

Accuracy of the CH-Druck/Pressure Scan ERKA ambulatory blood pressure measuring system determined by the British Hypertension Society protocol*

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Objective: To evaluate the CH-Druck/Pressure Scan ERKA 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 CH-Druck/Pressure Scan ERKA recorders passed the before-use interdevice variability test, after which 89% of inflations recorded with these devices during the in-use phase gave valid readings, 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 CH-Druck/Pressure Scan ERKA achieved a grade A rating for both systolic and 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 ± 4 mmHg and -2 ± 4 mmHg for diastolic pressure between the test device and the mercury sphygmomanometer. Subject acceptability was good and manufacturer's manual was satisfactory.

Conclusion: On the basis of these results, the CH-Druck/Pressure Scan ERKA can be recommended for ambulatory blood pressure measurement in clinical practice.

Journal of Hypertension 1993, 11 (suppl 2):S1-S7

Keywords: CH-Druck/Pressure Scan ERKA, 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 their accuracy has been

demanding [4]. To ensure that ambulatory systems are accurate and perform satisfactorily 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 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, unlike

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The paper published in this supplement is the full supporting paper relating to the short report published in *J Hypertens* 1992, 10:1283-1284.

Sponsorship: This study was supported by the Charitable Infirmary Charitable Trust and the Royal College of Surgeons in Ireland.

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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.

Date of receipt: 9 March 1992; revised: 24 April 1992; accepted: 30 April 1992.

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 CH-Druck/Pressure Scan ERKA, an ambulatory system which measures blood pressure by detecting Korotkoff sounds with a microphone, was evaluated according to the BHS protocol.

Methods

CH-Druck ambulatory system

The CH-Druck system consists of a portable recorder, a random-access memory (RAM) card, left and right arm cuffs and bladders (a large cuff and bladder is available for obese subjects) containing a microphone which can be removed from a pocket allowing direct placement on the skin, two rechargeable batteries (500 mA h for about 200 measurements and 250 mA h for about 100 measurements) and a carrying bag with strap and belt. The recorder is 145 × 84 × 40 mm and weighs about 410 g including the 250 mA h battery and RAM card. A connector on the inflation tube allows calibration against a mercury sphygmomanometer.

Approximately 10 s after an audible signal the cuff is inflated by a rotary micropump to a preprogrammed pressure level and then deflated at a constant rate of 3 mmHg/s. Korotkoff sounds are detected by the microphone. Inflation is reactivated if a Korotkoff sound is detected within the first 10 mmHg of cuff deflation. Pressure measurements can be made over the ranges 70–280 mmHg for systolic blood pressure (SBP) and 40–150 mmHg for diastolic blood pressure (DBP), and 40–180 beats/min for the pulse rate. Information on the system status, results and error codes is provided by a small liquid-crystal display. The system can be operated manually using two buttons.

A large number of program options can be initiated by the removable RAM card. The subject's name, sex, date of birth or code number, and the selection of measurement for one to four successive periods over 24 h with measurement intervals of between 5 and 90 min can be entered on the software program. The selected 24-h program can be initiated continuously over days. The 32-Kbit memory is capable of storing as many as 8000 values during each period of monitoring. Using a RAM card interface linked to a standard IBM-compatible personal computer, data can be retrieved from the RAM card after use for display on a screen, computer storage or printing. The RAM card is re-initialized for each subject.

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. The criteria for this assessment were that 90% of SBP and DBP differences between the trainees and the 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 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 CH-Druck to a mercury column and checking that pressures throughout the pressure range were within ± 3 mmHg.

Before-use interdevice variability assessment

A connector on the inflation tube of the CH-Druck may be attached to tubing from 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 CH-Druck. The manometers were connected by Y-connectors to a further mercury manometer which was read by a third observer (the 'controller'). All three manometers were connected to a CH-Druck 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 deflation 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. Thus, there were 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 CH-Druck 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 to provide at

least 600 recordings per device. The BHS 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 use, to determine whether there had been any change in interdevice agreement during ambulatory use.

Device validation

As there was no alteration in interdevice variability after the month in use, one device was arbitrarily selected for the main validation test. Eighty-six subjects aged from 15 to 80 years were selected with blood pressure in the range recommended by the BHS protocol [5]. 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. As this was not possible for DBP, sequential same-arm measurements with the CH-Druck and a standard mercury sphygmomanometer were 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, then 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 trainee observers passed the accuracy criteria.

Before-use and after-use interdevice variability assessments

All three devices were within the error limits permitted.

In-use assessment

Eighty-nine per cent of 24-h measurements recorded with the three devices were valid, thus fulfilling the protocol requirement. The CH-Druck 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 CH-Druck does not register 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 shown in Table 1.

Table 1. In-use assessment.

	24-Hour			Day		Night	
	Inf.	Valid	Rejected	Inf.	Valid	Inf.	Valid
CH-Druck							
n	1900	1694	206	1477	1348	423	346
Inf. (%)		89	11		91		82

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

Patient/subject acceptability

Each subject was asked to comment on the performance of the device. Comments from 24 subjects were generally favourable, but seven subjects complained of discomfort from the cuff and one subject had an erythematous area following removal of the cuff.

Device validation

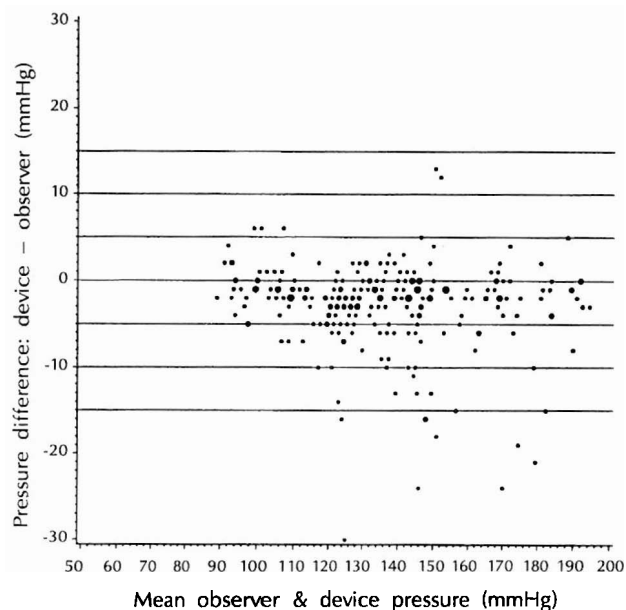
The percentage of measurements differing from the mercury standard by 5, 10 and 15 mmHg or less are shown in Table 2 and plotted in Figs 1 and 2. To obtain a particular grade all three cumulative percentages had to exceed the tabulated values. The CH-Druck achieved grade A for both SBP and DBP according to the BHS criteria [5] and was comfortably within the AAMI criteria of a mean difference of no greater than 5 mmHg and standard deviation of 8 mmHg [6]: mean differences -3 ± 4 mmHg in SBP and -2 ± 4 mmHg in DBP. The mean and SD of the first mercury sphygmomanometer measurements were $141 \pm 25/85 \pm 17$ mmHg.

The calibration accuracy of the CH-Druck after undergoing the above programme of testing remained within ± 3 mmHg.

Table 2. British Hypertension Society grading criteria.

	Grade	Difference between standard and test device (mmHg)			
		≤ 5	≤ 10	≤ 15	
Cumulative percentage of readings	A	80	90	95	
	B	65	85	95	
	C	45	75	90	
	D	Worse than C			AAMI
CH-Druck					
SBP	A	81	93	97	-3 ± 4
DBP	A	85	97	98	-2 ± 4

Values are expressed as mean \pm SD. AAMI, Association for the Advancement of Medical Instrumentation; SBP, systolic blood pressure; DBP, diastolic blood pressure.



Mean observer & device pressure (mmHg)
Fig. 1. Plot of systolic blood pressure (mmHg) measured with a mercury sphygmomanometer versus the simultaneously measured difference (mmHg) between the mercury and CH-Druck measurement in 86 subjects ($n=258$). Reference lines, -15 to $+15$ mmHg in 5-mmHg steps.

Graphic presentation

The data are displayed as plots of the mean pressure for both observers with a mercury sphygmomanometer versus the difference between the CH-Druck and the nearer of these observer measurements in 86 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 CH-Druck were assessed.

Model identification

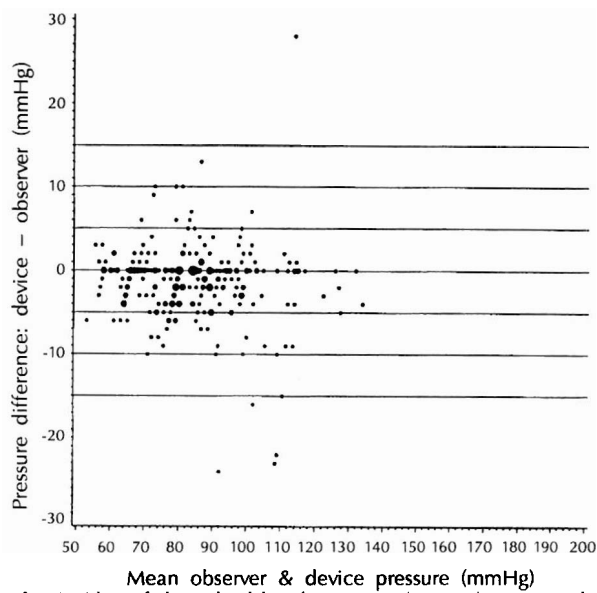
The model was clearly identified as the CH-Druck/Pressure Scan ERKA.

Costs

The cost of the CH-Druck/Pressure Scan ERKA in 1991 was £3100 sterling (exclusive of import duties, value-added tax and delivery charges) for the recorder, batteries, cuffs, microphone, battery charger, RAM card, RAM card interface, connecting cables and analysis software package.

Compliance with standard(s)

There is no mention in the manual of compliance with national or international safety and performance standards. The CH-Druck recently (14 January 1991) obtained approval of the Physikalisch Technische Bundesanstalt, the German standards authority (personal communication to E.O'B. from the manufacturers).



Mean observer & device pressure (mmHg)
Fig. 2. Plot of diastolic blood pressure (mmHg) measured with a mercury sphygmomanometer versus the sequentially measured difference (mmHg) between the mercury and CH-Druck measurement in 86 subjects ($n=258$). Reference lines, -15 to $+15$ mmHg in 5-mmHg steps.

Validation studies and results

No published validation results were listed by the manufacturer.

Instructions for use

The instruction manual provided with the CH-Druck is adequate and easy to follow.

Patient instruction card

A card for distribution to patients using an ambulatory recorder giving simple operational instructions together with instructions concerning what precautions to take in the event of the device malfunctioning was not provided as recommended in the BHS protocol.

Precautions for use

The BHS protocol requires that the operator 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. This information is not provided in the manual.

Power supply

The manual supplies adequate detail on the power requirements. Two rechargeable batteries may be chosen: 250 mA h for about 100 measurements, weighing 95 g, and 500 mA h for about 200 measurements, weighing 150 g. The batteries must be recharged with the Disetronic charger (the Accutrainer), a process that takes 3–4 h.

Instructions for care and maintenance

The manual does not give the operator instructions on the day-to-day care of the equipment, and mainte-

nance of the system is not discussed. Product warranty for 1 year is proved separately with the device, but is not documented 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 cuff bladders, which are polyurethane rather than rubber, are conically shaped, together with the covering cloth, and two standard cuffs are provided (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. A large adult cuff (bladder 34.5 cm upper and 31.5 cm lower edge) and a small adult cuff (bladder 18 × 9 cm) are also available. The BHS recommends a cuff containing a bladder of dimensions 35 × 12 cm for most adult arms [16]. A Velcro adhesive patch is provided to anchor the cuff to the skin.

Method(s) of blood pressure measurement

The CH-Druck measures blood pressure using the Riva Rocci technique of cuff occlusion and detection of Korotkoff sounds with a microphone. Electrocardiogram gating with electrodes is not required.

Artefact editing

The CH-Druck rejects measurements when the difference between SBP and DBP is ≤ 10 mmHg. Otherwise the CH-Druck does not have inbuilt editing criteria, but it is possible to program the computer to reject measurements that the user may decide are unsuitable.

Facility for checking device accuracy

The RAM card can be reconfigured to a calibration mode, which permits the recorder to be calibrated throughout the pressure range against a mercury sphygmomanometer.

Facility for device recalibration

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

Factors affecting accuracy

The manual does not state conditions, such as car driving or cardiac arrhythmias, that may affect the

accuracy of the recorder. The following instruction is given: 'During the measurement, the patient should as far as possible always adopt the same position and remain calm!'

Operator training requirements

The CH-Druck 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

Requirements are selected via one of the file pulldown menus. Two of these menus, 'Help' and 'Quit', are very basic, whereas the remaining three menus offer a further five options each. As one set is used to configure the system for the user's site, it may be accessed only once. Therefore, use of the software consists mainly of referring to two sets of features: one to access the RAM card and the other to examine and process the ambulatory blood pressure measurements. Each option is briefly described at the bottom of the screen as it is highlighted. Although the software is almost self-explanatory, the manual contains a detailed 12-page explanation of every feature with many screen dumps to assist cross-referral between software and manual.

Problem list and solutions

Common operational problems are indicated by 14 error codes which are clearly listed in the manual with the appropriate solution.

Supplier names and addresses

The following are the names, addresses and telephone numbers of UK, Irish and other EC suppliers:

ERKA Richard Kallmeyer Nachf., Im Farchet, Postfach 1320, D-8170 Bad Tolz, Germany. Tel: +49 8041 80090; Fax: +49 8041 800939.

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

Mr Alan Morton, Morton Healthcare, 51 Hurst Park Road, GB-Twyford, Berkshire RG10 0EZ, UK. Tel: +44 734 342128.

Fannin Health Care Ltd, Fannin House, 14-18 Redmonds Hill, Dublin 2, Ireland. Tel: +353 1 782211; Fax: +353 1 782895.

CH-Druck is a registered trade name of Disetronic Systems AG; Pressure Scan is a registered trade name of ERKA Richard Kallmeyer Nachf.

Support for validation

The manufacturers, Disetronic Systems AG, supplied three CH-Druck systems for the study and contributed to the financial costs of the validation.

Discussion

In this study the CH-Druck/Pressure Scan ERKA 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 CH-Druck system fulfilled the AAMI criteria [8] and achieved a grade A rating for both SBP and DBP, with more than 80% of pressures being within 5 mmHg of the mercury sphygmomanometer and over 90% within 10 mmHg. These results are similar to those obtained in a smaller validation study of the CH-Druck in normotensive subjects [17]. 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 comparison but, as the CH-Druck 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, and this validation was performed after the CH-Druck had been subjected to 1 month of ambulatory use.

The period in use also permits some expression by the user concerning device acceptance. For example, experience with the CH-Druck during the present 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 seven 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 CH-Druck manual was generally found to be comprehensive and clearly written, if somewhat unattractively presented. The use of actual display options on the recorder is particularly helpful. However, there were some omissions: suppliers and service centres were not given, costings and bladder dimensions were not provided.

The BHS protocol requires a statement on the computer aspects of the system. The CH-Druck program is very user-friendly and all options are selected with ease. The choice of colour displays ensures that at least one combination is visually appealing. A single line on each option as it is highlighted provides a useful reminder while not cluttering the screen with unnecessary information. However, there are three areas where improvements could be made. First, the memory card interface must be connected to the computer for the software to run, and as serial interfaces are frequently used for a number of peripherals this can cause unnecessary inconvenience when access to the RAM card is not required. The second area where improvement might be made is in graphical presentation, which is done by using graphics characters. Although having the advantage of not being device-dependent, this form of presentation is rather crude, especially when compared with the graphics facilities now available on most modern computers and printers. It would be reasonable to expect revised software to exploit these facilities. Finally, all choices must be made using the keyboard, whereas the additional option of access with a mouse is desirable and in line with software developments.

The manufacturers have been informed of these criticisms and suggestions, and are presently modifying the CH-Druck to incorporate as many improvements as possible in future models.

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 and 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 Profilmomat [18] and the CH-Druck, have now been evaluated according to the BHS protocol. The

CH-Druck is the most accurate device yet evaluated, having achieved a grade A rating.

In conclusion, the CH-Druck/Pressure Scan ERKA ambulatory system achieved a grade A rating for both SBP and DBP according to the criteria of the BHS protocol, and it can therefore be recommended for ambulatory blood pressure measurement.

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