

Validation of the OMRON OMRON M6-HEM-7211-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 M6-HEM-7211-E
Manufacturer	OMRON HEALTHCARE
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	42			mmHg	All	On Rx
Total Excluded	9			< 90	0	
Ranges Complete	9		Low	90-129	11	6
Range Adjustment	0	SBP	Medium	130-160	11	8
Arrhythmias	0		High	161-180	11	10
Device Failure	0			> 180	0	
Poor Quality Sounds	0					
Cuff Size Unavailable	0		Low	< 40	0	7
Observer Disagreement	0		Medium	40-79	11	7
Distribution	0	DBP	High	80-100	11	7
Other Reasons	0			101-130	11	10
Total Recruited	33			> 130	0	

Subject Details

Sex	Male:Female	15:18	
Age (years)	Range (Low:High)	25:79	
	Mean (SD)	60.1 (13.0)	
Arm Circumference (cm)	Range (Low:High)	25:36	
	Mean (SD)	29.2 (3.0)	
Cuff for Test Device	Standard	32	
	Large	1	
Recruitment BP (mmHg)	Range (Low:High)	SBP 96:180	DBP 50:119
	Mean (SD)	143.9 (25.0)	86.1 (18.0)

Observer Measurements in each Recruitment Range

SBP (mmHg)		DBP (mmHg)	
Overall Range (Low:High)	89:189	Overall Range (Low:High)	49:118
Low (< 130)	37	Low (< 80)	38
Medium (130 – 160)	34	Medium (80 – 100)	36
High (> 160)	28	High (> 100)	25
Maximum Difference	9	Maximum Difference	13

Observer Differences

		SBP (mmHg)	DBP (mmHg)
Observer 2 – Observer 1	Range (Low:High)	-2:+2	-4:+2
	Mean (SD)	+0.2 (1.1)	-0.0 (1.1)

Validation of the OMRON M6-HEM-7211-E Upper Arm blood pressure monitor, for self/home measurement, according to the revised (2010) European Society of Hypertension International Protocol.

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	89	99	99	Pass	1.6	2.9
	DBP	96	99	99	Pass	-0.9	2.5

Part 2		$2/3 \leq 5$ mmHg	$0/3 \leq 5$ mmHg	Grade 2	Grade 3
Pass Req.		≥ 24	≤ 3		
Achieved	SBP	32	0	Pass	Pass
	DBP	33	0	Pass	Pass

Part 3

Result

Pass

