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 Willis Chan, (Name of a Company Director) a Director of Microlife Corporation Co.,, (Company name)

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

Maker[a]	Microlife Corporation Co.,	*Address*	9F,431,RuiGuang Road,Nei-Hu,Taipei,114,Taiwan,R.O.C
Manufacturer[b]	KAZ Home Appliances	*Address*	Flat 4B&4C,Productivity Building,2nd High Technology Road,Science and industy Park, NanShan District,Shenzhen,PRC
Brand[c]	BRAUN	Model[d]	BP2200

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]	Microlife Corporation Co.,	*Address*	9F,431,RuiGuang Road,Nei-Hu,Taipei,114,Taiwan,R.O.C
Manufacturer[b]	Microlife Corporation Co.,	*Address*	9F,431,RuiGuang Road,Nei-Hu,Taipei,114,Taiwan,R.O.C
Brand[c]	Microlife	Model[d]	W100

Existing validated blood pressure measuring device.

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

Paolo Palatini, Francesca Dorigatti, Elisa Bonso and Fabio Ragazzo; Validation of Microlife BP W100 wrist device assessed according to the European Society of Hypertension and the British Hypertension Society protocols.

Full reference

Blood Press Monit 2009, **14**:41–44

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.

Attachment: BP2200 Comparison table for more explanation on items No 9, 10, 11, 14 and 18.

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 Willis Chan

Date Jan. 8. 2014

Signature of Witness _____

Name Gerhard Frick

Address Microlife AG, 9443 Widnau, Switzerland

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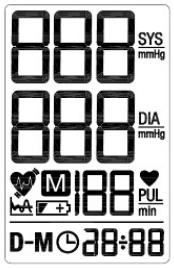
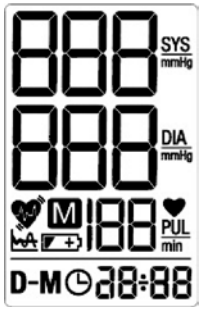
Comparison of the BRAUN BP2200 with the Microlife BP W100

Devices	BRAUN BP2200 9	Microlife W100 9
Image	10 	10 
Validation		ESH, BHS
LCD Display	11 	11 
Device Criteria	14 **Memory Capacity for stored values:** - 90 sets - shown with symbol «M» and date and time - allows averaging of the last 3 readings	14 **Memory Capacity for stored values:** - 200 sets - shown with symbol «M» and date and time - no memory average function
	Other Facilities 18 **Display/Symbols/Indicators** - Irregular Heartbeat Indicator: YES - Pulse Beep during measurement: NO - Date and Time: YES (no alarm function) - Measurement range (heart rate): 0 - 199	**Other Facilities** 18 **Display/Symbols/Indicators** - Irregular Heartbeat Indicator: YES - Pulse Beep during measurement: YES - Date and Time: YES (2 alarm times i.e. for medication) - Measurement range (heart rate): 0 - 200
Web Link		http://www.microlife.com/products/hypertension/wrist/bp-w100/

Comparison of the Braun BP 2200 (BBP2200) with the Microlife BP W100

Devices	Braun BP 2200 (BBP2200)	Microlife BP W100
Pictures		
Display		
Validation		ESH
Device 1 Criteria	***Display/Symbols/Indicators*** *Post Measurement* Average 11, 13, 14 ***Algorithms*** *Averages and Differences* Last 3 measurements mean 13	
Same Criteria	***Measurement*** *Accuracy* BP accuracy ± 3 mmHg 1, 5 Pulse accuracy ± 5% 1, 5 *Method* Oscillometric measurement method 1, 5 BP 20 mmHg – 280 mmHg 1, 5, 7, 8 Manually initiated measurements 13	***Measurement*** *Accuracy* BP accuracy ± 3 mmHg 1, 5 Pulse accuracy ± 5% 1, 5 *Method* Oscillometric measurement method 1, 5 BP 20 mmHg – 280 mmHg 1, 5, 7, 8 Manually initiated measurements 13

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Devices	Braun BP 2200 (BBP2200)		Microlife BP W100	
Same Criteria (Continued)	***Measurement (Continued)***		***Measurement (Continued)***	
	Method (Continued)		*Method (Continued)*	
	Measurements are from single inflations	13	Measurements are from single inflations	13
	Inflation		*Inflation*	
	Inflation 0 mmHg – 300 mmHg	1, 5, 7	Inflation 0 mmHg – 300 mmHg	1, 5, 7
	Automatic Inflation	7	Automatic Inflation	7
	Deflation		*Deflation*	
	Automatic Deflation	8	Automatic Deflation	8
	Cuffs		*Cuffs*	
	Wrist circ. 13.5 cm – 21.5 cm	6	Wrist circ. 13.5 cm – 21.5 cm	6
	Sensors		*Sensors*	
	Pressure sensor: capacitive	5	Pressure sensor: capacitive	5
	Buttons/Switches		***Buttons/Switches***	
	Power		*Power*	
	On/Off with Start/Stop (ⓘ symbol)	10	On/Off with Start/Stop (ⓘ symbol)	10
	Measurement Records		*Measurement Records*	
	Memory	10	Memory	10
	Settings		*Settings*	
	Date/Time set	10	Date/Time set	10
	Display/Symbols/Indicators		***Display/Symbols/Indicators***	
	Measurement Procedure		*Measurement Procedure*	
	During Measurement: BP Level & Heartbeat	11	During Measurement: BP Level & Heartbeat	11
	Beep after measurement	18	Beep after measurement	18
	Post Measurement		*Post Measurement*	
	SBP, DBP and Pulse	11	SBP, DBP and Pulse	11
	Measurement error Err 1, Err 2, Err 3, Err 5, Hi, Lo	11	Measurement error Err 1, Err 2, Err 3, 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
	Memory recall number (Replaces pulse rate momentarily)	11	Memory recall number (Replaces pulse rate momentarily)	11
	Date and Time		*Date and Time*	
	Date and Time	11	Date and Time	11
	Date and Time (During memory recall)	11	Date and Time (During memory recall)	11
	Power		*Power*	
	Low and exhausted battery	11, 17	Low and exhausted battery	11, 17
	Algorithms		***Algorithms***	
	Diagnostic		*Diagnostic*	
	Irregular heartbeat detection	13	Irregular heartbeat detection	13

Devices	Braun BP 2200 (BBP2200)	Microlife BP W100
Same Criteria (Continued)	***Casing*** *Display* Single screen display 10 Segment LCD 10 *Power* 2 “AAA” batteries ~ 200 measurements Query 2 17 Automatic switch-off when not used for 1 min 17 Rechargeable batteries permitted but not recommended Query 3 17	***Casing*** *Display* Single screen display 10 Segment LCD 10 *Power* 2 “AAA” batteries 17 Automatic switch-off when not used for 1 min 17 Rechargeable batteries permitted 17
Comparable Criteria	***Measurement*** *Method* Pulse 40 bpm – 199 bpm Query 1 1, 5, 8 *Measurement Records* Memory: 90 measurements 14	***Measurement*** *Method* Pulse 40 bpm – 200 bpm Query 1 1, 5, 8 *Measurement Records* Memory: 200 measurements 14
Device 2 Criteria		***Display/Symbols/Indicators*** *Measurement Procedure* Audible pulse indicator during deflation 18 *Date and Time* Alarm reminder (2 alarms/day) / Alarm reminder off 18

Comments	Microlife are acting as an OEM manufacturer for the Braun BP2200. The device stores fewer measurements than the BP W100 but provides a last tree measurements average.		
	1	Query	The manual for the Braun BP2200 (and BP2000) states that the measurement range for the pulse is 40 bpm to-199 bpm whereas the manual for the Microlife BP W100 states that the measurement range for the pulse is 40 bpm to 200 bpm. Why the slight difference?
		Response	It is because of the display limitation. The 3rd digit in the Braun is only a “1”, whereas, in the Microlife, it can show a “2”. We have listed the difference in the comparison table.
		Comment	The explanation is accepted.
	2	Query	The manual for the Braun BP2200 (and BP2000) states that new batteries will provide approximately 200 measurements. No such information is provided in the manual for the Microlife BP W100. How many measurements can be made by the Microlife BP W100 with a fresh set of batteries?
		Response	Both, the Braun and the Microlife devices have the same power supply and electronic circuitry, which is good for 400 measurement cycles with usual standard quality batteries. For the avoidance of enquiries and user complaints in case of lower quality batteries, Braun prefers to claim only 200 measurements in their user manual. This does not mean any technical difference between the products.
		Comment	The explanation is accepted.
	3	Query	The manual for the Microlife BP W100 states that rechargeable batteries are permitted. The manual for the Braun BP2200 (and BP2000) contains no information on whether or not rechargeable batteries are permitted. Are rechargeable batteries permitted for the Braun BP2200?
		Response	Both, the Braun and the Microlife devices have the same power supply and electronic circuitry which also allows the use of standard quality rechargeable batteries. For the avoidance of enquiries or complaints due to use of poor quality or exhausted rechargeable batteries, Braun prefers to abstain from recommending rechargeable batteries at all. This does not mean any technical difference between the products.
		Comment	The explanation is accepted.
Recommendation	Equivalence is Recommended		
Date	13 February 2014		