

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 Gerhard Frick 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 WatchBP home A (BP3MX1-3)
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Microlife WatchBP home (BP3MX1-1)
Existing validated blood pressure measuring device

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

George S. Stergiou, Periklis P. Giovas, Charilaos P. Gkinos, John D. Patouras
Authors(s)

Validation of the Microlife WatchBP Home device for self home blood pressure

measurement according to the International Protocol
Title

Blood Pressure Mon, ISSN 1359-5237 2007, Vol 12 No 3 Page 185-188
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 below.)

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

Brief explanations of differences and further relevant details: 9) Different model name. 11) Display also indicating Atrial Fibrillation (no effect on BP measurement) 13) Software also detecting and indicating Atrial Fibrillation.

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 Gerhard Frick

Date 28.10.09

Signature of Witness 

Name ChinChing Chang

Company Stamp/Seal

microlife

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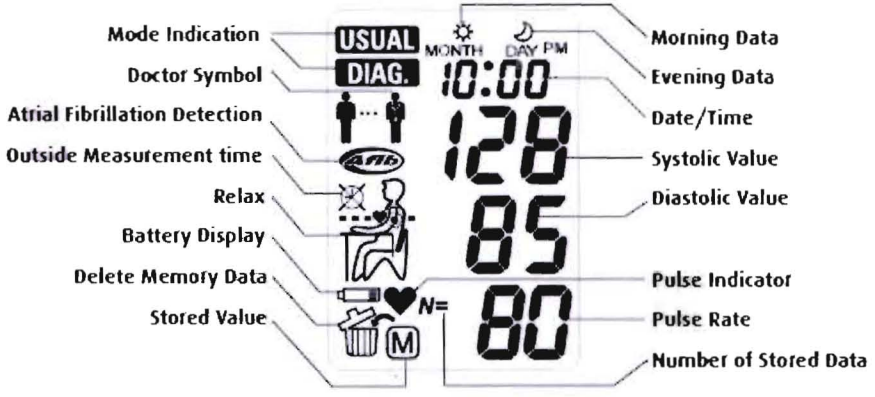
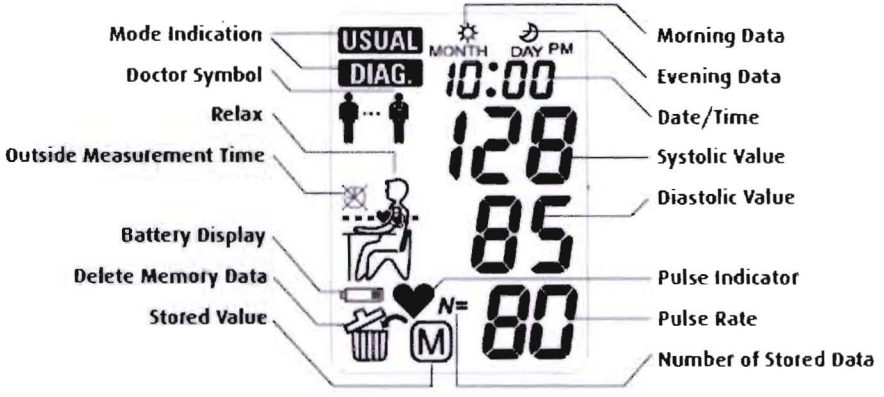


Address

9F, No 431, RuiGuang Rd. Taipei, Taiwan


Comparison of the Microlife WatchBP Home A (3MX1-3) and the WatchBP Home (3MX1-1)

Devices	Microlife WatchBP Home A (3MX1-3)	Microlife WatchBP Home (3MX1-1)
Pictures		
Validation		ESH validated
Same Criteria	Memory: 250 in USUAL mode; 28 in DIAG. mode Error code (1, 2, 3 & 5) Cuffs: M (L as accessory) Optional mains adapter One-touch operation Fuzzy logic	Memory: 250 in USUAL mode; 28 in DIAG. mode Error code (1, 2, 3 & 5) Cuffs: M (L as accessory) Optional mains adapter One-touch operation Fuzzy logic
Minor modification without changing the measurement algorithm	Different model name Display also indicating Atrial Fibrillation Software also detecting and indicating Atrial Fibrillation	

		
Comments	There are essentially minor modifications without changing the algorithm and accuracy of the device.	
Recommendation	Accept	

As provided by the manufacturer

Comparison of the **Microlife WatchBP Home A** with the **Microlife WatchBP Home**

Devices	Microlife WatchBP Home A (BP3MX1-3)	Microlife WatchBP Home (BP3MX1-1)
Pictures		
Validation		ESH
Device 1 Criteria	<p>Display/Symbols/Indicators</p> <p>Atrial fibrillation 11</p> <p>Algorithms</p> <p>Atrial fibrillation detection 13</p>	
Same Criteria	<p>Measurement</p> <p>Accuracy ± 3 mmHg 1, 5</p> <p>Oscillometric measurement method 1, 5</p> <p>BP 30 mmHg to 280 mmHg, Pulse 40-200 bpm 1, 5, 7, 8</p> <p>Cuff: (Arm circ. 22 to 32 cm) 6</p> <p>Optional large (AC 32-42 cm) cuffs 6</p> <p>Automatic Inflation and Deflation 7, 8</p> <p>Measurements are from single inflations (<i>Usual mode</i>) 13</p> <p>Two measurements recorded automatically (<i>Diag. mode</i>) 13, 14</p> <p>Memory: 250 measurements (<i>Usual mode</i>) 11, 14</p> <p>Memory: 28 measurements (7 × 2 × 2) (<i>Diagnostic mode</i>) 11, 14</p> <p>Buttons/Switches</p> <p>On/Off 10</p> <p>Memory 10</p> <p>Mode 10</p> <p>Display/Symbols/Indicators</p> <p>Measurement error 11</p> <p>Date and Time 11</p> <p>During Measurement: Heartbeat 11</p> <p>Memory 11</p> <p>Delete memory 11</p> <p>Morning/Evening mean 11, 13</p> <p>Low battery 11, 17</p>	<p>Measurement</p> <p>Accuracy ± 3 mmHg 1, 5</p> <p>Oscillometric measurement method 1, 5</p> <p>BP 30 mmHg to 280 mmHg, Pulse 40-200 bpm 1, 5, 7, 8</p> <p>Cuff: (Arm circ. 22 to 32 cm) 6</p> <p>Optional large (AC 32-42 cm) cuffs 6</p> <p>Automatic Inflation and Deflation 7, 8</p> <p>Measurements are from single inflations (<i>Usual mode</i>) 13</p> <p>Two measurements recorded automatically (<i>Diag. mode</i>) 13, 14</p> <p>Memory: 250 measurements (<i>Usual mode</i>) 11, 14</p> <p>Memory: 28 measurements (7 × 2 × 2) (<i>Diagnostic mode</i>) 11, 14</p> <p>Buttons/Switches</p> <p>On/Off 10</p> <p>Memory 10</p> <p>Mode 10</p> <p>Display/Symbols/Indicators</p> <p>Measurement error 11</p> <p>Date and Time 11</p> <p>During Measurement: Heartbeat 11</p> <p>Memory 11</p> <p>Delete memory 11</p> <p>Morning/Evening mean 11, 13</p> <p>Low battery 11, 17</p>

Devices (continued)	Microlife WatchBP Home A (BP3MX1-3)	Microlife WatchBP Home (BP3MX1-1)
	<p>Display/Symbols/Indicators (continued)</p> <p>Controlled measurement series complete (ESH Guidelines) 11, 13</p> <p>Controlled measurement times only (ESH Guidelines) (<i>Diag</i>) 11, 13</p> <p>Non-controlled measurements (<i>Usual</i>) 11</p> <p>Outside controlled measurement times (measurement lock) 11, 13</p> <p>Posture and arm position reminder 11</p> <p>Algorithms</p> <p>Morning/Evening mean 13</p> <p>All measurements mean 13</p> <p>ESH Guidelines mean 13</p> <p>Case</p> <p>Single screen display 10</p> <p>USB port, cable and PC software 16, 18</p> <p>Power: 4 "AA" batteries 17</p> <p>Power: Optional AC adapter 17</p>	<p>Display/Symbols/Indicators (continued)</p> <p>Controlled measurement series complete (ESH Guidelines) 11, 13</p> <p>Controlled measurement times only (ESH Guidelines) (<i>Diag</i>) 11, 13</p> <p>Non-controlled measurements (<i>Usual</i>) 11</p> <p>Outside controlled measurement times (measurement lock) 11, 13</p> <p>Posture and arm position reminder 11</p> <p>Algorithms</p> <p>Morning/Evening mean 13</p> <p>All measurements mean 13</p> <p>ESH Guidelines mean 13</p> <p>Case</p> <p>Single screen display 10</p> <p>USB port, cable and PC software 16, 18</p> <p>Power: 4 "AA" batteries 17</p> <p>Power: Optional AC adapter 17</p>
Comparable Criteria		
Device 2 Criteria		
Web link	http://www.watchbp.com/devices/home/overview/ http://www.microlife.com/products/hypertension/professional/watchbp-home/?L=en	

Comments	<p>The devices appear to be identical except for the addition of an AF detection algorithm and indicator in the Home A device.</p> <p>In the supplementary sheets, the manufacturers refer to "fuzzy logic" in both devices. This is not mentioned in either manual and is therefore extra information. It is assumed to refer to the method of detecting the pressure to which the device should inflate.</p>
Recommendation	Equivalence recommended
Date	14/12/2009