Validation of the Omron i-Q142(HEM-1040-E), an 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

Performance of the Omron i-Q142(HEM-1040-E), 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	i-Q142(HEM-1040-E)
Manufacturer	OMRON HEALTHCARE Co., Ltd
Location	Upper Arm
Method	Oscillometry
Purpose	Clinic Measurement, Self/ Home Measurement
Operation	Fully Automatic
Arm Cuff	Standard Adult: 22.0 cm to 42.0 cm
Other Features	The function to detect body motion.
	The function to detect irregular heartbeat.
	The function to wrap cuff automatic.
	The function to detect incorrectly posture.
	The indicator for hypertension.
	Memory capacity for 84 readings for two users.
	3 readings average value within 10 minutes.
	Morning and Evening Weekly Averages.
	The function to interface with PC or printer.

Methodology

Familiarisation

Hundreds of test-measurements were carried out. No problems were encounterd.

Recruitment

Hypertensive subjects were recruited from outpatients clinic in department of cardiology in the Kansai Medical University, Hirakata Hospital (Osaka, Japan). 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		42			mmHg	All	On Rx
Total Excluded		9		Low	< 90	1	1
Ranges Complete	0				90 - 129	10	
Ranges Adjustment	0		SBP	Medium	130 - 160	12	1
Arrhythmias	2			High	161 - 180	8	3
Device Failure	0				> 180	2	
Poor Quality Sounds	0						
Cuff Size Unavailable	0			Low	< 40	0	2
Observer Disagreement	0				40 - 79	10	
Distribution	0		DBP	Medium	80 - 100	11	2
Other Reasons	7			High	101 - 130	11	1
Total Recruited		33			> 130	1	

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	17 : 16	
Age (years)		
Range (Low : High)	27 : 75	
Mean (SD)	50.5 (12.8)	
Arm Circumference (cm)		
Range (Low : High)	22.2 : 34.1	
Mean (SD)	28.0 (2.9)	
Cuff for test device		
Standard	33	(22.0 - 42.0 cm)
	SBP	DBP
Recruitment BP (mmHg)		
Range (Low : High)	86 : 234	44 : 136
Mean (SD)	143.2 (29.8)	87.3 (21.0)

Observer Measurements in each Recruitment Range

SBP (mmHg)		DBP (mmHg)	
Overall Range (Low : High)	82 : 222	Overall Range (Low : High)	48 : 143
Low (< 130)	39	Low (< 80)	31
Medium (130 – 160)	38	Medium (80 – 100)	42
High (> 160)	22	High (> 100)	26
Maximum Difference	17	Maximum Difference	16

Observer Differences

	SBP (mmHg)	DBP (mmHg)	Repeated measurements
Observer 2 – Observer 1			
Range (Low : High)	-2 : +2	-2 : +2	
Mean (SD)	0.1 (1.3)	0.0 (1.2)	0

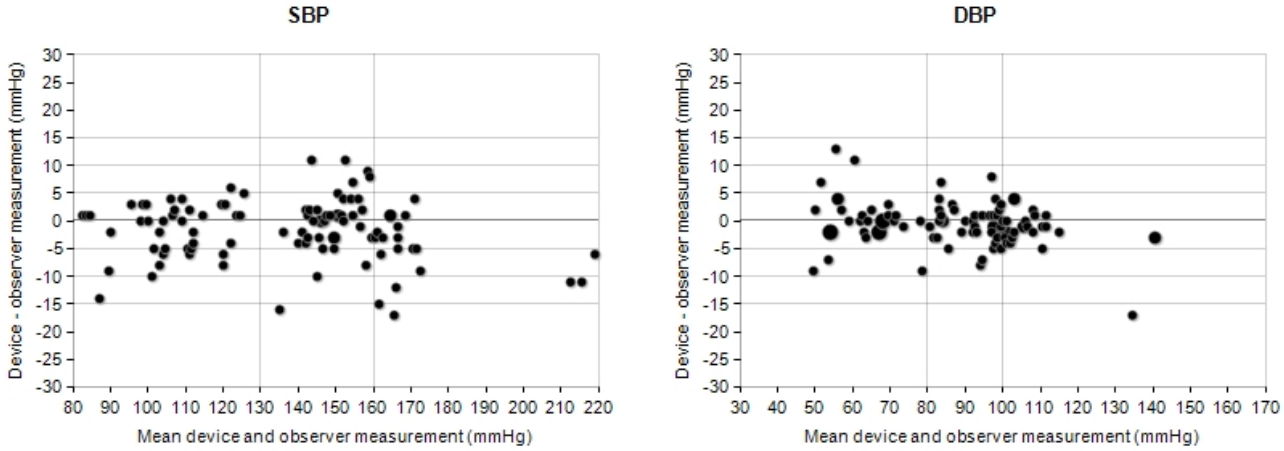
Validation Results

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	74	90	97	Pass	-1.7	5.4
	DBP	88	96	98	Pass	-0.6	3.9

Part 2		2/3 ≤ 5 mmHg	0/3 ≤ 10 mmHg	Grade 2	Grade 3
	Pass Requirements	≥ 24	≤ 3		
	Achieved				
	SBP	25	1	Pass	Pass
	DBP	31	0	Pass	Pass

Part 3	Result
	PASS

Plots



Discussion

Recruitment of subjects with 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 clinical and 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.