Validation of the OMRON RS3 (HEM-6130-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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Abstract

The OMRON RS3 (HEM-6130-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	RS3 (HEM-6130-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	An indicator for blood pressure level
	A function to guide cuff wrapping
	Memory capacity for 60 readings
	3 readings average value within 10 minutes
	A function to detect body motion
	A 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		82			mmHg	All	On Rx
Total Excluded		49		Low	< 90	0	1
Ranges Complete	0				90 - 129	11	
Ranges Adjustment	0		SBP	Medium	130 - 160	10	3
Arrhythmias	7			High	161 - 180	9	4
Device Failure	0				> 180	3	
Poor Quality Sounds	1						
Cuff Size Unavailable	0			Low	< 40	0	1
Observer Disagreement	0				40 - 79	11	
Distribution	0		DBP	Medium	80 - 100	12	4
Other Reasons	41			High	101 - 130	10	3
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	15 : 18	
Age (years)		
Range (Low : High)	32 : 75	
Mean (SD)	49.8 (11.8)	
Arm Circumference (cm)		
Range (Low : High)	13.6 : 20.8	
Mean (SD)	17.0 (2.2)	
Cuff for test device		
Wrist	0	(13.5 - 21.5 cm)
	SBP	DBP
Recruitment BP (mmHg)		
Range (Low : High)	94 : 209	52 : 120
Mean (SD)	143.7 (31.1)	86.6 (19.9)

Observer Measurements in each Recruitment Range

SBP (mmHg)		DBP (mmHg)	
Overall Range (Low : High)	84 : 184	Overall Range (Low : High)	49 : 120
Low (< 130)	37	Low (< 80)	33
Medium (130 – 160)	39	Medium (80 – 100)	35
High (> 160)	23	High (> 100)	31
Maximum Difference	16	Maximum Difference	4

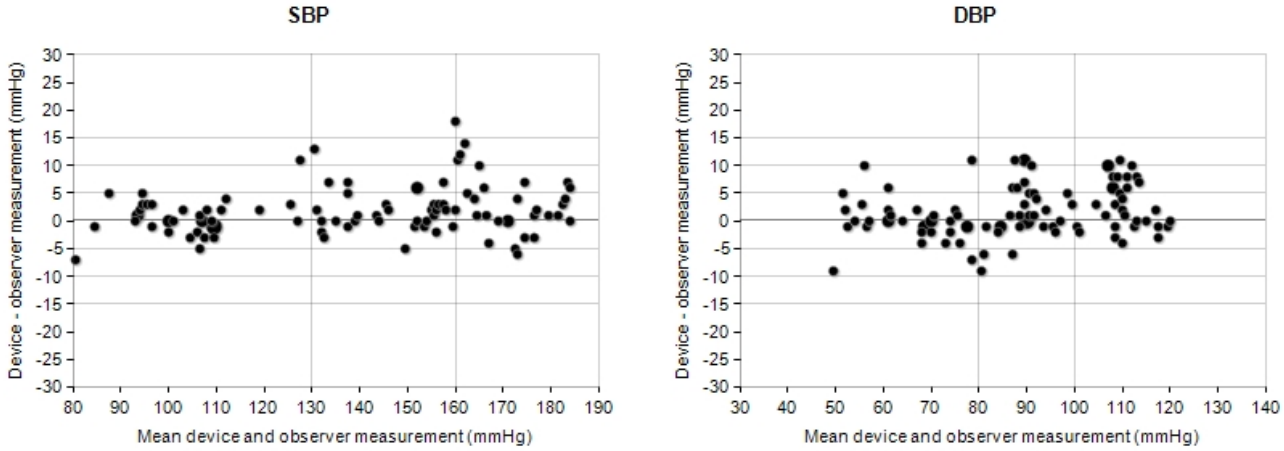
Observer Differences

	SBP (mmHg)	DBP (mmHg)	Repeated measurements
Observer 2 – Observer 1			
Range (Low : High)	-4 : +4	-4 : +4	
Mean (SD)	-0.4 (1.6)	-0.3 (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	81	93	98	Pass	1.8	4.3
	DBP	72	94	99	Pass	1.7	4.5
Part 2		2/3 ≤ 5 mmHg		0/3 ≤ 10 mmHg	Grade 2		Grade 3
	Pass Requirements	≥ 24		≤ 3			
	Achieved						
	SBP	27		0	Pass		Pass
	DBP	26		3	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.