

Validation of the OMRON RS8 (HEM-6310F-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

Hakuo Takahashi, Toyohiko Yokoi and Masamichi Yoshika

Keywords: blood pressure, device, European Society of Hypertension, guideline, measurement

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 2-3-1, Hirakata Osaka 573-1191, Japan

Tel: +81 72 804 2773; e-mail: takahash@hirakata.kmu.ac.jp

Abstract

The OMRON RS8 (HEM-6310F-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	RS8 (HEM-6310F-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 100 readings for two users, 3 readings average value within 10 minutes, The indicator for blood pressure level, The graph function of blood pressure trend, 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 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	43		mmHg	All	On Rx
Total Excluded	10		< 90	1	0
Ranges Complete	0		Low 90 - 129	10	0
Ranges Adjustment	0	SBP	Medium 130 - 160	12	4
Arrhythmias	3		High 161 - 180	9	6
Device Failure	0		> 180	1	
Poor Quality Sounds	2				
Cuff Size Unavailable	0		Low < 40	0	0
Observer Disagreement	0		40 - 79	12	
Distribution	0	DBP	Medium 80 - 100	11	5
Other Reasons	5		High 101 - 130	10	5
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	20 : 13	
Age (years)		
Range (Low : High)	28 : 72	
Mean (SD)	49.8 (12.3)	
Arm Circumference (cm)		
Range (Low : High)	13.7 : 21.2	
Mean (SD)	17.6 (2.0)	
Cuff for test device		
Wrist	0	(13.5 - 21.5 cm)
	SBP	DBP
Recruitment BP (mmHg)		
Range (Low : High)	88 : 219	50 : 118
Mean (SD)	139.8 (32.5)	84.8 (19.9)

Observer Measurements in each Recruitment Range

SBP (mmHg)	DBP (mmHg)
Overall Range (Low : High)	Overall Range (Low : High)
86 : 222	50 : 139
Low (< 130)	Low (< 80)
33	33
Medium (130 – 160)	Medium (80 – 100)
42	38
High (> 160)	High (> 100)
24	28
Maximum Difference	Maximum Difference
18	10

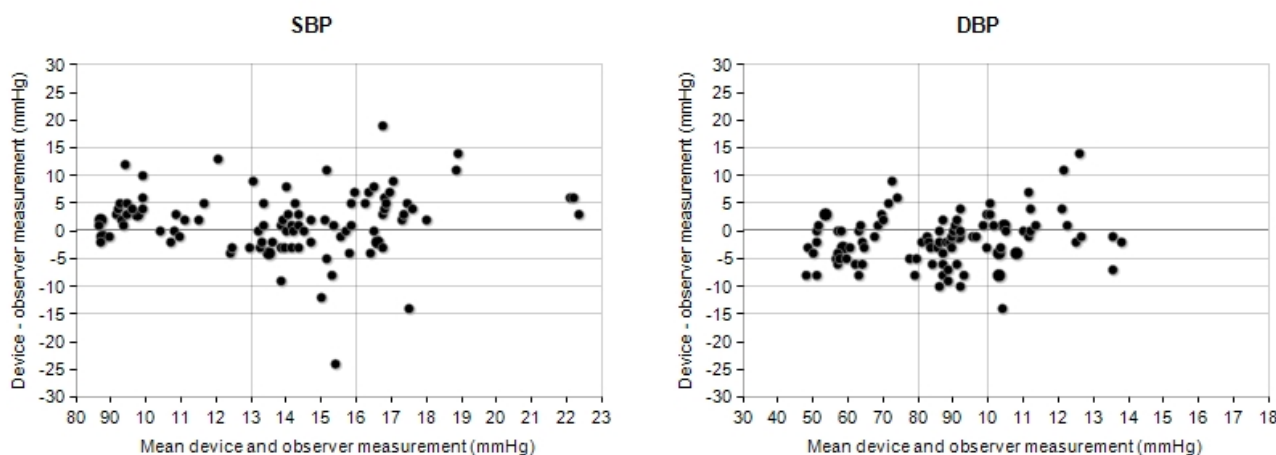
Observer Differences

	SBP (mmHg)	DBP (mmHg)	Repeated measurements
Observer 2 – Observer 1			
Range (Low : High)	-4 : +2	-4 : +2	
Mean (SD)	-0.2 (1.3)	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	76	90	97	Pass	1.5	5.8
DBP	74	96	99	Pass	-1.7	4.6
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	26	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.