

### DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2013

A SIGNED COPY WILL BE POSTED ON THE [www.dableducational.org](http://www.dableducational.org) WEBSITE

#### SECTION A - Please complete all items.

I **Gerhard Frick,** a 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

Maker<sup>a</sup> **ONBO** Address **497 Dalang South Road, Longhua, Shenzhen, Guangdong, China**  
 Manufacturer<sup>b</sup> **Microlife AG** Address **Espenstrasse 139, 9444 Widnau**  
 Brand<sup>c</sup> **Microlife** Model<sup>d</sup> **A6 PC / BP 3GU1-8Y**

Blood pressure measuring device for which validation is claimed. If alternative model names are used, include all.

blood pressure measuring device and the validated blood pressure measuring device

Maker<sup>a</sup> **ONBO** Address **497 Dalang South Road, Longhua, Shenzhen, Guangdong, China**  
 Manufacturer<sup>b</sup> **Microlife AG** Address **Espenstrasse 139, 9444 Widnau**  
 Brand<sup>c</sup> **Microlife** Model<sup>d</sup> **BP3BT0-A**

Existing validated blood pressure measuring device.

which has previously passed the BHS protocol, the results of which were published as follows:

Reinders A, Cuckson AC, Lee JTM, Shennan AH. An accurate automated blood pressure device for use in pregnancy and pre-eclampsia: the Microlife 3BT0-A. BJOG 2005;112(7):915-920

Refer to attached documents.

Full reference

The only differences between the devices involve the following components:

Tick one box for each item 1-18.

Part I	1	Algorithm for Oscillometric Measurements	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A <sup>e</sup> <input type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>f</sup> <input checked="" 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"/>	N/A <sup>f</sup> <input checked="" type="checkbox"/>
	5	Pressure Transducer	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	6	Cuffs or Bladders	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 checked="" 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 checked="" type="checkbox"/>	N/A <sup>g</sup> <input type="checkbox"/>
	16	Communication Facilities	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>g</sup> <input type="checkbox"/>
	17	Power Supply	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	18	Other Facilities	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>g</sup> <input type="checkbox"/>

**An explanation of each item ticked "Yes" must be included in Section B or on a separate sheet.**

- Notes:
- a Provide the name and address of the actual maker of the device.
  - b Provide the name and address of the legal manufacturer of the device, even if it is the same as that of the maker.
  - c Provide the name of the brand under which it is sold, even if it is the same as that of the manufacturer or maker.
  - d Provide the model name. If alternative or internal model names are used, include all. Each device must be uniquely identifiable.
  - e Only tick N/A (Not Applicable) if neither device measures blood pressure using the oscillometric method.
  - f Only tick N/A (Not Applicable) if neither device measures blood pressure using the auscultatory method.
  - g Only tick N/A (Not Applicable) if neither device provides printing, communication or other facilities, as appropriate.

**SECTION B** An explanation for each item, 1 to 18, ticked "Yes" in Section A must be provided here or in an attached document. All differences between the devices must be described.

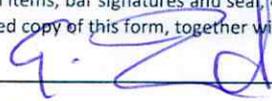
As attached file : A6PC Comparison items No 9, 10, 11, 13, 14, 16, 17, 18 are explained in the attached table.

**SECTION C** Please check that the following are included with the application

- A manual for the validated device
- A manual for the device for which equivalence is being sought
- An image of the validated device
- An image of the device for which equivalence is being sought
- An image of the screen layout of validated device\*
- An image of the screen layout of the device for which equivalence is being sought\*

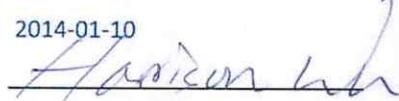
\* Screen layouts shown complete, and without obscuring labels or lines, in manuals need not be included separately.

**SECTION D** Complete all items, bar signatures and seal, online and print. Sign and seal it then send the original to our address below. Please email a signed copy of this form, together with the manuals and images for both devices, to [info@dableducational.org](mailto:info@dableducational.org).

Signature of Director  Company Stamp/Seal

Name Gerhard Frick

Date 2014-01-10

Signature of Witness 

Name Harrison Wu

Address 9F,NO.431,RuiGuang Road,Nei-Hu,  
Taipei,11492,Taiwan.R.O.C

**microlife**

Microlife AG  
Esenstrasse 139  
9443 Widnau / Switzerland  
Phone +41 / 71 727 70 30  
Fax +41 / 71 727 70 39

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2013

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Name of a Company Director Company name

hereby state that there are no differences that will affect blood pressure measuring accuracy between the

Maker<sup>a</sup> ONBO Address 497 Dalang South Road, Longhua, Shenzhen, Guangdong, China  
 Manufacturer<sup>b</sup> Microlife AG Address Espenstrasse 139, 9444 Widnau  
 Brand<sup>c</sup> Microlife Model<sup>d</sup> A6 PC / BP 3GU1-8Y  
Blood pressure measuring device for which validation is claimed. If alternative model names are used, include all.

blood pressure measuring device and the validated blood pressure measuring device

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 Manufacturer<sup>b</sup> Microlife AG Address Espenstrasse 139, 9444 Widnau  
 Brand<sup>c</sup> Microlife Model<sup>d</sup> BP A100 Plus  
Existing validated blood pressure measuring device.

which has previously passed the ESH protocol, the results of which were published as follows:

Elisa Bonso, Francesca Saladini, Ada Zanier, Elisabetta Benetti, Francesca Dorigatti and Paolo Palatini. Accuracy of a single rigid conical cuff with standard-size bladder coupled to an automatic oscillometric device.....

Refer to attached documents.

Full reference

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Tick one box for each item 1-18.

Part I	1	Algorithm for Oscillometric Measurements	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A <sup>e</sup> <input type="checkbox"/>
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Part II	9	Model Name or Number	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
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	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 checked="" type="checkbox"/>	N/A <sup>g</sup> <input type="checkbox"/>
	16	Communication Facilities	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>g</sup> <input type="checkbox"/>
	17	Power Supply	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	18	Other Facilities	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>g</sup> <input type="checkbox"/>

An explanation of each item ticked "Yes" must be included in Section B or on a separate sheet.

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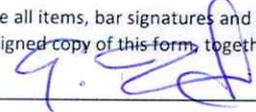
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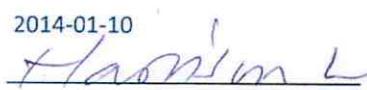
\* Screen layouts shown complete, and without obscuring labels or lines, in manuals need not be included separately.

**SECTION D** Complete all items, bar signatures and seal, online and print. Sign and seal it then send the original to our address below. Please email a signed copy of this form, together with the manuals and images for both devices, to [info@dablededucational.org](mailto:info@dablededucational.org).

Signature of Director  Company Stamp/Seal

Name Gerhard Frick

Date 2014-01-10

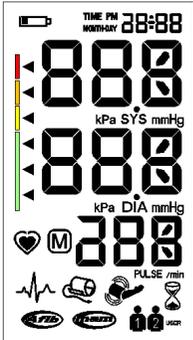
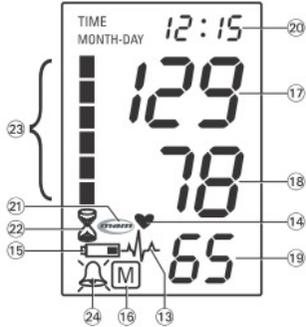
Signature of Witness 

Name Harrison Wu

Address 9F,NO.431,RuiGuang Road,Nei-Hu,  
Taipei,11492,Taiwan.R.O.C

  
Microlife AG  
Esenstrasse 139  
9443 Widnau / Switzerland  
Phone +41 / 71 727 70 30  
Fax +41 / 71 727 70 39

Comparison of the Microlife A6 PC (BP3GU1-8Y) with the Microlife BP3BT0-A and Microlife BP A100 Plus

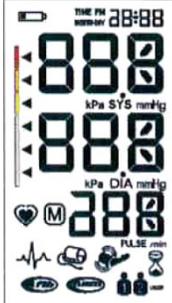
Devices	Microlife A6 PC (BP3GU1-8Y) 9	BP3BT0-A 9	Microlife BP A100 Plus 9
Image	 <p>10</p>	 <p>10</p>	 <p>10</p>
Validation		BHS	ESH
LCD Display	 <p>11</p>	 <p>11</p>	 <p>11</p>

<b>Device Criteria</b>	<b>Memory Capacity for stored values: 14</b> - 99 set - shown with symbol «M» and date and time - allows indicate all-memory average (see I/B)	<b>14</b> - 1 set - shown with symbol «M»	<b>14</b> - 200 set - shown with symbol «M» and date and time - no all-memory average
	<b>PC-Link Function: 13, 16</b> - via Microlife BP Analyser Software (PC) - CD + download - USB Interface (mini B5 connector)	<b>PC-Link Function: No 13, 16</b>	<b>PC-Link Function: No 13, 16</b>
	<b>Other Facilities: 18</b> <b>Display/Symbols/Indicators</b> - Cuff Check Indicator (symbol instead of Error, improved function) - Arm Movement Indicator (symbol instead of Error, improved function) - MAM Function (triplicate measurement): No - Pulse Arrhythmia Indicator (PAD): No - Atrial Fibrillation Indicator (AFIB): Yes	<b>18</b> <b>Display/Symbols/Indicators</b> - Error 3 (leakage) - Error 2 (artifact) - MAM Function (triplicate measurement): No - Pulse Arrhythmia Indicator (PAD): No - Atrial Fibrillation Indicator (AFIB): No	<b>18</b> <b>Display/Symbols/Indicators</b> - Error 3 (leakage) - Error 2 (artifact) - MAM Function (triplicate measurement): Yes - Pulse Arrhythmia Indicator (PAD): Yes indicates pulse irregularities during measurement which may affect the reading - Atrial Fibrillation Indicator (AFIB): No

	<p>- Pulse Beep during measurement: No (less disturbance for the patient)</p> <p>- Date and Time display: Yes (no alarm function)</p> <p><b>Cuff compartment: Yes</b> (accessory)</p> <p><b>Measurement range (blood pressure):</b> 20 – 280 mmHg</p> <p><b>Traffic Light Indication: Yes</b> (following ESH/JSH for HBPM)</p> <p><b>2 User Function: Yes</b> (switchable)</p>	<p>- Pulse Beep during measurement: Yes</p> <p>- Date and Time display: No</p> <p><b>Cuff compartment: No</b></p> <p><b>Measurement range (blood pressure):</b> 30 – 280 mmHg (no separate range for SBP and DBP specified)</p> <p><b>Traffic Light Indication: No</b></p> <p><b>2 User Function: No</b></p>	<p>- Pulse Beep during measurement: Yes</p> <p>- Date and Time display: Yes (2 alarm times i.e. for medication)</p> <p><b>Cuff compartment: Yes</b> (part of the casing)</p> <p><b>Measurement range (blood pressure):</b> 30 – 280 mmHg (no separate range for SBP and DBP specified)</p> <p><b>Traffic Light Indication: Yes</b> (following WHO 2003)</p> <p><b>2 User Function: No</b></p>
	<p><b>Power Supply:</b> <b>19</b> 4xAAA Batteries, Mains Adapter 6VDC Two level battery indicator</p>	<p><b>Power Supply:</b> <b>19</b> 4xAA Batteries, Mains Adapter 6VDC 1 level battery indicator</p>	<p><b>Power Supply:</b> <b>19</b> 4xAA Batteries, Mains Adapter 6VDC Two level battery indicator</p>

	<b>Cuffs:</b> <b>6</b> Microlife S-Cuff (17-22cm) Microlife M-Cuff (22-32cm)  Microlife M-L-Rigid Conical Cuff (22-42cm) <sup>4</sup>	<b>Cuffs:</b> <b>6</b>  Microlife AC-1-M-Cuff (22-32cm) <sup>1)</sup> Microlife AC-1-L-Cuff (32-42cm) <sup>1)</sup>	<b>Cuffs:</b> <b>6</b> Microlife S-Cuff (17-22cm) <sup>2)</sup> Microlife M-Cuff (22-32cm) <sup>2)</sup> Microlife L-Cuff (32-42cm) <sup>2)</sup> Microlife M-L-Cuff (22-42cm) <sup>3)</sup> Microlife M-L-Rigid Conical Cuff (22-42cm) <sup>4)</sup>
<b>Reference documents</b>	<p><sup>1)</sup> Reference dev. BP 3BTO-A – validated with standard Microlife AC-1-L-Cuff and AC-1-M-Cuff  <i>Cuckson AC, Reinders A, Shabeeh H, Shennan AH. Validation of the Microlife BP 3BTO-A oscillometric blood pressure monitoring device according to a modified British Hypertension Society protocol Blood Press Monit 2002;7(6):319-324</i></p> <p><sup>2)</sup> Reference dev. BP A100 Plus – validated with Microlife S-Cuff (17-22cm), M-Cuff (22-32cm) and L-Cuff (32-42cm)  <i>Stergiou GS, Giovas PP, Neofytou MS, Adamopoulos DN. Validation of the Microlife BP A 100 Plus device for self-home blood pressure measurement according to the International Protocol Blood Press Monit 2006;11:157-160</i></p> <p><sup>3)</sup> Reference dev. BP A100 Plus – validated with Microlife M-L-Cuff (22-42cm)  <i>Bonso E, Dorigatti F, Palatini P. 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. Blood Press Monit 2009;14:216-219</i></p> <p><sup>4)</sup> Reference dev. BP A100 Plus – validated with Microlife M-L-Cuff Rigid Conical Cuff (22-42cm)  <i>Elisa Bonso, Francesca Saladini, Ada Zanier, Elisabetta Benetti, Francesca Dorigatti and Paolo Palatini. Accuracy of a single rigid conical cuff with standard-size bladder coupled to an automatic oscillometric device over a wide range of arm circumferences. Hypertension Research (2010) 33, 1186–1191</i></p>		
<b>Web link</b>	<a href="http://www.microlife.com/products/hypertension/automatic/bp-a6-pc/">http://www.microlife.com/products/hypertension/automatic/bp-a6-pc/</a>	<a href="http://www.microlife.com/products/hypertension/automatic/bp-3bt0-a-2/">http://www.microlife.com/products/hypertension/automatic/bp-3bt0-a-2/</a>	<a href="http://www.microlife.com/products/hypertension/automatic/bp-a100-plus/">http://www.microlife.com/products/hypertension/automatic/bp-a100-plus/</a>

Comparison of the Microlife BP A6 PC (BP3GU1-8Y) with the Microlife BP 3BT0-A

Devices	Microlife BP A6 PC (BP3GU1-8Y)	Microlife BP 3BT0-A
Pictures		
Display		
Validation		BHS AAMI
Device 1 Criteria	<p><b>Measurement</b></p> <p><i>Method</i></p> <p>Optional repeated measurements (3) 13</p> <p><i>Inflation</i></p> <p>Press button if BP expected to be “very high” 7</p> <p><i>Cuffs</i></p> <p>L-XL (Arm circ. 32 cm to 52 cm) (Optional) <sup>Query 1</sup> 6</p> <p>M-L Rigid (Arm circ. 22 cm to 42 cm) <sup>Query 1</sup> 6</p> <p>Small (Arm circ. 17 cm to 22 cm) S-Cuff (Optional) <sup>Query 1</sup> 6</p> <p><b>Buttons/Switches</b></p> <p><i>Measurement Records</i></p> <p>Mode (Single, Triple) 10</p> <p>User ID 10</p>	

Devices	Microlife BP A6 PC (BP3GU1-8Y)	Microlife BP 3BT0-A	
<b>Device 1 Criteria (continued)</b>	<b>Buttons/Switches (continued)</b>		
	<i>Settings</i>		
	Backward	10	
	Button Lock	10	
	Date/Time set	10	
	Forward	10	
	<b>Display/Symbols/Indicators</b>		
	<i>Measurement Procedure</i>		
	Multiple measurements (3)	11, 13	
	Multiple measurements interval (hourglass)	11	
	<i>Post Measurement</i>		
	<b>Display/Symbols/Indicators</b>		
	Measurement error $E_{rr}$ 5	11	
	Hypertension (Indicator strip) <sup>Query 4</sup>	11, 13	
	Green, yellow and red backlights	11, 13, 18	
	Body movement error	3, 11, 13, 18	
	Atrial fibrillation (Triple measurement mode)	11, 13, 18	
	Air leak / Cuff connection error	11, 13, 18	
	<i>Measurement Records</i>		
	Memory recall number <sup>Query 4</sup>	11	
	User (1 or 2)	11	
	<i>Date and Time</i>		
	Date and Time	11	
	Date and Time (During memory recall) <sup>Query 5</sup>	11	
	<b>Algorithms</b>		
	<i>Averages and Differences</i>		
	All measurements mean <sup>Query 5</sup>	13	
	<i>Diagnostic</i>		
BP classification <sup>Query 4</sup>	13		
Atrial fibrillation detection	13		
Body movement error detection	3, 13		
<b>Casing</b>			
<i>Ports</i>			
USB port, cable and PC software	16, 18		
<i>Power</i>			
Rechargeable batteries permitted	17		

Devices	Microlife BP A6 PC (BP3GU1-8Y)	Microlife BP 3BT0-A
Same Criteria	<b>Measurement</b>	<b>Measurement</b>
	<i>Accuracy</i>	<i>Accuracy</i>
	BP accuracy $\pm 3$ mmHg	BP accuracy $\pm 3$ mmHg
	Pulse accuracy $\pm 5\%$	Pulse accuracy $\pm 5\%$
	<i>Method</i>	<i>Method</i>
	Oscillometric measurement method	Oscillometric measurement method
	BP 20 mmHg – 280 mmHg	BP 20 – 280 mmHg (In Manual 30– 280 mmHg) <sup>Query 2</sup>
	Pulse 40 bpm – 200 bpm	Pulse 40 bpm – 200 bpm
	Manually initiated measurements	Manually initiated measurements
	Measurements are from single inflations	Measurements are from single inflations
	<i>Inflation</i>	<i>Inflation</i>
	Inflation 0 mmHg – 299 mmHg	Inflation 0 mmHg – 299 mmHg
	Automatic Inflation	Automatic Inflation
	<i>Deflation</i>	<i>Deflation</i>
	Automatic Deflation	Automatic Deflation
	<i>Sensors</i>	<i>Sensors</i>
	Pressure sensor: capacitive <sup>Query 3</sup>	Pressure sensor: capacitive <sup>Query 3</sup>
	<b>Display/Symbols/Indicators</b>	<b>Display/Symbols/Indicators</b>
	<i>Measurement Procedure</i>	<i>Measurement Procedure</i>
	During Measurement: BP Level & Heartbeat	During Measurement: BP Level & Heartbeat
<i>Post Measurement</i>	<i>Post Measurement</i>	
SBP, DBP and Pulse	SBP, DBP and Pulse	
Measurement error <i>Err 1, Err 2, Err 3, Err 4, Err 5, H 1, Lo</i>	Measurement error <i>Err 1, Err 2, Err 3, Err 4, Err 5, H 1, Lo</i>	
<b>Casing</b>	<b>Casing</b>	
<i>Display</i>	<i>Display</i>	
Single screen display	Single screen display	
Segment LCD	Segment LCD	
<i>Power</i>	<i>Power</i>	
AC adapter (Optional)	AC adapter (Optional)	
Comparable Criteria	<b>Measurement</b>	<b>Measurement</b>
	<i>Cuffs</i>	<i>Cuffs</i>
	Medium (Arm circ. 22 to 32 cm) M-Cuff (Optional) <sup>Query 1</sup>	Medium (Arm circ. 22 to 32 cm) AC-1-M <sup>Query 1</sup>
<i>Measurement Records</i>	<i>Measurement Records</i>	
Memory: 99 measurements $\times$ 2 users	Memory: 1 measurement	

Devices	Microlife BP A6 PC (BP3GU1-8Y)	Microlife BP 3BT0-A
<b>Comparable Criteria (continued)</b>	<p><b>Buttons/Switches</b> <i>Power</i> On/Off with Start/Stop (Ⓜ symbol) 10</p> <p><i>Measurement Records</i> Memory 10</p> <p><b>Display/Symbols/Indicators</b> <i>Measurement Records</i> Memory “M” symbol <sup>Query 5</sup> 11</p> <p><i>Power</i> Low and flat battery 11, 17</p> <p><b>Casing</b> <i>Power</i> 4 “AAA” batteries 17 Automatic switch-off when not used for 1 min 17</p>	<p><b>Buttons/Switches</b> <i>Power</i> On/Off including Memory 10</p> <p><b>Display/Symbols/Indicators</b> <i>Measurement Records</i> Memory “MR” symbol 11</p> <p><i>Power</i> Low battery 11, 17</p> <p><b>Casing</b> <i>Power</i> 4 “AA” batteries 17 Automatic switch-off when not used for 5 min 17</p>
<b>Device 2 Criteria</b>		<p><b>Measurement</b> <i>Cuffs</i> Large (Arm circ. 32 cm to 42 cm) AC-1-L (Optional) <sup>Query 1</sup> 6</p> <p><b>Display/Symbols/Indicators</b> <i>Measurement Procedure</i> Audible pulse indicator during deflation 18</p> <p><i>Not described</i> Hourglass 11, 18</p>

Queries	1	Query	There appears to be no commonality between the cuffs supplied with the BP A6 PC and with the BP 3BT0-A. Yet item 6 in Part I of Section A (Cuffs or Bladders) in the Declarations of Equivalence for the comparison with the BP 3BT0-A is ticked as “No”. Please explain how the devices can be equivalent given they require different cuffs.																																																												
		Response	The AC-1-M-cuff and M-cuff are the same cuffs, but have different nylon enclosure and colour, and different artwork (printing) on the cuff. The bladder material and size is the same. The AC-1-L-cuff and L-cuff are the same cuffs, but have different nylon enclosure and colour, and different artwork (printing) on the cuff. The bladder material and size is the same.																																																												
Comment	There is no difference between the AC-1-M and M-Cuff cuffs and between the AC-1-L and L-Cuff cuffs. The BP A100 Plus, BP 2BT0-A and WatchBP Office ABI have each been validated separately with these cuffs <sup>1,2,5,7,8</sup> . Furthermore, the BP A100 Plus has been validated with both the M-L Soft cuff <sup>3</sup> and the M-L Rigid cuff <sup>4</sup> and the WatchBP Office ABI has been validated with the L-XL cuff <sup>6</sup> . Given also that the sensors are the same for all Microlife devices, it is reasonable to conclude that all the cuffs are interchangeable between all of the devices, including the BP A6 PC. The L-Cuff and M-L Soft cuff are not advertised as being available for the BP A6 PC.																																																														
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		Response	Apology for the inconsistent labelling. In fact, all devices have the same technology inside and are therefore identical in terms of measurement range. The new value is correct. 20 – 280 mmHg. It is not changed in Section B to remain consistent with the user manuals.																																																												
		Comment	This is clear.																																																												
	3	Query	What sensors are used in each device?																																																												
		Response	The same capacitive sensors, manufactured by Microlife, are used in all upper arm devices.																																																												
		Comment	This is clear.																																																												

4

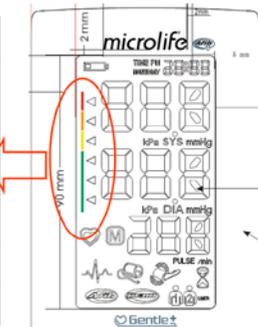
**Query** The BP A6 PC has an indicator strip to classify the level of blood pressure.

The manual for the BP A6 PC states that blood pressure should be evaluated according to international guidelines (ESH, AHA, JSH). It provides five classification levels, the top four of which correspond to a mix of these guidelines<sup>9-11</sup> rounded to the nearest 5 mmHg.

Please clarify the blood pressure levels at which the six markers on the BP A6 PC are displayed, as it is not obvious from the charts provided.

**Response** The markers are displayed as follows:

A6PC	SBP	DBP
Red	≥ 180	≥ 100
Orange	135 - 159	85 - 99
Yellow	130-134	80-84
Green	120-129	74-79
	110-119	67-73
	≤ 109	≤ 66



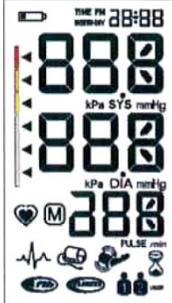
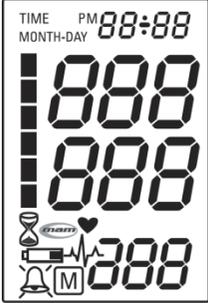
**Comment** The levels are clarified. The BP A6 PC levels do not correspond to levels described in the manuals nor to the published guidelines to which they refer. This is an observation and not an issue affecting equivalence.

	BP	Guidelines ESH <sup>9</sup> /JSH <sup>10</sup>	Guidelines AHA <sup>11</sup>	BP A6 PC Indicator
<b>SBP (mmHg)</b>	≥ 180	Grade 3	Stage 2	Red
	160-179	Grade 2		
	140-159	Grade 1	Stage 1	Orange
	135-139	High Normal	Pre-Hypertension	
	130-134			
	120-129	Normal	Normal	Green (Level 3)
	110-119	Optimal		Green (Level 2)
≤ 109	Green (Level 1)			
<b>DBP (mmHg)</b>	≥ 110	Grade 3	Stage 2	Red
	100-109	Grade 2		
	90-99	Grade 1	Stage 1	Orange
	85-89	High Normal	Pre-Hypertension	
	80-84			
	74-79	Optimal	Normal	Green (Level 3)
	67-73			Green (Level 2)
≤ 66	Green (Level 1)			

5	<p>Query On the BP A6 PC,</p> <ol style="list-style-type: none"> <li>a. What symbol is used, if any, to indicate that the average is shown?</li> <li>b. Is this the arithmetic mean, per user, of all of the stored measurements?</li> <li>c. When the user displays the stored measurements, which of the following distinguishes the measurements? <ol style="list-style-type: none"> <li>i. The date and time of the measurement only.</li> <li>ii. The measurement number only.</li> <li>iii. The date and time of the measurement and the measurement number.</li> </ol> </li> </ol> <p>Response</p> <ol style="list-style-type: none"> <li>a. The &lt;M&gt; symbol on the LCD indicates the average of all readings in the memory.</li> <li>b. Average means the arithmetic mean, per user, of all stored values.</li> <li>c. Date and time and measurement number distinguishes the measurements.</li> </ol> <p>Comment This is clear.</p>
References	<ol style="list-style-type: none"> <li>1. Stergiou GS, Giovas PP, Neofytou MS, Adamopoulos DN. Validation of the Microlife BP A100 Plus device for self-home blood pressure measurement according to the International Protocol. <i>Blood Press Monit.</i> 2006;<b>11</b>:157-60.</li> <li>2. Belghazi J, El Feghali RN, Moussalem T, Rejdych M, Asmar RG. Validation of four automatic devices for self-measurement of blood pressure according to the International Protocol of the European Society of Hypertension <i>Vascular Health and Risk Management</i> 2007;<b>3</b>(4):389-400</li> <li>3. Bonso E, Dorigatti F, Palatini P. 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. <i>Blood Press Monit</i> 2009;<b>14</b>:216-19</li> <li>4. Bonso E, Saladini F, Zanier A, Benetti E, Dorigatti F, Palatini P. Accuracy of a single rigid conical cuff with standard-size bladder coupled to an automatic oscillometric device over a wide range of arm circumferences. <i>Hypertens Res.</i> 2010;<b>33</b>(11):1186-91.</li> <li>5. Saladini F, Benetti E, Masiero S, Palatini P. Accuracy of Microlife WatchBP Office ABI monitor assessed according to the 2002 European Society of Hypertension protocol and the British Hypertension Society protocol. <i>Blood Press Monit</i> 2011;<b>16</b>(5):258-61</li> <li>6. Masiero S, Saladini F, Benetti E, Palatini P. Accuracy of the Microlife large-extra large-sized cuff (32-52 cm) coupled to an automatic oscillometric device. <i>Blood Press Monit.</i> 2011;<b>16</b>(2):99-102. doi: 10.1097/MBP.0b013e328344c73c.</li> <li>7. Cuckson AC, Reinders A, Shabeeh H, Shennan AH. Validation of the Microlife BP 3BTO-A oscillometric blood pressure monitoring device according to a modified British Hypertension Society protocol <i>Blood Press Monit.</i> 2002;<b>7</b>(6):319-324.</li> <li>8. Reinders A, Cuckson AC, Lee JTM, Shennan AH. An accurate automated blood pressure device for use in pregnancy and pre-eclampsia: the Microlife 3BTO-A. <i>BJOG</i> 2005;<b>112</b>(7):915-920.</li> <li>9. Mancia G, Fagard R, Narkiewicz K, Redon J, Zanchetti A, Böhm M et al. 2013 ESH/ESC guidelines for the management of arterial hypertension: the Task Force for the Management of Arterial Hypertension of the European Society of Hypertension (ESH) and of the European Society of Cardiology (ESC). <i>Eur Heart J.</i> 2013;<b>34</b>(28):2159-219. doi: 10.1093/eurheartj/eh151.</li> <li>10. Ogihara T, Kikuchi K, Matsuoka H, Fujita T, Higaki J, Horiuchi M et al; Japanese Society of Hypertension Committee. The Japanese Society of Hypertension Guidelines for the Management of Hypertension (JSH 2009) Chapter 2. Measurement and clinical evaluation of blood pressure. <i>Hypertens Res.</i> 2009;<b>32</b>(1):11-23 doi:10.1038/hr.2008.2.</li> </ol>

	11. Pickering TG, Hall JE, Appel LJ, Falkner BE, Graves J, Hill MN et al. Recommendations for blood pressure measurement in humans and experimental animals: part 1: blood pressure measurement in humans: a statement for professionals from the Subcommittee of Professional and Public Education of the American Heart Association Council on High Blood Pressure Research. <i>Circulation</i> . 2005; <b>111</b> (5):697-716.
<b>Recommendation</b>	Equivalence is Recommended
<b>Date</b>	7 <sup>th</sup> February 2014

Comparison of the Microlife BP A6 PC (BP3GU1-8Y) with the Microlife BP A100 Plus

Devices	Microlife BP A6 PC (BP3GU1-8Y)	Microlife BP A100 Plus
Pictures		
Display		
Validation		ESH-IP 2002
Device 1 Criteria	<p><b>Measurement</b></p> <p><i>Inflation</i></p> <p>Press button if BP expected to be “very high” 7</p> <p><i>Cuffs</i></p> <p>L-XL (Arm circ. 32 cm to 52 cm) (Optional) 6</p> <p><b>Buttons/Switches</b></p> <p><i>Measurement Records</i></p> <p>User ID 10</p> <p><i>Settings</i></p> <p>Backward 10</p> <p>Button Lock 10</p> <p>Forward 10</p> <p><b>Display/Symbols/Indicators</b></p> <p><i>Post Measurement</i></p> <p>Body movement error 3, 11, 13, 18</p>	

Devices	Microlife BP A6 PC (BP3GU1-8Y)	Microlife BP A100 Plus
<b>Device 1 Criteria (continued)</b>	<p><b>Display/Symbols/Indicators (continued)</b>  <i>Post Measurement (continued)</i>            Air leak / Cuff connection error 11, 13, 18  <i>Measurement Records</i>            User (1 or 2) 11</p> <p><b>Algorithms</b>  <i>Averages and Differences</i>            All measurements mean<sup>Query 5</sup> 13  <i>Diagnostic</i>            Body movement error detection 3, 13</p> <p><b>Casing</b>  <i>Ports</i>            USB port, cable and PC software 16, 18</p>	
<b>Same Criteria</b>	<p><b>Measurement</b>  <i>Accuracy</i>            BP accuracy ± 3 mmHg 1, 5            Pulse accuracy ± 5% 1, 5  <i>Method</i>            Oscillometric measurement method 1, 5            BP 20 mmHg – 280 mmHg 1, 5, 7, 8            Pulse 40 bpm – 200 bpm 1, 5, 8            Manually initiated measurements 13            Measurements are from single inflations 13            Optional repeated measurements (3) 13  <i>Inflation</i>            Inflation 0 mmHg – 299 mmHg 1, 5, 7            Automatic Inflation 7  <i>Deflation</i>            Automatic Deflation 8  <i>Cuffs</i>            M-L Rigid (Arm circ. 22 cm to 42 cm)<sup>Query 1</sup> 6            Medium (Arm circ. 22 to 32 cm) M-Cuff (Optional)<sup>Query 1</sup> 6            Small (Arm circ. 17 cm to 22 cm) S-Cuff (Optional)<sup>Query 1</sup> 6  <i>Sensors</i>            Pressure sensor: capacitive<sup>Query 3</sup> 5</p>	<p><b>Measurement</b>  <i>Accuracy</i>            BP accuracy ± 3 mmHg 1, 5            Pulse accuracy ± 5% 1, 5  <i>Method</i>            Oscillometric measurement method 1, 5            BP 20 – 280 mmHg (In Manual 30– 280 mmHg)<sup>Query 2</sup> 1, 5, 7, 8            Pulse 40 bpm – 200 bpm 1, 5, 8            Manually initiated measurements 13            Measurements are from single inflations 13            Optional repeated measurements (3) 13  <i>Inflation</i>            Inflation 0 mmHg – 299 mmHg 1, 5, 7            Automatic Inflation 7  <i>Deflation</i>            Automatic Deflation 8  <i>Cuffs</i>            M-L Rigid (Arm circ. 22 cm to 42 cm) (Optional)<sup>Query 1</sup> 6            Medium (Arm circ. 22 to 32 cm) M-Cuff<sup>Query 1</sup> 6            Small (Arm circ. 17 cm to 22 cm) S-Cuff (Optional)<sup>Query 1</sup> 6  <i>Sensors</i>            Pressure sensor: capacitive<sup>Query 3</sup> 5</p>

Devices	Microlife BP A6 PC (BP3GU1-8Y)	Microlife BP A100 Plus
<b>Same Criteria (continued)</b>	<p><b>Buttons/Switches</b></p> <p><i>Power</i></p> <p>On/Off with Start/Stop (Ⓢ symbol) 10</p> <p><i>Measurement Records</i></p> <p>Memory 10</p> <p>Mode (Single, Triple) 10</p> <p><i>Settings</i></p> <p>Date/Time set 10</p> <p><b>Display/Symbols/Indicators</b></p> <p><i>Measurement Procedure</i></p> <p>During Measurement: BP Level &amp; Heartbeat 11</p> <p>Multiple measurements (3) 11, 13</p> <p>Multiple measurements interval (hourglass) 11</p> <p><i>Post Measurement</i></p> <p>SBP, DBP and Pulse 11</p> <p>Measurement error <i>Err 1, Err 2, Err 3, Err 4, Err 5, Err 6, H i, Lo</i> 11</p> <p><i>Measurement Records</i></p> <p>Memory “M” symbol<sup>Query 5</sup> 11</p> <p>Memory recall number<sup>Query 5</sup> 11</p> <p><i>Date and Time</i></p> <p>Date and Time 11</p> <p>Date and Time (During memory recall)<sup>Query 5</sup> 11</p> <p><i>Power</i></p> <p>Low and flat battery 11, 17</p> <p><b>Casing</b></p> <p><i>Display</i></p> <p>Single screen display 10</p> <p>Segment LCD 10</p> <p><i>Power</i></p> <p>AC adapter (Optional) 17</p> <p>Automatic switch-off when not used for 1 min 17</p> <p>Rechargeable batteries permitted 17</p>	<p><b>Buttons/Switches</b></p> <p><i>Power</i></p> <p>On/Off with Start/Stop (Ⓢ symbol) 10</p> <p><i>Measurement Records</i></p> <p>Memory 10</p> <p>Mode (Single, Triple) 10</p> <p><i>Settings</i></p> <p>Date/Time set 10</p> <p><b>Display/Symbols/Indicators</b></p> <p><i>Measurement Procedure</i></p> <p>During Measurement: BP Level &amp; Heartbeat 11</p> <p>Multiple measurements (3) 11, 13</p> <p>Multiple measurements interval (hourglass) 11</p> <p><i>Post Measurement</i></p> <p>SBP, DBP and Pulse 11</p> <p>Measurement error <i>Err 1, Err 2, Err 3, Err 4, Err 5, Err 6, H i, Lo</i> 11</p> <p><i>Measurement Records</i></p> <p>Memory “M” symbol 11</p> <p>Memory recall number 11</p> <p><i>Date and Time</i></p> <p>Date and Time 11</p> <p>Date and Time (During memory recall) 11</p> <p><i>Power</i></p> <p>Low and flat battery 11, 17</p> <p><b>Casing</b></p> <p><i>Display</i></p> <p>Single screen display 10</p> <p>Segment LCD 10</p> <p><i>Power</i></p> <p>AC adapter (Optional) 17</p> <p>Automatic switch-off when not used for 1 min 17</p> <p>Rechargeable batteries permitted 17</p>
<b>Comparable Criteria</b>	<p><b>Measurement</b></p> <p><i>Measurement Records</i></p> <p>Memory: 99 measurements × 2 users 14</p>	<p><b>Measurement</b></p> <p><i>Measurement Records</i></p> <p>Memory: 200 measurements 14</p>

Devices	Microlife BP A6 PC (BP3GU1-8Y)	Microlife BP A100 Plus
<b>Comparable Criteria (continued)</b>	<p><b>Display/Symbols/Indicators</b></p> <p><i>Post Measurement</i></p> <p>Atrial fibrillation 11, 13, 18</p> <p>Hypertension (Indicator strip) <sup>Query 4</sup> 11, 13</p> <p><b>Algorithms</b></p> <p><i>Diagnostic</i></p> <p>BP classification <sup>Query 4</sup> 13</p> <p>Atrial fibrillation detection (Triple measurement mode) 13</p> <p><b>Casing</b></p> <p><i>Power</i></p> <p>4 “AAA” batteries 17</p>	<p><b>Display/Symbols/Indicators</b></p> <p><i>Post Measurement</i></p> <p>Irregular heartbeat 11, 13, 18</p> <p>Hypertension (Indicator strip) (WHO/ESH/JSH) <sup>Query 4</sup> 11, 13</p> <p><b>Algorithms</b></p> <p><i>Diagnostic</i></p> <p>BP classification (WHO/ESH/JSH) <sup>Query 4</sup> 13</p> <p>Irregular heartbeat detection 13</p> <p><b>Casing</b></p> <p><i>Power</i></p> <p>4 “AA” batteries 17</p>
<b>Device 2 Criteria</b>		<p><b>Measurement</b></p> <p><i>Cuffs</i></p> <p>M-L Soft (Arm circ. 22 cm to 42 cm) (Optional) <sup>Query 1</sup> 6</p> <p>Large (Arm circ. 32 cm to 42 cm) L-Cuff (Optional) <sup>Query 1</sup> 6</p> <p><b>Display/Symbols/Indicators</b></p> <p><i>Measurement Procedure</i></p> <p>Audible pulse indicator during deflation 18</p> <p><i>Post Measurement</i></p> <p>Green, yellow and red backlights 11, 13, 18</p> <p><i>Date and Time</i></p> <p>Alarm reminder (2 alarms/day) 18</p> <p><b>Casing</b></p> <p><i>Features</i></p> <p>Integrated cuff compartment 10</p> <p>Card Holder 10</p>

Queries	1	Query	Please clarify which cuffs were validated with the BP A100/BP A100 Plus and which cuffs match which description.																																																	
		Response	<p>Microlife does not use particular cuff codes, the cuffs are identified as “Microlife + cuff name”.</p> <p>The BP A100 Plus was validated with the Microlife S-Cuff (17-22 cm)<sup>1,2</sup>, M-Cuff (22-32 cm)<sup>1,2</sup>, L-Cuff (32-42 cm)<sup>1,2</sup>, M-L Soft Cuff (22-42 cm)<sup>3</sup> and M-L-Cuff Rigid Conical Cuff (22-42 cm)<sup>4</sup>. The Watch BP Office ABI was validated with the L-XL Cuff (32-52 cm)<sup>6</sup>.</p> <p>The BP A6 PC optionally comes with the validated Wide Range Conical Rigid Cuff (same as M-L rigid cuff, One-Size-Cuff). The Microlife L-XL Cuff, S-Cuff and M-Cuff are available as accessories.</p>																																																	
Comment	<p>The WatchBP Office ABI was also validated with the M-Cuff and L-Cuff<sup>5</sup>. Given also that the sensors are the same for all Microlife devices, it is reasonable to conclude that all the cuffs are interchangeable between all of the devices, including the BP A6 PC. The L-Cuff and M-L Soft cuff are not advertised as being available for the BP A6 PC.</p>																																																			
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	2	Query	According to each of the respective manuals, the measurement ranges are 20 mmHg to 280 mmHg for the BP A6 PC but 30 mmHg to 280 mmHg for the BP A100 Plus. Please explain the inconsistency and anomaly.																																																	
		Response	Apology for the inconsistent labelling. In fact, all devices have the same technology inside and are therefore identical in terms of measurement range. The new value is correct. 20 – 280 mmHg. It is not changed in Section B to remain consistent with the user manuals.																																																	
		Comment	This is clear.																																																	
	3	Query	What sensors are used in each device?																																																	
		Response	The same capacitive sensors, manufactured by Microlife, are used in all upper arm devices.																																																	
		Comment	This is clear.																																																	

4

**Query** The BP A100 Plus and BP A6 PC each have an indicator strip to classify the level of blood pressure.

The manual for the BP A100 Plus states that blood pressure should be evaluated according to the WHO 2003 guidelines<sup>7</sup>. It provides seven classification levels, the top three of which correspond to the WHO guidelines<sup>10</sup> and the top six of which correspond to the WHO 1999<sup>8</sup>/ESH<sup>9</sup>/JSH<sup>10</sup> guidelines, except for a rounding, to the nearest 5 mmHg, of the upper ranges. These top six correspond to the six markers on the indicator strip.

The manual for the BP A6 PC states that blood pressure should be evaluated according to international guidelines (ESH, AHA, JSH). It provides five classification levels, the top four of which correspond to a mix of these guidelines<sup>9-11</sup> rounded to the nearest 5 mmHg.

Please clarify the blood pressure levels at which the six markers on the BP A6 PC are displayed, as it is not obvious from the charts provided.

**Response** The markers are displayed as follows:

**BP A6 PC**

A6PC	SBP	DBP
Red	≥ 160	≥ 100
Orange	135 - 159	85 - 99
Yellow	130-134	80-84
Green	120-129	74-79
	110-119	67-73
	≤ 109	≤ 66

**BP A100 Plus**

<p>4 ctd.</p>	<p><b>Comment</b> The levels are clarified. The BP A6 PC levels do not correspond to levels described in the manuals nor to the published guidelines to which they refer. This is an observation and not an issue affecting equivalence.</p> <table border="1" data-bbox="725 248 1830 834"> <thead> <tr> <th colspan="2"></th> <th colspan="2">Guidelines</th> <th>BP A6 PC</th> <th colspan="2">BP A100 Plus</th> </tr> <tr> <th colspan="2">BP</th> <th>WHO<sup>8</sup>/ESH<sup>9</sup>/JSH<sup>10</sup></th> <th>AHA<sup>11</sup></th> <th>Indicator</th> <th>Indicator</th> <th>Backlight</th> </tr> </thead> <tbody> <tr> <td rowspan="8"><b>SBP (mmHg)</b></td> <td>≥ 180</td> <td>Grade 3</td> <td rowspan="2">Stage 2</td> <td rowspan="2">Red</td> <td>Maroon</td> <td rowspan="3">Red</td> </tr> <tr> <td>160-179</td> <td>Grade 2</td> <td>Red</td> </tr> <tr> <td>140-159</td> <td>Grade 1</td> <td>Stage 1</td> <td>Orange</td> <td>Orange</td> </tr> <tr> <td>135-139</td> <td rowspan="2">High Normal</td> <td rowspan="3">Pre-Hypertension</td> <td rowspan="2">Yellow</td> <td rowspan="2">Yellow</td> <td rowspan="2">Yellow</td> </tr> <tr> <td>130-134</td> </tr> <tr> <td>120-129</td> <td>Normal</td> <td>Green (Level 3)</td> <td>Dark Green</td> </tr> <tr> <td>110-119</td> <td rowspan="2">Optimal</td> <td rowspan="2">Normal</td> <td rowspan="2">Green (Level 2)</td> <td rowspan="2">Light Green</td> <td rowspan="2">Green</td> </tr> <tr> <td>≤ 109</td> <td>Green (Level 1)</td> </tr> <tr> <td rowspan="8"><b>DBP (mmHg)</b></td> <td>≥ 110</td> <td>Grade 3</td> <td rowspan="2">Stage 2</td> <td rowspan="2">Red</td> <td>Maroon</td> <td rowspan="3">Red</td> </tr> <tr> <td>100-109</td> <td>Grade 2</td> <td>Red</td> </tr> <tr> <td>90-99</td> <td>Grade 1</td> <td>Stage 1</td> <td>Orange</td> <td>Orange</td> </tr> <tr> <td>85-89</td> <td>High Normal</td> <td rowspan="2">Pre-Hypertension</td> <td rowspan="2">Yellow</td> <td rowspan="2">Dark Green</td> <td rowspan="2">Yellow</td> </tr> <tr> <td>80-84</td> <td>Normal</td> </tr> <tr> <td>74-79</td> <td rowspan="3">Optimal</td> <td rowspan="3">Normal</td> <td rowspan="3">Green (Level 3)</td> <td rowspan="3">Light Green</td> <td rowspan="3">Green</td> </tr> <tr> <td>67-73</td> </tr> <tr> <td>≤ 66</td> <td>Green (Level 2)</td> </tr> <tr> <td></td> <td></td> <td></td> <td>Green (Level 1)</td> <td></td> <td></td> </tr> </tbody> </table>			Guidelines		BP A6 PC	BP A100 Plus		BP		WHO <sup>8</sup> /ESH <sup>9</sup> /JSH <sup>10</sup>	AHA <sup>11</sup>	Indicator	Indicator	Backlight	<b>SBP (mmHg)</b>	≥ 180	Grade 3	Stage 2	Red	Maroon	Red	160-179	Grade 2	Red	140-159	Grade 1	Stage 1	Orange	Orange	135-139	High Normal	Pre-Hypertension	Yellow	Yellow	Yellow	130-134	120-129	Normal	Green (Level 3)	Dark Green	110-119	Optimal	Normal	Green (Level 2)	Light Green	Green	≤ 109	Green (Level 1)	<b>DBP (mmHg)</b>	≥ 110	Grade 3	Stage 2	Red	Maroon	Red	100-109	Grade 2	Red	90-99	Grade 1	Stage 1	Orange	Orange	85-89	High Normal	Pre-Hypertension	Yellow	Dark Green	Yellow	80-84	Normal	74-79	Optimal	Normal	Green (Level 3)	Light Green	Green	67-73	≤ 66	Green (Level 2)				Green (Level 1)		
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<p>5</p>	<p><b>Query</b> On the BP A6 PC,</p> <ol style="list-style-type: none"> <li>What symbol is used, if any, to indicate that the average is shown?</li> <li>Is this the arithmetic mean of all of the stored measurements?</li> <li>When the user displays the stored measurements, which of the following distinguishes the measurements?             <ol style="list-style-type: none"> <li>The date and time of the measurement only.</li> <li>The measurement number only.</li> <li>The date and time of the measurement and the measurement number.</li> </ol> </li> </ol> <p><b>Response</b></p> <ol style="list-style-type: none"> <li>The &lt;M&gt; symbol on the LCD indicates the average of all readings in the memory.</li> <li>Average means the arithmetic mean of all stored values.</li> <li>Date and time and measurement number distinguishes the measurements.</li> </ol> <p><b>Comment</b> This is clear.</p>																																																																																						

<b>References</b>	<ol style="list-style-type: none"> <li>1. Stergiou GS, Giovas PP, Neofytou MS, Adamopoulos DN. Validation of the Microlife BP A100 Plus device for self-home blood pressure measurement according to the International Protocol. <i>Blood Press Monit.</i> 2006;<b>11</b>:157-60.</li> <li>2. Belghazi J, El Feghali RN, Moussalem T, Rejdych M, Asmar RG. Validation of four automatic devices for self-measurement of blood pressure according to the International Protocol of the European Society of Hypertension <i>Vascular Health and Risk Management</i> 2007;<b>3</b>(4):389-400</li> <li>3. Bonso E, Dorigatti F, Palatini P. 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. <i>Blood Press Monit</i> 2009;<b>14</b>:216-19</li> <li>4. Bonso E, Saladini F, Zanier A, Benetti E, Dorigatti F, Palatini P. Accuracy of a single rigid conical cuff with standard-size bladder coupled to an automatic oscillometric device over a wide range of arm circumferences. <i>Hypertens Res.</i> 2010;<b>33</b>(11):1186-91.</li> <li>5. Saladini F, Benetti E, Masiero S, Palatini P. Accuracy of Microlife WatchBP Office ABI monitor assessed according to the 2002 European Society of Hypertension protocol and the British Hypertension Society protocol. <i>Blood Press Monit</i> 2011;<b>16</b>(5):258-61</li> <li>6. Masiero S, Saladini F, Benetti E, Palatini P. Accuracy of the Microlife large-extra large-sized cuff (32-52 cm) coupled to an automatic oscillometric device. <i>Blood Press Monit.</i> 2011;<b>16</b>(2):99-102. doi: 10.1097/MBP.0b013e328344c73c.</li> <li>7. Whitworth JA; World Health Organization, International Society of Hypertension Writing Group. 2003 World Health Organization (WHO)/International Society of Hypertension (ISH) statement on management of hypertension. <i>J Hypertens.</i> 2003;<b>21</b>(11):1983-92.</li> <li>8. Chalmers J et al. WHO-ISH Hypertension Guidelines Committee. 1999 World Health Organization - International Society of Hypertension Guidelines for the Management of Hypertension. <i>J Hypertens</i> 1999;<b>17</b>:151-85.</li> <li>9. Mancia G, Fagard R, Narkiewicz K, Redon J, Zanchetti A, Böhm M et al. 2013 ESH/ESC guidelines for the management of arterial hypertension: the Task Force for the Management of Arterial Hypertension of the European Society of Hypertension (ESH) and of the European Society of Cardiology (ESC). <i>Eur Heart J.</i> 2013;<b>34</b>(28):2159-219. doi: 10.1093/eurheartj/eh151.</li> <li>10. Ogihara T, Kikuchi K, Matsuoka H, Fujita T, Higaki J, Horiuchi M et al; Japanese Society of Hypertension Committee. The Japanese Society of Hypertension Guidelines for the Management of Hypertension (JSH 2009) Chapter 2. Measurement and clinical evaluation of blood pressure. <i>Hypertens Res.</i> 2009;<b>32</b>(1):11-23 doi:10.1038/hr.2008.2.</li> <li>11. Pickering TG, Hall JE, Appel LJ, Falkner BE, Graves J, Hill MN et al. Recommendations for blood pressure measurement in humans and experimental animals: part 1: blood pressure measurement in humans: a statement for professionals from the Subcommittee of Professional and Public Education of the American Heart Association Council on High Blood Pressure Research. <i>Circulation.</i> 2005;<b>111</b>(5):697-716.</li> </ol>
<b>Recommendation</b>	Equivalence is Recommended
<b>Date</b>	7 <sup>th</sup> February 2014