

Medaval Accreditation Assessment

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Report 1602

05 August 2016

Accreditation assessment of the blood pressure measurement technology used in the iHealth Feel (BP5) 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 iHealth Feel (BP5) upper arm monitor, as validated according to the European Society of Hypertension International Protocol revision 2010. *Medical Device Assessment*. 2016 Aug 5; **2016**(1602). 5 p. Epub: 2019 Jan 31. Available from: <https://www.medaval.ie/MDA/2016/MDA1602.pdf>.

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Accreditation assessment of the blood pressure measurement technology used in the iHealth Feel (BP5) 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	iHealth Feel (BP5)	Requirement satisfactory
Model	BP5	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)	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
Cuffs	Standard: 22 cm to-42 cm XLarge: 42 cm to 48 cm	Cuffs Listed: Requirement satisfactory Arm Circumferences: Requirement satisfactory

Study Details

Original Publication Shang F, Zhu Y, Zhu Z, Liu L, Wan Y. Validation of the iHealth BP5 wireless upper arm blood pressure monitor for self-measurement according to the European Society of Hypertension International Protocol revision 2010. *Blood Press Monit.* 2013 Oct;**18**(5):278-81. doi: 10.1097/MBP.0b013e3283638f04. PMID: 23797053.

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 Preparation	BHS Tutorial	Requirement satisfactory
Observer Familiarisation	20 test 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 and outpatients	Requirement satisfactory
NBP Subjects Selection	Accompanying persons & 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			42	Value within requirements
Total Excluded			9	Value within requirements
	Ranges Complete		7	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	11	Value within requirements
	High		11	Value within requirements
		161 – 180 mmHg	11	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			0	Value within requirements
On Treatment Ranges				
SBP	Low	< 130 mmHg	0	Value within requirements
	Medium	130 – 160 mmHg	3	Value within requirements
	High	> 160 mmHg	4	Value within requirements
DBP	Low	< 80 mmHg	0	Value within requirements
	Medium	80 – 100 mmHg	3	Value within requirements
	High	> 100 mmHg	8	Value within requirements
Table 1 Assessment				Checks 36
				Permitted Modifications 0
				Violations 0

Study Results

Table 2: Subject Details

			<u>Assessment</u>	
Sex	Male:Female	20:13	Value within requirements	Value within requirements
Age (years)	Range (Low:High)	26:80	Value within requirements	Value within requirements
	Mean (SD)	49.2 (13.2)	Value within requirements	Value within requirements
Arm Circumference (cm)	Range (Low:High)	22:36	Value within requirements	Value within requirements
	Mean (SD)	26.7 (3.1)	Value within requirements	Value within requirements
Cuff for Test Device (cm)	Standard (22 to 42)	33		
	XLarge (42 to 48)	0		
	Total	33	Value within requirements	
Recruitment SBP (mmHg)	Range (Low:High)	96:180	Value within requirements	Value within requirements
	Mean (SD)	140.4 (23.9)	Value within requirements	Value within requirements
Recruitment DBP (mmHg)	Range (Low:High)	46:121	Value within requirements	Value within requirements
	Mean (SD)	86.4 (16.4)	Value within requirements	Value within requirements
Table 2 Assessment			Checks	23
			Permitted Modifications	0
			Violations	0

Table 3: Observer Measurements in each Recruitment Range

			<u>Assessment</u>	
SBP	Overall Range mmHg (Low:High)	92:186	Value within requirements	Value within requirements
	Low (< 130 mmHg)	34	Value within requirements	Value within requirements
	Medium (130 – 160 mmHg)	41	Value within requirements	Value within requirements
	High (> 160 mmHg)	24	Value within requirements	Value within requirements
	Maximum Difference	17	Value within requirements	Value within requirements
DBP	Overall Range mmHg (Low:High)	46:120	Value within requirements	Value within requirements
	Low (< 80 mmHg)	36	Value within requirements	Value within requirements
	Medium (80 – 100 mmHg)	39	Value within requirements	Value within requirements
	High (> 100 mmHg)	24	Value within requirements	Value within requirements
	Maximum Difference	15	Value within requirements	Value within requirements
Table 3 Assessment			Checks	12
			Permitted Modifications	0
			Violations	0

Table 4: Observer Differences

			<u>Assessment</u>	
Observer 2 – Observer 1				
SBP (mmHg)	Range (Low:High)	-4:+4	Value within requirements	Value within requirements
	Mean (SD)	+0.1 (2.4)	Value within requirements	Value within requirements
DBP (mmHg)	Range (Low:High)	-4:+4	Value within requirements	Value within requirements
	Mean (SD)	+0.4 (2.3)	Value within requirements	Value within requirements
Repeated Measurements		1	Value within requirements	
Table 4 Assessment			Checks	9
			Permitted Modifications	0
			Violations	0

Table 5: Validation Results

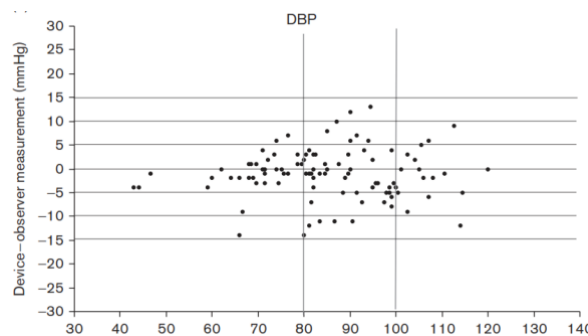
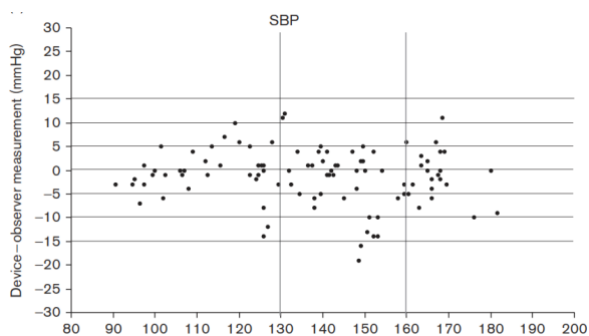
Part 1	Pass Req.		Achieved		Assessment	
	Two of	All of	SBP	DBP		
≤ 5 mmHg	73	65	71	73	Value within lower passing criteria	Value within passing criteria
≤ 10 mmHg	87	81	89	90	Value within passing criteria	Value within passing criteria
≤ 15 mmHg	96	93	97	99	Value within passing criteria	Value within passing criteria
Grade 1			Pass	Pass	Value within lower passing criteria	Value within passing criteria
Mean mmHg			-1.21	-1.04	Value within requirements	Value within requirements
SD mmHg			5.87	5.28	Value within requirements	Value within requirements

Part 2	Pass Req.	Achieved		Assessment	
		SBP	DBP		
2/3 ≤ 5 mmHg	≥ 24	25	28	Value within passing criteria	Value within passing criteria
0/3 ≤ 5 mmHg	≤ 3	3	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 lower passing criteria	Value within passing criteria

Part 3	Result	Pass	Value within lower passing criteria

Table 5 Assessment	Checks	21
	Permitted Modifications	0
	Violations	0

Plots



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

Requirement satisfactory
 Requirement satisfactory

Plots Assessment	Checks	2
	Permitted Modifications	0
	Violations	0

Recommendations

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

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

Certification Decision

The iHealth Feel (BP5), with the Standard: 22 cm to-42 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: 3rd 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.