

Accuracy of the Profilomat ambulatory blood pressure measuring system determined by the British Hypertension Society protocol*

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Objective: To evaluate the Profilomat monitor for ambulatory blood pressure measurement according to the British Hypertension Society (BHS) protocol.

Design: The BHS protocol consists of six phases: I, observer training and assessment; II, before-use interdevice variability assessment; III, in-use assessment; IV, after-use interdevice variability assessment; V, device validation; and VI, preparation of report.

Method: Three Profilomat recorders passed the before-use interdevice variability test, after which they entered the in-use phase during which the three recorders are worn by subjects over 24 h. In 12 recording days the Profilomat failed to achieve the required 70% valid recordings. This was identified as being due to the inability of the Profilomat to take a second measurement when the first one failed, and when this facility was provided the Profilomat fulfilled the in-use requirement and the three devices subsequently passed the after-use interdevice variability test. The main validation test was carried out in 86 subjects with a wide range of pressures, the results being analysed according to the BHS grading system from A to D.

Results: The Profilomat achieved grade B rating for systolic blood pressure and grade A for diastolic blood pressure, and satisfied the criteria for accuracy of the Association for the Advancement of Medical Instrumentation (AAMI) with a mean difference (\pm SD) for systolic pressure of -3 ± 5 mmHg and -1 ± 5 mmHg for diastolic pressure. Subject acceptability was good and the manufacturer's manual was satisfactory.

Conclusion: On the basis of these results, the Profilomat can be recommended for ambulatory blood pressure measurement in clinical practice.

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Keywords: Profilomat, validation, 24-h ambulatory blood pressure, British Hypertension Society protocol, Association for the Advancement of Medical Instrumentation Standard.

Introduction

Ambulatory blood pressure measurement is now accepted as a valuable procedure in the clinical management of hypertension [1,2]. The increased demand for 24-h blood pressure measurement has resulted in the production of a variety of ambulatory devices, and there are at least 15 systems now available with many more in the development phase [3].

Systems to measure ambulatory blood pressure are expensive, and independent validation of accuracy has been demanded [4]. To ensure that ambulatory systems are accurate and perform well in clinical practice, the British Hypertension Society (BHS) published a comprehensive protocol for the evaluation of blood pressure measuring devices with special reference to ambulatory systems [5]. This protocol follows the previously established validation criteria

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*The British Hypertension Society protocol has been revised recently (see page S43 of this supplement); the validation reported in this paper was conducted according to the original protocol.

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of the Association for the Advancement of Medical Instrumentation (AAMI) [6], but includes additional aspects of validation, such as ambulatory use, and the accuracy requirements are graded rather than absolute, as in the AAMI Standard. The BHS protocol has been used previously to evaluate the SpaceLabs 90202 [7] and the SpaceLabs 90207 [8], Novacor DIASYS 200 [9], Takeda TM-2420 [10], Takeda TM-2420, model 7 [11] and the Del Mar Avionics Pressurometer IV [12]. In the present study the Profilomat, an ambulatory system which measures blood pressure by detecting Korotkoff sounds with a microphone, was evaluated according to the BHS protocol.

Methods

Profilomat ambulatory system

The Profilomat, which is especially designed for use in general practice, consists of a portable recorder, left and right arm cuffs (a large cuff is available for obese subjects and a small adult cuff for subjects with arm circumferences between 18 and 27 cm) containing a microphone which can be removed from a pocket allowing direct placement on the skin, two rechargeable batteries, a back-up battery, a battery charger, a carrying bag with strap and a Brother M-1109 dot-matrix printer. The recorder is 145 × 84 × 40 mm and weighs about 395 g, including the battery. A connector on the inflation tube allows for calibration against a mercury sphygmomanometer.

The recorder is operated by means of two buttons which permit the device to function in two modes: first, a STOP mode whereby single measurements, which are not stored, are used to sense the appropriate pressure level for an individual patient; secondly, a RUN mode which programs the recorder to make automatic measurements at intervals from 5 to 90 min over a 24-h period. There is the facility to set measurement intervals for two periods (for example, day and night). The cuff is inflated by a rotary micro-pump to a preprogrammed pressure level 10 s after an audible signal and is then deflated at a constant rate of 3 mmHg/s. Korotkoff sounds are detected by the microphone. In the first Profilomat recorders submitted for validation, modifications to the parent CH-Druck recorder for use in general practice had removed the facility for repeat measurements which could only be obtained by pressing one of the buttons. As this resulted in too few measurements being obtained over the 24-h period, the manufacturers restored the facility for a repeat measurement in the event of a failed measurement. Inflation is reactivated if a Korotkoff sound is detected within the first 10 mmHg of cuff deflation. The pressure ranges are 70–280 mmHg for systolic blood pressure (SBP) and 40–150 mmHg for diastolic blood pressure (DBP). The pulse rate in beats/min may also be displayed. Information on the

system status, results and error codes it provided by a small liquid-crystal display. A series of error codes are displayed and stored.

A printout of the 24-h recording may be obtained by connecting the recorder to the dot-matrix printer. This consists of patient details, time of recording, heart rate, SBP, DBP and a horizontal plot of the individual pressures together with the mean and median values and the standard deviations. A histogram shows the percentage of measurements within 10-mmHg bands.

Evaluation programme

The BHS evaluation programme [5] consists of six phases: I, observer training and assessment; II, before-use interdevice variability assessment; III, in-use (field) assessment; IV, after-use interdevice variability assessment; V, device validation; and VI, report of evaluation.

Observer training and assessment

Three nurses were trained and assessed according to the criteria of the BHS protocol [5,13] using the BHS video film 'Blood pressure measurement' [14]. This was followed by an instruction session by an expert (E.O'B.) using a multiheaded stethoscope. After training, the observers were tested for accuracy against each other and the expert observer on five subjects. Criteria for this assessment are that 90% of SBP and DBP differences between the trainees and expert should not differ by more than 5 mmHg and 98% by not more than 10 mmHg, and that 85% of SBP and DBP differences between each trainee should not differ by more than 5 mmHg and 95% by not more than 10 mmHg. After successfully passing the training assessment, the observers were instructed in the use of the devices to be tested, and practice measurements were made on a number of subjects.

The calibration accuracy was checked according to the manufacturer's instructions before any testing began, by connecting the Profilomat to a mercury column and checking that pressure differences throughout the pressure range were within ± 3 mmHg.

Before-use interdevice variability assessment

A connector on the inflation tube of the Profilomat may be joined with a Y-connector to a mercury sphygmomanometer to check the 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' in booths from each other. Observer 1 read a recently calibrated mercury column and observer 2 read the Profilomat. The manometers were connected by Y-connectors to a further mercury manometer, which were read by a third observer (the 'controller'). All three manometers were connected to a Profilomat cuff 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 the pressure. There were five calls per defla-

tion according to a randomized 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. There were six deflations per device with five readings per deflation, providing 30 readings per device. There were thus 90 readings for analysis. At least 95% of readings had to be within the recommended limits of 3 mmHg, and if this criterion was not fulfilled further testing was not performed.

In-use assessment

The three Profilomat monitors used for the interdevice assessment were next used to test performance during and after 24-h ambulatory monitoring in 24 subjects over a 4-week period. However, after testing in 12 subjects it became apparent that the Profilomat was failing the BHS requirement, and this was identified as being due to failure to repeat measurements. The manufacturers later modified the Profilomat, replacing the facility for repeat measurement. The in-use phase was then repeated in 24 subjects to provide at least 600 recordings per device. The protocol requires that at least 85% of the possible 75 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.

After-use interdevice variability

At the end of the month of ambulatory assessment the three monitors were retested for interdevice variability in the same way as before, to determine whether there had been any change in interdevice agreement during ambulatory use.

Device validation

As there was no alteration in the interdevice variability after the month of use, one device was arbitrarily selected for the main validation test. Eighty-six subjects aged from 15 to 80 years with blood pressure in the range recommended by the BHS protocol [5] were selected. Simultaneous measurement of blood pressure by a mercury sphygmomanometer and the device being evaluated is recommended as the validation test of choice in the BHS protocol. However, this was not possible for DBP and sequential same-arm measurements with the Profilomat and a standard mercury sphygmomanometer were therefore performed for DBP as recommended in the protocol [5,15]. The test measurement is bracketed by two readings with the standard mercury sphygmomanometers, the difference being calculated as follows: if the device pressure lies between the first and third pressure, the difference is taken as zero, otherwise the nearer of the two readings is subtracted to give the difference [15]. The procedure was performed in 43 subjects by observer 1 and in the other 43 subjects by observer 2. A total of 258 (3 × 86) sets of measurements were available for analysis. All pressures were recorded with the subject in the seated position.

Results

Observer training and assessment

All three trainee observers passed the accuracy criteria.

Before-use and after-use interdevice variability assessments

All of the devices were within the permitted error limits.

Table 1. In-use assessment.

	24-Hour			Day		Night	
	Inf.	Valid	Rejected	Inf.	Valid	Inf.	Valid
Profilomat							
n	1918	1702	216	1486	1350	432	352
Inf. (%)		89	11		91		81

Figures are for 24 recording days in 24 subjects. Inf., inflations.

In-use assessment

In the first in-use assessment in 12 subjects the Profilomat failed to achieve the required 70% valid readings on five out of 12 recording days. After identifying the problem as being the failure of the Profilomat to repeat failed measurements, the manufacturers offered to restore this facility which had been removed from the parent CH-Druck, and the main validation test proceeded. However, when this had been completed the same Profilomat recorders used in the first in-use phase were modified and the in-use phase was repeated in 24 subjects. Eighty-nine per cent of 24-h measurements recorded with the three devices were valid, thus fulfilling the protocol requirement. The Profilomat provided an average of 79 measurements on each of the 24 recording days. The excess measurements were due mostly to the device being operative for a little longer than 24 h. The Profilomat does not indicate the number of inflations made, and it was therefore not possible to assess the number of excess inflations during the 24-h period. An analysis of performance during the in-use phase is given in Table 1.

Patient/subject acceptability

Each subject was asked to comment on the performance of the device. Comments from 24 subjects were generally favourable, but 12 subjects complained of discomfort from the cuff.

Device validation

The percentage of measurements differing from the mercury standard by 5, 10 and 15 mmHg or less are shown in Table 2 and plotted in Figs 1 and 2. To obtain a particular grade all three cumulative percentages had to exceed the tabulated values. The Profilomat achieved B grading for SBP and A grading for DBP according to the BHS crite-

ria [5], and was comfortably within the AAMI criteria of a mean difference of 5 mmHg and SD of 8 mmHg [6] with mean differences of -3 ± 5 mmHg for SBP and -1 ± 5 mmHg for DBP. The means \pm SD of the first mercury sphygmomanometer measurements were $139 \pm 28/84 \pm 20$ mmHg.

Table 2. British Hypertension Society grading criteria.

	Grade	Difference between standard and test device (mmHg)			AAMI
		≤ 5	≤ 10	≤ 15	
Cumulative percentage of readings	A	80	90	95	
	B	65	85	95	
	C	45	75	90	
	D	Worse than C			
Profilomat					
SBP	B	77	88	95	-3 ± 5
DBP	A	80	92	95	-1 ± 5

AAMI, Association for the Advancement of Medical Instrumentation; SBP, systolic blood pressure; DBP, diastolic blood pressure.

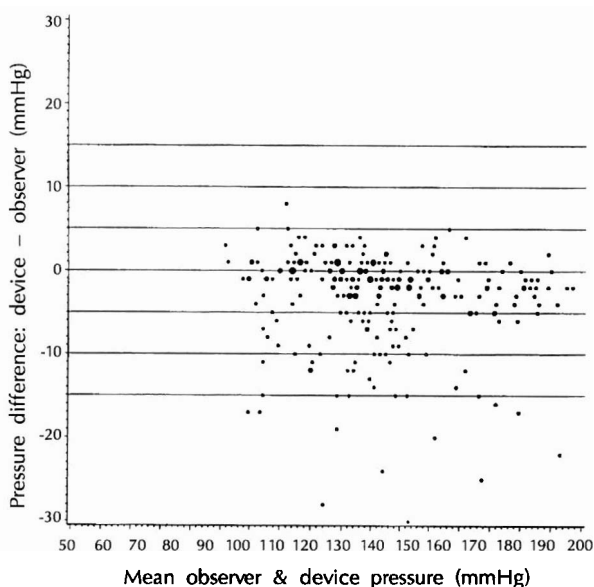


Fig. 1. Plot of systolic blood pressure (mmHg) measured with a mercury sphygmomanometer versus the simultaneously measured difference (mmHg) between the mercury and Profilomat measurement for 86 subjects ($n=258$). Reference lines, -15 to $+15$ mmHg in 5-mmHg steps. \triangle , Outlying values.

The calibration accuracy of the Profilomat 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 Profilomat and the nearer of these observer measurements in 86

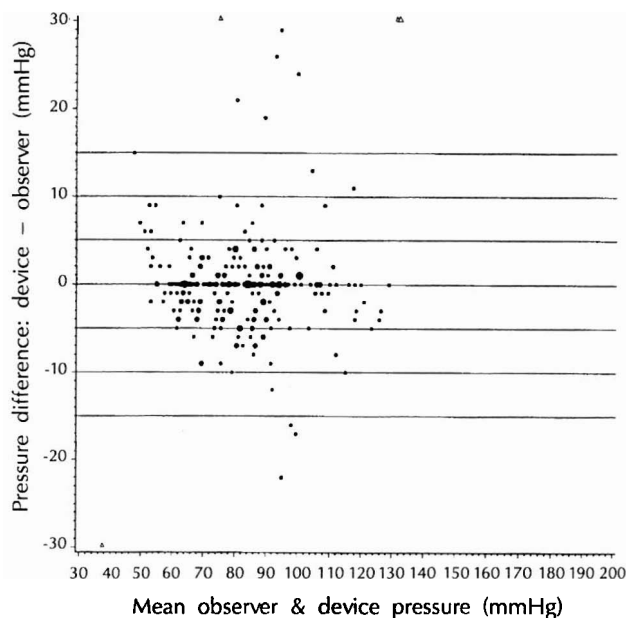


Fig. 2. Plot of diastolic blood pressure (mmHg) measured with a mercury sphygmomanometer versus the sequentially measured difference (mmHg) between the mercury and Profilomat measurement in 86 subjects ($n=258$). Reference lines, -15 to $+15$ mmHg in 5-mmHg steps. \triangle , Outlying values.

subjects ($n=258$) for SBP and DBP in Figs 1 and 2. The reference lines indicate -15 to $+15$ mmHg in 5-mmHg steps.

Basic information

In accordance with Appendix B of the BHS protocol [5], the following aspects of the Profilomat were assessed.

Model identification

The model was clearly identified as the Profilomat Roche.

Costs

The cost of the Profilomat is £1500 sterling (exclusive of import duties, value-added tax and delivery charges) for the recorder, a back-up battery, two standard cuffs, microphone, two rechargeable batteries, Accutrain battery charger, dot-matrix printer, connecting cables 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 no mention in the manual of compliance with national or international safety and performance standards.

Validation studies and results

No published validation results were listed by the manufacturer.

Instructions for use

The instruction manual provided with the Profilomat is adequate and easy to follow.

Patient instruction card

A card is provided for distribution to patients using the ambulatory recorder, which gives simple operational instructions and provides a diary for entering activity or symptoms at the time of measurement. Instructions concerning what precautions to take in the event of the device malfunctioning are not provided, although there is space to enter the doctor's telephone number to be used in the event of difficulty.

Precautions for use

The BHS protocol requires that the operator be alerted as 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 criteria are not provided in the manual.

Power supply

The manual does not provide adequate detail on the power requirements. For example, there is no mention of the battery power or the number of measurements that might be anticipated from a battery charge. The manufacturers have provided the information that power is provided by rechargeable 6 V/250 mA h batteries to provide in excess of 100 measurements.

Instructions for care and maintenance

The manual does not give the operator instructions on the day-to-day care of the equipment, and maintenance of the system is not discussed. Product warranty information is not included in the manual.

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 supplied were not provided. The bladders, which are vinyl rather than rubber, are shaped so that it is necessary to have two cuffs; one for the right arm and one for the left arm. The bladder dimensions for the standard cuff were length 24.5 cm on the upper edge and 22.5 cm on the lower edge, and width 12 cm. The BHS recommends a cuff containing a bladder with dimensions 35 × 12 cm for most adult arms [17]. A

Velcro adhesive patch is provided to anchor the cuff to the skin.

Method(s) of blood pressure measurement

The Profilomat measures blood pressure using the Riva Rocci technique of cuff occlusion and detection of Korotkoff sounds with a microphone.

Artefact editing

The Profilomat does not have in-built editing criteria.

Facility for checking device accuracy

Accuracy is easily checked against a mercury sphygmomanometer throughout the pressure range.

Facility for device recalibration

The manual recommends returning the recorder to the manufacturer if the Profilomat is not within ± 3 mmHg of the mercury sphygmomanometer during calibration testing.

Factors affecting accuracy

The manual does not state conditions, such as car driving or cardiac arrhythmias, which may affect the accuracy of the recorder.

Operator training requirements

The Profilomat system is reasonably easy to operate and the instruction manual takes the operator through the operative procedure step by step. It should be possible for users without previous experience of ambulatory monitoring to set up and operate the system, especially if instruction is given by the manufacturer or its agent.

Computer analysis

The Profilomat is not provided with the facility to be connected to a personal computer, although a cable and software program to do so are obtainable on request from the manufacturers. This permits an ASCII file of the data to be created.

Problem list and solutions

Common operational problems are indicated by 12 error codes which are clearly listed in the manual with the appropriate solution.

Supplier names and addresses

The following is the name, address and telephone number of the Swiss supplier:

F. Hoffmann-La Roche AG Pharma, CH-4002 Basel, Switzerland. Tel: +41 61 6881111; Fax: +41 61 6910261.

The manufacturer is: Disetronic Medical Systems AG, Brunnmattstrasse 6, CH-3401 Burgdorf, Switzerland. Tel: +41 34 231333; Fax: +41 34 231385.

Support for validation

The suppliers, F. Hoffmann-La Roche, supplied three Profilomat systems for the study and contributed to the financial costs of the validation.

Discussion

In the present study the Profilomat ambulatory blood pressure measuring system was evaluated according to the British Hypertension Society protocol [5]. This protocol contains many of the recommendations of the earlier AAMI Standard [6], but has a number of additional features. These include strict criteria for observer training and assessment before the evaluation procedure begins, an assessment of interdevice variability before and after a period in use, and an assessment of the product information and the instructions for operation provided by the manufacturer.

In addition, the BHS protocol takes a new approach to the methods of assessing device accuracy. Whereas the AAMI criteria for acceptable inaccuracy allow a mean difference of 5 mmHg with an SD of 8 mmHg, the BHS protocol regards this as too liberal and recommends instead a system of grading that ranges from grade A, representing the accuracy achieved with trained observers using a mercury sphygmomanometer, to grade D.

The Profilomat system fulfilled the AAMI criteria [8] and achieved a grade B rating for SBP and grade A for DBP, with 77% of SBP and 80% of DBP measurements being within 5 mmHg of the mercury sphygmomanometer, and 88% of SBP and 90% of DBP measurements being within 10 mmHg. In this validation a unique situation has arisen in relation to the method of analysis. The BHS protocol recommends using simultaneous same-arm comparisons when this is feasible and sequential same-arm comparisons when the deflation mechanism renders this impossible. For SBP it was possible to use simultaneous same-arm comparisons, but as the Profilomat cuts out shortly after detecting DBP, making simultaneous same-arm comparison inaccurate, sequential same-arm comparison was used for DBP [5,15].

To overcome the problem of devices losing accuracy under the stress of everyday use, the BHS protocol stipulates that validation should take place only after the device has had a reasonable period in use. This validation was performed after the Profilomat had been subjected to 1 month of ambulatory use. Two important features of the BHS protocol were highlighted during the in-use phase of the Profilomat evaluation. The protocol states that when a device, which may previously have been shown to be accurate, is modified, it must be re-evaluated even if the manufacturers are confident that the recording mechanism has not been affected by the modification. The Profilomat was developed by Disetronic Medical Systems AG for F. Hoffmann-La Roche Ltd, for use in general practice. Hoffmann-La Roche requested a device that would be inexpensive, uncomplicated to operate and accurate. To achieve this Disetronic scaled down the ambulatory system, the CH-Druck, which has subsequently been shown to comply with the

BHS requirements, achieving grade A ratings for both SBP and DBP [16]. The manufacturers were initially of the opinion that the Profilomat would not require full BHS validation as the recording mechanism in the modified device (the Profilomat) was unchanged. We argued that this assumption was unacceptable and the manufacturers agreed to a full validation for the Profilomat. As has been demonstrated, this was the correct decision. When the BHS protocol was first being drafted, the value of the in-use phase was debated intensely and eventually it was decided to let it stand and review its value in practice. During the in-use phase assessment of the Profilomat it became evident that it was faring badly, providing less than the required 70% of valid measurements on five of 12 days of ambulatory use. Comparing these results with the satisfactory results obtained with the CH-Druck it seemed likely that Disetronic, in scaling down the CH-Druck for use in general practice, had removed the facility for a repeat measurement in the event of a failed measurement, and this was confirmed by the manufacturers, who were confident that the facility could be easily replaced. It was therefore agreed to continue with the main validation test, after which the in-use phase would be repeated on the three recorders used in the first in-use phase modified to record failed measurements. The modified recorders comfortably fulfilled the protocol requirements.

The period in use also permits some expression by the user concerning the device acceptance. For example, experience with the Profilomat during this study suggested that the microphone should not be enclosed in the cloth cuff, but rather attached directly to the skin over the brachial artery. In this way cuff movement during use will not affect the microphone position. This aspect of performance needs to be evaluated further. Because 12 subjects complained of discomfort from the material used for the cuff, the manufacturers have agreed to redesign the cuff.

A critical analysis of the manual accompanying ambulatory systems is one of the BHS stipulations. The Profilomat manual was generally found to be comprehensive, clearly written and well illustrated. The use of actual display options on the recorder is particularly helpful. However, there are some omissions: suppliers and service centres are not given and costings of the device and components are not provided, although these are obtainable from the manufacturers.

The BHS protocol requires a statement on the computer aspects of the system. The Profilomat is not dependent on linkage to a personal computer, which may be seen as an advantage since it serves as a stand-alone device for use in general practice. However, this is a disadvantage for hospital use, where a research component may be additional to service requirements. The multicentre European study on isolated systolic hypertension in the elderly (Syst-Eur), for example, requires that all ambulatory data be

entered directly into the database in Lueven, and as this is not possible with the Profilomat it would be excluded from the study (O'Brien E, personal communication, 1992). However, a software program with this facility, which is not provided with the standard recorder, can now be obtained from the manufacturers on request.

Although the BHS protocol provides an assessment of performance during ambulatory use, it needs to be emphasized that blood pressure measurements are usually made with the subject at rest, and an ambulatory device that meets the criteria of this protocol cannot be assumed to be accurate during physiological manoeuvres, such as exercise, isometric handgrip or Valsalva manoeuvre. Moreover, the protocol does not test the device in the variety of positions in which ambulatory measurement may be made.

One of the reasons for establishing the BHS protocol was to provide a standardized protocol whereby it would be possible to make comparisons between ambulatory systems evaluated according to the protocol. Eight ambulatory systems, the SpaceLabs 90202 [7] and the SpaceLabs 90207 [8], the Novacor DIASYS 200 [9], the Takeda TM-2420 [10], the Takeda TM-2420, model 7 [11], the Del Mar Avionics Pressurometer IV [12], the CH-Druck [16] and the Profilomat, have now been evaluated according to the BHS protocol. Using accuracy criteria as a comparative guide, the CH-Druck is the most accurate device evaluated to date, having achieved grade A rating for SBP and DBP, and is followed closely by the Profilomat with B grading for SBP and A grading for DBP.

In conclusion, the Profilomat ambulatory system achieved grade B rating for SBP and grade A rating for DBP according to the criteria of the BHS protocol, and it can therefore be recommended for ambulatory blood pressure measurement.

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