

Medaval Accreditation Assessment

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Accreditation assessment of the blood pressure measurement technology used in the Omron RS6 (HEM-6221-E) wrist monitor, as validated according to the European Society of Hypertension International Protocol revision 2010

Approved by the Medaval Advisory Board

Eoin O'Brien (Chair)	Yutaka Imai	Andrew Shennan
George S. Stergiou (Deputy Chair)	Martin Myers	Jan Staessen
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Alejandro de la Sierra	Takayoshi Ohkubo	Paolo Verdecchia
Peter W. de Leeuw	Paolo Palatini	Bernard Waeber
Eamon Dolan	Gianfranco Parati	J-Guang Wang
Geoffrey A. Head		

Reference

Medaval Ltd. Accreditation assessment of the blood pressure measurement technology used in the Omron RS6 (HEM-6221-E) wrist monitor, as validated according to the European Society of Hypertension International Protocol revision 2010. *Medical Device Assessment*. 2016 Aug 5;**2016**(1611). 6 p. Epub: 2019 Jan 31. Available from: <https://www.medaval.ie/MDA/2016/MDA1611.pdf>.

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Medaval Accreditation-Assessment Report – 5th August 2016

Test Device Details

		Assessment
Full Name	Omron RS6	Requirement satisfactory
Model	HEM-6221-E	Requirement satisfactory
Measurement Site	Wrist	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		Modification: Standard image, not photograph, in paper
Manufacturer(s)	Sole: Omron Healthcare, Kyoto Head Office, Shiokoji Horikawa, Shimogyo ku, Kyoto 600 8530, JAPAN.	Requirement satisfactory
Cuffs	Integrated 13.5 cm to 21.5 cm	Cuffs Listed: Requirement satisfactory Wrist Circumferences: Requirement satisfactory

Study Details

Original Publication Takahashi H, Yoshika M, Yokoi T. Validation of Omron RS8, RS6, and RS3 home blood pressure monitoring devices, in accordance with the European Society of Hypertension International Protocol revision 2010. *Vasc Health Risk Manag.* 2013;9:265-72. Epub: 2013 May 28. doi: 10.2147/VHRM.S44569. PMID: 23745050.

Protocol The European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults¹

		Assessment
Adherence	Not stated.	Modification: Missing value accepted by paper review
Adjustments	None	Requirement satisfactory
Study Meas. Method	Oscillometric	Requirement satisfactory
Study Measurement Site	Wrist	Requirement satisfactory
Observers		
Supervisor + 2 Observers	Yes	Requirement satisfactory
Observer Training	BHS online training	Requirement satisfactory
Observer Familiarisation	Not described	Modification: Missing value accepted by paper review
Observers Blinded	From each other stated	Modification: Missing value accepted by paper review
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
	Permitted Modifications	4
	Violations	0

Procedure

Table 1: Screening and Recruitment Details

Screening and Recruitment				Assessment
Total Screened			41	Value within requirements
Total Excluded			8	Value within requirements
	Ranges Complete		4	Value within requirements
	Range Adjustment		0	Value within requirements
	Arrhythmias		3	Value within requirements
	Device Failure		0	Value within requirements
	Poor Quality Sounds		0	Value within requirements
	Cuff Size Unavailable		0	Value within requirements
	Observer Disagreement		0	Value within requirements
	Distribution		0	Value within requirements
	Other Reasons*		1	Value within requirements
Total Recruited			33	Value within requirements
*Explanation Summary				
	None provided			Modification: Missing value accepted by paper review.
Recruitment Ranges				
SBP	Total		33	Value within requirements
	Low	< 90 mmHg	0	Value within requirements
		90 – 129 mmHg	11	Value within requirements
		130 – 160 mmHg	11	Value within requirements
	Medium	130 – 160 mmHg	11	Value within requirements
		161 – 180 mmHg	8	Value within requirements
	High	> 180 mmHg	3	Value within requirements
DBP	Total		33	Value within requirements
	Low	< 40 mmHg	0	Value within requirements
		40 – 79 mmHg	12	Value within requirements
		80 – 100 mmHg	11	Value within requirements
	Medium	80 – 100 mmHg	11	Value within requirements
		101 – 130 mmHg	9	Value within requirements
	High	> 130 mmHg	1	Value within requirements
Total Extremes			4	Value within requirements
On Treatment Ranges				
SBP	Low	< 130 mmHg	0	Value within requirements
	Medium	130 – 160 mmHg	5	Value within requirements
	High	> 160 mmHg	2	Value within requirements
DBP	Low	< 80 mmHg	0	Value within requirements
	Medium	80 – 100 mmHg	2	Value within requirements
	High	> 100 mmHg	5	Value within requirements
Table 1 Assessment				
Checks				36
Permitted Modifications				1
Violations				0

Study Results

Table 2: Subject Details

			Assessment	
Sex	Male:Female	21:12	Value within requirements	Value within requirements
Age (years)	Range (Low:High)	28:70	Value within requirements	Value within requirements
	Mean (SD)	50 (11.6)	Value within requirements	Value within requirements
Arm Circumference (cm)	Range (Low:High)	20:41	Value within requirements	Value within requirements
	Mean (SD)	28.3 (4.2)	Value within requirements	Value within requirements
Wrist Circumference (cm)	Range (Low:High)	13.5:21.2	Value within requirements	Value within requirements
	Mean (SD)	17.8 (2.2)	Value within requirements	Value within requirements
Cuff for Test Device (cm)	Wrist (13.5 – 21.5)	33		
	Total	33	Value within requirements	
Recruitment SBP (mmHg)	Range (Low:High)	94:226	Value within requirements	Value within requirements
	Mean (SD)	142.1 (32.0)	Value within requirements	Value within requirements
Recruitment DBP (mmHg)	Range (Low:High)	51:134	Value within requirements	Value within requirements
	Mean (SD)	86.8 (21.7)	Value within requirements	Value within requirements
Table 2 Assessment			Checks	23
			Permitted Modifications	0
			Violations	0

Table 3: Observer Measurements in each Recruitment Range

			Assessment	
SBP	Overall Range mmHg (Low:High)	88:226	Modification: Missing value accepted by paper review. Estimate from plot proves compliance	Modification: Missing value accepted by paper review. Estimate from plot proves compliance
	Low (< 130 mmHg)	38..39	Modification: Missing value accepted by paper review. Estimate from plot proves compliance	
	Medium (130 – 160 mmHg)	32..33	Modification: Missing value accepted by paper review. Estimate from plot proves compliance	
	High (> 160 mmHg)	28..29	Modification: Missing value accepted by paper review. Estimate from plot proves compliance	
	Maximum Difference	9..11	Modification: Missing value accepted by paper review. Estimate from plot proves compliance	
DBP	Overall Range mmHg (Low:High)	48:146	Modification: Missing value accepted by paper review. Estimate from plot proves compliance	Modification: Missing value accepted by paper review. Estimate from plot proves compliance
	Low (< 80 mmHg)	37..44	Modification: Missing value accepted by paper review. Estimate from plot proves compliance	
	Medium (80 – 100 mmHg)	26..33	Modification: Missing value accepted by paper review. Estimate from plot proves compliance	
	High (> 100 mmHg)	29..36	Modification: Missing value accepted by paper review. Estimate from plot proves compliance	
	Maximum Difference	4..18	Modification: Missing value accepted by paper review. Estimate from plot proves compliance	
Table 3 Assessment			Checks	12
Note: Countable points 98 SBP and 92 DBP.			Permitted Modifications	12
			Violations	0

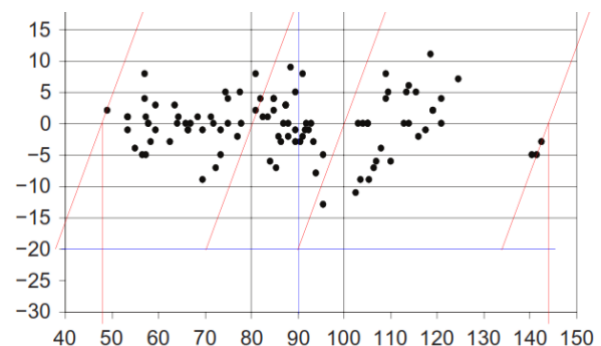
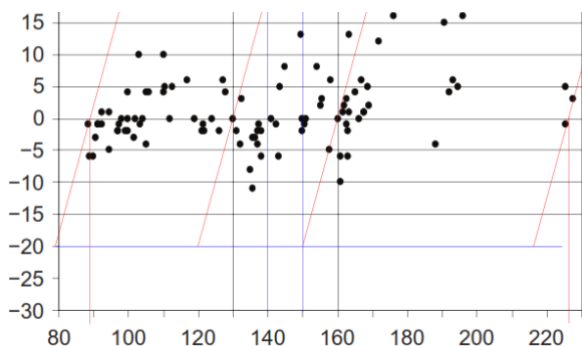
Table 4: Observer Differences

			Assessment	
Observer 2 – Observer 1				
SBP (mmHg)	Range (Low:High)	?:?	Modification: Missing value accepted by paper review.	Modification: Missing value accepted by paper review.
	Mean (SD)	0.0 (1.4)	Value within requirements	Value within requirements
DBP (mmHg)	Range (Low:High)	?:?	Modification: Missing value accepted by paper review.	Modification: Missing value accepted by paper review.
	Mean (SD)	0.2 (1.5)	Value within requirements	Value within requirements
Repeated Measurements		?	Modification: Missing value accepted by paper review.	
Table 4 Assessment			Checks	9
			Permitted Modifications	5
			Violations	0

Table 5: Validation Results

				Assessment		
Part 1						
	Pass Req.		Achieved			
	Two of	All of	SBP	DBP		
≤ 5 mmHg	73	65	99	99	Value within lower passing criteria	Value within lower passing criteria
≤ 10 mmHg	87	81	99	99	Value within passing criteria	Value within passing criteria
≤ 15 mmHg	96	93	99	99	Value within passing criteria	Value within passing criteria
Grade 1			Pass	Pass	Value within lower passing criteria	Value within lower passing criteria
Mean mmHg			-0.0	-0.0	Value within requirements	Value within requirements
SD mmHg			0.0	0.0	Value within requirements	Value within requirements
Part 2						
	Pass Req.	Achieved				
		SBP	DBP			
$2/3 \leq 5$ mmHg	≥ 24	33	33	Value within passing criteria	Value within passing criteria	
$0/3 \leq 5$ mmHg	≤ 3	0	0	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 lower passing criteria	Value within lower passing criteria
Part 3						
Result	Pass		Value within lower passing criteria			
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

<i>Number of checks</i>	125
<i>Number of permitted modifications</i>	22
<i>Number of violations</i>	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 RS6 (HEM-6221-E) 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

1. 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.