Validation of the Omron EVOLV (HEM-7600T-E) upper arm blood pressure monitor, in oscillometry mode, for self measurement in a general population, according to the European Society of Hypertension International Protocol revision 2010

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Abstract

The Omron EVOLV (HEM-7600T-E), an upper arm blood pressure monitor, in oscillometry mode, for personal 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 fulfilled the standards of the protocol.

Device Details

Brand	Omron
Model	EVOLV
Manufacturer	Omron healthcare CO., LTD.
Location	Upper Arm
Method	Oscillometry
Purpose	Self/ Home Measurement
Operation	Fully Automatic
Arm Cuff	Standard Adult: 22.0 cm to 42.0 cm
Other Features	The function to guide cuff wrapping, to detect body movement, to detect irregular heartbeat. This device connects to user's smart device using Bluetooth.

Methodology

Familiarisation

Numerous test-measurements were carried out. No problem was found.

Recruitment

Hypertensive subjects were recruited from outpatients clinic in the Department of Cardiology in Biwako Central Hospital (Shiga, 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	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	10	2
Arrhythmias	2		High	161 - 180	12	2
Device Failure	0			> 180	0	
Poor Quality Sounds	0					
Cuff Size Unavailable	1		Low	< 40	0	0
Observer Disagreement	0			40 - 79	11	
Distribution	0	DBP	Medium	80 - 100	10	2
Other Reasons	5		High	101 - 130	12	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)	26 : 91	
Mean (SD)	53.6 (14.1)	
Arm Circumference (cm)		
Range (Low : High)	22.0 : 42.0	
Mean (SD)	29.1 (4.9)	
Cuff for test device		
Standard	33	(22.0 - 42.0 cm)
	SBP	DBP
Recruitment BP (mmHg)		
Range (Low : High)	90 : 179	51 : 126
Mean (SD)	141.9 (28.2)	89.4 (20.3)

Observer Measurements in each Recruitment Range

SBP (mmHg)		DBP (mmHg)	
Overall Range (Low : High)	90 : 185	Overall Range (Low : High)	50 : 127
Low (< 130)	37	Low (< 80)	35
Medium (130 – 160)	39	Medium (80 – 100)	27
High (> 160)	23	High (> 100)	37
Maximum Difference	16	Maximum Difference	10

Observer Differences

	SBP (mmHg)	DBP (mmHg)	Repeated measurements
Observer 2 – Observer 1			
Range (Low : High)	-4 : +4	-4 : +4	
Mean (SD)	0.1 (1.4)	-0.1 (1.5)	0

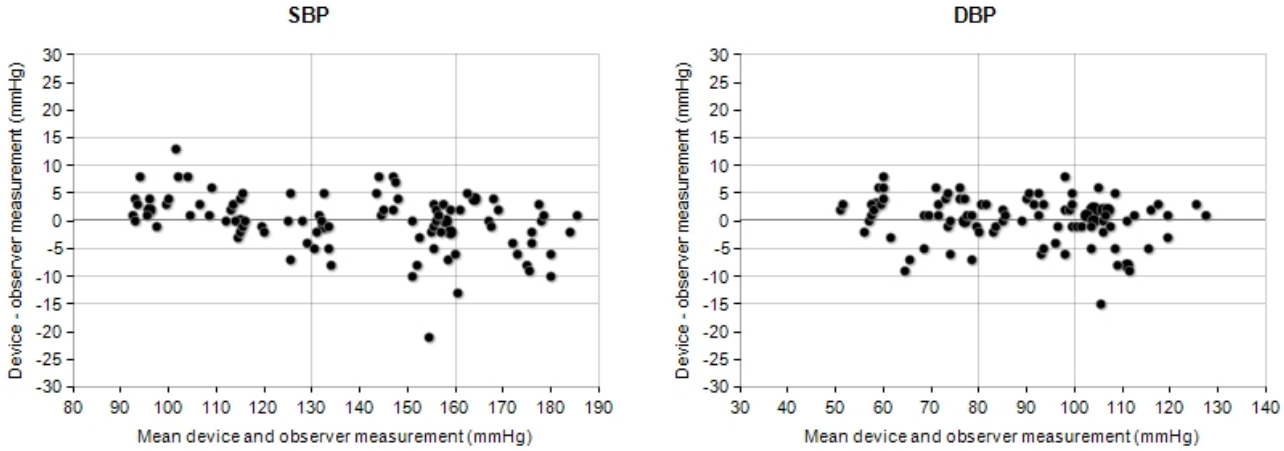
Validation Results

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	78	96	98	Pass	-0.1	5.0
	DBP	81	98	99	Pass	0.2	4.1

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

Part 3	Result
	PASS

Plots



Discussion

The study finished without any problems. However, it was hard to recruit patients with high blood pressure levels of 161 to 180mmHg. The agreement between observer and device was similar in the three BP ranges and the magnitude of discrepancies were within 15mmHg.

Conclusion

As the device has reached the required standards, it is recommended for personal use in a general population.

Acknowledgements and Conflict of Interest

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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.