

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 S (BP3MX1-5)
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Microlife WatchBP Home (BP3MX1-1), Microlife WatchBP Office (for optional electr. valve)
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. Giovanas, 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

Blood Pressure Mon, ISSN 1359-5237 2007, Vol 12 No 3 Page 185-188
Title 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 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 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. 16) No USB.

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 [Signature]

Name Gerhard Frick

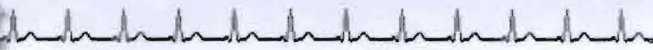
Date 28.10.09

Signature of Witness [Signature] 10/02/09



Name Chik Ching Chang

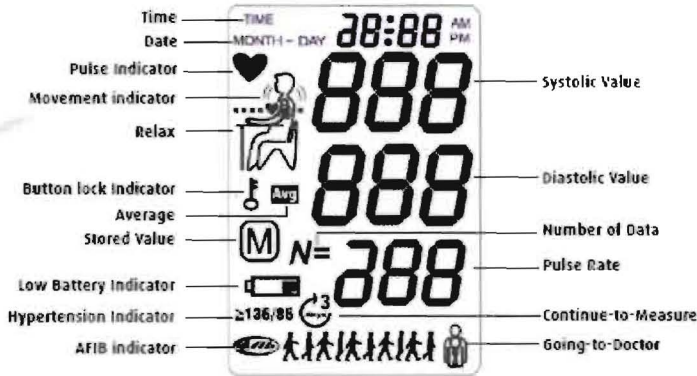
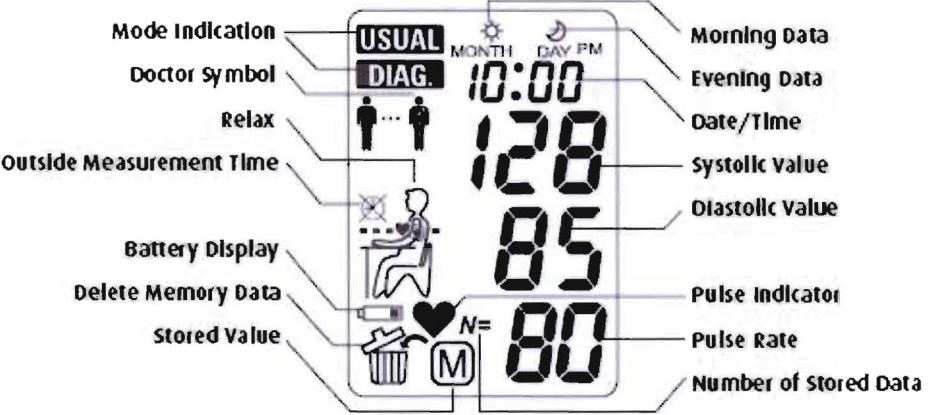
Company Stamp/Seal

Microlife AG
 Espenstrasse 139
 9443 Widnau / Switzerland
 Phone +41 / 71 727 70 30
 Fax +41 / 71 727 70 30




Comparison of Microlife WatchBP Home_S (BP3MX1-5) with Microlife WatchBP Home (BP3MX1-1)

Devices	Microlife WatchBP Home_S (BP3MX1-5)	Microlife WatchBP Home (BP3MX1-1)
Pictures		
Validation		ESH validated and DABL Listed
Same criteria	<ul style="list-style-type: none"> 1) Error code (1, 2, 3 & 5) 2) Cuffs: M (L as accessory) 3) Optional mains adapter 4) One-touch operation 5) Fuzzy logic 	<ul style="list-style-type: none"> 1) Error code (1, 2, 3 & 5) 2) Cuffs: M (L as accessory) 3) Optional mains adapter 4) One-touch operation 5) Fuzzy logic

<p>Minor modification without alternation to measurement algorithm</p>	<ol style="list-style-type: none"> 1) Different case 2) no mode for selection 3) Automatic 3 consecutive measurements after Start button is pressed 4) Memory size: 30 sets 5) Passive valve. Optional: Electronic valve (same as WatchBP Office and WatchBP O3 both Dabl listed.) 6) No USB connectivity 7) A switch to lock the button function to avoid accidental activation when carry (button locker). 8) Different LCD for improved user interface. 	<ol style="list-style-type: none"> 1) Different case 2) 2 measurement modes: DIAG. and USUAL model 3) Take 1 measurement after Start button is pressed. Automatically take 2 consecutive measurements after Start button is pressed in DIAG. mode. 4) Memory size of USUAL mode 250 memories; DIAG. mode: 28 memories. 5) Passive valve 6) USB connectivity with PC 7) No button locker 8) Different LCD display: 
<p>Web link</p>	<p>http://www.watchbp.com/devices/home/overview/</p>	
<p>Comments</p>	<p>There are essentially minor modifications without changing the algorithm and accuracy of the device. The optional electronic valve has been validated in two other models WatchBP Office and WatchBP O3 (both Dabl listed).</p>	

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

Devices	Microlife WatchBP Home s (BP3MX1-5)	Microlife WatchBP Home (BP3MX1-1)
Pictures		
Validation		ESH
Device 1 Criteria	<p>Buttons/Switches</p> <p>Button Lock 10</p> <p>Display/Symbols/Indicators</p> <p>Body movement error 3, 11, 13</p> <p>Hypertension 11, 13</p> <p>Atrial fibrillation 11</p> <p>Average 11</p> <p>Advised measurement series reminder (3-day cycle) 11, 13</p> <p>Visit doctor 11, 13</p> <p>Buttons Locked 11, 18</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>Buttons/Switches</p> <p>On/Off 10</p> <p>Memory 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>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>Buttons/Switches</p> <p>On/Off 10</p> <p>Memory 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>Low battery 11, 17</p>

Devices (continued)	Microlife WatchBP Home s (BP3MX1-5)	Microlife WatchBP Home (BP3MX1-1)
	<p>Display/Symbols/Indicators (continued) Posture and arm position reminder 11</p> <p>Case Single screen display 10 Power: 4 “AA” batteries 17 Power: Optional AC adapter 17</p>	<p>Display/Symbols/Indicators (continued) Posture and arm position reminder 11</p> <p>Case Single screen display 10 Power: 4 “AA” batteries 17 Power: Optional AC adapter 17</p>
Comparable Criteria	<p>Measurement Measurements are means from 3 inflations 13</p> <p>Memory: 30 measurements 11, 14</p>	<p>Measurement Measurements are from single inflations (<i>Usual mode</i>) 13 Two measurements recorded automatically (<i>Diag. mode</i>) 13, 14 Memory: 250 measurements (<i>Usual mode</i>) 11, 14 Memory: 28 measurements (7 × 2 × 2) (<i>Diagnostic mode</i>) 11, 14</p>
Device 2 Criteria		<p>Measurement Two measurements recorded automatically 13, 14</p> <p>Buttons/Switches Mode 10</p> <p>Display/Symbols/Indicators Delete memory 11 Morning/Evening mean 11, 13 Controlled measurement series complete (ESH Guidelines) 11, 13 Controlled measurement times only (ESH Guidelines) (<i>Diag</i>) 11, 13 Non-controlled measurements (<i>Usual</i>) 11 Outside controlled measurement times (measurement lock) 11, 13</p> <p>Algorithms Morning/Evening mean 13 All measurements mean 13 ESH Guidelines mean 13</p> <p>Case USB port, cable and PC software 16, 18</p>
Web link	<p style="text-align: right;">http://www.watchbp.com/devices/home/overview/ http://www.microlife.com/products/hypertension/professional/watchbp-home/?L=en</p>	

Devices (continued)	Microlife WatchBP Home s (BP3MX1-5)	Microlife WatchBP Home (BP3MX1-1)
Comments	<p>From a blood pressure perspective, the Home S device is a simpler device than the original Home device. Instead of the diagnostic mode which is intended to facilitate home measurement according to the ESH guidelines, it provides the simpler “mean of three measurements” facility. If an individual measurement is required, this must be terminated before the second measurement.</p> <p>The Home S device, however, provides an AF detection algorithm and indicator not available in the Home device.</p> <p>The Home device provides a USB port and software to load the values to a PC is provided. It can also store more measurements.</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> <p>These devices only differ in the sequencing of measurements offered, the resulting mean BPs, the provision of AF detection and in PC linking.</p>	
Recommendation	Equivalence recommended	
Date	14/12/2009	