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, 9443 Widnau
Brand[c]	Microlife	Model[d]	BP A150 AFIB

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, 9443 Widnau
Brand[c]	Microlife	Model[d]	BP A100

Existing validated blood pressure measuring device.

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

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;14:216-9

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.
Tel + 353 1 278 0247
Fax + 353 1 278 3835
(dabl®Educational Trust Limited is a not-for-profit organisation)
Email info@dableducational.org
Web www.dableducational.org

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: BP A150 AFIB 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 2016-04-08

Signature of Witness _____

Name Jerry Lin

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

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Manufacturer[b]	Microlife AG	*Address*	Espenstrasse 139, 9443 Widnau
Brand[c]	Microlife	Model[d]	BP A150 AFIB

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, 9443 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 A 100 Plus device for self-home blood pressure measurement according to the International. Protocol Blood Press Monit 2006;11:157-60

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:
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- 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 DET7 130102

(dabl®Educational Trust Limited is a not-for-profit organisation)
Tel +353 1 278 0247 Email info@dableducational.org
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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: BP A150 AFIB Comparison items No. 9, 10, 11, 14, 18 are explained in the attached table.

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

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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

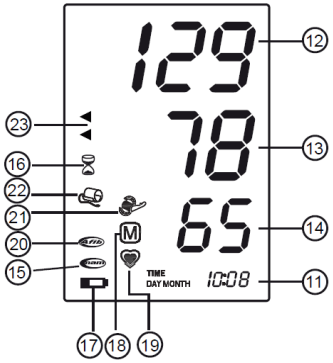
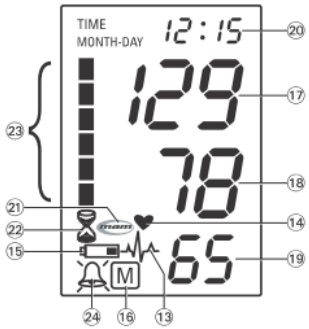
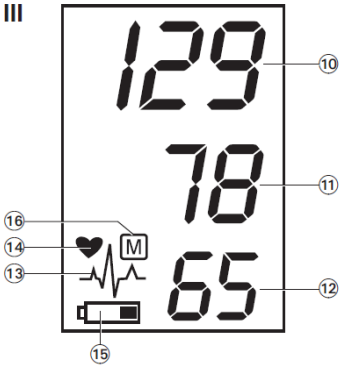
Date 2016-04-08

Signature of Witness _____

Name Jerry Lin

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

Comparison of the Microlife BP A150 AFIB with the Microlife BP A100 Plus and Microlife BP A100

Devices	Microlife BP A150 AFIB 9	Microlife BP A100 Plus 9	Microlife BP A100 9
Image	**10** 	**10** 	**10** 
Validation		ESH 2002	ESH 2002
LCD Display	**11** 	**11** 	**11** 
Device Criteria	**Memory Capacity for stored values:** **14** - 30 set - shown with symbol «M»	**14** - 200 set - shown with symbol «M» and date and time	**14** - 1 set - shown with symbol «M» and date and time

Carraig Court, George's Avenue, Blackrock, Co. Dublin, Ireland Tel +353 1 278 0247 Fax +353 1 278 0882 Email info@dableducational.org Web www.dableducational.org

	Other Facilities: **18** **Display/Symbols/Indicators** - Error 6 (AFIB/MAM Mode) - Cuff check Indicator (symbol instead of Error, improved function) - Armmovement Indicator (symbol instead of Error, improved function) - MAM Function (triplicate measurement): Yes - Pulse Arrhythmia Indicator (PAD): No - Pulse Beep during measurement: No **AFIB:** Yes [1), 2)] - Software other than algorithm (Detection of atrial fibrillation) - Date and Time display: Yes **Cuff compartment:** No **Traffic Light Indication:** Yes (following ESH) **Cuffs:** Microlife M-Cuff (22-32cm) [3)] Microlife L-Cuff (32-42cm) [3)] Microlife M-L-Cuff (22-42cm) [4)] optional: Microlife M-L-Rigid-conical Cuff (22-42cm) [5)]	**18** **Display/Symbols/Indicators** - Error 6 (MAM Mode) - 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 **AFIB:** No - Date and Time display: Yes (with 2 alarm times i.e. for medication) **Cuff compartment:** Yes (part of the casing) **Traffic Light Indication:** Yes (following WHO 2003) **Cuffs:** Microlife M-Cuff (22-32cm) [3)] Microlife L-Cuff (32-42cm) [3)]	**18** **Display/Symbols/Indicators** - Error 3 (leakage) - Error 2 (artifact) - MAM Function (triplicate measurement): No - Pulse Arrhythmia Indicator (PAD): Yes (indicates pulse irregularities during measurement which may affect the reading) - Pulse Beep during measurement: Yes **AFIB:** No - Date and Time display: No **Cuff compartment:** Yes (part of the casing) **Traffic Light Indication:** No **Cuffs:** Microlife M-Cuff (22-32cm) [3)] Microlife L-Cuff (32-42cm) [3)] Microlife M-L-Cuff (22-42cm) [4)] optional: Microlife M-L-Rigid-conical Cuff (22-42cm) [5)]

Reference documents	[1] *Reference dev. BP A150 AFIB* *Stergiou GS, Karpettas N, Protogerou A, Nasothimiou EG, Kyriakidis M. Diagnostic accuracy of a home blood pressure monitor to detect atrial fibrillation. Journal of Human Hypertension 2009; 23, 654-658* [2] *Reference dev. BP A150 AFIB* *Kearly K, Selwood M, Van den Bruel A, Thompson M, Mant D, FD Hobbs R, Fitzmaurice D, Heneghan C.* *Triage tests for identifying atrial fibrillation in primary care: a diagnostic accuracy study comparing single-lead ECG and modified BP monitors.* *BMJ Open 2014; 4, 1 -7* [3] *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* [4] *Reference dev. BP A100 – 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* [5] *Reference dev. BP A100 – 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-a150-afib/	http://www.microlife.com/products/hypertension/automatic/bp-a100-plus	http://www.microlife.com/products/hypertension/automatic/bp-a100/
Recommend.	**Equivalence is recommended**		
Date	**9 May 2016**		