dabl® Educational Trust — Declaration of Equivalence Form

Declaration of Blood Pressure Measuring Device Equivalence 2013

A SIGNED COPY WILL BE POSTED ON THE www.dableducational.org WEBSITE

SECTION A - Please complete all items.

I Gerhard Frick, (Name of a Company Director) a Director of Microlife AG, (Company name)

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

Maker[a]	ONBO	*Address*	497 Dalang South Road, Longhua, Shenzhen, Guangdong, China
Manufacturer[b]	Microlife AG	*Address*	Espenstrasse 139, 9444 Widnau
Brand[c]	Microlife	Model[d]	A1 EASY / BP 3GR1-1P

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[a]	ONBO	*Address*	497 Dalang South Road, Longhua, Shenzhen, Guangdong, China
Manufacturer[b]	Microlife AG	*Address*	Espenstrasse 139, 9444 Widnau
Brand[c]	Microlife	Model[d]	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 3BTO-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 ☐	No ☒	N/A[e] ☐
	2	Algorithm for Auscultatory Measurements	Yes ☐	No ☐	N/A[f] ☒
	3	Artefact/Error Detection	Yes ☐	No ☒	
	4	Microphone(s)	Yes ☐	No ☐	N/A[f] ☒
	5	Pressure Transducer	Yes ☐	No ☒	
	6	Cuffs or Bladders	Yes ☐	No ☒	
	7	Inflation Mechanism	Yes ☐	No ☒	
	8	Deflation Mechanism	Yes ☐	No ☒	
Part II	9	Model Name or Number	Yes ☒	No ☐	
	10	Casing	Yes ☒	No ☐	
	11	Display	Yes ☒	No ☐	
	12	Carrying/Mounting Facilities	Yes ☐	No ☒	
	13	Software other than Algorithm	Yes ☐	No ☒	
	14	Memory Capacity/Number of stored measurements	Yes ☐	No ☒	
	15	Printing Facilities	Yes ☐	No ☒	N/A[g] ☐
	16	Communication Facilities	Yes ☐	No ☒	N/A[g] ☐
	17	Power Supply	Yes ☐	No ☒	
	18	Other Facilities	Yes ☒	No ☐	N/A[g] ☐

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.

Carraig Court, Georges Avenue, Blackrock, Co. Dublin, Ireland.
Form/DEET 130102

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Web www.dableducational.org

dabl® Educational Trust

Declaration of Equivalence Form

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 : A1 Easy Comparison items No 9, 10, 11, 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.

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

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Declaration of Blood Pressure Measuring Device Equivalence 2013

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SECTION A - Please complete all items.

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

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Manufacturer[b]	Microlife AG	*Address*	Espenstrasse 139, 9444 Widnau
Brand[c]	Microlife	Model[d]	A1 EASY / BP 3GR1-1P

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[a]	ONBO	*Address*	497 Dalang South Road, Longhua, Shenzhen, Guangdong, China
Manufacturer[b]	Microlife AG	*Address*	Espenstrasse 139, 9444 Widnau
Brand[c]	Microlife	Model[d]	BP A100 Plus

Existing validated blood pressure measuring device.

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

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. Blood Press Monit 2006; 11:157–160. ..

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 ☐	No ☒	N/A[e] ☐
	2	Algorithm for Auscultatory Measurements	Yes ☐	No ☐	N/A[f] ☒
	3	Artefact/Error Detection	Yes ☐	No ☒	
	4	Microphone(s)	Yes ☐	No ☐	N/A[f] ☒
	5	Pressure Transducer	Yes ☐	No ☒	
	6	Cuffs or Bladders	Yes ☐	No ☒	
	7	Inflation Mechanism	Yes ☐	No ☒	
	8	Deflation Mechanism	Yes ☐	No ☒	
Part II	9	Model Name or Number	Yes ☒	No ☐	
	10	Casing	Yes ☒	No ☐	
	11	Display	Yes ☒	No ☐	
	12	Carrying/Mounting Facilities	Yes ☐	No ☒	
	13	Software other than Algorithm	Yes ☐	No ☒	
	14	Memory Capacity/Number of stored measurements	Yes ☒	No ☐	
	15	Printing Facilities	Yes ☐	No ☒	N/A[g] ☐
	16	Communication Facilities	Yes ☐	No ☒	N/A[g] ☐
	17	Power Supply	Yes ☐	No ☒	
	18	Other Facilities	Yes ☒	No ☐	N/A[g] ☐

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.

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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 : A1 Easy Comparison items No 9, 10, 11, 14, 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.

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

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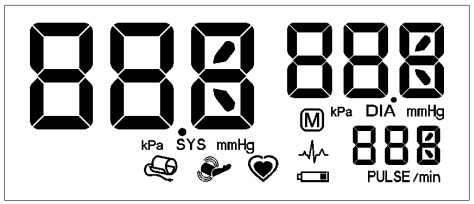
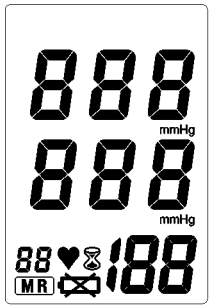
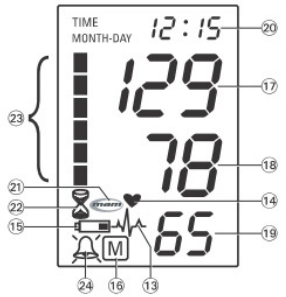
Comparison of the Microlife A1 Easy (BP3GR1-1P) with the Microlife BP3BT0-A and Microlife BP A100 Plus

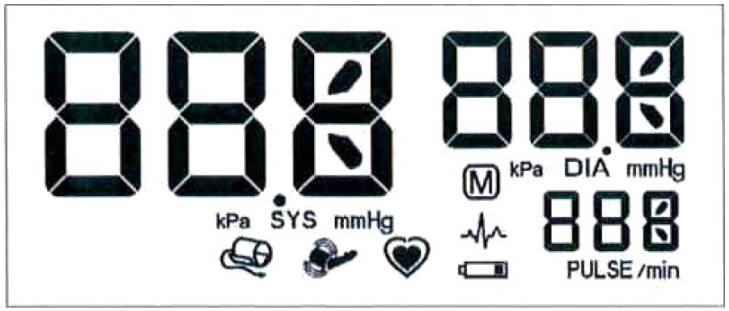
Devices	**Microlife A1 Easy (BP3GR1-1P)** 9	**BP3BT0-A** 9	**Microlife BP A100 Plus** 9
Image	**10** 	**10** 	**10** 
Validation		BHS	ESH
LCD Display	**11** 	**11** 	**11** 
Device Criteria	**Memory Capacity for stored values:** 14 - 1 set	**14** - 1 set	**14** - 200 set

	- shown with symbol «M»	- shown with symbol «M»	- shown with symbol «M» and date and time - no all-memory average
	Other Facilities: **18** **Display/Symbols/Indicators** - 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): Yes (indicates pulse irregularities during measurement which may affect the reading) - Pulse Beep during measurement: No (less disturbance for the patient) - Date and Time display: No **Cuff compartment:** No	**18** **Display/Symbols/Indicators** - Error 3 (leakage) - Error 2 (artifact) - MAM Function (triplicate measurement): No - Pulse Arrhythmia Indicator (PAD): No - Pulse Beep during measurement: Yes - Date and Time display: No **Cuff compartment:** No	**18** **Display/Symbols/Indicators** - 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) - Pulse Beep during measurement: Yes - Date and Time display: Yes; (with 2 alarm times i.e. for medication) **Cuff compartment:** Yes; (part of the casing)

	Measurement range (blood pressure): 20 – 280 mmHg **Traffic Light Indication:** No **2 User Function:** No	**Measurement range (blood pressure):** 30 – 280 mmHg (no separate range for SBP and DBP specified) **Traffic Light Indication:** No **2 User Function:** No	**Measurement range (blood pressure):** 30 – 280 mmHg (no separate range for SBP and DBP specified) **Traffic Light Indication:** Yes (following WHO 2003) **2 User Function:** No
	Power Supply: **19** 4xAA Batteries, Mains Adapter 6VDC Two level battery indicator	**Power Supply:** **19** 4xAA Batteries, Mains Adapter 6VDC 1 level battery indicator	**Power Supply:** **19** 4xAA Batteries, Mains Adapter 6VDC Two level battery indicator
	Cuffs: **6** Microlife S-Cuff (17-22cm) Microlife M-Cuff (22-32cm) Microlife M-L-Cuff (22-42cm) optional: Microlife M-L-Rigid Conical Cuff (22-42cm) [4]	**Cuffs:** **6** Microlife AC-1-M-Cuff (22-32cm) [1)] Microlife AC-1-L-Cuff (32-42cm) [1)]	**Cuffs:** **6** Microlife S-Cuff (17-22cm) [2)] Microlife M-Cuff (22-32cm) [2)] Microlife L-Cuff (32-42cm) [2)] Microlife M-L-Cuff (22-42cm) [3)] Microlife M-L-Rigid Conical Cuff (22-42cm) [4)]

Reference documents	[1] *Reference dev. BP 3BTO-A – validated with standard Microlife AC-1-L-Cuff and AC-1-M-Cuff* *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* [2] *Reference dev. BP A100 Plus – validated with Microlife S-Cuff (17-22cm), M-Cuff (22-32cm) and L-Cuff (32-42cm)* *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* [3] *Reference dev. BP A100 Plus – validated with Microlife M-L-Cuff (22-42cm)* *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* [4] *Reference dev. BP A100 Plus – validated with Microlife M-L-Cuff Rigid Conical Cuff (22-42cm)* *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*		
Web link	http://www.microlife.com/products/hypertension/automatic/bp-a1-easy/	http://www.microlife.com/products/hypertension/automatic/bp-3bt0-a-2/	http://www.microlife.com/products/hypertension/automatic/bp-a100-plus/

Comparison of the Microlife BP A1 Easy (BP 3GR1-1P) with the Microlife BP 3BT0-A

Devices	Microlife BP A1 Easy (BP 3GR1-1P)	Microlife BP 3BT0-A
Pictures		
Display		
Validation		BHS AAMI
Device 1 Criteria	***Measurement*** *Method* Press button if BP expected to be "very high" 7 *Cuffs* L-XL (Arm circ. 32 cm to 52 cm) (Optional) Query 1 6 M-L Soft (Arm circ. 22 cm to 42 cm) Query 1 6 M-L Rigid (Arm circ. 22 cm to 42 cm) (Optional) Query 1 6 Small (Arm circ. 17 cm to 22 cm) S-Cuff (Optional) Query 1 6 ***Display/Symbols/Indicators*** *Post Measurement* Body movement error 3, 11, 13, 18 Irregular heartbeat 11, 13, 18 Air leak / Cuff connection error 11, 13, 18	

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Devices	Microlife BP A1 Easy (BP 3GR1-1P)		Microlife BP 3BT0-A	
Device 1 Criteria (continued)	***Algorithms***			
	Diagnostic			
	Irregular heartbeat detection	13		
	Body movement error detection	3, 13		
	Casing			
	Power			
	Rechargeable batteries permitted	17		
Same Criteria	***Measurement***		***Measurement***	
	Accuracy		*Accuracy*	
	BP accuracy ± 3 mmHg	1, 5	BP accuracy ± 3 mmHg	1, 5
	Pulse accuracy ± 5%	1, 5	Pulse accuracy ± 5%	1, 5
	Method		*Method*	
	Oscillometric measurement method	1, 5	Oscillometric measurement method	1, 5
	BP 20 mmHg – 280 mmHg Query 2	1, 5, 7, 8	BP 20 – 280 mmHg (In Manual 30– 280 mmHg) Query 2	1, 5, 7, 8
	Pulse 40 bpm – 200 bpm	1, 5, 8	Pulse 40 bpm – 200 bpm	1, 5, 8
	Manually initiated measurements	13	Manually initiated measurements	13
	Measurements are from single inflations	13	Measurements are from single inflations	13
	Inflation		*Inflation*	
	Inflation 0 mmHg – 299 mmHg	1, 5, 7	Inflation 0 mmHg – 299 mmHg	1, 5, 7
	Automatic Inflation	7	Automatic Inflation	7
	Deflation		*Deflation*	
	Automatic Deflation	8	Automatic Deflation	8
	Sensors		*Sensors*	
	Pressure sensor: capacitive Query 3	5	Pressure sensor: capacitive Query 3	5
	Measurement Records		*Measurement Records*	
	Memory: 1 measurement	14	Memory: 1 measurement	14
	Buttons/Switches		***Buttons/Switches***	
	Power		*Power*	
	On/Off including Memory	10	On/Off including Memory	10
	Display/Symbols/Indicators		***Display/Symbols/Indicators***	
	Measurement Procedure		*Measurement Procedure*	
	During Measurement: BP Level & Heartbeat	11	During Measurement: BP Level & Heartbeat	11
	Post Measurement		*Post Measurement*	
	SBP, DBP and Pulse	11	SBP, DBP and Pulse	11
	Measurement error Err 1, Err 2, Err 3, Err 4, Err 5, H ı, Lo	11	Measurement error Err 1, Err 2, Err 3, Err 4, Err 5, H ı, Lo	11

Devices	Microlife BP A1 Easy (BP 3GR1-1P)	Microlife BP 3BT0-A
Same Criteria (continued)	***Casing*** *Display* Single screen display 10 Segment LCD 10 *Power* 4 “AA” batteries 17 AC adapter (Optional) 17	***Casing*** *Display* Single screen display 10 Segment LCD 10 *Power* 4 “AA” batteries 17 AC adapter (Optional) 17
Comparable Criteria	***Measurement*** *Cuffs* Medium (Arm circ. 22 to 32 cm) M-Cuff (Optional) Query 1 6 ***Display/Symbols/Indicators*** *Measurement Records* Memory “M” symbol 11 *Power* Low and flat battery 11, 17 ***Casing*** *Power* Automatic switch-off when not used for 1 min 17	***Measurement*** *Cuffs* Medium (Arm circ. 22 to 32 cm) AC-1-M Query 1 6 ***Display/Symbols/Indicators*** *Measurement Records* Memory “MR” symbol 11 *Power* Low battery 11, 17 ***Casing*** *Power* Automatic switch-off when not used for 5 min 17
Device 2 Criteria		***Measurement*** *Cuffs* Large (Arm circ. 32 cm to 42 cm) AC-1-L (Optional) Query 1 6 ***Display/Symbols/Indicators*** *Measurement Procedure* Audible pulse indicator during deflation 18 *Not described* Hourglass 11, 18

Queries

1

Query: There appears to be no commonality between the cuffs supplied with the BP A1 Easy 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[1,2,5,7,8]. Furthermore, the BP A100 Plus has been validated with both the M-L Soft cuff[3] and the M-L Rigid cuff[4] and the WatchBP Office ABI has been validated with the L-XL cuff[6]. 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 A1 Easy. The L-Cuff is not advertised as being available for the BP A1 Easy.

Cuff			**Device**			
Size	**Name**	**Arm Circ.** (cm)	**BP A1 Easy**	**BP A100 Plus**	**BP 3BT0-A**	**WatchBP Office ABI**
L-XL	L-XL	32 to 52	Opt.			Opt[6]
Large	L-Cuff / AC-1-L	32 to 42		Opt[1,2]	Opt[7,8]	Opt[5]
M-L	M-L Soft (Wide Range Conical Soft, One-Size, M-L) Cuff	22 to 42	Std.	Opt[3]		
	M-L Rigid Conical (Wide Range Conical Rigid, One-Size, Preformed conical) Cuff	22 to 42	Opt.	Opt[4]		
Medium	M-Cuff / AC-1-M	22 to 32	Opt.	Std[1,2]	Std[7,8]	Std[5]
Small	S-Cuff	17 to 22	Opt.	Opt[1,2]		

2

Query: According to each of the respective manuals, the measurement ranges are 20 mmHg to 280 mmHg for the BP A1 Easy but 30 mmHg to 280 mmHg for the BP 3BT0-A. 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

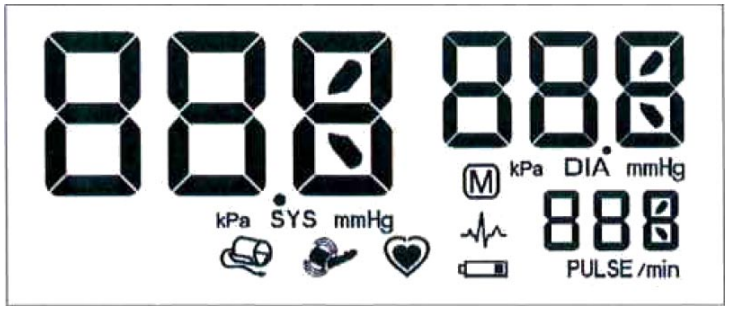
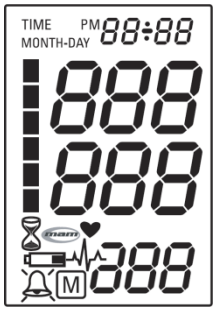
Query: What sensors are used in each device?

Response: The same capacitive sensors, manufactured by Microlife, are used in all upper arm devices.

Comment: This is clear.

References	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. *Blood Press Monit.* 2006;**11**:157-60. 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 *Vascular Health and Risk Management* 2007;**3**(4):389-400 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. *Blood Press Monit* 2009;**14**:216-19 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. *Hypertens Res.* 2010;**33**(11):1186-91. 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. *Blood Press Monit* 2011;**16**(5):258-61 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. *Blood Press Monit.* 2011;**16**(2):99-102. doi: 10.1097/MBP.0b013e328344c73c. 7. Cuckson AC, Reinders A, Shabeeh H, Shennan AH. Validation of the Microlife BP 3BT0-A oscillometric blood pressure monitoring device according to a modified British Hypertension Society protocol *Blood Press Monit.* 2002;**7**(6):319-324. 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. *BJOG* 2005;**112**(7):915-920.
Recommendation	Equivalence is Recommended
Date	7th February 2014

Comparison of the Microlife BP A1 Easy (BP 3GR1-1P) with the Microlife BP A100 Plus

Devices	Microlife BP A1 Easy (BP 3GR1-1P)	Microlife BP A100 Plus
Pictures		
Display		
Validation		ESH-IP 2002
Device 1 Criteria	***Measurement*** *Inflation* Press button if BP expected to be "very high" 7 *Cuffs* L-XL (Arm circ. 32 cm to 52 cm) (Optional) [Query 1] 6 ***Display/Symbols/Indicators*** *Post Measurement* Body movement error 3, 11, 13, 18 Air leak / Cuff connection error 11, 13, 18 ***Algorithms*** *Diagnostic* Body movement error detection 3, 13	
Same Criteria	***Measurement*** *Accuracy* BP accuracy ± 3 mmHg 1, 5	***Measurement*** *Accuracy* BP accuracy ± 3 mmHg 1, 5

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Devices	Microlife BP A1 Easy (BP 3GR1-1P)		Microlife BP A100 Plus	
Same Criteria (continued)	***Measurement (continued)***		***Measurement (continued)***	
	Accuracy (continued)		*Accuracy (continued)*	
	Pulse accuracy ± 5%	1, 5	Pulse accuracy ± 5%	1, 5
	Method		*Method*	
	Oscillometric measurement method	1, 5	Oscillometric measurement method	1, 5
	BP 20 mmHg – 280 mmHg Query 2	1, 5, 7, 8	BP 20 – 280 mmHg (In Manual 30– 280 mmHg) Query 2	1, 5, 7, 8
	Pulse 40 bpm – 200 bpm	1, 5, 8	Pulse 40 bpm – 200 bpm	1, 5, 8
	Manually initiated measurements	13	Manually initiated measurements	13
	Measurements are from single inflations	13	Measurements are from single inflations	13
	Inflation		*Inflation*	
	Inflation 0 mmHg – 299 mmHg	1, 5, 7	Inflation 0 mmHg – 299 mmHg	1, 5, 7
	Automatic Inflation	7	Automatic Inflation	7
	Deflation		*Deflation*	
	Automatic Deflation	8	Automatic Deflation	8
	Cuffs		*Cuffs*	
	M-L Soft (Arm circ. 22 cm to 42 cm) Query 1	6	M-L Soft (Arm circ. 22 cm to 42 cm) (Optional) Query 1	6
	M-L Rigid (Arm circ. 22 cm to 42 cm) (Optional) Query 1	6	M-L Rigid (Arm circ. 22 cm to 42 cm) (Optional) Query 1	6
	Medium (Arm circ. 22 to 32 cm) M-Cuff (Optional) Query 1	6	Medium (Arm circ. 22 to 32 cm) M-Cuff Query 1	6
	Small (Arm circ. 17 cm to 22 cm) S-Cuff (Optional) Query 1	6	Small (Arm circ. 17 cm to 22 cm) S-Cuff (Optional) Query 1	6
	Sensors		*Sensors*	
	Pressure sensor: capacitive Query 3	5	Pressure sensor: capacitive Query 3	5
	Display/Symbols/Indicators		***Display/Symbols/Indicators***	
	Measurement Procedure		*Measurement Procedure*	
	During Measurement: BP Level & Heartbeat	11	During Measurement: BP Level & Heartbeat	11
	Post Measurement		*Post Measurement*	
	SBP, DBP and Pulse	11	SBP, DBP and Pulse	11
	Measurement error Err 1, Err 2, Err 3, Err 4, Err 5, Hi, Lo	11	Measurement error Err 1, Err 2, Err 3, Err 4, Err 5, Hi, Lo	11
	Irregular heartbeat	11, 13, 18	Irregular heartbeat	11, 13, 18
	Measurement Records		*Measurement Records*	
	Memory “M” symbol	11	Memory “M” symbol	11
	Power		*Power*	
	Low and flat battery	11, 17	Low and flat battery	11, 17
	Algorithms		***Algorithms***	
	Diagnostic		*Diagnostic*	
	Irregular heartbeat detection	13	Irregular heartbeat detection	13

Devices	Microlife BP A1 Easy (BP 3GR1-1P)	Microlife BP A100 Plus
Same Criteria (continued)	***Casing***	***Casing***
	Display	*Display*
	Single screen display 10	Single screen display 10
	Segment LCD 10	Segment LCD 10
	Power	*Power*
	4 “AA” batteries 17	4 “AA” batteries 17
	AC adapter (Optional) 17	AC adapter (Optional) 17
	Automatic switch-off when not used for 1 min 17	Automatic switch-off when not used for 1 min 17
	Rechargeable batteries permitted 17	Rechargeable batteries permitted 17
Comparable Criteria	***Buttons/Switches***	***Buttons/Switches***
	Power/Measurement Records	*Power*
	On/Off Including Memory 10	On/Off with Start/Stop (⏻ symbol) 10
	10	*Measurement Records*
	Measurement	Memory 10
	Measurement Records	***Measurement***
	Memory: 1 measurement 14	*Measurement Records*
		Memory: 200 measurements 14
Device 2 Criteria		***Measurement***
		Method
		Optional repeated measurements (3) 13
		Cuffs
		Large (Arm circ. 32 cm to 42 cm) L-Cuff (Optional) [Query 1] 6
		Buttons/Switches
		Measurement Records
		Mode (Single, Triple) 10
		Settings
		Date/Time set 10
		Display/Symbols/Indicators
		Measurement Procedure
		Audible pulse indicator during deflation 18
		Multiple measurements (3) 11, 13
		Multiple measurements interval (hourglass) 11
		Post Measurement
		Measurement error Err 6 11
		Hypertension (Indicator strip) (WHO/ESH/JSH) 11, 13
		Green, yellow and red backlights 11, 13, 18

Devices	Microlife BP A1 Easy (BP 3GR1-1P)	Microlife BP A100 Plus
Device 2 Criteria (continued)		***Display/Symbols/Indicators (continued)*** *Measurement Records* Memory recall number 11 *Date and Time* Date and Time 11 Date and Time (During memory recall) 11 Alarm reminder (2 alarms/day) 18 ***Algorithms*** *Diagnostic* BP classification (WHO/ESH/JSH) 13 ***Casing*** *Features* Integrated cuff compartment 10 Card Holder 10

Queries

1

Query: Please clarify which cuffs were validated with the BP A100/BP A100 Plus and which cuffs match which description.

Response: Microlife does not use particular cuff codes, the cuffs are identified as “Microlife + cuff name”.

The BP A100 Plus was validated with the Microlife S-Cuff (17-22 cm)[1,2], M-Cuff (22-32 cm)[1,2], L-Cuff (32-42 cm)[1,2], M-L Soft Cuff (22-42 cm)[3] and M-L-Cuff Rigid Conical Cuff (22-42 cm)[4]. The Watch BP Office ABI was validated with the L-XL Cuff (32-52 cm)[6].

The BP A1 Easy optionally comes with the validated Wide Range Conical Soft Cuff (same as M-L soft cuff, One-Size-Cuff). The Microlife L-XL Cuff, S-Cuff, M-Cuff and M-L-Cuff Wide Range Conical Rigid Cuff are available as accessories.

Comment: The WatchBP Office ABI was also validated with the M-Cuff and L-Cuff[5]. 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 A1 Easy. The L-Cuff is not advertised as being available for the BP A1 Easy.

Cuff			**Device**		
Size	**Name**	**Arm Circ.** (cm)	**BP A1 Easy**	**BP A100 Plus**	**WatchBP Office ABI**
L-XL	L-XL	32 to 52	Opt.		Opt[6]
Large	L-Cuff	32 to 42		Opt[1,2]	Opt[5]
M-L	M-L Soft (Wide Range Conical Soft, One-Size, M-L) Cuff	22 to 42	Std.	Opt[3]	
	M-L Rigid Conical (Wide Range Conical Rigid, One-Size, Preformed conical) Cuff	22 to 42	Opt.	Opt[4]	
Medium	M-Cuff	22 to 32	Opt.	Std[1,2]	Std[5]
Small	S-Cuff	17 to 22	Opt.	Opt[1,2]	

2

Query: According to each of the respective manuals, the measurement ranges are 20 mmHg to 280 mmHg for the BP A1 Easy 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.

References	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. *Blood Press Monit.* 2006;**11**:157-60. 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 *Vascular Health and Risk Management* 2007;**3**(4):389-400 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. *Blood Press Monit* 2009;**14**:216-19 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. *Hypertens Res.* 2010;**33**(11):1186-91. 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. *Blood Press Monit* 2011;**16**(5):258-61 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. *Blood Press Monit.* 2011;**16**(2):99-102. doi: 10.1097/MBP.0b013e328344c73c.
Recommendation	Equivalence is Recommended
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