

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 Wan-Chin Liu 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
Novartis-Microlife ExactBP (BP3MD1-3)
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

Authors(s)
Prof. Paolo Palatini
Title
M-L Size Cuff used on BP A100 (with reference to the listing on dableducational.org)
Publication pending Year Volume Pages pending

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 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 explanation of differences and further relevant details:

9. Model names has been changed from BPA100 to BP3MD1-3
10. The colour 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 buttons, and its 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 cyclically. The switch is to allow the options between single measurement and three consecutive measurements.
11. "Target 1" icon is added to indicate the measurement is being/has been done with 140/90 target.
 "Target 2" icon is added to indicate the measurement is being/has been done with 130/80 target.

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“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 lid when both Dis/Sys pressure results are lower than the target.

“Red backlight” will lid when either or both Dis/Sys pressure results are higher than the target.

“M” icon indicates the display of stored data.

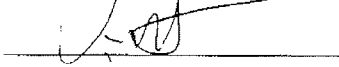
- The core algorithm of measurement is 100% identical. The difference are the additional option of 3 consecutive measurement, the display of difference between results and targets, the colored backlight, and additional memory entries up to 30 sets. However, the Microlife patented arrhythmia detector (PAD) is deleted from A100 for Novartis-Microlife ExactBP.
- There is an additional memory capacity of 30 sets for Novartis-Microlife ExactBP. The Memory Button allows switching through the stored readings. BPA100 provides memory of the last measurement only.

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 Wan-Chin Liu

Date 22.12.2008

Signature of Witness 

Name Vincent Chen

Address Microlife AG, Espenstrasse 139, CH-9443 Widnau, Switzerland

Company Stamp/Seal

microlife

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Comparison of the Novartis-Microlife ExactBP with the Microlife BPA100

Devices	Novartis/Microlife ExactBP (BP3MD1-3)	Microlife BPA100
Pictures		
Validation	ESH	
Device 1 Criteria	Memory button 10 Triple Mode (3 measurements averaged - switch, symbol) 10, 11, 13 Hypertension indicator 11, 13 BP above target 140/90 mmHg or 130/80 mmHg) display 11, 13 Pulse pressure display 11, 13 Display of individual readings from Triple Mode 11	
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 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 Power: 4 "AA" batteries 17 Power: Optional AC adapter 17
Comparable Criteria	Cuff: M-L (22 to 42) cm 6 Two On/Off buttons (140/90 mmHg and 130/80 mmHg Targets) 10 Memory: 30 measurements 11, 14	Cuffs: M-L (22 to 42) cm, S (17 to 22) cm, M (22 to 32) cm, L (32 to 42) cm 6 On/Off button 10 Memory: 1 measurement 11, 14
Device 2 Criteria		Arrhythmia detection 11, 13
Web link		http://www.microlife.com/index.php?id=2486&pro_id=2

Comments	<p>The blood pressure algorithms appear to be identical. Extra features in the ExactBP are a warning if the BP is above a target, the ability to take and average three measurements and the ability to store 30 measurements. On the other hand, it does not have the arrhythmia detection that is a feature of the BPA100.</p> <p>An original application was made on 18/12/2008. This had the following omissions</p> <ol style="list-style-type: none"> 1) On page 4 of the ExactBP manual, it states that there is a maximum memory capacity of 30 measurements and that these can be seen cyclically by pressing the memory button. On page 5 of the BPA100 manual, it simply states that the memory button can be used to view the last measurement. By inference, this appears to be the only measurement stored. In the declaration, it is stated that there is no difference between the memory capacities. 2) The BPA100 has an arrhythmia indicator. This is not present in the Exact BP. No mention of this is made in the declaration. <p>These were corrected satisfactorily on the resubmission on 22/12/2008.</p>
Recommendation	Equivalence is recommended.
Date	22/12/2008