Validation of the A&D UM-101 professional hybrid device for office blood pressure measurement according to the International Protocol

George S. Stergiou, Periklis P. Giovas, Charilaos P. Gkinos and Dimitris G. Tzamouranis

Objective **Assessment of the accuracy of the A&D UM-101 mercury-free professional device for auscultatory blood pressure (BP) measurement according to the European Society of Hypertension International Protocol. Further to auscultation, the device has a button to mark readings during deflation.**

Methods **Fifteen adults were included in phase 1 and another 18 in phase 2. Simultaneous BP measurements were taken by two observers (connected mercury sphygmomanometers) four times, sequentially with three measurements using the tested device (two connected tested devices, one used with and the other without the mark button).**

Results **In phase 1, the device produced 44/45/45 measurements within 5/10/15 mmHg, respectively, for systolic BP (SBP) and 39/43/45 for diastolic (DBP). In phase 2.1, 87/97/99 measurements within 5/10/15 mmHg, respectively, for SBP, and 91/97/99 for DBP (using the mark button 65/93/98 for SBP and 76/96/99 for DBP). In phase 2.2, 29 participants had at least two of their SBP differences within 5 mmHg and none had any differences within 5 mmHg, whereas 32 and none, respectively, for DBP (with mark 24/4 participants for SBP; 29/1 for DBP). Mean SBP differences were −1.5 ± 3.5 mmHg and DBP −1.3 ± 3.0 (with mark −3.6 ± 4.2 and −2.8 ± 3.7). The difference in SBP measured by the tested device with versus without using the mark button was 3.0 ± 3.3 mmHg ($P < 0.001$) and DBP 1.9 ± 2.5 mmHg ($P < 0.001$).**

Conclusion **The device comfortably passed the validation protocol requirements. Using the mark button, the device, however, failed to meet the validation criteria. Therefore, it is recommended for clinical use without using the mark button.** ***Blood Press Monit*** **13:37–42 © 2008 Wolters Kluwer Health | Lippincott Williams & Wilkins.**

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Third University Department of Medicine, Hypertension Center, Sotiria Hospital, Athens, Greece

Correspondence to George S. Stergiou, MD, Hypertension Center, Third University Department of Medicine, Sotiria Hospital, 152 Mesogion Avenue, Athens 11527, Greece
Tel: +30 210 776 3117; fax: +30 210 771 9981; e-mail: gstergi@med.uoa.gr

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Introduction

Aiming to environmental protection, mercury is progressively being banned from medical use in several European countries [1,2]. The conventional mercury sphygmomanometer, however, is still regarded as the gold standard for blood pressure (BP) measurement against which any new device should be tested for its accuracy [3–6]. Electronic monitors that measure BP using the oscillometric principle have dominated the market of ambulatory and home monitoring [6,7]. Still no agreement on what will replace the mercury device for the conventional office measurement [3,7], however, exists.

The increasing list of electronic devices that satisfy the currently accepted accuracy criteria [8] suggests that the oscillometric technology for BP measurement is advancing. Automated oscillometric manometers have the additional advantage that avoid the observer prejudice and bias, which are known to be present in self-home and in professional office BP measurements taken using the auscultatory technique [7].

It should be mentioned, however, that the currently used protocols for device validation accept a significant level of inaccuracy to be present. For example, according to the International Protocol of the European Society of Hypertension Working Group on Blood Pressure Monitoring [9], an accurate monitor might have a BP difference greater than 5 mmHg from the reference measurement (using a mercury sphygmomanometer) in 39 of 99 comparisons, a difference greater than 10 mmHg in 24 of 99 and greater than 15 mmHg in nine of 99 comparisons. In addition, for a monitor that fulfills the validation requirements, the protocol allows one out of three participants to have one of their three BP comparisons with a greater than 5 mmHg difference from

the reference measurement and three of 33 participants with all their three comparisons greater than 5 mmHg [9]. Despite these relatively undemanding criteria, only few oscillometric devices have succeeded to pass the International Protocol [7–9]. It appears that, at present, the currently accepted accurate oscillometric monitors might be inadequate as a replacement of the professional mercury sphygmomanometer.

An interesting proposal for a professional device alternative to the mercury sphygmomanometer is the so-called hybrid sphygmomanometer [3,4,6], which has a vertical liquid crystal display (LCD) that resembles a conventional mercury column and works using the auscultatory technique by an observer. The device has the potential to eliminate the terminal digit preference through the use of a button that marks systolic (SBP) and diastolic blood pressure (DBP) readings on the LCD display during cuff deflation.

This paper presents the results of a validation study of the A&D UM-101 (A&D Company, Ltd., Toshima Ku, Tokyo, Japan), which is a mercury-free professional device that has the features of a hybrid sphygmomanometer, according to the European Society of Hypertension International Protocol for Validation of Blood Pressure Measuring Devices in Adults [9].

Methods

Tested device

The A&D UM-101 (A&D Company, Ltd) is a mercury-free device for professional use by the physician in the office or clinic using the auscultatory BP measurement. The device has a vertical LCD display that resembles a conventional mercury column, a standard bulb to inflate the cuff manually and a button for the observer to mark the systolic and diastolic readings on the LCD display during cuff deflation. It allows measurements of BP at a range between 0 and 300 mmHg using the auscultatory method by an observer. In addition, it automatically measures pulse rate during deflation at a range between 30 and 200 beats/min and indicates the value on a numerical display in the end of each measurement. This numerical display also shows the level of cuff pressure as it is progressively reduced during deflation. It is powered by two 1.5-V batteries. Three cuffs are available to be used with the device: small cuff (for arm circumference 17–25 cm), standard (23–33 cm) and large cuff (33–45 cm). The dimensions of the device are similar to those of a conventional mercury sphygmomanometer ($96 \times 66 \times 322$ mm) and its weight is 940 g without batteries. Two devices were obtained from the local distributor for the purpose of the study together with a written declaration that they were standard production models.

Familiarization session

To familiarize themselves with the tested device and particularly with the use of the mark button, the investigators took multiple practice BP measurements in a busy hypertension clinic for a period of 3 weeks. During this phase, it was suspected that the use of the mark button might affect the accuracy of BP measurement. Therefore, a modification of the International Protocol was deemed necessary to allow a separate validation of the device, with and without using the mark button.

Blood pressure measurements

One supervisor and two trained observers experienced in the methodology of BP measurement were involved in this validation study. The observers were retested for agreement in BP measurement according to the British Hypertension Society protocol [10] before the study initiation. Two standard mercury sphygmomanometers (Riester, diplomat-presameter, Rud. Riester GmbH Co. KG, Jungingen, Germany), the components of which have been carefully checked before the study, and a Littman teaching stethoscope were used for simultaneous (Y tube) observer-taken reference BP measurements. The supervisor measured BP with the tested device without using the mark button, and also checked the agreement of BP measurements taken by the two observers who were blinded from each other's readings. To assess the function of the mark button of the device, the tested device used by the supervisor was connected with a second device of the same type (Y tube), which was simultaneously used by one of the observers in random order (again using a Littman teaching stethoscope), always using the mark button (supervisor without using the mark button versus observer using the mark button). For all measurements taken using the tested device, both the observers and the supervisor exclusively used the vertical LCD column to record BP. Observer readings with a difference greater than 4 mmHg were repeated until closer agreement was reached. Two cuffs of the tested device (normal and large) were used for all measurements taken using the tested and the mercury device according to the manufacturer's instructions to fit the arm circumference of each individual. All measurements were taken on the left arm, which was supported at heart level. The protocol was approved by the hospital scientific committee.

Participants

According to the International Protocol, in phase 1 a total of 15 treated or untreated participants are included who fulfill the age, sex and entry BP range requirements (age 30 years or older, at least five men and five women, five participants with entry BP within each of the ranges 90–129 mmHg, 130–160 mmHg and 161–180 for SBP and 40–79 mmHg, 80–100 mmHg and 101–130 mmHg for DBP). If analysis of these data is successful, additional

participants are recruited until a total of 33 participants fulfill the age, sex and entry BP range requirements for phase 2 (age 30 years or older, at least 10 men and 10 women, 11 participants with entry BP within each of the abovementioned BP ranges for SBP and DBP). Participants with sustained arrhythmia or irregular pulse during the validation procedure were excluded. Written informed consent was obtained from all participants who participated in the study.

Procedure

The validation study was conducted in an isolated room where disturbing noise was avoided. Age, sex and arm circumference of each participant was recorded, together with the cuff size used and the date and time of the validation procedure. After 10–15-min sitting rest, BP was measured by the two observers (entry BP). This measurement was used to classify participants into the low, medium and high range, separately for SBP and DBP, as described above. Device detection measurement followed by the supervisor, to ensure that the device was able to measure BP of each individual. The two observers took readings BP1, BP3, BP5 and BP7 using the double-headed stethoscope and the mercury sphygmomanometers. The supervisor took readings BP2, BP4 and BP6 using the test device without using the mark button. The validation analysis was based on the last seven measurements (BP1–BP7).

As mentioned above, for each of the measurements taken by the supervisor using the tested device, a simultaneous measurement was obtained using a second device of the same type (Y tube connected) by one of the observers in random order, always using the mark button. This approach allowed the application of the International Protocol criteria for the assessment of the accuracy of the device twice: (a) without using the mark button (readings BP2, BP4, BP6 taken by the supervisor) and (b) by using the mark button (readings taken by the observers simultaneously with BP2, BP4, BP6).

Analysis

Each pair of observer measurements was averaged and was then subtracted from the device measurement. The absolute differences between BP2–BP1, BP2–BP3, BP4–BP3, BP4–BP5, BP6–BP5 and BP6–BP7 were calculated and paired according to the device reading. For each pair, the one with the smaller difference was used in the analysis. These BP differences were classified into three zones (within 5, 10 and 15 mmHg), separately for SBP and DBP, for 15 participants in phase 1 and for all the 33 in phase 2.1. For each individual participant, the number of readings with a difference within 5 mmHg was also calculated (phase 2.2). To assess the accuracy of the device using the mark button, the analysis of phase 2 was repeated after replacing the supervisor's measurements (BP2, BP4, BP6) with the simultaneous measurements taken by the observers using the second tested device and the mark button. In addition, simultaneous BP readings taken by the supervisor and the observers using the tested devices (with versus without using the mark button) were compared using paired *t*-tests. Statistical analysis was performed using the MINITAB INC Statistical Software (release 13.31) (Stage College, Pennsylvania, USA).

Results

Study participants

A total of 38 participants were recruited from an Outpatients Blood Pressure Clinic and from ambulatory patients and staff of a University Department of Medicine. To facilitate the recruitment procedure, emphasis was placed to recruit participants with high diastolic and low SBP first, and those with high systolic and low diastolic later, as recommended by the International Protocol [9]. One participant was initially excluded because his entry BP was out of the range required for study inclusion and was included later in the study after treatment modification. No participant was excluded due to arrhythmia. In seven BP readings there was a difference between the observers' measurements greater than 4 mmHg. These were repeated to reach closer agreement.

The first 15 participants (45 BP readings), who fulfilled the International Protocol criteria regarding sex and systolic and diastolic entry BP range, were included in the analysis of phase 1. Analysis of phases 2.1 and 2.2 was based on the first 33 participants (99 BP readings), who fulfilled the study inclusion criteria regarding sex and entry BP. The characteristics of participants in study phase 1 and 2 are presented in Table 1. The standard cuff was used in 29 of the 33 participants and the large one in the remaining four.

Validation criteria

The use of the tested device was straightforward and there were no operational problems during the study.

Table 1 **Characteristics of participants in study phase 1 and 2**

	Participants (men/women)	Mean age ± SD years (range)	Mean arm circ ± SD cm (range)	Entry SBP ± SD mmHg (range)	Entry DBP ± SD mmHg (range)
Phase 1	15 (7/8)	45.7 ± 9.9 (32–65)	28.9 ± 3.4 (24–36)	140.7 ± 27.3 (99–177)	88.7 ± 16.4 (62–111)
Phase 2	33 (16/17)	48.7 ± 13.6 (31–83)	28.5 ± 3.3 (23–36)	140.4 ± 25.3 (99–177)	88.5 ± 15.8 (62–115)

Arm circ, arm circumference; DBP, diastolic blood pressure; SBP, systolic blood pressure.

Table 2 Results of the validation analysis (in parentheses results using the mark button of the tested device)

Phase 1	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Recomm.	Mean diff.	SD
Required						
One of	25	35	40			
achieved						
SBP	44	45	45	Continue	−0.9	2.6
DBP	39	43	45	Continue	−1.2	3.8
Phase 2.1	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Recomm.	Mean diff.	SD
Required						
Two of	65	80	95			
All of	60	75	90			
achieved						
SBP	87 (65)	97 (93)	99 (98)	Pass	−1.5 (−3.6)	3.5 (4.2)
DBP	91 (76)	97 (96)	99 (99)	Pass	−1.3 (−2.8)	3.0 (3.7)
Phase 2.2	2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg		Recomm.		
Required						
	≥ 22	≤ 3				
Achieved						
SBP	29 (24)	0 (4)		Pass (Fail)		
DBP	32 (29)	0 (1)		Pass (Pass)		

DBP, diastolic blood pressure; SBP, systolic blood pressure; Recomm, Recommendation; Mean diff, mean difference.

The requirements of the International protocol for phases 1, 2.1 and 2.2 and the results of the validation analysis are presented in Table 2. The differences in BP between the observer readings and the tested device without using the mark button (99 readings) are presented in Fig. 1 and those obtained using the mark button in Fig. 2.

In phase 1, the tested device passed all the three criteria (one required), for both SBP and DBP (Table 2). The mean BP differences between the tested device and the reference method were -0.9 ± 2.6 mmHg for SBP and -1.2 ± 3.8 mmHg for DBP. In phase 2.1, the device comfortably satisfied all the six criteria (five required), for both SBP and DBP (Table 2). The performance of the device significantly deteriorated by using the mark button, yet the device fulfilled the requirements of phase 2.1 (Table 2, numbers in parentheses). The mean BP differences between the device and the reference method in all the 33 participants were -1.5 ± 3.5 mmHg for SBP and -1.3 ± 3.0 mmHg for DBP. Using the mark button these differences were -3.6 ± 4.2 and -2.8 ± 3.7 for SBP and DBP, respectively. In phase 2.2, the device also passed all the protocol criteria for SBP and DBP. Using the mark button the device, however, marginally failed to fulfill the protocol criteria for SBP (Table 2).

The mean difference between simultaneous measurements taken by the supervisor (using the tested device without pressing the mark button) and those taken by the observers (using the second tested device and the mark button) was 3.0 ± 3.3 mmHg (95% confidence intervals 2.4, 3.7; $P < 0.001$) for SBP and 1.9 ± 2.5 mmHg (95% confidence intervals 1.4, 2.4; $P < 0.001$) for DBP.

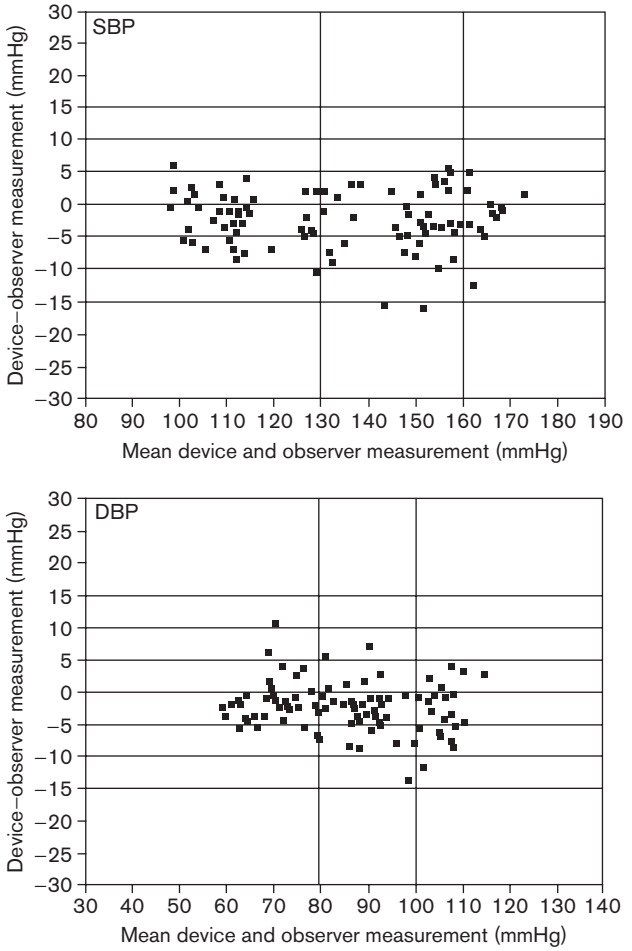
Discussion

This study provides information on the accuracy of the A&D UM-101 professional mercury-free device for auscultatory BP measurement. The study showed that the device comfortably passes all the validation requirements of the International Protocol, provided that it is used by well-trained observers without using the mark button. In fact, the device appeared to be nearly perfect and more accurate than recently validated oscillometric devices [8]. On the other hand, when using the device button to mark the systolic and diastolic readings on the LCD display, the accuracy of the device significantly deteriorated and the device failed to satisfy the phase 2.2 criteria.

The A&D UM-101 professional device is a challenging mercury-free simulation of the conventional mercury sphygmomanometer that remains the gold standard for accurate BP measurement. Apart from addressing the environmental issue with mercury toxicity, the A&D UM-101 has the potential to eliminate another important drawback of the conventional mercury sphygmomanometer. This is due to the use of the auscultatory technique, which is known to be subject to the terminal digit preference and the observer bias [7]. By using a button to mark on the LCD display the BP values, the observer bias might be eliminated. These features of the device (LCD display and mark button) are those of the so called 'hybrid' device [3,4,6].

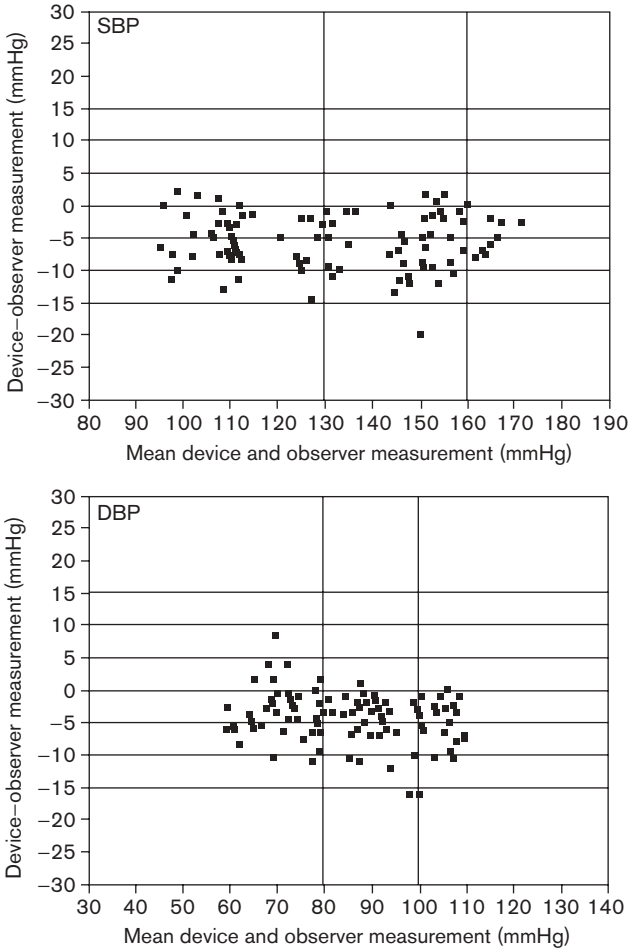
Unfortunately, the reaction time needed for the observer to press the button appeared to have a significant impact on the device accuracy and resulted in systematic underestimation of BP. This drawback was realized by the investigators during the prestudy familiarization

Fig. 1



Scatterplots presenting differences in blood pressure between the observer readings and the tested device used without the mark button (99 readings). Recruitment limits regarding entry blood pressure ranges (low, medium and high) are indicated by the vertical lines DBP, diastolic blood pressure; SBP, systolic blood pressure.

Fig. 2



Scatterplots presenting differences in blood pressure between the observer readings and the tested device used with the mark button (99 readings). Recruitment limits regarding entry blood pressure ranges (low, medium and high) are indicated by the vertical lines DBP, diastolic blood pressure; SBP, systolic blood pressure.

phase and the study design was modified to allow the assessment of the device accuracy with and without using the mark button. As the reaction time is known to increase with age, the performance of the tested device using the mark button is expected to deteriorate if used by physicians older than the study observers (age of observers was 32–35 years) [11].

In conclusion, the A&D UM-101 device used by well-trained observers and the auscultatory technique comfortably passed the validation requirements of the International Protocol. The use of the device button to mark the readings, however, resulted in a significant underestimation of BP. Therefore, the A&D UM-101 device without using the mark button provides an excellent solution for professional mercury-free BP measurement, but has the drawbacks of the auscultatory technique, such as the observer bias and the terminal digit preference.

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