Validation of the OMRON M6 COMFORT IT (HEM-7322U-E) Upper Arm blood pressure monitor for self/home measurement, according to the revised (2010) European Society of Hypertension International Protocol

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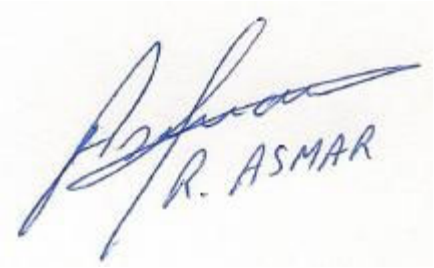

Date: May 20, 2016 Signature Pr. R. ASMAR

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Device Details

Brand	OMRON
Model	M6 COMFORT IT (HEM-7322U-E)
Manufacturer	OMRON
Location	Upper Arm
Method	Oscillometry
Purpose	self/home measurement
Operation	Automatic
Arm Cuffs device	ONE UNIVERSAL RIGID CUFF 22- 42 CM
Arm Cuffs mercury	Medium: 22 cm to 32 cm and Large: 32 cm to 42 cm
Other features	VALIDATION OF THE OMRON M6 COMFORT IN THE DIABETIC POPULATION

Screening and Recruitment Details

Screening and Recruitment		
Total Screened		56
Total Excluded		23
Ranges Complete	14	
Range Adjustment	0	
Arrhythmias	0	
Device Failure	0	
Poor Quality Sounds	1	
Cuff Size Unavailable	0	
Observer Disagreement	0	
Distribution	0	
Other Reasons	8	
Total Recruited		33

Recruitment Ranges				
		mmHg	All	On Rx
SBP	Low	< 90	0	0
		90-129	11	
	Medium	130-160	11	0
	High	161-180	11	0
		> 180	0	
DBP	Low	< 40	0	0
		40-79	11	
	Medium	80-100	11	0
	High	101-130	11	0
		> 130	0	

Subject Details

Sex	Male:Female	12:21	
Age (years)	Range (Low:High)	43:85	
	Mean (SD)	60.9 (11.0)	
Arm Circumference (cm)	Range (Low:High)	24:36	
	Mean (SD)	30.2 (3.0)	
Wrist Circumference (cm)	Range (Low:High)	15:20	
	Mean (SD)	17.3 (1.0)	
Cuff for Test Device	Standard	20	
	Large	13	
Mercury Cuff	Small	0	
	Standard	20	
	Large	13	
		SBP	DBP
Recruitment BP (mmHg)	Range (Low:High)	105:178	51:107
	Mean (SD)	144.4 (23.0)	86.3 (17.0)

Observer Measurements in each Recruitment Range

SBP (mmHg)		DBP (mmHg)	
Overall Range (Low:High)	101:175	Overall Range (Low:High)	50:109
Low (< 130)	36	Low (< 80)	33
Medium (130 – 160)	32	Medium (80 – 100)	35
High (> 160)	31	High (> 100)	31
Maximum Difference	5	Maximum Difference	4

Observer Differences

		SBP (mmHg)	DBP (mmHg)
Observer 2 – Observer 1	Range (Low:High)	-4:+4	-4:+4
	Mean (SD)	-0.2 (2.2)	+0.3 (2.1)

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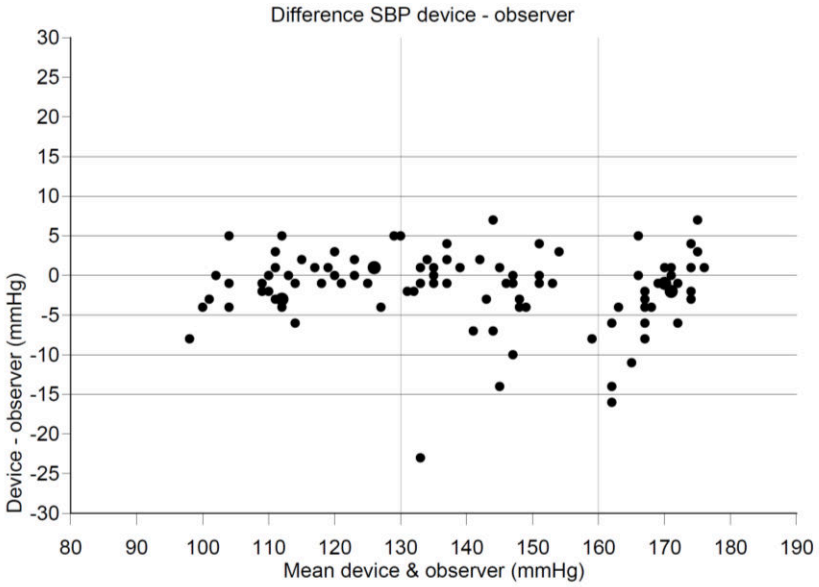
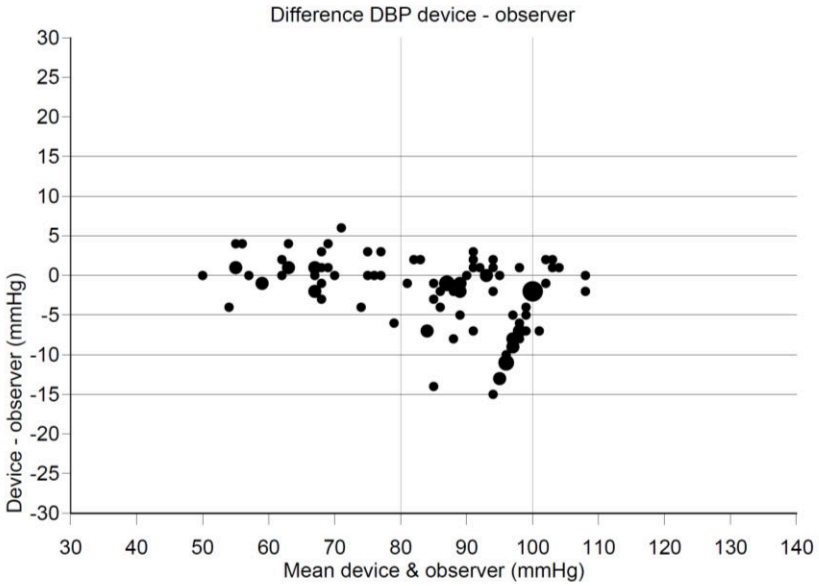
Validation Results

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	82	94	97	Pass	-1.6	4.7
	DBP	75	92	99	Pass	-2.2	4.5

Part 2		2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg	Grade 2	Grade 3
Pass Req.		≥ 24	≤ 3		
Achieved	SBP	29	0	Pass	Pass
	DBP	25	2	Pass	Pass

Part 3	Result
	Pass





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(2) Association for the Advancement of Medical Instrumentation. American national standard: electronic or automated sphygmomanometers. Arlington, VA: AAMI; 1993.

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OMRON
HEM-FL31
22-42cm
OMRON
M6 Comfort IT
Intelli sense
SYS
mmHg
DIA
mmHg
PULSE
/min
7:30
118
78
70
135
85
START
STOP