

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-525 and the AND UB-543

Devices – Item 9	AND UB-525	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/ ▲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></p>	<p>Measurement <i>Accuracy</i> Pressure: ±3 mmHg Pulse: ±5 %</p> <p><i>Method</i> Oscillometric measurement</p> <p><i>Ranges</i></p>

	<p>Pressure: 0 - 299 mmHg 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 Blood pressure classification bar Pressure Indicator bar</p> <p>Algorithms Irregular HeartBeat(I.H.B.) detection</p>	<p>Pressure: 0 - 299 mmHg 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	