

## Medaval Accreditation Assessment

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Report 1619

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### **Accreditation assessment of the blood pressure measurement technology used in the Omron HEM-7320F upper arm monitor, as validated according to the European Society of Hypertension International Protocol revision 2010**

#### **Approved by the Medaval Advisory Board**

Eoin O'Brien (Chair)	Yutaka Imai	Andrew Shennan
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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 HEM-7320F upper arm monitor, as validated according to the European Society of Hypertension International Protocol revision 2010. *Medical Device Assessment*. 2016 Aug 5; **2016**(1619). 5 p. Epub: 2019 Jan 31. Available from: <https://www.medaval.ie/MDA/2016/MDA1619.pdf>.

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# Accreditation assessment of the blood pressure measurement technology used in the Omron HEM-7320F 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>	Omron HEM-7320F	Requirement satisfactory
<b>Model</b>	HEM-7320F	Requirement satisfactory
<b>Measurement Site</b>	Upper Arm	Requirement satisfactory
<b>Client Use</b>	Suitable for self-measurement.	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>		Photograph not in paper. Standard image shown.
<b>Manufacturer(s)</b>	Sole: Omron Healthcare, Kyoto Head Office, Shiokoji Horikawa, Shimogyo ku, Kyoto 600 8530, JAPAN.	Requirement satisfactory
<b>Cuffs</b>	Omron HEM-FM31: Wide Range 17 cm to-36 cm	Cuffs Listed: Requirement satisfactory Arm Circumferences: Requirement satisfactory

## Study Details

<b>Original Publication</b>	Takahashi H, Yoshika M, Yokoi T. Validation of three automatic devices for the self-measurement of blood pressure according to the European Society of Hypertension International Protocol revision 2010: the Omron HEM-7130, HEM-7320F, and HEM-7500F. <i>Blood Press Monit.</i> 2015 Apr;20(2):92-7. doi: 10.1097/MBP.0000000000000096. PMID: 25462531.	
<b>Protocol</b>	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>	Not stated but, apart from paper, inferred from text.	Requirement accepted as 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>	BHS online training	Requirement satisfactory
<b>Observer Familiarisation</b>	Not described but assumed completed	Requirement accepted as satisfactory
<b>Observers Blinded</b>	From each other and assumed from device	Requirement satisfactory
<b>Sample</b>		
<b>Population</b>	A general population	Requirement satisfactory
<b>Circumstances</b>	None	Requirement satisfactory
<b>HBP Subjects Selection</b>	Outpatients	Requirement satisfactory
<b>NBP Subjects Selection</b>	Hospital staff & volunteers	Requirement satisfactory

<b>Test Device Details and Study Details Assessment</b>	<b>Checks</b>	22
	<b>Permitted Modifications</b>	1
	<b>Violations</b>	0

**Procedure**

**Table 1: Screening and Recruitment Details**

Screening and Recruitment				Assessment
Total Screened			<b>41</b>	Value within requirements
Total Excluded			<b>8</b>	Value within requirements
	Ranges Complete		<b>0</b>	Value within requirements
	Range Adjustment		<b>3</b>	Value within requirements
	Arrhythmias		<b>2</b>	Value within requirements
	Device Failure		<b>0</b>	Value within requirements
	Poor Quality Sounds		<b>1</b>	Value within requirements
	Cuff Size Unavailable		<b>0</b>	Value within requirements
	Observer Disagreement		<b>0</b>	Value within requirements
	Distribution		<b>0</b>	Value within requirements
	Other Reasons*		<b>2</b>	Value within requirements
Total Recruited			<b>33</b>	Value within requirements
*Explanation Summary				
The only reason for exclusion, stated in the text and not included above, is body movement error. It is assumed 2 subjects were excluded for this reason.				Broad explanation accepted
Recruitment Ranges				
SBP	Total		<b>33</b>	Value within requirements
	Low	< 90 mmHg	<b>1</b>	Value within requirements
		90 – 129 mmHg	<b>10</b>	Value within requirements
		130 – 160 mmHg	<b>11</b>	Value within requirements
	Medium	161 – 180 mmHg	<b>10</b>	Value within requirements
		> 180 mmHg	<b>1</b>	Value within requirements
	High		<b>11</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>12</b>	Value within requirements
	Medium	101 – 130 mmHg	<b>10</b>	Value within requirements
		> 130 mmHg	<b>0</b>	Value within requirements
	High		<b>10</b>	Value within requirements
Total Extremes			<b>2</b>	Value within requirements
On Treatment Ranges				
SBP	Low	< 130 mmHg	<b>0</b>	Value within requirements
	Medium	130 – 160 mmHg	<b>2</b>	Value within requirements
	High	> 160 mmHg	<b>1</b>	Value within requirements
DBP	Low	< 80 mmHg	<b>1</b>	Value within requirements
	Medium	80 – 100 mmHg	<b>1</b>	Value within requirements
	High	> 100 mmHg	<b>1</b>	Value within requirements
<b>Table 1 Assessment</b>				
				<b>Checks</b>
				<b>Permitted Modifications</b>
				<b>Violations</b>
				36
				0
				0

### Study Results

**Table 2: Subject Details**

			<b>Assessment</b>	
Sex	Male:Female	<b>18:15</b>	Value within requirements	Value within requirements
Age (years)	Range (Low:High)	<b>36:72</b>	Value within requirements	Value within requirements
	Mean (SD)	<b>50 (11)</b>	Value within requirements	Value within requirements
Arm Circumference (cm)	Range (Low:High)	<b>19.2:35.3</b>	Value within requirements	Value within requirements
	Mean (SD)	<b>27.7 (5.7)</b>	Value within requirements	Value within requirements
Cuff for Test Device (cm)	Standard (17 – 36)	<b>33</b>		
	Total	<b>33</b>	Value within requirements	
Recruitment SBP (mmHg)	Range (Low:High)	<b>88:208</b>	Value within requirements	Value within requirements
	Mean (SD)	<b>139 (29.8)</b>	Value within requirements	Value within requirements
Recruitment DBP (mmHg)	Range (Low:High)	<b>50:128</b>	Value within requirements	Value within requirements
	Mean (SD)	<b>88 (20.7)</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**

			<b>Assessment</b>	
SBP	Overall Range mmHg (Low:High)	<b>86:185</b>	Value within requirements	Value within requirements
	Low (< 130 mmHg)	<b>41</b>	Value within requirements	Value within requirements
	Medium (130 – 160 mmHg)	<b>33</b>	Value within requirements	Value within requirements
	High (> 160 mmHg)	<b>25</b>	Value within requirements	Value within requirements
	Maximum Difference	<b>16</b>	Value within requirements	Value within requirements
DBP	Overall Range mmHg (Low:High)	<b>50:128</b>	Value within requirements	Value within requirements
	Low (< 80 mmHg)	<b>34</b>	Value within requirements	Value within requirements
	Medium (80 – 100 mmHg)	<b>37</b>	Value within requirements	Value within requirements
	High (> 100 mmHg)	<b>28</b>	Value within requirements	Value within requirements
	Maximum Difference	<b>9</b>	Value within requirements	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**

			<b>Assessment</b>	
Observer 2 – Observer 1 SBP (mmHg)	Range (Low:High)	<b>-4:+4</b>	Value within requirements	Value within requirements
	Mean (SD)	<b>+0.3 (1.5)</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>+0.2 (1.5)</b>	Value within requirements	Value within requirements
Repeated Measurements		<b>0</b>	Value within requirements	

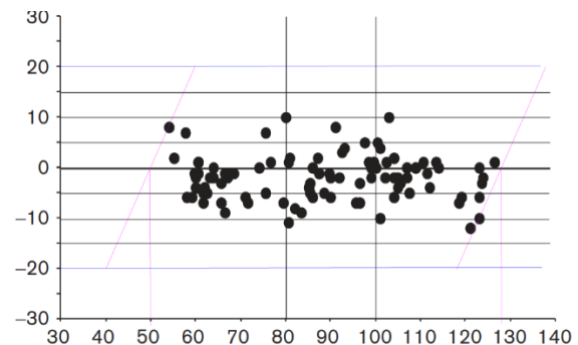
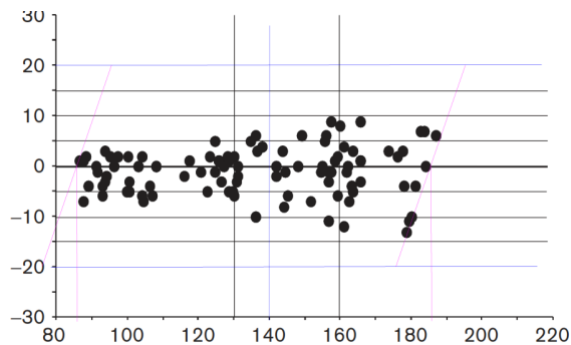
<b>Table 4 Assessment</b>	<b>Checks</b>	9
	<b>Permitted Modifications</b>	0
	<b>Violations</b>	0

**Table 5: Validation Results**

Part 1	Pass Req.		Achieved		Assessment	
	Two of	All of	SBP	DBP		
≤ 5 mmHg	73	65	<b>73</b>	<b>71</b>	Value within passing criteria	Value within lower passing criteria
≤ 10 mmHg	87	81	<b>95</b>	<b>97</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 lower passing criteria
Mean mmHg			<b>-0.9</b>	<b>-1.9</b>	Value within requirements	Value within requirements
SD mmHg			<b>4.7</b>	<b>4.4</b>	Value within requirements	Value within requirements
Part 2	Pass Req.		Achieved			
			SBP	DBP		
2/3 ≤ 5 mmHg	≥ 24		<b>27</b>	<b>26</b>	Value within passing criteria	Value within passing criteria
0/3 ≤ 5 mmHg	≤ 3		<b>1</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 lower passing criteria
Part 3	Result		Pass			
					Value within lower passing criteria	

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

**Plots**



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

Assessment	
Requirement satisfactory	
Requirement satisfactory	

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

**Recommendations**

**Overall Summary**

Number of checks 121  
 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 HEM-7320F, with the HEM-FM31 wide-range 17 cm to-36 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.