Medical Device Assessment

Medaval Accreditation Assessment

Volume 2016 Report 1601 05 August 2016

Accreditation assessment of the blood pressure measurement technology used in the iHealth BP3 upper arm monitor, as validated according to the European Society of Hypertension International Protocol revision 2010

Reference Medaval Ltd. Accreditation assessment of the blood pressure measurement technology used in the iHealth BP3 upper arm monitor, as validated according to the European Society of Hypertension International Protocol revision 2010. *Medical Device Assessment*. 2016 Aug 5;**2016**(1601). 5 p. Epub: 2019 Jan 30. Available from: https://www.medaval.ie/MDA/2016/MDA1601.pdf.

Medical Device Assessment is published by

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

Accreditation assessment of the blood pressure measurement technology used in the iHealth BP3 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 BP3	Requirement satisfactory
Model	BP3	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-30 cm Large: 30 cm to-42 cm XLarge: 42 cm to-48 cm	Cuffs Listed: Requirement satisfactory Arm Circumferences: Requirement satisfactory

Study Details

Original Publication	Chen C, Shang F, Wang J, Chen J, Ji N, Wan Y. Validation of the iHealth BP3 upper-arm blood pressure monitor, for clinic use and self-measurement, according to the European Society of Hypertension International Protocol revision 2010. *Blood Press Monit*. 2012 Dec;**17**(6):253-6. doi: 10.1097/MBP.0b013e32835b9ecb. PMID: 23147535.
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	Oscillometric	Requirement satisfactory
Study Measurement Site	Upper Arm	Requirement satisfactory
Observers		
Supervisor + 2 Observers	Yes	Requirement satisfactory
Observer Training	Not stated.	Modification: Inferred from following protocol precisely.
Observer Familiarisation	12 test measurements	Requirement satisfactory
Observers Blinding	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	1
	Violations	0

Procedure

Table 1: Screening and Recruitment Details

Screening and Recruitment					Assessment
Total Screened				**54**	Value within requirements
Total Excluded				**21**	Value within requirements
	Ranges Complete		**16**		Value within requirements
	Range Adjustment		**5**		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*	**10**		Value within requirements
		> 180 *mmHg*	**1**		Value within requirements
DBP	Total			**33**	Value within requirements
	Low		**11**		Value within requirements
		< 40 *mmHg*	**0**		Value within requirements
		40 –79 *mmHg*	**11**		Value within requirements
	Medium	80 – 100 *mmHg*	**10**		Value within requirements
	High		**12**		Value within requirements
		101 – 130 *mmHg*	**12**		Value within requirements
		> 130 *mmHg*	**0**		Value within requirements
Total Extremes			**1**		Value within requirements

On Treatment Ranges				
SBP	Low	< 130 *mmHg*	**1**	Value within requirements
	Medium	130 – 160 *mmHg*	**5**	Value within requirements
	High	> 160 *mmHg*	**7**	Value within requirements
DBP	Low	< 80 *mmHg*	**3**	Value within requirements
	Medium	80 – 100 *mmHg*	**3**	Value within requirements
	High	> 100 *mmHg*	**7**	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)*	**27:69**	Value within requirements	Value within requirements
	Mean (SD)	**47.1 (12.3)**	Value within requirements	Value within requirements
Arm Circumference	Range *(Low:High)*	**22:38**	Value within requirements	Value within requirements
(cm)	Mean (SD)	**30.0 (4.4)**	Value within requirements	Value within requirements
Cuff for Test Device	Standard *(22 to 30)*	**17**		
(cm)	Large *(30 to 42)*	**16**		
	XLarge *(42 to 48)*	**0**		
	Total	**33**	Value within requirements	
Recruitment SBP	Range *(Low:High)*	**89:190**	Value within requirements	Value within requirements
(mmHg)	Mean (SD)	**143.9 (27.4)**	Value within requirements	Value within requirements
Recruitment DBP	Range *(Low:High)*	**46:121**	Value within requirements	Value within requirements
(mmHg)	Mean (SD)	**90.1 (18.3)**	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)*	**91:192**	Value within requirements	Value within requirements
	Low *(< 130 mmHg)*	**31**	Value within requirements	
	Medium *(130 – 160 mmHg)*	**35**	Value within requirements	
	High *(> 160 mmHg)*	**33**	Value within requirements	
	Maximum Difference	**4**	Value within requirements	
DBP	Overall Range *mmHg* (Low:High)	**46:122**	Value within requirements	Value within requirements
	Low (< 80 *mmHg*)	**29**	Value within requirements	
	Medium (80 – 100 *mmHg*)	**34**	Value within requirements	
	High (> 100 *mmHg*)	**36**	Value within requirements	
	Maximum Difference	**7**	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)*	**–4:+4**	Value within requirements	Value within requirements
	Mean (SD)	**+0.1 (2.3)**	Value within requirements	Value within requirements
DBP *(mmHg)*	Range *(Low:High)*	**–4:+4**	Value within requirements	Value within requirements
	Mean (SD)	**+0.2 (2.0)**	Value within requirements	Value within requirements
Repeated Measurements		**3**	Value within requirements	

Table 4 Assessment		
	Checks	9
	Permitted Modifications	0
	Violations	0

Table 5: Validation Results

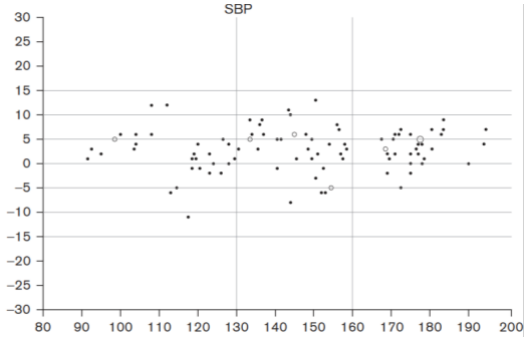
Part 1	Pass Req.		Achieved		**Assessment**	
	Two of	All of	SBP	DBP		
≤ 5 *mmHg*	73	65	**72**	**85**	Value within lower passing criteria	Value within passing criteria
≤ 10 *mmHg*	87	81	**94**	**99**	Value within passing criteria	Value within passing criteria
≤ 15 *mmHg*	96	93	**99**	**99**	Value within passing criteria	Value within passing criteria
Grade 1			**Pass**	**Pass**	Value within lower passing criteria	Value within passing criteria
Mean *mmHg*			**2.8**	**–0.4**	Value within requirements	Value within requirements
SD *mmHg*			**4.2**	**3.5**	Value within requirements	Value within requirements

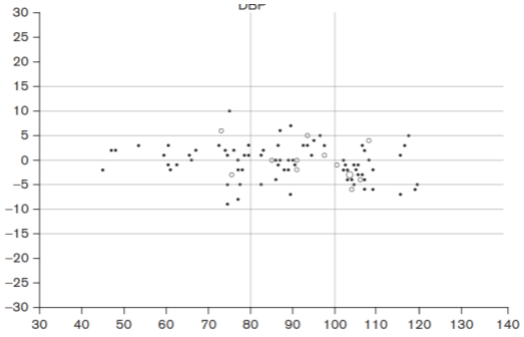
Part 2	Pass Req.	Achieved SBP	Achieved DBP		
2/3 ≤ 5 *mmHg*	≥ 24	**24**	**29**	Value within passing criteria	Value within passing criteria
0/3 ≤ 5 *mmHg*	≤ 3	**0**	**1**	Value within passing criteria	Value within passing criteria
Grade 2		**Pass**	**Pass**	Value within passing criteria	Value within passing 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





		Assessment
SBP Plot Provided	**Yes**	Requirement satisfactory
DBP Plot Provided	**Yes**	Requirement satisfactory

Plots Assessment		
	Checks	2
	Permitted Modifications	0
	Violations	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 iHealth BP3, with either the Standard 22 cm to-30 cm or the Large 30 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

1. 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.

