

## Medaval Accreditation Assessment

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### **Accreditation assessment of the blood pressure measurement technology used in the custo med custo screen 400 upper arm monitor, as validated according to the European Society of Hypertension International Protocol revision 2010**

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#### **Reference**

Medaval Ltd. Accreditation assessment of the blood pressure measurement technology used in the custo med custo screen 400 upper arm monitor, as validated according to the European Society of Hypertension International Protocol revision 2010. *Medical Device Assessment*. 2016 Aug 5;2016(1616). 5 p. Epub: 2019 Jan 31. Available from: <https://www.medaval.ie/MDA/2016/MDA1616.pdf>.

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# Accreditation assessment of the blood pressure measurement technology used in the custo med custo screen 400 upper arm monitor, as validated according to the European Society of Hypertension International Protocol revision 2010

*Medaval Accreditation-Assessment Report – 5<sup>th</sup> August 2016*

## Test Device Details

		Assessment
<b>Full Name</b>	custo screen 400	Requirement satisfactory
<b>Model</b>	Not provided	Modification: Missing value accepted by paper review
<b>Measurement Site</b>	Upper Arm	Requirement satisfactory
<b>Client Use</b>	Suitable for ABPM	Requirement satisfactory
<b>Operation Method</b>	Oscillometry, automatic during deflation	Requirement satisfactory
<b>Measurement Occurrence</b>	Single Measurements Only	Requirement satisfactory
<b>Device Photograph</b>		Modification: Standard image, not photograph, in paper
<b>Manufacturer(s)</b>	custo med GmbH, Leibnizstrasse 7, D-85521 Ottobrunn, GERMANY	Requirement satisfactory
<b>Cuffs</b>	Small 20 cm to 24 cm Standard 24 cm to 32 cm XL 32 cm to 40 cm XXL 38 cm to 50 cm	Cuffs Listed: Requirement satisfactory Arm Circumferences: Requirement satisfactory

## Study Details

**Original Publication** Bramlage P, Deutsch C, Krüger R, Wolf A, Müller P, Zwingers T, Beime B, Mengden T. Validation of the custo screen 400 ambulatory blood pressure-monitoring device according to the European Society of Hypertension International Protocol revision 2010. *Vasc Health Risk Manag.* 2014 May 13;10:303-9. doi: 10.2147/VHRM.S63602. PMID: 24868162. Available from: [www.ncbi.nlm.nih.gov/pmc/articles/PMC4027883/pdf/vhrm-10-303.pdf](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4027883/pdf/vhrm-10-303.pdf).

**Protocol** The European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults<sup>1</sup>

		Assessment
<b>Adherence</b>	Followed Precisely	Requirement satisfactory
<b>Adjustments</b>	None	Requirement satisfactory
<b>Study Meas. Method</b>	Oscillometric	Requirement satisfactory
<b>Study Measurement Site</b>	Upper Arm	Requirement satisfactory
<b>Observers</b>		
<b>Supervisor + 2 Observers</b>	Yes	Requirement satisfactory
<b>Observer Training</b>	Not specified - experienced	Requirement satisfactory
<b>Observer Familiarisation</b>	Unspecified measurements	Requirement satisfactory
<b>Observers Blinded</b>	From device and each other	Requirement satisfactory
<b>Sample</b>		
<b>Population</b>	A general population	Requirement satisfactory
<b>Circumstances</b>	None	Requirement satisfactory
<b>HBP Subjects Selection</b>	Institut für Pharmakologie und	Requirement satisfactory
<b>NBP Subjects Selection</b>	Präventive Medizin, Cloppenburg, Germany	Requirement satisfactory

<b>Test Device Details and Study Details Assessment</b>	<b>Checks</b>	22
	<b>Permitted Modifications</b>	2
	<b>Violations</b>	0

**Procedure**

**Table 1: Screening and Recruitment Details**

<b>Screening and Recruitment</b>				<b>Assessment</b>
Total Screened			<b>37</b>	Value within requirements
Total Excluded			<b>4</b>	Value within requirements
	Ranges Complete		<b>0</b>	Value within requirements
	Range Adjustment		<b>2</b>	Value within requirements
	Arrhythmias		<b>0</b>	Value within requirements
	Device Failure		<b>0</b>	Value within requirements
	Poor Quality Sounds		<b>0</b>	Value within requirements
	Cuff Size Unavailable		<b>0</b>	Value within requirements
	Observer Disagreement		<b>0</b>	Value within requirements
	Distribution		<b>2</b>	Value within requirements
	Other Reasons*		<b>0</b>	Value within requirements
Total Recruited			<b>33</b>	Value within requirements
*Explanation Summary				No details required
<b>Recruitment Ranges</b>				
SBP	Total		<b>33</b>	Value within requirements
	Low	< 90 mmHg	<b>0</b>	Value within requirements
		90 – 129 mmHg	<b>11</b>	Value within requirements
		130 – 160 mmHg	<b>10</b>	Value within requirements
	Medium	161 – 180 mmHg	<b>11</b>	Value within requirements
		> 180 mmHg	<b>1</b>	Value within requirements
	High		<b>12</b>	Value within requirements
DBP	Total		<b>33</b>	Value within requirements
	Low	< 40 mmHg	<b>0</b>	Value within requirements
		40 – 79 mmHg	<b>11</b>	Value within requirements
		80 – 100 mmHg	<b>11</b>	Value within requirements
	Medium	101 – 130 mmHg	<b>11</b>	Value within requirements
		> 130 mmHg	<b>0</b>	Value within requirements
High		<b>11</b>	Value within requirements	
Total Extremes			<b>1</b>	Value within requirements
<b>On Treatment Ranges</b>				
SBP	Low	< 130 mmHg	<b>4</b>	Value within requirements
	Medium	130 – 160 mmHg	<b>5</b>	Value within requirements
	High	> 160 mmHg	<b>8</b>	Value within requirements
DBP	Low	< 80 mmHg	<b>5</b>	Value within requirements
	Medium	80 – 100 mmHg	<b>5</b>	Value within requirements
	High	> 100 mmHg	<b>7</b>	Value within requirements
<b>Table 1 Assessment</b>				
<b>Checks</b>				<b>36</b>
<b>Permitted Modifications</b>				<b>0</b>
<b>Violations</b>				<b>0</b>

### Study Results

**Table 2: Subject Details**

			Assessment	
Sex	Male:Female	<b>13:20</b>	Value within requirements	Value within requirements
Age (years)	Range (Low:High)	<b>25:87</b>	Value within requirements	Value within requirements
	Mean (SD)	<b>57.4 (13.0)</b>	Value within requirements	Value within requirements
Arm Circumference (cm)	Range (Low:High)	<b>24:36</b>	Value within requirements	Value within requirements
	Mean (SD)	<b>28.9 (2.9)</b>	Value within requirements	Value within requirements
Cuff for Test Device (cm)	Small (20 – 24)	<b>0</b>		
	Standard (24 – 32)	<b>31</b>		
	XL (32 – 40)	<b>2</b>		
	XXL (38 – 50)	<b>0</b>		
	Total	<b>33</b>	Value within requirements	
Recruitment SBP (mmHg)	Range (Low:High)	<b>106:218</b>	Value within requirements	Value within requirements
	Mean (SD)	<b>143.9 (28.1)</b>	Value within requirements	Value within requirements
Recruitment DBP (mmHg)	Range (Low:High)	<b>49:123</b>	Value within requirements	Value within requirements
	Mean (SD)	<b>87.9 (17.9)</b>	Value within requirements	Value within requirements
<b>Table 2 Assessment</b>			<b>Checks</b>	19
			<b>Permitted Modifications</b>	0
			<b>Violations</b>	0

**Table 3: Observer Measurements in each Recruitment Range**

			Assessment	
SBP	Overall Range mmHg (Low:High)	<b>100:220</b>	Value within requirements	Value within requirements
	Low (< 130 mmHg)	<b>43</b>	Value within requirements	
	Medium (130 – 160 mmHg)	<b>30</b>	Value within requirements	
	High (> 160 mmHg)	<b>26</b>	Value within requirements	
	Maximum Difference	<b>17</b>	Value within requirements	
DBP	Overall Range mmHg (Low:High)	<b>49:123</b>	Value within requirements	Value within requirements
	Low (< 80 mmHg)	<b>40</b>	Value within requirements	
	Medium (80 – 100 mmHg)	<b>34</b>	Value within requirements	
	High (> 100 mmHg)	<b>25</b>	Value within requirements	
	Maximum Difference	<b>15</b>	Value within requirements	
<b>Table 3 Assessment</b>			<b>Checks</b>	12
			<b>Permitted Modifications</b>	0
			<b>Violations</b>	0

**Table 4: Observer Differences**

			Assessment	
Observer 2 – Observer 1				
SBP (mmHg)	Range (Low:High)	<b>-2:+4</b>	Value within requirements	Value within requirements
	Mean (SD)	<b>+0.4 (1.4)</b>	Value within requirements	Value within requirements
DBP (mmHg)	Range (Low:High)	<b>-4:+4</b>	Value within requirements	Value within requirements
	Mean (SD)	<b>-0.4 (1.5)</b>	Value within requirements	Value within requirements
Repeated Measurements		<b>0</b>	Value within requirements	
<b>Table 4 Assessment</b>			<b>Checks</b>	9
			<b>Permitted Modifications</b>	0
			<b>Violations</b>	0

**Table 5: Validation Results**

Part 1	Pass Req.		Achieved		Assessment	
	Two of	All of	SBP	DBP		
≤ 5 mmHg	73	65	<b>84</b>	<b>93</b>	Value within passing criteria	Value within passing criteria
≤ 10 mmHg	87	81	<b>98</b>	<b>99</b>	Value within passing criteria	Value within passing criteria
≤ 15 mmHg	96	93	<b>99</b>	<b>99</b>	Value within passing criteria	Value within passing criteria
Grade 1			<b>Pass</b>	<b>Pass</b>	Value within passing criteria	Value within passing criteria
Mean mmHg			<b>-0.5</b>	<b>-0.1</b>	Value within requirements	Value within requirements
SD mmHg			<b>4.5</b>	<b>3.3</b>	Value within requirements	Value within requirements

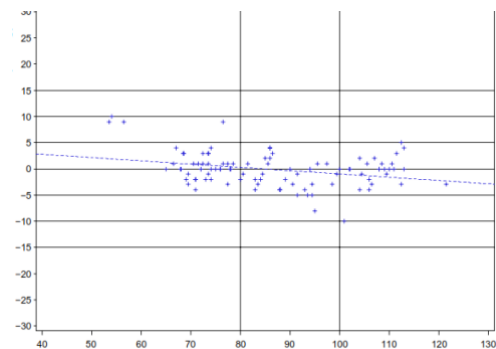
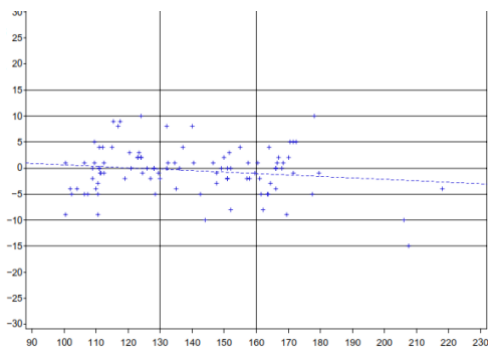
Part 2	Pass Req.	Achieved		Assessment	
		SBP	DBP		
2/3 ≤ 5 mmHg	≥ 24	<b>30</b>	<b>32</b>	Value within passing criteria	Value within passing criteria
0/3 ≤ 5 mmHg	≤ 3	<b>0</b>	<b>1</b>	Value within passing criteria	Value within passing criteria
Grade 2		<b>Pass</b>	<b>Pass</b>	Value within passing criteria	Value within passing criteria
Grade 3		<b>Pass</b>	<b>Pass</b>	Value within passing criteria	Value within passing criteria

Part 3	Result	Pass	Value within passing criteria
Table 5 Assessment			

<b>Table 5 Assessment</b>	<b>Checks</b>	21
	<b>Permitted Modifications</b>	0
	<b>Violations</b>	0

**Plots**



SBP Plot Provided	<b>Yes</b>
DBP Plot Provided	<b>Yes</b>

Assessment	
Requirement satisfactory	
Requirement satisfactory	

<b>Plots Assessment</b>	<b>Checks</b>	2
	<b>Permitted Modifications</b>	0
	<b>Violations</b>	0

**Recommendations**

accurate for ambulatory blood pressure measurement in adults, is correct.

**Overall Summary**

Number of checks	121
Number of permitted modifications	2
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

**Certification Decision**

The custo screen 400, with the standard 24 cm to 32 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: 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.