

Medaval Accreditation Assessment

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Accreditation assessment of the blood pressure measurement technology used in the Omron BP-760N (HEM-7320-Z) upper arm monitor, as validated according to the AAMI/ANSI/ISO 81060-2:2013 standard for a general study in adults

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 BP-760N (HEM-7320-Z) upper arm monitor, as validated according to the AAMI/ANSI/ISO 81060-2:2013 standard for a general study in adults. *Medical Device Assessment*. 2016 Aug 5; **2016**(1624). 5 p. Epub: 2019 Jan 31. Available from: <https://www.medaval.ie/MDA/2016/MDA1624.pdf>.

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Medaval Accreditation-Assessment Report – 5th August 2016

Test Device Details

		Assessment
Full Name	Omron BP-760N	Requirement satisfactory
Model	HEM-7320-Z	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		
Manufacturer(s)	Sole: Omron Healthcare, Kyoto Head Office, Shiokoji Horikawa, Shimogyo ku, Kyoto 600 8530, JAPAN.	Requirement satisfactory
Cuffs	Omron HEM-FL31: Medium-Large 22 cm to-42 cm	Cuffs Listed: Requirement satisfactory Arm Circumferences: Requirement satisfactory

Study Details

Original Publication	Takahashi H, Yoshika M, Yokoi T. Validation of two automatic devices for the self-measurement of blood pressure according to the ANSI/AAMI/ISO81060-2:2009 guidelines: the Omron BP765 (HEM-7311-ZSA) and the Omron BP760N (HEM-7320-Z). <i>Vasc Health Risk Manag.</i> 2015 Jan; 9 (11):49-53. doi: 10.2147/VHRM.S72438. PMID: 25657587.	
Protocol	Followed: The AAMI/ANSI/ISO 81060-2:2009 standard for a general study in adults. ¹ Fulfils: The AAMI/ANSI/ISO 81060-2:2013 standard for a general study in adults. ¹	
		Assessment
Reference Determination	Sequential same-arm	Requirement satisfactory
Adherence	81060-2:2009 covers 2013	Optional data satisfactory
Adjustments	None	Optional data satisfactory
Study Meas. Method	Oscillometric	Requirement satisfactory
Study Measurement Site	Upper Arm	Requirement satisfactory
Observers		
Supervisor + 2 Observers	Yes	Optional data satisfactory
Observer Training	BHS online training	Optional data satisfactory
Observer Familiarisation	Not specified	Optional data not provided
Observers Blinded	From device and each other	Optional data satisfactory
Sample		
Population	A general population	Requirement satisfactory
Circumstances	None	Requirement satisfactory
HBP Subjects Selection	Hospital outpatients	Optional data satisfactory
NBP Subjects Selection	Hospital staff	Optional data satisfactory

Test Device Details and Study Details Assessment	Checks	22
	Permitted Modifications	0
	Violations	0

Procedure

Table 1: Screening and Recruitment Details

Screening and Recruitment		Assessment
Total Screened	105	Value within requirements
Total Excluded	20	Value within requirements
Device Failure		Optional detail not provided
Poor Quality Sounds		Optional detail not provided
Cuff Size Unavailable		Optional detail not provided
Observer Disagreement		Optional detail not provided
Bigeminy		Optional detail not provided
Trigeminy		Optional detail not provided
Isolated VPB		Optional detail not provided
Atrial Fibrillation		Optional detail not provided
Other Reasons*		Optional detail not provided
Total Recruited	85	Value within requirements
*Explanation Summary		
Subjects < 20 years old, arm circumference outside 22 cm to 42 cm, with arrhythmias, who moved their arms during measurements or had unclear K5 were excluded.		Optional detail not provided

Table 1 Assessment	Checks	13
	Permitted Modifications	0
	Violations	0

Study Results

Table 2: Subject Details

			Assessment	
Sex	Male:Female	40:45	Value within requirements	Value within requirements
Age (years)	Range (Low:High)	22:79	Value within requirements	Value within requirements
	Mean (SD)	48 (11.1)	Optional data satisfactory	Optional data satisfactory
Arm Circumference (cm)	Range (Low:High)	23.5:42.0	Optional data satisfactory	Optional data satisfactory
	Mean (SD)	32.0 (5.0)	Optional data satisfactory	Optional data satisfactory
	Adults:Children	85:0	Value within requirements	Value within requirements
Cuff for Test Device (cm)	ML (22- 42)	85	Value within requirements	
	Q1 (22 – 27)	24	Value within requirements	
	Q2 (27.1 – 32)	15	Value within requirements	
	Q3 (32.1 – 37)	27	Value within requirements	
	Q4 (37.1 – 42)	19	Value within requirements	
Recruitment SBP (mmHg)	Range (Low:High)	18:177	Control data provided instead	Control data provided instead
	Mean (SD)	127 (22.8)	Control data provided instead	Control data provided instead
Recruitment DBP (mmHg)	Range (Low:High)	48:121	Control data provided instead	Control data provided instead
	Mean (SD)	82 (14.5)	Control data provided instead	Control data provided instead

Table 2 Assessment	Checks	25
	Permitted Modifications	0
	Violations	0

Table 3: Observer Measurements Range-Requirements

			Assessment	
SBP	≤ 100 mmHg	16%	Value within requirements	
	101 – 139 mmHg	58%	Value within requirements	
	140 – 159 mmHg	15%	Value within requirements	
	≥ 160 mmHg	11%	Value within requirements	
DBP	≤ 60 mmHg	7%	Value within requirements	
	61 – 84 mmHg	53%	Value within requirements	
	85 – 99 mmHg	29%	Value within requirements	
	≥ 100 mmHg	11%	Value within requirements	
DBP sounds used	K4:K5 (subjects)	0:85	Value within requirements	Value within requirements
Table 3 Assessment			Checks	10
			Permitted Modifications	0
			Violations	0

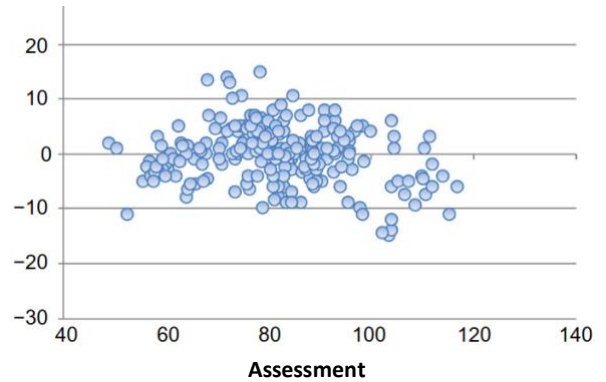
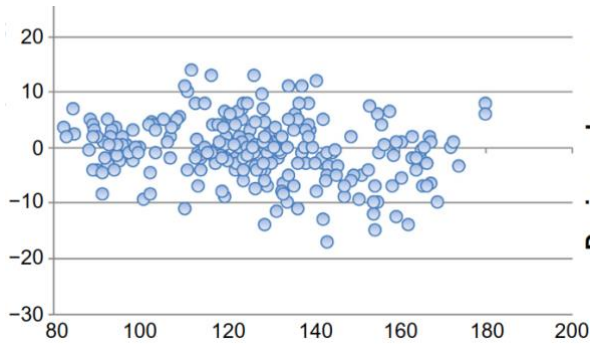
Table 4: Observer Differences

				Assessment	
Observer 2 – Observer 1					
SBP (mmHg)	Range (Low:High)	?:?	Optional data not provided	Optional data not provided	
	Mean (SD)	0 (1.3)	Optional data provided	Optional data provided	
DBP (mmHg)	Range (Low:High)	?:?	Optional data not provided	Optional data not provided	
	Mean (SD)	0 (1.4)	Optional data provided	Optional data provided	
Repeated Measurements		?	Modification: Missing value accepted by paper review		
Table 4 Assessment			Checks	9	
			Permitted Modifications	1	
			Violations	0	

Table 5: Validation Results

Criterion 1	Pass Req.	Achieved		Assessment	
		SBP	DBP		
Measurement pairs		255		Value within requirements	
Mean mmHg	≤ 5	-0.6	-0.1	Value within passing criteria	Value within passing criteria
SD mmHg	≤ 8	5.3	5.0	Value within passing criteria	Value within passing criteria
Grade 1		Pass	Pass	Value within passing criteria	Value within passing criteria
Criterion 2					
Number of subjects		85		Value within requirements	
Mean mmHg		-0.6	-0.1	Value within passing criteria	Value within passing criteria
SD mmHg	≤ 6.91:6.95	4.1	4.3	Value within passing criteria	Value within passing criteria
Grade 2		Pass	Pass	Value within passing criteria	Value within passing criteria
Result		Pass		Value within passing criteria	
Table 4 Assessment			Checks	15	
			Permitted Modifications	0	
			Violations	0	

Plots



SBP Plot Provided **Yes**
 DBP Plot Provided **Yes**

Optional data provided
 Optional data provided

Plots Assessment	Checks	2
	Permitted Modifications	0
	Violations	0

Recommendations

Overall Summary

Number of checks 96
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 BP-760N (HEM-7320-Z), with the HEM-FL31 22 cm to-42 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 AAMI/ANSI/ISO 81060-2:2013 standard.

Date of Advisory Board Approval: 29th July 2016.

References

1. American National Standards Institute, Association for the Advancement of Medical Instrumentation, International Electrotechnical Commission. ANSI/AAMI/IEC 80601-2-30:2009 & A1:2013, Medical electrical equipment - Part 2-30: Particular requirements for basic safety and essential performance of automated type non-invasive sphygmomanometers and Amendment 1. Geneva, Switzerland: IEC Central Office; 2009.
2. Association for the Advancement of Medical Instrumentation, American National Standards Institute, International Organization for Standardization. AAMI/ANSI/ISO 81060-2:2013, Non-invasive Sphygmomanometers - Part 2: Clinical Investigation of Automated Measurement Type. Geneva, Switzerland: ISO; 2013.