Validation of the A&D UA-705 device for self-measurement of blood pressure according to the British Hypertension Society protocol
Paolo Verdecchia, Fabio Angeli, Roberto Gattobigio, Enrica Angeli, Silvia Pede and Loretta Pittavini

Objectives We tested the accuracy of the UA-705 blood pressure semi-automatic monitor.

Methods Device evaluation was performed according to the modified British Hypertension Society protocol released in 1993. Eighty-five patients with characteristics outlined in the British Hypertension Society protocol were recruited among those attending our out-patient clinic. Sequential readings were taken for the main validation test. Outcome was classified according to the British Hypertension Society criteria, which are based on four zones of accuracy differing from the mercury standard by 5, 10 and 15 mmHg, or more.

Results The mean blood pressure difference (±1 SD) between device and observers was 0.4 mmHg (SD 0.7) for systolic blood pressure and 0.3 mmHg (SD 0.8) for diastolic blood pressure. Overall, 96% (observer 1) and 95% (observer 2) of readings between device and observers differed by 15 mmHg or less for both systolic and diastolic blood pressure. The device achieved a grade A for both systolic and diastolic blood pressure.

Conclusions This study shows that the A&D UA-705 device satisfies the British Hypertension Society standard for accuracy by achieving a grade A for both systolic and diastolic blood pressure. Blood Press Monit 11:223–227 © 2006 Lippincott Williams & Wilkins.

Keywords: device, home blood pressure measurement, hypertension, validation

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Introduction

The interest in semi-automatic devices for home blood pressure (BP) measurement is supported by the growing evidence that home BP measurements significantly refine cardiovascular risk stratification [1,2].

Among the semi-automatic devices, the models that use oscillometric techniques are increasingly popular. Usually, these devices require little training and may be particularly suitable for patients with infirmities such as arthritis and deafness. Only a few semi-automatic devices, however, successfully passed rigorous validation studies according to internationally established criteria [3]. The list of BP devices that have been tested according to the British Hypertension Society (BHS) protocol and met the BHS criteria is available on the web (http://www.bhsoc.org/Blood_pressure_list.htm).

The BHS provided a standard protocol for validating BP monitors in order to establish their accuracy when compared with standard mercury sphygmomanometers [4]. This protocol, first released in 1990, was subsequently updated in 1993 [4].

We adopted this revised version of the protocol to execute a validation study of the UA-705 compact desktop semi-automatic monitor produced by the A&D Company (Toshimi-ku, Tokyo, Japan) for self-measurement of BP. Such devices measure BP at arm level, using an oscillometric algorithm. Measurement range is 20–280 mmHg for BP and 40–200 beat/min for heart rate. The device works with one battery (1.5 V, type AA). The dimensions of the device are approximately 81 mm × 54 mm × 105 mm and its weight is approximately 120 g excluding the batteries. Operating conditions range from +10 to +40°C and storage conditions from −10 to +60°C. The UA-705 has a large display (BP measurement is displayed as numerals) and a single start button for switching the device on and off. The arm cuff is connected by an air connector plug to a rubber bulb used to pressurize. Deflation is automatic and different cuff sizes are available. The device can store up to 30
measurements for monitoring the trend of BP measurements and the average value. An average of all the stored data is shown at each start up, giving a condensed reading history at a glance.

Data are retained as long as the battery is in the device and measurements can be recalled easily. After each measurement, the device displays automatically, on a bar indicator, a segment based on the current data corresponding to the World Health Organization classification (optimal, normal, high normal and mild, moderate and severe hypertension) [5]. The device also has an irregular heart beat indicator that can help users find an irregular heartbeat.

Methods
We used the revised version of the BHS protocol to validate the device. Briefly, this protocol is based on sequential measurement comparisons. The protocol consisted of four phases and successful completion of each phase was required to continue to the next [4]. In phase 1, pressure calibration of the devices was performed. We received three devices from the manufacturer, who gave a written declaration that the devices were standard production models. Each device underwent dynamic calibration using three observers who were blinded from each other. The device was connected in parallel to two sphygmomanometers, and all three manometers were then connected to a cuff, which was placed around a cylinder. By using the calibration table in the protocol, the widest range of BP applicable to the device was selected. The first observer inflated the cuff and called out at five randomly pre-selected pressure points during deflation. The second observer noted the pressure on the mercury column and the third observer noted the pressure on the device. This procedure was repeated six times, for a total of 30 readings. Readings obtained from observers 2 and 3 were then compared; the difference had to be less than 3 mmHg in at least 28 of the readings.

In phase 2 (in-field phase), the three devices were put into clinical use. Each device underwent at least 400 inflations in the out-patient clinic.

In phase 3, calibration procedures were repeated again after in-field use. At least two of the three devices had to pass calibration successfully in order to continue to phase 4.

In phase 4, one single device was randomly selected for validation. Phase 4 was carried out in 85 study participants recruited according to the criteria outlined by the BHS protocol. The range of BP and number of participants required in each category are shown in Table 1. Exclusion criteria were cardiac arrhythmias or Korotkoff sounds that did not disappear. Two observers were trained for BP measurement with a mercury sphygmomanometer using a CD ROM produced by the BHS. Interobserver accuracy was monitored by comparing differences in simultaneous mercury readings after every 20 patients. The participants were seated for at least 5 min in a warm, quiet room before the measurements were taken. BP measurements were taken, alternating between simultaneous mercury sphygmomanometer readings (by both observers) and the device. The effect of venous congestion and variability of BP were minimized by allowing more than 30 s and less than 1 min between measurements. The first mercury reading was used only to ‘assign’ the patient to one of the predefined pressure ranges (Table 1) and was not used in analysis.

The remaining seven readings (four by mercury sphygmomanometer and three by device) were subsequently used in the sequential analysis according to the BHS protocol [4].

Differences between the device and the observers were then established by calculating three sets of differences for each observer and for systolic and diastolic BP, respectively: (1) the difference between the device reading and the previous mercury reading; and (2) the difference between the device reading and the subsequent mercury reading.

For sequential analysis, the lowest set of differences (one or two as above) for each participant was used to calculate the mean and standard deviation for systolic and diastolic BP separately.

BHS grading was determined by the percentage of differences \( \leq 5 \), \( \leq 10 \) and \( \leq 15 \text{mmHg} \). The BHS protocol indicates that the device needs to grant a grade A or B for both systolic and diastolic BP measurement in order to be recommended (Table 2).

Results
Eighty-five participants were recruited in our out-patient clinic according to the criteria set by the BHS protocol.
At the beginning of validation, interobserver accuracy was satisfactory. Indeed, 98% of readings ranged within 5 mmHg, and 100% within 10 mmHg, for both systolic and diastolic BP. Similar results were noted after every 20 patients analyzed during phase 4.

In the first phase, the difference between readings obtained from observers 2 and 3 was less than 3 mmHg in 30 of the readings.

The second phase was also successfully completed with a good performance of the device. After this phase, the calibration procedure was repeated (phase 3) and all the three devices passed calibration successfully.

To assess static device validation, 85 participants were selected to fulfill criteria specified by the BHS protocol (Table 1). Systolic BP ranged from 85 to 198 mmHg and diastolic BP from 50 to 118 mmHg. The main clinical and demographic characteristics of the participants recruited are listed in Table 3. The mean difference and standard deviation were 0.4 mmHg (7.7) for systolic and 0.3 mmHg (8.2) for diastolic BP in the sequential analysis (Table 4).

Overall, the device achieved an A grade for both systolic and diastolic BP.

An additional tool of analysis, the difference between device and observer readings was plotted against the mean pressure of both for systolic and diastolic BP according to the Bland–Altman [6] method (Figs 1 and 2). Horizontal lines are drawn at the mean difference, and at the mean difference ± 1.96 times the standard deviation of the differences. As depicted in the figures, there was no systematic trend in the differences between device and observers with progressively higher BP values.

All three devices passed a post-validation calibration test, as described previously, by achieving differences within 2 mmHg in 29 out of 30 readings.

**Discussion**

The UA-705 device tested in the present study met the requirements set by the revised version of the BHS protocol [3], which look quite rigorous. Our results show that the device met the requirements for use in adults over a wide range of BP values.

The device achieved a grade ‘A’ for both systolic and diastolic BP and, as shown in Figs 1 and 2, was accurate over a wide range of BP values. Overall, the device was simple to use and readings were easy to read owing to the large screen.

Recently, two other A&D devices (UA-774 and UA-704) have been validated [7,8]. These devices have the same BP determination algorithm as the UA-705 (A&D, written communication). Both devices yielded a BHS A/A grade [7,8].

Current indications for self-measurement of BP at home include screening for ‘white-coat’ hypertension, resistant hypertension, evaluation of long-term follow-up and improving adherence to treatment [9]. Other potential indications include hypertension in the elderly, hypertension in diabetic individuals, and hypertension in

### Table 2 British Hypertension Society grading criteria

<table>
<thead>
<tr>
<th>Cumulative percentage of readings (%)</th>
<th>≤ 5</th>
<th>≤ 10</th>
<th>≤ 15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade A</td>
<td>60</td>
<td>85</td>
<td>95</td>
</tr>
<tr>
<td>Grade B</td>
<td>50</td>
<td>75</td>
<td>90</td>
</tr>
<tr>
<td>Grade C</td>
<td>40</td>
<td>65</td>
<td>85</td>
</tr>
<tr>
<td>Grade D</td>
<td>Worse than C</td>
<td>Worse than C</td>
<td>Worse than C</td>
</tr>
</tbody>
</table>

To obtain a grade, the device must achieve percentages greater than or equal to those reported in the table in the three categories (≤ 5, ≤ 10 and ≤ 15 mmHg).

### Table 3 Main characteristics of participants recruited

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>50 ± 13</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male sex (%)</td>
<td>55</td>
</tr>
<tr>
<td>Systolic blood pressure (mmHg)</td>
<td>139 ± 29</td>
</tr>
<tr>
<td>Diastolic blood pressure (mmHg)</td>
<td>85 ± 19</td>
</tr>
<tr>
<td>Heart rate</td>
<td>73 ± 12</td>
</tr>
</tbody>
</table>

### Table 4 British Hypertension Society grading

<table>
<thead>
<tr>
<th>Systolic blood pressure</th>
<th>≤ 5</th>
<th>≤ 10</th>
<th>≤ 15</th>
<th>Mean (± SD) (mmHg)</th>
<th>Mean (± SD) of differences (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observer 1 A</td>
<td>61</td>
<td>86</td>
<td>96</td>
<td>136.5 (23.3)</td>
<td>0.5 (7.9)</td>
</tr>
<tr>
<td>Observer 2 A</td>
<td>63</td>
<td>86</td>
<td>95</td>
<td>136.7 (23.1)</td>
<td>0.4 (7.7)</td>
</tr>
<tr>
<td>Diastolic blood pressure</td>
<td>≤ 5</td>
<td>≤ 10</td>
<td>≤ 15</td>
<td>83.9 (14.7)</td>
<td>0.3 (8.2)</td>
</tr>
<tr>
<td>Observer 1 A</td>
<td>65</td>
<td>85</td>
<td>96</td>
<td>84.1 (14.8)</td>
<td>0.4 (7.7)</td>
</tr>
<tr>
<td>Observer 2 A</td>
<td>65</td>
<td>87</td>
<td>95</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Observer comparison</td>
<td>A</td>
<td>99</td>
<td>100</td>
<td>100</td>
<td>0.2 (0.7)</td>
</tr>
<tr>
<td>Systolic blood pressure</td>
<td>A</td>
<td>99</td>
<td>100</td>
<td>100</td>
<td>0.1 (0.9)</td>
</tr>
<tr>
<td>Diastolic blood pressure</td>
<td>A</td>
<td>99</td>
<td>100</td>
<td>100</td>
<td></td>
</tr>
</tbody>
</table>

Numbers under the difference between standard and test device denote the percentages of test device readings within ≤ 5, ≤ 10 and ≤ 15 mmHg. The mean blood pressure values by observer and the mean of differences between the test device and the observers are also shown.
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Weight
120 g excluding batteries

List of components
UA-705 device including its cuff, carrying case, one alkaline battery, and instruction manual

Method of BP measurement
Oscillometric

Factors affecting accuracy
Sources of inaccurate measurements may be arrhythmia or noise due to arm or wrist movements

Operator training requirements
The instrumentation does not require specific expertise because it is very easy to operate