

Medaval Accreditation Assessment

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Accreditation assessment of the blood pressure measurement technology used in the Omron HEM-7251G upper arm monitor, as validated according to the European Society of Hypertension International Protocol revision 2010

Approved by the Medaval Advisory Board

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Reference

Medaval Ltd. Accreditation assessment of the blood pressure measurement technology used in the Omron HEM-7251G upper arm monitor, as validated according to the European Society of Hypertension International Protocol revision 2010. *Medical Device Assessment*. 2016 Aug 5; **2016**(1628). 5 p. Epub: 2019 Jan 31. Available from: <https://www.medaval.ie/MDA/2016/MDA1628.pdf>.

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Accreditation assessment of the blood pressure measurement technology used in the Omron HEM-7251G upper arm monitor, as validated according to the European Society of Hypertension International Protocol revision 2010

Medaval Accreditation-Assessment Report – 5th August 2016

Test Device Details

		Assessment
Full Name	Omron HEM-7251G	Requirement satisfactory
Model	HEM-7251G	Requirement satisfactory
Measurement Site	Upper Arm	Requirement satisfactory
Client Use	Suitable for self-measurement.	Requirement satisfactory
Operation Method	Oscillometry, automatic during deflation	Requirement satisfactory
Measurement Occurrence	Single Measurements Only	Requirement satisfactory
Device Photograph		Photograph not in paper. Standard image shown.
Manufacturer(s)	Sole: Omron Healthcare, Kyoto Head Office, Shiokoji Horikawa, Shimogyo ku, Kyoto 600 8530, JAPAN.	Requirement satisfactory
Cuffs	Omron HEM-CUFF-R22: ML 17 cm to 32 cm	Cuffs Listed: Requirement satisfactory Arm Circumferences: Requirement satisfactory

Study Details

Original Publication	Takahashi H, Yoshika M, Yokoi T. Validation of two automatic devices: Omron HEM-7252G-HP and Omron HEM-7251G for self-measurement of blood pressure according to the European Society of Hypertension International Protocol revision 2010. <i>Blood Press Monit.</i> 2015 Oct; 20 (5):286-90. Epub: 2015 Apr 29. doi: 0.1097/MBP.0000000000000127. PMID: 25932887.	
Protocol	The European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults ¹	

		Assessment
Adherence	Not stated but, apart from paper, inferred from text.	Requirement satisfactory
Adjustments	None	Requirement satisfactory
Study Meas. Method	Oscillometric	Requirement satisfactory
Study Measurement Site	Upper Arm	Requirement satisfactory
Observers		
Supervisor + 2 Observers	Yes	Requirement satisfactory
Observer Training	BHS online training	Requirement satisfactory
Observer Familiarisation	General testing	Requirement satisfactory
Observer Blinding	From device and each other ^{Note}	Requirement satisfactory
Sample		
Population	A general population	Requirement satisfactory
Circumstances	None	Requirement satisfactory
HBP Subjects Selection	Outpatients	Requirement satisfactory
NBP Subjects Selection	Hospital staff & volunteers	Requirement satisfactory

Test Device Details and Study Details Assessment	Checks	22
Note: Blinded from device is not stated but there is no reason to suspect otherwise.	Permitted Modifications	0
	Violations	0

Procedure

Table 1: Screening and Recruitment Details

Screening and Recruitment				Assessment
Total Screened			48	Value within requirements
Total Excluded			15	Value within requirements
	Ranges Complete		0	Value within requirements
	Range Adjustment		2	Value within requirements
	Arrhythmias		4	Value within requirements
	Device Failure		0	Value within requirements
	Poor Quality Sounds		1	Value within requirements
	Cuff Size Unavailable		2	Value within requirements
	Observer Disagreement		0	Value within requirements
	Distribution		0	Value within requirements
	Other Reasons*		6	Value within requirements
Total Recruited			33	Value within requirements
*Explanation Summary				
The device displayed a body movement error in six individuals who were excluded for this reason.				Details satisfactory
Recruitment Ranges				
SBP	Total		33	Value within requirements
	Low	< 90 mmHg	0	Value within requirements
		90 – 129 mmHg	10	Value within requirements
		Medium 130 – 160 mmHg	11	Value within requirements
	High	> 180 mmHg	3	Value within requirements
		161 – 180 mmHg	9	Value within requirements
	Total		33	Value within requirements
DBP	Low	< 40 mmHg	0	Value within requirements
		40 – 79 mmHg	12	Value within requirements
		Medium 80 – 100 mmHg	10	Value within requirements
	High	> 130 mmHg	0	Value within requirements
		101 – 130 mmHg	11	Value within requirements
	Total		3	Value within requirements
Total Extremes				Value within requirements
On Treatment Ranges				
SBP	Low	< 130 mmHg	3	Value within requirements
	Medium	130 – 160 mmHg	7	Value within requirements
	High	> 160 mmHg	3	Value within requirements
DBP	Low	< 80 mmHg	4	Value within requirements
	Medium	80 – 100 mmHg	5	Value within requirements
	High	> 100 mmHg	4	Value within requirements
Table 1 Assessment				
				Checks
				36
				Permitted Modifications
				0
				Violations
				0

Study Results

Table 2: Subject Details

			Assessment	
Sex	Male:Female	16:17	Value within requirements	Value within requirements
Age (years)	Range (Low:High)	27:72	Value within requirements	Value within requirements
	Mean (SD)	53 (10)	Value within requirements	Value within requirements
Arm Circumference (cm)	Range (Low:High)	22.6:31.4	Value within requirements	Value within requirements
	Mean (SD)	28.1 (2.4)	Value within requirements	Value within requirements
Cuff for Test Device (cm)	Small (17–22)	1		
	Medium (22 – 32)	30		
	Large (32 – 42)	2		
	Total	33	Value within requirements	
Recruitment SBP (mmHg)	Range (Low:High)	104:212	Value within requirements	Value within requirements
	Mean (SD)	147 (26)	Value within requirements	Value within requirements
Recruitment DBP (mmHg)	Range (Low:High)	55:112	Value within requirements	Value within requirements
	Mean (SD)	89 (16.5)	Value within requirements	Value within requirements

Table 2 Assessment	Checks	19
	Permitted Modifications	0
	Violations	0

Table 3: Observer Measurements in each Recruitment Range

			Assessment	
SBP	Overall Range mmHg (Low:High)	98:191	Value within requirements	Value within requirements
	Low (< 130 mmHg)	32	Value within requirements	
	Medium (130 – 160 mmHg)	39	Value within requirements	
	High (> 160 mmHg)	28	Value within requirements	
	Maximum Difference	11	Value within requirements	
DBP	Overall Range mmHg (Low:High)	49:120	Value within requirements	Value within requirements
	Low (< 80 mmHg)	34	Value within requirements	
	Medium (80 – 100 mmHg)	35	Value within requirements	
	High (> 100 mmHg)	30	Value within requirements	
	Maximum Difference	5	Value within requirements	

Table 3 Assessment	Checks	12
	Permitted Modifications	0
	Violations	0

Table 4: Observer Differences

			Assessment	
Observer 2 – Observer 1				
SBP (mmHg)	Range (Low:High)	-4:+4	Value within requirements	Value within requirements
	Mean (SD)	0 (1.4)	Value within requirements	Value within requirements
DBP (mmHg)	Range (Low:High)	-4:+4	Value within requirements	Value within requirements
	Mean (SD)	0 (1.5)	Value within requirements	Value within requirements
Repeated Measurements		0	Value within requirements	

Table 4 Assessment	Checks	9
	Permitted Modifications	0
	Violations	0

Table 5: Validation Results

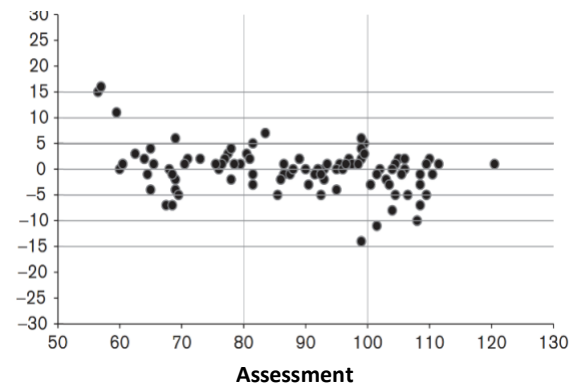
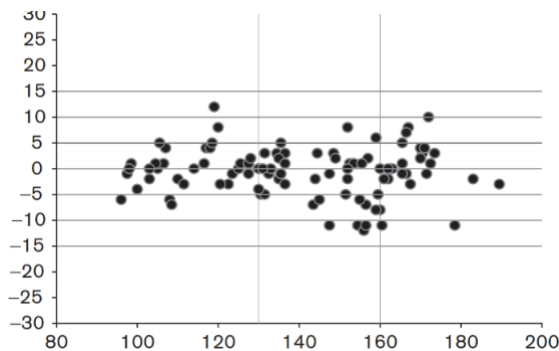
Part 1	Pass Req.		Achieved		Assessment	
	Two of	All of	SBP	DBP		
≤ 5 mmHg	73	65	77	85	Value within passing criteria	Value within passing criteria
≤ 10 mmHg	87	81	92	94	Value within passing criteria	Value within passing criteria
≤ 15 mmHg	96	93	99	98	Value within passing criteria	Value within passing criteria
Grade 1			Pass	Pass	Value within passing criteria	Value within passing criteria
Mean mmHg			-0.6	-0.2	Value within requirements	Value within requirements
SD mmHg			4.7	4.4	Value within requirements	Value within requirements

Part 2	Pass Req.	Achieved		Assessment	
		SBP	DBP		
2/3 ≤ 5 mmHg	≥ 24	26	31	Value within passing criteria	Value within passing criteria
0/3 ≤ 5 mmHg	≤ 3	1	1	Value within passing criteria	Value within passing criteria
Grade 2		Pass	Pass	Value within passing criteria	Value within passing criteria
Grade 3		Pass	Pass	Value within passing criteria	Value within passing criteria

Part 3	Pass	Value within passing criteria
Result		

Table 5 Assessment	Checks	21
	Permitted Modifications	0
	Violations	0

Plots



SBP Plot Provided	Yes	Requirement satisfactory
DBP Plot Provided	Yes	Requirement satisfactory

Plots Assessment	Checks	2
	Permitted Modifications	0
	Violations	0

Recommendations

Overall Summary

Number of checks	121
Number of permitted modifications	1
Number of violations	0

Assessment Summary

The validation has been checked and is verified as having been conducted in accordance with the protocol requirements. Therefore, the results are considered to be valid, the null hypothesis, that the device is inaccurate in measuring blood pressure, is rejected and the conclusion, that the device is accurate for self-measurement in adults, is correct.

Certification Decision

The Omron HEM-7251G, with the original medium 22 cm to 32 cm cuff, is certified by Medaval Ltd., for blood pressure measurement in adults, as it fulfilled the conditions required for a pass in a validation study carried out in accordance with the requirements of the International Protocol of the European Society of Hypertension 2010 Revision.

Date of Advisory Board Approval: 29th July 2016.

Reference

- O'Brien E, Atkins N, Stergiou G, Karpettas N, Parati G, Asmar R, Imai Y, Wang J, Mengden T, Shennan A; 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. doi: 10.1097/MBP.0b013e3283360e98. PMID: 20110786. Erratum in *Blood Press Monit.* 2010;**15**(3):171-2.