

Medaval Accreditation Assessment

Volume 2016

Report 1612

05 August 2016

Accreditation assessment of the blood pressure measurement technology used in the Omron RS8 (HEM-6301F-E) wrist 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 RS8 (HEM-6301F-E) wrist monitor, as validated according to the European Society of Hypertension International Protocol revision 2010. *Medical Device Assessment*. 2016 Aug 5; **2016**(1612). 6 p. Epub: 2019 Jan 31. Available from: <https://www.medaval.ie/MDA/2016/MDA1612.pdf>.

Medical Device Assessment is published by

Medaval Ltd., Unit 107, SBC, Serpentine Ave., Ballsbridge, Dublin D04 H522, IRELAND.

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Medaval Accreditation-Assessment Report – 5th August 2016

Test Device Details

		Assessment
Full Name	Omron RS8	Requirement satisfactory
Model	HEM-6301F-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. <i>Vasc Health Risk Manag.</i> 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 adults ¹	

		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
Subject Preparation	Seated and rested as required	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			43	Value within requirements
Total Excluded			10	Value within requirements
	Ranges Complete		0	Value within requirements
	Range Adjustment		0	Value within requirements
	Arrhythmias		2	Value within requirements
	Device Failure		0	Value within requirements
	Poor Quality Sounds		1	Value within requirements
	Cuff Size Unavailable		0	Value within requirements
	Observer Disagreement		0	Value within requirements
	Distribution		0	Value within requirements
	Other Reasons*		7	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	1	Value within requirements
		90 – 129 mmHg	10	Value within requirements
		130 – 160 mmHg	12	Value within requirements
	Medium	161 – 180 mmHg	9	Value within requirements
		> 180 mmHg	1	Value within requirements
	High		10	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	101 – 130 mmHg	10	Value within requirements
		> 130 mmHg	0	Value within requirements
	High		10	Value within requirements
Total Extremes			2	Value within requirements
On Treatment Ranges				
SBP	Low	< 130 mmHg	0	Value within requirements
	Medium	130 – 160 mmHg	4	Value within requirements
	High	> 160 mmHg	6	Value within requirements
DBP	Low	< 80 mmHg	0	Value within requirements
	Medium	80 – 100 mmHg	5	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	20:13	Value within requirements	Value within requirements
Age (years)	Range (Low:High)	28:72	Value within requirements	Value within requirements
	Mean (SD)	50 (12.3)	Value within requirements	Value within requirements
Arm Circumference (cm)	Range (Low:High)	21.2:35.0	Value within requirements	Value within requirements
	Mean (SD)	28.6 (3.4)	Value within requirements	Value within requirements
Wrist Circumference (cm)	Range (Low:High)	13.7:21.2	Value within requirements	Value within requirements
	Mean (SD)	17.6 (2.0)	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)	88:219	Value within requirements	Value within requirements
	Mean (SD)	140 (32.5)	Value within requirements	Value within requirements
Recruitment DBP (mmHg)	Range (Low:High)	50:118	Value within requirements	Value within requirements
	Mean (SD)	85 (19.9)	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)	86:222	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)	30..34	Modification: Missing value accepted by paper review. Estimate from plot proves compliance	
	Medium (130 – 160 mmHg)	42..46	Modification: Missing value accepted by paper review. Estimate from plot.	
	High (> 160 mmHg)	19..23	Modification: Missing value accepted by paper review. Estimate from plot.	
	Maximum Difference	7..27	Modification: Missing value accepted by paper review. Estimate from plot.	
DBP	Overall Range mmHg (Low:High)	50:138	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)	31..37	Modification: Missing value accepted by paper review. Estimate from plot proves compliance	
	Medium (80 – 100 mmHg)	37..43	Modification: Missing value accepted by paper review. Estimate from plot proves compliance	
	High (> 100 mmHg)	25..31	Modification: Missing value accepted by paper review. Estimate from plot proves compliance	
	Maximum Difference	6..18	Modification: Missing value accepted by paper review. Estimate from plot proves compliance	
Table 3 Assessment			Checks	12
Note: Countable points 95 SBP and 93 DBP.			Permitted Modifications	12
			Violations	0

Table 4: Observer Differences

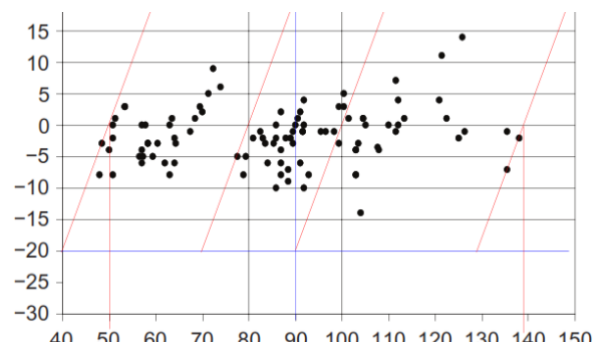
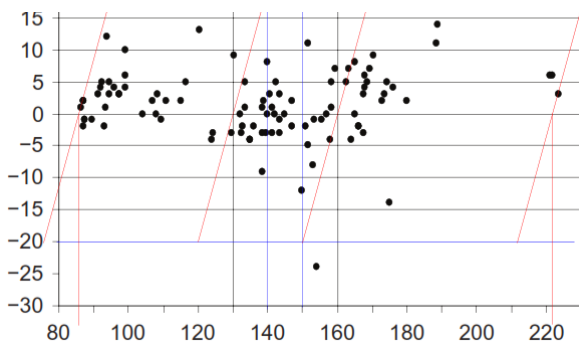
			Assessment	
Observer 2 – Observer 1				
SBP (mmHg)	Range (Low:High)	?:?	Modification: Missing value accepted by paper review.	Modification: Missing value accepted by paper review.
	Mean (SD)	-0.2 (1.3)	Value within requirements	Value within requirements
DBP (mmHg)	Range (Low:High)	?:?	Modification: Missing value accepted by paper review.	Modification: Missing value accepted by paper review.
	Mean (SD)	+0.3 (1.4)	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	76	74	Value within passing criteria	Value within passing criteria
≤ 10 mmHg	87	81	90	96	Value within passing criteria	Value within passing criteria
≤ 15 mmHg	96	93	97	99	Value within passing criteria	Value within passing criteria
Grade 1			Pass	Pass	Value within passing criteria	Value within passing criteria
Mean mmHg			+1.5	-1.7	Value within requirements	Value within requirements
SD mmHg			5.8	4.6	Value within requirements	Value within requirements
Part 2						
		Pass Req.	Achieved			
		≥ 24	SBP	DBP		
2/3 ≤ 5 mmHg		≥ 24	26	26	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						
Result	Pass			Value within passing criteria		

Table 5 Assessment			Checks	21
			Permitted Modifications	0
			Violations	0

Plots



			Assessment	
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 RS8 (HEM-6301F-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.