHg)					
SBP	A	65	85	98	81
DBP	A	71	99	99	72
High pressure range (>160/100 mmHg)					
SBP	A	67	91	98	90
DBP	A	70	89	100	84

DBP, diastolic blood pressure; SBP, systolic blood pressure; *n*, number of device–observer difference values.

The BHS protocol allows the selection of the results from the best observer, in this case observer 2 for systolic and observer 1 for diastolic pressures. The Omron M7 (HEM-780-E), therefore, achieves an overall A rating (the 'final grade' as shown in Table 1) for both systolic and diastolic.

Figure 1a and b shows the Bland–Altman plots [12] corresponding to the better observer measurements for diastolic and systolic pressures, respectively. Here, the 255 values of the difference between the device and the better observer (in mmHg) are plotted against the mean value of the device and observer readings (in mmHg). These graphs show a random scatter centred about the mean device–observer difference. They also show that there are no trends in the data. These are both required features of the Bland–Altman plots for the results to be generalizable.

Table 2 gives a breakdown of the results by pressure range. Applying the BHS criteria within these ranges, the Omron M7 (HEM-780-E) achieves an A/A rating for low, medium and high pressure ranges.

Discussion

The Omron M7 (HEM-780-E) achieved an overall A grade for both SBP and DBP according to the BHS protocol. It also satisfied the AAMI criteria. It should be pointed out that the participant population, designed here to meet the BHS protocol requirements, differed from the AAMI standard requirements. AAMI requires participants representing an adult population to be distributed such that at least 10% have SBP and DBP readings below 100 and 60 mmHg, respectively, and 10% of participants have SBP and DBP above 160 and 100 mmHg, respectively. These conditions were satisfied here in three out of the four specified ranges: in the low DBP range (< 60 mmHg) there was one participant less than required minimum of nine. The AAMI standard for adult populations also specifies the arm circumference distribution requirements such that at least 10% of participants have an arm circumference above 35 cm, and 10% have an arm circumference below 25 cm. In this study, eight out of 85 participants (9%) had an arm circumference above 35 cm, one less than the minimum required, and seven participants (8%) had an arm circumference below 25 cm, two less than required. The device can be considered to have passed the AAMI criteria for the study population, which in practice, deviates only slightly from that specified by AAMI.

The device performed well over low, medium and also high BP ranges. This is an encouraging finding as it has been observed previously that oscillometric monitors have a tendency to underestimate the high values of BP. An earlier study [9] showed that the Omron 705IT (HEM-759-E), for example, while achieving an overall A/A rating, slipped to a 'C' rating for DBP in the high range (> 100 mmHg) with only 46% of differences between standard and test device readings being ≤ 5 mmHg compared with 70% for the Omron M7 (HEM-780-E).

The recruitment attrition rate (36%) and total duration of the study (27 months) were similar to those reported for a recently published BHS validation at the same centre [9]. It is instructive to examine the reasons for the observed high value of the attrition rate, which accounts for around 9 months of unproductive work. Thirty participants were excluded because the relevant BP category was already full. A further six participants were excluded after reassignment within the defined BP categories to ensure that paired values of the SBP and DBP fitted the categories. Five participants were excluded because the Korotkoff sounds were inaudible. The test device failed to register a BP in three participants; two participants withdrew because of discomfort during cuff inflations and one was excluded because of disruption of the study by an unruly accompanying child.

The difficulty in recruiting participants for validations in the high BP ranges is the main limitation on the speed with which these studies can be completed. Recruitment of hypertensive participants is unlikely to get easier as the prevalence of hypertension in the United Kingdom continues to fall [4]. The commercial and health service imperatives for speed in completing validations make it critical that both customers for validations and users can remain confident in the quality of results. Some reassurance of quality is provided by the bodies that currently perform a retrospective peer review of published results. These bodies list on their web sites the device ratings along with a critique of the study where appropriate [13,14]. Although this is an important service that can filter cases where the publication itself reveals inadequacies in the study, there is currently no means of monitoring the degree to which validation centres

themselves comply with the validation protocols [1–3] and national research governance standards [10].

It is suggested here that the policy and procedures followed by a validation centre, detailing among other things the approach used to implement the research protocol and governance standards, could usefully be incorporated within an established quality management system through which the centre could demonstrate its competence. The international standard ISO17025 [15], for example, defines a quality system used by test and calibration laboratories. BP monitor validation centres share many management processes with device test laboratories, including well-defined protocols and the need to provide assurance of the accuracy of test results. Incorporating the requirements of the relevant validation protocol and national governance standards within the centre's ISO17025 quality system policies and procedures would, for example, provide assurance that a validation centre was regularly audited as to its competence. Our centre has recently applied to the United Kingdom Accreditation Service for accreditation to ISO17025 for BP monitor validations. Although accreditation represents a cost overhead, it is expected to provide useful assurance of a centre's competence to run these studies.

Conclusion

On the basis of both BHS and AAMI requirements, the Omron M7 (HEM-780-E) can be recommended for professional as well as home-use in an adult population. Only a limited number of automated devices currently recommended by the advisory body, dable Educational Trust [13], have achieved a BHS A/A grade. This device will usefully increase the currently limited choice of validated automated devices.

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Conflicts of interest: none.

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