Validation of the OMRON HEM-7251G upper arm blood pressure monitor, in oscillometry 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 OMRON HEM-7251G, 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 for clinical use.

Device Details

Brand	OMRON
Model	HEM-7251G
Manufacturer	OMRON Healthcare Co., Ltd.
Location	Upper Arm
Method	Oscillometry
Purpose	Clinic Measurement, Self/ Home Measurement
Operation	Fully Automatic
Arm Cuff	17.0 cm to 32.0 cm
Other Features	The function to guide cuff wrapping
	Memory capacity for 90 readings for two users
	3rd generation of mobile telecommunications technology to connect with the dedicated server
	The function to measure room temperature

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 difficultlites in recruiting subjects with DBP with in the high range.

Screening and Recruitment Details

Screening and Recruitment		Recruitment Ranges				
Total Screened	48			mmHg	All	On Rx
Total Excluded	15		Low	< 90	0	3
Ranges Complete	0			90 - 129	10	
Ranges Adjustment	0	SBP	Medium	130 - 160	11	7
Arrhythmias	4		High	161 - 180	9	3
Device Failure	0			> 180	3	
Poor Quality Sounds	1					
Cuff Size Unavailable	2		Low	< 40	0	4
Observer Disagreement	0			40 - 79	12	
Distribution	0	DBP	Medium	80 - 100	10	5
Other Reasons	8		High	101 - 130	11	4
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	16 : 17		
Age (years)			
Range (Low : High)	28 : 70		
Mean (SD)	51.3 (9.8)		
Arm Circumference (cm)			
Range (Low : High)	22.6 : 31.4		
Mean (SD)	28.1 (2.4)		
Cuff for test device			
Other	33	(17.0 - 32.0 cm)	
	SBP	DBP	
Recruitment BP (mmHg)			
Range (Low : High)	104 : 212	55 : 112	
Mean (SD)	147.3 (26.0)	88.9 (16.5)	

Observer Measurements in each Recruitment Range

SBP (mmHg)		DBP (mmHg)	
Overall Range (Low : High)	98 : 191	Overall Range (Low : High)	49 : 120
Low (< 130)	32	Low (< 80)	34
Medium (130 – 160)	39	Medium (80 – 100)	35
High (> 160)	28	High (> 100)	30
Maximum Difference	11	Maximum Difference	5

Observer Differences

	SBP (mmHg)	DBP (mmHg)	Repeated measurements
Observer 2 – Observer 1			
Range (Low : High)	-4 : +4	-4 : +4	
Mean (SD)	0.2 (1.5)	0.3 (1.5)	0

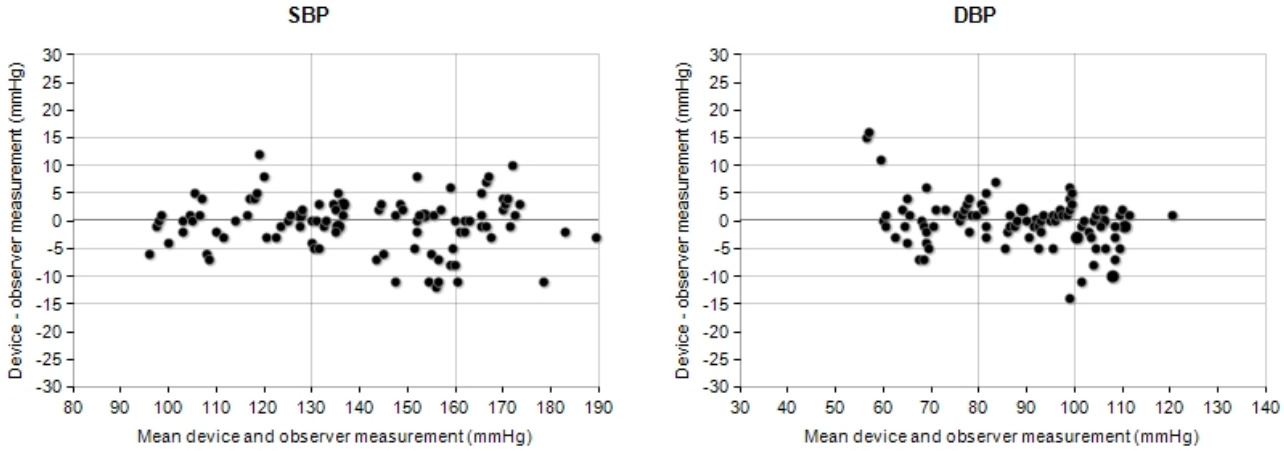
Validation Results

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	77	92	99	Pass	-0.6	4.7
	DBP	85	94	98	Pass	-0.2	4.4

Part 2		2/3 ≤ 5 mmHg	0/3 ≤ 10 mmHg	Grade 2	Grade 3
	Pass Requirements	≥ 24	≤ 3		
	Achieved				
	SBP	26	1	Pass	Pass
	DBP	31	1	Pass	Pass

Part 3	Result
	PASS

Plots



Discussion

Recruitment of subjects with high BP, particularly 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 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

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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.