

Accuracy of the Del Mar Avionics Pressurometer IV determined by the British Hypertension Society Protocol

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Objective: To evaluate the Del Mar Avionics Pressurometer IV Ambulatory Blood Pressure System according to the protocol of the British Hypertension Society (BHS).

Methods: Three Pressurometer IV 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 86% 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 assessment. The main validation test was carried out in 86 subjects with a wide range of pressures, the results being analysed according to a grading system from A to D. The Pressurometer IV achieved C rating for systolic pressure and D rating for diastolic pressure. The first Pressurometer used in the main validation test failed to function after testing in 32 subjects and had to be replaced. The Pressurometer IV failed to satisfy the criteria for accuracy of the Association for the Advancement of Medical Instrumentation (AAMI), with an average difference (\pm s.d.) of -2 ± 11 and -3 ± 11 mmHg for systolic and diastolic pressure, respectively. Subject acceptability was poor, primarily because the monitor was cumbersome to wear and excessively noisy. The manufacturer's manual was clear and reasonably comprehensive.

Conclusions: The Pressurometer IV ambulatory monitor achieved C rating for systolic pressure and a D rating for diastolic pressure according to the criteria of the BHS protocol and failed to satisfy the AAMI criteria for both systolic and diastolic pressure. It also performed badly during the validation test and on the basis of these results cannot be recommended for ambulatory measurement in clinical practice.

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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 clinical

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 incorporates many of the previ-

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ously established validation criteria of the Association for the Advancement of Medical Instrumentation (AAMI) [8], but includes additional aspects of validation such as evaluation after 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 Del Mar Avionics Pressurometer IV ambulatory blood pressure system.

Methods

Pressurometer IV system

The Model 1990A/1991 Pressurometer System consists of the Pressurometer IV, a battery operated ambulatory blood pressure monitoring device, and the Pressurometer Programmer, a microcomputer used to program the Pressurometer IV. An expanded version of the system can be interfaced with the data processing capabilities of IBM PC, XT, AT or IBM-compatible computers. The Pressurometer IV Monitor has the following dimensions: 19 (length) × 10 (width) × 3.5 (height) cm and weighs 794 g with batteries, designed to take up to 307 blood pressure measurements (range of pressure not provided) and heart rate measurements (range not provided) for up to 48 h at the rate of one measurement every 10 min. The frequency of recording may be adjusted from 5 to 60 min. The measurements may be recorded and stored in the monitor for transmission to the Model 1991 Pressurometer Programmer which can be interfaced with a dot matrix printer or a software programme may be obtained to interface the Monitor with a computer for analysis, graphic presentation, storage and/or printing. Data may be transferred by telephone via a Pressurometer Programmer at the sending and receiving locations. In this study, data from the Pressurometer IV was interfaced directly with an IBM-compatible computer and the Programmer was not used. The monitor is carried in a pouch on a waist belt. Blood pressure is measured by detection of Korotkoff sounds, with a microphone being placed over the brachial artery with an adhesive pad before the cuff is wrapped around the arm over the microphone. Three electrocardiographic electrodes are placed on the chest to provide R-wave electrocardiographic gating. Abrasive pads are provided for preparing the skin before applying the electrodes. The Pressurometer IV has a sensitivity testing facility whereby high, low or normal gain settings can be selected for individual patients. Performance of a sensitivity test on each subject is time-consuming and as the manual states that 'proper sensitivity will be achieved with the gain set to normal', this procedure was followed throughout the validation. The monitor may be programmed

according to the duration of the monitoring period and the measurement interval. Deflation of the cuffs is in 3 mmHg steps.

Evaluation programme

The evaluation programme [7] consisted 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.

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 Pressurometer IV 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 Pressurometer IV monitors were assessed in six subjects, with blood pressure in the range 82–202/42–120 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 Pressurometer IV was not an appropriate test because, after recording diastolic pressure, the Pressurometer IV system deflated rapidly without af-

fording an auscultatory observer the opportunity of accurately recording the diastolic pressure. Therefore, sequential same-arm testing was used in all further evaluation phases [7,10].

In-use assessment

The three Pressurometer IV 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 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 88–180/40–120 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 Pressurometer IV because of the rapid deflation rate and sequential same-arm measurements with the Pressurometer IV and a standard mercury sphygmomanometer were, therefore, performed as recommended in the protocol [7]. The test measurement is bracketed by two readings with the standard mercury sphyg-

momanometers, 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. The Pressurometer IV failed to function after testing in 32 subjects and had to be replaced by one of the other devices for the remainder of the validation test. A total of 258 (3 × 86) sets of measurements were available for analysis.

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 the 24-h measurements recorded with the three devices were valid on 22 of the 24 recording days, with more than 70% of measurements being present on the remaining 2 days, thus fulfilling the protocol requirement. Excess measurements on some days were mostly due 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 measurements was 3.2 : 1. An analysis of performance for each 24 h period 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.

Table 1. In-use assessment.

	24 h							Day		Night	
	Inflations	Valid	Rejected	Aborted	Second	Valid second	Day : night	Inflations	Valid	Inflations	Valid
					attempt	attempt	ratio				
Goal:											
n	1800	1800	0	0	0	–	3 : 1	1350	1350	450	450
%	100	100	0	0	0	100	–	100	100	100	100
Pressurometer IV:											
n	2111	1814	66	231	190	103	3.2 : 1	1608	1409	503	405
%	117	86	3	11	9	54	–	119	88	112	81

Figures are for 24 recording days in 24 subjects.

Table 2. Summary of comments from 24 subjects.

Specific problems:	Nine commented on the cuff being uncomfortable Five commented on the tubing being rough and irritating Fifteen found it excessively cumbersome Three commented on lack of warning bleep Two accidentally activated device
General impression:	Excessively cumbersome
Comfort/discomfort:	Fourteen commented on cuff and tubing discomfort and another three commented on general discomfort
Interference of sleep:	Eleven commented on disturbed sleep, mostly due to noise
Noise:	Thirteen commented on noise disturbance
Anxiety:	Two mentioned anxiety associated with use
Difficulty in use:	No comments
Clarity of instructions:	Four commented favourably
Suggestions:	Three subjects found measurements every 15 min too frequent

Table 3. British Hypertension Society grading criteria.

Grade	Difference between standard and test device (mmHg)			
	≤ 5	≤ 10	≤ 15	
Grading criteria:				
Cumulative % of readings	A	80	90	95
	B	65	85	95
	C	45	75	90
	D		worse than C	
Pressurometer IV:				
SBP	C	62	82	90
DBP	D	59	77	85

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

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 Pressurometer IV system 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 exceed the tabulated values. The Pressurometer IV achieved a C grading for systolic and D grading for diastolic pressure according to the BHS criteria [7]. It failed to satisfy the AAMI criteria that the test device should not differ by more than 5 mmHg from the mercury measurement, with a standard deviation of 8 mmHg [8] (mean differences, -2 ± 11 mmHg systolic and -3 ± 11 mmHg diastolic pressure).

Calibration accuracy of the Pressurometer IV after undergoing the above programme of testing remained within ± 4 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

Pressurometer IV 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.

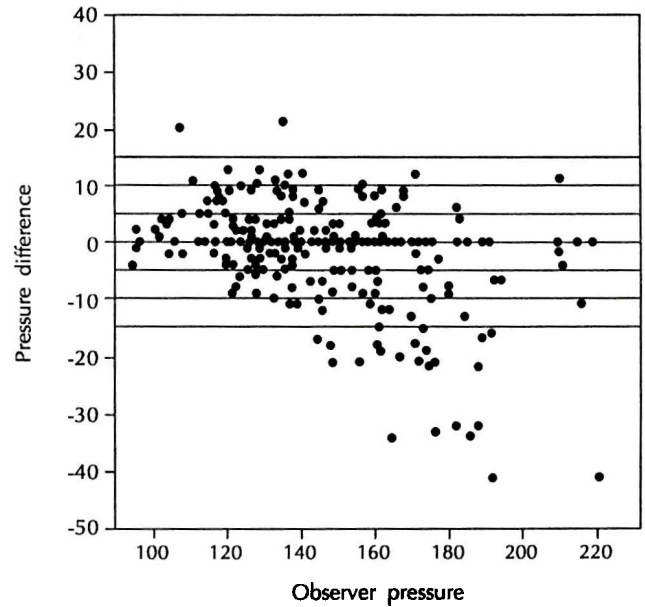


Fig. 1. Plot of the mean pressure for both observers with a mercury sphygmomanometer versus the difference between the Pressurometer IV and the nearer of observer measurements in 86 subjects (n = 258) for systolic pressure. Reference lines: - 15 to +15 mmHg in 5 mmHg steps.

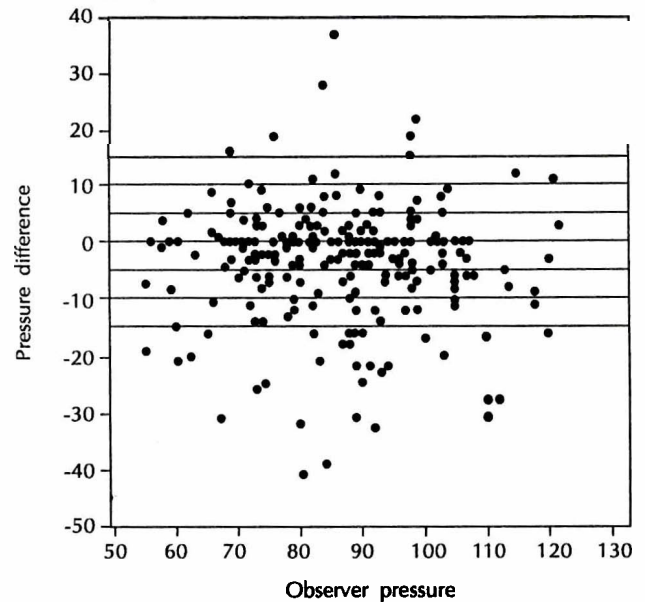


Fig. 2. Plot of the mean pressure for both observers with a mercury sphygmomanometer versus the difference between the Pressurometer IV and the nearer of observer measurements in 86 subjects (n = 258) for diastolic pressure. Reference lines: - 15 to +15 mmHg in 5 mmHg steps.

Basic information

In accordance with Appendix B of the BHS protocol [7], the following aspects of the Pressurometer system were assessed:

Model identification

The model was clearly identified as Model 1990A/1991 Pressurometer IV.

Costs

The cost of the recorder, the decoder, computer analysis facilities, components and the consumables needed for device operation have been provided by Del Mar Avionics (Prices are in £ sterling, exclusive of VAT, in 1991):

Pressurometer IV Monitor	2828
IBM-compatible Software	1532

(Cost of 33 accessories listed for Pressurometer IV and 12 accessories listed for Pressurometer Programmer not provided.)

Compliance with standard(s)

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

Validation studies and results

Details of published validation studies [12–15] are not provided in the manual.

Instructions for use

The instruction manual provided with the Pressurometer IV is reasonably clear and easy to follow but the layout and design could be improved. The instructions for using the software applied to a different version than that supplied.

Patient instruction card

A diary/instruction card is provided for distribution to patients using the ambulatory recorder, which gives simple operational instructions but does not give instructions as to what precautions should be taken in the event of the device malfunctioning.

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

Two 9 V batteries will provide up to 307 measurements. Error codes alert the operator to inadequate power.

Instructions for care and maintenance

The manual gives the operator brief instructions on the day-to-day care of the equipment. Cleaning instructions are provided but there are no instructions for maintenance and recalibration. It is recommended that the cuff should be dry cleaned, a recommendation that would prove impracticable in practice; we washed the cuff frequently during the study without any apparent ill-effects. Product warranty information is not 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 facilities outside the United States.

Dimensions

The dimensions and weights of the Pressurometer IV and the Pressurometer Programmer are provided in the manual.

List of components

The various components of the system are listed in the manual but not priced as recommended in the protocol. The dimensions of the bladders available were not provided.

Method(s) of blood pressure measurement

The Pressurometer IV measures blood pressure by Korotkoff sound detection with R-wave gating by electrocardiograph. If the Pressurometer fails to detect R-waves, this is indicated. Similarly, failure to detect Korotkoff sounds is indicated and gain controls may be used to alter the sensitivity of the transducer.

Artefact editing

A variety of editing options can be selected by the operator. Error (status) codes are signalled for systolic pressure < 40 mmHg.

Facility for checking device accuracy and recalibration

A 'Correlation' Test is recommended before each ambulatory measurement. This is performed by measuring systolic pressure simultaneously in the same arm with a mercury sphygmomanometer and the Pressurometer IV. The measurements should be within 5 mmHg.

Factors affecting accuracy

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

Operator training requirements

The Pressurometer IV is reasonably easy to operate but the instruction manual could be improved in terms of layout and design.

Computer analysis

The manufacturers requested by questionnaire details of the computer facilities in our department and then supplied the program appropriate for our IBM-compatible system without supplying the relevant instructions for its operation. However, the software was easy to use because of window management facilities and it was not difficult to familiarize oneself with the program which was efficient and fast to operate. There was considerable flexibility in selecting sections of the report for display or printing. How-

ever, some warning messages were difficult to obey and, in one instance, had to be ignored because of the absence of the correct instruction manual for clarification.

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 US and EC suppliers: Mr Jack Hammond, Senior Vice President, Del Mar Avionics, 1601 Alton Avenue, Irvine, California 92714-4870, USA. Tel: 1-714-2503200; Fax: 1-714-2610529.

Mr Patrick Mestadg, Del Mar Avionics, Vilvoordelaan 5, 1930 Zaventem, Belgium. Tel: 32-2-7208055; Fax: 32-2-7211983.

Discussion

In this study, the Del Mar Avionics Pressurometer IV ambulatory blood pressure 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 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 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 Pressurometer IV failed to satisfy the AAMI criteria for both systolic and diastolic pressure [8] and achieved a Grade C rating for systolic and a Grade D rating for diastolic pressures.

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 Pressurometer IV had been subjected to a month of ambulatory use. The first Pressurometer used in the main validation test failed to function after testing in 32 subjects and had to be replaced. This must be seen as a serious occurrence which normally would result in the validation procedure being abandoned. However, so as to obtain as much information as possible

from the evaluation, the non-functioning recorder was replaced. It must be emphasized, therefore, that the Pressurometer IV did not complete the BHS evaluation as laid down in the protocol.

The period of ambulatory use also permits some expression by the user as to device acceptability. The patients in this study found the Pressurometer IV cumbersome and excessively noisy. 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 13 attempted measurements were rejected or aborted by the Pressurometer IV and a repeat measurement was attempted in eight resulting in only four valid readings. The perfect device should provide a valid measurement for each inflation. The Pressurometer IV had to perform approximately 13 excess inflations in order to achieve the required 75 readings over the 24-h period. 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 is one of the BHS stipulations. The Pressurometer manual was reasonably comprehensive, but the design and layout could be improved to facilitate the user and there were some omissions. The addresses of service centres outside the United States are not given, costings are not provided and the bladder sizes available are not listed in the manual.

Similarly, the BHS protocol requires a statement on the computer aspects of the system. The Pressurometer may be interfaced with IBM personal computers. A number of programs are available but as only one is referred to in the instruction manual, operation of the other software options is difficult.

Comparison of our results with other studies is difficult because of the different methodologies used [15,16]. In one other study using the AAMI criteria [13], the Pressurometer IV was within the limit of the standard for systolic pressure (1.1 ± 4.1 mmHg, mean \pm s.d.) but outside the limit for diastolic pressure (4.1 ± 16 mmHg).

Although this validation 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 hand-grip, 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 Pressurometer IV ambulatory monitor achieved C rating for systolic and D rating

for diastolic pressure according to the criteria of the BHS protocol and failed to satisfy the AAMI criteria for both systolic and diastolic pressures. Moreover, it failed to satisfy the in-use criteria of the protocol. It cannot, therefore, be recommended for ambulatory measurement in clinical practice.

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