

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 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-522/525/533

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-IP 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. [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 type="checkbox"/>	No <input checked="" 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:UB-522/525/533

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

12)carrying case

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

14)UB-543&UB-533:Last 60 measurements each for user1 and user2

UB-522&UB-525:Last 60 measurements

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 November 7, 2017





Signature of Witness *S. Ozaki*

Name Shinobu Ozaki

Address 3-23-14, Higashi-Ikebukuro, Toshima-ku, Tokyo 170-0013 JAPAN



Comparison of the AND UB-522 with the AND UB-543

Devices – Item 9	AND UB-522	AND UB-543
Pictures		
Display Image		
Validation	-	ESH 2010
Category	Wrist Blood pressure monitor	Wrist Blood pressure monitor

Casing – Item 10	<p><i>Dimensions</i> Approx : 56 [W] × 88 [H] × 21.5 [D] mm</p> <p><i>Ports</i> None</p> <p><i>Features</i> Start Button</p>	<p><i>Dimensions</i> Approx : 56 [W] × 88 [H] × 18 [D] mm</p> <p><i>Ports</i> None</p> <p><i>Features</i> start button/set button/ ▲button</p>
Display – Item 11	<p><i>Type</i> liquid crystal display</p>	<p><i>Type</i> liquid crystal display</p>
Carrying/Mounting Facilities – Item 12	Carrying : No	Carrying : Yes
Software other than Algorithm – Item 13	Irregular Heart Beat(I.H.B.) detection	Irregular Heart Beat(I.H.B.) detection Date and Time Multi-user
Memory Capacity Item 14	<p><i>Number of stored measurements</i> Last 60 measurements</p>	<p><i>Number of stored measurements</i> Last 60 measurements each for user1 and user2</p>
Printing Facilities Item 15	N/A	N/A
Communication Facilities – Item 16	N/A	N/A
Power Supply Item 17	2×1.5V alkaline batteries(LR03 or AAA)	2×1.5V alkaline batteries(LR03 or AAA)
Other differences	<p><i>Sensors</i> Semiconductor sensor</p>	<p><i>Sensors</i> Capacitance sensor</p>
Same Criteria	<p>Measurement <i>Accuracy</i> Pressure: ±3 mmHg Pulse: ±5 %</p> <p><i>Method</i> Oscillometric measurement</p> <p><i>Ranges</i> Pressure: 0 - 299 mmHg</p>	<p>Measurement <i>Accuracy</i> Pressure: ±3 mmHg Pulse: ±5 %</p> <p><i>Method</i> Oscillometric measurement</p> <p><i>Ranges</i> Pressure: 0 - 299 mmHg</p>

	<p>Pulse: 40 - 180 beats/minute</p> <p><i>Inflation</i> Constant speed pressurization</p> <p><i>Deflation</i> Rapid exhaust valve</p> <p><i>Cuffs (Please state sizes and materials used)</i> 13.5cm-21.5cm,Nylon</p> <p><i>Measurement Records</i> SYS,DIA,PUL</p> <p><i>Measurements other than Blood Pressure</i> None</p> <p>Buttons/Switches Start button</p> <p>Display/Symbols/Indicators IHB Average Memory Blood pressure classification bar Pressure Indicator bar</p> <p>Algorithms Irregular HeartBeat(I.H.B.) detection</p>	<p>Pulse: 40 - 180 beats/minute</p> <p><i>Inflation</i> Constant speed pressurization</p> <p><i>Deflation</i> Rapid exhaust valve</p> <p><i>Cuffs(Please state sizes and materials used)</i> 13.5cm-21.5cm,Nylon</p> <p><i>Measurement Records</i> SYS,DIA,PUL</p> <p><i>Measurements other than Blood Pressure</i> None</p> <p>Buttons/Switches Start button Set button ▲button</p> <p>Display/Symbols/Indicators IHB Average Memory Multi-user Blood pressure classification bar Pressure Indicator bar Date and Time</p> <p>Algorithms Irregular HeartBeat(I.H.B.) detection</p>
<p>Comparable Criteria</p>		

Comments		
Recommendation	Recommended	
Date	17th November 2017	