Validation of the Omron HEM-7252G-HP 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

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Abstract

The Omron HEM-7252G-HP, 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	HEM-7252G-HP
Manufacturer	Omron Healthcare Co., Ltd.
Location	Upper Arm
Method	Oscillometry
Purpose	Clinic Measurement, Self/ Home Measurement
Operation	Fully Automatic
Arm Cuffs	Small Adult: 17.0 cm to 22.0 cm, Standard Adult: 22.0 cm to 32.0 cm and Large Adult: 32.0 cm to 42.0 cm
Other Features	The function to guide cuff wrapping, to detect body movement, to detect irregular heart beat, and to measure room temperature Memory capacity for 255 readings Third generation of mobile telecommunications technology to connect with the dedicated server The function to measure blood pressure during user sleep

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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	44			mmHg	All	On Rx
Total Excluded	11		Low	< 90	0	0
Ranges Complete	0			90 - 129	12	
Ranges Adjustment	0	SBP	Medium	130 - 160	11	2
Arrhythmias	4		High	161 - 180	6	2
Device Failure	0			> 180	4	
Poor Quality Sounds	1					
Cuff Size Unavailable	0		Low	< 40	0	0
Observer Disagreement	0			40 - 79	11	
Distribution	0	DBP	Medium	80 - 100	11	2
Other Reasons	6		High	101 - 130	11	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	19 : 14	
Age (years)		
Range (Low : High)	28 : 78	
Mean (SD)	49.7 (11.6)	
Arm Circumference (cm)		
Range (Low : High)	20.1 : 37.2	
Mean (SD)	28.1 (4.6)	
Cuff for test device		
Small	4	(17.0 - 22.0 cm)
Standard	23	(22.0 - 32.0 cm)
Large	6	(32.0 - 42.0 cm)
	SBP	DBP
Recruitment BP (mmHg)		
Range (Low : High)	90 : 207	48 : 129
Mean (SD)	144.2 (32.7)	89.8 (20.2)

Observer Measurements in each Recruitment Range

SBP (mmHg)		DBP (mmHg)	
Overall Range (Low : High)	86 : 218	Overall Range (Low : High)	48 : 134
Low (< 130)	41	Low (< 80)	26
Medium (130 – 160)	28	Medium (80 – 100)	42
High (> 160)	30	High (> 100)	31
Maximum Difference	13	Maximum Difference	16

Observer Differences

	SBP (mmHg)	DBP (mmHg)	Repeated measurements
Observer 2 – Observer 1			
Range (Low : High)	-2 : +4	-2 : +4	
Mean (SD)	-0.1 (1.2)	0.1 (1.3)	0

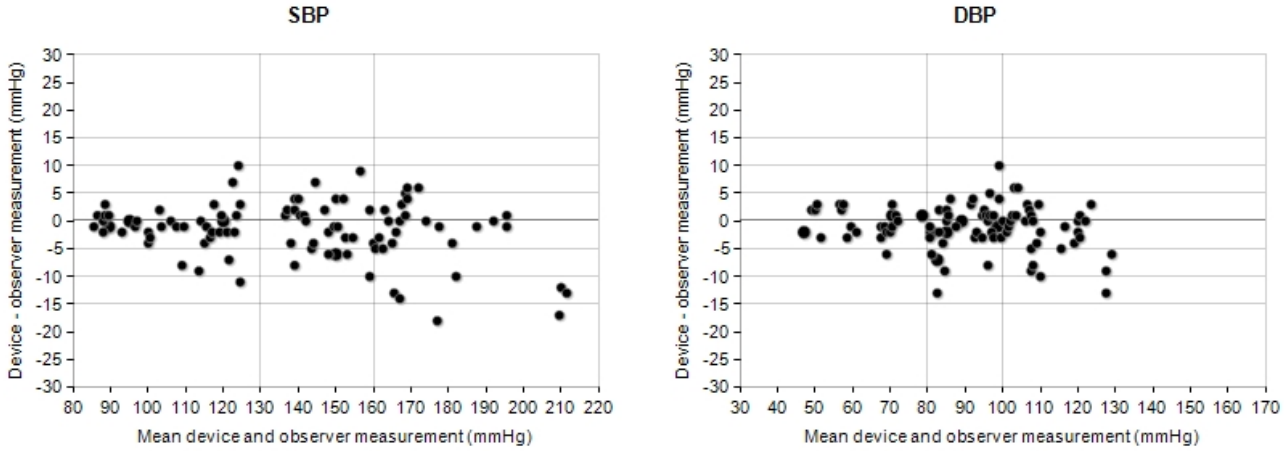
Validation Results

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	92	97	Pass	-1.5	5.1
	DBP	83	97	99	Pass	-1.2	3.9

Part 2		2/3 ≤ 5 mmHg	0/3 ≤ 10 mmHg	Grade 2	Grade 3
	Pass Requirements	≥ 24	≤ 3		
	Achieved				
	SBP	28	1	Pass	Pass
	DBP	29	2	Pass	Pass

Part 3	Result
	PASS

Plots



Discussion

No specific problems 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 almost BP discrepancies were within 15mmHg.

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

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References

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