

# 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 encountered.

### 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 difficulties 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		< 90	1	1
Ranges Complete	0	Low	90 - 129	10	1
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		< 40	0	2
Cuff Size Unavailable	0	Low	40 - 79	10	
Observer Disagreement	0	DBP	Medium 80 - 100	11	2
Distribution	0		High 101 - 130	11	
Other Reasons	7		> 130	1	1
Total Recruited	33				

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

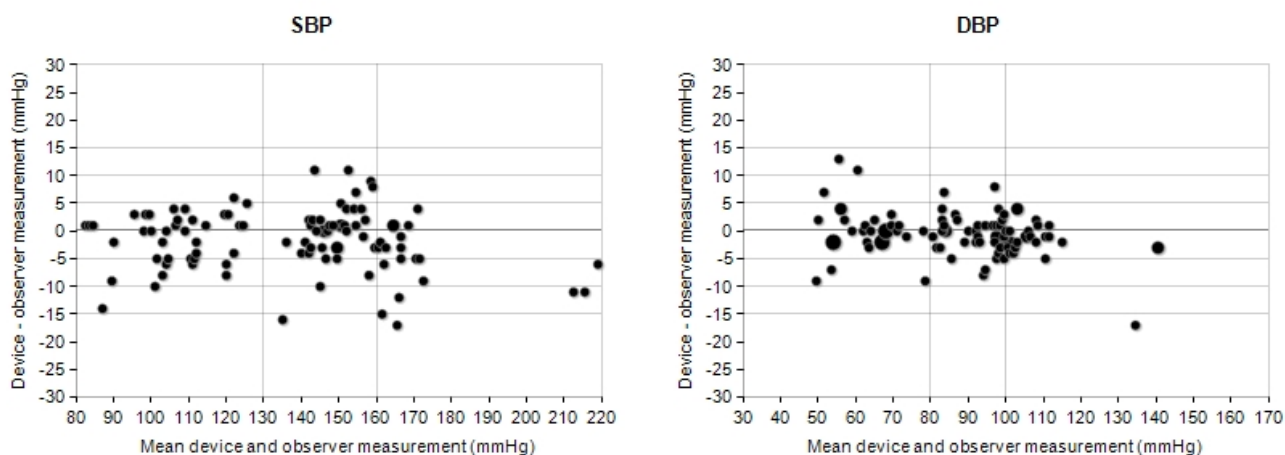
**Observer Differences**

	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
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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
<hr/>						
Part 3						Result
						<b>PASS</b>

**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.