Medical Device Assessment

Medaval Certified Accuracy

Medaval Accreditation Assessment

Volume 2016 Report 1604 05 August 2016

Accreditation assessment of the blood pressure measurement technology used in the Microlife W2 Slim wrist 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

Reference Medaval Ltd. Accreditation assessment of the blood pressure measurement technology used in the Microlife W2 Slim wrist 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**(1604). 8 p. Epub: 2019 Jan 31. Available from: https://www.medaval.ie/MDA/2016/MDA1604.pdf.

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Accreditation assessment of the blood pressure measurement technology used in the Microlife W2 Slim wrist 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 W2 Slim	Requirement satisfactory
Model	Not stated	Modification: Missing value accepted by paper review.
Measurement Site	Wrist	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 Image		Modification: No photograph in paper. Standard image shown in report.
Manufacturer(s)	Sole: Microlife Corporation, 9F, 431 RuiGuang Road, NeiHu, Taipei 11492, TAIWAN	Requirement satisfactory
Cuffs	Integrated 13.5 cm to-23 cm	Cuffs Listed: Requirement satisfactory Wrist Circumferences: Requirement satisfactory

Test Device Details and Study Details Assessment	**Checks**	10
	Permitted Modifications	2
	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. *Blood Press Monit*. 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	Wrist	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				**41**	Value within requirements
Total Excluded				**8**	Value within requirements
	Ranges Complete		**5**		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		**2**		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*	**10**		Value within requirements
	High		**12**		Value within requirements
		161 – 180 *mmHg*	**9**		Value within requirements
		> 180 *mmHg*	**3**		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*	**11**		Value within requirements
	High		**10**		Value within requirements
		101 – 130 *mmHg*	**10**		Value within requirements
		> 130 *mmHg*	**0**		Value within requirements
Total Extremes			**3**		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*	**7**	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

			Assessment	
Sex	Male:Female	**16:17**	Value within requirements	Value within requirements
Age *(years)*	Range *(Low:High)*	**25:85**	Value within requirements	Value within requirements
	Mean (SD)	**65.6 (17.2)**	Value within requirements	Value within requirements
Arm Circumference	Range *(Low:High)*	**21:38**	Value within requirements	Value within requirements
(cm)	Mean (SD)	**29.2 (4.5)**	Value within requirements	Value within requirements
Wrist Circumference	Range *(Low:High)*	**15:23**	Value within requirements	Value within requirements
(cm)	Mean (SD)	**18.9 (2.5)**	Value within requirements	Value within requirements
Cuff for Test Device	Wrist *(13.5 – 23)*	**33**		
(cm)	Total	**33**	Value within requirements	
Recruitment SBP	Range *(Low:High)*	**90:187**	Value within requirements	Value within requirements
(mmHg)	Mean (SD)	**145.2 (29.6)**	Value within requirements	Value within requirements
Recruitment DBP	Range *(Low:High)*	**47:122**	Value within requirements	Value within requirements
(mmHg)	Mean (SD)	**84.9 (19.6)**	Value within requirements	Value within requirements

Table 2 Assessment		
	Checks	23
	Permitted Modifications	0
	Violations	0

Table 3: Observer Measurements in each Recruitment Range

			Assessment	
SBP	Overall Range *mmHg (Low:High)*	**88:187**	Value within requirements	Value within requirements
	Low *(< 130 mmHg)*	**36**	Value within requirements	
	Medium *(130 – 160 mmHg)*	**28**	Value within requirements	
	High *(> 160 mmHg)*	**35**	Value within requirements	
	Maximum Difference	**8**	Value within requirements	
DBP	Overall Range *mmHg* (Low:High)	**46:122**	Value within requirements	Value within requirements
	Low (< 80 *mmHg*)	**39**	Value within requirements	
	Medium (80 – 100 *mmHg*)	**35**	Value within requirements	
	High (> 100 *mmHg*)	**25**	Value within requirements	
	Maximum Difference	**14**	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	**68**	**72**	Value within lower passing criteria	Value within lower passing criteria
≤ 10 *mmHg*	87	81	**88**	**90**	Value within passing criteria	Value within passing criteria
≤ 15 *mmHg*	96	93	**97**	**98**	Value within passing criteria	Value within passing criteria
Grade 1			**Pass**	**Pass**	Value within lower passing criteria	Value within lower passing criteria
Mean *mmHg*			**+1.0**	**+0.7**	Value within requirements	Value within requirements
SD *mmHg*			**6.4**	**5.7**	Value within requirements	Value within requirements

Part 2	Pass Req.	Achieved SBP	Achieved DBP		
2/3 ≤ 5 *mmHg*	≥ 24	**25**	**25**	Value within passing criteria	Value within passing criteria
0/3 ≤ 5 *mmHg*	≤ 3	**3**	**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 lower 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	**ISO plot only**	Modification: Missing plot accepted by paper review.
DBP Plot Provided	**ISO plot only**	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.0000000000000169. *PMID: 26683381*.

Protocol

The AAMI/ANSI/ISO 81060-2:2013 standard for a general study in adults.[2]

		Assessment
Reference Determination	Sequential same-arm	Requirement satisfactory
Adherence	Followed Precisely	Optional data satisfactory
Adjustments	None	Optional data satisfactory
Study Meas. Method	Oscillometric	Requirement satisfactory
Study Measurement Site	Wrist	Requirement satisfactory

Observers

Supervisor + 2 Observers	Yes	Requirement satisfactory
Observer Preparation	BHS tutorial	Optional data satisfactory
Observer Familiarisation	Not specified	Optional data not provided
Observers Blinded	From device and each other	Optional data satisfactory

Sample

Population	A general population	Requirement satisfactory
Circumstances	None	Requirement satisfactory
HBP Subjects Selection	Inpatients and outpatients	Optional data satisfactory
NBP Subjects Selection	Inpatients and outpatients	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	**39:46**	Value within requirements	Value within requirements
Age *(years)*	Range *(Low:High)*	**20:88**	Value within requirements	Value within requirements
	Mean (SD)	**65.4 (16.1)**	Optional data satisfactory	Optional data satisfactory
	Adults:Children	**85:0**	Value within requirements	Value within requirements
Arm Circumference	Range *(Low:High)*	**20:38**	Optional data satisfactory	Optional data satisfactory
(cm)	Mean (SD)	**28.6 (4.4)**	Optional data satisfactory	Optional data satisfactory
Wrist Circumference	Range *(Low:High)*	**14:23**	Optional data satisfactory	Optional data satisfactory
(cm)	Mean (SD)	**18.5 (2.6)**	Optional data satisfactory	Optional data satisfactory
Cuff for Test Device	Integrated *(13.5- 23)*	**85**	Value within requirements	
(cm)	Q1 *(13.5 – 15.5)*	**18**	Value within requirements	
	Q2 *(16 – 18)*	**23**	Value within requirements	
	Q3 *(18.5 – 20.5)*	**25**	Value within requirements	
	Q4 *(21 – 23)*	**19**	Value within requirements	
Recruitment SBP	Range (Low:High)	**?:?**	Optional data not provided	Optional data not provided
(mmHg)	Mean (SD)	**? (?)**	Optional data not provided	Optional data not provided
Recruitment DBP	Range (Low:High)	**?:?**	Optional data not provided	Optional data not provided
(mmHg)	Mean (SD)	**? (?)**	Optional data not provided	Optional data not provided

Table 2 Assessment		
	Checks	29
	Permitted Modifications	0
	Violations	0

Table 3: Observer Measurements Range-Requirements

			Assessment	
SBP	≤ 100 mmHg	**23 (9.0%)**	Value within requirements	
	101 – 139 mmHg	**122 (47.9%)**	Value within requirements	
	140 – 159 mmHg	**29 (11.3%)**	Value within requirements	
	≥ 160 mmHg	**81 (31.8%)**	Value within requirements	
DBP	≤ 60 mmHg	**46 (18.0%)**	Value within requirements	
	61 – 84 mmHg	**95 (37.3%)**	Value within requirements	
	85 – 99 mmHg	**51 (20.0%)**	Value within requirements	
	≥ 100 mmHg	**63 (24.7%)**	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 *(mmHg)*	Range *(Low:High)*	**?:?**	Optional data not provided	Optional data not provided
	Mean (SD)	**? (?)**	Optional data not provided	Optional data not provided
DBP *(mmHg)*	Range *(Low:High)*	**?:?**	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	

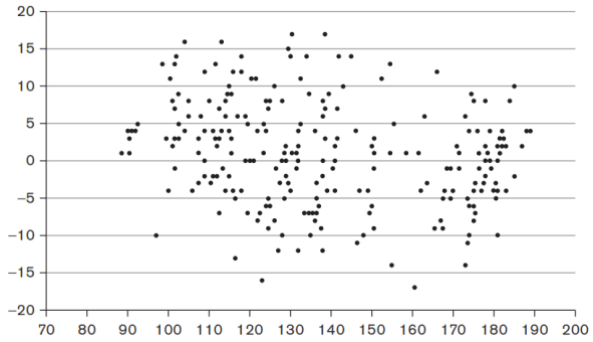
Table 4 Assessment	**Checks**	9
	Permitted Modifications	1
	Violations	0

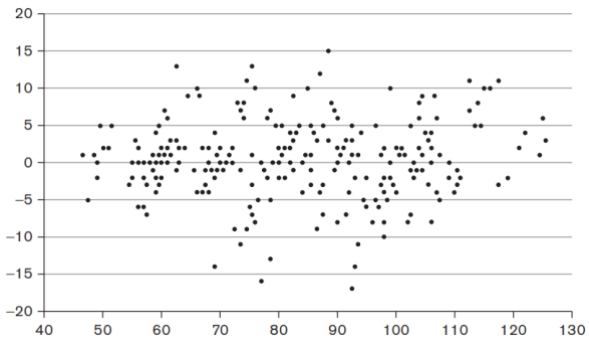
Table 5: Validation Results

	Pass Req.	Achieved SBP	Achieved DBP	Assessment	
Criterion 1					
Measurement pairs		**255**		Value within requirements	
Mean *mmHg*	≤ 5	**+1.01**	**+0.34**	Value within passing criteria	Value within passing criteria
SD *mmHg*	≤ 8	**6.80**	**5.62**	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 *mmHg*		**+1.01**	**+0.34**	Value within passing criteria	Value within passing criteria
SD *mmHg*	≤ 6.87:6.95	**5.94**	**4.63**	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





		Assessment
SBP Plot Provided	**Yes**	Optional plot provided instead of required ESH-IP plot
DBP Plot Provided	**Yes**	Optional plot provided instead of required ESH-IP plot

Plots Assessment		
	Checks	2
	Permitted Modifications	0
	Violations	0

Recommendations

Overall Summary

Number of checks	216
Number of permitted modifications	7
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 W2 Slim 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

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.

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.

