

Validation of the A&D UM-101 Professional Device for Office BP Measurement According to the International Protocol

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INTRODUCTION

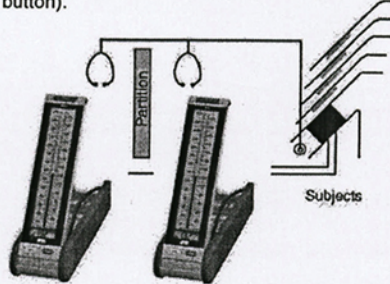
- As mercury is being banned from clinical use, the development of mercury-free professional devices for office BP measurement is needed.
- The A&D UM-101 is a novel professional device for office BP measurement. It has a vertical LCD display that resembles a conventional mercury column, a standard bulb to inflate the cuff manually, and a Mark button to mark the BP readings during cuff deflation.

OBJECTIVE

- To assess the accuracy of the A&D UM-101 mercury-free professional device for auscultatory BP measurement, according to the European Society of Hypertension International Protocol.
- To assess the effect of using the mark button on the device accuracy.

METHODS

- 15 adults were studied in Phase 1 and additional 18 subjects in Phase 2 (total 33).
- Simultaneous BP measurements were taken by 2 trained observers (Y tube connected mercury sphygmomanometers) 4 times, sequentially with 3 measurements taken using the tested device (2 connected tested devices for BP measurement with and without using the mark button).



- Subjects were classified in 3 BP ranges:

	SYSTOLIC	DIASTOLIC
LOW	90-129	40-79
MEDIUM	130-160	80-100
HIGH	161-180	101-130

- The absolute differences between BP2-BP1, BP2-BP3, BP4-BP3, BP4-BP5, BP6-BP5, BP6-BP7 were calculated and paired according to the device reading.

- Phase 2.1 criterion:** BP differences classified into 3 zones (within 5, 10, 15 mmHg), separately for systolic and diastolic BP.

- Phase 2.2 criterion:** Number of readings with a difference within 5 mmHg was calculated for each individual.

RESULTS

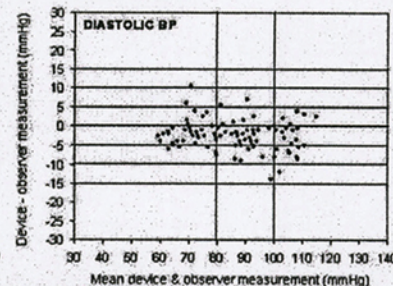
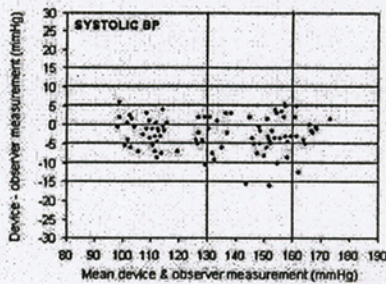
RESULTS OF THE VALIDATION ANALYSIS (in parentheses results using the mark button of the tested device)

SBP, systolic BP
DBP, diastolic BP
Recomm, Recommendation
Mean diff, mean difference

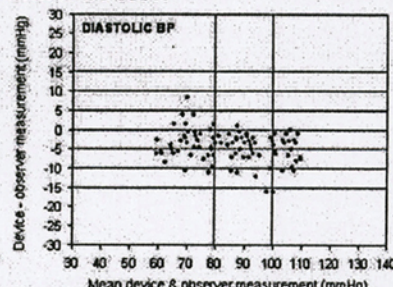
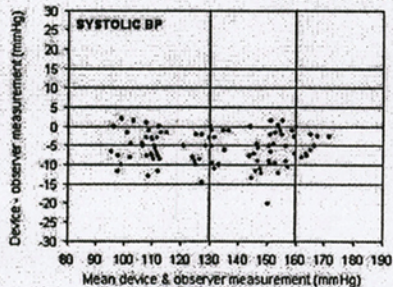
Phase		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Recomm.	Mean diff.	SD
Phase 1	Required	One of 25	35	40			
	Achieved SBP	44	45	45	Continue	-0.9	2.6
	DBP	39	43	45	Continue	-1.2	3.8
Phase 2.1	Required	Two of 65	80	95			
	All of 60	75	90				
	Achieved SBP	87 (65)	97 (93)	99 (98)	Pass	-1.5 (-3.6)	3.5 (4.2)
DBP	91 (76)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

BLAND-ALTMAN PLOTS OF BLOOD PRESSURE DIFFERENCES BETWEEN THE TESTED DEVICE AND THE OBSERVERS

WITHOUT the Mark button



WITH the Mark button



MEAN DIFFERENCES ± SD

WITHOUT Mark button SBP -1.5±3.5 mmHg
DBP -1.3±3.0 mmHg

WITH Mark button SBP -3.6±4.2 mmHg
DBP -2.8±3.7 mmHg

CONCLUSIONS

- The A&D UM-101 professional device comfortably passed all the validation requirements of the International Protocol.
- Using the Mark button the device failed to meet the validation criteria and was shown to underestimate blood pressure.
- The A&D UM-101 device is recommended for clinical use without using the Mark button.

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