Validation of the Omron M6W upper arm blood pressure monitor, in oscillometry mode, for self measurement in a general population, according to the European Society of Hypertension International Protocol revision 2010

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Abstract

The Omron M6W(HEM-7213-E), an upper arm blood pressure monitor, in oscillometry 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

Device Details

Brand	Omron
Model	M6W (HEM-7213-E)
Manufacturer	OMRON Healthcare Co., Ltd.
Location	Upper Arm
Method	Oscillometry
Purpose	Clinic Measurement, Self/ Home Measurement
Operation	Fully Automatic
Arm Cuff	Standard Adult: 22.0 cm to 42.0 cm
Other Features	The function to detect body motion.
	The function to guide cuff wrapping.
	The function to detect irregular heartbeat.
	The indicator for blood pressure level.
	Memory capacity for 100 readings for two users
	. 3 readings average value within 10 minutes.
	Confirmation by second sensor that device is accurate.

Methodology

Familiarisation

Hundreds of test-measurements were carried out. No problems were encountered.

Recruitment

Hypertensive subjects were recruited from outpatients clinic in department of cardiology in the Kansai Medical University, Hirakata Hospital (Osaka, Japan). Some participated immediately without appointment. Normotensive subjects were recruited from outpatients and volunteers. There were some difficultlies in recruiting subjects with DBP in the high range.

Screening and Recruitment Details

Screening and Recruitment			Recruitment Ranges				
Total Screened		57			mmHg	All	On Rx
Total Excluded		24		Low	< 90	1	0
Ranges Complete	0				90 - 129	11	
Ranges Adjustment	0		SBP	Medium	130 - 160	10	2
Arrhythmias	2			High	161 - 180	11	3
Device Failure	0				> 180	0	
Poor Quality Sounds	0						
Cuff Size Unavailable	0			Low	< 40	0	1
Observer Disagreement	0				40 - 79	10	
Distribution	0		DBP	Medium	80 - 100	11	2
Other Reasons	22			High	101 - 130	12	2
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	19 : 14	
Age (years)		
Range (Low : High)	28 : 77	
Mean (SD)	50.8 (10.1)	
Arm Circumference (cm)		
Range (Low : High)	22.8 : 39.7	
Mean (SD)	31.0 (4.1)	
Cuff for test device		
Standard	33	(22.0 - 42.0 cm)
	SBP	DBP
Recruitment BP (mmHg)		
Range (Low : High)	88 : 180	48 : 120
Mean (SD)	141.7 (25.6)	90.3 (16.8)

Observer Measurements in each Recruitment Range

SBP (mmHg)		DBP (mmHg)	
Overall Range (Low : High)	90 : 178	Overall Range (Low : High)	49 : 120
Low (< 130)	34	Low (< 80)	33
Medium (130 – 160)	42	Medium (80 – 100)	37
High (> 160)	23	High (> 100)	29
Maximum Difference	19	Maximum Difference	8

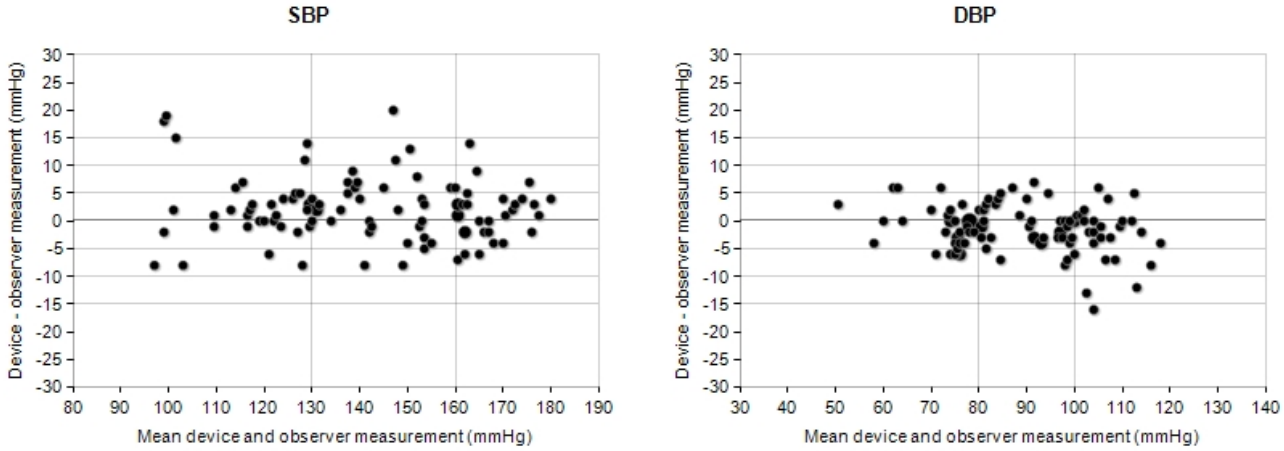
Observer Differences

	SBP (mmHg)	DBP (mmHg)	Repeated measurements
Observer 2 – Observer 1			
Range (Low : High)	-2 : +2	-2 : +2	
Mean (SD)	0.1 (1.3)	0.1 (1.3)	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	69	90	96	Pass	2.2	5.8
	DBP	78	96	98	Pass	-1.3	4.2
Part 2		2/3 ≤ 5 mmHg		0/3 ≤ 10 mmHg	Grade 2		Grade 3
	Pass Requirements	≥ 24		≤ 3			
	Achieved						
	SBP	27		2	Pass		Pass
	DBP	28		2	Pass		Pass
Part 3							Result
							PASS

Plots



Discussion

Recruitment of subjects with high BP, particularly high DBP, proved to be difficult and accunted 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 115mmHg.

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 OMRON Healthcare Co., Ltd. who also funded the study. None of the authors has any association with OMRON Healthcare Co., Ltd. or has received any personal benefit from OMRON Healthcare Co., Ltd.

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.