

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 N (BP3MX1-4)
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

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Author(s)

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

measurement according to the International Protocol

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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.)

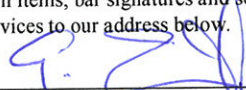
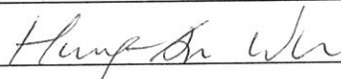
Part I	1	Algorithm for Oscillometric Measurements	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	3	Artefact/Error Detection	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	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 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:



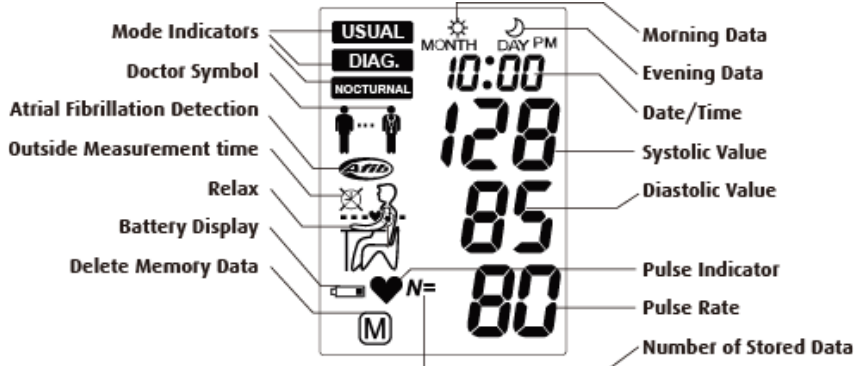
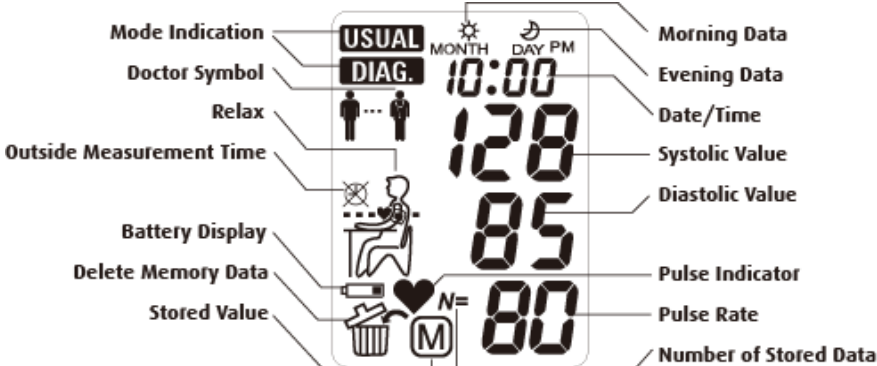
- 9) Model name has been changed from BP3MX1-1 to BP3MX1-4.
- 10) The mode switch has been changed from two modes (i.e. USUAL and DIAG.) to three modes (i.e. USUAL, DIAG. and NOCTURNAL).
 An extra button for medication records has been added to the casing.
 The casing has been minor modified; however, the color of the casing is the same.
- 11) Display indicates "NOCTURNAL" mode and Atrial Fibrillation. The icon of trash can is omitted.
 The changes do not effect the BP measurements.
- 13) Software also detecting and indicating Atrial Fibrillation.
- 14) 84 sets of memories in "Nocturnal" has been added; however, the memory capacities in "USUAL" mode and "DIAG." mode are the same .

15) The communication socket has been changes from USB to serial port.

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.



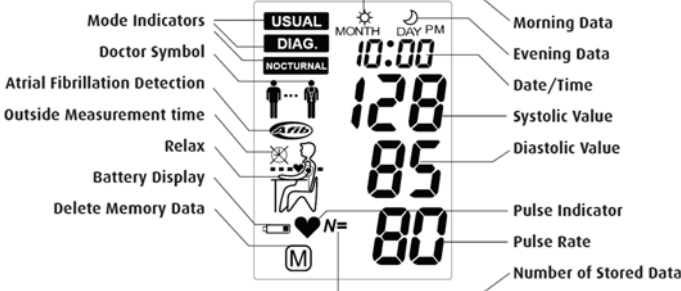
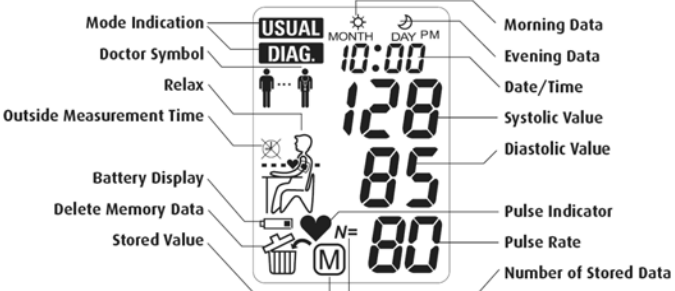
Signature of Director		Company Stamp/Seal
Name	<u>Gerhard Frick</u>	
Date	<u>13.1.2010</u>	
Signature of Witness		
Name	<u>Hung-An Wu</u>	
Address	_____	

Comparison of the Microlife WatchBP Home N (BP3MX1-4) and the WatchBP Home (BP3MX1-1)

Devices	Microlife WatchBP Home N (BP3MX1-4)	Microlife WatchBP Home (BP3MX1-1)
Images		
Validation		ESH validated
Device 1 Criteria	<p>“NOCTURNAL” mode has been added 10, 11, 13</p> <p>“Pill” button has been added 10, 11, 13</p> <p>Software detects and indicates Atrial Fibrillation 13</p> <p>Display also indicates Atrial Fibrillation 11</p> <p>84 sets of memory added in “NOCTURNAL” mode 14</p> <p>50 sets of memory added for “Pill” records 14</p> 	

Same Criteria	<p>Accuracy: ± 3 mmHg BP measurement: 30 mmHg to 280 mmHg Automatic inflation and deflation Single screen display During measurement: heart beat symbol Memory symbol Memory: 250 in USUAL mode; 28 in DIAG. mode Error code (1, 2, 3 & 5) Cuffs: M size (L as accessory) Power: 4 "AA" batteries. Power: optional mains adapter One-touch operation Fuzzy logic</p>	<p>Accuracy: ± 3 mmHg BP measurement: 30 mmHg to 280 mmHg Automatic inflation and deflation Single screen display During measurement: heart beat symbol Memory symbol Memory: 250 in USUAL mode; 28 in DIAG. mode Error code (1, 2, 3 & 5) Cuffs: M size (L as accessory) Power: 4 "AA" batteries. Power: optional mains adapter One-touch operation Fuzzy logic</p>
Comparable Criteria	<p>Pulse: 30 to 200 bpm Serial port</p>	<p>Pulse: 40 to 200 bpm USB port</p>
Web Link	http://www.watchbp.com/devices/homen/overview/	http://www.watchbp.com/devices/home/overview/
Comments	The blood pressure algorithms of both devices are identical. The extra features added in BP3MX1-4 are "NOCTURNAL" mode, medication records and Atrial Fibrillation detection function.	
Recommendation	Equivalence is recommended.	

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

Devices	Microlife WatchBP Home N (BP3MX1-4)	Microlife WatchBP Home (BP3MX1-1)
Pictures		
Display		
Validation		ESH
Device 1 Criteria	<p>Measurement</p> <p><i>Method</i></p> <p>Four measurements recorded hourly (<i>Nocturnal mode</i>) 13, 14</p> <p><i>Measurement Records</i></p> <p>Memory: 84 measurements (21 × 4) (<i>Nocturnal mode</i>) 11, 14</p> <p>Memory: 50 “medication taken” records 11, 14</p> <p>Buttons/Switches</p> <p><i>Event Marking</i></p> <p>Medication 10</p> <p>Display/Symbols/Indicators</p> <p><i>Post Measurement</i></p> <p>Atrial fibrillation 11, 13</p> <p>Algorithms</p> <p><i>Diagnostic</i></p> <p>Atrial fibrillation detection 13</p>	

Same Criteria	Measurement	Measurement
	<i>Accuracy</i>	<i>Accuracy</i>
	BP accuracy \pm 3 mmHg 1, 5	BP accuracy \pm 3 mmHg 1, 5
	Pulse accuracy \pm 5% 1, 5	Pulse accuracy \pm 5% 1, 5
	<i>Method</i>	<i>Method</i>
	Oscillometric measurement method 1, 5	Oscillometric measurement method 1, 5
	BP 30 mmHg - 280 mmHg 1, 5, 7, 8	BP 30 mmHg - 280 mmHg 1, 5, 7, 8
	Measurements are from single inflations (<i>Usual mode</i>) 13	Measurements are from single inflations (<i>Usual mode</i>) 13
	Two measurements recorded automatically (<i>Diag. mode</i>) 13, 14	Two measurements recorded automatically (<i>Diag. mode</i>) 13, 14
	<i>Inflation</i>	<i>Inflation</i>
	Inflation 0 mmHg - 299 mmHg 1, 5, 7	Inflation 0 mmHg - 299 mmHg 1, 5, 7
	Automatic Inflation 7	Automatic Inflation 7
	<i>Deflation</i>	<i>Deflation</i>
	Automatic Deflation 8	Automatic Deflation 8
	<i>Cuffs</i>	<i>Cuffs</i>
	Medium (Arm circ. 22 to 32 cm) 6	Medium (Arm circ. 22 to 32 cm) 6
	Large (Arm circ. 32-42 cm) (Optional) 6	Large (Arm circ. 32-42 cm) (Optional) 6
	<i>Measurement Records</i>	<i>Measurement Records</i>
	Memory: 250 measurements (<i>Usual mode</i>) 11, 14	Memory: 250 measurements (<i>Usual mode</i>) 11, 14
	Memory: 28 measurements ($7 \times 2 \times 2$) (<i>Diagnostic mode</i>) 11, 14	Memory: 28 measurements ($7 \times 2 \times 2$) (<i>Diagnostic mode</i>) 11, 14
	Buttons/Switches	Buttons/Switches
	<i>Power</i>	<i>Power</i>
	On/Off/Start 10	On/Off/Start 10
	<i>Measurement Records</i>	<i>Measurement Records</i>
	Memory 10	Memory 10
	Display/Symbols/Indicators	Display/Symbols/Indicators
	<i>Measurement Procedure</i>	<i>Measurement Procedure</i>
	Posture and arm position reminder 11	Posture and arm position reminder 11
	Heartbeat symbol during deflation 11	Heartbeat symbol during deflation 11
	Controlled measurement series complete (ESH Guidelines) 11, 13	Controlled measurement series complete (ESH Guidelines) 11, 13
	Controlled measurement times only (ESH Guidelines) (<i>Diag</i>) 11, 13	Controlled measurement times only (ESH Guidelines) (<i>Diag</i>) 11, 13
	Mode for controlled measurement times (ESH) (<i>Diagnostic</i>) 11	Mode for controlled measurement times (ESH) (<i>Diagnostic</i>) 11
	Mode for Free measurement times (<i>Usual</i>) 11	Mode for Free measurement times (<i>Usual</i>) 11
	Outside controlled measurement times (measurement lock) 11, 13	Outside controlled measurement times (measurement lock) 11, 13
	<i>Post Measurement</i>	<i>Post Measurement</i>
	SBP, DBP and Pulse 11	SBP, DBP and Pulse 11
	Measurement error (Er 1, Er 2, Er 3, Er 5, HI, LO) 11	Measurement error (Er 1, Er 2, Er 3, Er 5, HI, LO) 11
	Morning/Evening mean 11, 13	Morning/Evening mean 11, 13

Devices	Microlife WatchBP Home N (BP3MX1-4)	Microlife WatchBP Home (BP3MX1-1)
Same Criteria (continued)	<p>Display/Symbols/Indicators (continued) <i>Post Measurement (continued)</i> Visit doctor 11, 13</p> <p><i>Measurement Records</i> Memory, number of stored measurements 11</p> <p><i>Date and Time</i> Date and Time 11</p> <p><i>Power</i> Low battery 11, 17</p> <p>Algorithms <i>Averages</i> All measurements mean 13 Morning/Evening mean 13 ESH Guidelines mean 13</p> <p>Case <i>Display</i> Single screen display 10</p> <p><i>Power</i> 4 “AA” batteries 17 AC adapter (Optional) 17</p>	<p>Display/Symbols/Indicators (continued) <i>Post Measurement (continued)</i> Visit doctor 11, 13</p> <p><i>Measurement Records</i> Memory, number of stored measurements 11</p> <p><i>Date and Time</i> Date and Time 11</p> <p><i>Power</i> Low battery 11, 17</p> <p>Algorithms <i>Averages</i> All measurements mean 13 Morning/Evening mean 13 ESH Guidelines mean 13</p> <p>Case <i>Display</i> Single screen display 10</p> <p><i>Power</i> 4 “AA” batteries 17 AC adapter (Optional) 17</p>
Comparable Criteria	<p>Measurement <i>Method</i> Pulse 30 bpm -200 bpm 1, 5</p> <p>Buttons/Switches <i>Measurement Records</i> Mode (Usual, Diagnostic, Nocturnal) 10</p> <p>Display/Symbols/Indicators <i>Measurement Records</i> Delete memory (⌫ symbol) 11</p> <p>Case <i>Ports</i> Serial port, cable and PC software 16, 18</p>	<p>Measurement <i>Method</i> Pulse 40 bpm -200 bpm 1, 5</p> <p>Buttons/Switches <i>Measurement Records</i> Mode (Usual, Diagnostic) 10</p> <p>Display/Symbols/Indicators <i>Measurement Records</i> Delete memory (bin symbol) 11</p> <p>Case <i>Ports</i> USB port, cable and PC software 16, 18</p>
Device 2 Criteria		
Web link	http://www.watchbp.com/devices/homen/overview/	http://www.watchbp.com/devices/home/overview/ and http://www.microlife.com/products/hypertension/professional/watchbp-home/?L=en

Comments	<p>From a blood pressure perspective, the Home N device is the same as the original Home device with the addition of a “Nocturnal” mode, medication records and AF detection.</p> <p>Query 1 The manual does not provide information on how the nocturnal measurements or medication records are retrieved. The Medication button and feature is omitted from the declaration.</p> <p>Response 1 <i>Please find attached updated manual with the claimed information included now. We apology for submitting an incomplete manual before.</i></p> <p>Query 2 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>Response 2 <i>That is correct. Fuzzy logic is a method description for the automatic start pressure determination during inflation. This is common technology and not particularly mentioned in the user manual.</i></p> <p>Query 3 The pulse range that can be detected differs between the devices and this could be due to hardware and/or software changes. Please explain (30 bpm -200 bpm on the WatchBP Home N (BP3MX1-4), 40 bpm -200 bpm on the WatchBP Home (BP3MX1-1)) Please explain.</p> <p>Response 3 <i>Because in the Nocturnal Mode the pulse rate sometimes can be lower than 40, so we implemented HR measurement down to 30 bpm. The BP algorithm is not affected from this.</i></p> <p>Query 4 Regarding the lower pulse rate on the WatchBP Home N (BP3MX1-4), while we acknowledge that it is unlikely that rates below 40 bpm are ever likely to occur during a validation study, we would like to be reassured that the deflation rate of the device at these low pulse rates is low enough to ensure that the number of beats recorded is sufficient to generate the wave envelope required for the algorithm to determine both SBP and DBP. The deflation rate of the device normally is 5mmHg/s.</p> <p>Response 4 <i>When a pulse rate of < 40 bpm is detected, the measurement automatically restarts with a deflation rate of 3 mmHg/s which allows BP measurement at pulse rate lower than 40 bpm.</i></p> <p>Query 5 It is still unclear from the manual how to view the pill times. If one enters this mode as described, a new pill time will be recorded automatically. By inference, it appears that one should press the Medication button until the pill icon flashes but not until it beeps and then, perhaps, press the memory button to look at previous entries.</p> <p>Response 5 <i>The pill times can be viewed only in the pc-link program. We have revised the instruction booklet to make this clear.</i></p>
Recommendation	Equivalence is recommended
Date	22/04/2011