dabl®Educational Trust — Declaration of Equivalence Form

Declaration of Blood Pressure Measuring Device Equivalence

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

SECTION A - Please complete all items.

I Yasuhiko Shinozaki, (Name of a Company Director) a Director of A&D Compnay,Limited, (Company name)

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

Maker[a] A&D Compnay,Limited *Address* 3-23-14 Higashi-ikebukuro Toshima-Ku,Tokyo 170-0013 JAPAN

Manufacturer[b] A&D Compnay,Limited *Address* 3-23-14 Higashi-ikebukuro Toshima-Ku,Tokyo 170-0013 JAPAN

Brand[c] A&D Model[d] UB-1100BLE

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 Compnay,Limited *Address* 3-23-14 Higashi-ikebukuro Toshima-Ku,Tokyo 170-0013 JAPAN

Manufacturer[b] A&D Compnay,Limited *Address* 3-23-14 Higashi-ikebukuro Toshima-Ku,Tokyo 170-0013 JAPAN

Brand[c] A&D Model[d] UB-543

Existing validated blood pressure measuring device.

which has previously passed the ESH-2010 protocol, the results of which were published as follows:

Fania C., Benetti E. and Palatini P. Validation of the A&D BP UB-543 wrist device for home blood pressure measurement according to the European Society of Hypertension International Protocol revision 2010.

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.

5)The pressure sensor is replaced to a piezo electric sensor from an electrostatic capacitive sensor, but the accuracy of blood pressure measurement is equivalent between the two sensors.

9)The equivalent device model name:UB-1100BLE

10)Difference of case design. Both devices have the different casing.

11)The display type is different

13)Difference of Display function / Bluetooth communication etc

14)UB-1100BLE : 100 x 5 measurements, UB-543 : 60 x 2 measurements

16)UB-1100BLE : Bluetooth® Ver.4.1 Low Energy, UB-543 :N/A

17)UB-1100BLE : 3.7V Li-ion 325mAh, UB-543 : 2×1.5V alkaline batteries

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	☒
Completed DET9 Form	☒
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 Yasuhiko Shinozaki

Company Stamp/Seal

A&D Company, Limited AND Japan

Name Yasuhiko Shinozaki

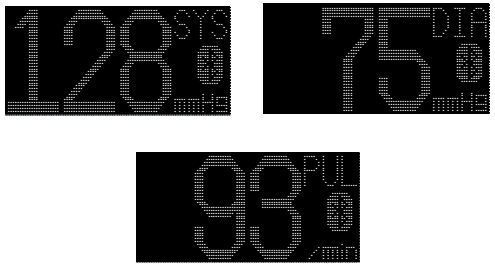
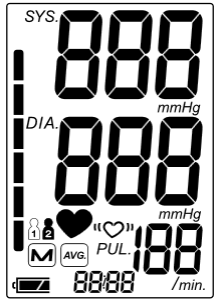
Date 26 July 2019

Signature of Witness

Name Shinobu Ozaki

Address 3-23-14 Higashi-ikebukuro Toshima-Ku,Tokyo 170-0013 JAPAN

Comparison of the A&D UB-1100BLE with the A&D UB-543

Devices – Item 9	A&D UB-1100BLE	A&D UB-543
Pictures		
Display Image		
Validation		ESH 2010
Category	Wrist Blood pressure monitor	Wrist Blood pressure monitor
Casing – Item 10	*Dimensions* Approx：54【W】× 76【H】× 21【D】mm *Ports* Cuff port USB connector port (charge only) *Features* start Button reset Button	*Dimensions* Approx：56【W】×88【H】×18【D】mm *Ports* Cuff port *Features* start button / set button / ◀ button Brand logo printing Model name printing User printing WHO Classification

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Display – Item 11	*Type* White OLED display (dot matrix)	*Type* liquid crystal display
Carrying/Mounting Facilities – Item 12	N/A	N/A
Software other than Algorithm – Item 13	Display function(OLED) Bluetooth communication	Display function(LCD)
Memory Capacity Item 14	*Number of stored measurements* Last 100 measurements each for 5 users	*Number of stored measurements* Last 60 measurements each for user1 and user2
Printing Facilities Item 15	N/A	N/A
Communication Facilities – Item 16	Bluetooth® Ver.4.1 Low Energy	N/A
Power Supply Item 17	3.7V Li-ion 325mAh	2×1.5V alkaline batteries(LR03 or AAA)
Other differences	*Other Details on Equivalent device that are different to Validated device* *Sensors* Semiconductor sensor	*Other Details on Validated device that are different to Equivalent device* *Sensors* Capacitance sensor
Same Criteria	***Measurement*** *Accuracy* Pressure: ±3 mmHg Pulse: ±5 % *Method* Oscillometric measurement *Ranges* Pressure: 0 - 299 mmHg Systolic pressure: 60 - 279 mmHg Diastolic pressure: 40 - 200 mmHg Pulse: 40 - 180 beats/minute *Inflation* Automatic inflation *Deflation* Rapid exhaust valve	***Measurement*** *Accuracy* Pressure: ±3 mmHg Pulse: ±5 % *Method* Oscillometric measurement *Ranges* Pressure: 0 - 299 mmHg Systolic pressure: 60 - 279 mmHg Diastolic pressure: 40 - 200 mmHg Pulse: 40 - 180 beats/minute *Inflation* Automatic inflation *Deflation* Rapid exhaust valve

	Cuffs (Please state sizes and materials used) 13.5cm-21.5cm Nylon *Measurement Records* SYS,DIA,PUL,Date&Time,IHB *Measurements other than Blood Pressure* Heart rate ***Buttons/Switches*** *Power* Start button *Analysis* N/A *Event Marking* N/A *Communication* N/A ***Display/Symbols/Indicators*** *Preparation* Positioning indicator Zero is blinking *Power* Battery detection symbol *Features* N/A *Not described* N/A ***Algorithms*** *Diagnostic* N/A	*Cuffs(Please state sizes and materials used)* 13.5cm-21.5cm Nylon *Measurement Records* SYS,DIA,PUL,Date&Time,IHB *Measurements other than Blood Pressure* Heart rate ***Buttons/Switches*** *Power* Start button *Analysis* N/A *Event Marking* N/A *Communication* N/A ***Display/Symbols/Indicators*** *Preparation* Positioning indicator Zero is blinking *Power* Battery detection symbol *Features* N/A *Not described* N/A ***Algorithms*** *Diagnostic* N/A

Comparable Criteria		
	Measurement	***Measurement***
	Sensors	*Sensors*
	Semiconductor sensor	Capacitance sensor
	Buttons/Switches	***Buttons/Switches***
	Measurement Records	*Measurement Records*
	N/A (The App display at mobile device by Bluetooth communication)	Memory recall button - ◀ button
	Function	*Function*
	N/A	Date and time setting - set button
	Display/Symbols/Indicators	***Display/Symbols/Indicators***
	Measurement Procedure	*Measurement Procedure*
	Pressure value Heart mark Wrist movement symbol Cuff fit error symbol	Pressure value Heart mark Pressure bar indicator Date and Time
	Date and Time	*Date and Time*
	N/A (The App display at mobile device by Bluetooth communication)	Year, Month, Day, Hour, Minute
	Post Measurement	*Post Measurement*
	Systolic blood pressure Diastolic blood pressure Pulse rate	Systolic blood pressure Diastolic blood pressure Pulse rate WHO classification Date and Time
	Measurement Records	*Measurement Records*
	N/A (The App display at mobile device by Bluetooth communication)	Systolic blood pressure Diastolic blood pressure Pulse rate WHO classification Date and Time Memory mark symbol Memory number

	Function N/A *Communication* Bluetooth communication symbol ***Algorithms*** *Averages and Differences* N/A *Functions* Wrist movement detection Cuff fit error detection IHB detection *Communication* Bluetooth® Ver.4.1 Low Energy	*Function* Average data *Communication* N/A ***Algorithms*** *Averages and Differences* Average of the all measurements Average of the morning measurements Average of the evening measurements *Functions* WHO classification IHB detection *Communication* N/A

Comments		
Recommendation	**Recommended**	
Date	**12th August 2019**	