Evaluation of three devices for self-measurement of blood pressure according to the revised British Hypertension Society Protocol: the Omron HEM-705CP, Philips HP5332, and Nissei DS-175

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Objective We evaluated three devices for self-measurement of blood pressure – the Omron HEM-705CP, the Philips HP5332 and the Nissei DS-175 – according to the revised protocol of the British Hypertension Society (BHS). The results were also analysed according to the criteria for accuracy of the revised standard of the Association for the Advancement of Medical Instrumentation (AAMI).

Design The revised BHS protocol is divided into two parts. Part I, the part applicable to this study, comprises the main validation procedure and has five phases: Before-use device calibration; in-use (field) phase; after-use device calibration; static device validation; report of evaluation.

Methods Three models of each device passed the before-use device calibration test, after which they entered the in-use phase, which involved use of the three recorders for a month; inter-device calibration was assessed again at the end of the month. There was no difference in calibration testing between the three models of each device, and therefore one of each was selected randomly; the main validation test was carried out in 85 subjects with a wide range of pressures, and the results were analysed according to the BHS grading system from A to D.

Results The Omron HEM-705CP achieved an overall B/A grading and fulfilled the AAMI accuracy criteria; the Philips HP5332 achieved an overall C/A grading and failed the AAMI accuracy criteria for measuring systolic pressure; the Nissei DS-175 achieved an overall D/A grading and failed the AAMI accuracy criteria for measuring systolic pressure. When the BHS and AAMI criteria were applied to tertiles of pressure (low-pressure range < 130/80 mmHg; medium-pressure range 130–160/80–100 mmHg; high-pressure range >160/100 mmHg) all three devices were less accurate in the high-pressure range: the Omron HEM-705CP achieved C/B grading while continuing to fulfil the AAMI criteria; the Philips HP5332 dropped to D grading for systolic pressure and the Nissei DS-175 achieved a lower D grading for systolic pressure. The mean and standard deviation of the first mercury sphygmomanometer measurements were 148 ± 35/88 ± 22 mmHg. Acceptability by the users was good and the manufacturer's manual was satisfactory for all three devices.

Conclusions On the basis of these results, the Omron HEM-705CP was the most accurate of the three devices tested, achieving Grade B for systolic and Grade A for diastolic pressure, as well as fulfilling the AAMI criteria for accuracy for both systolic and diastolic pressure. It can therefore be recommended for the clinical measurement of blood pressure and is the first inexpensive device to satisfy the accuracy criteria of these protocols.

Blood Pressure Monitoring 1996, 1:55–61

Keywords: Omron HEM-705CP, Philips HP5332, Nissei DS-175, self/home blood pressure measurement, validation, BHS protocol

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Sponsorship: Support from Synthélabo, Belgium, the Charitable Infirmary Charitable Trust, the Royal College of Surgeons in Ireland and Beaumont Hospital is acknowledged with gratitude.

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Received 2 July 1995
Accepted August 1995

 ISSN 1359-5237

Introduction

In recent years many automated devices have been manufactured for self-measurement of blood pressure. The most accurate devices have been expensive sophisticated systems, such as devices used for ambulatory blood pressure measurement [1]. Inexpensive devices for measuring blood pressure, for example in the home, which might also have a wider application in clinical practice, have generally proved to be unacceptably inaccurate [2]. In this study, three popular devices for home measurement of blood pressure were validated according to the revised protocol of the British Hypertension Society (BHS), each in 85 subjects [3]. The results were also analysed according to the criteria for accuracy of the revised standard of the Association for the Advancement of Medical Instrumentation (AAMI) [4].

Methods

Omron HEM-705CP

The Omron HEM-705CP records blood pressure oscillometrically with an electrostatic capacitance-type pressure sensor in the range of 0–280 mmHg and heart rates in the

range of 40–200 beats/min. The results are displayed on a liquid crystal digital display. Inflation is by an automatic pumping system and deflation by means of an automatic pressure releasing valve. The results displaying systolic, diastolic and mean blood pressure and the date and time of recording are printed on a small thermal dot printer incorporated in the unit; measured pressure may also be printed graphically. A series of error codes indicate malfunction or inappropriate use. The unit is powered by four 6V 4W dry cell batteries which provide for about 500 cycles of measurement. The unit weighs approximately 720 g (with batteries) and measures 202 (w) × 73 (h) × 142 (d) mm. A cuff measuring 140 (w) × 480 (l) mm is provided with an inflatable bladder, the dimensions of which are not stipulated.

Philips HP5332

For the Philips HP5332, many technical details, such as its dimensions and the range of pressures that may be recorded, were not specified. Blood pressure is recorded by oscillometry with an inflatable cuff which is inflated automatically. The cuff is provided in standard, small and large sizes; the dimensions of the inflatable bladder were not detailed. The unit is powered by four 1.5 V alkaline batteries (type LR14) but may be connected to the mains by an AC adapter. The time, date, blood pressure and heart rate may be displayed on a liquid crystal digital display. These data and stored data may also be printed.

Nissei DS-175

The Nissei DS-175 records pressure oscillometrically, and systolic, diastolic blood pressures and heart rate can be displayed on a liquid crystal digital display and printed. Inflation of the cuff is with an automatic air pump. Pressure in the range 0–300 mmHg and pulse rates in the range of 40–150 beats/min can be recorded. The unit is powered by UM-3 or AA or R16 type 4PCS or by an AC adapter. The Nissei DS-275 measures 210 (w) × 150 (d) × 42 (h) and weighs approximately 55 g including batteries. Systolic and diastolic blood pressure, heart rate and the time and date can be printed.

Evaluation programme

The revised BHS evaluation programme consists of five phases: 1 Before-use device calibration; 2 In-use (field) assessment; 3 After-use device calibration; 4 Device validation; 5 Report of evaluation [3].

Before-use device calibration

A connector on the inflation tube of each device may be joined with a Y-connector to a mercury sphygmomanometer to check device calibration. The automatic pressure system and the blood pressure detection mechanism were disabled so that the device acted simply as a manometer. Three observers were blinded to each other's findings in booths. Observer 1 read a recently calibrated mercury column and observer 2 read one of the devices. The manometers were connected by Y-connectors to a further mercury manometer, which was read by a third observer (the 'controller'). All three manometers were connected to the cuff of the device being tested, which was wrapped around a cylinder. The 'controller' observer deflated the cuff at 2 mmHg/s and called out 'now' to denote the moment for the two observers to record pressure.

The BHS protocol stipulates that there should be five calls per deflation according to a randomized selection of pressure levels to ensure that all devices receive the same pressure calls but in an order indiscernible to the observers. There should be six deflations per device with five readings per deflation to provide 30 readings per device yielding 90 readings for analysis, of which at least 95% have to be within the recommended limits of 3 mmHg; if this criterion is not fulfilled further testing is not performed.

In-use assessment

The three devices (the Omron HEM-705CP, the Philips HP5332 and the Nissei DS-175) used for the inter-device assessment were subsequently used to test performance during and after a 1-month period of use. Each of the three instruments was exposed to routine use in the coronary care unit and the Accident and Emergency Department; they each performed at least 400 inflations. Problems encountered by those using the device during this phase were documented.

After-use device calibration

At the end of the month of use the three monitors were re-tested for device variability in the same way as previously to determine whether there had been any change in inter-device agreement during ambulatory use.

Device validation

Observer training

Three nurse observers were tested for accuracy against each other and against an expert observer in booths as described in the BHS protocol [3]. Five subjects with a range of blood pressure from 110/60 mmHg to 189/110 mmHg were seated behind a partition and 10 measurements were made by each observer on each subject, giving a total of 50 measurements for each observer.

Device comparison

No alteration in inter-device variability after the month of use was observed, and therefore one device was arbitrarily selected for the main validation test.

Sequential same-arm measurements between the test instrument and a standard mercury sphygmomanometer were carried out according to the sequence in the protocol [3]. All pressures were recorded with the patient seated. Analysis was carried out separately for Observers 1 and 2 using three pairs of readings from each subject. To com-

pare one observer and the test instrument, one of two sequences was used: sequence (a): — BP1 versus BP2, BP3 versus BP4, and BP5 versus BP6 or sequence (b): — BP2 versus BP3, BP4 versus BP5, and BP6 versus BP7. So as to obviate the possibility that chance might disadvantage the test device, the sequence used was the one most favourable to the test device for each subject; this sequence was repeated in 85 subjects. A total of 255 pairs of measurements by each observer and the test instrument were available for analysis of each of the three devices.

Accuracy criteria

The percentages of test instrument measurements differing from the mercury standard by 5, 10 and 15 mmHg or less were calculated separately for each observer and separately for systolic and diastolic pressure for each of the three devices. Each device was graded A, B, C or D separately for each observer, as shown in Tables 1–3. To obtain a particular grade all three percentages had to equal or exceed the tabulated values. The final grade for each systolic and diastolic pressure was the better of the grades obtained by the two observers. The difference (device–observer), for systolic and diastolic pressure separately (using the data on which the final grade is based), was plotted against the mean of the device pressure and the observer pressure, using all 255 points (Figures 1–3). Eighty per cent of the observers' measurements were within 5 mmHg of each other and 95% within 10 mmHg.

Blood pressures were also classified and analysed as follows: low-pressure range <130/80 mmHg; medium-pressure range 130–160/80–100 mmHg; high-pressure range >160/100 mmHg. For this analysis, each subject was classified on the basis of the initial mercury measurement.

The mean differences and standard deviation of the differences are also given to determine if the device is within the AAMI recommendations, which stipulate that the mean difference shall be equal to or less than 5 mmHg and the standard deviation equal to or less than 8 mmHg (Tables 1–3).

Results

Observer training and assessment

All three trainee observers passed the accuracy criteria, with 45 of systolic and diastolic differences between each trainee and between trainees and expert not being more than 5 mmHg and 48 not more than 10 mmHg.

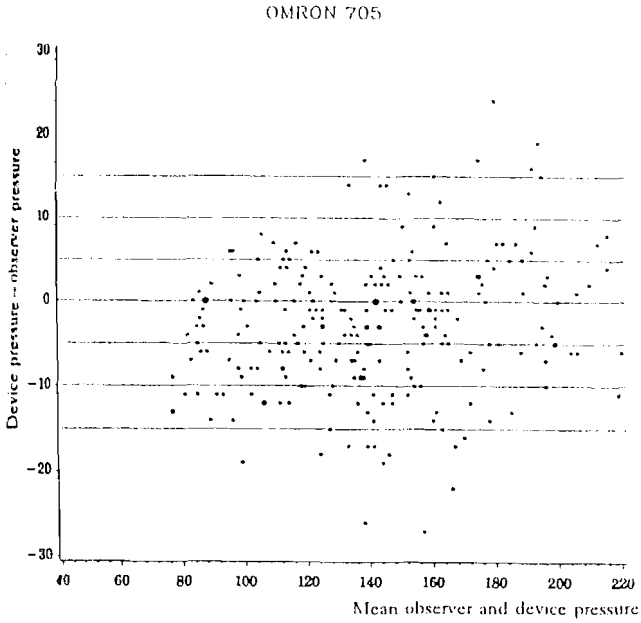
Before-use and after-use device calibration

All the devices were within the error limits permitted.

In-use assessment

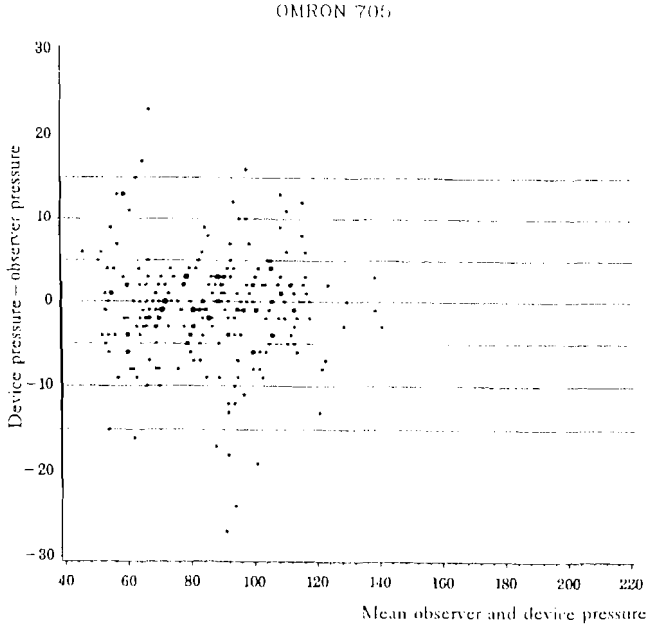
In this phase, the nine devices were tested in working areas of the hospital so that all devices underwent at least 400 inflation/deflation sequences. During this phase the percentage of failed recordings for each series of three

Fig. 1a.



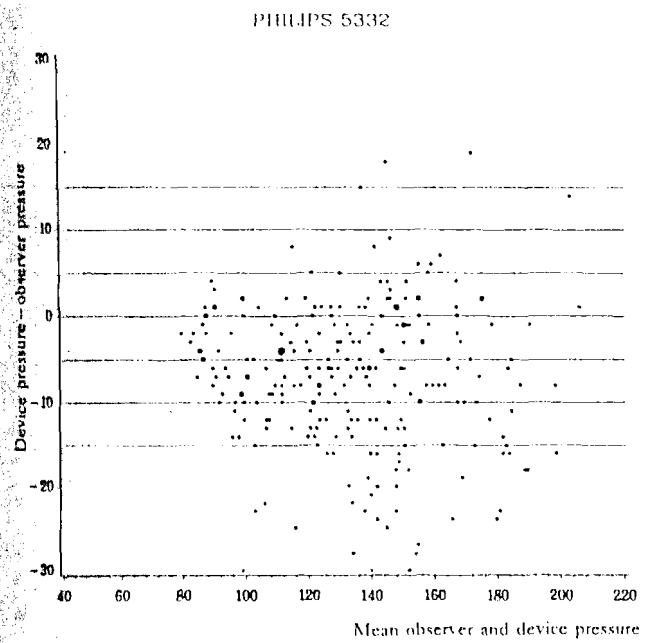
Systolic blood pressure measured using a mercury sphygmomanometer versus the simultaneously measured difference between the mercury and Omron HEM-705CP measurements in 85 participants (n = 255)
Reference lines: − 15 to + 15 mmHg in 5 mmHg steps

Fig. 1b.



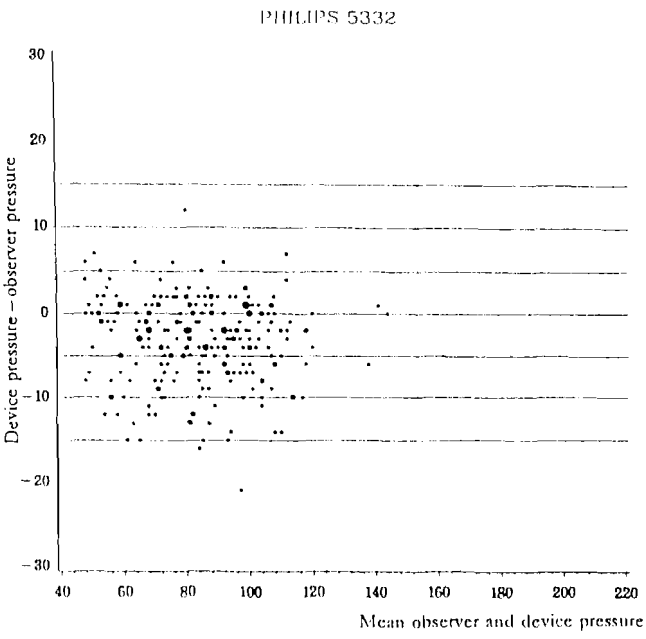
Diastolic blood pressure measured using a mercury sphygmomanometer versus the simultaneously measured difference between the mercury and Omron HEM-705CP measurements in 85 participants (n = 255)
Reference lines: − 15 to + 15 mmHg in 5 mmHg steps

Fig. 2a.



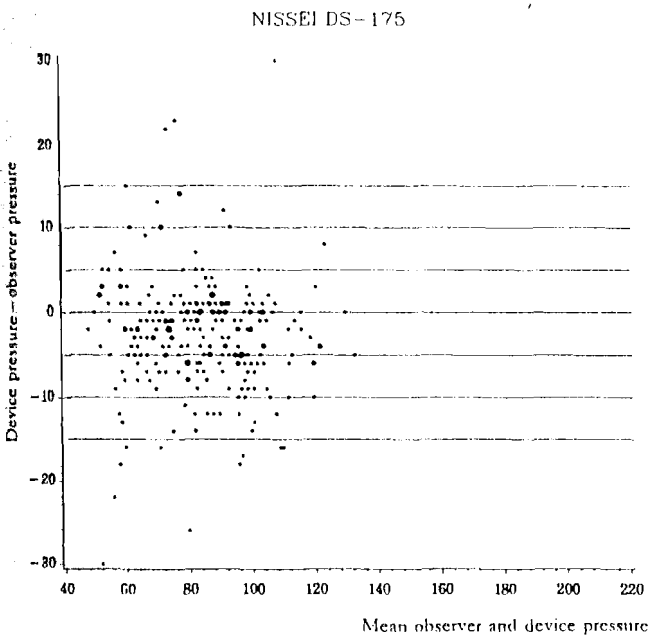
Systolic blood pressure measured using a mercury sphygmomanometer versus the simultaneously measured difference between the mercury and Philips HP5332 measurements in 85 participants (n = 255)
Reference lines: − 15 to + 15 mmHg in 5 mmHg steps

Fig. 2b.



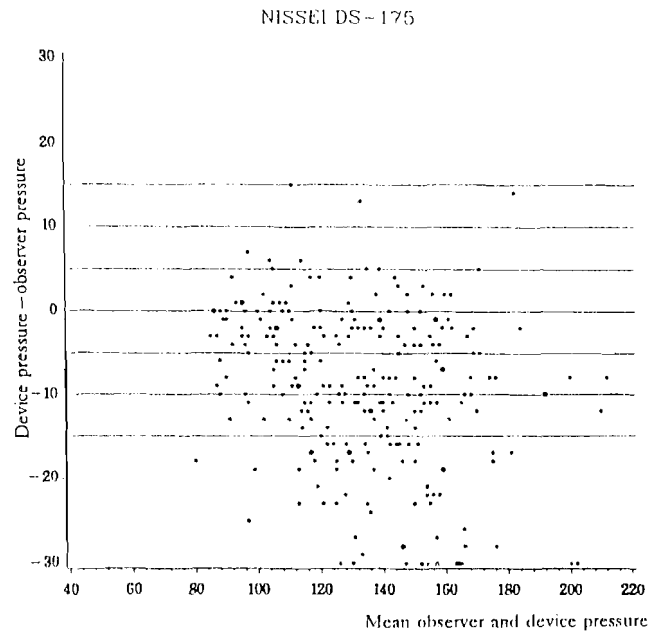
Diastolic blood pressure measured using a mercury sphygmomanometer versus the simultaneously measured difference between the mercury and Philips HP5332 measurements in 85 participants (n = 255)
Reference lines: − 15 to + 15 mmHg in 5 mmHg steps

Fig. 3a.



Diastolic blood pressure measured using a mercury sphygmomanometer versus the simultaneously measured difference between the mercury and Nissei DS-240 measurements in 85 participants (n = 255)
Reference lines: − 15 to + 15 mmHg in 5 mmHg steps

Fig. 3b.



Systolic blood pressure measured using a mercury sphygmomanometer versus the simultaneously measured difference between the mercury and Nissei DS-240 measurements in 85 participants (n = 255)
Reference lines: − 15 to + 15 mmHg in 5 mmHg steps.

devices was: Omron HEM-705CP 7%, Nissei DS-175 37%, Philips HP5332 5%.

Patient/subject acceptability

The nurses in charge of the in-use phase were asked to comment on the performance of the device. There were no adverse comments on the Omron HEM-705CP and the Philips HP5332. The Nissei DS-175 was not liked by either the operating nurses or the patients. The device tended to reinflate without completing deflation and without giving an error code, which often resulted in much discomfort for the patient and annoyance for the operator. Changing the paper in the printer was noted to be difficult.

Device validation

The percentage of measurements differing from the mercury standard by 5, 10 and 15 mmHg or less shown in Tables 1–3 and plotted in Figures 1–3. To obtain a particular grade, all three cumulative percentages had to exceed the tabulated values.

Eighty-five subjects with blood pressures within the recommended ranges were selected. Arm circumferences ranged from 21 to 41 cm (mean 29 ± 3 cm). A total of 255 (3×85) sets of measurements were available for analysis. All pressures were recorded in the seated position. The percentage of measurements differing from the mercury standard by 5, 10 and 15 mmHg or less for the best observer are shown in Tables 1–3 with the AAMI criteria for accuracy. To obtain a particular grade, all three cumulative percentages had to exceed the tabulated values. The Omron HEM-705CP achieved an overall B/A grading and fulfilled the AAMI accuracy criteria; the Philips HP5332 achieved an overall C/A grading and failed the AAMI accuracy criteria for systolic pressure; the Nissei DS-175 achieved an overall D/A grading and failed the AAMI accuracy criteria for sytolic pressure. Applying the BHS and AAMI criteria to tertiles of pressure (low-pressure range <130/80 mmHg; medium-pressure range 130–160/80–100 mmHg; high-pressure range >160/100 mmHg) all three devices were less accurate in the high-pressure range: the Omron HEM-705CP achieved C/B grading while continuing to fulfil the AAMI criteria; the Philips HP5332 dropped to D grading for systolic pressure and the Nissei DS-175 achieved a lower D grading for systolic pressure. The mean and standard deviation of the first mercury sphygmomanometer measurements were 148 ± 35/88 ± 22 mmHg. Calibration accuracy of all three devices after undergoing the above programme of testing remained within ± 3 mmHg.

Graphic presentation

The data are displayed as plots of the mean pressure for both observers with a mercury sphygmomanometer versus the difference between the test device and the nearer of these observer measurements in 85 subjects (n = 255) for systolic and diastolic pressure (Figs 1–3). Reference lines indicate − 15 to + 15 mmHg in 5 mmHg steps.

Device performance

The Omron HEM-705CP tended to deflate rapidly at diastolic levels but performed well overall.

The inflation/deflation mechanism of the Philips HP5332 was erratic in that it frequently failed to inflate to the preset levels. In the course of the test, the randomly selected device failed to operate and had to be replaced; the replacement later failed and the third device had to be substituted. According to the BHS protocol, the Philips HP5332 would be deemed to have failed the validation on this account but the other devices were substituted so as to reach an assessment of overall accuracy.

As experienced in the in-use phase, the inflation/deflation mechanism of the Nissei DS-175 was erratic and, because of the need for repeat measurements, caused considerable discomfort to patients and in some patients resulted in discoloration from repeated inflations. Again, changing the printer paper was noted to be difficult and the tubing was too short.

Table 1 British Hypertension Society (BHS) grading and Association for the Advancement of Medical Instrumentation (AAMI) criteria for the Omron HEM-705CP at different pressure levels.

		BHS				AAMI	
	n	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade	Mean (SD)	Grade
Omron HEM-705CP							
All							
SBP	255	52	78	93	B	− 2 (7)	P
DBP	255	73	90	96	A	− 1 (6)	P
Low							
SBP	87	49	81	99	C	− 2 (6)	P
DBP	93	69	88	96	A	1 (7)	P
Mid							
SBP	63	60	88	100	A	− 2 (6)	P
DBP	75	88	100	100	A	− 1 (4)	P
High							
SBP	105	47	71	87	C	− 3 (8)	P
DBP	87	64	83	93	B	− 2 (7)	P

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

Table 2 British Hypertension Society (BHS) grading and Association for the Advancement of Medical Instrumentation (AAMI) criteria for the Philips HP5332 at different pressure levels.

		BHS				AAMI	
	n	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade	Mean (SD)	Grade
Philips HP5332							
All							
SBP	255	42	70	85	C	−6 (7)	F
DBP	255	68	91	99	A	−3 (5)	P
Low							
SBP	93	51	86	98	C	−5 (5)	P
DBP	93	69	88	96	A	−2 (5)	P
Mid							
SBP	66	50	78	94	B	−4 (6)	P
DBP	84	72	93	100	A	−4 (5)	P
High							
SBP	96	32	58	73	D	−9 (9)	F
DBP	78	67	92	98	A	−4 (5)	P

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

Table 3 British Hypertension Society (BHS) grading and Association for the Advancement of Medical Instrumentation (AAMI) criteria for the Nissei DS-175 at different pressure levels.

		BHS				AAMI	
	n	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade	Mean (SD)	Grade
Nissei DS-175							
All							
SBP	255	38	59	75	D	−8 (9)	F
DBP	255	66	88	95	A	−3 (7)	P
Low							
SBP	93	59	83	94	B	−4 (6)	P
DBP	93	73	90	94	B	−0 (9)	F
Mid							
SBP	66	24	43	69	D	−9 (6)	F
DBP	81	69	86	96	A	−4 (7)	P
High							
SBP	96	24	44	60	D	−12 (11)	F
DBP	81	67	90	96	A	−4 (6)	P

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

Discussion

In this study, three devices for the home measurement of blood pressure, the Omron HEM-705CP, the Philips HP5332 and the Nissei DS-75 were evaluated according to the revised protocol of the BHS [3]. Of the three devices, only the Omron HEM-705CP achieved a satisfactory overall B/A grading for systolic and diastolic blood pressures according to the BHS protocol while also fulfilling the AAMI accuracy criteria. The Philips HP5332 achieved a C/A grading and failed the AAMI accuracy criteria for systolic pressure and the Nissei DS-175 achieved only a D/A grade for systolic blood pressure and also failed the AAMI criteria. Both these devices are inaccurate in measuring systolic blood pressure and cannot be recommended for clinical use when accuracy of systolic blood pressure measurement is required.

From the operational viewpoint, the Omron HEM-705CP was favoured by both the subjects on whom it was tested and by the operator. It is a neat and compact device that was simple to use and reliable, at least over the period of this validation. Some modifications, such as lengthening the tubing between the cuff and the device, would be necessary if it was to be adapted for use in hospitals. A selection of cuffs with different bladder sizes should be available. The Philips HP5332, while reasonably easy to use, was unreliable, and the device used in the main validation study had to be replaced twice. The inflation mechanism was erratic and the device did not always inflate to the pre-selected levels. The Nissei DS-175 was not favoured either by the subjects on whom it was tested or by the operator. This was due mainly to erratic inflation and deflation, which often resulted in excessive inflations that caused discomfort to the subject.

Omron are the first manufacturers of devices for self-measurement of blood pressure to have passed the requirements of the BHS protocol [5], as far as we are aware. Foster and colleagues [6] recently reported on the Omron HEM-706, which achieved BHS grades B/C in the overall pressure range. These grades are not quite as good as those achieved with the Omron HEM-705CP, but both

validations represent a considerable improvement on devices tested in our laboratory in 1990 when seven devices failed to fulfil the BHS requirements [2]. Another model, the Omron HEM-703CP, was shown to be accurate when compared with direct intra-arterial blood pressure measurements [7]. The Omron HEM-403C was evaluated according to the BHS protocol by Walma and colleagues [8] but the protocol was violated by substitution of the Hawksley random zero sphygmomanometer for the standard mercury sphygmomanometer. As our group has shown [8], devices assessed against the Hawksley sphygmomanometer may be disadvantaged, and the C grades obtained for both systolic and diastolic pressures with the Omron HEM403C are at best questionable.

Having established the accuracy of the Omron HEM-705CP, it is now reasonable to consider its uses in clinical medicine. The device is easy to use for self-measurement of blood pressure and, as it provides a printout with the date and time of blood pressure measurement thereby removing observer prejudice, it should be useful in home measurement of blood pressure. This may be particularly so in the elderly in whom measurement with automatic devices has been shown to be more precise than equipment that is dependent on manual cuff inflation [9]. However, in keeping with the recommendations of the BHS protocol, the Omron HEM-705CP should be evaluated in elderly subjects before it is recommended for clinical use [3].

The revised BHS protocol recommends that accuracy of devices should be examined for different pressure ranges, with the caveat that such analyses, which are dependent on fewer subjects than in the overall analysis, should be interpreted with caution. Interestingly, the Omron HEM-705CP improves its grading from the low- to mid-pressure range but, in keeping with the Philips HP5332 and the Nissei DS-175, and with most ambulatory systems that we have analysed according to pressure ranges [10], it is not accurate at pressures higher than 160/100 mmHg.

Conclusion

The Omron HEM-705CP was the most accurate of the three devices tested, achieving Grade A for diastolic and Grade B for systolic pressure, as well as fulfilling the AAMI criteria for accuracy for both sytolic and diastolic pressure. It can, therefore, be recommended for the clinical measurement of blood pressure.

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