# 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] | A2 Classic / BP 3UG1-2E |

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 3BT0-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 DET7 130102

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Fax +353 1 278 3835 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 : A2 Basic 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

# 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] A2 Classic / BP 3UG1-2E

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

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

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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As attached file : A2 Basic 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 | ☒ |
| 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

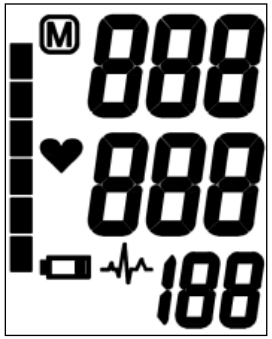
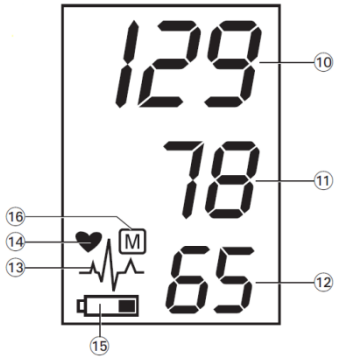
Signature of Witness _____

Name Jerry Lin

Address 9F,NO.431,RuiGuang Road,Nei-Hu,

Taipei,11492,Taiwan.R.O.C

## Comparison of the Microlife A2 Classic with the Microlife 3BT0-A and Microlife BP A100

| Devices | Microlife A2 Classic (BP 3UG1-2E) 9 | Microlife BP 3BT0-A 9 | Microlife BP A100 9 |
|---|---|---|---|
| **Image** | **10**  | **10**   | **10**  |
| **Validation** | | BHS | ESH 2002 |
| **LCD Display** | **11**  | **11**   | **11**   |
| | **Memory Capacity for stored values:** **14**<br>- 30 sets<br>- shown with symbol «M»<br>- allows indicate all-memory average (see I/B) | **Memory Capacity for stored values:** **14**<br>- 1 set<br>- shown with symbol «M» | **Memory Capacity for stored values:** **14**<br>- 1 set<br>- shown with symbol «M» |
| | **Other Facilities:** **18**<br>**Display/Symbols/Indicators** | **Other Facilities** **18**<br>**Display/Symbols/Indicators** | **Other Facilities** **18**<br>**Display/Symbols/Indicators** |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| | | | |
|---|---|---|---|
| | **Pulse Arrhythmia Indicator (PAD):** Yes<br>(indicates pulse irregularities during measurement which may affect the reading)<br><br>**Pulse Beep during measurement:** No<br>(less disturbance for the patient)<br><br>**Cuff compartment:** No<br><br>***Measurement***<br>*Accuracy*<br>Blood Pressure Accuracy ± 3 mmHg<br>Pulse Accuracy ± 5%<br><br>*Method*<br>Oscillometric<br><br>*Ranges*<br>Cuff pressure: 0 -299 mmHg<br>Measurement: 20 mmHg – 280 mmHg<br><br>Pulse rate: 40-200 beats/minute<br><br>**Traffic Light Indicator:** Yes<br>(following WHO 2003)<br><br>**Cuffs:**<br>Microlife M-Cuff (22-32cm) [1)]<br>Microlife L-Cuff (32-42cm) [1)]<br>Microlife M-L-Cuff (22-42cm) [2)]<br>Microlife M-L-Rigid Conical Cuff (22-42cm) [3)] | **Pulse Arrhythmia Indicator (PAD):** No<br><br>**Pulse Beep during measurement:** Yes<br><br>**Cuff compartment:** No<br><br>***Measurement***<br>*Accuracy*<br>Blood Pressure Accuracy ± 3 mmHg<br>Pulse Accuracy ± 5%<br><br>*Method*<br>Oscillometric<br><br>*Ranges*<br>Cuff pressure: 0 -299 mmHg<br>Measurement: 30 mmHg – 280 mmHg<br>(no separate range for SBP and DBP specified)<br>Pulse rate: 40-200 beats/minute<br><br>**Traffic Light Indicator:** No<br><br>**Cuffs:**<br>Microlife AC-1-M-Cuff (22-32cm) [1)]<br>Microlife AC-1-L-Cuff (32-42cm) [1)] | **Pulse Arrhythmia Indicator (PAD):** Yes<br>(indicates pulse irregularities during measurement which may affect the reading)<br><br>**Pulse Beep during measurement:** Yes<br><br>**Cuff compartment:** Yes<br><br>***Measurement***<br>*Accuracy*<br>Blood Pressure Accuracy ± 3 mmHg<br>Pulse Accuracy ± 5%<br><br>*Method*<br>Oscillometric<br><br>*Ranges*<br>Cuff pressure: 0 -299 mmHg<br>Measurement: 20 mmHg – 280 mmHg<br>(no separate range for SBP and DBP specified)<br>Pulse rate: 40-200 beats/minute<br><br>**Traffic Light Indicator:** No<br><br>**Cuffs:**<br>Microlife M-Cuff (22-32cm) [1)]<br>Microlife L-Cuff (32-42cm) [1)]<br>Microlife M-L-Cuff (22-42cm) [2)]<br>Microlife M-L-Rigid Conical Cuff (22-42cm) [3)] |
| **Reference documents** | *[1)] Reference dev. BP 3BTO-A – validated with standard Microlife AC-1-L-Cuff and AC-1-M-Cuff*<br>*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 – validated with Microlife M-L-Cuff (22-42cm)*<br>*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*<br><br>*[3] Reference dev. BP A100 – validated with Microlife M-L-Cuff Rigid Conical Cuff (22-42cm)*<br>*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* | | |
| **Web link** | n/a | http://www.microlife.com/products/hypertension/automatic/bp-3bt0-a-2/ | n/a |
| **Recommendation** | **Equivalence is recommended** | | |
| **Date** | **9 May 2016** | | |