Accuracy of the Novacor DIASYS 200 determined by the British Hypertension Society Protocol

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Objective: To evaluate the Novacor DIASYS 200 Ambulatory Blood Pressure System according to the protocol of the British Hypertension Society (BHS).

Methods: Three DIASYS 200 recorders were evaluated according to the BHS protocol which consists of six phases: (1) observer training and assessment; (2) before-use interdevice variability assessment; (3) in-use (field) assessment; (4) after-use interdevice variability assessment; (5) device validation; and (6) report of evaluation.

Results: The three recorders passed the before-use interdevice variability assessment, after which they entered the in-use phase, and the three devices subsequently passed the after-use interdevice variability assessment. The DIASYS 200 did not fulfill the in-use criteria in that there were 3, rather than the permitted 2, failed days in 24 recording days. The main validation test was carried out on one device in 86 subjects with a wide range of pressures, the results being analysed according to a grading system from A to D. The DIASYS 200 achieved C rating for both systolic and diastolic pressures and also satisfied the criteria for accuracy of the Assocation for the Advancement of Medical Instrumentation (AAMI), with an average difference (\pm s.d.) of -1 ± 8 and 0 ± 8 mmHg for systolic and diastolic pressure, respectively. Subject acceptability was good. The manufacturer's manual lacked much of the detail required by the BHS protocol.

Conclusions: The DIASYS 200 ambulatory monitor achieved C rating for systolic and diastolic pressures according to the criteria of the BHS protocol and fulfilled the AAMI criteria of the protocol for both systolic and diastolic pressure. It just failed to satisfy the in-use criteria of the protocol. It can be recommended, therefore, for ambulatory measurment, especially in circumstances in which Korotkoff sound detection is preferred to oscillometry, with the proviso that the manufactures should improve the ambulatory performance of the device.

Journal of Hypertension 1991, 9 (suppl 5):S9-S15

Keywords: Novacor DIASYS 200, validation, 24-h ambulatory blood pressure measurement, British Hypertension Society Protocol, Association for the Advancement of Medical Instrumentation Standard.

Introduction

Ambulatory blood pressure measurement is rapidly gaining acceptance as a useful procedure in the clinical management of hypertension [1,2], in the assessment of antihypertensive drugs [3] and as a means of predicting outcome in hypertension [4]. The procedure also gives data on the physiology of blood pressure behaviour [5]. Ambulatory blood pressure provides an assessment of blood pressure behaviour over time in the patient's environment and is likely to result in reappraisal of the clini-

cal management of hypertension which is presently based upon conventional measurement techniques [6]. It is not surprising, therefore, that many devices are being marketed for the measurement of 24-h blood pressure. Most are technically complex and expensive. In an effort to ensure that such devices are manufactured to meet the requirements of clinical practice, the British Hypertension Society (BHS) recently published a comprehensive protocol for the evaluation of blood pressure measuring devices, with special reference to ambulatory systems [7]. This protocol follows the previously estab-

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The paper published in this supplement is the full supporting paper relating to the short report published in *J Hypertens* 1991, 9:569–570. Sponsorship: Support from the Charitable Infirmary Charitable Trust and the Royal College of Surgeons in Ireland is acknowledged with gratitude.

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Date of receipt: 30 July 1990; revised: 6 December 1990.

lished validation criteria of the Association for the Advancement of Medical Instrumentation (AAMI) [8], 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 is used in this study to evaluate the Novacor DIASYS 200 ambulatory blood pressure system.

Methods

Novacor DIASYS 200 System

The Novacor DIASYS 200 is an ambulatory monitor with a built-in keypad and liquid crystal display, thus allowing the monitor to be programmed independently of other computer units. The DIASYS 200 Monitor is a compact unit (16 cm in length × 7.9 cm in width \times 3.8 cm in height), weighing 520 g with batteries, designed to take up to 250 blood pressure measurements for a blood pressure range of 30 to 290 mmHg and heart rate measurements (range not provided) for up to 72 h. These measurements are recorded and stored on read only memory in the monitor for transmission to a printer, IBM personal computer or Apple computer for analysis, graphic presentation, storage and/or printing. The monitor is carried in a pouch which may be worn on a waistbelt or on a shoulder strap. Blood pressure is measured by detection of Korotkoff sounds, with a microphone in the cuff which may be inflated at predetermined intervals which may be as short as 1 min. Electrocardiographic gating is optional and is recommended when greater reliability of measurements is required or where interference is anticipated. The monitor may be programmed according to the duration of the monitoring period, measurement display, the time format, the measurement interval, the presence or absence of the audible monitor tone during specified periods of the recording period (e.g. sleep) and whether or not to display readings on the digital display for reading by the subject.

Evaluation programme

The evaluation programme [7] consisted of six phases: (1) observer training and assessment; (2) before-use interdevice variability assessment; (3) inuse (field) assessment; (4) after-use interdevice variability assessment; (5) device validation; and (6) report of evaluation.

Observer training and assessment

Three nurses were trained and assessed according to the criteria of the BHS protocol [7] using the British Hypertension Society video film 'Blood Pressure Measurement' [9]. After training, the observers were tested for accuracy against each other and the expert observer on five subjects, in each of whom

10 blood pressure measurements were made. Criteria for this assessment are that 90% of systolic and diastolic differences between the trainees and expert must not differ by more than 5 mmHg and 98% by not more than 10 mmHg, and that 85% of systolic and diastolic 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.

Calibration accuracy was checked according to the manufacturer's instructions before any testing began by connecting the DIASYS 200 to a mercury column and checking that pressures throughout the pressure range were within ± 4 mmHg.

Before-use interdevice variability assessment

This test differed from that recommended in the published BHS protocol [7] which had not been finalized at the time of the study. It was originally planned that the interdevice variability test used in this study would be incorporated in the protocol, but experience in performing the test demonstrated its impracticality for general use and the final protocol included a simpler calibration test. Three DIA-SYS 200 monitors were assessed in six subjects, with blood pressure in the range 78-164/48-124 mmHg, by one observer who measured blood pressure simultaneously in the same arm with the test device and a mercury sphygmomanometer connected by a Y connector. Six pairs of blood pressure measurements were made in each of the six subjects in a randomized sequence to give 12 pairs of measurements per device and 36 pairs overall. During this phase, it became apparent that simultaneous measurement between a mercury sphygmomanometer and the DIASYS 200 was not an appropriate test because when the monitor sensed that it was close to the blood pressure, cuff deflation slowed, thereby alerting an observer using a simultaneous mercury sphygmomanometer that a pressure reading was about to be recorded, with the attendant potential for bias. After detecting systolic blood pressure a further period of sharp deflation preceded slow deflation before diastolic pressure was detected. Furthermore, after recording diastolic pressure the DIASYS 200 deflated rapidly without affording an auscultatory observer the opportunity of accurately recording the diastolic pressure. For this reason, sequential same-arm testing was used in all further evaluation phases [7,10].

In-use assessment

The three DIASYS 200 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

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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 that, on 4 of the remaining 6 recording days, at least 70% of the readings should be valid, thus allowing for 2 failed recording days.

After-use interdevice variability assessment

At the end of the month of ambulatory assessment, the three monitors were retested for interdevice variability to determine whether there had been any change in interdevice agreement during ambulatory use. The test was similar to the before-use test except that sequential same-arm comparisons were used. The range of blood pressure in the 10 subjects was 92–180/62–102 mmHg.

Device validation

As there was no alteration in interdevice variability after the month of use, one device was randomly selected for the main validation test. Eighty-six subjects aged from 15 to 80 years were selected, with blood pressures in the range recommended by the BHS protocol [7]. 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 practicable with the DIASYS 200 for the reasons explained above and sequential samearm measurements with the DIASYS 200 and a standard mercury sphygmomanometer were performed, therefore, as recommended in the protocol [7]. 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 0, otherwise the nearer of the two readings is subtracted to give the difference [10]. The procedure was performed in 43 subjects by observer one and in the other 43 subjects by observer two. A total of 258 (3 × 86) sets of measurements were available for analysis.

Table 1. In-use assessment.

	24 h						Day		Night		
				Aborted	Second attempt	Valid second attempt	Day: night ratio				
	Inflations	Valid	Rejected					Inflations	Valid	Inflations	Valid
Goal:											
n .	1800	1800	0	0	0	_	3:1	1350	1350	450	450
%	100	100	0	0	0	100	_	100	100	100	100
DIASYS 200:											
n	2168	1671	1	496	310	108	2.8:1	1592	1327	576	344
%	120	77	0	23	14	35	_	118	98	128	76

Figures are for 24 recording days in 24 subjects.

Results

Evaluation programme

Observer training and assessment

All three trainee observers passed the accuracy criteria.

Before-use and after-use interdevice variability assessment Analysis of variance did not demonstrate any change in interdevice variability between the three devices before and after the in-use phase.

In-use assessment

Eighty-five per cent of 24-h measurements recorded with the three devices were valid on 20 of the 24 recording days, with 79% being valid on 1 day and 15%, 60% and 64% of possible measurements being obtained on 3 days, which were classified as failed days in accordance with the protocol [7]. The DIA-SYS 200, therefore, failed the protocol requirements which recommends withdrawing devices which fail to fulfill the preliminary tests, but it was decided to proceed with the validation as the DIASYS 200 had provided an average of 69.6 measurements on each of the 24 recording days. Excess measurements on some days were due mostly to the device being operative for a little longer than 24 h and to the occasional patient-activated additional measurement. The average ratio of day: night measurement was 2.8:1. An analysis of performance during the in-use phase is shown in Table 1.

Patient/subject acceptability

Each subject was asked to comment on the performance of the device and these comments are summarized in Table 2.

Device validation

The percentage of measurements differing from the mercury standard by 5, 10 and 15 mmHg or less are shown in Table 3 and plotted in Figs 1 and 2; the DIASYS 200 was graded as A, B, C or D according to the criteria in Table 3. To obtain a particular grade, all three cumulative percentages had to ex-

Table 2. Summary of comments from 24 subjects.

Specific problems:	Seven commented on the cuff being uncomfortable
	Four commented on the tubing being rough and irritating
	Three commented on electrode sensitivity
	Four commented on loose connectors
General impression:	Light/easy to use
Comfort/discomfort:	Ten commented on cuff and tubing discomfort
Interference of sleep:	Six commented on disturbed sleep
Noise:	Three commented on noise disturbance
Anxiety:	Two mentioned anxiety associated with use
Difficulty in use:	No comments
Clarity of instructions:	Two commented favourably
Suggestions:	One subject found measurements every 15 min too frequent

ceed the tabulated values. The DIASYS 200 achieved a C grading for both systolic and diastolic pressure according to the BHS criteria [7] and was within the AAMI criteria of a mean difference of 5 mmHg and standard deviation of 8 mmHg [8] (mean differences, -1 ± 8 mmHg systolic and 0 ± 8 mmHg diastolic pressure).

Table 3. British Hypertension Society grading criteria.

		Difference between standard and test device (mmHg)			
	Grade	≤5	≤10	≤15	
Grading criteria:	A	80	90	95	
Cumulative %	В	65	85	95	
of readings	С	45	75	90	
_	D	Worse than C			
DIASYS 200:					
SBP	С	63	85	94	
DBP	С	64	86	96	

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

Calibration accuracy of the DIASYS 200 after undergoing the above programme of testing remained within $\pm 4\,\mathrm{mmHg}$.

Graphic presentation

The data is displayed as plots of the mean pressure for both observers with a mercury sphygmomanometer versus the difference between the DIA-SYS 200 and the nearer of these observer measurements in 86 subjects (n = 258) for systolic and diastolic pressure (Figs 1 and 2). Reference lines indicate -15 to +15 mmHg in 5 mmHg steps.

Basic information

In accordance with Appendix B of the BHS Protocol [7], the following aspects of the Novacor DIASYS 200 system were assessed:

Model identification

The model was clearly identified as the DIASYS 200.

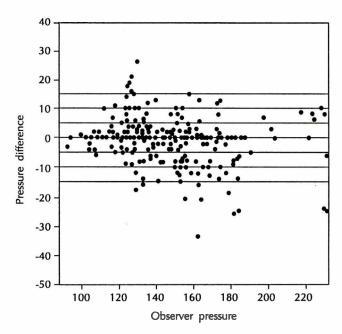


Fig. 1. Plot of the mean pressure for both observers with a mercury sphygmomanometer versus the difference between the DIASYS 200 and the nearer of observer measurements in 86 subjects (n = 258) for systolic pressure. References lines: – 15 to +15 mmHg in 5 mmHg steps.

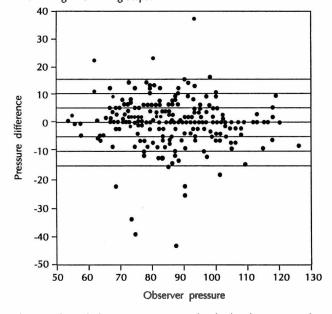


Fig. 2. Plot of the mean pressure for both observers with a mercury sphygmomanometer versus the difference between the DIASYS 200 and the nearer of observer measurements in 86 subjects (n = 258) for diastolic pressure. Reference lines: -15 to +15 in 5 mmHg steps.

Costs

The cost of the recorder, the decoder, computer analysis facilities, components and the consumables needed for device operation have been provided by Novacor (prices are in £ Sterling, exclusive of VAT, in 1991):

DIASYS 200 Monitor* 3097 Software: standard version 500

Software: Plus version	750			
Panasonic printer	310			
Set of recharging batteries including multipurpose				
recharger set of six rechargeable nickel cadmium				
batteries	77			
Air hose with one integrated electroca	ardiogram cabl			
Large size	270			
Medium size	2472			
Paediatric	228			
Leather case	63			
Leather belt	14			
Leather shoulder strap	14			
Aluminium case	136			
Cuff cover	31			
Cable link to RS232 (9 or 25 points)	124			

*The price of the monitor includes the necessary components for operation such as cable, case, cuff, etc.

Compliance with standard(s)

Details of compliance with international standards are not provided in the manual.

Validation studies and results

There is only one published abstract on the DIASYS 200 [11].

Instructions for use

The instruction manual provided with the DIASYS 200 is in French and English. The step by step instructions are reasonably clear and easy to follow. The instructions for using the software are adequate.

Patient instruction card

A diary/instruction card for distribution to patients using the ambulatory recorder, giving simple operational instructions together with instructions as to what precautions to take in the event of the device malfunctioning, was not provided as recommended in the BHS protocol [7].

Precautions for use

The BHS protocol requires that the operator must 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. Safety factors are not mentioned in the manual.

Power supply

Six alkaline batteries (1.5 V) or six rechargeable 1.25 V batteries may be used, but the manual does not indicate how many inflations/measurements each set of batteries will provide. Error messages alert the operator to inadequate power and there are memory safeguard features in the event of battery failure.

Instructions for care and maintenance

The manual gives the operator brief instructions on the day-to-day care of the equipment. No instructions are provided with regard to maintenance and the indications for recalibration. Product warranty information is provided 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. The manual does not list service and maintenance facilities.

Dimensions

The dimensions and weights of all components and the means of attachment etc. are not provided in the manual but are listed in the information sheets provided by the manufacturer.

List of components

The various components of the system were provided on request, with prices by the manufacturers, but are not listed in the manual as recommended in the BHS protocol. The dimensions of the bladders available were not provided. One adult cuff was provided with each monitor and when extra cuffs were requested, these were supplied promptly, but the microphones could not be fitted into the pouches in the new cuffs. This was due to a defect in a small number of cuffs and has been rectified by the manufacturers. The cuffs tended to shrink with washing.

Method(s) of blood pressure measurement

The DIASYS 200 measures blood pressure by Korotkoff sound detection with electrocardiographic gating as an optional facility 'for increased accuracy and improved rejection of artefacts'. Details as to the circumstances in which this facility might be useful are not provided. If electrocardiographic gating is selected but cannot be activated for a particular measurement, the recorder will measure blood pressure but indicate that electrocardiographic gating was not operational.

Artefact editing

The editing facility of the DIASYS 200 is preset and cannot be altered by the operator. Messages are signalled for the following: systolic pressure > 290 mmHg; systolic pressure < 50 mmHg; diastolic pressure < 30 mmHg; diastolic pressure 30 mmHg < 60 mmHg not confirmed after reinflation.

Facility for checking device accuracy and recalibration No instructions for checking device accuracy are provided and no recommendations are made for calibration or recalibration.

Factors affecting accuracy

There are no recommendations as to circumstances that might affect performance or accuracy of the device.

Operator training requirements

The DIASYS 200 is reasonably easy to operate and the instruction manual takes the operator through the operative procedure step by step.

Computer analysis

A printer can be supplied with the DIASYS 200. However, programming the DIASYS 200 to function in a stand-alone mode with its own printer rather than with a compatible computer is a rather laborious procedure. A full printed report with tables, graphs and statistical analysis may be requested, but all data is provided and selection of discrete parts of the report is not possible and, because printing of the graphics is very slow, obtaining a report is protracted. The lack of detailed instructions on the use of the software puts the user at a disadvantage in that problems have to be overcome by trial and error. These criticisms aside, the DIASYS 200 has excellent software which provides great flexibility for the user and particularly useful graphics which are best appreciated on a colour monitor.

Problem list and solutions

A list of common operational problems with solutions is provided.

Supplier names and addresses

The following are the names, addresses and telephone numbers of EC and UK suppliers: Mr Gilles Ascher, President, Novacor, 4 passage Saint-Antoine, 92508 Rueil-Malmaison Cedo, France. Tel: 33-1-47080666; Fax: 33-1-47324576.

Mr W. Dempsey, Cardiac Services (Ireland) Ltd, 128 Slaney Rd, Dublin Industrial Estate, Glasnevin, Dublin 11. Tel: 353-1-307499; Fax: 353-1-307622.

Discussion

In this study, the Novacor DIASYS 200 ambulatory blood pressure measuring system was evaluated according to the BHS protocol [7]. This protocol contains many of the recommendations of the earlier AAMI standard [8] 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, 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 allows a mean difference of 5 mmHg with a standard deviation 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 DIASYS 200 system fulfilled the AAMI criteria [8] and achieved a Grade C rating for both systolic and diastolic pressures, with just 60% of systolic and diastolic pressures being within 5 mmHg of the mercury sphygmomanometer and 85% within 10 mmHg.

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 of use and this validation was performed after the DIASYS 200 had been subjected to a month of ambulatory use.

The period of ambulatory use also permits some expression by the user as to the device acceptance. For example, as a result of the comments made in this study, we can ask the manufacturers to improve the quality of cloth in the cuff to minimize discomfort during inflation and to provide more flexible and less irritating tubing between the cuff and monitor. Furthermore, as operators we can recommend to the manufacturers that an extra cuff should be provided with each bladder to facilitate washing of the cuff and that a range of bladder sizes should be supplied with the system rather than having to be purchased separately.

The data from the in-use assessment was helpful in arriving at an estimate of the unnecessary disturbance to the subject by repeated inflations. For example, on each recording day, an average of 15 attempted measurements were rejected or aborted by the DIASYS 200 and a repeat measurement was attempted in 13, resulting in five valid readings. The perfect device should provide a valid measurement for each deflation. The DIASYS 200 had to perform approximately 15 excess inflations to achieve the required 75 readings over the 24-h period. There were 3 days on which the DIASYS 200 failed to achieve the minimum 70% of measurements required by the protocol. The device was not withdrawn from the validation as is recommended by the protocol because it had performed well otherwise. However, this number of failed recording days is clearly an aspect of performance that should be improved by the manufacturers. Manufacturers should attempt to reduce the number of repeat inflations so as to keep disturbance to the patient at a minimum and to reduce interference with daily activities.

A critical analysis of the manual accompanying ambulatory systems has not been performed previously, but is one of the BHS stipulations. The DIASYS 200 manual was generally found to be comprehensive, clearly written and well presented. However, there were some omissions and errors. The

addresses of suppliers and service centres are not given, costings are not provided and the bladder sizes available are not listed in the manual.

The DIASYS 200 has excellent software, which provides great flexibility for the user, and particularly useful graphics which are best appreciated on a colour monitor. This facility could be enhanced by the provision of more comprehensive software instructions, especially for the user who may not be a computer expert.

Although the BHS protocol provides an assessment of performance during ambulatory use, it needs to be emphasised 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, Valsalva manoeuvre, etc. Moreover, the protocol does not test the device in the variety of positions in which ambulatory measurement may be made.

In conclusion, the DIASYS 200 ambulatory monitor achieved C rating for both systolic and diastolic pressure according to the criteria of the BHS protocol but did not satisfy the in-use criteria of the protocol. If fulfilled the accuracy criteria of the AAMI Standard. It can be recommended, therefore, for ambulatory measurement, especially in circumstances in which Korotkoff sound detection is preferred to oscillometry, with the proviso that the manufacturers should improve the ambulatory performance of the device.

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