

Medaval Accreditation Assessment

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Accreditation assessment of the blood pressure measurement technology used in the Thermor BIOS BD-215 upper arm 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 Thermor BIOS BD-215 upper arm monitor, as validated according to the European Society of Hypertension International Protocol revision 2010. *Medical Device Assessment*. 2016 Aug 5;2016(1615). 5 p. Epub: 2019 Jan 31. Available from: <https://www.medaval.ie/MDA/2016/MDA1615.pdf>.

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Accreditation assessment of the blood pressure measurement technology used in the Thermor BIOS BD-215 upper arm 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	Thermor BIOS BD-215	Requirement satisfactory
Model	BD-215	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		Requirement satisfactory
Manufacturer(s)	Thermor Ltd., 16975 Leslie Street, Newmarket, Ontario L3Y 9A1, CANADA	Requirement satisfactory
Cuffs	Wide-Range: 24 cm to 43 cm	Cuffs Listed: Requirement satisfactory Arm Circumferences: Requirement satisfactory

Study Details

Original Publication	Benetti E, Fania C, Márquez Hernández V, Palatini P. Validation of the Thermor BIOS BD215 device for home blood pressure measurement according to the European Society of Hypertension International Protocol revision 2010. <i>Blood Press Monit.</i> 2014 Jun; 19 (3):176-9. doi: 10.1097/MBP.0000000000000030. PMID: 24589529.	
Protocol	The European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults ¹	

		Assessment
Adherence	Followed Precisely	Requirement satisfactory
Adjustments	None	Requirement satisfactory
Study Meas. Method	Oscillometric	Requirement satisfactory
Study Measurement Site	Upper Arm	Requirement satisfactory
Observers		
Supervisor + 2 Observers	Yes	Requirement satisfactory
Observer Training	Expert training	Requirement satisfactory
Observer Familiarisation	40 measurements	Requirement satisfactory
Observers Blinded	From device and each other	Requirement satisfactory
Sample		
Population	A general population	Requirement satisfactory
Circumstances	None	Requirement satisfactory
HBP Subjects Selection	Inpatients, outpatients & day patients	Requirement satisfactory
NBP Subjects Selection	Inpatients, outpatients, day patients & medical staff	Requirement 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			44	Value within requirements
Total Excluded			11	Value within requirements
	Ranges Complete		9	Value within requirements
	Range Adjustment		2	Value within requirements
	Arrhythmias		0	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*		0	Value within requirements
Total Recruited			33	Value within requirements
*Explanation Summary				No details required
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	12	Value within requirements
	High		10	Value within requirements
		161 – 180 mmHg	10	Value within requirements
		> 180 mmHg	0	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	11	Value within requirements
	High		11	Value within requirements
		101 – 130 mmHg	11	Value within requirements
		> 130 mmHg	0	Value within requirements
Total Extremes			0	Value within requirements
On Treatment Ranges				
SBP	Low	< 130 mmHg	2	Value within requirements
	Medium	130 – 160 mmHg	9	Value within requirements
	High	> 160 mmHg	4	Value within requirements
DBP	Low	< 80 mmHg	3	Value within requirements
	Medium	80 – 100 mmHg	8	Value within requirements
	High	> 100 mmHg	4	Value within requirements
Table 1 Assessment				Checks 36
				Permitted Modifications 0
				Violations 0

Study Results

Table 2: Subject Details

			Assessment	
Sex	Male:Female	17:16	Value within requirements	Value within requirements
Age (years)	Range (Low:High)	25:80	Value within requirements	Value within requirements
	Mean (SD)	57.0 (15.0)	Value within requirements	Value within requirements
Arm Circumference (cm)	Range (Low:High)	24:33	Value within requirements	Value within requirements
	Mean (SD)	28.0 (3.0)	Value within requirements	Value within requirements
Cuff for Test Device (cm)	Universal (24 – 43)	33		
	Total	33	Value within requirements	
Recruitment SBP (mmHg)	Range (Low:High)	100:178	Value within requirements	Value within requirements
	Mean (SD)	142.0 (20.3)	Value within requirements	Value within requirements
Recruitment DBP (mmHg)	Range (Low:High)	50:120	Value within requirements	Value within requirements
	Mean (SD)	88.0 (14.6)	Value within requirements	Value within requirements

Table 2 Assessment	Checks	19
	Permitted Modifications	0
	Violations	0

Table 3: Observer Measurements in each Recruitment Range

			Assessment	
SBP	Overall Range mmHg (Low:High)	100:177	Value within requirements	Value within requirements
	Low (< 130 mmHg)	34	Value within requirements	
	Medium (130 – 160 mmHg)	41	Value within requirements	
	High (> 160 mmHg)	24	Value within requirements	
	Maximum Difference	17	Value within requirements	
DBP	Overall Range mmHg (Low:High)	48:123	Value within requirements	Value within requirements
	Low (< 80 mmHg)	35	Value within requirements	
	Medium (80 – 100 mmHg)	40	Value within requirements	
	High (> 100 mmHg)	24	Value within requirements	
	Maximum Difference	16	Value within requirements	

Table 3 Assessment	Checks	12
	Permitted Modifications	0
	Violations	0

Table 4: Observer Differences

			Assessment		
Observer 2 – Observer 1	SBP (mmHg)	Range (Low:High)	-4:+4	Value within requirements	Value within requirements
		Mean (SD)	-0.6 (2.4)	Value within requirements	Value within requirements
DBP (mmHg)	Range (Low:High)		-4:+4	Value within requirements	Value within requirements
		Mean (SD)		-0.5 (2.3)	Value within requirements
Repeated Measurements		0		Value within requirements	

Table 4 Assessment	Checks	9
	Permitted Modifications	0
	Violations	0

Table 5: Validation Results

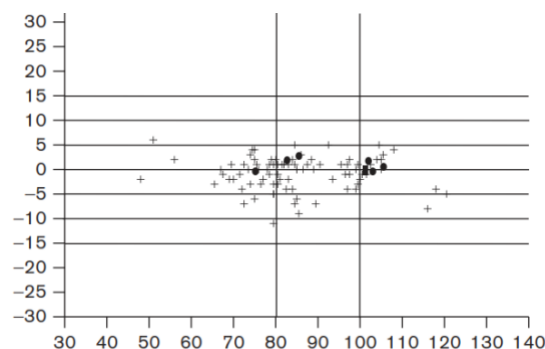
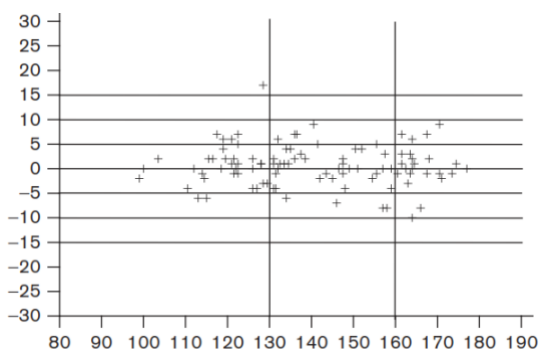
Part 1	Pass Req.		Achieved		Assessment	
	Two of	All of	SBP	DBP		
≤ 5 mmHg	73	65	78	90	Value within passing criteria	Value within passing criteria
≤ 10 mmHg	87	81	98	98	Value within passing criteria	Value within passing criteria
≤ 15 mmHg	96	93	98	99	Value within passing criteria	Value within passing criteria
Grade 1			Pass	Pass	Value within passing criteria	Value within passing criteria
Mean mmHg			+0.6	-0.5	Value within requirements	Value within requirements
SD mmHg			4.2	3.2	Value within requirements	Value within requirements

Part 2	Pass Req.	Achieved		Assessment	
		SBP	DBP		
2/3 ≤ 5 mmHg	≥ 24	28	31	Value within passing criteria	Value within passing criteria
0/3 ≤ 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 passing criteria	Value within passing criteria

Part 3	Result	Pass	Value within passing criteria
Table 5 Assessment			

Table 5 Assessment	Checks	21
	Permitted Modifications	0
	Violations	0

Plots



SBP Plot Provided	Yes
DBP Plot Provided	Yes

Assessment	
Requirement satisfactory	
Requirement satisfactory	

Plots Assessment	Checks	2
	Permitted Modifications	0
	Violations	0

Recommendations

pressure, is rejected and the conclusion, that the device is accurate for self-measurement in adults, is correct.

Overall Summary

Number of checks	121
Number of permitted modifications	0
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

Certification Decision

The Thermor BIOS BD-215, with the wide-range 24 cm to 43 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 International Protocol of the European Society of Hypertension 2010 Revision.

Date of Advisory Board Approval: 4th August 2016.

Reference

- 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.