

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 Office Afib (TWIN200 AFS)

Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Microlife WatchBP Office (TWIN200)

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

Stergiou GS, Tzamouranis D, Protogerou A, Nasothimiou E, Kapralos C.

Authors(s)

Validation of the Microlife Watch BP Office professional device for office blood pressure

measurement according to the International protocol

Title

Blood Pressure Mon, ISSN 1359-5237

Publication

2008; Vol 13 No 5: Page 299-303

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 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 type="checkbox"/>

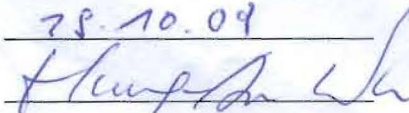
Brief explanations of differences and further relevant details: 9) Model Name has been changed to TWIN200 AFS. 10) Color of casing has been changed. 11) Display also indicating Atrial Fibrillation (no effect on BP measurement). 13) Software also detecting and indicating Atrial Fibrillation. 16) No communication feature.

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 Hung-An Wu

Company Stamp/Seal



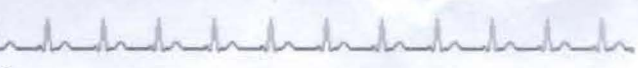
Microlife AG

Espenstrasse 139



9443 Widnau / Switzerland

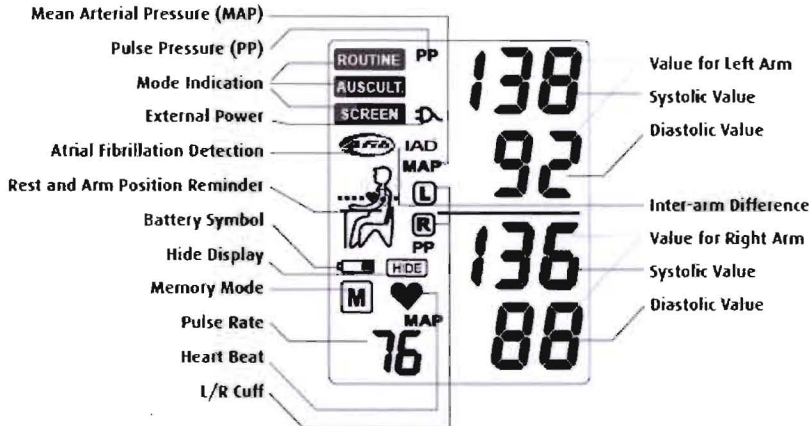
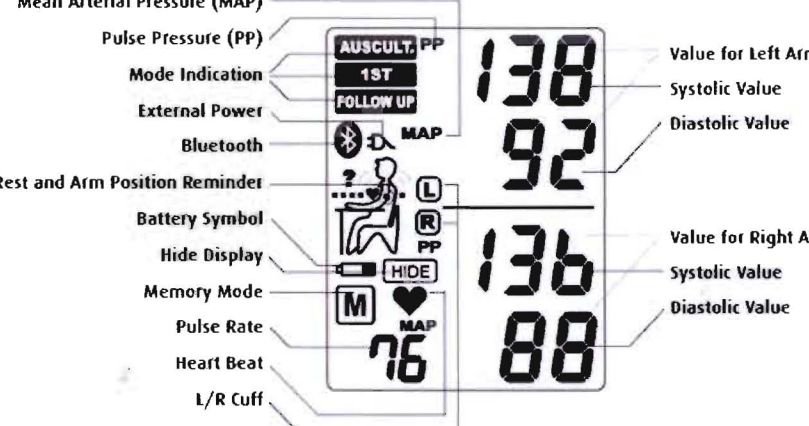
Phone +41 / 71 727 70 30

Fax +41 / 71 727 70 39




Comparison of the Microlife WatchBP Office (TWIN200 AFS) and the Microlife WatchBP Office (TWIN200)

Devices	Microlife WatchBP Office with Afib (TWIN200 AFS)	Microlife WatchBP Office (TWIN200)
<p>Pictures</p>		
<p>Validation</p>		<p>ESH Validated</p>
<p>Same Criteria</p>	<p>Algorithm for oscillometric measurements Memory: 1 set value automatically stored One-touch operation Deflation Rate: «AUSCULTATION» mode: 2.0-4.0 mmHg/sec. «Screen» and «Routine» mode: 2.0-6.9 mmHg/sec. Cuffs: 2 M size cuffs and 2 L size cuffs Error code (1, 2, 3 & 5) Power: rechargeable batteries, optional mains adapter Measurement accuracy: Pressure - within ± 3 mmHg or 2% of reading > 200 mmHg. Pulse - within $\pm 5\%$ of reading.</p>	<p>Algorithm for oscillometric measurements Memory: 1 set value automatically stored One-touch operation Deflation Rate: «AUSCULTATION» mode: 2.0-4.0 mmHg/sec. «1st Visit» and «Follow-up» mode: 2.0-6.9 mmHg/sec. Cuffs: 2 M size cuffs and 2 L size cuffs Error code (1, 2, 3 & 5) Power: rechargeable batteries, optional mains adapter Measurement accuracy: Pressure - within ± 3 mmHg or 2% of reading > 200 mmHg. Pulse - within $\pm 5\%$ of reading.</p>

<p>Minor modification without changing the measurement algorithm</p>	<ul style="list-style-type: none"> * Model name has been changed to TWIN200 AFS. * Color of casing has been changed. * Display also indicating Atrial Fibrillation. (there is no effect on blood pressure measurement)  <ul style="list-style-type: none"> * Software also detecting and indicating Atrial Fibrillation. * No communication feature. * Optional fuzzy logic inflation control. 	
<p>Comments</p>	<p>There are essentially minor modifications without changing the algorithm and the accuracy of the devices.</p>	
<p>Recommendation</p>	<p>Accept</p>	

Comparison of the **Microlife WatchBP Office AFIB (TWIN 200 AFS)** with the **Microlife WatchBP Office (TWIN 200)**

Devices	Microlife WatchBP Office AFIB (TWIN 200 AFS)	Microlife WatchBP Office (TWIN 200)
Pictures		
Validation		ESH
Device 1 Criteria	<p>Measurement</p> <p>Inflation: Fuzzy logic (optional) 7</p> <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. 22-32 cm × 2 and 32-42 cm × 2) 6</p> <p>Automatic Inflation and Deflation 7, 8</p> <p>Inflation: Manually adjustable inflation pressure 7</p> <p>BPs are means from 3 inflations, 2 cuffs (<i>Screen Mode</i>) 13</p> <p>Manual sphygmomanometer mode (<i>Auscultatory Mode</i>) 7, 8</p> <p>Memory: Individual readings from last series 11, 14</p> <p>Buttons/Switches</p> <p>On/Off 10</p> <p>Start/Stop 10</p> <p>Memory 10</p> <p>Mode 10</p> <p>Display/Symbols/Indicators</p> <p>Left and right arm pressures (<i>Screen Mode</i>) 11</p> <p>Arm with higher BP (<i>Screen Mode</i>) 11, 13</p> <p>MAP 11</p> <p>PP 11</p> <p>During Measurement: Heartbeat 11</p> <p>Memory 11</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. 22-32 cm × 2 and 32-42 cm × 2) 6</p> <p>Automatic Inflation and Deflation 7, 8</p> <p>Inflation: Manually adjustable inflation pressure 7</p> <p>BPs are means from 3 inflations, 2 cuffs (<i>1st Visit Mode</i>) 13</p> <p>Manual sphygmomanometer mode (<i>Auscultatory Mode</i>) 7, 8</p> <p>Memory: Individual readings from last series 11, 14</p> <p>Buttons/Switches</p> <p>On/Off 10</p> <p>Start/Stop 10</p> <p>Memory 10</p> <p>Mode 10</p> <p>Display/Symbols/Indicators</p> <p>Left and right arm pressures (<i>1st Visit Mode</i>) 11</p> <p>Arm with higher BP (<i>1st Visit Mode</i>) 11, 13</p> <p>MAP 11</p> <p>PP 11</p> <p>During Measurement: Heartbeat 11</p> <p>Memory 11</p>

Devices (continued)	Microlife WatchBP Office AFIB (TWIN 200 AFS)	Microlife WatchBP Office (TWIN 200)
	<p>Display/Symbols/Indicators (continued)</p> <p>Low battery 11, 17</p> <p>Posture and arm position reminder 11</p> <p>BP display hidden 11</p> <p>AC Power 11, 17</p> <p>Algorithms</p> <p>Last sequence of measurements mean 13</p> <p>Case</p> <p>Single screen display 10</p> <p>Power: Rechargeable battery pack 17</p> <p>Power: AC adapter 17</p>	<p>Display/Symbols/Indicators (continued)</p> <p>Low battery 11, 17</p> <p>Posture and arm position reminder 11</p> <p>BP display hidden 11</p> <p>AC Power 11, 17</p> <p>Algorithms</p> <p>Last sequence of measurements mean 13</p> <p>Case</p> <p>Single screen display 10</p> <p>Power: Rechargeable battery pack 17</p> <p>Power: AC adapter 17</p>
Comparable Criteria	<p>Measurement</p> <p>BPs are means from 2 inflations, 1 cuff (<i>Routine Mode</i>) 13</p> <p>Display/Symbols/Indicators</p> <p>Mode (<i>Auscultatory, Screen, Routine</i>) 11, 13, 14</p>	<p>Measurement</p> <p>BPs are means from 3 inflations, 1 cuff (<i>Follow-up Mode</i>) 13</p> <p>Display/Symbols/Indicators</p> <p>Mode (<i>Auscultatory, 1st Visit, Follow-up</i>) 11, 13, 14</p>
Device 2 Criteria		<p>Buttons/Switches</p> <p>Bluetooth 10</p> <p>Display/Symbols/Indicators</p> <p>Bluetooth connection 11, 16</p> <p>Other</p> <p>Bluetooth receiver and PC software 18</p>
Web link	<p align="right"> http://www.watchbp.com/devices/office/overview/ http://www.microlife.com/products/hypertension/professional/watchbp-office/?L=en </p>	

Comments	<p>Both devices contain the same hardware and BP detection algorithms. One, of the three modes, is presented slightly differently in the Office AFIB device. This device also contains an AF detection algorithm and an indicator. The original Office device contains Bluetooth interface facilities.</p> <p>Though average BPs are presented by default, the measured BPs can be viewed using the memory facility.</p>
Recommendation	Equivalence recommended
Date	14/12/2009