Validation of the A&D wrist-cuff UB-511 (UB-512) device for self-measurement of blood pressure

Fabio Angeli, Mariagrazia Sardone, Enrica Angeli, Salvatore Repaci, Roberto Gattobigio and Paolo Verdecchia

Objectives To determine the accuracy of the A&D UB-511 (UB-512) oscillometric wrist-cuff device for self-measurement of blood pressure, the only difference between the two devices being the size of storage memory.

Methods Device evaluation was performed according to the modified British Hypertension Society protocol released in 1993. Eighty-five study participants with characteristics outlined in the British Hypertension Society protocol were recruited among those attending our out-patient clinic. The device was evaluated according to the various steps of the protocol. The non-dominant arm was used for blood pressure measurement. To maintain the wrist at cardiac level during validation, the arm was kept horizontal at the mid-sternum level and supported by a soft table. The wrist was kept extended. Sequential readings were taken for the main validation test. Outcome was classified according to the criteria of the British Hypertension Society recommendations, which are based on four strata of accuracy differing from the mercury standard by 5, 10 and 15 mmHg, or more.

Results The device achieved a British Hypertension Society grade B for systolic and a grade B for diastolic blood pressure. The device tended to overestimate arm blood pressure, the mean difference (± 1 SD) between device and observers being 4.3 ± 8.7 mmHg for systolic blood pressure and 3.7 ± 8.1 mmHg for diastolic blood pressure for observer 2, and 4.4 ± 8.6 mmHg for systolic blood pressure and 3.8 ± 7.9 mmHg for diastolic blood pressure for observer 1. In a logistic regression analysis, age was the sole predictor of an achieved difference between device and mercury column by 5 mmHg or less (hazard ratio 1.020; 95% confidence interval 1.003–1.04; P = 0.024).

Conclusions These data show that the A&D UB-511 (UB-512) device satisfies the British Hypertension Society recommendations with a grade B/B. The device tends to overestimate cuff blood pressure and its accuracy increases with age. Blood Press Monit 11:349–354 © 2006 Lippincott Williams & Wilkins.


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

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The devices used in this study were provided by A&D Co. Ltd., Tokyo, Japan and were chosen at random from the production line.

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Introduction

Although several devices for self-measurement of blood pressure (BP) have been validated according to protocols developed by international scientific societies [1], many models currently available in the market have not yet passed rigorous validation studies [2].

The devices that measure BP below the elbow are currently included in the list of the models not yet supported by proper validation studies. In particular, conflicting data exist on the accuracy of wrist-cuff devices for self-measurement of BP. Several validation studies failed to support the accuracy of wrist devices for clinical use [3–10]. Thus, current hypertension guidelines recommend considering these devices ‘with caution’ [11] or simply state that these devices ‘should be avoided’ [12].

Technological improvements for wrist-cuff devices are warranted [10]. Indeed, wrist BP measurement is generally easy to take and possibly more comfortable than traditional BP measurement at arm level in some categories of individuals including the elderly, handicapped and those with large upper arms.

In the present study, we have used the revised version of the British Hypertension Society (BHS) protocol,
released in 1993 [13], as a directive to determine the accuracy of the A&D Company (Toshimi-ku, Tokyo, Japan) UB-511 (UB-512) wrist BP measuring device.

The UB-511 and UB-512 models are fast and ultra-compact monitors that measure BP at the wrist using an identical oscillometric algorithm; these devices complete BP measurement while inflating the wrist cuff. They have an irregular heart beat indicator that lights up if an irregular beat is detected during the measurement and a BP classification indicator according to current World Health Organization guidelines [12] for detection and treatment of hypertension, which indicates BP position for each measurement (from optimal to severe hypertension).

The only difference between the two devices is the different size of the storage memory (A&D, written communication). The UB-512 has two large sets of large memory for 30 readings for monitoring the trend of measurements. Both UB-511 and UB-512 show an average of all the stored data at each start up. Measurement range is 20–280 mmHg for BP and 40–200 beats/min for heart rate. The device works with two batteries (type AAA) and weighs approximately 82 g excluding the batteries. Data are retained as long as the batteries are in the device and measurements can be recalled easily.

**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 consists of four phases and successful completion of each phase is required to continue to the next one [13].

**Phase 1**

In phase 1, BPs obtained from the device were compared with those obtained with a calibrated mercury column. We received three devices from the manufacturer, who gave written declaration that the devices were standard production models. Each device underwent dynamic calibration by using three observers who were blinded from each other. The device was connected in parallel to two mercury sphygmomanometers and all three manometers were then connected to a cuff that was placed around a cylinder. 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.

**Phase 2**

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.

**Phase 3**

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

**Phase 4**

In phase 4, one single device was randomly selected for validation. Phase 4 was carried out in 85 participants recruited according to 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 during cuff deflation. Two observers were trained for BP measurement with mercury sphygmomanometry 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.

Great care was taken to maintain the arm of the participant horizontal at mid sternum level and supported by a soft table. The wrist was kept extended during validation.

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 [13].

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**Table 1** Minimum number of participants required within each blood pressure group and actual number of participants recruited in each group

<table>
<thead>
<tr>
<th>Systolic BP (mmHg)</th>
<th>Diastolic BP (mmHg)</th>
<th>Minimum number of participants required</th>
<th>Number of participants examined</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;90</td>
<td>&lt;60</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>90–129</td>
<td>60–79</td>
<td>20</td>
<td>24</td>
</tr>
<tr>
<td>130–160</td>
<td>80–100</td>
<td>20</td>
<td>22</td>
</tr>
<tr>
<td>161–180</td>
<td>101–110</td>
<td>20</td>
<td>22</td>
</tr>
<tr>
<td>&gt;180</td>
<td>&gt;110</td>
<td>8</td>
<td>8</td>
</tr>
</tbody>
</table>

BP, blood pressure.
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.
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 \( \leq 15 \) mmHg. The BHS protocol indicates that the device needs to grant a grade A or B for both systolic and diastolic BP measurements in order to be recommended (Table 2).

### Results

At the beginning of validation study, interobserver accuracy was very good, 98% of the readings lying within 5 mmHg and 100% within 10 mmHg for both systolic and diastolic BP. The same results were confirmed after every 20 patients were analyzed during phase 4.

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

The second phase was completed with a good performance and general acceptability of the device by doctors and nurses. At the end of this phase, the calibration procedure (phase 3) was repeated and all the three devices passed calibration successfully.

To assess static device validation, 85 participants attending the out-patient clinic were selected to fulfill criteria specified by the BHS protocol (Table 1). Systolic BP ranged between 85 and 200 mmHg and diastolic BP between 50 and 122 mmHg.

The mean BP difference (±1 SD) between device and observer 1 was 4.4 ± 8.6 mmHg for systolic BP and 3.8 ± 7.9 mmHg for diastolic BP, while the difference between device and observer 2 was 4.3 ± 8.7 mmHg for systolic BP and 3.7 ± 8.1 mmHg for diastolic BP (Table 3).

For systolic BP, 55, 79 and 91% of differences from the mercury column were \( \leq 5 \), \( \leq 10 \) and \( \leq 15 \) mmHg, respectively, for observer 1, and 53, 81 and 92% of differences were \( \leq 5 \), \( \leq 10 \) and \( \leq 15 \) mmHg, respectively, for observer 2.

Overall, the device achieved a B grade for both systolic and diastolic BP.

The difference between device and observer readings was plotted against the mean pressure for systolic and diastolic BP [14] (Figs 1 and 2).

All three devices passed a post-validation calibration test, as described previously by achieving differences falling within 2 mmHg in 28 out of 30 readings.

### Impact of age

The device tended to overestimate cuff BP and the degree of overestimation was inversely associated with age. Figure 3 shows the significant inverse association between age and the difference in systolic BP between device and mercury column \( (r = -0.30; P < 0.0001) \). We also analyzed the possible determinants of device accuracy as defined by a difference of \( \leq 5 \) mmHg between device and mercury column. In a logistic regression analysis, the only independent determinant of device accuracy was the age of the participants (relative ratio 1.020; 95% confidence interval: 1.003–1.04; \( P = 0.024 \)). Sex, height, weight, body mass index and systolic and diastolic BP did not achieve significance to enter the model, with a \( P \) value > 0.05. Figure 4

### Table 2 British Hypertension Society grading criteria

<table>
<thead>
<tr>
<th>Cumulative percentage of readings (%)</th>
<th>( \leq 5 )</th>
<th>( \leq 10 )</th>
<th>( \leq 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 (\( \leq 5 \), \( \leq 10 \), and \( \leq 15 \) mmHg).

### Table 3 Main characteristics of participants recruited

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>55 ± 15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male sex (%)</td>
<td>52</td>
</tr>
<tr>
<td>Systolic blood pressure (mmHg)</td>
<td>141 ± 30</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 3 Main characteristics of participants recruited
shows the probability of a difference of \( \leq 5 \text{ mmHg} \) between the device and mercury column readings according to age.

**Discussion**

The tested device, UB-511 (UB-512), fulfilled the BHS validation criteria for systolic (grade B) and diastolic (grade B) BP. The device, however, provided a slight systematic overestimation of arm BP, with a mean difference between device and observers of 4.3/3.7 mmHg for observer 2, and 4.4/3.8 mmHg for observer 1. The discrepancy between device and observer tended to be greater in the young than in the elderly, age being an independent predictor \((P = 0.024)\) of a small discrepancy \((\leq 5 \text{ mmHg})\).

In the present study, great care was taken to maintain the position of the wrist at heart level. Therefore, the arm
was kept horizontal at the mid-sternum level and supported by a soft table, with the wrist kept extended. A recent report issued by the European Society of Hypertension remarked on the importance of a correct arm position for self-measurement of BP even with wrist-cuff devices [11]. It has been noted that even if many of these devices may be inherently inaccurate, measurements may become even less accurate if the wrist is not held at heart level during measurement [11].

Such a position is supported by a recent study by Mourad and coworkers [15], in which the horizontal position of the arm resulted in a closer association between the wrist and arm BP measurements when compared with the traditional position of the arm (i.e. dependent on a table).

In the present study, in spite of the systematic overestimation of arm BP by the wrist-cuff device, the reasonable agreement between device and mercury column may have been an effect of the horizontal position of the arm, ensuring the wrist remains at heart level during the validation procedure.

A new finding of the present study was the impact of age on the accuracy of the wrist-cuff device. An increased stiffness of large elastic arteries is a well-recognized mechanism of the increase in systolic BP and pulse pressure with age [16,17]. It is well established that the pressure wave shows a progressive amplification from the large elastic arteries to the peripheral arterioles, which tends to decrease with age [18,19]. It could be speculated that some amplification of the pressure wave may have occurred along the arterial tree even between the brachial and wrist level. Following this line of reasoning, wrist BP could overestimate brachial BP to a greater extent in the young than in the elderly.

The possibility that wrist-cuff devices may be particularly suitable for self-measurement of BP in the elderly warrants further investigation. To maintain similar experimental conditions as in the present study, the position of the arm should be maintained horizontal and be supported by a soft table during validation procedures.

Conclusions
The wrist-cuff UB-511 (UB-512) BP monitor achieved BHS grade B/B and hence can be recommended for use in an adult population. The device tends to overestimate cuff BP and its accuracy increases with age. These results cannot be extrapolated to specific sets of individuals including pregnant women and children.

Acknowledgements
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References


**Appendix**

In this appendix, the basic information of the device is reported, following the suggestions of the BSH protocol [13].

**Device identification**

- Compliance with Standard
- The device conforms to the European Directive 93/42 EEC for Medical Products (CE mark 0366).
- Validation studies
- No other validation studies.
- Dimensions
- 0.8 (diameter) × 2.5 (width) × 2.2” (height) (21 × 63 × 56 mm)
- Dimensions with case
- 3.5 (diameter) × 3.4 (width) × 2.7” (height) (89 × 86 × 69 mm)
- Weight
- 2.9 oz (82 g) without batteries
- Display digital
- 1/0.7 mm character height
- Pressurization
- Automatic, using micro-pump
- Deflation
- Constant air release-valve system
- Pressure range
- 20–280 mmHg
- Pulse range
- 40–200 pulses per minute
- Power source
- Two type AAA alkaline batteries (1.5V)
- Operating environment
- 50104 F (10–40°C)
- Storage environment
- 14–140 F (–10–60°C)
- Instructions for use, care, and maintenance
- These are reported in detail in the instruction manual.
- Number of measurements
- 400

**Service facilities**

- Japan: A&D Company Ltd, 3-23-14 Higashi-Ikebukuro, Toshima-ku, Tokyo 170-0013, Japan. Tel: +81 03 5391 6132; fax: +81 03 5391 6148.
- USA: A&D Engineering Inc., 1555 McCandless Drive, Milpitas, CA, 95035 USA. Tel: +1 408 263 5333; fax: +1 408 263 0119.
- Europe: A&D Instruments Ltd, Abingdon Science Park, Abingdon, Oxford OX14 3SY, UK. Tel: +44 (0)1235 550420; fax: +44 (0)1235 550485.
- Italy: INTERMED Srl, Piazza C Donizetti, 1. 20133 Milan, Italy. Tel: +39 02 706 32324; fax: +39 02 706 33770.
- Australia: A&D Mercury Pty Ltd, 32 Dew Street, Thebarton, South Australia 5031, Australia. Tel: +61 8832 3503; fax: +61 88 352 7409.

**List of components**

- UB-511 and UB-512 device including carrying case, two alkaline batteries, and instruction manual.

**Factors affecting accuracy**

- Sources of inaccurate measurements may be noise due to arm or wrist movements.

**Operator training requirements**

- The instrumentation does not require specific expertise because it is very easy to operate.