

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 RM 100
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Microlife BP 3BTO-A
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

Cuckson AC, Reinders A, Shabeeh H, Shennan AH

Authors(s)

Validation of the Microlife BP 3BTO-A oscillometric blood pressure monitoring device according to a modified British Hypertension Society protocol

Title

Blood Pressure Monitoring, ISSN 1359-5237 2002, Vol 7 No 6 Page 319-324

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 type="checkbox"/>	No <input checked="" type="checkbox"/>
	15	Printing Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	17	Power Supply	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	18	Other Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Further relevant details: 10) different housing, different colour, additional buttons for Risk Factor input, Confirm Risk Factor, Time, MAM

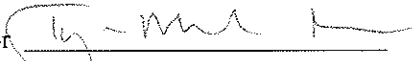
11) indication for risk settings, risk classes, memory, date/time, MAM

13) Includes MAM technology (Microlife Average Mode),

additional error code: ERR 6 (MAM relevant),

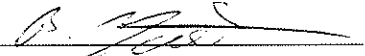
includes "Risk Factor Input" to pre-select 7 risk factors according to the WHO to categorize patients with high BP into 4 classes (see IB).

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 RM 100 with the Microlife BP 3BT0-A

Devices	Microlife RM 100	Microlife BP 3BT0-A
Pictures		
Validation	BHS - A/A grading	BHS - A/A grading, Gütesiegel/Quality Seal, German Design Award
Device 1 Criteria	Different case with extra buttons 10 Risk, Memory, Date/Time, MAM display 11 MAM (average mode) or standard mode selection 13 Risk factor classification. 13	
Same Criteria	Memory: 1 measurement (See comments) Oscillometric measuring method Cuffs: M (L as accessory) Optional mains adapter	Memory: 1 measurement Oscillometric measuring method 0 Cuffs: M (L as accessory) Optional mains adapter
Comparable Criteria	Error code (1, 2, 3, 5 & 6)	Error code (1, 2, 3 & 5)
Device 2 Criteria		
Web link	http://mldata.ria.ch/detail.asp?Produkt_ID=1100&Sprach_ID=2	http://mldata.ria.ch/detail.asp?Produkt_ID=156&Sprach_ID=2
Comments	<p>This unit has quite a few extras. Some extra memory is required for the averaging facility but blood pressures stored for this reason cannot be recalled. The declared single measurement storage is therefore correct.</p> <p><i>Only one measurement is stored for recall purposes. Quite separately, all measurements taken during the current day are stored. The average is stored elsewhere. Once the day changes, the list begins again and a new average is updated. Up to seven consecutive daily averages are stored. Data older than seven days are erased. The unit displays the average of the seven (or whatever available) daily averages.</i></p>	
Recommendation	Accept	