

Validation of the Omron HEM-7320F 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-7320F, 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-7320F
Manufacturer	Omron Healthcare Co.,Ltd
Location	Upper Arm
Method	Oscillometry
Purpose	Clinic Measurement, Self/ Home Measurement
Operation	Fully Automatic
Arm Cuff	Standard Adult: 17.0 cm to 36.0 cm
Other Features	The function to guide cuff wrapping, Memory capacity for 90 readings, 3 readings average value within 10 minutes, morning/evening average, The indicator for blood pressure level, The function to detect body motion, The function to detect irregular heartbeat, Near field communication to connect with Personal computer and smartphone.



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 Knasai Medical University, Hirakata Hospital (Osaka, Japan). Some participated immediately without appointment. Normotensive subjects were recruited from outpatients and volunteers. There were some difficulties in recruiting subjects with DBP in the high range.

Screening and Recruitment Details

Screening and Recruitment			Recruitment Ranges		
Total Screened	41		mmHg	All	On Rx
Total Excluded	8		< 90	1	0
Ranges Complete	0		Low	90 - 129	10
Ranges Adjustment	0	SBP	Medium	130 - 160	11
Arrhythmias	2		High	161 - 180	10
Device Failure	0		> 180	1	1
Poor Quality Sounds	0				
Cuff Size Unavailable	1		Low	< 40	0
Observer Disagreement	0		40 - 79	11	1
Distribution	0	DBP	Medium	80 - 100	12
Other Reasons	5		High	101 - 130	10
Total Recruited	33		> 130	0	1

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)	36 : 72	
Mean (SD)	50.3 (11.0)	
Arm Circumference (cm)		
Range (Low : High)	19.2 : 35.3	
Mean (SD)	27.7 (5.7)	
Cuff for test device		
Standard	33	(17.0 - 36.0 cm)
	SBP	DBP
Recruitment BP (mmHg)		
Range (Low : High)	88 : 208	50 : 128
Mean (SD)	138.9 (29.8)	88.0 (20.7)

Observer Measurements in each Recruitment Range

SBP (mmHg)	DBP (mmHg)
Overall Range (Low : High)	Overall Range (Low : High)
86 : 185	50 : 128
Low (< 130)	Low (< 80)
41	34
Medium (130 – 160)	Medium (80 – 100)
33	37
High (> 160)	High (> 100)
25	28
Maximum Difference	Maximum Difference
16	9

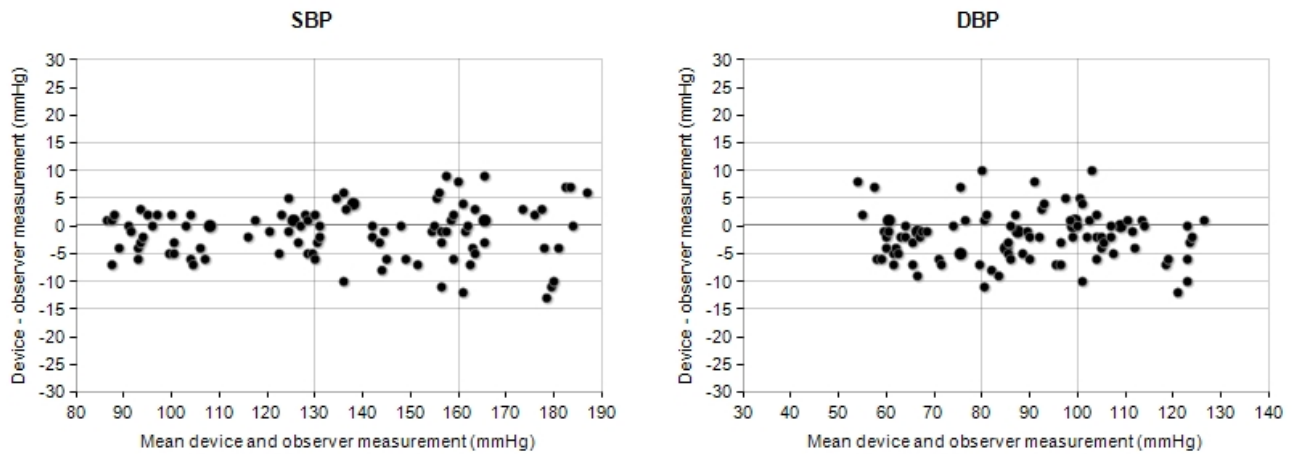
Observer Differences

	SBP (mmHg)	DBP (mmHg)	Repeated measurements
Observer 2 – Observer 1			
Range (Low : High)	-4 : +4	-4 : +4	
Mean (SD)	0.2 (1.6)	0.3 (1.6)	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	73	95	99	Pass	-0.9	4.7
DBP	71	97	99	Pass	-1.9	4.4
Part 2	2/3 ≤ 5 mmHg	0/3 ≤ 10 mmHg	Grade 2	Grade 3		
Pass Requirements						
	≥ 24	≤ 3				
Achieved						
SBP	27	1	Pass			Pass
DBP	26	2	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 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

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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.