

**Validation of the OMRON M6 COMFORT (HEM-7221-E8) Upper Arm blood pressure monitor, for self/home measurement, according to the revised (2010) European Society of Hypertension International Protocol.**

**Device Details**

Brand	OMRON
Model	M6 COMFORT (HEM-7221-E8)
Manufacturer	OMRON
Location	Upper Arm
Method	Oscillometry
Purpose	self/home measurement
Operation	Automatic
Arm Cuffs device	Comfort fit universal: 22 cm to 42 cm
Arm Cuffs mercury	Small: 18 cm to 22 cm, Medium: 22 cm to 32 cm and Large: 32 cm to 42 cm
Other features	VALIDATION II

**Screening and Recruitment Details**

Screening and Recruitment		Recruitment Ranges				
Total Screened	39			mmHg	All	On Rx
Total Excluded	6			< 90	0	
Ranges Complete	1		Low	90-129	11	4
Range Adjustment	5	SBP	Medium	130-160	11	3
Arrhythmias	0		High	161-180	11	6
Device Failure	0			> 180	0	
Poor Quality Sounds	0					
Cuff Size Unavailable	0		Low	< 40	0	4
Observer Disagreement	0			40-79	11	
Distribution	0	DBP	Medium	80-100	11	6
Other Reasons	0		High	101-130	11	3
Total Recruited	33			> 130	0	

**Subject Details**

Sex	Male:Female	15:18		
Age (years)	Range (Low:High)	26:77		
	Mean (SD)	55.7 (13.0)		
Arm Circumference (cm)	Range (Low:High)	24:42		
	Mean (SD)	30.7 (4.0)		
Wrist Circumference (cm)	Range (Low:High)	0:0		
	Mean (SD)	0.0 (0.0)		
Cuff for Test Device	Standard	1		
	Large	0		
	Small	0		
Mercury Cuff	Standard	23		
	Large	10		
	Small	0		
Recruitment BP (mmHg)	Range (Low:High)	91:179	SBP	DBP
	Mean (SD)	143.3 (25.0)	49:121	89.4 (18.0)

**Observer Measurements in each Recruitment Range**

	SBP (mmHg)	DBP (mmHg)
Overall Range (Low:High)	87:180	50:121
Low (< 130)	37	34
Medium (130 – 160)	31	33
High (> 160)	31	32
Maximum Difference	6	2

**Observer Differences**

		SBP (mmHg)	DBP (mmHg)
Observer 2 – Observer 1	Range (Low:High)	-4:+4	-4:+4
	Mean (SD)	+0.1 (2.3)	-1.0 (2.2)

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**Validation Results**

Part 1		$\leq 5$ mmHg	$\leq 10$ mmHg	$\leq 15$ mmHg	Grade 1	Mean mmHg	SD mmHg
Pass Req.	Two of	73	87	96			
	All of	65	81	93			
Achieved	SBP	84	98	99	Pass	-0.1	3.9
	DBP	79	93	99	Pass	0.7	4.7
Part 2		$2/3 \leq 5$ mmHg		$0/3 \leq 5$ mmHg	Grade 2		Grade 3
Pass Req.		$\geq 24$		$\leq 3$			
Achieved	SBP	29		1	Pass		Pass
	DBP	27		3	Pass		Pass

Part 3

Result  
Pass

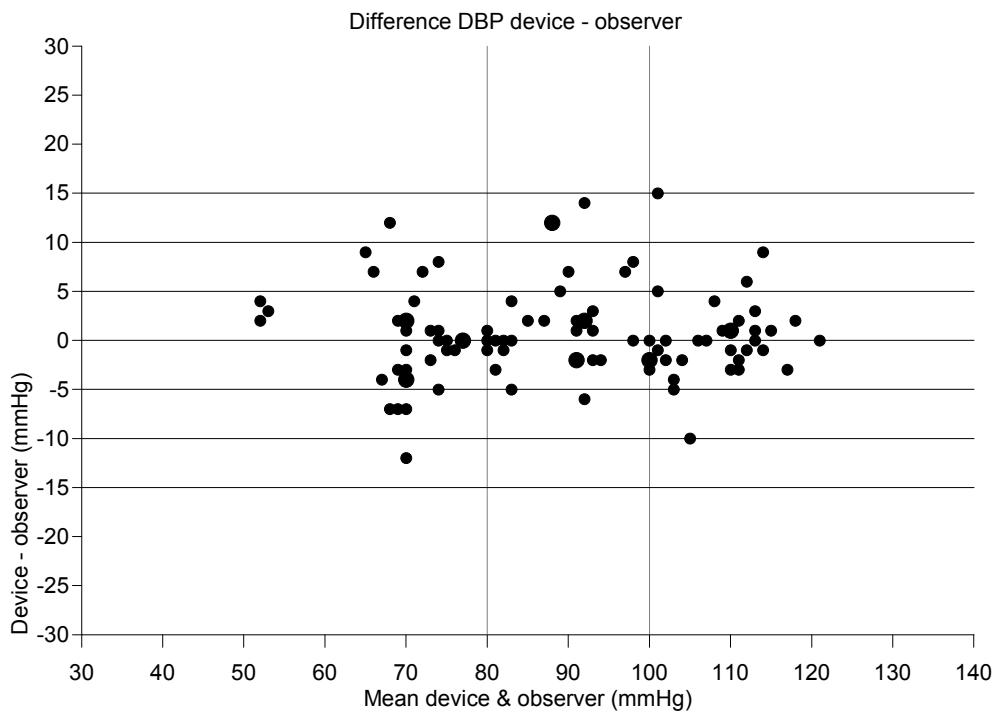
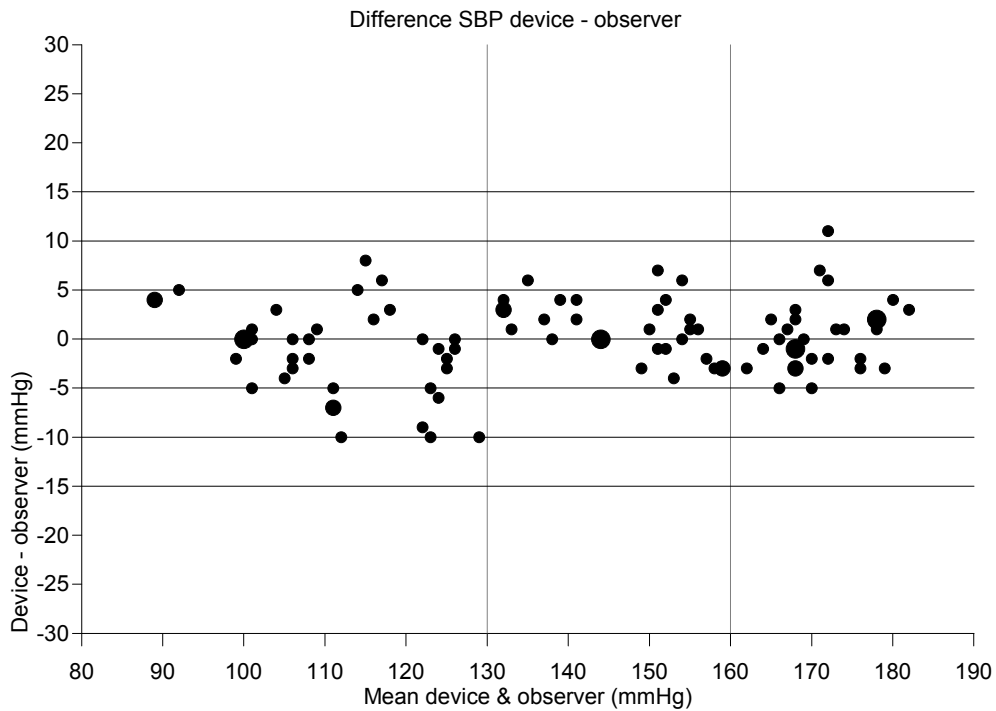


PHOTO - The Omron M6 COMFORT (HEM-7221-E8)

