Validation of the UEBE Visomat Double Comfort upper arm blood pressure monitor, in auscultation mode, for clinic use and self measurement in a general population, according to the European Society of Hypertension International Protocol revision 2010

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Abstract

The UEBE Visomat Double Comfort, an upper arm blood pressure monitor, in auscultation mode, for clinical use and self measurement, was validated, in a general population, according to the European Society of Hypertension International Protocol revision 2010. The protocol requirements were followed precisely. The device passed all of the requirements and, fulfilling the standards of the protocol, is recommended for clinical use.

Device Details

Brand	UEBE
Model	Visomat Double Comfort
Manufacturer	UEBE
Location	Upper Arm
Method	Auscultation
Purpose	Clinic Measurement
Operation	Fully Automatic
Arm Cuffs	Other cuffs: 23.0 cm to 43.0 cm
Other Features	Combines auscultatory and oscillometric determination of blood pressure. The Auscultatory measurement is the reference procedure.

Methodology

Familiarisation

Forty-one test-measurements were carried out. No problems were encountered.

Recruitment

Hypertensive subjects were recruited from those attending the hypertension clinic in the Medical Policlinic, University of Padua, Italy. All 42 participated immediately and without appointment. The 11 normotensive subjects were recruited from inpatients (four) and from hospital staff (seven). There was some difficulty in recruiting subjects with SBP and DBP in the high range but, other than that, there were no problems.

Screening and Recruitment Details

Screening and Recruitment		Recruitment Ranges				
Total Screened	42			mmHg	All	On Rx
Total Excluded	9		Low	< 90	1	1
Ranges Complete	1			90 - 129	10	
Ranges Adjustment	7	SBP	Medium	130 - 160	12	8
Arrhythmias	0		High	161 - 180	9	7
Device Failure	0			> 180	1	
Poor Quality Sounds	1					
Cuff Size Unavailable	0		Low	< 40	0	1
Observer Disagreement	0			40 - 79	12	
Distribution	0	DBP	Medium	80 - 100	10	6
Other Reasons	0		High	101 - 130	11	9
Total Recruited	33			> 130	0	

Procedure

The European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults was followed precisely.[1] Overseen by an independent supervisor, measurements were recorded by two observers blinded from both each other's readings and from the device readings.

Results

Subject Details

Sex		
Male : Female	18 : 15	
Age (years)		
Range (Low : High)	25 : 88	
Mean (SD)	55.0 (20.2)	
Arm Circumference (cm)		
Range (Low : High)	23.0 : 38.0	
Mean (SD)	29.1 (4.1)	
Cuff for test device		
Other	33	(23.0 - 43.0 cm)
	SBP	DBP
Recruitment BP (mmHg)		
Range (Low : High)	84 : 190	50 : 120
Mean (SD)	140.0 (28.0)	86.6 (17.2)

Observer Measurements in each Recruitment Range

SBP (mmHg)		DBP (mmHg)	
Overall Range (Low : High)	79 : 191	Overall Range (Low : High)	49 : 122
Low (< 130)	33	Low (< 80)	41
Medium (130 – 160)	42	Medium (80 – 100)	34
High (> 160)	24	High (> 100)	24
Maximum Difference	18	Maximum Difference	17

Observer Differences

	SBP (mmHg)	DBP (mmHg)	Repeated measurements
Observer 2 – Observer 1			
Range (Low : High)	-2 : +4	-4 : +4	
Mean (SD)	0.2 (1.9)	0.0 (1.9)	0

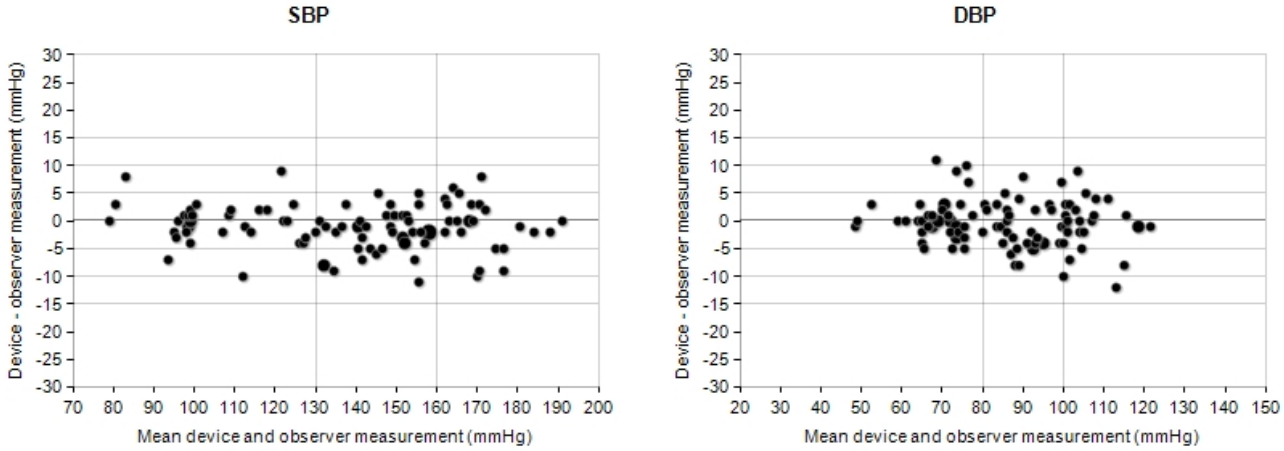
Validation Results

Part 1	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade 1	Mean (mmHg)	SD (mmHg)
Pass Requirements						
Two of	73	87	96			
All of	65	81	93			
Achieved						
SBP	83	98	99	Pass	-1.1	4.0
DBP	85	97	99	Pass	-0.4	4.1

Part 2	2/3 ≤ 5 mmHg	0/3 ≤ 10 mmHg	Grade 2	Grade 3
Pass Requirements	≥ 24	≤ 3		
Achieved				
SBP	31	0	Pass	Pass
DBP	30	0	Pass	Pass

Part 3	Result
	PASS

Plots



Discussion

Recruitment of subjects with high DBP proved to be difficult and accounted for most of the extra screened subjects; this is reflected in the overall distribution, as shown in the DBP plot, in which most of the points are below 115 mmHg. On the other hand, the agreement between observer and device was similar in the three BP ranges and all BP discrepancies were within 15 mmHg.

The visomat double comfort monitor is provided with two operational modalities, a microphonic mode and an oscillometric mode. In the standard operational modality, tested in the present study, the device uses the microphonic method and when a failing auscultatory measurement occurs the oscillometric measurement is taken into account. The UEBE visomat double comfort device used in the microphonic mode fulfilled the validation criteria of the International protocol.

Conclusion

As the device has reached the required standards, it is recommended for clinical and personal use in a general population.

Acknowledgements and Conflict of Interest

Three monitors were supplied for the purposes of the study by the manufacturer who also funded the study. None of the authors has any association with UEBE or has received any personal benefit from UEBE.

References

1. O'Brien E, Atkins N, Stergiou G, Karpettas N, Parati G, Asmar R, Imai Y, Wang J, Mengden T, Shennan A; on behalf of the Working Group on Blood Pressure Monitoring of the European Society of Hypertension. European Society of Hypertension International Protocol revision 2010 for the Validation of Blood Pressure Measuring Devices In Adults. Blood Press Monit 2010;15:23–38.