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

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Objective To evaluate the Profilomat II® 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 Profilomat II® recorders passed the before-use device calibration test. They then entered the in-use (field) assessment phase during which the three recorders were each worn by ten subjects for 24-h, after which the calibration was again assessed. Since no difference in calibration testing was observed between the three devices, one was selected randomly and the main validation test was carried out in 85 subjects, who had a wide range of blood pressures, using the sphygmocorder. The results were analysed according to the BHS grading system from A to D. The data was 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 $\leq$ 5 mmHg with a standard deviation of $\leq$ 8 mmHg.

Results The Profilomat II® achieved a BHS grade C rating for systolic blood pressure and grade B for diastolic blood pressure; it satisfied the criteria for accuracy of the AAMI for diastolic but not systolic blood 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), the Profilomat II® was less accurate in the high pressure range, achieving a D/C grading, and failed the AAMI criteria for systolic and diastolic blood pressures. The mean and standard deviation of the first mercury sphygmomanometer measurements were 145 ± 34/87 ± 20 mmHg. Subject acceptability was good and the manufacturers manual was satisfactory.

Conclusion On the basis of these results, the Profilomat II® cannot be recommended for ambulatory blood pressure measurement in clinical practice where accurate measurements are required. *Blood Press Monit* 3:353–361 © 1998 Lippincott Williams & Wilkins.

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Introduction

In recent years, ambulatory blood pressure measurement has become accepted as a valuable procedure in the clinical management of hypertension [1,2]. The increased demand for 24-h blood pressure has resulted in the production of a variety of ambulatory devices, and there are at least 43 systems now available with many more in the development phase [1]. Ambulatory blood pressure measuring systems are expensive, and independent validation of their accuracy is therefore necessary [3]. In order 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 the present study, the Profilomat II® device was submitted to independent

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validation according to the two protocols [6]. The auscultatory standard against which Profilomat II® (Disetronic Medical Systems AG, Burgdorf, Switzerland) is compared were recorded by an audio-visual technique using the Sphygmocorder device [7,8].

Methods

Profilomat II® ambulatory system

The Profilomat II® consists of a portable monitor, cuffs designed for small, standard and large arms which can be adjusted to be worn on the right or left arm as required, a rechargeable battery known as the accupack, a carrying bag with strap, and a console for operating and programming the monitor which also contains a unit for charging the accupacks and serves as an interface to a personal computer and/or printer. The recorder measures 124 × 89.5 × 26 mm and weighs 275 g including the accupack. A mercury sphygmomanometer may be inserted into the console to check the calibration of the monitor.

The recorder is operated by means of a start/stop button which permits the device to function. The monitor has three different measurement modes: the single, the ambulatory blood pressure monitoring (ABPM) and the home measurement mode. These modes may be programmed into the monitor via the console. The measurements conducted in the single measurement mode are not stored. During the ABPM programming, intervals may be set to 5, 10, 15, 20, 30, 45 and 60 min over the 24-h period via the console and 0 to 240 min in 1 min steps via the personal computer. These measurement intervals may be set independently for two periods (day/night) via the console and for six periods via the computer. The first of the 24-h ABPM interval measurements commences 5–10 min after the monitor has been removed from the console, and deflates at a constant rate of 5 mmHg/s. Pressure ranges are from 70 to 280 mmHg for systolic and 30 to 150 mmHg for diastolic blood pressures. The pulse range is from 30 to 220 beats/min.

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. Two messages only will appear on the monitor, '0' denoting an error during measurement, or 'Err' denoting that the accupack is low or that there is a hardware error. However, more detailed error messages are displayed on the display of the console when the monitor is inserted into the console to retrieve the blood pressure data. In addition, a series of error codes are displayed and stored on each patient record.

A print-out of the 24-h recording or the home measurements may be obtained by connecting the recorder, via the console, to a printer. Alternatively, the console may be connected to a serial port on a personal computer and data can be extracted via a simple DOS program. A short or long report may be obtained. The long report provides patient details, time of recording, systolic and diastolic blood pressures and heart rate. It also includes a plot of the individual pressures together with the mean and median values and the standard deviations, maximum and minimum pressures, total number of daytime and night-time recordings, success rate statistics, graphics of the measurement data, histograms and the measured values listed with error messages. The alternative short report provides the total of daytime and night-time recordings, success rate statistics, graphics of the measured data and histograms. All graphics consist of text character sequences.

An additional feature is that the Profilomat II® may be set up in English, French, German and Italian.

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: pregnancy, the elderly, children, during exercise, and in different positions. Part II is only performed if the device obtains 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 millimetre of mercury, inclusion of the AAMI accuracy criteria in the analysis, and increasing the number of 24-h studies from 24 to 30 and 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

The calibration accuracy was checked according to the manufacturer's instructions before any testing began, by connecting the Profilomat II®, 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 blood pressure detection mechanism of the Profilomat II® 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 the mercury column and observer 2 read the Profilomat II®. The manometers were connected by Y-connectors to a further mercury manometer which was read by a third observer (the controller). Both sphygmomanometers and a Profilomat II® 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. Five calls were made per deflation according to a randomised selection of pressure levels to ensure that all devices received the same pressure calls but in an order that was not discernible to the observers [4]. Six deflations were performed 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 control and test measurement pairs had to be within 3 mmHg of each other [4]. If devices did not fulfil this criteria, no further testing was performed.

In-use (field) assessment

The Profilomat II® monitors were next used to test performance during and after 24-h ABPM in 30 subjects over a 1- to 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 should be valid on 18 of the 24 recording days, and on four of the remaining six recording days at least 70 % of readings should be valid, thus allowing for two failed recording days. 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 if there had been any change in inter-device agreement during ambulatory use.

Device validation

The Sphygmocorder

In order to reduce the fallibility of auscultatory blood pressure measurement by the human observer, and to provide audio-visual data which could be checked by re-playing the video-tape, 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. The Profilomat II® device was connected by a Y-tube to the mercury sphygmomanometer of the Sphygmocorder. During recording only one trained observer needed be present to ensure good quality recordings, but the recorded video-tapes were later checked by another trained observer and replayed by two trained observers if the sounds were unclear, of low intensity, distorted by artefactual sounds, or of poor quality when a decision as to 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].

Device comparison

The BHS protocol recommends sequential same-arm measurement of blood pressure with a mercury sphygmomanometer and the device being evaluated [4]; 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 in 85 subjects to give a total of 3×255 pairs of measurements for analysis. All pressures were recorded with the subject in the seated position.

Results

Before-use use device calibration

The three Profilomat II® devices were within the error limits permitted in the before-use phase.

In-use (field) assessment

The three Profilomat II® monitors completed the required number of recording days comfortably, fulfilling the criteria of the BHS and AAMI protocols in 30 subjects [6]. Each recorder provided an average of 82 measurements out of the expected 83 measurements on each of the 30 recording days, exceeding the 85% required by the protocols [6]. An analysis of performance during the in-use phase is shown in Table 1. Patient assessment of the device was generally very positive except for a few negative comments regarding discomfort; the tubing on one cuff separated on six occasions during measurement. Since the in-use assessment phase was completed successfully, the main validation test proceeded.

After-use device calibration

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

Device validation

The validation test was performed on 85 subjects aged 19–77 years, as recommended by the BHS and AAMI protocols [6]. The mean age of the subjects was 50 ± 12 years; mean arm circumference was 31 ± 3 cm (range 22–40 cm) (Table 2).

Analysis was performed separately on the Sphygmocorder video-tapes 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 as recommended by the BHS protocol [4]. In order to obviate the possibility that chance might disadvantage the test device, the sequence most favourable to the Profilomat II® for each subject separately was used. A total of 255 pairs of measurements by each observer and the test instrument were available for analysis of each of the three devices. To comply with the AAMI criteria for accuracy, simultaneous measurements

Table 1 In-use assessment

Instrument	Subject number	24-hour Valid	Invalid	Daytime Valid	Invalid	Night-time Valid	Invalid	Grade
A	2	82	1	56	1	26	0	***
A	5	83	0	57	0	26	0	***
A	8	81	2	55	2	26	0	***
A	11	80	1	54	1	26	0	***
A	13	82	1	57	0	25	1	***
A	15	79	4	54	3	25	1	***
A	17	83	0	57	0	26	0	***
A	21	83	0	57	0	26	0	***
A	22	82	1	56	1	26	0	***
A	25	82	1	56	1	26	0	***
B	3	82	1	57	0	25	1	***
B	6	83	0	57	0	26	0	***
B	9	82	1	56	1	26	0	***
B	12	83	0	57	0	26	0	***
B	16	83	0	57	0	26	0	***
B	18	83	0	57	0	26	0	***
B	20	81	2	56	1	25	1	***
B	24	83	0	57	0	26	0	***
B	27	81	0	55	0	26	0	***
B	30	83	0	57	0	26	0	***
C	1	83	0	57	0	26	0	***
C	4	82	1	56	1	26	0	***
C	7	83	0	57	0	26	0	***
C	10	82	1	56	1	26	0	***
C	14	79	4	53	4	26	0	***
C	19	82	1	56	1	26	0	***
C	23	82	1	56	1	26	0	***
C	26	81	2	55	2	26	0	***
C	28	81	2	56	1	25	1	***
C	29	79	4	56	1	23	3	***
Total		2455	31	1683	23	772	8	
		99%	1%	99%	1%	99%	1%	
Expected		83		57		26		
80% target		67		46		21		***
70% target		59		40		19		**
50% target		42		29		13		*

Figures are for 30 recording days in 30 subjects, with the number of measurements shown for each recording period.

were used. The percentage of measurements differing from the mercury standard by 5, 10 and 15 mmHg or less for the best sequence, the BHS grading criteria [4], and the AAMI criteria for accuracy [5] are shown in Tables 3 and 4. To obtain a particular BHS grade all three cumulative percentages had to exceed the tabulated values. The final grade for each systolic and diastolic pressure was the better of the grades obtained for the two sequences. The Profilomat II® achieved an overall grade of C for systolic and B for diastolic blood pressure according to the BHS criteria [4], and fulfilled the AAMI accuracy criterion for diastolic (mean difference 1 mmHg, standard deviation 8 mmHg) but not for systolic blood pressure (mean difference 1 mmHg, standard deviation 9 mmHg) [5].

Table 2 Subject characteristics

SBP (mmHg)	<90	90–129	130–160	161–180	>180	Mean	SD
	5	26	25	20	9	145	34
DBP (mmHg)	<60	60–79	80–100	101–110	>110	Mean	SD
	9	22	29	14	11	87	20

Data are number of subjects. Mean age of subjects was 50 ± 12 years. Mean arm circumference was 31 ± 3 cm. Twenty-three subjects required a large cuff.

The difference 'device minus Sphygmocorder', for systolic and diastolic pressures separately (using the data on which the final grade is based), in 85 subjects was plotted against the mean of the device pressure and the observer pressure, using all 255 points (Figs 1, 2).

The mean and standard deviation of the first mercury sphygmomanometer measurements were 145 ± 34/87 ± 20 mmHg.

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

Table 3 Accuracy criteria of the British Society of Hypertension protocol (BHS)

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

Table 4 Accuracy of Profilomat II® device

			BHS				AAMI		
After comparisons		n	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade	Mean	SD	Grade
Overall	SBP	255	42	69	85	C	1	9	F
	DBP	255	53	78	94	B	1	8	P
Lower	SBP	93	56	81	97	B	−1	6	P
	DBP	93	57	82	98	B	−1	7	P
Middle	SBP	75	39	69	84	D	2	9	F
	DBP	87	53	84	97	B	1	7	P
Upper	SBP	87	31	58	72	D	4	11	F
	DBP	75	47	67	87	C	2	9	F

Data are numbers of measurements. SBP, systolic blood pressure; DBP, diastolic blood pressure; BHS, British Hypertension Society, AAMI, Association for the Advancement of Medical Instrumentation.

the BHS and AAMI criteria to tertiles of pressure the Profilomat II® dropped to a D/C grading in the high pressure tertile and failed to fulfil the AAMI criteria for both systolic and diastolic blood pressures (Tables 3 and 4).

Basic information

In accordance with the BHS protocol, basic information relating to the Profilomat II® is given in the Appendix.

Discussion

In this study, the Profilomat II® ABPM system was evaluated according to the protocols of the BHS and the AAMI [4–6]. According to the BHS protocol, the Profilomat II® achieved a grade C rating for systolic pressure and grade B for diastolic pressures, with 42% of systolic and 53% of diastolic blood pressures being within 5 mmHg of the mercury sphygmomanometer [4]. According to the AAMI protocol, the Profilomat II® fulfilled the criteria for diastolic but not for systolic pressure [5].

The BHS protocol recommends that the accuracy of devices should be examined in 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 [4]. In keeping with most devices [9], the Profilomat II® improves its grading marginally in low pressure analysis but worsens considerably in the high pressure tertile.

From the operational viewpoint, the Profilomat II® was favoured by both the subjects on whom it was tested and by the operator. It is a neat and compact device which is simple to use and reliable, at least for the period of this validation. However, extra measurements after completion of the 24-h period cannot be obtained, since the Profilomat II® stops recording at the end of 24 h. Instructions as to the use of the 'OK' option should be clearer on the liquid crystal display. The Velcro® plaster pads for securing the cuff need to be improved to prevent discomfort from the irritation of cuff movement.

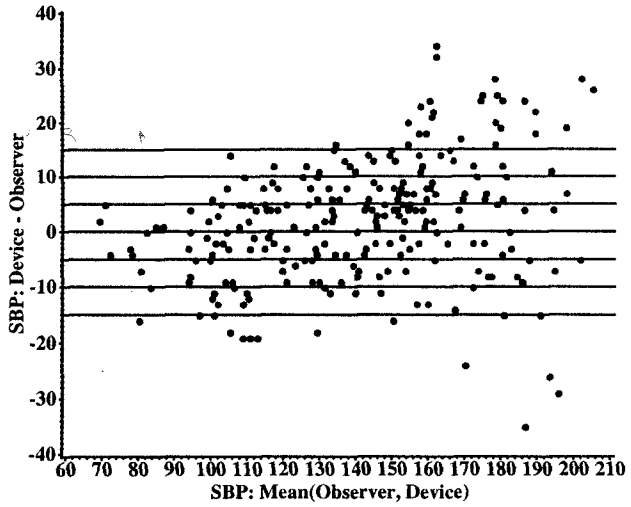
The BHS protocol stipulates that the manual accompanying devices should be critically evaluated [4]. The Profilomat II® manual was generally found to be comprehensive. The use of actual display options on the console is particularly helpful. However, there were some omissions; for example, suppliers and service centres are not given, replacement components, service and maintenance are not provided, although these are obtainable from the manufacturer.

In previous validation studies, a number of strategies have been employed to overcome observer error. Using the BHS film combined with direct instruction we have been able to bring all paired nurse observer measurements to within 5 mmHg of each other for both systolic and diastolic pressure [10]. However, although 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 over time and require re-training [11].

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 [1,12], especially at higher levels of blood pressure [9]. It will be some time, therefore, before automated devices can be substituted for the traditional gold standard, namely, an accurate observer using a standard mercury sphygmomanometer and stethoscope.

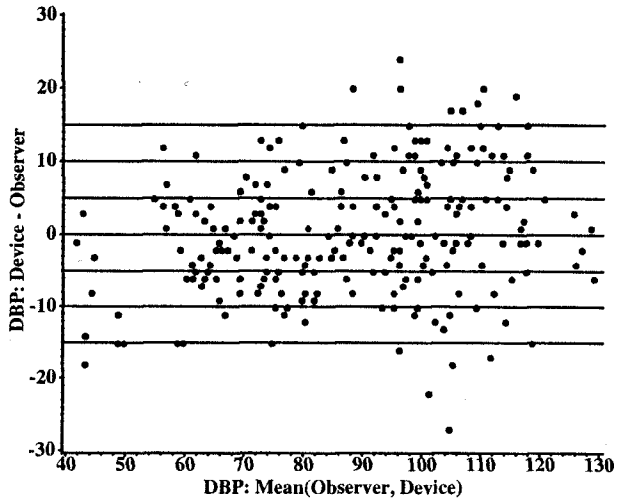
The Sphygmocorder innovatively combines technology that has been available for some time to provide the facility for storing recorded data while preserving the time-honoured technique of blood pressure measurement with the mercury sphygmomanometer and an auscultating observer. Other advantages of the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

Fig. 1



Systolic blood pressure (SBP) measured using a mercury sphygmomanometer versus the difference between the mercury and Profilomat II® measurement in 85 subjects (number of measurements = 255). Reference lines: −15 to +15 mmHg in 5 mmHg steps.

Fig. 2



Diastolic blood pressure (DBP) measured using a mercury sphygmomanometer versus the difference between the mercury and Profilomat II® measurement in 85 subjects (number of measurements = 255). Reference lines: −15 to +15 mmHg in 5 mmHg steps.

Table 5 Automated devices for ambulatory blood pressure measurement available on the market which have been subjected to validation by the British Hypertension Society (BHS) and Association for the Advancement of Medical Instrumentation (AAMI) protocols

Device	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* [19]	Aus		Passed	B/A	Rest/pressure ranges
Profilomat* [20]	Aus		Passed	B/C	Pregnancy
QuietTrak* [21,22]	Aus		Passed	B/B	Rest
QuietTrak* [23]	Aus		Failed	B/B	Pregnancy
QuietTrak* [24]	Aus		Passed	A/A	Rest
					Exercise
					Posture
					Elderly
					Children
					Pregnancy
Schiller BR [25]	Aus		Passed	B/B	Rest/pressure ranges
	Osc		Failed	D/B	Rest/pressure ranges
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
					Posture
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. *Model number not denoted. Criteria for fulfilment of BHS protocol: devices must achieve at least grade B/B. Criteria for fulfilment of AAMI standard: mean difference ≤ 5 ± 8 mmHg (mean ± SD).
Osc, oscillometric mode; Aus, auscultatory mode.

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			BHS				AAMI		
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recordings, such as those with weak Korotkoff sounds, which are often a source of doubt and error in once-off auscultation; and the elimination of observer inattention or loss of concentration [8]. The incorporation of an automatic inflation/deflation system, which guarantees a constant inflation and deflation rate, allows for computer-controlled inflation and deflation of upper arm cuffs of various dimensions, thereby eliminating human variability and bias in the deflation procedure [8].

One of the main reasons for establishing the BHS and AAMI protocols was to provide a standardised method for assessing blood pressure measuring devices and to provide a means of comparing devices with similar clinical applications. Table 5 lists ambulatory devices which have been subjected to evaluation by the BHS and AAMI protocols [1]. From this, it is apparent that the Profilomat II® ambulatory system, which achieved a C/B grading according to the BHS protocol and failed to fulfil the AAMI accuracy criterion for systolic blood pressure, cannot be recommended for clinical use when accuracy of blood pressure measurement is required. However, the manufacturers, with whom we maintained close contact throughout the validation study, have subsequently analysed the algorithm, especially with regard to the influence on accuracy of the material and dimensions of the inflatable bladder. After due validation, a new algorithm will be incorporated in future models. A new software analysis program for Windows™ 95 (Microsoft Corporation, Redmond, Washington, USA) has also been produced by the manufacturer.

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Appendix: Basic information

In accordance with Appendix C of the BHS protocol [4] the following aspects of the Profilomat II® device were assessed.

Device identification: The model was clearly identified as the Profilomat II® Disetronic. It measures blood pressure oscillometrically compared with the earlier Profilomat model which measured blood pressure by the auscultatory method.

Costs: The basic cost of the Profilomat II® monitor together with the software is US$ 3785 (exclusive of import duties, VAT and delivery charges) for the recorder, one carrying bag with shoulder strap, one standard and one large cuff, Velcro® adhesives to hold the cuff in place, one AC/AC adapter, two accupack (rechargeable batteries), console, connecting cable, one data transfer software, one print programme and operating manual. A full list of prices for replacement and spare parts and accessories is available on request.

Compliance with standard(s): There is mention in the manual of compliance with national and international safety and performance standards.

Validation studies and results: There are no published validation results as yet.

Instructions for use: The instruction manual provided with the Profilomat II® is adequate and comparatively easy to follow. The English in the manual could be improved upon before its next publication. Individual error codes are not listed in the manual, which is frustrating for user and subject.

Patient instruction card: No instruction card is provided.

Precautions for use: The BHS protocol requires that the operator must be alerted to any weaknesses in the system which might affect performance or patient safety and that the safety precautions incorporated in the system to prevent the cuff remaining inflated be clearly stated; these precautions are stipulated in the manual.

Power supply: The manual should provide more detail on power requirements. The number of measurements that might be anticipated from a battery charge is > 200 measurements (standard cuff, inflation pressure 160 mmHg) with one accupack. The accupacks contain two 1.2V NiMH-cells with 1200 mAh capacity and a shelf-life of up to 1000 charging cycles. Commercially available batteries can be used (AAA 1.5 V) but a special battery housing, which must be purchased separately, is required.

Instructions for care and maintenance: The manual does not give the operator instructions on the day-to-day care of the equipment apart from suggesting that cuffs should be

washed. It is suggested that the user check calibration at least twice yearly. Product warranty is for 12 months and the service warranty is for 3 years.

Service facilities: The BHS protocol recommends that the location of national and international service facilities should 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 should be given. This information is not provided.

Dimensions: The dimensions and weights of the recorder and the batteries are provided (see methods).

List of components: The major components of the system are listed in the manual. The dimensions of the bladders available are not provided. Each cuff with vinyl bladder, is designed so that it can be used on either arm. The following are the cuff dimensions: small cuff for 18–27 cm arms; standard cuff for 24–33 cm arms and a large cuff for 33–42 cm arms.

Method(s) of blood pressure measurement: The Profilomat II® measures blood pressure using the oscillometric technique.

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 is carried out at 6-monthly intervals. Recalibration can only be performed by the manufacturer or agent and should be carried out every 2 years.

Factors affecting accuracy: The manual does not mention that certain conditions, such as exercise, car driving or cardiac arrhythmias, may affect the accuracy of the recorder.

Operator training requirements: The Profilomat II® system is reasonably easy to operate and the instruction manual takes the operator through the operative procedure step by step.

Computer analysis: The Profilomat II® can be connected to a personal computer permitting an ASCII® file of the data to be created, and a cable and software program for this is provided. Instructions for operating this software are not included in the manual.

Problem list and solutions: Common operational problems, error codes and possible solutions are not listed in the manual.

Supplier names and addresses: The following is the name, address and telephone number of the manufacturer: Disetronic Medical Systems AG, Brunnmattstr 6, CH-3401 Burgdorf, Switzerland. Tel: +41 34 427 11 11; fax: +41 34 427 11 22.

Support for validation: The manufacturers, Disetronic Medical Systems AG, supplied three Profilomat II® systems for the study and contributed to the financial costs of the validation.