Validation of the A&D UM-212BLE monitor according to ISO 81060-2, 2018: a device with clinically important programmability

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Objective **The objective of this report was to describe the validation of the A&D UM-212BLE automated oscillometric sphygmomanometer to the ISO 81060-2, 2018 protocol. The device is specifically designed for enhanced office and out-of-office programmability.**

Methods **A combined pediatric (n=35) and adult (n=50) population was studied at Clinmark LLC in Louisville, Colorado, USA. Same-arm sequential testing was performed following the ISO 81060-2, 2018 requirements. Five cuffs were tested with a total arm circumference range from 12 to 50 cm. Reference readings were done by two blinded observers performing simultaneous auscultation.**

Results **For validation of Criterion 1 the mean ± SD (mmHg) of the device minus the reference differences were 3.94 ± 6.89 for SBP and 2.09 ± 6.68 for DBP. Both passed the Standard limits for Criterion 2; the systolic(S)SD achieved was 5.56 (5.70 permitted) and the diastolic(D)SD was 6.01 (6.62 permitted). All other Standard requirements were met.**

Conclusions **The UM-212BLE passed all requirements. The features that make this device clinically superior include settings for automated office BP, variable pressure inflation, dual measurement modes (oscillometry, auscultation), the wide range of cuffs tested, automated irregular heartbeat detection, and full validation in a pediatric population. The inclusion of all of these features makes the UM-212BLE a highly attractive device for both office and out-of-office BP estimation.** ***Blood Press Monit*** **28: 113–115**

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Introduction

Currently, the worldwide Standard for validation of automated sphygmomanometers is ISO 81060-2, 2018 [1]. Clinically it is critical that devices estimate blood pressure (BP) accurately for optimal diagnosis and treatment of numerous conditions, especially hypertension. Out-of-office BP readings have become more accepted, as they have been shown to be of great value [2]. To address this evolving clinical trend, A&D Medical has developed and tested the UM-212BLE in adults and children.

Methods

Testing was performed at Clinimark LLC in Louisville, Colorado, USA. Subjects were recruited from the general population; many had been tested before in previous validation studies. Their BPs have been noted to be consistent and often in BP 'bins' required by the Standard, which can be somewhat difficult to fill. The subjects were categorized as required for BP, gender, age, and arm circumference. Subjects with detected cardiac arrhythmias were excluded, as were subjects whose other criteria values were outside of the desired ranges [1].

The UM-212BLE is a battery-operated oscillometric device that has a feature that allows the clinician to listen to K-sounds during cuff deflation. The inflation pressure and deflation speed are adjustable (variable inflation). There are also settings for the estimation of automated office BP [2]. The device has Bluetooth as a standard feature.

Five BP cuffs were tested with arm circumference ranges from 12 to 17 cm, 16 to 24 cm, 22 to 32 cm, 31 to 45 cm, and 41 to 50 cm. The reference auscultatory cuff was of a two-piece construction. The cuff selected for reference measurements fulfilled the bladder width-to-arm circumference ratio of 0.37–0.50 [2].

The protocol followed was that described in the Standard [1]. In brief, the subjects were seated in a quiet room for 5 min with feet flat on the floor, back supported, and the arm with the cuff supported at the level of the heart. No talking was allowed. The procedure used was the same-arm sequential comparing bracketed auscultatory values by two observers blinded both to each other and the device values. There was a 60-s interval between sequential BP estimates. Korotkoff (K) 1 and K5 (last K sound

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audible) sounds were used to determine auscultatory SBP and DBP, respectively.

Table 1 Blood pressure values and differences: distribution of auscultatory reference blood pressure estimates [*n* (%)]

	SBP (mmHg)		DBP (mmHg)
≤100	103 (40.4)	≤60	33 (12.9)
≥140	53 (20.8)	≥85	74 (29.0)
≥160	13 (5.1)	≥100	15 (5.9)

Table 2 Blood pressure values and differences: device minus reference blood pressures

	Criterion 1		Criterion 2	
	Mean	SD	SD permitted	SD achieved
SBP	3.94	6.89	5.70	5.56
DBP	2.09	6.68	6.62	6.01
Allowed	5.0	8.0		

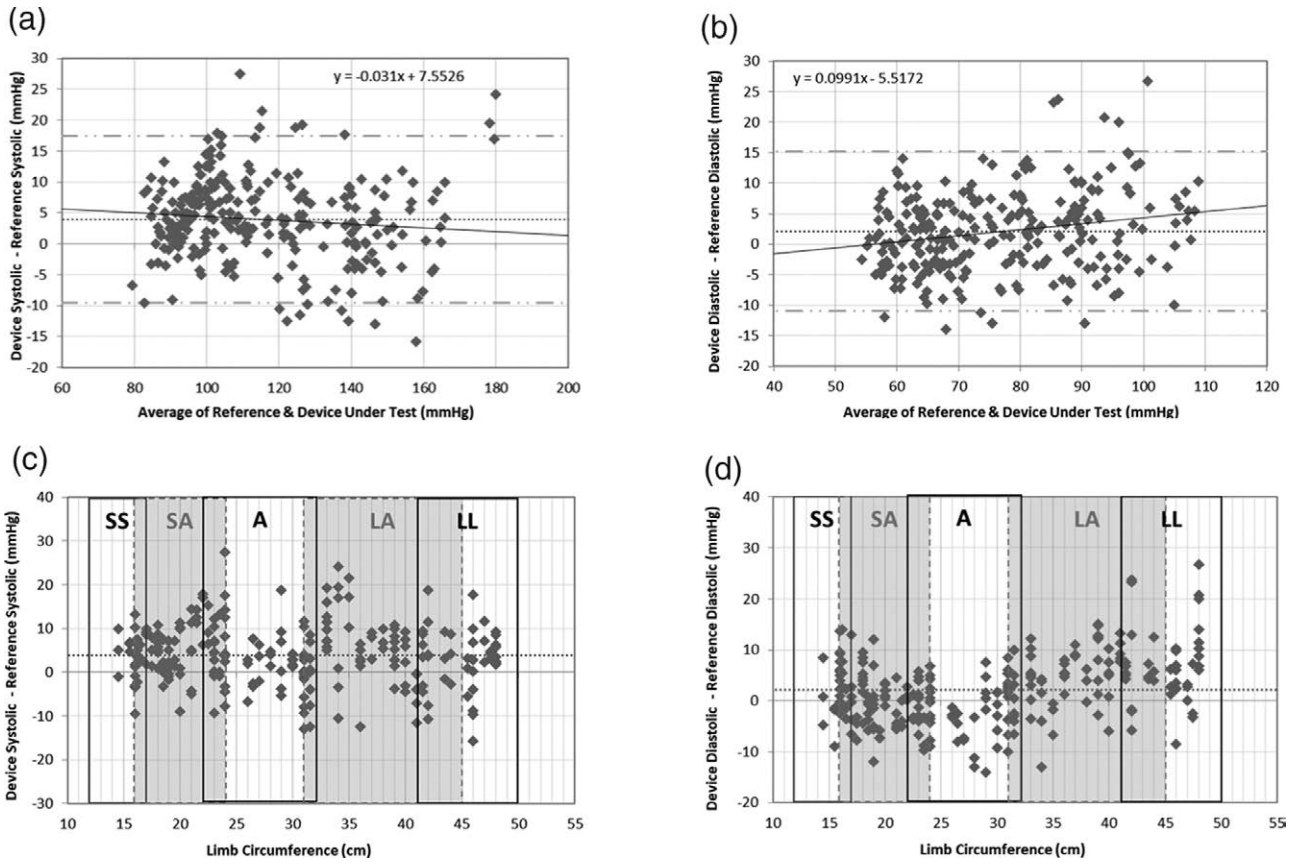
The data reported followed the Standard requirements [1], that is, the mean and SD of the device values minus auscultatory values. Results of Criteria 1 and 2 analyses are reported (Tables 1 and 2). Bland–Altman and Alpert [3] plots were constructed for clinical examination (Fig. 1a–d).

Results

A total of 101 subjects were recruited. Sixteen were not included because of BP variability, arrhythmia, or failure to cooperate. The final study group consisted of 85 subjects (44 females and 41 males) ranging in age from 3 to 80 years old. There were 35 children (ages 3–12) and 50 adults (ages 13–80).

Tables 1 and 2 demonstrate the BP values achieved; all values met or exceeded the Standard requirements. In addition, this table shows the required Criterion 1 and Criterion 2 statistical results. All achieved values passed the Standard requirements. Tables 3 and 4 show the data for the cuff and limb size requirements analyses.

Fig. 1



(a) Bland–Altman plot of SBP; (b) Bland–Altman plot of DBP; (c) Alpert plot of SBP error by limb circumference; (d) Alpert plot of DBP error by limb circumference; SS, extra small; SA, small adult; A, adult; LA, large adult; LL, extra large.

Table 3 Limb size distribution

Distribution of test participants' limb circumference in the full cuff size range (12–50 cm) of the test device						
	Lower octile 12–16.75 cm	First quartile 12–21.5 cm	Second quartile 21.5–31 cm	Third quartile 41.5–55.75 cm	Fourth quartile 55.75–70 cm	Upper octile 62.875–70 cm
ISO required percentage	10%	20%	20%	20%	20%	10%
% of Participants (of 85)	11%	31%	28%	21%	20%	11%
# of Participants	9	26	24	18	17	9
Meets bin requirement	Yes	Yes	Yes	Yes	Yes	Yes

Table 4 Cuff distribution

Distribution of test participant arm circumference in the specified cuff size range of the test device				
Cuff	Specified range (cm)	Minimum required # of participants (of 85 participants)	Number of test participants	Meets requirement
SS	12–17	6	13	Yes
SA	16–24	9	24	Yes
A	22–32	11	16	Yes
LA	31–45	16	18	Yes
LL	41–50	10	14	Yes

A, adult; SS, extra small; SA, small adult; LA, large adult; LL, extra large.

Figure 1a and b shows the Bland–Altman plots for both SBP and DBP. There does not appear to be any systematic trend for inaccuracy across the BP ranges studied. In addition, the newly required plots of device minus reference values on the *y*-axis and arm circumference on the *x*-axis (Alpert plot; [3]) for both SBP and DBP are shown in Fig. 1c and d. There does not appear to be any systematic trend for inaccuracy from the smallest to largest arm circumference for either SBP or DBP.

Discussion

The A&D UM-212BLE passed all of the requirements in the worldwide ISO 81060-2, 2018, Standard. The features that make this device clinically superior include automated office BP, variable inflation, dual measurement (oscillometry, auscultation) modes, a wide range of tested cuffs, and full validation in the pediatric population. As out-of-office BP measurement becomes more critical, having variable programmable automated office BP is desirable. The ability to control both the height of inflation and the speed of deflation will improve subject/patient comfort. If the clinician has concerns about the automated oscillometric readings, he/she can switch to the auscultatory mode and listen to K sounds for confirmation. A wide range of cuff sizes, from 12 to 50 cm, is needed for clinical care of children up to and including large/obese arms. Large arm sizes have become more prevalent in the worldwide population [2]. There are relatively few devices currently available that have been validated in children: the UM-212BLE fills that gap. Another 'added feature' is automated arrhythmia detection to alert the clinician to the possibility of issues with accurate BP estimation.

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Conflicts of interest

There are no conflicts of interest.

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