Medical Device Assessment

Medaval Accreditation Assessment

Volume 2016 Report 1610 05 August 2016

Accreditation assessment of the blood pressure measurement technology used in the Omron RS3 (HEM-6130-E) wrist monitor, as validated according to the European Society of Hypertension International Protocol revision 2010

Reference Medaval Ltd. Accreditation assessment of the blood pressure measurement technology used in the Omron RS3 (HEM-6130-E) wrist monitor, as validated according to the European Society of Hypertension International Protocol revision 2010. *Medical Device Assessment*. 2016 Aug 5;**2016**(1610). 6 p. Epub: 2019 Jan 31. Available from: https://www.medaval.ie/MDA/2016/MDA1610.pdf.

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Accreditation assessment of the blood pressure measurement technology used in the Omron RS3 (HEM-6130-E) wrist 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 RS3	Requirement satisfactory
Model	HEM-6130-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 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				**81**	Value within requirements
Total Excluded				**48**	Value within requirements
	Ranges Complete	**32**			Value within requirements
	Range Adjustment	**0**			Value within requirements
	Arrhythmias	**7**			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*	**8**			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		**11**		Value within requirements
		< 90 *mmHg*	**0**		Value within requirements
		90 – 129 *mmHg*	**11**		Value within requirements
	Medium	130 – 160 *mmHg*	**10**		Value within requirements
	High		**12**		Value within requirements
		161 – 180 *mmHg*	**9**		Value within requirements
		> 180 *mmHg*	**3**		Value within requirements
DBP	Total			**33**	Value within requirements
	Low		**11**		Value within requirements
		< 40 *mmHg*	**0**		Value within requirements
		40 –79 *mmHg*	**11**		Value within requirements
	Medium	80 – 100 *mmHg*	**12**		Value within requirements
	High		**10**		Value within requirements
		101 – 130 *mmHg*	**10**		Value within requirements
		> 130 *mmHg*	**0**		Value within requirements
Total Extremes			**3**		Value within requirements

On Treatment Ranges				
SBP	Low	< 130 *mmHg*	**1**	Value within requirements
	Medium	130 – 160 *mmHg*	**3**	Value within requirements
	High	> 160 *mmHg*	**4**	Value within requirements
DBP	Low	< 80 *mmHg*	**1**	Value within requirements
	Medium	80 – 100 *mmHg*	**4**	Value within requirements
	High	> 100 *mmHg*	**3**	Value within requirements

Table 1 Assessment		
	Checks	36
	Permitted Modifications	1
	Violations	0

Study Results

Table 2: Subject Details

			Assessment	
Sex	Male:Female	**15:18**	Value within requirements	Value within requirements
Age *(years)*	Range *(Low:High)*	**32:75**	Value within requirements	Value within requirements
	Mean (SD)	**50 (11.8)**	Value within requirements	Value within requirements
Arm Circumference *(cm)*	Range *(Low:High)*	**19.9:38.2**	Value within requirements	Value within requirements
	Mean (SD)	**28.8 (4.8)**	Value within requirements	Value within requirements
Wrist Circumference *(cm)*	Range *(Low:High)*	**13.6:20.8**	Value within requirements	Value within requirements
	Mean (SD)	**17.0 (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)*	**94:209**	Value within requirements	Value within requirements
	Mean (SD)	**144 (31.1)**	Value within requirements	Value within requirements
Recruitment DBP *(mmHg)*	Range *(Low:High)*	**52:120**	Value within requirements	Value within requirements
	Mean (SD)	**87 (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)*	**84:184**	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)*	**32..39**	Modification: Missing value accepted by paper review. Estimate from plot proves compliance	
	Medium *(130 – 160 mmHg)*	**38..45**	Modification: Missing value accepted by paper review. Estimate from plot	
	High *(> 160 mmHg)*	**22..29**	Modification: Missing value accepted by paper review. Estimate from plot proves compliance	
	Maximum Difference	**9..23**	Modification: Missing value accepted by paper review. Estimate from plot	
DBP	Overall Range *mmHg* (Low:High)	**48:120**	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*)	**29..38**	Modification: Missing value accepted by paper review. Estimate from plot proves compliance	
	Medium (80 – 100 *mmHg*)	**32..41**	Modification: Missing value accepted by paper review. Estimate from plot proves compliance	
	High (> 100 *mmHg*)	**29..38**	Modification: Missing value accepted by paper review. Estimate from plot proves compliance	
	Maximum Difference	**≤ 12**	Modification: Missing value accepted by paper review. Estimate from plot proves compliance	

Table 3 Assessment	**Checks**	12
Note: Countable points 92 SBP and 90 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)	**–0.4 (1.6)**	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

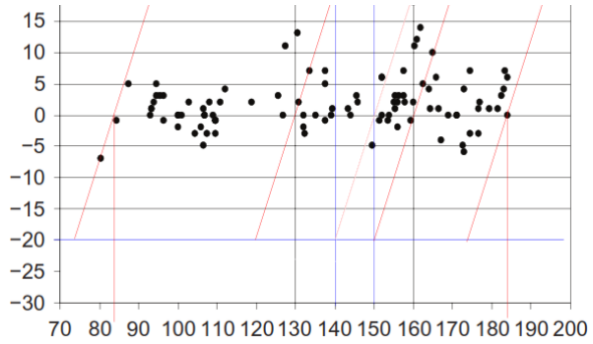
Part 1	Pass Req.		Achieved		Assessment	
	Two of	All of	SBP	DBP		
≤ 5 *mmHg*	73	65	**81**	**72**	Value within passing criteria	Value within lower passing criteria
≤ 10 *mmHg*	87	81	**93**	**94**	Value within passing criteria	Value within passing criteria
≤ 15 *mmHg*	96	93	**98**	**99**	Value within passing criteria	Value within passing criteria
Grade 1			**Pass**	**Pass**	Value within passing criteria	Value within lower passing criteria
Mean *mmHg*			**1.8**	**1.7**	Value within requirements	Value within requirements
SD *mmHg*			**4.3**	**4.5**	Value within requirements	Value within requirements

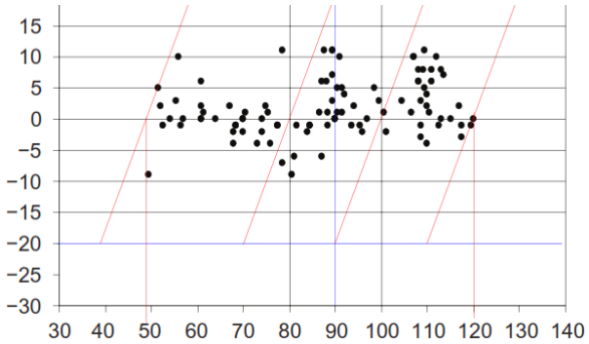
Part 2	Pass Req.	Achieved SBP	Achieved DBP		
2/3 ≤ 5 *mmHg*	≥ 24	**27**	**26**	Value within passing criteria	Value within passing criteria
0/3 ≤ 5 *mmHg*	≤ 3	**0**	**3**	Value within passing criteria	Value within passing criteria
Grade 2		**Pass**	**Pass**	Value within passing criteria	Value within passing criteria
Grade 3		**Pass**	**Pass**	Value within passing criteria	Value within lower passing criteria

Part 3			
Result	**Pass**	Value within lower 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

Number of checks	125
Number of permitted modifications	22
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 RS3 (HEM-6130-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.

