

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 Director of Microlife AG
Name of a Company Director 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
Author(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 2005, Vol 10 No 6 Page 325-331
Publication 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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	3	Artefact/Error Detection	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	4	Microphone(s)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	5	Pressure Transducer	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	6	Cuff or Bladder	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	7	Inflation Mechanism	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	8	Deflation Mechanism	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Part II	9	Model Name or Number	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	10	Casing	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	11	Display	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	12	Carrying/Mounting Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	13	Software other than Algorithm	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	14	Memory Capacity/Number of stored measurements	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	15	Printing Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	16	Communication Facilities	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	17	Power Supply	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	18	Other Facilities	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

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

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

Microlife



Max Schmidheiny-Strasse 201

9435 Heerbrugg / Switzerland

Phone +41 / 71 727 70 00

Fax +41 / 71 727 70 01

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 <i>11, 13</i> Memory: 99 measurements <i>14</i> USB Port <i>16</i> PC Link <i>18</i>	
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 <i>10</i> Current User <i>11</i> Memory: 2 x 30 measurements – 2 persons monitor <i>14</i> Printer Port <i>16</i>
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.	