

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,** 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 **UA-767S**

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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A ^e <input type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^f <input checked="" type="checkbox"/>
	3	Artefact/Error Detection	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	4	Microphone(s)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^f <input checked="" type="checkbox"/>
	5	Pressure Transducer	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	6	Cuffs or Bladders	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	7	Inflation Mechanism	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	8	Deflation Mechanism	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
Part II	9	Model Name or Number	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	10	Casing	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	11	Display	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	12	Carrying/Mounting Facilities	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	13	Software other than Algorithm	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	14	Memory Capacity/Number of stored measurements	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	15	Printing Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input checked="" type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input checked="" type="checkbox"/>
	17	Power Supply	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	18	Other Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A ^g <input type="checkbox"/>

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.

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-767S

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

14) stores 60 readings

SECTION C Please check that the following are included with the application

- A manual for the validated device [x]
A manual for the device for which equivalence is being sought [x]
An image of the validated device [x]
An image of the device for which equivalence is being sought [x]
An image of the screen layout of validated device* [x]
An image of the screen layout of the device for which equivalence is being sought* [x]

* 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 [Signature]

Company Stamp/Seal

Name Kazuhiko Niwano

Date 14 Oct, 2014



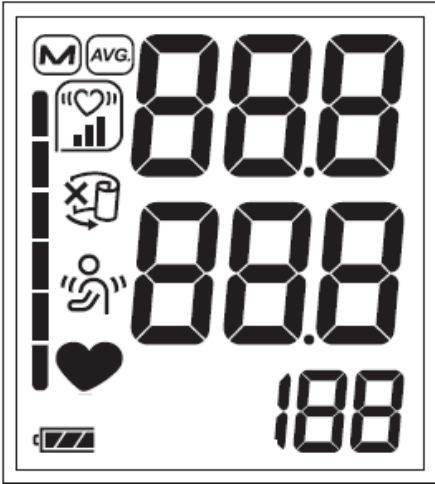
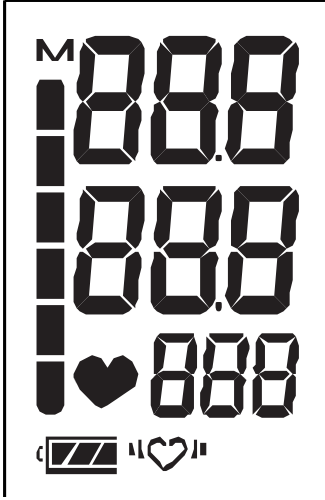
Signature of Witness [Signature]

Name

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



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

Devices	UA-767S	UA-651
Images		
Display		
Validation		ESH 2010

Device 1 Criteria	Algorithms: % Irregular HeartBeat(I.H.B.) detection Cuff Fit Error detection Movement error detection	
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 \times 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	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 \times 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	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-767S is the model that added the % Irregular HeartBeat (I.H.B.) detection, Cuff Fit Error detection and Movement error detection.
Recommendation	Equivalence Recommended
Date	December 2014