

Medaval Accreditation Assessment

Volume 2016

Report 1622

05 August 2016

Accreditation assessment of the blood pressure measurement technology used in the Omron M3500 NIBP module, for hospital monitors, as validated according to the AAMI/ANSI/ISO 81060-2:2013 standard for a general study in adults and children

Approved by the Medaval Advisory Board

Eoin O'Brien (Chair)	Yutaka Imai	Andrew Shennan
George S. Stergiou (Deputy Chair)	Martin Myers	Jan Staessen
Roland Asmar	Gbenga Ogedegbe	Martin J. Turner
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 M3500 NIBP module, for hospital monitors, as validated according to the AAMI/ANSI/ISO 81060-2:2013 standard for a general study in adults and children. *Medical Device Assessment*. 2016 Aug 5; **2016**(1622). 8 p. Epub: 2019 Jan 31. Available from: <https://www.medaval.ie/MDA/2016/MDA1622.pdf>.

Medical Device Assessment is published by

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

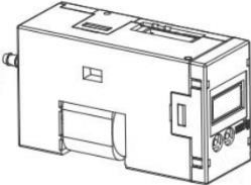
© 2016-2019 Medaval Ltd. All rights reserved.

Permissions: Requests for permissions to reproduce figures, tables, or portions of reports or articles originally published in *Medical Device Assessment* can be obtained by email request to info@medaval.ie.

Accreditation assessment of the blood pressure measurement technology used in the Omron M3500 NIBP module, for hospital monitors, as validated according to the AAMI/ANSI/ISO 81060-2:2013 standard for a general study in adults and children

Medaval Accreditation-Assessment Report – 5th August 2016

Test Device Details

		Assessment
Full Name	Omron M3500 NIBP Module	Requirement satisfactory
Model	M3500	Requirement satisfactory
Measurement Site	Upper Arm	Requirement satisfactory
Client Use	Suitable for professional measurement.	Requirement satisfactory
Operation Method	Oscillometry, automatic during deflation	Requirement satisfactory
Measurement Occurrence	Single Measurements Only	Requirement satisfactory
Device Diagram		
Manufacturer(s)	Sole: Omron, Kyoto Head Office, Shiokoji Horikawa, Shimogyo ku, Kyoto 600 8530, JAPAN	Requirement satisfactory
Cuffs	Super-Small 12 cm to 18 cm Small 17 cm to 22 cm Medium 22 cm to 32 cm Large 32 cm to 42 cm Extra-Large 42 cm to 50 cm	Cuffs Listed: Requirement satisfactory Arm Circumferences: Requirement satisfactory

Test Device Details and Study Details Assessment	Checks	9
	Permitted Modifications	0
	Violations	0

Normal-Speed Mode Study

Study Details

Original Publication	Chahine MN, Assemaani N, Sayed Hassan G, Cham M, Salameh P, Asmar R. Validation of the OMRON M3500 Blood Pressure Measuring Device Using Normal- and High-Speed Modes in Adult and Specific Populations (Obese and Children) According to AAMI Protocol. <i>J Clin Hypertens (Greenwich)</i> . Epub: 2015 Apr 2. doi: 10.1111/jch.12540.. PMID: 25833259.	
Protocol	Followed: The AAMI/ANSI/ISO 81060-2:2009 standard for a general study in adults and children. ¹ Fulfils: The AAMI/ANSI/ISO 81060-2:2013 standard for a general study in adults and children. ¹	
		Assessment
Reference Determination	Sequential same arm	Requirement satisfactory
Adherence	Followed Precisely	Optional data provided
Adjustments	None	Optional data provided
Study Meas. Method	Oscillometric	Requirement satisfactory
Study Measurement Site	Upper Arm	Requirement satisfactory
Observers		
Supervisor + 2 Observers	Yes	Optional data provided
Observer Training	Training video	Optional data provided
Observer Familiarisation	Outpatient clinic for 2 weeks	Optional data provided
Observers Blinded	From device and each other	Optional data provided

Sample

Population	A general population	Requirement satisfactory
Circumstances	Normal Speed	Requirement satisfactory
HBP Subjects Selection	Not specified	Optional data not provided
NBP Subjects Selection	Not specified	Optional data not provided

Study Details Assessment	Checks	13
	Permitted Modifications	0
	Violations	0

Procedure

Table 1: Screening and Recruitment Details

Screening and Recruitment		Assessment
Total Screened	135	Optional data not included
Total Excluded		Optional data not included
Device Failure		Optional data not included
Poor Quality Sounds		Optional data not included
Cuff Size Unavailable		Optional data not included
Observer Disagreement		Optional data not included
Bigeminy		Optional data not included
Trigeminy		Optional data not included
Isolated VPB		Optional data not included
Atrial Fibrillation		Optional data not included
Other Reasons*		Optional data not included
Total Recruited	135	Value within requirements
*Explanation Summary		Optional data not included

Table 1 Assessment	Checks	13
	Permitted Modifications	0
	Violations	0

Study Results

Table 2: Subject Details

			Assessment	
Sex	Male:Female	74:61	Value within requirements	Value within requirements
Age (years)	Range (Low:High)	5:93	Value within requirements	Value within requirements
	Mean (SD)	39.8 (25.5)	Optional data provided	Optional data provided
	Adults:Children	100:35	Value within requirements	Value within requirements
Arm Circumference (cm)	Range (Low:High)	15:46	Optional data provided	Optional data provided
	Mean (SD)	27.7 (7.3)	Optional data provided	Optional data provided
Cuff for Test Device (cm)	Total	85	Value within requirements	
	SS (12 – 18)	2 (1.5%)	Cuff not counted - Value outside requirements	
	S (17 – 22)	41 (30.4%)	Value within requirements	
	M (22 – 32)	61 (45.2%)	Value within requirements	
	L (32 – 42)	16 (11.9%)	Value within requirements	
	XL (42 – 50)	15 (11.1%)	Value within requirements	
Recruitment SBP (mmHg)	Range (Low:High)	88:202	Optional data provided	Optional data provided
	Mean (SD)	126.6 (25.2)	Optional data provided	Optional data provided
Recruitment DBP (mmHg)	Range (Low:High)	40:107	Optional data provided	Optional data provided
	Mean (SD)	73.3 (14.7)	Optional data provided	Optional data provided

Table 2 Assessment	Checks	26
	Permitted Modifications	0
	Violations	0

Table 3: Observer Measurements Range-Requirements

			Assessment	
SBP	≤ 100 mmHg	11	Modification: Value per subject rather than measurement	
	101 – 139 mmHg	42	Modification: Value per subject rather than measurement	
	140 – 159 mmHg	33	Modification: Value per subject rather than measurement	
	≥ 160 mmHg	14	Modification: Value per subject rather than measurement	
DBP	≤ 60 mmHg	13	Modification: Value per subject rather than measurement	
	61 – 84 mmHg	48	Modification: Value per subject rather than measurement	
	85 – 99 mmHg	33	Modification: Value per subject rather than measurement	
	≥ 100 mmHg	6	Modification: Value per subject rather than measurement	
DBP sounds used	K4:K5 (subjects)	0:85	Modification: Understood from context	Modification: Understood from context

Table 3 Assessment	Checks	10
	Permitted Modifications	10
	Violations	0

Table 4: Observer Differences

			Assessment	
Observer 2 – Observer 1				
SBP (<i>mmHg</i>)	Range (<i>Low:High</i>)	-4:+4	Data provided generally	Data provided generally
	Mean (SD)	+1.50 (0.87)	Optional data provided	Optional data provided
DBP (<i>mmHg</i>)	Range (<i>Low:High</i>)	-4:+4	Data provided generally	Data provided generally
	Mean (SD)	+1.46 (0.90)	Optional data provided	Optional data provided
Repeated Measurements		?	Modification: Missing values accepted by paper review	

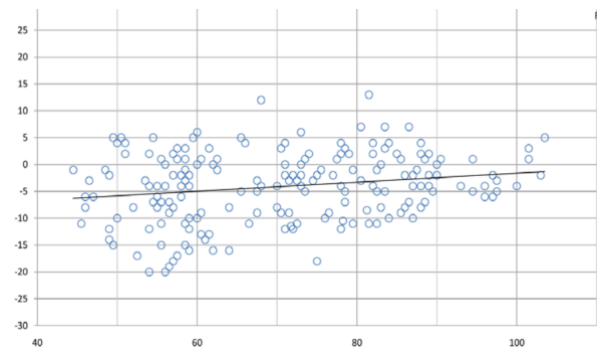
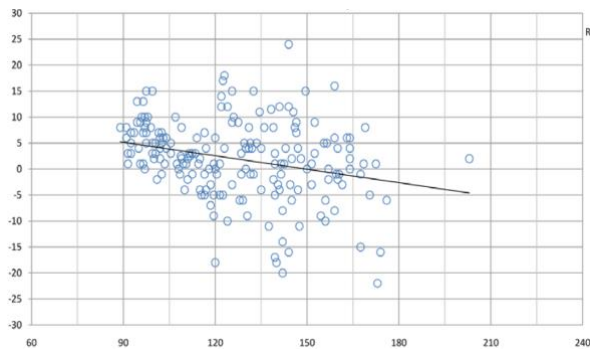
Table 4 Assessment	Checks	9
	Permitted Modifications	1
	Violations	0

Table 5: Validation Results

Criterion 1	Pass Req.	Achieved		Assessment	
		SBP	DBP		
Measurement pairs		405		Value within requirements	
Mean <i>mmHg</i>	≤ 5	+1.9	-3.9	Value within passing criteria	Value within passing criteria
SD <i>mmHg</i>	≤ 8	6.35	6.49	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		135		Value within requirements	
Mean <i>mmHg</i>		+1.9	-3.9	Value within passing criteria	Value within passing criteria
SD <i>mmHg</i>	≤ 6.71:5.77	5.14	5.57	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**

Assessment

Optional data provided
 Optional data provided

Plots Assessment	Checks	2
	Permitted Modifications	0
	Violations	0

High-Speed Mode Study

Study Details

Original Publication Chahine MN, Assemaani N, Sayed Hassan G, Cham M, Salameh P, Asmar R. Validation of the OMRON M3500 Blood Pressure Measuring Device Using Normal- and High-Speed Modes in Adult and Specific Populations (Obese and Children) According to AAMI Protocol. *J Clin Hypertens (Greenwich)*. Epub: 2015 Apr 2. doi: 10.1111/jch.12540.. PMID: 25833259.

Protocol
 Followed: The AAMI/ANSI/ISO 81060-2:2009 standard for a general study in adults and children.¹
 Fulfils: The AAMI/ANSI/ISO 81060-2:2013 standard for a general study in adults and children.¹

		Assessment
Reference Determination	Sequential same arm	Requirement satisfactory
Adherence	Followed Precisely	Optional data provided
Adjustments	None	Optional data provided
Study Meas. Method	Oscillometric	Requirement satisfactory
Study Measurement Site	Upper Arm	Requirement satisfactory
Observers		
Supervisor + 2 Observers	Yes	Optional data provided
Observer Training	SFHTA training program	Optional data provided
Observer Familiarisation	Outpatient clinic for 2 weeks	Optional data provided
Observers Blinded	From device and each other	Optional data provided
Sample		
Population	A general population	Requirement satisfactory
Circumstances	High Speed	Requirement satisfactory
HBP Subjects Selection	Not specified	Optional data not provided
NBP Subjects Selection	Not specified	Optional data not provided

Study Details Assessment	Checks	13
	Permitted Modifications	0
	Violations	0

Procedure

Table 1: Screening and Recruitment Details

Screening and Recruitment		Assessment
Total Screened		Optional data not included
Total Excluded		Optional data not included
Device Failure		Optional data not included
Poor Quality Sounds		Optional data not included
Cuff Size Unavailable		Optional data not included
Observer Disagreement		Optional data not included
Bigeminy		Optional data not included
Trigeminy		Optional data not included
Isolated VPB		Optional data not included
Atrial Fibrillation		Optional data not included
Other Reasons*		Optional data not included
Total Recruited	135	Value within requirements
*Explanation Summary		Optional data not included

Table 1 Assessment	Checks	13
	Permitted Modifications	0
	Violations	0

Study Results

Table 2: Subject Details

			Assessment	
Sex	Male:Female	68:67	Value within requirements	Value within requirements
Age (years)	Range (Low:High)	4:93	Value within requirements	Value within requirements
	Mean (SD)	40.2 (26.2)	Optional data provided	Optional data provided
	Adults:Children	100:35	Value within requirements	Value within requirements
Arm Circumference (cm)	Range (Low:High)	15:46	Optional data provided	Optional data provided
	Mean (SD)	27.7 (7.5)	Optional data provided	Optional data provided
Cuff for Test Device (cm)	Total	85	Value within requirements	
	SS (12 – 18)	3 (2.2%)	Cuff not counted - Value outside requirements	
	S (17 – 22)	42 (31.1%)	Value within requirements	
	M (22 – 32)	60 (44.4%)	Value within requirements	
	L (32 – 42)	15 (11.1%)	Value within requirements	
	XL (42 – 50)	15 (11.1%)	Value within requirements	
Recruitment SBP (mmHg)	Range (Low:High)	88:181	Optional data provided	Optional data provided
	Mean (SD)	126.3 (25.8)	Optional data provided	Optional data provided
Recruitment DBP (mmHg)	Range (Low:High)	40:103	Optional data provided	Optional data provided
	Mean (SD)	73.2 (14.6)	Optional data provided	Optional data provided

Table 2 Assessment	Checks	26
	Permitted Modifications	0
	Violations	0

Table 3: Observer Measurements Range-Requirements

			Assessment	
SBP	≤ 100 mmHg	11	Modification: Value per subject rather than measurement	
	101 – 139 mmHg	41	Modification: Value per subject rather than measurement	
	140 – 159 mmHg	32	Modification: Value per subject rather than measurement	
	≥ 160 mmHg	16	Modification: Value per subject rather than measurement	
DBP	≤ 60 mmHg	13	Modification: Value per subject rather than measurement	
	61 – 84 mmHg	49	Modification: Value per subject rather than measurement	
	85 – 99 mmHg	33	Modification: Value per subject rather than measurement	
	≥ 100 mmHg	5	Modification: Value per subject rather than measurement	
DBP sounds used	K4:K5 (subjects)	0:85	Modification: Understood from context	Modification: Understood from context

Table 3 Assessment	Checks	10
	Permitted Modifications	10
	Violations	0

Table 4: Observer Differences

			Assessment	
Observer 2 – Observer 1				
SBP (<i>mmHg</i>)	Range (<i>Low:High</i>)	-4:+4	Data provided generally	Data provided generally
	Mean (SD)	+1.47 (0.84)	Optional data provided	Optional data provided
DBP (<i>mmHg</i>)	Range (<i>Low:High</i>)	-4:+4	Data provided generally	Data provided generally
	Mean (SD)	+1.44 (0.90)	Optional data provided	Optional data provided
Repeated Measurements		?	Modification: Missing values accepted by paper review	

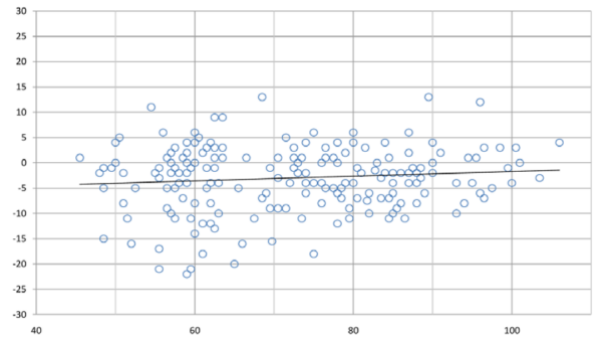
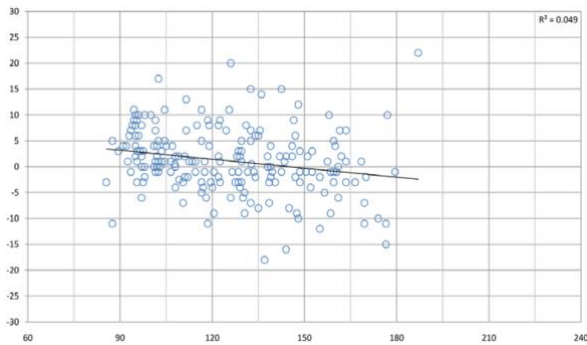
Table 4 Assessment	Checks	9
	Permitted Modifications	1
	Violations	0

Table 5: Validation Results

Criterion 1	Pass Req.	Achieved		Assessment	
		SBP	DBP		
Measurement pairs		405		Value within requirements	
Mean <i>mmHg</i>	≤ 5	+1.3	-2.6	Value within passing criteria	Value within passing criteria
SD <i>mmHg</i>	≤ 8	6.15	6.59	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		135		Value within requirements	
Mean <i>mmHg</i>		+1.3	-2.6	Value within passing criteria	Value within passing criteria
SD <i>mmHg</i>	≤ 6.82:6.43	4.76	5.37	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



Assessment

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 185
Number of permitted modifications 22
Number of violations 0

Assessment Summary

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

Certification Decision

The Omron M3500 NIBP module, with the Small 17 cm to 22 cm, Medium 22 cm to 32 cm, Large 32 cm to 42 cm or Extra-Large 42 cm to 50 cm cuff, is certified by Medaval Ltd., for blood pressure measurement, in adults or in children over three years old, using either normal speed or high speed mode, as it fulfilled the conditions required for a pass in two validation studies, both 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.