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 Kazuhiko Niwano, (Name of a Company Director) a Director of A&D Company LTD, (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]	UA-767F

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]	UA-651

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 UA-651 upper arm blood pressure monitor, for self measurement, according to the European Society of Hypertension International Protocol revision 2010 [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.

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) Model number: UA-767F

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

11) Cuff Fit Error Symbol Movement Error Symbol, %IHB Symbol, Average Symbol

12) carrying case

13) cuff fit error detection, movement error detection, %IHB detection, date and time

14) stores 60 * 4 readings

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 K. Niwano

Company Stamp/Seal

Name Kazuhiko Niwano

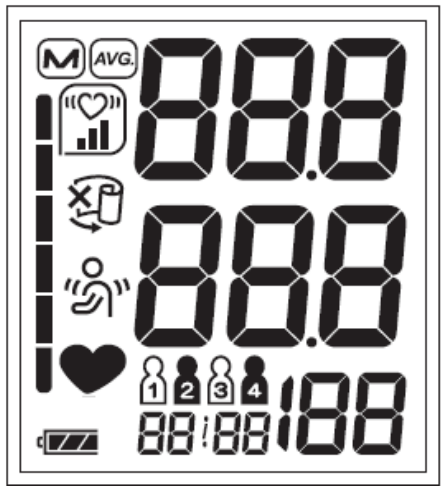
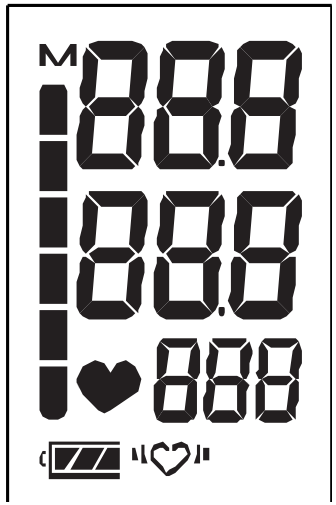
Date 14 Oct, 2014

Signature of Witness

Name

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

Comparison of the A&D UA-767F with the A&D UA-651

Devices	UA-767F	UA-651
Images		
Display		
Validation		ESH 2010
Device 1 Criteria	**Display/Symbols/Indicators:** % Irregular HeartBeat(I.H.B.) detection	

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	Cuff Fit Error detection Movement error detection Date and Time Multi-user **Buttons/Switches:** Up Down Setting	
Same Criteria	Measurement method: Oscillometric measurement Cuffs: D-ring cuff(SlimFit cuff) size: Adult(22-32cm) Inflation: Fuzzy logic inflation Deflation: Constant air release valve Measurement range: Pressure: 0 - 299 mmHg Pulse: 40 - 180 beats/minute Measurement accuracy: Pressure: ±3 mmHg Pulse: ±5 % Power supply: 4 × 1.5V batteries(R6P, LR6 or AA) AC adapter(TB-233) (optional) Display/Symbols:	Measurement method: Oscillometric measurement Cuffs: D-ring cuff(SlimFit cuff) size: Adult(22-32cm) Inflation: Fuzzy logic inflation Deflation: Constant air release valve Measurement range: Pressure: 0 - 299 mmHg Pulse: 40 - 180 beats/minute Measurement accuracy: Pressure: ±3 mmHg Pulse: ±5 % Power supply: 4 × 1.5V batteries(R6P, LR6 or AA) AC adapter(TB-233) (optional) Display/Symbols:

	Error symbols: Err, Err CUF, Err E and Err 9 Algorithms: Irregular HeartBeat(I.H.B.) detection Casing START button, DC Jack	Error symbols: Err, Err CUF, Err E and Err 9 Algorithms: Irregular HeartBeat(I.H.B.) detection Casing START button, DC Jack
Device 2 Criteria		
Web link	http://www.aandd.jp/products/medical/consumer/ua767fs.html	http://www.aandd.jp/products/medical/consumer/ua651_sl.html

Comments	UA-767F the model that added the % Irregular HeartBeat (I.H.B.) detection, Cuff Fit Error detection, Movement error detection and Date and time.
Recommendation	Equivalence Recommended
Date	December 2014