dabl® Educational Trust

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2006

A SIGNED COPY WILL BE POSTED ON THE www.dableducational.org WEBSITE

SECTION A - Please complete all items online.

I Ty-Minh Tan (Name of a Company Director) Director of Microlife AG (Company name)

hereby state that there are no differences that will affect blood pressure measuring accuracy between the

Microlife BP 3AC1-1 PC
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Microlife BP 3 AC1-1
Existing validated blood pressure measuring device

blood pressure measuring device, which has previously passed the BHS protocol, the results of which were published as follows

Topouchian JA, El Assad MA, Orobinskaia LV, El Feghali RN, Asmar RG
Authors(s)

Validation of two devices for self-measurement of brachial blood pressure according to the International Protocol of the European Society of Hypertension: the Seinex SE-9400 and the Microlife BP 3AC1-1
Title

Blood Pressure Monitoring, ISSN 1359-5237 (Publication) 2005, Vol 10 No 6 Page 325-331 (Year Volume Pages)

The only differences between the devices involve the following components:

(When a component is not relevant, both Yes and No should be left blank. Please provide details on any differences on the reverse of this form.)

Part I	1	Algorithm for Oscillometric Measurements	Yes ☐	No X
	2	Algorithm for Auscultatory Measurements	Yes ☐	No ☐
	3	Artefact/Error Detection	Yes ☐	No X
	4	Microphone(s)	Yes ☐	No ☐
	5	Pressure Transducer	Yes ☐	No X
	6	Cuff or Bladder	Yes ☐	No X
	7	Inflation Mechanism	Yes ☐	No X
	8	Deflation Mechanism	Yes ☐	No X
Part II	9	Model Name or Number	Yes X	No ☐
	10	Casing	Yes X	No ☐
	11	Display	Yes X	No ☐
	12	Carrying/Mounting Facilities	Yes ☐	No ☐
	13	Software other than Algorithm	Yes X	No ☐
	14	Memory Capacity/Number of stored measurements	Yes X	No ☐
	15	Printing Facilities	Yes ☐	No ☐
	16	Communication Facilities	Yes X	No ☐
	17	Power Supply	Yes ☐	No X
	18	Other Facilities	Yes X	No ☐

Further relevant details: 10) no Printer button, no Start button

11) indication for Pulse Arrhythmia, no 2 user indication

13) includes PAD technology (Pulse Arrhythmia Detection)

14) contains 99 Memory instead of 2x30

16) includes USB port instead of printer port

18) BP 3AC1-1 PC set includes PC link for data download and software on CD-ROM

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SECTION B - Complete all items, bar signatures and seal, online and print. Sign and seal it then send the original along with manuals for both devices to our address below.

Signature of Director _____

Name Ty-Minh Tan

Date July 7, 2006

Signature of Witness _____

Name Bernd Jaenecke

Address Microlife AG, Max-Schmidheiny-Strasse 201, CH-9435 Heerbrugg

Company Stamp/Seal

microlife
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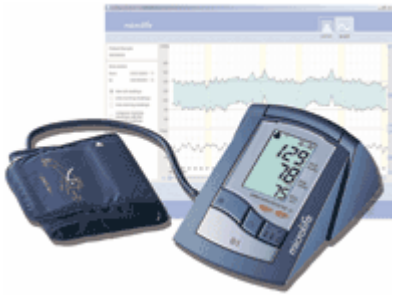
Comparison of the Microlife BP 3AC1-1 PC with the Microlife BP 3AC1-1

Devices	Microlife BP 3AC1-1 PC	Microlife BP 3AC1-1
Pictures		
Validation		BHS - A/A grading
Device 1 Criteria	PAD - Pulse Arrhythmia Detection *11, 13* Memory: 99 measurements *14* USB Port *16* PC Link *18*	
Same Criteria	MAM (average mode) or standard mode selection Oscillometric measuring method Cuffs: M (L as accessory) Optional mains adapter	MAM (average mode) or standard mode selection Oscillometric measuring method Cuffs: M (L as accessory) Optional mains adapter
Comparable Criteria	Error code (1, 2, 3, 5, 6, Hi & Lo)	Error code (1, 2, 3, 5 & 6)
Device 2 Criteria		Start and Printer Buttons *10* Current User *11* Memory: 2 x 30 measurements – 2 persons monitor *14* Printer Port *16*
Web link	http://mldata.ria.ch/detail.asp?Produkt_ID=1149&Sprach_ID=2	http://mldata.ria.ch/detail.asp?Produkt_ID=198&Sprach_ID=2

Comments	
Recommendation	Accept.