

Microlife Device Validation Table

Clinical Devices					
Device	AAMI	BHS	ESH	Circumstance	Reference
Microlife BP 3AS1-2			Pass	At rest	1
Microlife WatchBP O3 (3MZ0)			Pass	At rest	2
Microlife WatchBP O3 (3MZ1)			Pass	At rest	3
Microlife WatchBP Office			Pass	At rest	4
Microlife WatchBP Office ABI		A/A	Pass	At rest	5
			Pass	L-XL size cuff	4,6
				Accuracy in assessing ABI	7
				Accuracy in detecting Atrial Fibrillation	8,9
Microlife WatchBP Office AFIB			Pass	WatchBP Office Equivalence	4*
				Accuracy in detecting Atrial Fibrillation	8, 9
Microlife WatchBP Office Target			Pass	BP A100 Equivalence	10*

Self-measurement Devices					
Device	AAMI	BHS	ESH	Circumstance	Reference
Microlife BP 3AC1-1			Pass	At rest	11
	Pass	A/A		Pregnancy	12
	Pass	B/A		Pre-eclampsia	12
Microlife BP 3AC1-1 PC			Pass	BP 3AC1-1 Equivalence	11*
			Pass	ESRD population	13
Microlife BP 3AC1-2			Pass	BP 3AC1-1 Equivalence	11*
Microlife BP 3AG1		A/A		BP 3BT0-A Equivalence	14*
Microlife BP 3BT0-1		A/A		BP 3BT0-A Equivalence	14*
Microlife BP 3BT0-A		A/A		Small recruitment violation	14
	Pass	A/B		Normotensive Pregnancy	15
	Pass	B/B		Non-proteinuric HBP	15
	Pass	A/B		Pre-Eclampsia	15
Microlife BP 3BT0-A(2)		A/A		BP 3BT0-A Equivalence	15*
Microlife BP 3BT0-AP		A/A		BP 3BT0-A Equivalence	14*
Microlife BP A100			Pass	BP A100 Plus Equivalence	10*



Self-measurement Devices					
Device	AAMI	BHS	ESH	Circumstance	Reference
Microlife BP A100 Plus			Pass	With "M-L Size" Cuff	16
			Pass	At rest	10
			Pass	At rest	17
Microlife Exact BP (BP3MD1-3)			Pass	BP A100 Equivalence M-L cuff	16
Microlife RM 100		A/A		BP 3BT0-A Equivalence	14*
Microlife WatchBP Home (BP3MX1-1)			Pass	At rest	18
	Pass	A/A		Pregnancy	19
	Pass	A/A		Pre-eclampsia	19
Microlife WatchBP Home A (BP3MX1-3)			Pass	Watch BP Home Equivalence	18,19*
				Accuracy in detecting Atrial Fibrillation	8,9
Microlife WatchBP Home N (BP3MX1-4)			Pass	Watch BP Home Equivalence	18,19*
Microlife WatchBP Home S (BP3MX1-5)			Pass	Watch BP Home Equivalence	18,19*
				Accuracy in detecting Atrial Fibrillation	8,9
Microlife WatchBP O3 (3MZ0)			Pass	At rest	2
Microlife WatchBP O3 (3MZ1)			Pass	At rest	3

Wrist Devices					
Device	AAMI	BHS	ESH	Circumstance	Reference
Microlife BP W100	Pass	A/A	Pass	Supine position	20
Microlife BP W200-1			Pass	MAM averaging and supine position	21

* Indicates that the same validation applies to the device because of equivalence



References

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