Validation of the OMRON M6 Comfort (HEM-7321-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

Hakuo Takahashi, Toyohiko Yokoi and Masamichi Yoshika

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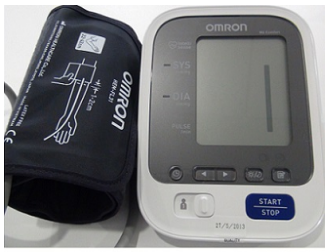
Department of Clinical Sciences and Laboratory Medicine, Kansai Medical University, Hirakata Osaka, Japan

Correspondence to Professor Hakuo Takahashi, MD, PhD, Department of Clinical Sciences and Laboratory Medicine, Kansai Medical University, Shin-machi 2-5-1, Hirakata Osaka 573-1010, Japan

Tel: +81 72 804 2691; e-mail: takahash@hirakata.kmu.ac.jp

Abstract

The OMRON M6 Comfort (HEM-7321-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 Comfort (HEM-7321-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 2 users, 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 heatbeat.

Methodology

Familiarisation

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

Recruitment

Hypertesive 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 difficultlies in recruiting subjects with DBP in the high range.

Screening and Recruitment Details

Screening and Recruitment		Recruitment Ranges				
Total Screened	43			mmHg	All	On Rx
Total Excluded	10		Low	< 90	2	1
Ranges Complete	0			90 - 129	9	
Ranges Adjustment	0	SBP	Medium	130 - 160	11	2
Arrhythmias	2		High	161 - 180	10	1
Device Failure	0			> 180	1	
Poor Quality Sounds	2					
Cuff Size Unavailable	0		Low	< 40	0	0
Observer Disagreement	0			40 - 79	11	
Distribution	0	DBP	Medium	80 - 100	12	3
Other Reasons	6		High	101 - 130	10	1
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	21 : 12	
Age (years)		
Range (Low : High)	28 : 79	
Mean (SD)	50.4 (11.1)	
Arm Circumference (cm)		
Range (Low : High)	24.2 : 41.2	
Mean (SD)	30.9 (4.5)	
Cuff for test device		
Standard	33	(22.0 - 42.0 cm)
	SBP	DBP
Recruitment BP (mmHg)		
Range (Low : High)	84 : 189	49 : 119
Mean (SD)	139.8 (30.7)	86.8 (19.1)

Observer Measurements in each Recruitment Range

SBP (mmHg)		DBP (mmHg)	
Overall Range (Low : High)	84 : 186	Overall Range (Low : High)	48 : 120
Low (< 130)	35	Low (< 80)	35
Medium (130 – 160)	37	Medium (80 – 100)	30
High (> 160)	27	High (> 100)	34
Maximum Difference	10	Maximum Difference	5

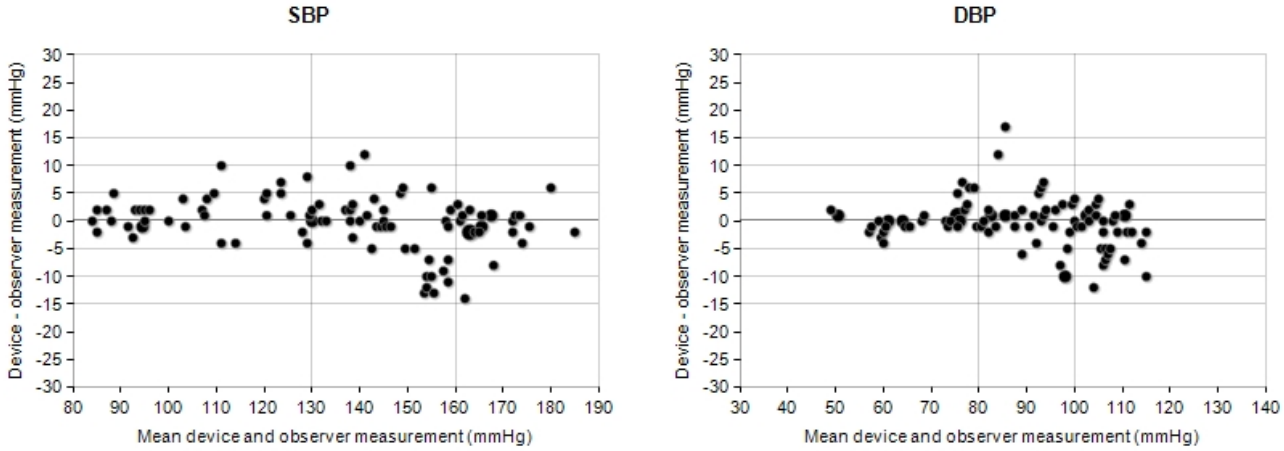
Observer Differences

	SBP (mmHg)	DBP (mmHg)	Repeated measurements
Observer 2 – Observer 1			
Range (Low : High)	-4 : +4	-4 : +4	
Mean (SD)	-0.1 (1.6)	0.2 (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	80	93	99	Pass	-0.3	4.8
	DBP	82	96	98	Pass	-0.2	4.2
Part 2		2/3 ≤ 5 mmHg		0/3 ≤ 10 mmHg	Grade 2		Grade 3
	Pass Requirements	≥ 24		≤ 3			
	Achieved						
	SBP	29		2	Pass		Pass
	DBP	28		1	Pass		Pass
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.