Validation of the OMRON RS6 (HEM-6221-E) wrist 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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Keywords: blood pressure, device, European Society of Hypertension, guideline, measurement

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Abstract

The OMRON RS6 (HEM-6221-E), a wrist 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	RS6 (HEM-6221-E)
Manufacturer	OMRON HEALTHCARE Co., Ltd
Location	Wrist
Method	Oscillometry
Purpose	Clinic Measurement, Self/ Home Measurement
Operation	Fully Automatic
Wrist Cuff	13.5 cm to 21.5 cm
Other Features	The function to guide cuff wrapping
	The function to guide measurement posture
	Memory capacity for 90 readings
	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 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	41			mmHg	All	On Rx
Total Excluded	8		Low	< 90	0	0
Ranges Complete	0			90 - 129	11	
Ranges Adjustment	0	SBP	Medium	130 - 160	11	5
Arrhythmias	4		High	161 - 180	8	2
Device Failure	0			> 180	3	
Poor Quality Sounds	1					
Cuff Size Unavailable	0		Low	< 40	0	0
Observer Disagreement	0			40 - 79	12	
Distribution	0	DBP	Medium	80 - 100	11	2
Other Reasons	3		High	101 - 130	9	5
Total Recruited	33			> 130	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	21 : 12	
Age (years)		
Range (Low : High)	28 : 70	
Mean (SD)	49.5 (11.6)	
Arm Circumference (cm)		
Range (Low : High)	13.5 : 21.2	
Mean (SD)	17.8 (2.2)	
Cuff for test device		
Wrist	0	(13.5 - 21.5 cm)
	SBP	DBP
Recruitment BP (mmHg)		
Range (Low : High)	94 : 226	51 : 134
Mean (SD)	142.1 (32.0)	86.8 (21.7)

Observer Measurements in each Recruitment Range

SBP (mmHg)		DBP (mmHg)	
Overall Range (Low : High)	89 : 226	Overall Range (Low : High)	48 : 144
Low (< 130)	40	Low (< 80)	38
Medium (130 – 160)	32	Medium (80 – 100)	30
High (> 160)	27	High (> 100)	31
Maximum Difference	13	Maximum Difference	8

Observer Differences

	SBP (mmHg)	DBP (mmHg)	Repeated measurements
Observer 2 – Observer 1			
Range (Low : High)	-2 : +4	-4 : +4	
Mean (SD)	0.0 (1.4)	0.2 (1.5)	0

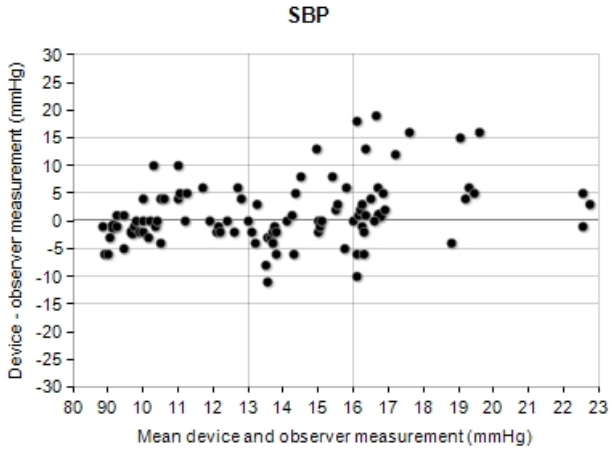
Validation Results

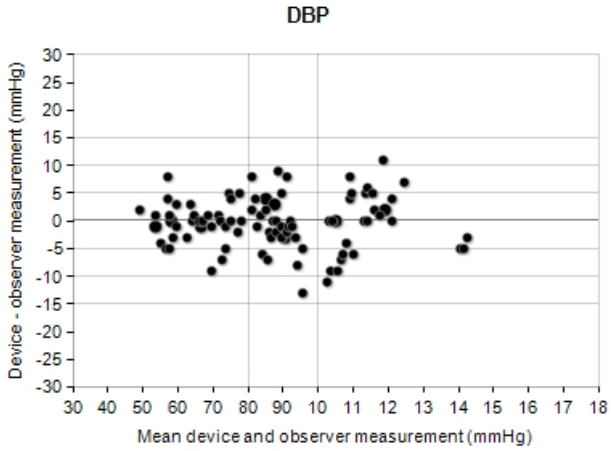
Part 1		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade 1	Mean (mmHg)	SD (mmHg)
	Pass Requirements						
	Two of	73	87	96			
	All of	65	81	93			
	Achieved						
	SBP	73	90	95	Pass	1.3	5.8
	DBP	79	96	99	Pass	-0.3	4.5

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	29	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 the points are below 115mmHg.

Conclusion

As the device has reached the required standards, it is recommended for personal use provided the wrist is supported according to the manufacturer's instructions.

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.