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 , a Director of A&D Company LTD,
Name of a Company Director — Company name

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

Maker[a]	A&D Company LTD	*Address*	1-243 Asahi, Kitamoto-shi, Saitama, 364-8585 Japan
Manufacturer[b]	A&D Company LTD	*Address*	1-243 Asahi, Kitamoto-shi, Saitama, 364-8585 Japan
Brand[c]	A&D	Model[d]	UM-102

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]	A&D Company LTD	*Address*	1-243 Asahi, Kitamoto-shi, Saitama, 364-8585 Japan
Manufacturer[b]	A&D Company LTD	*Address*	1-243 Asahi, Kitamoto-shi, Saitama, 364-8585 Japan
Brand[c]	A&D	Model[d]	UM-101

Existing validated blood pressure measuring device.

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

Benetti E1, Fania C, Palatini P. Validation of the A&D UM-101 upper arm blood pressure monitor, for self measurement, according to the European Society of Hypertension International Protocol revision 2002 [Internet].

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.

6)The material of the cuff and bladder has been replaced in LATEX FREE, but structure and dimensions are comparable between the two cuff and bladder .

9) Model number: UM-102

10) The submitted device and validated device have difference case design, both devices have the different casing.

13) Measurement range of Pulse rate is comparable.

18) Operating condition and Transport/Storage conditions are comrparable.

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 Kazuhiko Niwano Company Stamp/Seal

Name Kazuhiko Niwano

Date 1.Sep.2015

Signature of Witness S. Ozaki

Name Shinobu Ozaki

Address 1-243 Asahi, Kitamoto-shi, Saitama, 364-8585 Japan

Comparison of the A&D UM-102 with the A&D UM-101

Devices	*A&D UM-102*	*A&D UM-101*
Pictures		
Display		
Validation		ESH 2002
Device 1 Criteria		*Details on validated device that are different to Equivalent device* *Casing* *Material: elastomer* *Cuffs(Please state sizes and materials used)* Material:PVC 23-33cm
Device 2 Criteria	*Details on validated device that are different to Equivalent device* *Casing:* *Material: ABS* *Cuffs (Please state sizes and materials used)* Material: URETHAN 22-32cm	

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Same Criteria	***Measurement*** *Accuracy* Pressure: ±3 mmHg Pulse: ±5 % *Method* Stethoscope with stethoscope *Ranges* Pressure: 0 - 300 mmHg *Inflation* MANUAL PRESSURIZER(rubber ball) *Deflation* MANUAL EXHAUST VALVE SOLENOID VALVE *Sensors* Capacity type sensor *Measurement Records* N/A *Measurements other than Blood Pressure* PULSE RATE ***Buttons/Switches*** *Power* Start Button *Measurement Records* N/A *Function* Measurement with MARK Button Lifetime Counter	***Measurement*** *Accuracy* Pressure: ±3 mmHg Pulse: ±5 % *Method* Stethoscope with stethoscope *Ranges* Pressure: 0 - 300 mmHg *Inflation* MANUAL PRESSURIZER(rubber ball) *Deflation* MANUAL EXHAUST VALVE SOLENOID VALVE *Sensors* Capacity type sensor *Measurement Records* N/A *Measurements other than Blood Pressure* PULSE RATE ***Buttons/Switches*** *Power* Start Button *Measurement Records* N/A *Function* Measurement with MARK Button Lifetime Counter

	Analysis N/A *Event Marking* N/A *Communication* N/A ***Display/Symbols/Indicators*** *Preparation* All of the display symbols will appear for about one second. *Measurement Procedure* While the cuff is inflating, the pressure bar will move in turn the LCD will display a number indicating the pressure. When inflation is complete. Turn the exhaust valve screw to release air slowly. Measure the systolic pressure and the diastolic pressure by stethoscope. *Post Measurement* The pulse rate is shown on the numerical display when the measurement is complete, and meets the following conditions. *Measurement Records* N/A *Date and Time* N/A *Power* N/A *Function* Measurement with MARK Button （5 marking） Lifetime Counter	*Analysis* N/A *Event Marking* N/A *Communication* N/A ***Display/Symbols/Indicators*** *Preparation* All of the display symbols will appear for about one second. *Measurement Procedure* While the cuff is inflating, the pressure bar will move in turn the LCD will display a number indicating the pressure. When inflation is complete. Turn the exhaust valve screw to release air slowly. Measure the systolic pressure and the diastolic pressure by Stethoscope. *Post Measurement* The pulse rate is shown on the numerical display when the measurement is complete, and meets the following conditions. *Measurement Records* N/A *Date and Time* N/A *Power* N/A *Function* Measurement with MARK Button （5 marking） Lifetime Counter

	Communication N/A *Features* N/A *Not described* N/A ***Algorithms*** *Averages and Differences* N/A *Diagnostic* N/A *Functions* N/A *Communication* N/A ***Casing*** *Display* Rating label、Serial number *Ports* Cuff connector *Power* LR6/AA *Features* N/A	*Communication* N/A *Features* N/A *Not described* N/A ***Algorithms*** *Averages and Differences* N/A *Diagnostic* N/A *Functions* N/A *Communication* N/A ***Casing*** *Display* Rating label、Serial number *Ports* Cuff connector *Power* LR6/AA *Features* N/A

Comparable Criteria	Cuffs: Cuff size: Adult(22-32cm) Measurement range: Pulse: 40 - 180 beats/minute Operating Conditions: +10℃ to +40℃ / 15%RH to 85%RH 800 hPa to 1060 hPa Transport / Storage conditions: -20℃ to +60℃ / 10%RH to 95%RH Dimensions: Approx. 98[W] x 324[H] x 67[D] Weight: Approx. 520g, excluding batteries	Cuffs: Cuff size: Adult(23-33cm) Measurement range: Pulse: 30 - 200 beats/minute Operating Condition: +10℃ to +40℃ / 15%RH to 85%RH 800 hPa to 1060 hPa Transport / Storage conditions: -20℃ to +60℃ / 10%RH to 95%RH Dimensions: Approx. 96[W] x 322[H] x 66[D] Weight: Approx. 940g, excluding batteries

Comments		The circuit board and software are the same.
		Replies to queries; accepted.
Recommendation	***Equivalence Recommended without use of Mark Button***	
Date	8 October 2015	