

Validation of the OMRON OMRON M3- HEM-7002-E 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	OMRON M3- HEM-7002-E
Manufacturer	OMRON
Location	Upper Arm
Method	Oscillometry
Purpose	self/home measurement
Operation	Automatic
Arm Cuffs device	Standard Adult: 22 cm to 32 cm and Large Adult: 32 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	

Screening and Recruitment Details

Screening and Recruitment		Recruitment Ranges				
Total Screened	43			mmHg	All	On Rx
Total Excluded	10			< 90	0	
Ranges Complete	10		Low	90-129	11	4
Range Adjustment	0	SBP	Medium	130-160	12	10
Arrhythmias	0		High	161-180	10	9
Device Failure	0			> 180	0	
Poor Quality Sounds	0					
Cuff Size Unavailable	0		Low	< 40	0	5
Observer Disagreement	0		Medium	40-79	11	8
Distribution	0	DBP	High	80-100	11	10
Other Reasons	0			101-130	11	
Total Recruited	33			> 130	0	

Subject Details

Sex	Male:Female	16:17	
Age (years)	Range (Low:High)	31:78	
	Mean (SD)	59.9 (11.0)	
Arm Circumference (cm)	Range (Low:High)	25:36	
	Mean (SD)	29.3 (3.0)	
Cuff for Test Device	Standard	29	
	Large	4	
Recruitment BP (mmHg)	Range (Low:High)	SBP 90:179	DBP 50:119
	Mean (SD)	142.4 (25.0)	85.3 (18.0)

Observer Measurements in each Recruitment Range

SBP (mmHg)	DBP (mmHg)
Overall Range (Low:High)	Overall Range (Low:High)
88:180	50:118
Low (< 130)	Low (< 80)
35	37
Medium (130 – 160)	Medium (80 – 100)
37	40
High (> 160)	High (> 100)
27	22
Maximum Difference	Maximum Difference
10	18

Observer Differences

		SBP (mmHg)	DBP (mmHg)
Observer 2 – Observer 1	Range (Low:High)	-2:+2	-2:+4
	Mean (SD)	+0.1 (0.8)	-0.2 (1.0)

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Validation Results

Part 1		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade 1	Mean mmHg	SD mmHg
Pass Req.	Two of	73	87	96			
	All of	65	81	93			
Achieved	SBP	86	99	99	Pass	1.7	3.2
	DBP	94	99	99	Pass	-0.9	2.6
Part 2		$2/3 \leq 5$ mmHg		$0/3 \leq 5$ mmHg	Grade 2		Grade 3
Pass Req.		≥ 24		≤ 3			
Achieved	SBP	31		0	Pass		Pass
	DBP	33		0	Pass		Pass

Part 3

Result

Pass

