

Accuracy of the SpaceLabs 90207 determined by the British Hypertension Society Protocol

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Objective: To evaluate the SpaceLabs 90207 Ambulatory Blood Pressure System according to the protocol of the British Hypertension Society (BHS).

Methods: Three SpaceLabs 90207 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 84% 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 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 SpaceLabs 90207 achieved B rating for both systolic and diastolic pressures and also satisfied the criteria for accuracy of the Association for the Advancement of Medical Instrumentation (AAMI), with an average difference (\pm s.d.) of -1 ± 7 and -3 ± 6 mmHg for systolic and diastolic pressure, respectively. Subject acceptability was good. The manufacturer's manual was satisfactory overall, but contained a number of errors and omissions.

Conclusions: The SpaceLabs 90207 ambulatory monitor achieved B rating for systolic and diastolic pressures according to the criteria of the BHS protocol and fulfilled the AAMI criteria for both systolic and diastolic pressure. It can be recommended, therefore, for ambulatory measurement.

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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 follows the previously established validation criteria of the Association for the Advancement of Medical Instrumentation (AAMI) [8],

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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 SpaceLabs 90207 ambulatory blood pressure system.

Methods

SpaceLabs system

The SpaceLabs system consists of two main parts: the Model 90209 Data Interface Unit (DIU) and the model 90207 Ambulatory Blood Pressure (ABP) Monitor. The 90207 ABP Monitor is a small ($2.82 \times 8.56 \times 11.4$ cm) unit weighing 255 g without batteries and 440 g with batteries, pouch and strap, and is designed to take up to 240 blood pressure measurements (range, systolic 70–285; diastolic 40–200; mean 60–240 mmHg) and heart rate measurements (range, 40–180 beats/min) for a 24- or 48-h period. These measurements are recorded and stored in the monitor for transmission to the DIU for analysis and printing. The monitor is carried in a pouch which may be worn on a waist-belt or on a shoulder strap. Blood pressure and heart rate measurements are taken oscillometrically, using a cuff containing an occluding bladder on the subject's arm which is inflated in 15 s in daytime mode and 20 s in night-time mode. The DIU programmes the ABP monitor, specifying the duration of the monitoring period, subject information to be incorporated in the analysis, 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), event code display and whether or not to display data on the digital display for reading by the subject. The DIU can be used independently or as an interface between an IBM compatible computer and the monitor.

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 SpaceLabs 90207 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 Spacelabs 90207 monitors were assessed in six subjects, with blood pressure in the range 80–186/46–118 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 SpaceLabs 90207 was not an appropriate test because rapid deflation by the SpaceLabs 90207 in 8 mmHg bleed steps made accurate auscultation impossible. Therefore, sequential same-arm testing was used in all further evaluation phases [7,10].

In-use assessment

The three SpaceLabs 90207 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 a 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 84–186/38–122 mmHg.

Table 1. In-use assessment.

	24 h							Day		Night	
	Inflations	Valid	Rejected	Aborted	Second attempt	Valid second attempt	Day:night ratio	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
SpaceLabs 90207											
n	2192	1839	14	339	264	195	3.3:1	1684	1404	508	435
%	122	84	1	15	12	74	–	125	83	113	86

Figures are for 24 recording days in 24 subjects.

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 SpaceLabs 90207 because of the rapid deflation rate in 8 mmHg bleed steps and sequential same-arm measurements with the SpaceLabs 90207 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 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.

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-four per cent of 24-h measurements recorded with the three devices were valid, thus fulfilling the protocol requirement. The SpaceLabs 90207 provided an average of 91 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 and to the occasional patient-activated additional measurement. The average ratio of day:night measurements was 3.3:1. 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.

Table 2. Summary of comments from 24 subjects.

Specific problems:	Comments on cuff being uncomfortable, cuff needing tape and tubing being too long
General impression:	Light/easy to use/not intrusive
Comfort/discomfort:	No comments apart from cuff discomfort
Interference of sleep:	Two commented on disturbed sleep
Noise:	Three commented on slight noise disturbance
Anxiety:	Two mentioned anxiety associated with use
Difficulty in use:	No comments
Clarity of instructions:	Six commented favourably
Suggestions:	Four subjects found measurements every 15 min too frequent

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 SpaceLabs 90207 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 SpaceLabs 90207 achieved a B grading for both systolic and diastolic pressure according to the BHS criteria [7] and was comfortably within the AAMI criteria of a mean difference of 5 mmHg and standard deviation of 8 mmHg [8] (mean differences, -1.3 ± 6.7 mmHg systolic and -2.6 ± 5.7 mmHg diastolic pressure).

Calibration accuracy of the SpaceLabs 90207 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 sphyg-

Table 3. British Hypertension Society grading criteria.

	Grade	Difference between standard and test device (mmHg)		
		≤ 5	≤ 10	≤ 15
Grading criteria:	A	80	90	95
Cumulative % of readings	B	65	85	95
	C	45	75	90
	D		worse than C	
SpaceLabs 90207:				
SBP	B	69	89	96
DBP	B	69	91	98

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

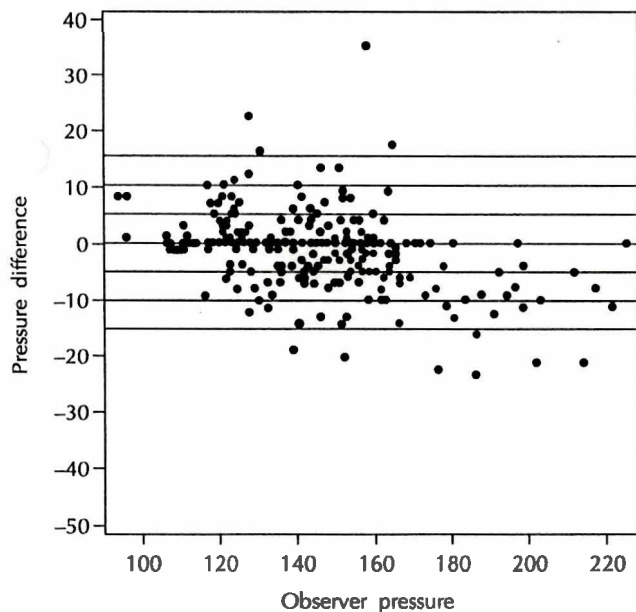


Fig. 1. Plot of the mean pressure for both observers with a mercury sphygmomanometer versus the difference between the SpaceLabs 90207 and the nearer of observer measurements in 86 subjects ($n=258$) for systolic pressure. Reference lines: -15 to $+15$ mmHg in 5 mmHg steps.

momanometer versus the difference between the SpaceLabs 90207 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 SpaceLabs system were assessed:

Model identification

The model was clearly identified as the 90207.

Costs

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

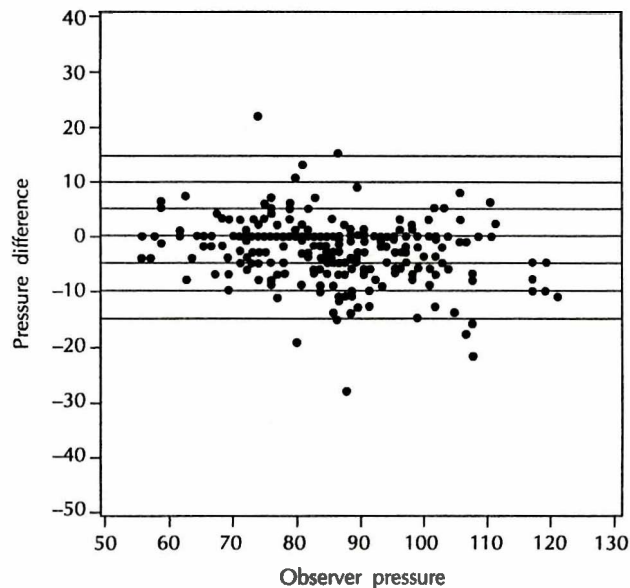


Fig. 2. Plot of the mean pressure for both observers with a mercury sphygmomanometer versus the difference between the SpaceLabs 90207 and the nearer of observer measurements in 86 subjects ($n=258$) for diastolic pressure. Reference lines: -15 to $+15$ mmHg in 5 mmHg steps.

90207 ABP Monitor	3360
90209 Local Report Generator (LRG)	1159
90206 Printer for LRG	+1
90209 PC Interface including cables and software	1504
Cuff	44
Cost for purchaser with compatible computer and printer (3310 + 1504)	4814

Compliance with standard(s)

The system is designed to meet AAMI, UL and IEC 601-1 specifications with regard to leakage current. It is stated in the manual that the monitor was within the AAMI standard for accuracy but there was no independent publication attesting to this at the time of publication of the manual.

Validation studies and results

There is only one published abstract on the SpaceLabs 90207 [11]; a number of validation studies have been carried out on its predecessor, the SpaceLabs 90202 [12-16].

Instructions for use

The instruction manual provided with the SpaceLabs is considered adequate although there is room for improvement and there are some serious inaccuracies, e.g. bladder size recommendations.

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. The manual states that there is an overpressure detection system but does not specify how this operates. The operator is warned to 'make certain the patient knows how to terminate the reading by pressing the STOP key'. The manual advises that the subject should not allow the monitor to become wet but can be assured that in the event of this happening there is no danger of injury.

Power supply

The manual supplies adequate detail on the power requirements. Four alkaline MN 1500 (1.5 V) batteries are recommended and these should be changed after 'each patient use', but the manual does not state if the batteries should be replaced after a period of 24- or 48-h use. The batteries are, in fact, capable of providing sufficient power for 48 h recording at 30-min intervals and one set of batteries can be used to record 24-h blood pressure at 30-min intervals in two subjects. Nickel cadmium rechargeable batteries may also be used and should be recharged after each period of patient monitoring. A 3 V lithium back-up battery is also required and should be replaced every 3 years. Error codes alert the operator to inadequate power in either the main or back-up batteries.

Instructions for care and maintenance

The manual gives the operator clear instructions on the day-to-day care of the equipment and the need for regular maintenance. Product warranty information is provided for the purchaser but should also be included in the manual as separate documents can be mislaid.

Service facilities

The BHS protocol recommends that the location of national and international services 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 SpaceLabs manual lists the telephone numbers for service and maintenance facilities in the United States but not elsewhere. Details of service costs and maintenance contracts are not given.

Dimensions

The dimensions and weights of all components and the means of attachment etc., are provided (see Methods) but the weight of the monitor with batteries is not given and had to be measured.

List of components

The major components of the system are listed in the manual. The dimensions of the bladders supplied

were not provided; it is stated in the manual that the proper sized cuff should be selected for the patient so that the 'cuff must wrap at least halfway around the arm'. This instruction is incorrect on a number of counts. First, the term cuff is used instead of bladder and the bladder should encircle at least 80% of the arm circumference [17]. The BHS recommends a cuff containing a bladder with the dimensions 35 × 12 cm for most adult arms [18]. The range of cuffs provided are for the following arm circumferences but the bladder dimensions are not given: small adult, 17 × 26 cm; average adult, 24 × 32 cm; large adult, 32 × 42 cm; paediatric, 13 × 20 cm.

Method(s) of blood pressure measurement

The SpaceLabs 90207 measures blood pressure by oscillometry but no details as to the methods of calculating the pressure are provided.

Artefact editing

The SpaceLabs system has three editing facilities which are clearly described and easy to operate. First, there is the 'event edit' mechanism which indicates that the device could not perform a measurement because of, for example, a loose cuff or air leak; the 'auto-edit' mechanism operates when the readings are outside the limits set by the operator when configuring the software program (these might include limits for systolic and diastolic pressures, heart rate and pulse pressure); finally, there is the 'manual edit' facility whereby the operator can edit out readings from the printed report but not from the data file.

Facility for checking device accuracy and recalibration

The following instructions for checking device accuracy are provided: 'The monitor bleeds pressure in discrete steps (not continuously) and, as a result, a correction factor is required to accurately measure manual systolic and diastolic pressures. For systolic, record the first pressure at which a Korotkoff sound is heard. Actual systolic is somewhere between the pressure when the sound is heard and the previous (higher) pressure where no sound was heard. The interval of uncertainty can be split by adding one-half of the bleed step size to the manual systolic pressure.' A similar procedure is described for checking the accuracy of diastolic pressure.

The manual does not make recommendations as to how the operator should proceed in the event of the calibration test showing inaccuracy.

Factors affecting accuracy

The manual states: 'As in manual methods, accurate readings might not always be achieved under some conditions. Patient movements, extreme heart rates and blood pressures, and various arrhythmias are several examples of patient conditions which can hinder a reading. Vibration, such as that in a moving automobile, is an environmental problem which can affect readings.'

Operator training requirements

The SpaceLabs system is reasonably easy to operate and the instruction manual takes the operator through the operative procedure step by step. Nonetheless, the manual carries the prudent caution: 'Users of this manual are expected to be familiar with all standard medical practices referenced in this manual. Use of the Model 90209 in the PC Interface, Data Interface and Remote Report modes assumes prior knowledge of IBM personal computer operation with a printer and modem.'

Computer analysis

The 90209 DIU may be used both with the 90207 and the older 90202 ABP Monitor. The function of the DIU is to take raw data from the monitor for assembly into reports that may be printed directly from the DIU or stored and analysed in an IBM compatible personal computer for later printing and/or connection to a modem. The DIU may be interfaced with an IBM XT, AT, or PS2 for data analysis and storage. Clear instructions are provided for setting recording conditions, retrieving recordings and saving data to disk, retrieving data from disk, displaying numerical data and graphics, importing data into statistical/graphic/spreadsheet software programs and printing results (excerpts or total).

Problem list and solutions

A list of common operational problems with solutions is provided for both the DIU 90209 and the ABP monitor 90207.

Supplier names and addresses

The following are the names, addresses and telephone numbers of UK, US and EC suppliers: Mr John Teeder, Director of Sales and Marketing, SpaceLabs International Inc., Mulberry Business Park, Fishponds Road, Wokingham, Berkshire RG11 2QJ, UK. Tel: 44-734-771711; Fax: 44-734-772260.

Mr T.R. Miskimon, Senior Director, International Operations, SpaceLabs Inc., 4200 150th Avenue, N.E., P.O. Box 97013, Redmond, WA 98073-9713, USA. Tel: 1-206-8823700; Fax: 1-206-8834498.

Mr J.W. Fransen, International Region Manager, SpaceLabs GmbH, Noveistrasse 56, D-4044 Kaarst, Germany. Tel: 39-2101-511751; Fax: 39-2101-510113.

Discussion

In this study, the SpaceLabs 90207 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 and an assessment of the prod-

uct information and the instructions for operation provided by the manufacturer.

In addition, the BHS protocol takes a new approach to the method 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 SpaceLabs system fulfilled the AAMI criteria [8] and achieved a Grade B rating for both systolic and diastolic pressures, with just 70% of systolic and diastolic pressures being within 5 mmHg of the mercury sphygmomanometer and 90% 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 SpaceLabs 90207 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 bladders with short and long connecting tubing to cater for people of small stature. 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 the 90207 system should be provided with all the available bladder sizes. The belts provided do not stand up to constant use and the manufacturers should supply firmer, preferably leather belts.

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 SpaceLabs 90207 and a repeat measurement was attempted in 11, resulting in eight valid readings. The perfect device should provide a valid measurement for each deflation. The SpaceLabs had to perform approximately 16 excess inflations 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 has not been previously performed but is one of the BHS stipulations. The SpaceLabs manual was generally found to be comprehensive, clearly written and well presented. However, there were some surprising omissions and errors. The ad-

dresses of service centres outside the United States are not given, costings are not provided, the deflation mechanism of the system is not stated and, perhaps most importantly, the way in which the device calculates the blood pressures are not provided. The manual recommends that the 'cuff' should only encircle 50% of the arm, which is clearly incorrect [18,19], and the manual does not distinguish between the cuff and the bladder. A complex technique for assessing accuracy is given which is not feasible in practice. The manual states that the system has satisfied the accuracy criteria of the AAMI; if this is so, the results of this evaluation have not been published and are not, therefore, available for scrutiny. Manufacturers should refrain from making claims which are not substantiated by published results.

Likewise, the BHS protocol requires a statement on the computer aspects of the system. The 90207 is connected to a personal computer via a special interface unit — the 90209. This unit can be used in stand-alone mode if required but, of course, without then being able to provide the flexibility of the computer software. The menu-driven program will not work if the 90209 is not connected and switched on. Screen presentation is clear and uncluttered. It is possible to run the software with only casual reference to the manual. As each screen is reproduced in the manual, it is easy for the operator to locate the operational position in the manual. User-friendly features such as displaying progress in reading data from monitors, assures the user that all is going well. Each feature of the report — graphs, data listings, etc. — can be included or excluded as required.

However, in programming a monitor, it is necessary to move through fields relating to the number of periods, their times and whether or not there are to be warning beeps or active display of blood pressure, before entering patient details; the former requirements are likely to remain reasonably constant for a particular group of subjects or even for a particular institution, and it would be more efficient to enter subjects' details on a separate page on the screen.

Though this 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 hand-grip, Valsalva manoeuvre, etc. Moreover, the protocol does not test the device in the variety of positions in which ambulatory measurements may be made.

In conclusion, the SpaceLabs 90207 ambulatory monitor achieved a B rating for both systolic and diastolic pressure according to the criteria of the BHS

protocol and can be recommended, therefore, for ambulatory measurement.

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