

Medaval Accreditation Assessment

Volume 2016

Report 1605

05 August 2016

Accreditation assessment of the blood pressure measurement technology used in the Microlife BP A200 Comfort (BP3MS1-4A) upper arm monitor, as validated according to the European Society of Hypertension International Protocol revision 2010 and also the AAMI/ANSI/ISO 81060-2:2013 standard for a general study in adults

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Reference

Medaval Ltd. Accreditation assessment of the blood pressure measurement technology used in the Microlife BP A200 Comfort (BP3MS1-4A) upper arm monitor, as validated according to the European Society of Hypertension International Protocol revision 2010 and also the AAMI/ANSI/ISO 81060-2:2013 standard for a general study in adults. *Medical Device Assessment*. 2016 Aug 5;2016(1605). 8 p. Epub: 2019 Jan 31. Available from: <https://www.medaval.ie/MDA/2016/MDA1605.pdf>.

Medical Device Assessment is published by

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Accreditation assessment of the blood pressure measurement technology used in the Microlife BP A200 Comfort (BP3MS1-4A) upper arm monitor, as validated according to the European Society of Hypertension International Protocol revision 2010 and also the AAMI/ANSI/ISO 81060-2:2013 standard for a general study in adults

Medaval Accreditation-Assessment Report – 5th August 2016

Test Device Details

		Assessment
Full Name	Microlife BP A200 Comfort	Requirement satisfactory
Model	BP3MS1-4A	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		Modification: Missing image accepted by paper review.
Manufacturer(s)	Sole: Microlife Corporation, 9F, 431 RuiGuang Road, NeiHu, Taipei 11492, TAIWAN	Requirement satisfactory
Cuffs	Small 17 cm to 22 cm Medium 22 cm to 32 cm M-L 22 cm to 42 cm L-XL 32 cm to 52 cm	Cuffs Listed: Requirement satisfactory Arm Circumferences: Requirement satisfactory
Test Device Details and Study Details Assessment		
	Checks	10
	Permitted Modifications	1
	Violations	0

ESH-IP 2010 Study

Study Details

Original Publication	Bing S, Chen K, Hou H, Zhang W, Li L, Wei J, Shu C, Wan Y. Validation of the Microlife BP A200 Comfort and W2 Slim automated blood pressure monitors in a general adult population according to the European Society of Hypertension and the ANSI/AAMI/ISO 81060-2: 2013 protocols. <i>Blood Press Monit.</i> 2016 Apr; 21 (2):118-23. Epub: 2015 Dec. doi: 10.1097/MBP.0000000000000169. PMID: 26683381.	
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	BHS tutorial	Requirement satisfactory
Observer Familiarisation	Not specified	Modification: Missing value accepted by paper review
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	Inpatients and outpatients	Requirement satisfactory
Test Device Details and Study Details Assessment		
	Checks	12
	Permitted Modifications	1
	Violations	0

Procedure

Table 1: Screening and Recruitment Details

Screening and Recruitment				Assessment
Total Screened			38	Value within requirements
Total Excluded			5	Value within requirements
	Ranges Complete		4	Value within requirements
	Range Adjustment		0	Value within requirements
	Arrhythmias		1	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	< 90 mmHg	0	Value within requirements
		90 – 129 mmHg	11	Value within requirements
		130 – 160 mmHg	10	Value within requirements
	Medium	130 – 160 mmHg	10	Value within requirements
		161 – 180 mmHg	8	Value within requirements
	High	> 180 mmHg	2	Value within requirements
DBP	Total		33	Value within requirements
	Low	< 40 mmHg	0	Value within requirements
		40 – 79 mmHg	12	Value within requirements
		80 – 100 mmHg	10	Value within requirements
	Medium	80 – 100 mmHg	10	Value within requirements
		101 – 130 mmHg	11	Value within requirements
	High	> 130 mmHg	0	Value within requirements
Total Extremes			0	0 Value within requirements
On Treatment Ranges				
SBP	Low	< 130 mmHg	6	Value within requirements
	Medium	130 – 160 mmHg	5	Value within requirements
	High	> 160 mmHg	10	Value within requirements
DBP	Low	< 80 mmHg	6	Value within requirements
	Medium	80 – 100 mmHg	6	Value within requirements
	High	> 100 mmHg	9	Value within requirements
Table 1 Assessment				
				Checks 36
				Permitted Modifications 0
				Violations 0

Study Results

Table 2: Subject Details

			Assessment	
Sex	Male:Female	17:16	Value within requirements	Value within requirements
Age (years)	Range (Low:High)	25:84	Value within requirements	Value within requirements
	Mean (SD)	65.2 (17.0)	Value within requirements	Value within requirements
Arm Circumference (cm)	Range (Low:High)	21:38	Value within requirements	Value within requirements
	Mean (SD)	29.6 (4.4)	Value within requirements	Value within requirements
Cuff for Test Device (cm)	Small (17 – 22)	3		
	Medium (22 – 32)	0		
	M-L (22 – 42)	30		
	L-XL (32 – 52)	0		
	Total	33	Value within requirements	
Recruitment SBP (mmHg)	Range (Low:High)	90:187	Value within requirements	Value within requirements
	Mean (SD)	145.3 (29.7)	Value within requirements	Value within requirements
Recruitment DBP (mmHg)	Range (Low:High)	47:122	Value within requirements	Value within requirements
	Mean (SD)	85.5 (20.2)	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)	89:186	Value within requirements	Value within requirements
	Low (< 130 mmHg)	37	Value within requirements	
	Medium (130 – 160 mmHg)	26	Value within requirements	
	High (> 160 mmHg)	36	Value within requirements	
	Maximum Difference	11	Value within requirements	
DBP	Overall Range mmHg (Low:High)	47:122	Value within requirements	Value within requirements
	Low (< 80 mmHg)	35	Value within requirements	
	Medium (80 – 100 mmHg)	33	Value within requirements	
	High (> 100 mmHg)	31	Value within requirements	
	Maximum Difference	4	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)	0.0 (1.7)	Value within requirements	Value within requirements
DBP (mmHg)	Range (Low:High)	-4:+4	Value within requirements	Value within requirements
	Mean (SD)	0.0 (1.6)	Value within requirements	Value within requirements
Repeated Measurements		?	Modification: Missing value accepted by paper review.	
Table 4 Assessment			Checks	9
			Permitted Modifications	1
			Violations	0

Table 5: Validation Results

Part 1	Pass Req.		Achieved		Assessment	
	Two of	All of	SBP	DBP		
≤ 5 mmHg	73	65	75	77	Value within passing criteria	Value within passing criteria
≤ 10 mmHg	87	81	93	97	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 passing criteria	Value within passing criteria
Mean mmHg			+0.6	+0.85	Value within requirements	Value within requirements
SD mmHg			4.8	4.3	Value within requirements	Value within requirements
Part 2	Pass Req.	Achieved		Assessment		
		SBP	DBP			
2/3 ≤ 5 mmHg	≥ 24	26	27	Value within passing criteria	Value within passing criteria	
0/3 ≤ 5 mmHg	≤ 3	0	2	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 passing criteria	Value within passing criteria	
Part 3	Result	Pass	Value within passing criteria			
Table 5 Assessment					Checks	21
					Permitted Modifications	0
					Violations	0

Plots

SBP Plot Provided	DBP Plot Provided	ISO plot only	ISO plot only	Assessment	
				Modification: Missing plot accepted by paper review.	Modification: Missing plot accepted by paper review.
Plots Assessment				Checks	2
				Permitted Modifications	2
				Violations	0

AAMI/ANSI/ISO 81060-2:2013 Study

Study Details

Original Publication Bing S, Chen K, Hou H, Zhang W, Li L, Wei J, Shu C, Wan Y. Validation of the Microlife BP A200 Comfort and W2 Slim automated blood pressure monitors in a general adult population according to the European Society of Hypertension and the ANSI/AAMI/ISO 81060-2: 2013 protocols. *Blood Press Monit.* 2016 Apr;**21**(2):118-23. Epub: 2015 Dec. doi: 10.1097/MBP.000000000000169. PMID: 26683381.

Protocol The AAMI/ANSI/ISO 81060-2:2013 standard for a general study in adults²

Reference Determination	Adherence	Adjustments	Study Meas. Method	Study Measurement Site	Assessment	
					Requirement satisfactory	Optional data satisfactory
Sequential same-arm	Followed Precisely	None	Oscillometric	Upper Arm	Requirement satisfactory	Optional data satisfactory
Observers					Requirement satisfactory	Optional data satisfactory
Supervisor + 2 Observers	Yes	BHS tutorial	Not specified	From device and each other	Optional data not provided	Optional data satisfactory
Observer Training						
Observer Familiarisation						
Observers Blinded						
Sample					Requirement satisfactory	Optional data satisfactory
Population	A general population				Requirement satisfactory	Optional data satisfactory
Circumstances	None				Optional data satisfactory	Optional data satisfactory
HBP Subjects Selection	Inpatients and outpatients				Optional data satisfactory	Optional data satisfactory
NBP Subjects Selection	Inpatients and outpatients				Optional data satisfactory	Optional data satisfactory
Study Details Assessment					Checks	13
					Permitted Modifications	0
					Violations	0

Procedure

Table 1: Screening and Recruitment Details

Screening and Recruitment		Assessment
Total Screened		Optional detail not provided
Total Excluded		Optional detail not provided
Device Failure		Optional detail not provided
Poor Quality Sounds		Optional detail not provided
Cuff Size Unavailable		Optional detail not provided
Observer Disagreement		Optional detail not provided
Bigeminy		Optional detail not provided
Trigeminy		Optional detail not provided
Isolated VPB		Optional detail not provided
Atrial Fibrillation		Optional detail not provided
Other Reasons*		Optional detail not provided
Total Recruited	85	Value within requirements
*Explanation Summary		Optional detail not provided

Table 1 Assessment	Checks	13
	Permitted Modifications	0
	Violations	0

Study Results

Table 2: Subject Details

			Assessment	
Sex	Male:Female	40:45	Value within requirements	Value within requirements
Age (years)	Range (Low:High)	22:79	Value within requirements	Value within requirements
	Mean (SD)	48 (11.1)	Optional data satisfactory	Optional data satisfactory
	Adults:Children	85:0	Value within requirements	Value within requirements
Arm Circumference (cm)	Range (Low:High)	23.5:42.0	Optional data satisfactory	Optional data satisfactory
	Mean (SD)	32.0 (5.0)	Optional data satisfactory	Optional data satisfactory
Cuff for Test Device (cm)	Small (17 – 22)	12 (14.1%)	Value within requirements	
	Medium (22 – 32)	28 (32.9%)	Value within requirements	
	M-L (22 – 42)	29 (34.1%)	Value within requirements	
	L-XL (32 – 52)	16 (18.8%)	Value within requirements	
	Total	85	Value within requirements	
Recruitment SBP (mmHg)	Range (Low:High)	?:?	Optional data not provided	Optional data not provided
	Mean (SD)	? (?)	Optional data not provided	Optional data not provided
Recruitment DBP (mmHg)	Range (Low:High)	?:?	Optional data not provided	Optional data not provided
	Mean (SD)	? (?)	Optional data not provided	Optional data not provided

Table 2 Assessment	Checks	25
	Permitted Modifications	0
	Violations	0

Table 3: Observer Measurements Range-Requirements

			Assessment	
SBP	≤ 100 mmHg	25 (9.8%)	Value within requirements	
	101 – 139 mmHg	119 (46.7%)	Value within requirements	
	140 – 159 mmHg	30 (11.7%)	Value within requirements	
	≥ 160 mmHg	81 (31.8%)	Value within requirements	
DBP	≤ 60 mmHg	25 (9.8%)	Value within requirements	
	61 – 84 mmHg	115 (45.1%)	Value within requirements	
	85 – 99 mmHg	47 (18.4%)	Value within requirements	
	≥ 100 mmHg	68 (26.7%)	Value within requirements	
DBP sounds used	K4:K5 (subjects)	0:85	Value within requirements	Value within requirements
Table 3 Assessment			Checks	10
			Permitted Modifications	0
			Violations	0

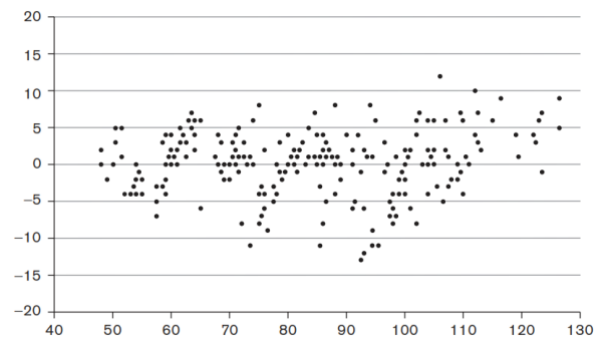
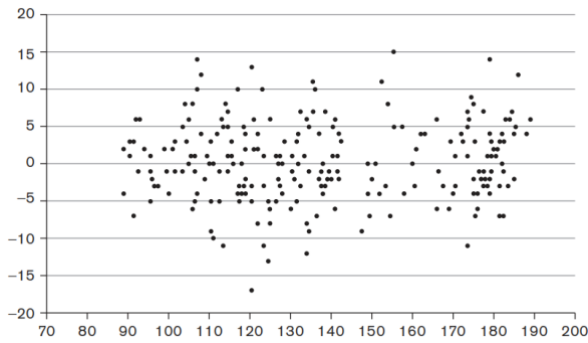
Table 4: Observer Differences

				Assessment	
Observer 2 – Observer 1					
SBP (<i>mmHg</i>)	Range (<i>Low:High</i>)	?:?	Optional data not provided	Optional data not provided	
	Mean (SD)	? (?)	Optional data not provided	Optional data not provided	
DBP (<i>mmHg</i>)	Range (<i>Low:High</i>)	?:?	Optional data not provided	Optional data not provided	
	Mean (SD)	? (?)	Optional data not provided	Optional data not provided	
Repeated Measurements		?	Modification: Missing value accepted by paper review		
Table 4 Assessment			Checks	9	
			Permitted Modifications	1	
			Violations	0	

Table 5: Validation Results

Criterion 1	Pass Req.	Achieved		Assessment	
		SBP	DBP		
Measurement pairs		255		Value within requirements	
Mean <i>mmHg</i>	≤ 5	+0.38	+0.28	Value within passing criteria	Value within passing criteria
SD <i>mmHg</i>	≤ 8	5.12	4.29	Value within passing criteria	Value within passing criteria
Grade 1		Pass	Pass	Value within passing criteria	Value within passing criteria
Criterion 2					
Number of subjects		85		Value within requirements	
Mean <i>mmHg</i>		+0.38	+0.28	Value within passing criteria	Value within passing criteria
SD <i>mmHg</i>	≤ 6.93:6.95	3.61	3.34	Value within passing criteria	Value within passing criteria
Grade 2		Pass	Pass	Value within passing criteria	Value within passing criteria
Result		Pass		Value within passing criteria	
Table 4 Assessment			Checks	15	
			Permitted Modifications	0	
			Violations	0	

Plots



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

Assessment

Optional plot provided instead of required ESH-IP plot
 Optional plot provided instead of required ESH-IP plot

Plots Assessment	Checks	2
	Permitted Modifications	0
	Violations	0

Recommendations

Overall Summary

Number of checks 208
Number of permitted modifications 6
Number of violations 0

Assessment Summary

The validations have been checked and are 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 Microlife BP A200 Comfort (BP3MS1-4A), with any of the small 17 cm to 22 cm, medium 22 cm to 32 cm, medium–large 22 cm to 42 cm or large–extra-large 32 cm to 52 cm cuffs, is certified by Medaval Ltd., for blood pressure measurement in adults, as it fulfilled the conditions required for a pass in two validation studies, one carried out in accordance with the requirements of the International Protocol of the European Society of Hypertension 2010 Revision and one in accordance with the requirements of the AAMI/ANSI/ISO 81060-2:2013 standard.

Date of Advisory Board Approval: 29th July 2016.

References

- 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.
- Association for the Advancement of Medical Instrumentation, American National Standards Institute, International Organization for Standardization. AAMI/ANSI/ISO 81060-2:2013, Non-invasive Sphygmomanometers - Part 2: Clinical Investigation of Automated Measurement Type. Geneva, Switzerland: ISO; 2013.