# **Medical Device Assessment**



#### Medaval Accreditation Assessment

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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

#### Approved by the Medaval Advisory Board

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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 – 5<sup>th</sup> August 2016

#### **Test Device Details**

	lest Devic	Assessme	at		
Full Name	Microlife W2 Slim	Requirement satisfactory			
Model	Not stated	Modification: Missing value acce	nted by naner review		
Measurement Site	Wrist	Requirement satisfactory	pied by paper review.		
Client Use	Suitable for self-measurement.	Requirement satisfactory Requirement satisfactory			
Operation Method	Oscillometry, automatic during	Requirement satisfactory			
Operation Method	deflation	Requirement satisfactory			
Measurement Occurrence	Single Measurements Only	Requirement satisfactory			
Device Image		Modification: No photograph in shown in report.	paper. Standard image		
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 satisfa Wrist Circumferences: Requirem	•		
Test Device Details and Stud	ly Details Assessment	Checks	10		
		Permitted Modifications	2		
		Violations	0		
	ESH-IP 20 Study D	Details			
Original Publication	<b>Study D</b> Bing S, Chen K, Hou H, Zhang W, Comfort and W2 Slim automated b to the European Society of Hypert	•	ult population according 2: 2013 protocols. <i>Blood</i>		
Original Publication Protocol	Study D Bing S, Chen K, Hou H, Zhang W, Comfort and W2 Slim automated b to the European Society of Hypert Press Monit. 2016 Apr; <b>21</b> (2):118- PMID: 26683381.	Details Li L, Wei J, Shu C, Wan Y. Validation o lood pressure monitors in a general adu ension and the ANSI/AAMI/ISO 81060-2 23. Epub: 2015 Dec. doi: 10.1097/M usion International Protocol revision 20	ult population according 2: 2013 protocols. <i>Blood</i> BP.0000000000000169.		
Protocol	<b>Study D</b> Bing S, Chen K, Hou H, Zhang W, Comfort and W2 Slim automated b to the European Society of Hyperter <i>Press Monit</i> . 2016 Apr; <b>21</b> (2):118- <i>PMID</i> : 26683381. The European Society of Hyperter blood pressure measuring devices	Details Li L, Wei J, Shu C, Wan Y. Validation o lood pressure monitors in a general adu ension and the ANSI/AAMI/ISO 81060-2 23. Epub: 2015 Dec. doi: 10.1097/M usion International Protocol revision 20 in adults <sup>1</sup>	ult population according 2: 2013 protocols. <i>Blood</i> IBP.00000000000000169. 10 for the validation of		
Protocol Adherence	Study D Bing S, Chen K, Hou H, Zhang W, Comfort and W2 Slim automated b to the European Society of Hyperter <i>Press Monit</i> . 2016 Apr; <b>21</b> (2):118- <i>PMID: 26683381</i> . The European Society of Hyperter blood pressure measuring devices in Followed Precisely	Details Li L, Wei J, Shu C, Wan Y. Validation o lood pressure monitors in a general adu ension and the ANSI/AAMI/ISO 81060-2 23. Epub: 2015 Dec. doi: 10.1097/M sion International Protocol revision 20 in adults <sup>1</sup> Assessmen Requirement satisfactory	ult population according 2: 2013 protocols. <i>Blood</i> IBP.00000000000000169. 10 for the validation of		
Protocol Adherence Adjustments	Study D Bing S, Chen K, Hou H, Zhang W, Comfort and W2 Slim automated b to the European Society of Hyperter <i>Press Monit</i> . 2016 Apr; <b>21</b> (2):118- <i>PMID: 26683381</i> . The European Society of Hyperter blood pressure measuring devices of Followed Precisely None	Details Li L, Wei J, Shu C, Wan Y. Validation o lood pressure monitors in a general adu ension and the ANSI/AAMI/ISO 81060-2 23. Epub: 2015 Dec. doi: 10.1097/M sion International Protocol revision 20 in adults <sup>1</sup> Assessmen Requirement satisfactory Requirement satisfactory	ult population according 2: 2013 protocols. <i>Blood</i> IBP.00000000000000169. 10 for the validation of		
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Protocol Adherence Adjustments Study Meas. Method Study Measurement Site Observers Supervisor + 2 Observers Observer Training	Study D Bing S, Chen K, Hou H, Zhang W, Comfort and W2 Slim automated b to the European Society of Hyperter <i>Press Monit</i> . 2016 Apr; <b>21</b> (2):118- <i>PMID: 26683381</i> . The European Society of Hyperter blood pressure measuring devices in Followed Precisely None Oscillometric Wrist Yes BHS tutorial	Details Li L, Wei J, Shu C, Wan Y. Validation o lood pressure monitors in a general add ension and the ANSI/AAMI/ISO 81060-2 23. Epub: 2015 Dec. doi: 10.1097/M asion International Protocol revision 20 in adults <sup>1</sup> Requirement satisfactory Requirement satisfactory Requirement satisfactory Requirement satisfactory Requirement satisfactory Requirement satisfactory Requirement satisfactory	ult population according 2: 2013 protocols. <i>Blood</i> IBP.00000000000000169. 110 for the validation of nt		
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## Procedure

## **Table 1: Screening and Recruitment Details**

	S	creening and Recruit	ment		Assessment		
Total S	Screened			41	Value within requirements		
Total E	Total Excluded Ranges Complete Range Adjustment		8		Value within requirements		
			5		Value within requirements		
			0		Value within requirements		
	Arrhythmi	as	1		Value within requirements		
	Device Fai	lure	0		Value within requirements		
	Poor Qual	ity Sounds	0		Value within requirements		
	Cuff Size L	Inavailable	2		Value within requirements		
	Observer	Disagreement	0		Value within requirements		
	Distributio		0		Value within requirements		
	Other Rea	sons*	0		Value within requirements		
Total F	Recruited			33	Value within requirements		
	nation Sum	mary					
·					No details required		
		Recruitment Rang	es				
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 <i>mmHg</i>		10	Value within requirements		
	High			12	Value within requirements		
		161 – 180 <i>mmHg</i>	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 <i>mmHg</i>	12		Value within requirements		
	Medium	80 – 100 <i>mmHg</i>		11	Value within requirements		
	High			10	Value within requirements		
		101 – 130 mmHg	10		Value within requirements		
		> 130 mmHg	0		Value within requirements		
Total E	Extremes			3	Value within requirements		
		On Treatment Rang	ges				
SBP	Low	< 130 mmHg		6	Value within requirements		
	Medium	130 – 160 <i>mmHg</i>		5	Value within requirements		
	High	> 160 <i>mmHg</i>		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 Assessme	nt			Checks	36	
					Permitted Modifications	0	
					Violations	0	

## **Study Results**

## **Table 2: Subject Details**

			Asses	sment
Sex Male:Fer	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 <i>(13.5 – 23)</i>	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 <i>mmHg</i> )	39	Value within	requirements
	Medium (80 – 100 <i>mmHg</i> )	35	Value within	requirements
	High (> 100 <i>mmHg</i> )	25	Value within	requirements
	Maximum Difference	14	Value within	requirements
Table 3	3 Assessment		Checks	12
			Permitted Modifications	0
			Violations	0

## **Table 4: Observer Differences**

			Assessment		
Observer 2 – Obser	ver 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 Measure	Repeated Measurements		Modification: Missing value	g value accepted by paper review.	
Table 4 Assessment			Checks	9	
			Permitted Modifications	1	
			Violations	0	

## **Table 5: Validation Results**

		s Req. Achieved			Assessment		
	wo of	All of	SBP	DBP			
<u>&lt;</u> 5 mmHg	73	65	68	72	Value within lower passing criteria	Value within lower passing criteria	
<u>&lt;</u> 10 mmHg	87	81	88	90	Value within passing criteria	Value within passing criteria	
<u>&lt;</u> 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 <i>mmHg</i>			+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 Reg.	Achi SBP	ieved DBP			
2/3 <u>&lt;</u> 5 mmHg		> 24	25	25	Value within passing criteria	Value within passing criteria	
0/3 <u>&lt;</u> 5 mmHg		<u>&lt;</u> 3	3	1	Value within passing criteria	Value within passing criteria	
Grade 2			Pass	Pass	Value within passing criteria	Value within passing criteri	
Grade 3			Pass	Pass	Value within lower passing criteria	Value within lower passing criteria	
Part 3			_				
Result			Pa	ass		er passing criteria	
Table 5 Assessment					Checks Permitted Modifications	21 0	
					Violations	0	
lots							
SBP Plot Provided			ISO	) plot only	Assessment Modification: Missing plot accepted by paper review.		
DBP Plot Provided				) plot only	Modification: Missing plot accepted by paper review.		
Plots Assessment					Checks	2	
					Permitted Modifications Violations	2 0	
			AAMI	/ANSI/ISO 8	1060-2:2013 Study		
			AAMI		-		
Original Publication		Comfort to the E Press M	Chen K, Ho and W2 Sl uropean So	<b>Study</b> bu H, Zhang W lim automated ociety of Hyper	<b>1060-2:2013 Study</b> <b>Details</b> , Li L, Wei J, Shu C, Wan Y. Validat blood pressure monitors in a gener tension and the ANSI/AAMI/ISO 81 8-23. Epub: 2015 Dec. doi: 10.10	ral adult population according 1060-2: 2013 protocols. <i>Bloo</i> d	
-		Comfort to the E Press M PMID: 2	Chen K, Ho : and W2 Sl uropean So Ionit. 2016 6683381.	<b>Study</b> bu H, Zhang W lim automated ociety of Hyper 5 Apr; <b>21</b> (2):113	<b>Details</b> , Li L, Wei J, Shu C, Wan Y. Validat blood pressure monitors in a gener tension and the ANSI/AAMI/ISO 82	ral adult population according 1060-2: 2013 protocols. <i>Blood</i> 197/MBP.00000000000000169	
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## 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**

			Asses	sment	
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		Value within requirements		
	85 – 99 mmHg	51 (20.0%) Value with		n 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	

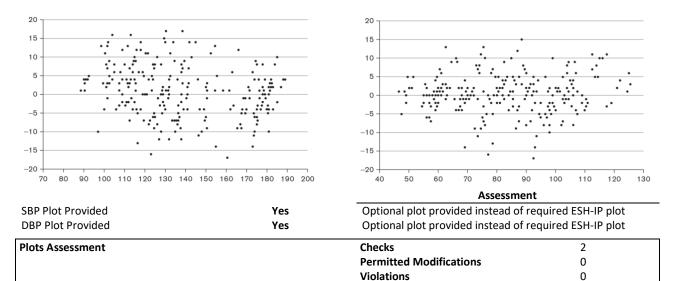
## **Table 4: Observer Differences**

			Assessment		
Observer 2 – Observ	ver 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 Measurer	Repeated Measurements ?		Modification: Missing value	e accepted by paper review	
Table 4 Assessment			Checks	9	
			Permitted Modifications	1	
			Violations	0	

#### **Table 5: Validation Results**

	Achieved		eved	Asses	ssment
Criterion 1	Pass Req.	SBP	DBP		
Measurement pairs		2	55	Value within	requirements
Mean <i>mmHg</i>	≤ 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		8	35	Value within	requirements
Mean <i>mmHg</i>		+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		Pa	ass	Value within	passing criteria
Table 4 Assessment				Checks	15
				Permitted Modifications	0
				Violations	0

#### Plots



#### 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

- 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.