

Medaval Accreditation Assessment

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Report 1609

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Accreditation assessment of the blood pressure measurement technology used in the UEBE Visomat Double Comfort 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 UEBE Visomat Double Comfort upper arm monitor, as validated according to the European Society of Hypertension International Protocol revision 2010. *Medical Device Assessment*. 2016 Aug 5; **2016**(1609). 8 p. Epub: 2019 Jan 31. Available from: <https://www.medaval.ie/MDA/2016/MDA1609.pdf>.

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Accreditation assessment of the blood pressure measurement technology used in the UEBE Visomat Double Comfort 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	UEBE Visomat Double Comfort	Requirement satisfactory
Model	24050	Requirement satisfactory
Measurement Site	Upper Arm	Requirement satisfactory
Client Use	Suitable for self-measurement.	Requirement satisfactory
Operation Method	Auscultation and Oscillometry, automatic during deflation	Requirement satisfactory
Measurement Occurrence	Single Measurements Only	Requirement satisfactory
Device Photograph		Modification: No photograph in papers. Standard image shown in report.
Manufacturer(s)	OEM: UEBE Medical GmbH, Zum Ottersberg 8-9, 97877 Wertheim am Main, GERMANY OBL: Visomat, Zum Ottersberg 8-9, 97877 Wertheim am Main, GERMANY	Requirement satisfactory
Cuffs	Universal 23 cm to 43 cm #2405001 Small 14 cm to 23 cm #2405005	Cuffs Listed: Requirement satisfactory Arm Circumferences: Requirement satisfactory

Test Device Details Assessment	Checks	10
	Permitted Modifications	1
	Violations	0

Auscultation study

Study Details

Original Publication	Masiero S, Fania C, Palatini P. Validation of the UEBE Visomat Double Comfort upper arm blood pressure monitor, in auscultation mode, for clinic use and self-measurement in a general population, according to the European Society of Hypertension International Protocol, revision 2010 <i>Blood Press Monit.</i> 2011 Aug; 16 (4):208-10. doi: 10.1097/MBP.0b013e328348b6a0. (<i>Details from: journals.lww.com/bpmonitoring/Abstract/2011/08000/Validation_of_the_UEBE_Visomat_Double_Comfort.9.aspx</i>)
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	Auscultatory	Requirement satisfactory
Study Measurement Site	Upper Arm	Requirement satisfactory
Observers		
Supervisor + 2 Observers	Yes	Requirement satisfactory
Observer Training	Expert training	Requirement satisfactory
Observer Familiarisation	41 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	Outpatients	Requirement satisfactory
NBP Subjects Selection	Inpatients & hospital staff	Requirement satisfactory

Study Details Assessment	Checks	12
	Permitted Modifications	0
	Violations	0

Procedure

Table 1: Screening and Recruitment Details

Screening and Recruitment				Assessment	
Total Screened			42	Value within requirements	
Total Excluded			9	Value within requirements	
	Ranges Complete		1	Value within requirements	
	Range Adjustment		7	Value within requirements	
	Arrhythmias		0	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*		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	1	Value within requirements	
		90 – 129 mmHg	10	Value within requirements	
	Medium	130 – 160 mmHg	12	Value within requirements	
	High		10	Value within requirements	
		161 – 180 mmHg	9	Value within requirements	
		> 180 mmHg	1	Value within requirements	
DBP	Total		33	Value within requirements	
	Low		12	Value within requirements	
		< 40 mmHg	0	Value within requirements	
		40 – 79 mmHg	12	Value within requirements	
	Medium	80 – 100 mmHg	10	Value within requirements	
	High		11	Value within requirements	
		101 – 130 mmHg	11	Value within requirements	
		> 130 mmHg	0	Value within requirements	
Total Extremes			2	Value within requirements	
On Treatment Ranges					
SBP	Low	< 130 mmHg	1	Value within requirements	
	Medium	130 – 160 mmHg	8	Value within requirements	
	High	> 160 mmHg	7	Value within requirements	
DBP	Low	< 80 mmHg	1	Value within requirements	
	Medium	80 – 100 mmHg	6	Value within requirements	
	High	> 100 mmHg	9	Value within requirements	
Table 1 Assessment				Checks	36
				Permitted Modifications	0
				Violations	0

Study Results

Table 2: Subject Details

			Assessment	
Sex	Male:Female	18:15	Value within requirements	Value within requirements
Age (years)	Range (Low:High)	25:88	Value within requirements	Value within requirements
	Mean (SD)	55.0 (20.2)	Value within requirements	Value within requirements
Arm Circumference (cm)	Range (Low:High)	23:38	Value within requirements	Value within requirements
	Mean (SD)	29.1 (4.1)	Value within requirements	Value within requirements
Cuff for Test Device (cm)	Universal (23 – 43)	33		
	Small (14 – 23)	0		
	Total	33	Value within requirements	
Recruitment SBP (mmHg)	Range (Low:High)	84:190	Value within requirements	Value within requirements
	Mean (SD)	140.0 (28.0)	Value within requirements	Value within requirements
Recruitment DBP (mmHg)	Range (Low:High)	50:120	Value within requirements	Value within requirements
	Mean (SD)	86.6 (17.2)	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)	79:191	Value within requirements	Value within requirements
	Low (< 130 mmHg)	33	Value within requirements	Value within requirements
	Medium (130 – 160 mmHg)	42	Value within requirements	Value within requirements
	High (> 160 mmHg)	24	Value within requirements	Value within requirements
	Maximum Difference	18	Value within requirements	Value within requirements
DBP	Overall Range mmHg (Low:High)	49:122	Value within requirements	Value within requirements
	Low (< 80 mmHg)	41	Value within requirements	Value within requirements
	Medium (80 – 100 mmHg)	34	Value within requirements	Value within requirements
	High (> 100 mmHg)	24	Value within requirements	Value within requirements
	Maximum Difference	17	Value within requirements	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)	-2:+4	Value within requirements	Value within requirements
	Mean (SD)	-0.2 (1.9)	Value within requirements	Value within requirements
DBP (mmHg)	Range (Low:High)	-4:+4	Value within requirements	Value within requirements
	Mean (SD)	-0.0 (1.9)	Value within requirements	Value within requirements
Repeated Measurements		0	Value within requirements	
Table 4 Assessment			Checks	9
			Permitted Modifications	0
			Violations	0

Table 5: Validation Results

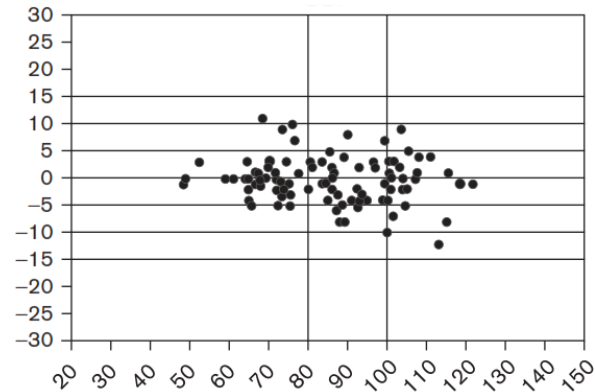
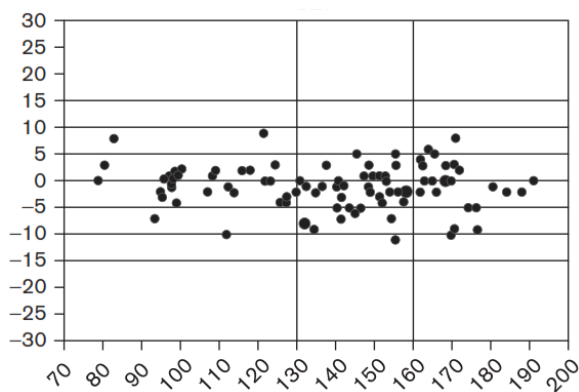
Part 1	Pass Req.		Achieved		Assessment	
	Two of	All of	SBP	DBP		
≤ 5 mmHg	73	65	83	85	Value within passing criteria	Value within passing criteria
≤ 10 mmHg	87	81	98	97	Value within passing criteria	Value within passing criteria
≤ 15 mmHg	96	93	99	99	Value within passing criteria	Value within passing criteria
Grade 1			Pass	Pass	Value within passing criteria	Value within passing criteria
Mean mmHg			-1.1	-0.4	Value within requirements	Value within requirements
SD mmHg			4.0	4.1	Value within requirements	Value within requirements

Part 2	Pass Req.	Achieved		Assessment	
		SBP	DBP		
2/3 ≤ 5 mmHg	≥ 24	31	30	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	Requirement satisfactory
DBP Plot Provided	Yes	Requirement satisfactory

Plots Assessment	Checks	2
	Permitted Modifications	0
	Violations	0

Oscillometric study

Study Details

Original Publication Masiero S, Fania C, Palatini P. Validation of the UEBE Visomat Double Comfort upper arm blood pressure monitor, in oscillometric mode, for clinic use and self-measurement in a general population according to the European Society of Hypertension International Protocol, revision 2010 *Blood Press Monit.* 2011 Oct;**16**(5):262-4. doi: 10.1097/MBP.0b013e32834b6694. PMID: 21885959.

Protocol The European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults¹

		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	41 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	Outpatients	Requirement satisfactory
NBP Subjects Selection	Inpatients & hospital staff	Requirement satisfactory

Test Device Details and Study Details Assessment	Checks	12
	Permitted Modifications	0
	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		1		Value within requirements	
Range Adjustment		8		Value within requirements	
Arrhythmias		0		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*		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	1		Value within requirements
		90 – 129 mmHg	10		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		12	Value within requirements	
		< 40 mmHg	0		Value within requirements
		40 – 79 mmHg	12		Value within requirements
	Medium	80 – 100 mmHg	10		Value within requirements
		High		11	Value within requirements
		101 – 130 mmHg	11		Value within requirements
	> 130 mmHg	0		Value within requirements	
Total Extremes			1	Value within requirements	
On Treatment Ranges					
SBP	Low	< 130 mmHg	2	Value within requirements	
	Medium	130 – 160 mmHg	8	Value within requirements	
	High	> 160 mmHg	7	Value within requirements	
DBP	Low	< 80 mmHg	2	Value within requirements	
	Medium	80 – 100 mmHg	6	Value within requirements	
	High	> 100 mmHg	9	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)	25:85	Value within requirements	Value within requirements
	Mean (SD)	56.3 (20.0)	Value within requirements	Value within requirements
Arm Circumference (cm)	Range (Low:High)	23:38	Value within requirements	Value within requirements
	Mean (SD)	29.3 (3.9)	Value within requirements	Value within requirements
Cuff for Test Device (cm)	Universal (23 – 43)	33		
	Small (14 – 23)	0		
	Total	33	Value within requirements	
Recruitment SBP (mmHg)	Range (Low:High)	84:180	Value within requirements	Value within requirements
	Mean (SD)	140.4 (27.7)	Value within requirements	Value within requirements
Recruitment DBP (mmHg)	Range (Low:High)	50:120	Value within requirements	Value within requirements
	Mean (SD)	86.8 (17.2)	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)	79:183	Value within requirements	Value within requirements
	Low (< 130 mmHg)	33	Value within requirements	Value within requirements
	Medium (130 – 160 mmHg)	40	Value within requirements	Value within requirements
	High (> 160 mmHg)	26	Value within requirements	Value within requirements
	Maximum Difference	14	Value within requirements	Value within requirements
DBP	Overall Range mmHg (Low:High)	49:120	Value within requirements	Value within requirements
	Low (< 80 mmHg)	38	Value within requirements	Value within requirements
	Medium (80 – 100 mmHg)	37	Value within requirements	Value within requirements
	High (> 100 mmHg)	24	Value within requirements	Value within requirements
	Maximum Difference	14	Value within requirements	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)	-2:+4	Value within requirements	Value within requirements
	Mean (SD)	+ 0.2 (1.9)	Value within requirements	Value within requirements
DBP (mmHg)	Range (Low:High)	-4:+4	Value within requirements	Value within requirements
	Mean (SD)	+ 0.1 (1.9)	Value within requirements	Value within requirements
Repeated Measurements		0	Value within requirements	
Table 4 Assessment			Checks	9
			Permitted Modifications	0
			Violations	0

Table 5: Validation Results

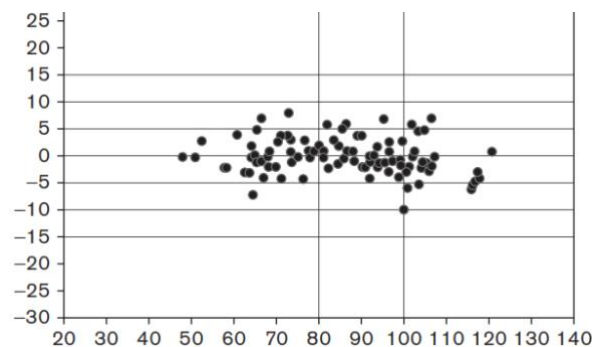
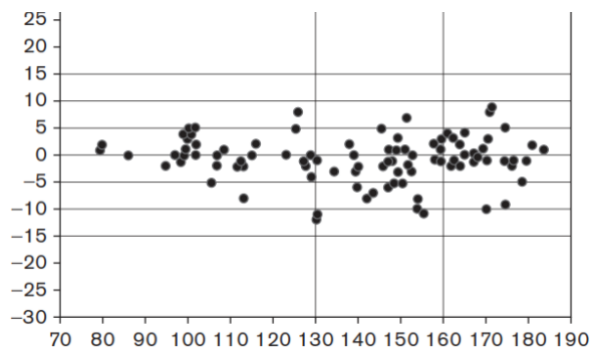
Part 1	Pass Req.		Achieved		Assessment	
	Two of	All of	SBP	DBP		
≤ 5 mmHg	73	65	83	88	Value within passing criteria	Value within passing criteria
≤ 10 mmHg	87	81	96	99	Value within passing criteria	Value within passing criteria
≤ 15 mmHg	96	93	99	99	Value within passing criteria	Value within passing criteria
Grade 1			Pass	Pass	Value within passing criteria	Value within passing criteria
Mean mmHg			-0.9	-0.1	Value within requirements	Value within requirements
SD mmHg			4.1	3.3	Value within requirements	Value within requirements

Part 2	Pass Req.	Achieved		Assessment	
		SBP	DBP		
2/3 ≤ 5 mmHg	≥ 24	31	33	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	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

Overall Summary

Number of checks 232
 Number of permitted modifications 1
 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 conclusions that the device is accurate for self-measurement in adults are correct.

Certification Decision

The UEBE Visomat Double Comfort, with the universal 23 cm to 43 cm cuff, is certified by Medaval Ltd., for blood pressure measurement, in adults, using either auscultatory or oscillometric mode, as it fulfilled the conditions required for a pass in two validation studies, each 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

- 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.