

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2006

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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 Office Target (BP3MD1-4)

Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

BPA100

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

Elisa Bonso, Francesca Dorigatti and Paolo Palatini

Authors(s)

Accuracy of the BP A100 blood pressure measuring device coupled with a single cuff with

standard-size bladder over a wide range of arm circumferences

Title

Blood Pressure Monitoring

Publication

2009 Oct;14(5):216-219

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 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"/>

Brief explanations of differences and further relevant details:

9. Model name has been changed from BPA100 to BP3MD1-4.

10. The color of the casing has been changed. An extra button and a switch have been added to the casing.

There are 3 buttons on the front panel, Target 140/90 (O/I), memory, Target 130/80 (O/I) from left to right.

A measurement can be activated by pressing either one of the O/I button, and the result will be compared to the corresponding target set by the button pressed at the end of each measurement.

The memory button can be pressed to look up the stored data.

The switch is for the options between single measurement and three consecutive measurements.

11. "Target 1" icon is add to indicate the measurment is being/has been done with 140/90 target.

"Target 2" icon is add to indicate the measurment is being/has been done with 130/80 target.

"OK" will display if the measurement result is lower than the target.


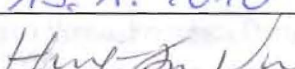
"PP" to indicate the pulse pressure.



"3" to indicate the measurement is being/has been done with 3 consecutive ones.
"Green backlight" will be on if the results of both Systolic/Diastolic pressures are lower than the target values.
"Red backlight" will be on if either or both results of Systolic/Diastolic pressures are higher than the target.
"M" icon indicates the display of stored data.



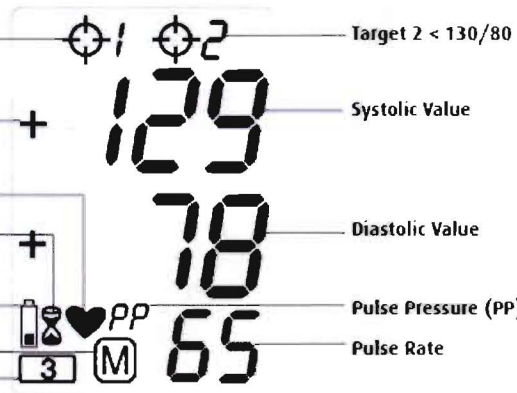
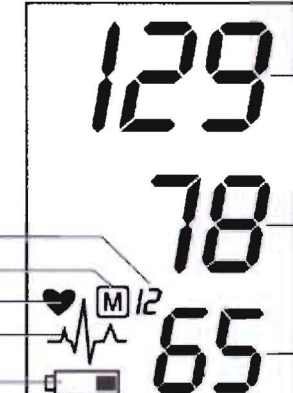
13. The core algorithm of measurement is 100% identical. The difference are the additional option of 3 consecutive measurement, the display of difference between results and targets, the colored backlight. However, the Micolife patented arrhythmia detector (PAD) is deleted from BPA100 for WatchBP Office Target.

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 Gerhard Frick
Date 13. 1. 2010
Signature of Witness 
Name Hung-An Wu
Address _____





Comparison of the Microlife WatchBP Office Target (BP3MD1-4) and the Microlife BPA100

Devices	Microlife WatchBP Office Target (BP3MD1-4)	Microlife BPA100
Imagess		
Validation		ESH validated
Device 1 Criteria	<p>Memory button 10</p> <p>Triple Mode (3 measurements averaged - switch,symbol) 10,11,13</p> <p>Hypertension indicator 11, 13</p> <p>BP above target 140/90 mmHg or 130/80 mmHg) display 11, 13</p> <p>Pulse pressure display 11, 13</p> <p>Display of individual readings from Triple Mode 11</p> <div style="display: flex; justify-content: space-around; align-items: flex-start;"> <div style="text-align: center;"> <p>Target 1 < 140/90</p> <p>Difference to Target Setting +</p> <p>Heart Beat</p> <p>Interval Time</p> <p>Battery Symbol</p> <p>Memory</p> <p>Triple Mode</p> </div> <div style="text-align: center;">  </div> <div style="text-align: center;"> <p>Target 2 < 130/80</p> <p>Systolic Value</p> <p>Diastolic Value</p> <p>Pulse Pressure (PP)</p> <p>Pulse Rate</p> </div> </div>	<div style="display: flex; justify-content: space-around; align-items: flex-start;"> <div style="text-align: center;"> <p>Systolic Value</p> <p>Diastolic Value</p> <p>Pulse Rate</p> </div> <div style="text-align: center;">  </div> <div style="text-align: center;"> <p>Memory Number</p> <p>Stored Value</p> <p>Heart Beat</p> <p>Heart Arrhythmia Indicator</p> <p>Battery Display</p> </div> </div>

Same Criteria	Accuracy ± 3 mmHg 1, 5 BP 30 mmHg to 280 mmHg, Pulse 40-200 bpm 1, 5, 7, 8 Automatic Inflation & Deflation 7, 8 Cuff Compartment 10 Single screen display 10 Memory symbol 11 During Measurement: Heartbeat Symbols, Audible Indicator 11, 13 Memory: 1 measurement 14 Power: 4 “AA” batteries 17 Power: Optional AC adapter 17	Accuracy ± 3 mmHg 1, 5 BP 30 mmHg to 280 mmHg, Pulse 40-200 bpm 1, 5, 7, 8 Automatic Inflation & Deflation 7, 8 Cuff Compartment 10 Single screen display 10 Memory symbol 11 During Measurement: Heartbeat Symbols, Audible Indicator 11, 13 Memory: 1 measurement 14 Power: 4 “AA” batteries 17 Power: Optional AC adapter 17
Comparable Criteria	Cuffs: S (17 to 22cm), M (22 to 32cm), L (32 to 42cm) 6 Two On/Off button (140/90 mmHg and 130/80 mmHg Targets) 10	Cuffs: M-L (22 to 42cm), S (17 to 22cm), M (22 to 32cm), L (32 to 42cm) 6 On/Off button 10
Device 2 Criteria		Arrhythmia detection
Web link		http://www.microlife.com/index.php?id=2486&pro_id=2
Comments	The blood pressure algorithms appear to be identical. The extra features in the BP3MD1-4 are as followings: 1. There is a warning signal if the blood pressure is above a target; 2.It is able to take and average three measurements. On the other hand, it does not have the arrhythmia detection which is a feature of the BPA100.	
Recommendation	Equivalence is recommended.	

Comparison of the Microlife WatchBP Office Target (BP3MD1-4) with the Microlife BP A100

Devices	Microlife WatchBP Office Target	Microlife BP A100
Pictures		
Display		
Validation		ESH
Device 1 Criteria	<p>Measurement</p> <p><i>Method</i></p> <p>Measurements are means from 3 inflations (Triple mode) 13</p> <p>Three measurements recorded automatically (Triple mode) 13, 14</p> <p><i>Memory</i></p> <p>Memory: 3 measurements (Triple mode) 14</p> <p>Buttons/Switches</p> <p><i>Power</i></p> <p>On/Off with 140/90 target 10</p> <p>On/Off with 130/80 target 10</p> <p><i>Measurement Record</i></p> <p>Memory 10</p> <p>Mode (Single, Triple) 10</p> <p>Display/Symbols/Indicators</p> <p><i>Measurement Procedure</i></p> <p>Target selection 11</p> <p>Multiple measurements (3) 11, 13</p> <p><i>Post Measurement</i></p> <p>PP 11</p> <p>Measurement-target difference if measurement > target 11, 13</p> <p>Measurement error (Err 6) 11</p> <p>Green and Red backlights 11, 13</p> <p><i>Other</i></p> <p>Hourglass (not described) 11</p> <p>Algorithms</p>	

	<i>Averages</i> 3 measurements mean 13 <i>Diagnostic</i> Self diagnosis (Select thresholds) 10, 11, 13	
Same Criteria	Measurement <i>Accuracy</i> Pulse accuracy \pm 5% 1, 5 <i>Method</i> Oscillometric measurement method 1, 5 BP 30 mmHg - 280 mmHg 1, 5, 7, 8 Pulse 40 bpm -200 bpm 1, 5 Measurements are from single inflations (Single mode) 13 <i>Inflation</i> Inflation 0 mmHg - 299 mmHg 1, 5, 7 Automatic Inflation 7 <i>Deflation</i> Automatic Deflation 8 <i>Cuffs</i> Medium cuff 152 mm \times 600 mm (Arm circ. 22 to 42 cm) 6 Large cuff (Arm circ. 32-42 cm) 6 <i>Memory</i> 1 measurement (Single mode) 14 Display/Symbols/Indicators <i>Measurement Procedure</i> Heartbeat symbol during deflation (not in manual) 11 Audible pulse indicator during deflation (not in manual) 18 <i>Post Measurement</i> SBP, DBP and Pulse 11 Measurement error (Err 1, Err 2, Err 3, Err 5, HI, LO) 11 <i>Memory</i> Memory 11 <i>Other</i> Low battery 11, 17 Case <i>Display</i> Single screen display 10 <i>Power</i> 4 “AA” batteries 17 AC adapter 17	Measurement <i>Accuracy</i> Pulse accuracy \pm 5% 1, 5 <i>Method</i> Oscillometric measurement method 1, 5 BP 30 mmHg - 280 mmHg 1, 5, 7, 8 Pulse 40 bpm -200 bpm 1, 5 Measurements are from single inflations 13 <i>Inflation</i> Inflation 0 mmHg - 299 mmHg 1, 5, 7 Automatic Inflation 7 <i>Deflation</i> Automatic Deflation 8 <i>Cuffs</i> Medium cuff (Arm circ. 22 to 32 cm) (Option 2) 6 Large cuff (Arm circ. 32-42 cm) (Option 2) 6 <i>Memory</i> 1 measurement 14 Display/Symbols/Indicators <i>Measurement Procedure</i> Heartbeat symbol during deflation 11 Audible pulse indicator during deflation 18 <i>Post Measurement</i> SBP, DBP and Pulse 11 Measurement error (Err 1, Err 2, Err 3, Err 5, HI, LO) 11 <i>Memory</i> Memory 11 <i>Other</i> Low battery 11, 17 Case <i>Display</i> Single screen display 10 <i>Power</i> 4 “AA” batteries 17 AC adapter (Optional) 17

	<i>Other</i> Cuff Compartment 10 Card Holder 10	<i>Other</i> Cuff Compartment 10 Card Holder 10
Comparable Criteria	Measurement <i>Accuracy</i> BP accuracy ± 3 mmHg or $\pm 2\% > 200$ mmHg 1, 5 Case <i>Power</i> AC adapter 17	Measurement <i>Accuracy</i> BP accuracy ± 3 mmHg 1, 5 Case <i>Power</i> AC adapter (Optional) 17
Device 2 Criteria		Measurement <i>Cuffs</i> M-L cuff 130 mm \times 240 mm (Arm circ. 22 to 42 cm) (Option 1) 6 Small cuff (Arm circ. 17-22 cm) (Option 2) 6 Buttons/Switches <i>Power</i> On/Off including Memory 10 Display/Symbols/Indicators <i>Post Measurement</i> Irregular heartbeat 11, 13 <i>Memory</i> Memory number (not described) 11 Algorithms <i>Other</i> Atrial fibrillation detection 13 Case <i>Power</i> Rechargeable batteries permitted 17
Web link	http://www.watchbp.com/fileadmin/pdf/brochures/DM_WatchBP%20Office%20Target.pdf	http://www.microlife.com/products/hypertension/automatic/bp-a100/

Comments	<p>The BP A100 comes with either the M-L cuff or three separate (small, medium and large) cuffs. Though claimed in the declaration to be supplied with the three separate cuffs, according to the manual, the BP 3MD1-4 comes with the medium and large cuffs only.</p> <p>The manual and the declaration state that the BP A100 only stores the last measurement but the website claims it has “30 memories”. It does have a memory number which on the screen the use of which is not described in the manual.</p> <p>The BP 3MD1-4 has an hourglass (interval time) symbol the use of which is not described in the manual. Neither does this manual refer to the</p>
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	<p>heartbeat symbol. The declaration states that, as with the BP A100 this is shown along with an audible beep during deflation.</p> <p>The manual for the BP 3MD1-4 includes a $\pm 2\%$ error margin for blood pressures over 200 mmHg that is not included in the BP A100 manual.</p> <p>The manual for the BP 3MD1-4 includes a reference to an optional “double mode” instead of the “triple mode” but it is not described further. It is not known whether this is a user selectable option chosen when purchasing the device.</p> <p>The additional Err 6 in the BP 3MD1-4 refers to too many errors during Triple mode.</p>
Recommendation	While clarification on some of the omissions in the manual and website discrepancies will be sought, none affect either the hardware or software for blood pressure detection. The differences between the devices are only in the extras offered. Therefore equivalence is recommended.
Date	04/03/2010