

Validation of the OMRON M6 AC (HEM-7322-E) 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 M6 AC (HEM-7322-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 for clinical use.

Device Details

Brand	OMRON
Model	M6 AC (HEM-7322-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 guide cuff wrapping, Memory capacity for 100 readings and 2users, 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.



Methodology

Familiarisation

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

Recruitment

Hypertensive subjects were recruited from outpatients clinic in the Department of Cardiology in Kansai 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	40		mmHg	All	On Rx
Total Excluded	7		< 90	0	1
Ranges Complete	0	Low	90 - 129	11	1
Ranges Adjustment	0	SBP	Medium 130 - 160	11	2
Arrhythmias	4		High 161 - 180	8	1
Device Failure	0		> 180	3	
Poor Quality Sounds	3				
Cuff Size Unavailable	0		< 40	0	2
Observer Disagreement	0		Low 40 - 79	10	
Distribution	0	DBP	Medium 80 - 100	12	2
Other Reasons	0		High 101 - 130	10	
Total Recruited	33		> 130	1	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	20 : 13	
Age (years)		
Range (Low : High)	28 : 71	
Mean (SD)	48.7 (11.5)	
Arm Circumference (cm)		
Range (Low : High)	22.2 : 41.8	
Mean (SD)	31.4 (5.7)	
Cuff for test device		
Standard	33	(22.0 - 42.0 cm)
	SBP	DBP
Recruitment BP (mmHg)		
Range (Low : High)	92 : 188	46 : 133
Mean (SD)	144.9 (26.7)	90.2 (19.0)

Observer Measurements in each Recruitment Range

SBP (mmHg)	DBP (mmHg)
Overall Range (Low : High)	Overall Range (Low : High)
84 : 188	48 : 128
Low (< 130)	Low (< 80)
34	24
Medium (130 – 160)	Medium (80 – 100)
42	40
High (> 160)	High (> 100)
23	35
Maximum Difference	Maximum Difference
19	16

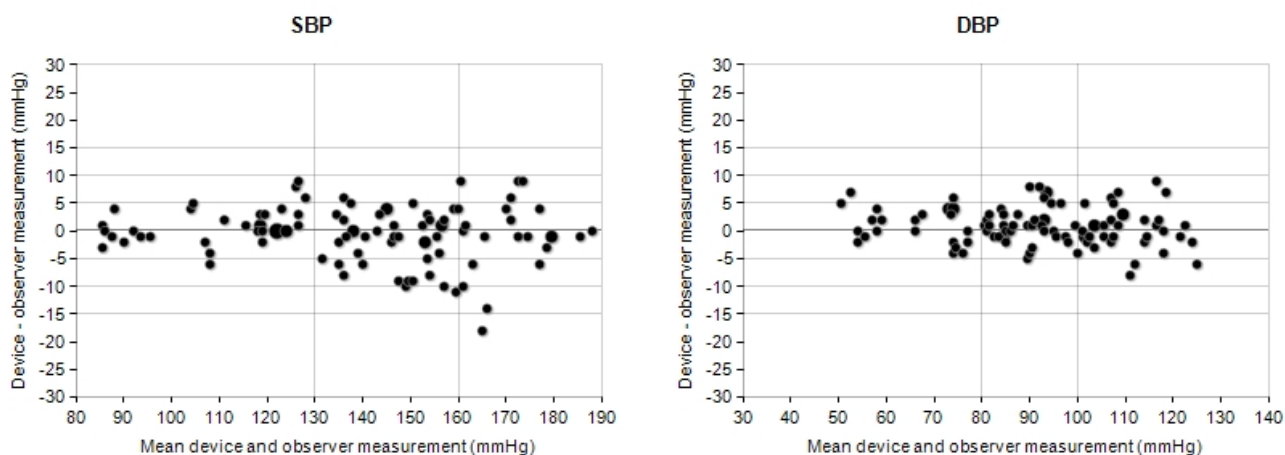
Observer Differences

	SBP (mmHg)	DBP (mmHg)	Repeated measurements
Observer 2 – Observer 1			
Range (Low : High)	-2 : +4	-4 : +4	
Mean (SD)	0.3 (1.3)	0.0 (1.4)	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	75	96	98	Pass	-0.5	5.0
DBP	85	99	99	Pass	1.1	3.4
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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	28	1	Pass			Pass
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Part 3						Result
						PASS

Plots



Discussion

No specific problems were encountered during validation and distribution conditions were fulfilled. But recruitment of subjects with high BP, particularly high DBP, was difficult.

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

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

The monitor was 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.