

# Do SpaceLabs ambulatory non-invasive blood pressure recorders measure blood pressure consistently over several years use?

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**Objective** To assess the measurement consistency of SpaceLabs ambulatory recorders (Spacelabs, Washington, USA) that are in regular use.

**Methods** A total of 14 SpaceLabs 90207 and one 90217 ambulatory recorders were tested for measurement consistency using the Dynatech CuffLink (Dynatech, Nevada, USA), a commercially available non-invasive blood pressure (NIBP) simulator. The NIBP recorders were tested at a range of pressures with 20 repeated determinations at a simulated 120/80 mmHg and five repeated determinations at simulated pressures of 80/50, 100/80, 150/100, 200/165 and 250/195 mmHg. Tests were carried out in 1998, 2002 and late 2003 or early 2004.

**Conclusions** All 15 SpaceLabs recorders measured consistently over the 6 years with 89.5% of the differences in average pressures, recorded by any particular device at each recorded pressure, less than 2 mmHg between successive test episodes. The maximum difference was 4.5 mmHg and 60.1% of the differences were less than

1 mmHg. The measurements for all devices were within the tolerances specified by the supplier for the device when tested with the simulator. Maintenance records also show that most devices required breakdown maintenance less than once every 3 years. The results show that the SpaceLabs devices maintain measurement consistency in the demanding conditions of ambulatory pressure recording over several years. *Blood Press Monit* 10:51–56  
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**Key words:** ambulatory blood pressure measurement equipment, measurement consistency, maintenance

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## Introduction

The developers of the British Hypertension Society (BHS) evaluation protocol for automated non-invasive blood pressure (NIBP) monitors recognized the importance of evaluating these devices after use as well as carrying out the more detailed initial accuracy assessment [1]. The protocol included the requirement that sample devices be checked after routine clinical use. However, the continuing accuracy of these devices after years of continuing use has not been rigorously assessed. It is known that auscultatory sphygmomanometers receive very limited routine checks despite recommendations that they be checked regularly [2,3]. Evidence backing up the frequency of routine calibration checks on automated devices has largely been unexplored.

Whilst commercially available NIBP simulators are not able to assess the systematic accuracy of NIBP devices [4], there is evidence that they can assess measurement consistency [4,5]. Simulators are in regular use in maintenance workshops where they assist with the repair and maintenance of NIBP monitors.

A commercially available simulator was used to routinely check the accuracy of the SpaceLabs ambulatory NIBP device over a 6-year period from 1998 to early 2004. The records were examined to assess the long-term consistency and reliability of the SpaceLabs devices.

## Methods

SpaceLabs 90207 and 90217 ambulatory recorders, which have been validated according to the BHS and AAMI protocols for automated NIBP devices ([6,7]: for a summary of validation studies refer to [8]), have been in regular use in the Cardiovascular Risk Clinic at the Western General Hospital in Edinburgh since 1991. The Clinic currently has 20 devices (19 of the 90207 and one 90217) of which 15 have been in regular use for at least eight years. These 15 devices were checked using a protocol that analyses 20 repeated determinations at a simulated 120/80 mmHg and five determinations at simulated pressures of 80/50, 100/80, 150/100, 200/165 and 250/195 mmHg [9]. The protocol was designed to test the devices over a range of low, normal and high pressures. The protocol included 20 determinations at a simulated pressure of 120/80 mmHg to examine the

**Table 1 Allowable range of recorded pressures used to verify the calibration of SpaceLabs ambulatory devices with a Dynatech CuffLink simulator. For comparison with Figure 4, each range is also shown as a bias, that is the difference between the measured pressure and simulator setting**

Simulator setting	100/65	120/80	150/100	200/150	255/195
Allowed systolic	95 to 106	113 to 125	142 to 158	190 to 210	243 to 267
Allowed systolic bias	-5 to +6	-7 to +5	-8 to +8	-10 to +10	-12 to +12
Allowed diastolic	60 to 70	74 to 88	92 to 108	142 to 158	185 to 205
Allowed diastolic bias	-5 to +5	-6 to +8	-8 to +8	-8 to +8	-10 to +10

No range was specified for the mean arterial pressure recording.

ability of the devices to measure consistently [5]. Tests were carried out in 1998, 2002 and late 2003 or early 2004.

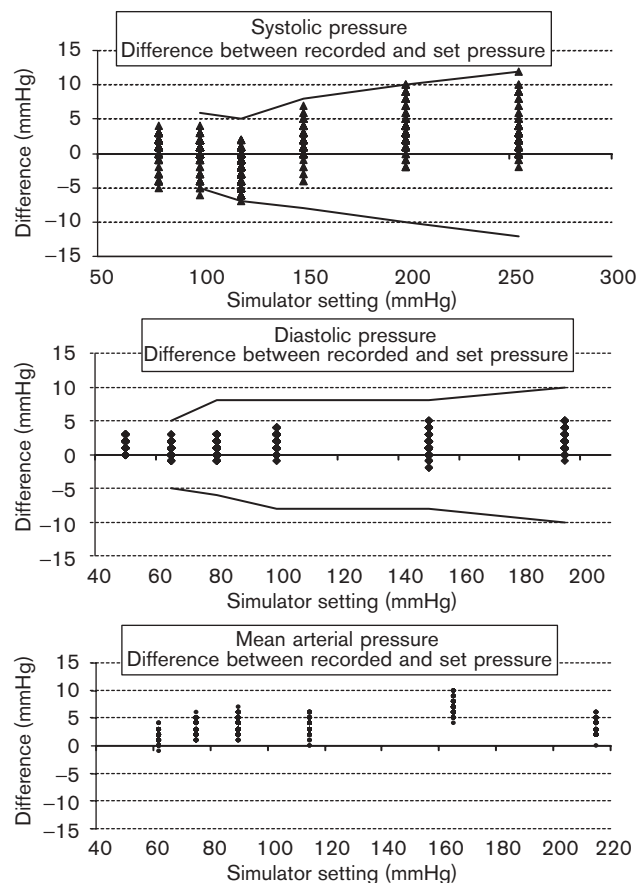
The blood pressure waveforms were simulated using the Dynatech CuffLink simulator [10]. The CuffLink simulates oscillometric pressure pulses in a cuff wrapped around a rigid mandrel, inserting the pulses via a 'T-piece' connector added to the hose between the SpaceLabs device and the cuff. Various pressures can be simulated and measurements made of the inflation and deflation rates, peak cuff inflation pressure and determination time. The simulator was controlled by a personal computer, which recorded the inflation and deflation rates, peak cuff pressure and determination time [9]. The NIBP readings from the SpaceLabs devices were stored internally by the device and transferred to a computer for analysis.

There are limited published normative data on which to base pass criteria when a particular device is tested using a commercially available simulator. However, pressure ranges within which the SpaceLabs ambulatory recorder should record pressures when tested on the Dynatech CuffLink have been described (Table 1; personal communication). Consistency, at a simulated pressure of 120/80 mmHg, has been defined as standard deviations of less than 2 mmHg for at least two of the recorded systolic, diastolic and mean arterial pressures, with all less than 3 mmHg [5]. In summary, the standards against which device consistency would be judged were: (1) the average recorded systolic and diastolic pressures should remain within the limits shown in Table 1; and (2) the standard deviation of the systolic, diastolic and mean arterial pressures recorded by all the devices over the full period of the study should be within 3 mmHg, with at least two-thirds within 2 mmHg.

## Results

The recorded pressures for all devices at each of the simulated pressures (a total of 1920 sets of systolic, diastolic and mean arterial pressures) are shown in Figure 1. Note that in most cases each 'dot' represents many recordings. The pressures are displayed as the difference between the recorded pressures and the simulator settings. The panels for the systolic and diastolic

**Fig. 1**



The differences between each recorded systolic, diastolic and mean arterial pressure and the simulator setting, plotted against the simulator set pressure. The graphs show 1920 sets of recorded pressure. The systolic and diastolic pressure panels show the limits within which the pressures should fall (Table 1).

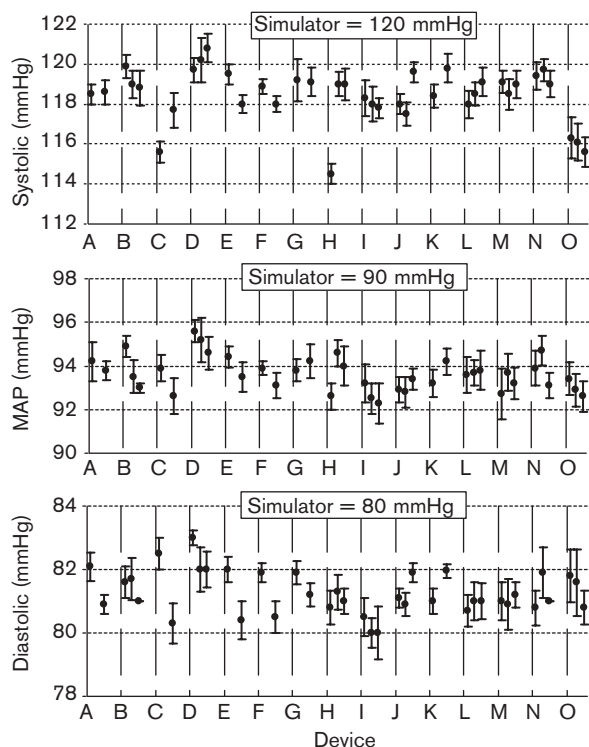
pressures also show the limits of the pressures expected to be measured by the SpaceLabs recorders with the simulated waveforms (Table 1). Only one of the 1920 individual measured pressures lay outside the limits – and that by 1 mmHg. Details are given in Table 2.

Besides examining the global range of pressures recorded by all the devices, we focused on the consistency of measurement by any particular device over the course of the 6 years. Figure 2 details the pressures measured by

**Table 2** Summary of recorded pressures from all 15 devices at each test period at each simulator setting

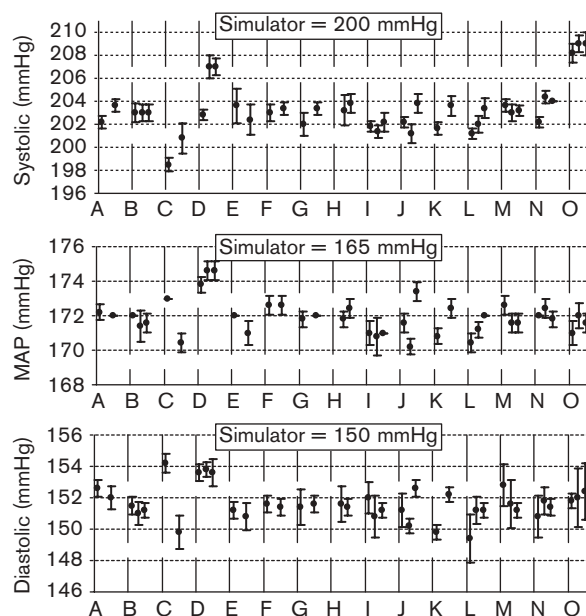
Simulator setting	80/50 (62)	100/65 (75)	120/80 (90)	150/100 (115)	200/150 (165)	255/195 (215)
Number of recorded pressure sets	234	227	858	198	212	191
Systolic average	81.1	100.7	118.4	151.9	203.3	257.8
Systolic standard deviation	1.64	1.62	1.48	1.58	2.28	2.37
Diastolic average	51.1	65.9	81.2	101.7	151.6	197.5
Diastolic standard deviation	0.84	0.88	0.84	1.08	1.33	1.20
MAP average	63.6	78.2	93.6	118.6	171.9	218.5
MAP standard deviation	0.91	1.10	1.04	1.11	1.14	0.99

MAP, mean arterial pressure.

**Fig. 2**

Mean and standard deviation of the systolic, mean arterial and diastolic pressures recorded by the 15 SpaceLabs ambulatory recorders when tested with a simulated 120/80 (90) mmHg waveform. Tests were carried out in 1998, 2002 and 2004. The devices are ranked in serial number (that is age) order. A total of 20 recordings were averaged for each device at each test episode. All the results were comfortably within the acceptable systolic and diastolic ranges of 113–125 mmHg and 74–88 mmHg respectively (see Table 1).

each of the 15 devices at each of the test periods (1998, 2002, 2004) when presented with 20 repeated simulated 120/80 (90) mmHg oscillometric waveforms. The letters A to O, ranging from the oldest to the most recent device, indicate the devices. Devices A and B were made in September and October 1990, devices C to E were made in 1991, with the remainder manufactured between 1993 and 1996. Devices A, C, E, F, G and K were not tested in 2002. Device O is the 90217. Figure 3 details the results when the devices were tested at a simulated 200/150 (165) mmHg.

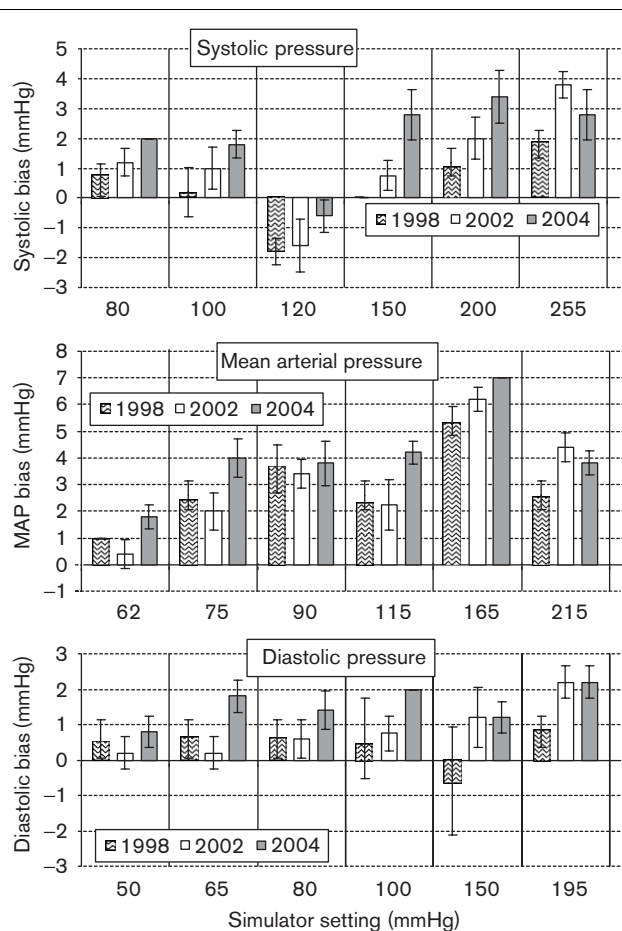
**Fig. 3**

Mean and standard deviation of the systolic, mean arterial and diastolic pressures recorded by the 15 SpaceLabs ambulatory recorders when tested with a simulated 200/150 (165) mmHg waveform. Tests were carried out in 1998, 2002 and 2004. The devices are ranked in serial number (that is age) order. Five recordings were averaged for each device at each test episode. All the results were within the acceptable systolic and diastolic ranges of 190–210 mmHg and 142–158 mmHg respectively (see Table 1).

Each monitor was tested over a range of pressures and Figure 4 depicts the results for one of the recorders (L) tested in 1998, 2002 and 2004. (This device was selected because it was tested at each of the three periods and its consistency over the measured period was typical of all the devices—refer to Figures 2 and 3). The differences (biases) between the recorded pressures and simulator settings are shown at simulator settings from 80/50 to 255/195. The maximum difference of the recorded pressures for device L, between any of the three tests, was 2.8 mmHg (at a simulated systolic pressure of 150 mmHg); the average difference was 1.5 mmHg.

The absolute differences of the average systolic, diastolic and mean arterial pressures recorded for any particular

Fig. 4



Mean bias and standard deviation of the systolic, mean arterial (MAP) and diastolic pressures recorded by device L at each simulated pressure for the tests in 1998, 2002 and 2004. The bias is the difference between the simulator setting and the recorded pressure. All results were comfortably within the acceptable systolic and diastolic ranges (Table 1).

device between each successive test episode were calculated.

Differences = average pressure recorded at 2000 – average pressure at 1998 and = average pressure recorded at 2004 – average pressure at 2000.

The differences were calculated at each simulated pressure. The absolute differences were plotted as a histogram drawn to show the distribution of pressure differences (Fig. 5). Most differences (60.1%) were less than 1 mmHg, 89.5% were less than 2 mmHg and 93.4% less than 3 mmHg. In over 5% of cases the average pressure recorded by a particular device did not differ between successive test episodes. The maximum difference was 4.5 mmHg.

These SpaceLabs ambulatory devices have been in regular use since purchased, each being used, on average

over the past 3 years, to record 95 24-h ambulatory recordings per year. Maintenance records are summarized in Figure 6. Major repairs required that the device be returned to the supplier; the hospital's Medical Physics department carried out the minor repairs. Most devices only required repair less than once every 2 years, none more than once a year.

## Discussion

The SpaceLabs ambulatory recorders recorded consistently over the 6-year study (Table 2 and Figs. 1–5). In some instances there was no difference in the average recorded pressure between years. We have previously shown measurement consistency by SpaceLabs devices over a particular recording session [11]; this study shows that the consistency is maintained over 6 years. The results fall within the criteria that the average of the recorded pressures at every testing interval should fall within the acceptable limits (Tables 1 and 2). Only one of the individual measurements was outside the limits (Fig. 1). The consistency criteria were also met, with standard deviations less than 2 mmHg except for the two higher systolic pressures (Table 2). Nearly 90% of the average systolic, diastolic and mean arterial pressures recorded by any device remained within 2 mmHg of their recordings at successive test intervals (Fig. 5).

The results also demonstrate consistency of measurement across all the devices, with a narrow band of variation between devices (Figs. 1–3). The differences between the 15 devices tested were within the bounds of the differences recorded from individual devices. This consistency was maintained when recording both low and high pressures.

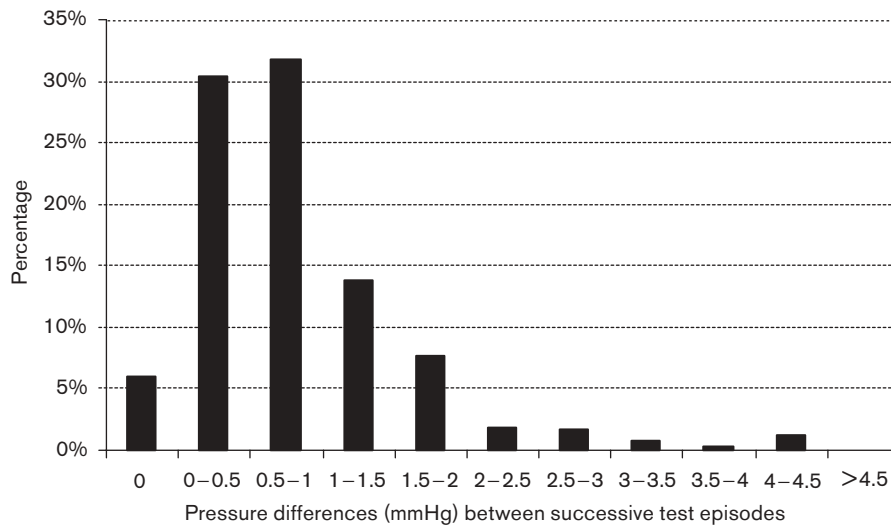
These devices have been in regular use, three of them in use since 1991. They are used nearly twice per week, sent out with patients for 24-h ambulatory pressure recordings. Despite this usage, that involves more wear and tear than is typical for hospital-based medical devices, the recorders proved very reliable with minimal major faults (Fig. 6).

Criteria for acceptable performance of an NIBP device when tested with a simulator have not yet been formally established. Simulators generate artificial waveforms and there is no expectation that a calibrated and validated device will record the same pressure that the simulator is set to [4,12]. The bias, that is the difference between the recorded pressure and the simulator setting, is the combination of the bias of the simulator and that of the device under test [12].

Bias = Bias of simulator + Bias of device under test

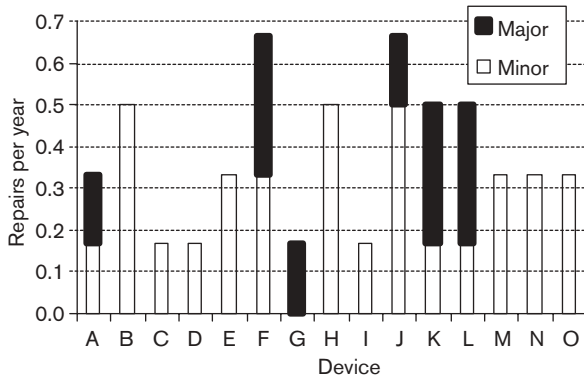
A high or low bias thus does not imply an invalid NIBP device. Normative data defining the systolic and diastolic

Fig. 5



Histogram showing the absolute pressure differences recorded for a particular device between successive test episodes. The differences were calculated for every device at each simulated pressure.

Fig. 6



Summary maintenance history of the 15 SpaceLabs devices.

pressures that the SpaceLabs should record when presented with waveforms simulated by the Dynatech Cufflink are available (Table 1) and these define the acceptable bias for the systolic and diastolic pressures. Normative data for the mean arterial pressure are not yet available. The predominant positive bias for the mean arterial pressure (Fig. 1) does not imply that these devices will record erroneously high mean arterial pressures, but rather may reflect the bias of the simulator. The widespread use of NIBP simulators, particularly in maintenance workshops, suggests the need for normative data for NIBP devices when tested on simulators. Studies such as this can help provide the normative data.

Whilst simulators cannot assess the actual bias of an NIBP device, there is evidence that simulators can assess measurement consistency [5]. Consequently the SpaceLabs performance was checked to ensure that standard deviation of the pressures was within 2–3 mmHg [5]. This standard deviation is tighter than that expected from clinical validation studies [13] because of the good reproducibility of simulated waveforms in contrast to the variabilities in clinical studies. The consistency of pressures recorded by the SpaceLabs devices comfortably met these requirements (Table 2).

Automated blood pressure devices can deteriorate with time due to transducer calibration drift, pump failure, blockage of internal airways or the pressure release valve, or leaks in internal tubes. Maintenance records for the devices studied showed a few pump failures and a slow leak in the internal tubes (which manifested itself by failure to record at high pressures and a relatively high cuff deflation rate). Decay of the external hoses and cuffs used with NIBP devices can cause debris to enter the internal pneumatic systems, causing partial blockages and for example, preventing rapid release of cuff pressure after completion of the measurement. The SpaceLabs device includes a small filter at the hose connector to protect against this. The results shown here for the SpaceLabs devices do not demonstrate any transducer or amplifier calibration drift with time or usage for these devices.

Simulator evaluations of automated NIBP devices suffer from the artificial nature of the generated waveforms

[12]. On the other hand, clinical validation studies [1,13] are expensive and new clinical validation studies requiring fewer subjects have been developed [14]. However, concern has been expressed that 'device errors' in clinical validation studies tend to cluster within persons, limiting the validity of clinical evaluation studies [15]. Perhaps this is analogous to the different pressures that are recorded by the same monitor when tested on different simulators [4]. The reasons for these differences are not clear, but do point to the need for further research to better understand the nature of the oscillometric technique [16]. Nonetheless, simulators do generate repeatable waveforms and can be used to assess the consistency of measurement by a particular device at a particular time, and also to examine the consistency of a group of devices of the same model over a period of time.

### Conclusion

The SpaceLabs devices tested showed good repeatability over the 6-year testing period despite being in frequent ambulatory use.

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