

## Medaval Accreditation Assessment

Volume 2016

Report 1603

05 August 2016

### **Accreditation assessment of the blood pressure measurement technology used in the iHealth Sense (BP7) wrist 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 iHealth Sense (BP7) wrist monitor, as validated according to the European Society of Hypertension International Protocol revision 2010. *Medical Device Assessment*. 2016 Aug 5; **2016**(1603). 5 p. Epub: 2019 Jan 31. Available from: <https://www.medaval.ie/MDA/2016/MDA1603.pdf>.

*Medical Device Assessment* is published by

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

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# Accreditation assessment of the blood pressure measurement technology used in the iHealth Sense (BP7) wrist 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>	iHealth Sense (BP7)	Requirement satisfactory
<b>Model</b>	BP7	Requirement satisfactory
<b>Measurement Site</b>	Wrist	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>		Requirement satisfactory
<b>Manufacturer(s)</b>	OEM: Andon Health Co. Ltd., 3 Jinping Road, Ya'an Street, Nankai District, Tianjin 300190, CHINA  OBL: iHealth Lab Inc, 3 rue Tronchet, 75008 Paris, FRANCE	Requirement satisfactory
<b>Cuffs</b>	Integrated 13.5 cm to-22 cm	Cuffs Listed: Requirement satisfactory Wrist Circumferences: Requirement satisfactory

## Study Details

**Original Publication** Wang Q, Zhao H, Chen W, Li N, Wan Y. Validation of the iHealth BP7 wrist blood pressure monitor, for self-measurement, according to the European Society of Hypertension International Protocol revision 2010. *Blood Press Monit.* 2014 Feb;**19**(1):54-7. doi: 10.1097/MBP.000000000000017. PMID: 24361919.

**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>	Wrist	Requirement satisfactory
<b>Observers</b>		
<b>Supervisor + 2 Observers</b>	Yes	Requirement satisfactory
<b>Observer Preparation</b>	BHS tutorial	Requirement satisfactory
<b>Observer Familiarisation</b>	10 test 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>	Inpatients and outpatients	Requirement satisfactory
<b>NBP Subjects Selection</b>	Hospital staff	Requirement satisfactory

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

**Procedure**

**Table 1: Screening and Recruitment Details**

Screening and Recruitment				Assessment
Total Screened			<b>47</b>	Value within requirements
Total Excluded			<b>14</b>	Value within requirements
	Ranges Complete		<b>9</b>	Value within requirements
	Range Adjustment		<b>3</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
Recruitment Ranges				
SBP	Total		<b>33</b>	Value within requirements
	Low		<b>11</b>	Value within requirements
		< 90 mmHg	<b>0</b>	Value within requirements
		90 – 129 mmHg	<b>11</b>	Value within requirements
	Medium	130 – 160 mmHg	<b>12</b>	Value within requirements
	High		<b>10</b>	Value within requirements
		161 – 180 mmHg	<b>10</b>	Value within requirements
		> 180 mmHg	<b>0</b>	Value within requirements
DBP	Total		<b>33</b>	Value within requirements
	Low		<b>11</b>	Value within requirements
		< 40 mmHg	<b>0</b>	Value within requirements
		40 – 79 mmHg	<b>11</b>	Value within requirements
	Medium	80 – 100 mmHg	<b>12</b>	Value within requirements
	High		<b>10</b>	Value within requirements
		101 – 130 mmHg	<b>10</b>	Value within requirements
		> 130 mmHg	<b>0</b>	Value within requirements
Total Extremes			<b>0</b>	Value within requirements
On Treatment Ranges				
SBP	Low	< 130 mmHg	<b>0</b>	Value within requirements
	Medium	130 – 160 mmHg	<b>4</b>	Value within requirements
	High	> 160 mmHg	<b>4</b>	Value within requirements
DBP	Low	< 80 mmHg	<b>0</b>	Value within requirements
	Medium	80 – 100 mmHg	<b>4</b>	Value within requirements
	High	> 100 mmHg	<b>8</b>	Value within requirements
<b>Table 1 Assessment</b>				<b>Checks</b> 36
				<b>Permitted Modifications</b> 0
				<b>Violations</b> 0

### Study Results

**Table 2: Subject Details**

			Assessment	
Sex	Male:Female	<b>22:11</b>	Value within requirements	Value within requirements
Age (years)	Range (Low:High)	<b>26:75</b>	Value within requirements	Value within requirements
	Mean (SD)	<b>48.5 (11.8)</b>	Value within requirements	Value within requirements
Arm Circumference (cm)	Range (Low:High)	<b>22:29</b>	Value within requirements	Value within requirements
	Mean (SD)	<b>26.3 (1.9)</b>	Value within requirements	Value within requirements
Wrist Circumference (cm)	Range (Low:High)	<b>14:19</b>	Value within requirements	Value within requirements
	Mean (SD)	<b>15.9 (1.7)</b>	Value within requirements	Value within requirements
Cuff for Test Device (cm)	Standard (13.5 – 22)	<b>33</b>		
	Total	<b>33</b>	Value within requirements	
Recruitment SBP (mmHg)	Range (Low:High)	<b>97:180</b>	Value within requirements	Value within requirements
	Mean (SD)	<b>140.1 (23.7)</b>	Value within requirements	Value within requirements
Recruitment DBP (mmHg)	Range (Low:High)	<b>46:121</b>	Value within requirements	Value within requirements
	Mean (SD)	<b>87.1 (16.2)</b>	Value within requirements	Value within requirements
<b>Table 2 Assessment</b>			<b>Checks</b>	23
			<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>92:187</b>	Value within requirements	Value within requirements
	Low (< 130 mmHg)	<b>34</b>	Value within requirements	
	Medium (130 – 160 mmHg)	<b>39</b>	Value within requirements	
	High (> 160 mmHg)	<b>26</b>	Value within requirements	
	Maximum Difference	<b>13</b>	Value within requirements	
DBP	Overall Range mmHg (Low:High)	<b>46:121</b>	Value within requirements	Value within requirements
	Low (< 80 mmHg)	<b>34</b>	Value within requirements	
	Medium (80 – 100 mmHg)	<b>40</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**

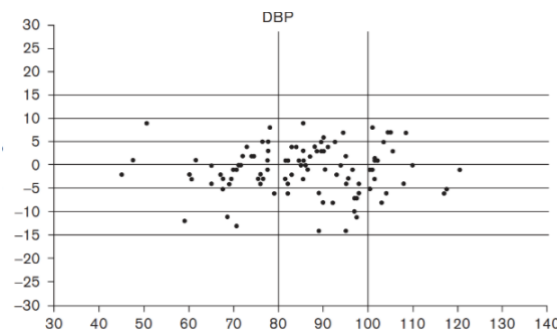
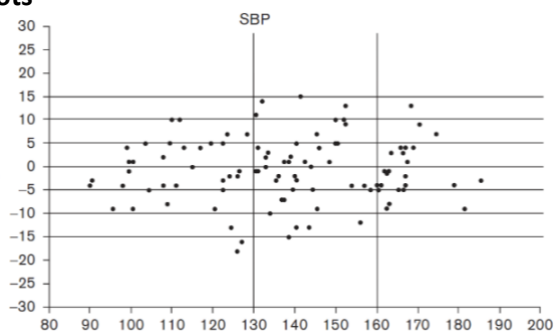
			Assessment	
Observer 2 – Observer 1				
SBP (mmHg)	Range (Low:High)	<b>-4:+4</b>	Value within requirements	Value within requirements
	Mean (SD)	<b>+0.2 (2.3)</b>	Value within requirements	Value within requirements
DBP (mmHg)	Range (Low:High)	<b>-4:+4</b>	Value within requirements	Value within requirements
	Mean (SD)	<b>+0.2 (2.3)</b>	Value within requirements	Value within requirements
Repeated Measurements		<b>2</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		
$\leq 5 \text{ mmHg}$	73	65	<b>66</b>	<b>72</b>	Value within lower passing criteria	Value within lower passing criteria
$\leq 10 \text{ mmHg}$	87	81	<b>87</b>	<b>93</b>	Value within passing criteria	Value within passing criteria
$\leq 15 \text{ mmHg}$	96	93	<b>97</b>	<b>99</b>	Value within passing criteria	Value within passing criteria
Grade 1			<b>Pass</b>	<b>Pass</b>	Value within lower passing criteria	Value within lower passing criteria
Mean <i>mmHg</i>			<b>-0.7</b>	<b>-1.0</b>	Value within requirements	Value within requirements
SD <i>mmHg</i>			<b>6.9</b>	<b>5.1</b>	Value within requirements	Value within requirements
<b>Part 2</b>		Pass Req.	Achieved			
			SBP	DBP		
$2/3 \leq 5 \text{ mmHg}$		$\geq 24$	<b>25</b>	<b>26</b>	Value within passing criteria	Value within passing criteria
$0/3 \leq 5 \text{ mmHg}$		$\leq 3$	<b>3</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 lower passing criteria	Value within lower passing criteria
<b>Part 3</b>	Result		<b>Pass</b>		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	<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**

**Overall Summary**

Number of checks	125
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

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

**Certification Decision**

The iHealth Sense (BP7) 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.