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Original Article

# Evaluation of the A&D UA-767 and Welch Allyn Spot Vital Signs noninvasive blood pressure monitors using a blood pressure simulator

P D Davis[1], J L Dennis[1] and R Railton[2]

[1]*Department of Clinical Physics and Bioengineering, Southern General Hospital, Glasgow, UK*

[2]*Department of Medical Physics, Monklands Hospital, Airdrie, UK*

*Correspondence to: PD Davis, Department of Clinical Physics and Bioengineering, Southern General Hospital, 1345 Govan Road, Glasgow, G51 4TF, UK. E-mail: paul.davis@sgh.scot.nhs.uk*

## Abstract

**The performance of five units of the A&D UA-767 NIBP monitor and five units of the Welch Allyn Spot Vital Signs noninvasive blood pressure monitor was evaluated with the Biotek BP Pump blood pressure simulator under a variety of conditions. Using the simulator to provide a normal blood pressure waveform at 80 bpm over a range of pressures, it was found that the mean bias for the combined results from the A&D monitors was 1.9±2.8 mmHg and from the Welch Allyn monitors was 0.7±2.4 mmHg. No individual measurement showed a bias greater than 10 mmHg. A bias of greater than 5 mmHg was present in 28 out of 150 measurements for the A&D monitor and 10 out of 150 measurements for the Welch Allyn monitor. These results are comparable with ratings achieved by the instruments when tested previously according to the British Hypertension Society protocol, but testing with a simulator allowed assessment of aspects of performance which were not included in the British Hypertension Society protocol.**

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## Keywords

noninvasive; blood pressure; monitor; protocol

## Introduction

The mercury sphygmomanometer is often regarded as the gold standard for the measurement of blood pressure. Although the interpretation of the Korotkoff sounds that identify systolic and diastolic pressures may result in variation in the measured pressure, the manometer itself is not prone to drift if it is serviced properly. However, the mercury sphygmomanometer has been replaced in many locations by other devices because of the health hazards associated with the use of mercury.[1] Oscillometric noninvasive blood pressure (NIBP) monitors are a popular choice as, unlike auscultatory blood pressure monitors, they do not require the identification of Korotkoff sounds in order to make the measurement. Some of these devices are sufficiently inexpensive to be regarded as not cost effective to repair, whereas the converse is true of others. Many more expensive NIBP monitors are usually available or purchased with other functions such as pulse oximetry, which increases the price of such devices. In order to assess whether users who require the facility to measure blood pressure alone could obtain acceptable performance from a comparatively inexpensive device, we compared the performance of an NIBP monitor costing less than £100 with an alternative more expensive model, which also provided the functions of pulse oximetry and temperature measurement.

The European Society of Hypertension has published an international protocol for validation of blood pressure measuring devices in adults,[2] which is based on previous work and protocols.[3, 4, 5, 6, 7, 8] This protocol requires measuring devices to be tested by independent observers on a relatively large number of subjects, some of whose blood pressures are hypotensive and some hypertensive. It is difficult to recruit the full range of subjects and time consuming to use the complete protocol. As an alternative, NIBP simulators are available that permit testing of an NIBP monitor over a range of blood pressures and pulse rates and with the introduction of different types and degrees of severity of artefact. A protocol has been developed for use in such situations[9] and tests from this protocol have been used in this investigation.

## Materials and methods

The Biotek BP Pump simulator produces simulated blood pressure pulses that vary in amplitude with the detected cuff pressure, and is thus suitable for analysing the performance of NIBP monitors that use the oscillometric measuring principle. The simulator is capable of generating a number of different waveforms corresponding to different systolic and diastolic pressures, pulse rates, pulse strengths and the addition of motion and tremor artefacts. The response of an NIBP monitor can therefore be assessed for a variety of potential clinical conditions. The static calibration of the particular simulator used was

traceable to national standards.

The A&D UA-767 and Welch Allyn Spot Vital Signs NIBP monitors both use the oscillometric principle for the measurement of blood pressure and were thus suitable for testing with the Biotek simulator. They were chosen for this study because of their local availability. The A&D monitor is an example of a low-cost instrument and the Welch Allyn a more expensive device. Devices were not calibrated before being tested in order to obtain a more representative determination of performance in a typical hospital setting. The performance of five Welch Allyn Spot Vital Signs and five A&D UA-767 NIBP monitors was tested using the blood pressure simulator.

In order to give an indication of the clinical significance of any inaccuracies in the measurements by the two types of monitor, relevant criteria from the International Protocol[2] were used as guidelines. These criteria categorise the differences into bands applicable to both the systolic and diastolic pressures and are summarised in Table 1 below. Any difference of ≤5 mmHg is not considered to be clinically significant.

Where reference is made to accuracy in this paper, the terms used are those given in this table.

Each of the 10 monitors was connected to the simulator in turn by attaching the cuff hose of the monitor to the output pressure port of the simulator. Measurements of systolic and diastolic pressures were made using the simulator to provide pressure waveforms according to a protocol specified by Amoore and Geake.[9] This protocol included measurements at a range of pressures, pulse rates, pulse strengths and with the addition of motion and tremor artefacts, and is summarised in Table 2 below. Pulse rates are 80 bpm and pulse strengths 100% unless otherwise stated.

Unless stated otherwise, five pressure measurements were made at intervals of 5 min for each simulator setting with each unit that was tested, in order to assess variation between measurements. For the first test, for example, this resulted in 300 measurements of systolic blood pressure (SBP) and 300 measurements of diastolic blood pressure (DBP), since there were five measurements and six pressure settings for each of the ten units being tested. The SBP, DBP and pulse rate displayed by the NIBP monitor and the time taken for the monitor to complete the measurement were recorded. Neither type of NIBP monitor provides a measurement of the mean arterial pressure (MAP). The difference between the pressure measured by the monitor and the pressure set on the simulator was calculated as the measurement bias and compared to the simulator set pressure. A mean bias and standard deviation were then calculated from these values.

The first test assessed the ability of the monitors to measure six different pressures increased in steps from 60/30 mmHg, corresponding to hypotension, to 200/150 mmHg, corresponding to hypertension. During this test, the peak inflation pressure of the cuff was also noted in order to compare this value with that of the previously measured systolic pressure; this indicated the degree to which a monitor adjusted its measurement procedure in response to the previous measured pressure.[9]

The second test involved measurements of a ramped pressure sequence with a single measurement taken at each pressure. The pressure was ramped from 60/30 to 255/195 mmHg and back to 60/30 mmHg, with the cycle then repeated. This test determines the response of a monitor to a change in blood pressure and is intended to assess any effect that might be due to the fact that the monitor inflates the cuff to a pressure determined by the previous SBP value measured. In this study, this test was found to be inappropriate as neither the A&D nor the Welch Allyn monitor appeared to store the previous SBP value for use as the basis for the next initial cuff inflation pressure. The inflation pressure is set by the user on the A&D monitor and was normally about 160–170 mmHg for the Welch Allyn unit. The ramping test was therefore not used for this study.

The effect of pulse rate on the measured blood pressure was determined by measurements over a range of pulse rates increased in steps from 40 to 200 bpm at a pressure of 120/80 mmHg.

In normal operation, the simulator moves a maximum volume of air of about 1.2 ml between itself and the NIBP monitor under test. The simulator allows the addition of motion and tremor artefacts to the pressure waveform. Different levels of severity categorised as 1, 2, 5 and 10 are provided, with level 1 corresponding to the addition of noise with a 0.2 ml peak-to-peak amplitude to the 1.2 ml amplitude normal waveform and level 2 having twice this noise amplitude. The simulator was used to generate motion and tremor artefacts at levels 1, 2 and 5 with a pressure of 120/80 mmHg and a pulse rate of 80 bpm.

A patient can present with a weak pulse for a variety of reasons, including obesity, loss of blood or fluids, vomiting, overdose or shock. It is therefore important to determine how a monitor responds to low pulse strength. For the final test in the protocol, the simulator was set to generate pulse strengths of 100, 75, 50, 25 and 10% of the nominal 1.2 ml volume displacement.

Means and standard deviations of the pressures measured by the 10 monitors were calculated. The results of all measurements by each of the 5 units of the two models for each set of parameters were combined and an overall mean bias and standard deviation for the systolic

pressure and for the diastolic pressure were determined.

## Results

*Pressure measurements*

The mean biases and standard deviations obtained from the systolic and diastolic pressure range tests for the A&D and Welch Allyn NIBP monitors are shown in Tables 3 and 4, Figures 1 and 2. Each entry in these and subsequent tables gives the mean and standard deviation of 25 measurements (five measurements from each of 5 units). The figures show the means±two standard deviations.

Combining all 300 measurements for each type of NIBP monitor gives a mean bias of 1.9±2.8 mmHg for the A&D monitor and 0.7±2.4 mmHg for the Welch Allyn monitor. A *t*-test indicates a significant difference between the means ($P<0.001$). For the A&D monitor, 28 out of 150 measurements, and for the Welch Allyn monitor, 10 out of 150 measurements showed an absolute bias greater than 5 mmHg. No measurements from either monitor showed an absolute bias greater than 10 mmHg.

One-way analyses of variance for individual units of both manufacturers showed that the difference in the means of the five measurements for each unit did not differ significantly for the Welch Allyn monitors, but showed some evidence of difference for the A&D monitors ($P<0.02$). The differences were not clinically relevant.

Two-way analyses of variance carried out separately for the SBP and DBP measured by the A&D monitor and for the SBP and DBP measured by the Welch Allyn monitor showed that there were significant differences between the mean biases for different units and for different pressures ($P<0.001$ in each case). In each case, variation in bias between blood pressures was greater than between units. The differences were not clinically relevant.

In the course of taking measurements with these monitors, it was found that an analysis of the peak inflation pressure as carried out by Amoore and Geake[9] would be inappropriate. This was due to the fact that the user sets the peak inflation pressure for the A&D unit, and that the 5 min gap between readings caused the Welch Allyn unit to enter its sleep mode, after which it always inflated to a peak pressure of around 160–170 mmHg, irrespective of the previously measured systolic pressure. No further work was therefore undertaken on the peak inflation pressure.

It was for this same reason that the ramped pressure test was not carried

out on all the units. As neither model stores the previous measurement as a guide to the required inflation pressure, this test was seen as inappropriate for these particular NIBP monitors.

*Effect of pulse rate*

The results from the pulse rate test are shown in Table 5. These again compare the measurement bias from the A&D and Welch Allyn monitors for SBP and DBP separately. It should be noted that the results for 40 and 200 bpm for the Welch Allyn monitor are not averaged over the full 25 measurements. These values are specified as the maximum and minimum limits of the range of this model and, on occasion, the unit gave no measurement result. In these instances, the monitor instead gave an error message that one of the parameters was not within its measurement range. The values presented in the table are therefore averages over 17 and 18 measurements for 40 and 200 bpm, respectively. All other values are means of the full 25 measurements.

The mean measurement time at each pulse rate was also calculated and the results for both models are shown in Table 6.

*Response to artefacts*

The results from the measurements of the systolic and diastolic pressures with the addition of motion and tremor artefacts of varying severity are shown in Table 7.

*Pulse strength*

Table 8 shows the results of measurements with decreasing pulse strength. Both models were able to determine the blood pressure at pulse strengths down to 50% of the simulator nominal waveform amplitude of 1.2 ml. The A&D unit gave no readings at 25 and 10%, while the Welch Allyn unit gave five results at 25% and no results at 10%. The A&D monitor gave no error code, but simply displayed a single '0' at the end of the measurement. The five results produced by the Welch Allyn monitor included two measurements from a single unit and one measurement from three others, with a single unit not recording any values. All other measurements resulted in an error code corresponding to excessive noise in the signal. Since the majority of attempted measurements gave no result, it was decided that no overall mean and standard deviation would be calculated for the Welch Allyn monitor at 25% pulse strength.

## Discussion

Both the A&D UA-767 monitor[10] and the Welch Allyn Vital Signs

monitor[11] have been tested according to the earlier protocol of the British Hypertension Society[7] and given an A rating for both SBP and DBP. To achieve this rating, at least 60% of readings must show an absolute difference between the standard and the test device of not greater than 5 mmHg, 85% not greater than 10 mmHg and 95% not greater than 15 mmHg. The measurements with the simulator reported here show that 81% of readings produced by the A&D monitor and 93% of readings produced by the Welch Allyn monitor showed a difference not greater than 5 mmHg. For both monitors, 100% of readings showed a difference not greater than 10 mmHg. Although the protocol used here is not the same as the BHS protocol because the measurements were made with a simulator rather than on subjects, it is reassuring to note that the method has produced the same A/A rating for both instruments.

Analysis of results according to the more recent protocol of the European Society of Hypertension[2] is more complex because the protocol includes an assessment of the variation in measurements grouped by individual subjects rather than the variation in the set of measurements as a whole. For example, to pass the final phase of the protocol, at least 22 of the 33 subjects must have at least two of their three comparisons lying within 5 mmHg. Such groupings cannot be applied to the results reported here because of the test method used, but if the groupings were combined and applied to the results obtained with the simulator, both monitors would pass such a modified protocol.

The results show that both devices are able to measure the systolic and diastolic pressures with better than 5 mmHg accuracy over a wide pressure range. Considering the results with reference only to Table 1, it was found that the mean errors in both systolic and diastolic pressure measurements for both monitors were not clinically relevant, with the exception of the SBP measurement by the A&D unit at high pressure (200 mmHg). The mean bias for this measurement was found to be 5.7±1.5 mmHg, requiring a rating of slightly inaccurate at this value of systolic pressure. The A&D monitor may therefore be unsuitable for measuring the blood pressure of hypertensive patients in situations where a very accurate result is required. However, the need for such accuracy at such a value of systolic pressure might be questioned. The Welch Allyn unit is accurate over the entire SBP range, but less so for the diastolic measurements, with a tendency to display a slightly high DBP at low pressure and a slightly low DBP at higher pressures. The errors are, however, less than 5 mmHg, and so are not considered to be clinically significant.

Analysis of variance indicated that, although there were significant differences in performance between individual units, these differences were less than the differences between performance at individual values of blood pressure. None of these differences were clinically relevant. The results merely indicate that the problem of maintaining a consistent

performance over a range of blood pressures currently appears to be more difficult to overcome than maintaining consistent performance among a selection of units, even when these units are not individually calibrated before testing.

The measurements taken over a range of pulse rates from 40 to 200 bpm showed that the Welch Allyn monitor gave an accurate indication of both the systolic and diastolic pressures over the entire pulse rate range. The A&D unit was accurate for all the SBP measurements, but showed some inaccuracy in the diastolic measurement at lower pulse rates. The calculated bias values for DBP at 40 and 60 bpm were 9.0±2.1 and 5.0±1.9 mmHg, respectively. Based on the criteria defined by O'Brien *et al*[2] and shown in Table 1 above, the monitor can be said to be slightly inaccurate at these low pulse rates. This would indicate that if a very accurate measure of the blood pressure of a patient with a slow pulse was required, the A&D may not be a suitable device to choose.

The results show that for both models the measurement time decreases as the pulse rate increases, indicating that both monitors alter the rate of cuff deflation based on the pulse rate. The measurement time for the Welch Allyn monitor was more variable, being longer than the A&D unit at low pulse rates and shorter at higher rates, while at a normal resting rate of around 80 bpm, the times were comparable. In general, there is therefore little to choose between the monitors in terms of this parameter.

Both monitors showed resistance to simulated motion and tremor artefacts over most of the range of severities generated by the simulator. Both models showed no clinically relevant errors in the systolic and diastolic pressure measurements for the three levels of motion (low frequency noise) artefact or for the lower two levels of tremor artefact (mixed low- and high-frequency noise). However, at the highest level of tremor artefact used in the test, both monitors showed significant errors. The Welch Allyn unit gave results that can be considered to be moderately inaccurate, with SBP and DBP mean bias values of 11.4±21.7 and 6.6±18.8 mmHg, respectively, while the A&D monitor gave very inaccurate results of 71.8±23.5 and 94.2±17.1 mmHg. Although the mean values for the Welch Allyn monitor indicate that it is not classed as very inaccurate according to Table 1, the large variation in the readings would indicate that it would be an unsuitable choice of NIBP monitor for this clinical situation. As the A&D monitor gives very inaccurate results, it would also be an inappropriate choice.

Several different clinical conditions can lead to the patient having a weak pulse, so the performance of the monitors when presented with lower pressure oscillations than normal is important. The Welch Allyn unit gave no clinically significant measurement error in either the systolic or diastolic pressures for pulse strengths down to 50% of the

normal value produced by the simulator. The A&D model was accurate down to the 75% level and only slightly inaccurate at 50%, with both the systolic and diastolic mean bias values at this level being less than 10 mmHg. A small number of readings were obtained from the Welch Allyn monitor at the 25% level, but these were too few to allow accurate estimates of the mean and standard deviation to be made, while the A&D unit was unable to determine the pressures at this level. Neither monitor gave any results at 10% of normal pulse strength. The tendency for both monitors was to register a lower systolic pressure and higher diastolic pressure as the pulse strength decreased. This indicates that neither of these NIBP monitors would be suitable for measuring blood pressure in a patient with a very weak pulse and that the Welch Allyn monitor would give a more accurate measurement than the A&D unit for pulses slightly weaker than normal.

The performance of the lower cost NIBP monitor tested here is comparable with a more expensive unit over a wide range of simulated clinical conditions and implies that this type of monitor could be used as a cost-effective alternative. A typical clinical use could be in nursing observation monitoring.

The analysis of the performance of blood pressure monitors using a blood pressure simulator, while different from the procedure defined in recent protocols requiring test subjects, is capable of producing results that are not at variance with those obtained elsewhere from the application of the protocols. Analysis using a simulator has some advantages, being easier to complete because it does not require the availability of observers and comparatively large numbers of test subjects, and providing information about performance under circumstances that the protocol does not test explicitly. These latter conditions include variations in pulse rates that are more extreme than would be expected to occur in normal subjects, pulse strength and the introduction of various types of artefact.

It may be appropriate to develop an approved protocol for testing with a simulator as a complement to testing with subjects.

## References


1 **Langford NJ, Ferner RE**. Toxicity of mercury. *J Hum Hypertens* 1999; **13**: 651–656. Article PubMed

2 **O'Brien E *et al.*** Working group on blood pressure monitoring of the European Society of Hypertension International Protocol for validation of blood pressure measuring devices in adults. *Blood Pressure Monit* 2002; **7**: 3–17. Article

3 **O'Brien E *et al* on behalf of the European Society of Hypertension Working Group on Blood Pressure Monitoring**. Blood pressure measuring devices: validated

instruments. *BMJ* 2001; **322**: 531–536. Article PubMed

4 **Association for the Advancement of Medical Instrumentation**. *The National Standard of Electronic or Automated Sphygmomanometers*. AAMI: Arlington, VA, 1987.

5 **O'Brien E *et al.*** The British Hypertension Society protocol for the evaluation of automated and semiautomated blood pressure measuring devices with special reference to ambulatory systems. *J Hypertens* 1990; **8**: 607–619. PubMed

6 **O'Brien E *et al.*** The British Hypertension Society protocol for the evaluation of blood pressure measuring devices. *J Hypertens* 1993; **11**(Suppl 2): S43–S63.

7 Association for the Advancement of Medical Instrumentation. *American National Standard. Electronic or Automated Sphygmomanometers*. AAMI: Arlington, VA, 1993.

8 **O'Brien E, Atkins N**. A comparison of the BHS and AAMI protocols for validating blood pressure measuring devices: can the two be reconciled? *J Hypertens* 1994; **12**: 1089–1094. PubMed

9 **Amoore JN, Geake WB**. Evaluation of the Critikon 8100 and Spacelabs 90207 non-invasive blood pressure monitors using a test simulator. *J Hum Hypertens* 1997; **11**: 163–169. Article

10 **Rogoza AN, Pavlova TS, Sergeeva MV**. Validation of A&D UA-767 device for the self easurement of blood pressure. *Blood Pressure Monit* 2000; **5**: 227–231. Article

11 **Jones CR, Taylor K, Poston L, Shennan AH**. Validation of the Welch Allyn 'Vital Signs' oscillometric blood pressure monitor. *J Hum Hypertens* 2001; **15**: 191–195. Article

## Figures



## Tables



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