Evaluation of the Schiller BR-102 ambulatory blood pressure system according to the protocols of the British Hypertension Society and the Association for the Advancement of Medical Instrumentation

Eoin O'Brien, Fáinsía Mee and Neil Atkins

Objective To evaluate the Schiller BR-102 monitor for ambulatory blood pressure measurement according to the protocols of the British Hypertension Society (BHS) and the Association for the Advancement of Medical Instrumentation (AAMI).

Design The BHS protocol is divided into two parts. Part I, which is 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; and report of evaluation.

Method Three Schiller BR-102 recorders passed the before-use device calibration test, after which they entered the in-use (field) assessment phase during which the three recorders were each worn by 10 subjects for 24 h, after which calibration was again assessed. Because there was no difference in results of calibration testing among the three devices, one was selected randomly and the main validation test was carried out on 85 subjects with a wide range of blood pressures both for the auscultatory mode and for the oscillometric mode using the Sphygmocorder. The results were analysed according to the BHS grading system from A to D. The data were also analysed according to the standard of the Association for the Advancement of Medical Instrumentation (AAMI), which stipulates that the mean difference between the test device and the standard shall be ≤5 mmHg with a standard deviation of ≤8 mmHg.

Results The Schiller BR-102 achieved a BHS grade B rating for systolic and diastolic blood pressures in the auscultatory mode and satisfied the criteria for accuracy of the AAMI protocol for systolic and diastolic blood pressures. In the oscillometric mode, the Schiller BR-102 achieved grade D for systolic blood pressure and grade B for diastolic blood pressure according to the BHS protocol and satisfied the AAMI criteria for diastolic but not systolic blood pressure. Applying the BHS and AAMI criteria to tertiles of blood pressure (low-pressure range <130/80 mmHg, medium-pressure range 130–160/80–100 mmHg, high-pressure range >160/100 mmHg) the Schiller BR-102 was less accurate in the high pressure range for diastolic blood pressure but more accurate for systolic blood pressure, achieving A/C grading, while satisfying the AAMI criteria both for systolic and for diastolic blood pressure in the auscultatory mode. In the oscillometric mode the device performed less accurately in the high-pressure range, achieving grade D/C, while failing to satisfy the AAMI criteria both for systolic and for diastolic blood pressure. The means ± SD of the first mercury sphygmomanometer measurements were 143 ± 32 mmHg for systolic blood pressure and 88 ± 21 mmHg for diastolic blood pressure. Acceptability to subjects was good and the manufacturer's manual was satisfactory.

Conclusion On the basis of these results, the Schiller BR-102 can be recommended for ambulatory blood pressure measurement in clinical practice using the auscultatory mode, but the oscillometric mode, which operates only if the device fails in the auscultatory mode, does not provide accurate measurements. *Blood Press Monit* 4:35–43 © 1999 Lippincott Williams & Wilkins.

Blood Pressure Monitoring 1999, **4**:35–43

Keywords: Schiller BR-102, validation, 24 h ambulatory blood pressure, British Hypertension Society protocol, Association for the Advancement of Medical Instrumentation standard, Sphygmocorder

The Blood Pressure Unit, Beaumont Hospital, Dublin 9, Ireland.
Correspondence and requests for reprints to Professor E. O'Brien, The Blood Pressure Unit, Beaumont Hospital, Dublin 9, Ireland.
Tel: +353 1 809 2160; fax: +353 1 809 3005

Sponsorship: Support from the Charitable Infirmary Charitable Trust, the Royal College of Surgeons in Ireland and Beaumont Hospital is acknowledged with gratitude. The study was commissioned and the devices were provided by Schiller AG, Switzerland.

Received 11 January 1999 **Accepted** 20 January 1999

Introduction

During recent years ambulatory blood pressure measurement has become accepted as a valuable procedure in the clinical management of hypertension [1,2]. The increase in demand for 24 h blood pressure monitoring has resulted in the production of a variety of ambulatory devices; there are at least 43 systems now available, with many more in the development phase [1]. Ambulatory blood pressure measuring systems are expensive, so independent validation of their accuracy is necessary [3]. To ensure that ambulatory systems are accurate and also perform well in clinical practice, the British Hypertension Society (BHS) and the Association for the Advancement of Medical

Instrumentation (AAMI) have published comprehensive protocols for the evaluation of blood pressure measuring devices [4,5]. In this study the Schiller BR-102 device is submitted to independent validation according to the two protocols [6] and comparative ausculatory data were recorded by an audio-visual technique using the Sphygmocorder [7,8].

Methods

Schiller BR-102 ambulatory system

The Schiller BR-102 device consists of a portable monitor, an inflatable cuff, a microphone, a rechargeable battery, disposable carrying bags and a printer with a connection cable. A mercury sphygmomanometer can be connected to check the calibration of the monitor.

The recorder is operated by a series of touch keys. The monitor can be used to record individual and long-term measurements at preset intervals around the clock for several days according to four different measurement programs. Pressure ranges are 15–300 mmHg at a deflation rate that is programmable in the range 2–9 mmHg.

A small liquid-crystal display provides information on system status, results and error codes. Measurements are repeated automatically in the event of an error message. A printout of the 24 h recording or the home measurements can be obtained by connecting the recorder to a printer. The report provides details of patients, times of recording, systolic and diastolic blood pressures and heart rate and the mode of measurement is indicated.

Evaluation programme

The BHS protocol is divided into two parts. Part I, which is 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; and report of evaluation [4]. Part II of the BHS protocol consists of validation procedures for special groups and circumstances: pregnant women, the elderly, children, during exercise and in various postures; part II is performed only if the device is awarded grade A or B during the part I validation. The BHS protocol was modified in order to incorporate certain features of the AAMI protocol. These included measurement to the nearest mmHg, inclusion of the AAMI accuracy criteria in the analysis, increasing the number of 24 h studies from 24 to 30 and decreasing the daytime recording intervals from 30 to 15 min [6]. The Sphygmocorder was used to record comparative blood pressures on audio-visual tapes, which were then evaluated by two trained observers [7,8].

Before-use device calibration

Calibration accuracy was checked according to the manufacturer's instructions before any testing began by connecting the Schiller BR-102 device, via the console, to a mercury manometer as a reference instrument and to a cuff, wrapped around a cylinder, to ensure that the pressure values from the monitor and the manometer were within ±2 mmHg of each other throughout the pressure range. The automatic pressure system and the mechanism for detection of blood pressure of the Schiller BR-102 device were disabled by entering the manometer mode on the console so that the device acted simply as a manometer. Three observers were blinded from each other in booths. Observer 1 read a recently calibrated mercury column and observer 2 read the Schiller BR-102 device. The manometers were connected by Y connectors to a further mercury manometer, which was read by a third observer (the controller). All three sphygmomanometers and a Schiller BR-102 device *in situ* on its console were connected to a cuff wrapped around a cylinder, which could be inflated and deflated by a pump bulb. The controller observer deflated the cuff at 2 mmHg/s and called out 'now' to denote the moment for the two observers to record the pressure. There were five calls per deflation according to a randomized selection of pressure levels to ensure that all devices were subjected to the same pressure calls but in an order that was not discernible to the observers [4]. There were six deflations per device with five readings per deflation to provide 30 readings per device, giving a total of 90 readings for analysis. At least 28 of 30 pairs of control and test measurements had to be within 3 mmHg of each other [4]. If devices do not satisfy this criterion no further testing is performed.

In-use (field) assessment

The Schiller BR-102 monitors were next used to test performance during and after 24 h ambulatory monitoring of 30 subjects over a 1–2-month period to provide 10 24 h recordings per device [6]. The BHS protocol requires that at least 85% of the measurements for the 24 h period be valid on 18 of the 24 recording days and that on four of the remaining six recording days at least 70% of readings be valid, thus allowing for two days of failed recording. The AAMI protocol recommends that 30 ambulatory blood pressure recordings be carried out at 15 min intervals over a 24 h period [5].

After use device calibration

At the end of this period of in-use assessment, the three monitors were re-tested in the same way as in the Before-use calibration phase to determine whether there had been any change in inter-device agreement during ambulatory use.

Device validation

The Sphygmocorder

To reduce the fallibility of auscultatory blood pressure measurement by the human observer and to provide audio-visual data that could be checked by re-playing the videotape, the Sphygmocorder was used to obtain an audio-visual

record of all measurements. The Sphygmocorder consists of a mercury sphygmomanometer, an occluding cuff, an automatic inflation–deflation source, a stethoscope, a microphone capable of detecting Korotkoff sounds, a camera and a display screen. During recording only one trained observer need be present to ensure that high-quality recordings are obtained, but the recorded video-tapes were later checked by another trained observer and re-played by two trained observers if the sounds, were not clear, of low intensity, distorted by artefactual sounds or of poor quality whereupon a decision regarding their inclusion in the study could be made. The Sphygmocorder, which has been described previously, has itself been validated for accuracy against the trained human observer using the protocol of the BHS [7,8].

Comparison of devices

Sequential same arm measurement of blood pressure with a mercury sphygmomanometer and the device being evaluated is recommended in the BHS protocol [4] and simultaneous or sequential measurement can be used with the AAMI standard [5]. Both simultaneous and sequential measurements of blood pressure were therefore recorded on video tapes using the Sphygmocorder. Both sequential and simultaneous sets of three paired measurements were obtained for 85 subjects to give a total of 3×255 pairs of measurements for analysis. All pressures were recorded with the subject seated.

Results

Before-use use device calibration

The three Schiller BR-102 devices gave results within the error limits permitted in the before-use phase.

In-use (field) assessment

The three Schiller BR-102 monitors completed the required number of recording days satisfying the criteria of the BHS and AAMI protocols for 30 subjects [6]. An analysis of performance during the in-use phase is shown in Table 1. Because the in-use assessment phase was completed successfully, the main validation test proceeded.

After-use device calibration

There was no difference in calibration accuracy among the three devices after the in-use phase; one device was arbitrarily selected for the main validation test.

Device validation

In order to satisfy the BHS range criteria it became necessary to recruit 24 subjects for analysis of their systolic blood pressures only and a complementary 24 subjects for analysis of their diastolic blood pressures only. Both blood pressures were analysed for 61 subjects so that 85 subjects were included for systolic and diastolic analysis, as recommended by the BHS and AAMI protocols [6]. The mean ages of the subjects were 51 ± 13 years (range 21–77 years) for the

Table 1 **In-use assessment for 30 recording days and 30 subjects**

		24 h		Daytime		Night-time	
Device	*Subject*	Valid	Invalid	Valid	Invalid	Valid	Invalid
A	1	80	9	59	2	21	7
A	2	88	5	57	4	26	1
A	3	100	0	60	0	40	0
A	4	81	20	55	18	26	2
A	5	78	19	57	10	21	9
A	6	85	6	59	6	26	0
A	7	84	0	58	0	26	0
A	8	85	1	59	1	26	0
A	9	86	5	60	4	26	1
A	10	85	0	59	0	26	0
B	1	83	4	58	3	25	1
B	2	87	0	61	0	26	0
B	3	84	1	58	1	26	0
B	4	85	2	59	0	26	2
B	5	85	4	60	3	25	1
B	6	84	1	58	1	26	0
B	7	84	2	58	1	26	1
B	8	81	7	56	4	25	3
B	9	72	14	51	8	21	6
B	10	87	2	61	2	26	0
C	1	84	5	58	3	26	2
C	2	89	2	63	1	26	1
C	3	81	12	55	11	26	1
C	4	85	0	59	0	26	0
C	5	64	26	42	20	22	6
C	6	83	1	57	1	26	0
C	7	83	3	57	3	26	0
C	8	81	5	57	3	24	2
C	9	81	0	55	0	26	0
C	10	83	6	57	6	26	0
Overall		2493 (94%)	162 (6%)	1723 (94%)	116 (6%)	770 (94%)	46 (6%)

Table 2 Characteristics of subjects

SBP (mmHg)	<90	90–129	130–160	161–180	> 180	Mean	SD	Age (years)	Circumference (cm)
	8	23	23	23	8	143	32	51 ± 13	32 ± 4
DBP (mmHg)	<60	60–79	80–100	101–110	>110	Mean	SD	Age (years)	Circumference (cm)
	8	23	23	23	8	88	21	52 ± 13	32 ± 4

Age and circumference are expressed as means ± SEM; other values are numbers of patients. SBP, systolic blood pressure; DBP, diastolic blood pressure.

systolic blood pressure group and 52 ± 13 years (range 21–80 years) for the diastolic blood pressure group. Mean arm circumference was 32 ± 4 cm for both groups (Table 2).

Analysis was done separately on the Sphygmocorder videotapes for two sets of measurements using three pairs of readings from each subject. To compare one set of measurements and the test instrument one of two sequences was used. In sequence (a) comparisons of first versus second, third versus fourth and fifth versus sixth blood pressure were performed. In sequence (b) comparisons of second versus third, fourth versus fifth and sixth versus seventh blood pressure were performed. To obviate the possibility that chance might disadvantage the test device, the sequence most favourable to the Schiller BR-102 device for each subject separately was used. In total, 255 pairs of measurements by each observer and the test instrument were available for analysis for each of the three devices. To comply with the AAMI criteria for accuracy, simultaneous measurements were used. The percentages of measurements differing from the mercury standard by 5, 10 and 15 mmHg or less for the best sequence and the BHS grading criteria [4], together with the AAMI criteria for accuracy [5], are shown in Table 3. To obtain a particular BHS grade, all three cumulative percentages had to exceed the tabulated values. The final grade for each systolic and diastolic blood pressure was the better of the grades obtained for the two sequences. The Schiller BR-102 device achieved overall grades of B for systolic and B for diastolic blood pressure according to the BHS criteria [4] and satisfied the AAMI accuracy criterion for systolic and diastolic blood pressures in the auscultatory mode; in the oscillometric mode the device achieved grade D for systolic and grade B for diastolic blood pressure and failed to satisfy the AAMI criteria for systolic blood pressure [5]. The means ± SD of the first mercury sphygmomanometer measurements were 143 ± 32 mmHg for systolic blood pressure and 88 ± 21 mmHg for diastolic blood pressure.

Blood pressures were also classified and analysed as low pressure range < 130 mmHg systolic (< 80 mmHg diastolic), medium-pressure range 130–160 mmHg systolic

Table 3 Accuracy criteria

	BHS Grades		
Grade	≤ 5 mmHg	≤ 10 mmHg	≤ 15th mmHg
A	60	85	95
B	50	75	90
C	40	65	85
D		Worse than C	

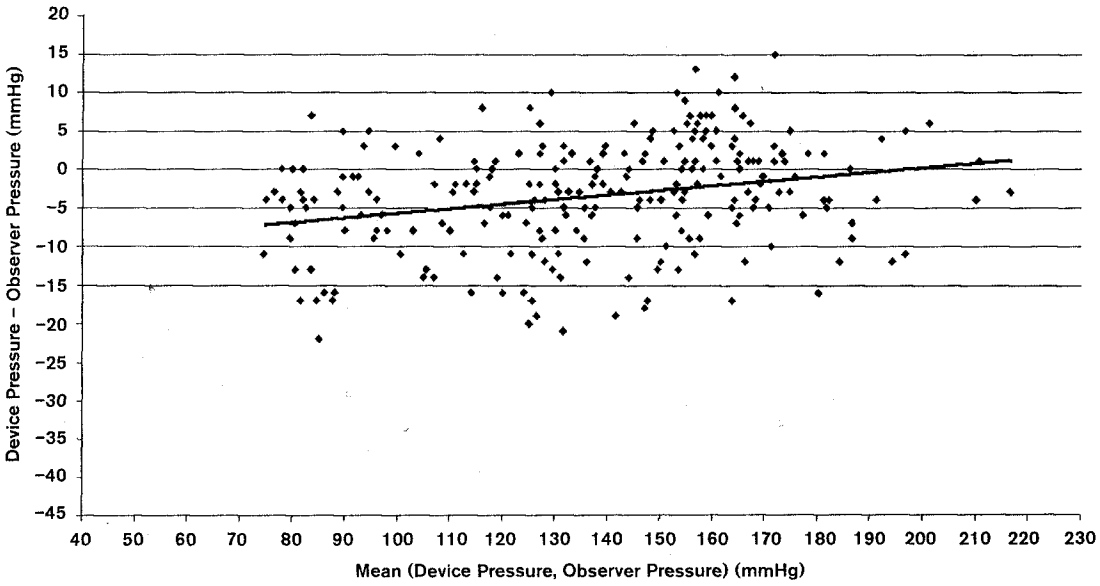
Analysis of auscultatory data

			BHS				AAMI		
		n	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade	Mean	SD	Grade
Overall	SBP	255	58	82	93	B	−2.8	4.7	Pass
	DBP	255	58	86	97	B	−3.1	4.5	Pass
Lower	SBP	93	47	72	88	C	−4.5	5.2	Pass
	DBP	93	60	90	98	A	−2.9	4.0	Pass
Middle	SBP	69	62	88	94	B	−1.8	4.2	Pass
	DBP	69	70	93	99	A	−2.6	3.4	Pass
Upper	SBP	93	66	86	97	A	−1.8	3.9	Pass
	DBP	93	47	75	94	C	−3.8	5.5	Pass

Analysis of oscillometric data

			BHS				AAMI		
		n	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade	Mean	SD	Grade
Overall	SBP	255	41	67	81	D	−5.9	7.5	Fail
	DBP	255	53	84	96	B	−3.8	4.9	Pass
Lower	SBP	93	48	76	94	C	−3.1	5.4	Pass
	DBP	93	61	91	100	A	−2.6	3.9	Pass
Middle	SBP	69	46	67	86	C	−5.4	7.3	Fail
	DBP	69	54	90	100	B	−3.5	4.0	Pass
Upper	SBP	93	29	58	66	D	−9.1	8.2	Fail
	DBP	93	43	72	89	C	−5.3	6.0	Fail

Fig. 1



Plot of systolic blood pressure (SBP) measured with a mercury sphygmomanometer versus the difference between the mercury and Schiller BR-102 measurement in 85 subjects (n = 255). Reference lines are −15 to +15 mmHg in 5 mmHg steps.

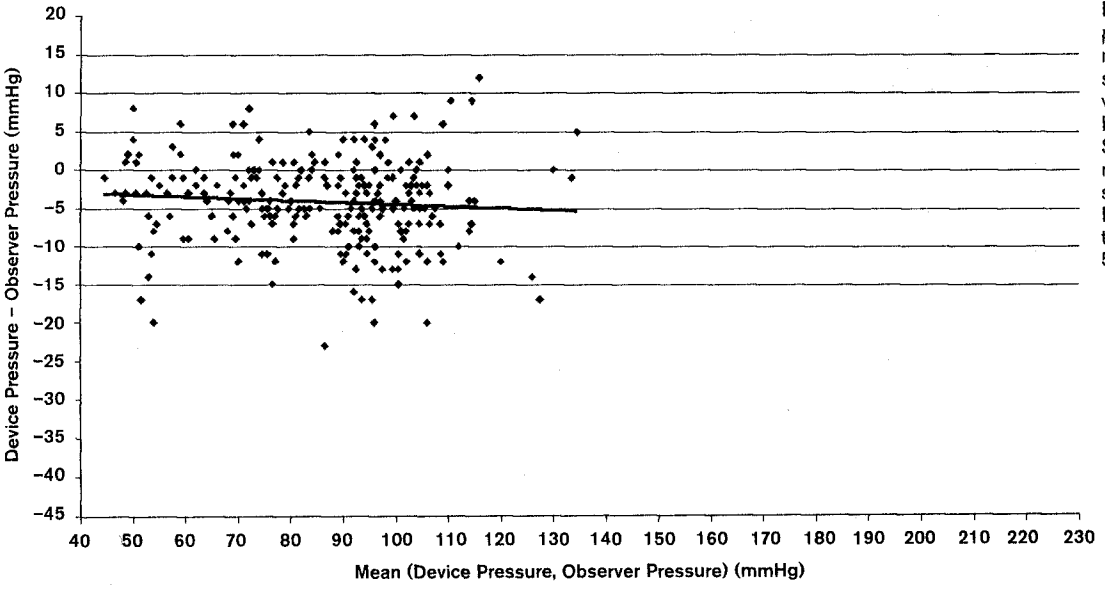
(80–100 mmHg diastolic) and high-pressure range > 160 mmHg systolic (> 100 mmHg diastolic). For this analysis each subject was classified by reference to the initial mercury sphygmomanometer measurement. On applying the BHS and AAMI criteria to tertiles of blood pressure, the Schiller BR-102 device's score rose to an A grade for systolic blood pressure and dropped to a C grade for diastolic blood pressure in the auscultatory mode while satisfying the AAMI criteria; in the oscillometric mode the device achieved a D/C grade and failed to satisfy the AAMI criteria both for systolic and for diastolic blood pressure (Table 3).

The separate differences (Device–Sphygmocorder) for systolic and diastolic pressures in 85 subjects (using the data on which the final grade is based) were plotted against the mean of the device pressure and the observer pressure, using all 255 points (Figs. 1 & 2).

Discussion

In this study the Schiller BR-102 ambulatory blood pressure measuring system was evaluated according to the protocols of the BHS and the AAMI [4–6]. According to the BHS protocol, the Schiller BR-102 device achieved a grade B rating for systolic and diastolic blood pressures in the

Fig. 2



Plot of diastolic blood pressure (DBP) measured with a mercury sphygmomanometer versus the difference between the mercury and Schiller BR-102 device measurement in 85 subjects (n = 255). Reference lines are −15 to +15 mmHg in 5 mmHg steps.

Table 4 Devices on the market that have been subjected to validation by the British Hypertension Society and Association for the Advancement of Medical Instrumentation protocols

Device	Reference	Mode		AAMI	BHS	Circumstance
Accutracker II (30/23)	[13]	Aus		Passed	A/C	Rest
CH-DRUCK (103)*	[14]	Aus		Passed	A/A	Rest, pressure ranges
Daypress 500	[15]	Osc		Passed	A/B	Rest
DIASYS 200	[16]	Aus		Passed	C/C	Rest
DIASYS Integra	[17]	Aus		Passed	B/A	Rest, pressure ranges
		Osc		Passed	B/B	Rest/Pressure ranges
Nissei DS-240	[18]	Osc		Passed	B/A	Rest
Profilomat[a]	[19]	Aus		Passed	B/A	Rest, pressure ranges
Profilomat[a]	[20]	Aus		Passed	B/C	Pregnancy
Profilomat II	[21]	Osc		Failed	C/B	Rest, pressure ranges
QuietTrak[a]	[22,23]	Aus		Passed	B/B	Rest
QuietTrak[a]	[24]	Aus		Failed	B/B	Pregnancy
QuietTrak[a]	[25]	Aus		Passed	A/A	Rest
						Exercise
						Postures
						Elderly
						Children
						Pregnancy
SpaceLabs 90202	[26]	Osc		Passed	B/B	Rest
SpaceLabs 90207	[27]	Osc		Passed	B/B	Rest, pressure ranges
SpaceLabs 90207	[28]	Osc		Passed	A/C	Pregnancy
SpaceLabs 90207	[29]	Osc		Passed	B/B	Pregnancy
SpaceLabs 90207	[30]	Osc		Passed	B/C	Pregnancy
SpaceLabs 90207	[31]	Osc	SBP	Passed	C	Children
			DBP	Failed	D	Children
SpaceLabs 90207	[32]	Osc		Passed	A/C	Elderly
				Postures		
TM-2420 Model 5	[33]	Osc		Passed	C/C	Rest
TM 2420 Model 6	[34]	Osc		Passed	B/B	Rest
TM-2421	[35]	Osc		Passed	B/A	Rest

Grades A–D according to BHS protocol: A, best agreement, D, worst agreement with mercury standard. [a]Model number not specified. [b]Criteria for accord with BHS protocol: devices must achieve at least grade B/B. [c]Criteria for accord with AAMI standard: mean difference ≤ 5 mmHg/SD ≤ 8 mmHg. Osc, oscillometric mode; Aus, auscultatory mode; *SBP*, systolic blood pressure; *DBP*, diastolic blood pressure.

auscultatory mode with 58% of systolic and diastolic blood pressures within 5 mmHg of the values obtained using a mercury sphygmomanometer [4]. The Schiller BR-102 device satisfied the criterion of the AAMI protocol both for systolic and for diastolic blood pressures [5]. However, in the oscillometric mode, the device achieved only a D/B grade and failed to satisfy the AAMI criteria for systolic blood pressure.

The BHS protocol recommends that accuracy of devices should be examined for various pressure ranges, with the caveat that such analyses, which are dependent on fewer subjects than are used in the overall analysis, should be interpreted with caution [4]. Unlike most devices, the Schiller BR-102 device has a better grading in the high-pressure range for systolic blood pressure, although, in keeping with most devices, it drops a grade for diastolic blood pressure.

From the operational viewpoint the Schiller BR-102 device was favoured both by the subjects on whom it was tested and by the operator. It is a neat and compact device that is simple to use and reliable, at least for the period of this validation. During use, the Schiller BR-102 device does not automatically delete clinically impossible measurements and the facility for repeating measurements is inconsistent even within subjects.

In previous validation studies several strategies have been employed to overcome observer error. By using the BHS film combined with direct instruction, we have been able to bring all paired nurse-observer measurements within 5 mmHg of each other both for systolic and for diastolic blood pressure [9]. However, whereas it is possible to bring observers to a high degree of accuracy for research work, the procedure of training is time consuming and expensive. Moreover, observers may lose accuracy with time and require re-training [10].

Semi-automated and automated devices have the potential advantage of eliminating errors of interpretation together with observer bias and terminal-digit preference. However, this apparent advance has to be balanced against the considerable inaccuracy of most such devices [1,11], especially at relatively high pressure levels [12]. It will be sometime, therefore, before automated devices can be substituted for the traditional standard, namely, an accurate observer using a standard mercury sphygmomanometer and stethoscope.

The Sphygmocorder innovatively combines technology that has been available for some time to provide the facility for storing recorded data while preserving the time-honoured technique of blood pressure measurement with the mercury sphygmomanometer and an auscultating observer.

Other advantages of the Sphygmocorder are the ability to review stored data at leisure; the facility for a number of expert observers to analyse the recorded data, thereby eliminating bias and terminal-digit preference from the measurement process; the removal of unsatisfactory recordings, such as those with weak Korotkoff sounds, which so often are a source of doubt and error in once-off auscultation, and the elimination of inattention by an observer or loss of concentration [8]. The incorporation of an automatic inflation–deflation system, which guarantees that one has constant rates of inflation and deflation, allows computer-controlled inflation and deflation of upper-arm cuffs of various dimensions, thereby eliminating human variability and bias from the deflation procedure [8].

One of the main reasons for establishing the BHS and AAMI protocols was to provide a standardized method for assessing blood pressure measuring devices and to provide a means of comparing devices with similar clinical applications. In Table 4 we list ambulatory devices that have been subjected to evaluation in terms of the BHS and AAMI protocols [1]. From this it is apparent that the Schiller BR-102 ambulatory system, which achieved a B/A grading according to the BHS protocol and satisfied the AAMI accuracy criterion for systolic and diastolic blood pressures in the auscultatory mode can be recommended for clinical use in this mode. However, as the device achieved only a D/B grade in the oscillometric mode, which operates when the device fails to record an auscultatory reading, systolic blood pressures in this mode cannot be relied upon.

References

1 O'Brien E. Automated blood pressure measurement: state of the market in 1998 and the need for an international validation protocol for blood pressure measuring devices. *Blood Press Monit* 1998; **3**:205–211.

2 Staessen JA, Byttebier G, Buntinx F, Celis H, O'Brien ET, Fagard R, for the Ambulatory Blood Pressure Monitoring and Treatment of Hypertension Investigators. Antihypertensive treatment based on conventional or ambulatory blood pressure measurement: a randomized controlled trial. *JAMA* 1997; **278**:1065–1072.

3 O'Brien E, Mee F, Atkins N, O'Malley K. Validation requirements for ambulatory blood pressure measuring systems *J Hypertens* 1991; **9 (suppl 8)**:S13–S15.

4 O'Brien E, Petrie J, Littler W, de Swiet M, Padfield PL, Altman D, *et al.* The British Hypertension Society protocol for the evaluation of blood pressure measuring devices *J Hypertens* 1993; **11 (suppl 2)**:S43–S62.

5 *American national standard. Electronic or automated sphygmomanometers.* Arlington, VA: Association for the Advancement of Medical Instrumentation. 1993.

6 O'Brien E, Atkins N. A comparison of the British Hypertension Society and Association for the Advancement of Medical Instrumentation protocols for validating blood pressure measuring devices: can the two be reconciled? *J Hypertens* 1994, **12**:1089–1094.

7 O'Brien E, Atkins N, Mee F, Coyle D, Syed S. A new audio-visual technique for recording blood pressure in research: the Sphygmocorder. *J Hypertens* 1995; **13**:1734–1737.

8 O'Brien E, Atkins N, Wesseling K, Guelen I. Increasing observer objectivity with audio-visual technology: the Sphygmocorder. *Blood Press Monit* 1997; **2**:269–272.

9 O'Brien E, Mee F, Tan KS, Atkins N, O'Malley K. Training and assessment of observers for blood pressure measurement. *J Hum Hypertens* 1991; **5**:7–10.

10 Mee F, Atkins N, O'Brien E. Problems associated with observer training in blood pressure measurement. *J Hum Hypertens* 1994; **8**:293.

11 O'Brien E, Mee F, Atkins N, O'Malley K. Inaccuracy of seven popular sphygmomanometers for home-measurement of blood pressure. *J Hypertens* 1990; **8**:621–634.

12 O'Brien E, Atkins N, Mee F, O'Malley K. Comparative accuracy of six ambulatory devices according to blood pressure levels. *J Hypertens* 1993; **11**:673–675.

13 Taylor R, Chidley K, Goodwin J, Broeders M, Kirby B. Accutracker II (version 30/23) ambulatory blood pressure monitor: clinical validation using the British Hypertension Society and Association for the Advancement of Medical Instrumentation standards. *J Hypertens* 1993; **11**:1275–1282.

14 O'Brien E, Mee F, Atkins N, O'Malley K. Accuracy of the CH-Druck Pressure ERKA ambulatory blood pressure measuring system determined by the British Hypertension Society protocol. *J Hypertens* 1993; **11 (suppl 22)**:S1–S7.

15 Livi R, Teghini L, Cagnoni S, Scarpelli PT. Simultaneous and sequential same-arm measurements in the validation studies of automated blood pressure measuring devices. *Am J Hypertens* 1996; **9**:1228–1231.

16 O'Brien E, Mee F, Atkins N, O'Malley K. Accuracy of the Novacor DIASYS 200 determined by the British Hypertension Society Protocol. *J Hypertens* 1991; **9 (suppl 5)**:S9–S15.

17 Gosse P, Laforge A, Ansoborto P, Jullien P, Lemetayer P, Clementy J. Clinical evaluation of the diasys integra blood pressure recorder [abstract]. *J Hypertens* 1997; **15 (suppl 17)**:S18.

18 Mee F, Atkins N, O'Brien E. Validation of the Nissei DS-240 ambulatory blood pressure measuring system as determined by the British Hypertension Society protocol [abstract]. *J Hum Hypertens* 1994; **8**:295.

19 O'Brien E, Mee F, Atkins N, O'Malley K. Accuracy of the Profilomat ambulatory blood pressure measuring system determined by the British Hypertension Society protocol. *J Hypertens* 1993; **11 (suppl 22)**:S9–S15.

20 Franx A, van der Post JAM, van Montfrans GA, Bruinse HW. Comparison of an auscultatory versus an oscillometric ambulatory blood pressure monitor in normotensive, hypertensive and preeclamptic pregnancy. *Hypertens Pregnancy* 1997; **16**:187–202.

21 Mee F, Atkins N, O'Brien E. Evaluation of the Profilomat II ambulatory blood pressure system according to the protocols of the British Hypertension Society and the Association for the Advancement of Medical Instrumentation. *Blood Press Monit* 1998; **3**:353–361.

22 White WB, Susser W, James G, Marra L, McCabe EJ, Pickering TG, *et al.* Multicenter assessment of the QuietTrak ambulatory blood pressure recorder according to the 1992 AAMI guidelines. *Am J Hypertens* 1994; **7**:509–514.

23 O'Shea JC, O'Neill A, O'Brien C, Murphy MB. Evaluation of Tycos Quiet-Trak ambulatory pressure recorder using British Hypertension Society (BHS) protocol [abstract]. *Am J Hypertens* 1994; **7**:118A.

24 Penny JA, Shennan AH, Rushbrook J, Halligan A, Taylor DJ, de Swiet M. Validation of the Welch Allyn QuietTrak ambulatory blood pressure monitor in pregnancy. *Hypertens Pregnancy* 1996; **15**:313–321.

25 Modesti PA, Costoli A, Cecioni I, Toccafondi S, Carnemolla A, Serneri GGN. Clinical evaluation of the QuietTrak blood pressure recorder according to the protocol of the British Hypertension Society. *Blood Press Monit* 1996; **1**:63–68.

26 O'Brien E, Atkins N, Mee F, O'Malley K. Evaluation of the SpaceLabs 90202 according to the AAMI standard and BHS criteria. *J Hum Hypertens* 1991; **5**:223–226.

27 O'Brien E, Mee F, Atkins N, O'Malley K. Accuracy of the SpaceLabs 90207 determined by to the British Hypertension Society Protocol. *J Hypertens* 1991; **9 (suppl 5)**:S25–S31.

28 O'Brien E, Mee F, Atkins N, Halligan A, O'Malley K. Accuracy of the SpaceLabs 90207 ambulatory blood pressure measuring system in normotensive pregnant women determined by the British Hypertension Society Protocol. *J Hypertens* 1993; **11 (suppl 5)**:869–873.

29 Shennan AH, Kissane J, De Swiet M. Validation of the SpaceLabs 90207 ambulatory blood pressure monitor in pregnancy. *Br J Obstet Gynaecol* 1993; **100**:904–908.

30 Shennan A, Halligan A, Gupta M, Taylor D, de Swiet M. Oscillometric blood pressure measurements in severe pre-eclampsia: validation of the SpaceLabs 90207. *Br J Obstet Gynaecol* 1996; **103**:171–173.

31 Belsha CW, Wells TG, Rice HB, Neaville WA, Berry PL. Accuracy of the SpaceLabs 90207 ambulatory blood pressure monitor in children and adolescents. *Blood Press Monit* 1996; **1**:127–133.

32 Iqbal P, Fotherby MD, Potter JF. Validation of the SpaceLabs 90207 automatic non-invasive blood pressure monitor in elderly subjects. *Blood Press Monit* 1996; 1:367–373.

33 White WB, Pickering TC, Morganroth J, James GD, McCabe EJ, Moucha O, *et al.* A multicenter evaluation of the A & D TM-2420 ambulatory blood pressure recorder. *Am J Hypertens* 1991; 4:890–896.

34 Palatini P, Penzo M, Canali C, Pessina AC. Validation of the accuracy of the A & D TM-2420 Model 7 for ambulatory blood pressure monitoring and effect of microphone replacement on its performance. *J Ambulatory Monit* 1991; 4:281–288.

35 Imai Y, Sasaki S, Minami N, Munakakata M, Hashimoto J, Sakuma H, *et al.* The accuracy and performance of the A & D TM 2421, a new ambulatory blood pressure monitoring device based on the cuff-oscillometric method and the Korotkoff sound technique. *Am J Hypertens* 1992; 5:719–726.

Appendix

In accordance with Appendix C of the BHS protocol [4], the following aspects of the Schiller BR-102 device were assessed.

Device identification

The model was clearly identified as the Schiller BR-102 device produced by Schiller AG.

Compliance with standard(s)

There is no mention in the manual provided of compliance with national or international safety and performance standards.

Validation studies and results

No validation results have been published.

Instructions for use

The instruction manual provided with the Schiller-102 recorder is very adequate and easy to follow and error messages are listed in the manual.

Patient instruction card

There are instructions for the patient, which are included on a patient diary card.

Precautions for use

The BHS protocol requires that the operator be alerted to any weaknesses in the system that could affect performance or safety of patients and that the safety precautions incorporated in the system to prevent the cuff remaining inflated be clearly stated; these criteria are not mentioned in the manual.

Power supply

The manual provides adequate information on power requirements. The BR-102 is powered by a rechargeable nickel–cadmium battery. When it is fully charged, about 200 blood pressure measurements can be made. The life expectancy of the battery is not mentioned in the manual.

Instructions for care and maintenance

The manual gives the operator instructions on the washing of cuffs and cleaning of the device, lists error messages, suggests that a calibration check be performed by users yearly and gives clear instructions with illustration on how this should be done. However, it does not mention how often the attachments should be checked or care of same. The product warranty is for a period of 1 year and any defective part or parts will be replaced.

Service facilities

The BHS protocol recommends that the location of national and international service facilities be listed and that an estimate of the cost of routine servicing out of warranty together with an estimate of the costs of transporting the equipment for such servicing be given. This information is not given.

Dimensions
The dimensions and weights of the recorder inclusive of battery are provided as follows: the size of Schiller device is 71 mm × 120 mm × 21 mm (width × height × depth). The weight is 310 g including accumulator.

List of components
A list of components for this system is given in the manual. There is mention only of a medium-sized cuff (13 cm) in the manual. The manual states that the cuffs are designed to fit on the left upper arm; there is no mention of the right arm. Under application of cuff the manual mentions to select the appropriately sized cuff according to the patient's arm size. The cuff/bladder dimensions are not listed anywhere in the manual.

Method(s) of blood pressure measurement
The Schiller BR-102 device measures blood pressure using the Riva Rocci–Korotkoff method of measuring blood pressure. The oscillometric method of measurement is used as a backup if the unit cannot take the pressure measurement by the auscultatory method.

Facility for device recalibration
Accuracy is easily checked against a mercury sphygmomanometer throughout the pressure range and it is recommended in the manual that this be carried out at yearly intervals. Recalibration is not mentioned in the manual but the manual states that the Schiller BR-102 device is calibrated for the life of the unit.

Operator training requirements
The Schiller BR-102 system is reasonably easy to operate and the instruction manual takes the operator through the operative procedures step by step.

Computer analysis
The Schiller BR-102 device can be connected to a personal computer.

Problem list and solution
All error codes and possible solutions are listed in the manual.

Supplier names and addresses
There is a list of Schiller Subsidiaries and addresses worldwide. The Swiss address is as follows: SCHILLER Reomed AG, Riedstrasse 14, CH-8953 Dietikon, Switzerland, Tel: +01 741 02 09, Fax: 01 740 37 10.

Support for validation
The manufacturers, Schiller Reomed AG, supplied three Schiller BR-102 systems for the study and contributed to the financial costs of the validation.