Validation of the A&D UA-631 (UA-779 Life Source) device for self-measurement of blood pressure and relationship between its performance and large artery compliance

Daniele Longo, Olivo Bertolo, Gianluca Toffanin, Paola Frezza and Paolo Palatini

Objectives To determine the accuracy of the UA-631 (UA-779 Life Source for the American market) blood pressure monitor developed by the A&D Company.

Design Device evaluation was performed using a new protocol proposed by the Working Group on blood pressure monitoring of the European Society of Hypertension (ESH). Monitor performance was assessed in relation to subjects’ gender, age, skinfold thickness, arm circumference, BMI, and elasticity index of large (C1) and small (C2) arteries.

Methods The A&D recorder was assessed according to the various phases of the protocol. Sequential readings were taken for the main validation test. Outcome was classified according to the criteria of ESH recommendations, which are based on four zones of accuracy differing from the mercury standard by 5, 10, 15 mmHg, or more.

Results The main validation test was performed in 66 subjects for a total of 198 device measurements. The A&D monitor passed all three phases both for systolic and diastolic blood pressure (SBP and DBP). Mean blood pressure difference between device and observers was 2 ± 5 mmHg for SBP and 1 ± 3 mmHg for DBP. The absolute discrepancy between device and observers (4 ± 4 mmHg for SBP, and 2 ± 2 mmHg for DBP) was related to age (negatively) and to C1 (positively), but in a multivariable regression analysis only C1 remained a significant independent predictor of the absolute device-observer discrepancy.

Conclusions These data show that the A&D UA-631 device satisfies the new recommended ESH accuracy levels for both SBP and DBP. Its performance seems to be better in subjects with stiffer arteries. Blood Press Monit 7: 1–6 © 2002 Lippincott Williams & Wilkins.

Blood Pressure Monitoring 2002, 7:1-6
Keywords: self-measurement, device, validation, blood pressure, arterial compliance

The authors have no affiliation with or financial involvement in any organization or entity with a direct financial interest in the subject matter or materials discussed in the manuscript.

Potential conflicts of interest: None.

Correspondence and requests for reprints Prof. Paolo Palatini, Dipartimento di Medicina Clinica e Sperimentale, Università di Padova, via Giustinian, 2 - 35126 Padova, Italy.
Tel: +39 49 821 2278; fax: +39 49 875 4179; e-mail: palatini@unipd.it

Received 26 December 2001 Revised 27 March 2002 Accepted 04 April 2002

Introduction
Since the last decade a growing number of models of automatic blood pressure (BP) monitors for home use have become available on the market [1] and only a few have passed clinical tests following international standards such as those of Association for Advancement of Medical Instrumentation (AAMI) [2] or of the British Hypertension Society (BHS) [3]. On the basis of the experience derived from the use of these protocols, they appeared rather complex, time-consuming, and expensive. The Working Group on ambulatory blood pressure monitoring of the European Society of Hypertension recently designed a new protocol for the evaluation of BP measuring devices, in order to make the validation process easier and more accurate [4]. We used these new recommendations to validate the UA-631 (UA-779 Life Source for the American market) oscillometric device from the A&D Company, for self blood pressure measurement.

Methods
Subjects
Sixty-six subjects (33 men) were recruited for the main validation study from outpatient clinics or department wards with the range of blood pressure required by the ESH rules (see Table 1). All agreed to participate in the protocol after they were briefed on the purpose of the study. Their mean ± SD lying systolic blood pressure (SBP) was 142 ± 31 mmHg (range = 84–206), diastolic blood pressure (DBP) 85 ± 18 mmHg (range = 54–118), and their age 49 ± 16 years (range = 18–76). Their body mass index was 25 ± 4 kg/m² (range = 16–32), and circumference of their arm was 29 ± 3 cm (range = 22–32).
Skinfold thickness was measured in triplicate with a Harpenden calliper at the triceps according to the procedure by Edwards *et al.* [5] and was 16.75 mm (range = 8–30). Patients distribution by blood pressure class is reported in Table 1.

**UA-631 and UA-779 Life Source models**

The UA-631 model is a portable recorder (145 x 130 x 55 mm, excluding the cuff), which measures blood pressure at the arm using the oscillometric method. Its measurement range is 20–280 mmHg for blood pressure and 40–200 beats/minute for heart rate. The device works with 4 x 1.5 V alkaline batteries and weighs approximately 320 g excluding the batteries. The UA-631 conforms to European Directive 93/42 EEC for Medical Products, which is evidenced by the CE mark.

The device can store the last thirty measurements in memory. Data is retained as long as the batteries are in the device and measurements can be recalled easily. It has a button for turning on and off and for starting the measurement.

The UA-779 Life Source monitor is identical to the UA-631 model except for its shape which was designed to meet the needs of American customers. Therefore, the validation should be extended to the UA-779 as well, even though the UA-631 model was the only one tested in the present study.

**Static device validation**

Sequential same-arm measurements were performed alternating measurements according to the sequence reported in Table 2. Observers 1 and 2 took measurements with Riva-Rocci sphygmomanometer at the arm using adult cuffs. Bladders had to cover at least 80% of the circumferences. If the difference (for SBP or DBP) between observer 1 and 2 was greater than 4 mmHg the measurement was repeated. The mean of the first observers’ measurement was used to determine the blood pressure class in which the subject was allocated.

The EHS protocol takes into account four zones of accuracy (Table 3) [4]. Zone 0 includes only very accurate measurements: its tolerance is 5 mmHg for SBP and DBP. Zone 1 includes slightly inaccurate measurements in addition to the measurements in zone 0. Its tolerance is 10. Zone 2 includes rather inaccurate measurements in addition to measurements from zones 0 and 1. Its tolerance is 15 mmHg. Zone 3 includes all measurements.

**Estimation of vascular compliance**

Vascular compliance was estimated by means of HDI/Pulsewave CR-2000 (Hypertension Diagnostic Inc), which measures large artery elasticity index (C1) and small artery elasticity index (C2) from radial artery waveforms using the Windkessel method [6,7]. The waveform was obtained with a proprietary tonometer, which was calibrated to the BP values taken by an oscillometric device, which is integrated in the CR-2000. The cuff was placed on the contralateral arm with respect to the tonometer. The values of C1 and C2 given in the output form are averages of the values obtained on individual waveforms during the 30-second recording period [8].

**Results**

**Inter-observer agreement**

Mean differences between the measurements of the two observers were 0.1 ± 2.3 mmHg and −0.1 ± 2.1 mmHg, respectively, for SBP and DBP.

**Phases 1 and 2**

In phase 1 we tested the device on the first 15 subjects for a total of 45 measurements (three measurements for each patient, Table 3). There were five subjects for each BP class shown in Table 1. For SBP, 32, 40, and 44 device measurements fell in zones 0, 1, and 2, respectively. For DBP, 43, 45, and 45 measurements fell in zones 0, 1, and 2, respectively. Therefore, the first phase, which requires at least 25, 35, and 40 successful measurements in zone 0, 1, and 2, respectively, was completed.

In the second phase, we tested the UA-631 on 66 subjects. The new ESH protocol requires a minimum of 33 subjects (11 people for each BP class of Table 1) therefore we conducted separate analyses for the entire study popula-

---

**Table 1 Patients distribution by blood pressure class**

<table>
<thead>
<tr>
<th>Classes of blood pressure</th>
<th>Systolic Blood Pressure (mmHg)</th>
<th>Diastolic Blood Pressure (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Subjects</td>
<td>Subjects</td>
</tr>
<tr>
<td></td>
<td>&lt; 130</td>
<td>&lt; 80</td>
</tr>
<tr>
<td></td>
<td>23</td>
<td>24</td>
</tr>
<tr>
<td></td>
<td>130–160</td>
<td>80–100</td>
</tr>
<tr>
<td></td>
<td>21</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td>&gt; 160</td>
<td>&gt; 100</td>
</tr>
<tr>
<td></td>
<td>22</td>
<td>19</td>
</tr>
</tbody>
</table>

**Table 2 Sequence of blood pressure measurements during validation test**

<table>
<thead>
<tr>
<th>Sequence</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Observers 1 and 2 with mercury standard</td>
</tr>
<tr>
<td>2</td>
<td>Observer 3 with test instrument</td>
</tr>
<tr>
<td>3</td>
<td>Observers 1 and 2 with mercury standard</td>
</tr>
<tr>
<td>4</td>
<td>Observer 3 with test instrument</td>
</tr>
<tr>
<td>5</td>
<td>Observers 1 and 2 with mercury standard</td>
</tr>
<tr>
<td>6</td>
<td>Observer 3 with test instrument</td>
</tr>
<tr>
<td>7</td>
<td>Observers 1 and 2 with mercury standard</td>
</tr>
</tbody>
</table>
tion and for 33 randomly chosen patients who fitted the required BP distribution. In the random sample of 33 subjects the measurements falling in zone 0, 1 and 2, were 72, 89, and 96 for SBP, and 93, 99, and 99 for DBP, respectively. Thus, the second phase was also successfully completed (Phase 2.1). The device showed a good performance also when the entire study sample was taken into account, as it gave 153, 185 and 195 measurements for SBP, and 182, 197 and 198 measurements for DBP, falling in zones 0, 1, and 2, respectively.

Finally, we conducted the analysis required for the last phase (Phase 2.2). Once again, these analyses were conducted separately for the 33 subjects randomly selected and for the whole sample. When the sample of 33 subjects was taken into account, the results were 22 and 1 subjects for SBP and 33 and 0 subjects for DBP, respectively (Table 3). Thus, this last phase was also successfully completed by the device. These results were confirmed by the analysis of the whole sample, as 48 subjects had at least two out of three comparisons in zone 0, and three subjects had no comparisons in zone 0 for SBP. With regard to DBP the results were 63 and 1, respectively.

Limits of agreement for the observers versus device are shown in Figure 1. The device-observer disagreement for the overall group was $2 \pm 5$ mmHg for SBP, and $1 \pm 3$ mmHg for DBP. In other words, the device overestimated SBP by 2 mmHg and DBP by 1 mmHg. The absolute device-observer discrepancy (disregarding the sign) was $4 \pm 4$ mmHg and $2 \pm 2$ mmHg, respectively for SBP and DBP. In univariate regression analyses, no relationship was found between the device-observer blood pressure differences, either in relative or absolute values, and subjects’ BMI, arm circumference, and skinfold thickness at the triceps. However, there was a significant negative association of relative SBP discrepancy and SBP, DBP, pulse pressure, and age and a positive association with arterial compliance (Table 4). In a multivariable regression, the negative association remained significant for age and SBP. For the absolute SBP discrepancy, a relationship was found only for age (negative) and large pressure (positive). However, in a multivariable regression model only arterial compliance remained a significant independent predictor of the absolute SBP difference ($p = 0.02$).

In the subjects divided into tertiles of large artery compliance, the device-observer SBP discrepancy adjusted for the above variables was greater in the tertile of subjects with greater compliance than in the other two groups (Figure 2). No technical problems were encountered during the validation tests.

**Discussion**

Although self-BP measurement is becoming increasingly popular for the management of hypertension among doctors and patients, only a few validated devices are available on the market [1]. The present study demonstrated that the A&D UA-631 (UA-779 Life Source in the U.S.A.) BP monitor met the recently proposed EHS standards for use in the general adult population because it passed all phases of the protocol.

As the accuracy of a device may not be uniform across subgroups of subjects [9,10], we wanted to ascertain whether the precision of the A&D UA-631 varied according to age, BP level, gender, degree of obesity, arm size and adiposity, or arterial stiffness. In the present study, the monitors proved to be accurate across the whole range of age, blood pressure, body mass, arm circumference, and skinfold thickness, and its performance did not vary according to gender. However, a slightly better performance was observed in subjects with stiffer arteries, as in the two tertiles with lower large artery compliance, the device-observer absolute SBP discrepancy was of about 3 mmHg, while in the tertile with greater compliance it was of 5 mmHg. The relative device-observer discrepancy (difference with sign) did not differ between the three groups.
Recent studies have shown that differences in performance may occur with oscillometric devices according to the characteristics of large arteries [11–14]. Generally, arterial stiffness was found to be associated with an overestimation of systolic and diastolic BP by oscillometric devices compared with traditional sphygmomanometry. At variance with those results, in the present study the relative error (difference with sign) of the A&D monitor was not independently related to large artery characteristics indicating that the UA-631 monitor did not overestimate BP in subjects with stiffer arteries. Arterial compliance was a significant independent predictor of the absolute error (difference disregarding the sign) suggesting that the monitor performance was slightly better in subjects with stiffer arteries. The significant negative association between age and absolute error found in univariate regression disappeared in the multivariable regression, indicating that it was due to the association between age and arterial stiffness.

The mechanism by which the UA-631 device works better in subjects with stiffer arteries is difficult to explain. The algorithms by which oscillometric devices identify SBP and DBP are not known publicly. Therefore, we cannot speculate about the effect of arterial wall characteristics on the oscillogram from which SBP and DBP are derived. Whatever the mechanism for this association, the present data suggest that the A&D UA-631 monitor performs

![Bland-Altman plot of the systolic (upper plot) and diastolic (lower plot) observer-device blood pressure difference. The x-axis represents the mean of the device and observer measurements. The y-axis represents the difference between the device and observer measurements. A positive value indicates that the device measurement is greater than the observers’ measurement. The bold line shows the mean difference. The dashed lines show the limits of agreement.](image)

**Table 4** Correlation coefficients between device-auscultatory systolic blood pressure discrepancy and biological variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>C1</th>
<th>C2</th>
<th>SBP</th>
<th>DBP</th>
<th>PP</th>
<th>AGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relative SBP discrepancy</td>
<td>$r = 0.37$</td>
<td>$r = 0.39$</td>
<td>$r = -0.52$</td>
<td>$r = -0.51$</td>
<td>$r = -0.36$</td>
<td>$r = -0.47$</td>
</tr>
<tr>
<td></td>
<td>$p &lt; 0.01$</td>
<td>$p &lt; 0.01$</td>
<td>$p &lt; 0.001$</td>
<td>$p &lt; 0.001$</td>
<td>$p &lt; 0.01$</td>
<td>$p &lt; 0.001$</td>
</tr>
<tr>
<td>Absolute SBP discrepancy</td>
<td>$r = 0.38$</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>$r = -0.31$</td>
</tr>
<tr>
<td></td>
<td>$p &lt; 0.01$</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>$p &lt; 0.01$</td>
</tr>
</tbody>
</table>

C1, large artery elasticity index; C2, small artery elasticity index; SBP, systolic blood pressure; DBP, diastolic blood pressure; PP, pulse pressure.
slightly better in older subjects with stiffer arteries than in their younger counterpart.

In conclusion, this validation trial demonstrated that the A&D UA-631 monitor is a reliable and accurate device for self BP measurement in adult subjects over a wide range of age and blood pressure. Its performance tends to be better in subjects with stiffer arteries.

Acknowledgements
The devices used in this study were donated by INTERMED Srl, Milan, Italy, and were chosen at random from the production line.

Appendix
In this appendix the basic information of the device is reported, following the suggestions of the ESH protocol.

Device identification
UA-631, A&D Company, Tokyo, Japan. In USA the device is called UA-779 Life Source.

Costs
90 USD.

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.

Instructions for use, care, and maintenance
These are reported in detail in the instruction manual.

Power supply
Four alkaline batteries 1.5 V (type LR6, type AA).

Number of measurements
400.

Service facilities
Japan
A&D Company, Limited. 3-23-14 Higashi-Ikebukuro, Toshima-ku, Tokyo 170-0013, Japan. Phone: +81 03 5391 6132; Fax: +81 03 5391 6148.

USA
A&D Engineering, Inc. 1555 McCandless Drive, Milpitas, Ca, 95035 USA. Phone: +1 408 263 5333; Fax: +1 408 263 0119.

Italy
INTERMED Srl, Pzza C Donegani,1. 20133 Milan, Italy. Phone: (2) 706 32324; Fax: (2) 706 33770.

Europe
A&D Instruments Ltd, Abingdon Science Park, Abingdon, Oxford OX14 3YS, UK. Phone: +44 (0)1235 550420; Fax: +44 (0)1235 550485.

Australia
A&D Mercury Pty Ltd, 32 Dew Street, Thebarton, South Australia 5031, Australia. Phone: +61 88 352 3033; Fax: +61 88 352 7409.

Dimensions
145 × 130 × 55 mm excluding cuff.

Weight
320 g excluding batteries.
List of components

UA-631 device including its cuff, carrying case, four alkaline batteries, 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.

References

### Queries and / or remarks

<table>
<thead>
<tr>
<th>Manuscript Page/line</th>
<th>Details required</th>
<th>Author’s response</th>
</tr>
</thead>
<tbody>
<tr>
<td>No queries</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>