Validation of the OMRON HBP-1300 upper arm blood pressure monitor, in oscillometry mode, for clinic use in a general population, according to the European Society of Hypertension International Protocol revision 2010

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

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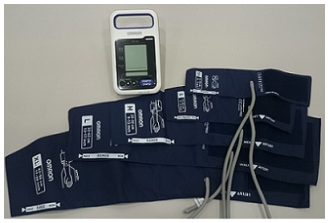
Abstract

The OMRON HBP-1300, an upper arm blood pressure monitor, in oscillometry mode, for clinical use, 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	HBP-1300
Manufacturer	OMRON HEALTHCARE Co., Ltd.
Location	Upper Arm
Method	Oscillometry
Purpose	Clinic Measurement
Operation	Fully Automatic
Arm Cuffs	Small Adult: 17.0 cm to 22.0 cm, Standard Adult: 22.0 cm to 32.0 cm, Large Adult: 32.0 cm to 42.0 cm and other cuffs: 12.0 cm to 50.0 cm
Other Features	The cuff size "Other" refers to either the Extra Small cuff, 12 cm to 18 cm, or to the Extra Large cuff 42 cm to 50 cm. There is a function to detect irregular pulse wave and body movement. The function to enable auscultation by an observer.

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.

Screening and Recruitment Details

Screening and Recruitment		Recruitment Ranges				
Total Screened	51			mmHg	All	On Rx
Total Excluded	18		Low	< 90	0	4
Ranges Complete	0			90 - 129	10	
Ranges Adjustment	0	SBP	Medium	130 - 160	11	9
Arrhythmias	3		High	161 - 180	10	4
Device Failure	0			> 180	2	
Poor Quality Sounds	3					
Cuff Size Unavailable	0		Low	< 40	0	6
Observer Disagreement	0			40 - 79	11	
Distribution	0	DBP	Medium	80 - 100	12	9
Other Reasons	12		High	101 - 130	10	2
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	12 : 21		
Age (years)			
Range (Low : High)	34 : 88		
Mean (SD)	56.9 (14.0)		
Arm Circumference (cm)			
Range (Low : High)	15.3 : 43.0		
Mean (SD)	28.3 (5.4)		
Cuff for test device			
Small	3	(17.0 - 22.0 cm)	
Standard	24	(22.0 - 32.0 cm)	
Large	4	(32.0 - 42.0 cm)	
Other	2	(12.0 - 50.0 cm)	
	SBP	DBP	
Recruitment BP (mmHg)			
Range (Low : High)	90 : 192	49 : 127	
Mean (SD)	144.9 (27.2)	86.8 (19.8)	

Observer Measurements in each Recruitment Range

SBP (mmHg)		DBP (mmHg)	
Overall Range (Low : High)	80 : 180	Overall Range (Low : High)	48 : 124
Low (< 130)	38	Low (< 80)	36
Medium (130 – 160)	38	Medium (80 – 100)	38
High (> 160)	23	High (> 100)	25
Maximum Difference	15	Maximum Difference	13

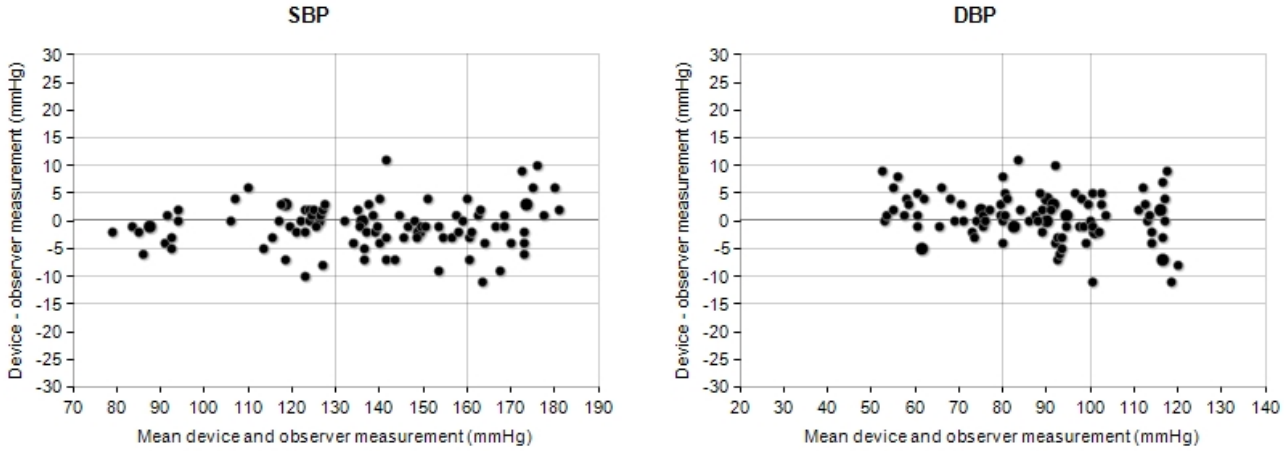
Observer Differences

	SBP (mmHg)	DBP (mmHg)	Repeated measurements
Observer 2 – Observer 1			
Range (Low : High)	-2 : +4	-4 : +4	
Mean (SD)	0.3 (1.3)	0.5 (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	97	99	Pass	-0.7	4.0
	DBP	82	96	99	Pass	0.7	4.2
Part 2		2/3 ≤ 5 mmHg		0/3 ≤ 10 mmHg	Grade 2		Grade 3
	Pass Requirements	≥ 24		≤ 3			
	Achieved						
	SBP	30		0	Pass		Pass
	DBP	27		0	Pass		Pass
Part 3							Result
							PASS

Plots



Discussion

No specific problem were encountered during validation and distribution conditions were fulfilled. But it was difficult to fulfill requirements of the International Protocol because some subjects were very hypertensive over SBP 200mmHg. The agreement between observer and device was similar in the three BP ranges and all BP discrepancies were within 15 mmHg.

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.