

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,** a Director of **A&D Compnay,Limited,**  
 Name of a Company Director Company name

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

Maker<sup>a</sup> **A&D Compnay,Limited** Address **3-23-14 Higashi-ikebukuro Toshima-Ku,Tokyo 170-0013 JAPAN**

Manufacturer<sup>b</sup> **A&D Compnay,Limited** Address **3-23-14 Higashi-ikebukuro Toshima-Ku,Tokyo 170-0013 JAPAN**

Brand<sup>c</sup> **A&D** Model<sup>d</sup> **UA-611Plus**

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<sup>a</sup> **A&D Compnay,Limited** Address **3-23-14 Higashi-ikebukuro Toshima-Ku,Tokyo 170-0013 JAPAN**

Manufacturer<sup>b</sup> **A&D Compnay,Limited** Address **3-23-14 Higashi-ikebukuro Toshima-Ku,Tokyo 170-0013 JAPAN**

Brand<sup>c</sup> **A&D** Model<sup>d</sup> **UA-1020**

Existing validated blood pressure measuring device.

which has previously passed the **BHS** protocol, the results of which were published as follows:

**Wei-Fang Zeng, Yuan-Yuan Kang, Ming Liu, Yan Li, Ji-Guang Wang.** Validation of the **A&D UA-1020** upper-arm blood pressure monitor with six different-shaped or different-sized cuffs according to the **British Hypertension Society Protocol.**

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 <sup>e</sup> <input type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>f</sup> <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 <sup>f</sup> <input checked="" type="checkbox"/>
	5	Pressure Transducer	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	6	Cuffs or Bladders	Yes <input checked="" type="checkbox"/>	No <input 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 type="checkbox"/>	No <input checked="" 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 <sup>g</sup> <input checked="" type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>g</sup> <input checked="" type="checkbox"/>
	17	Power Supply	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	18	Other Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A <sup>g</sup> <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.
- 6)The shapes of the connector are different
- 9)The equivalent device model name:UA-611Plus
- 10)Difference of case design. Both devices have the different casing.
- 11)The size and the symbols are different
- 13)Difference of Date and Time / Tricheck mode / Cuff Fit Error detection / Body Movement Error detection etc
- 14)UA-611Plus : 60 measurements, UA-1020 : 90 measurements
- 17)UA-611Plus is only battery operation

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



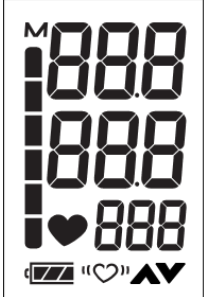
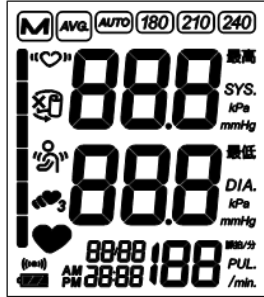
- A manual for the validated device
- A manual for the device for which equivalence is being sought
- Completed DET9 Form
- An image of the device for which equivalence is being sought
- An image of the screen layout of validated device\*
- An image of the screen layout of the device for which equivalence is being sought\*

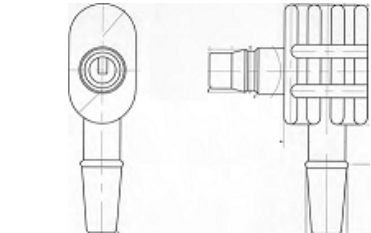
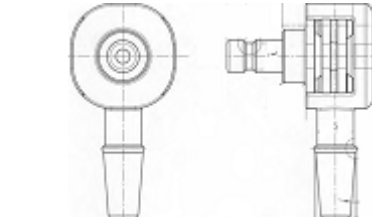
\* Screen layouts shown complete, and without obscuring labels or lines, in manuals need not be included separately.

**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](mailto:info@dableducational.org).

Signature of Director Yasuhiko Shinozaki Company Stamp/Seal  
 Name Yasuhiko Shinozaki  
 Date 18 June 2019  
 Signature of Witness S. Ozaki  
 Name Shinobu Ozaki  
 Address 3-23-14 Higashi-ikebukuro Toshima-Ku, Tokyo 170-0013 JAPAN

Comparison of the AND UA-611Plus with the AND UA-1020

Devices – Item 9	AND UA-611Plus	AND UA-1020
Pictures		
Display Image		
Validation		BHS
Category	Upper Arm Blood pressure monitor	Upper Arm Blood pressure monitor
Casing – Item 10	<p><i>Dimensions</i> Approx : 96 【W】 × 68 【H】 × 130 【D】 mm</p> <p><i>Ports</i> Cuff port</p> <p><i>Features</i> start Button Brand logo printing Model name printing SYS, DIA, PUL printing WHO Classification</p>	<p><i>Dimensions</i> Approx : 140 【W】 × 60 【H】 × 105 【D】 mm</p> <p><i>Ports</i> Cuff port AC adaptor port</p> <p><i>Features</i> start button / set button / ▲button / ▼button Brand logo printing Model name printing SYS, DIA, PUL printing WHO Classification</p>

<b>Display – Item 11</b>	<i>Type</i> liquid crystal display	<i>Type</i> liquid crystal display
<b>Carrying/Mounting Facilities – Item 12</b>	N/A	N/A
<b>Software other than Algorithm – Item 13</b>		Date and Time TriCheck™ mode MyPressure Setting mode (AUTO/180/210/240) Cuff Fit Error detection Body Movement Error detection
<b>Memory Capacity Item 14</b>	<i>Number of stored measurements</i> Last 60 measurements	<i>Number of stored measurements</i> Last 90 measurements
<b>Printing Facilities Item 15</b>	N/A	N/A
<b>Communication Facilities – Item 16</b>	N/A	N/A
<b>Power Supply Item 17</b>	4×1.5V batteries(R6P, LR6 or AA)	4×1.5V batteries(R6P, LR6 or AA) or AC adapter(TB-233C) (optional)
<b>Other differences</b>	<p><i>Other Details on Equivalent device that are different to Validated device</i></p> <p><i>Sensors</i> Semiconductor sensor</p> <p><i>Cuff plug</i> Outline</p> 	<p><i>Other Details on Validated device that are different to Equivalent device</i></p> <p><i>Sensors</i> Capacitance sensor</p> <p><i>Cuff plug</i> Outline</p> 
<b>Same Criteria</b>	<p><b>Measurement</b></p> <p><i>Accuracy</i> Pressure: ±3 mmHg Pulse: ±5 %</p>	<p><b>Measurement</b></p> <p><i>Accuracy</i> Pressure: ±3 mmHg Pulse: ±5 %</p>

	<p><i>Method</i> Oscillometric measurement</p> <p><i>Ranges</i> Pressure: 0 - 299 mmHg Systolic pressure: 60 - 279 mmHg Diastolic pressure: 40 - 200 mmHg Pulse: 40 - 180 beats/minute</p> <p><i>Inflation</i> Automatic inflation</p> <p><i>Deflation</i> Automatic deflation</p> <p><i>Cuffs (Please state sizes and materials used)</i> 16-24cm, 22-32cm, 23-37cm, 31-45cm Nylon</p> <p><i>Sensors</i> Semiconductor sensor</p> <p><i>Measurement Records</i> SYS,DIA,PUL</p> <p><i>Measurements other than Blood Pressure</i> Heart rate WHO classification</p> <p><b>Buttons/Switches</b> <i>Power</i> Start button</p> <p><i>Measurement Records</i> Memory recall button – Start button for 3sec</p> <p><i>Function</i> N/A</p> <p><i>Analysis</i></p>	<p><i>Method</i> Oscillometric measurement</p> <p><i>Ranges</i> Pressure: 0 - 299 mmHg Systolic pressure: 60 - 279 mmHg Diastolic pressure: 40 - 200 mmHg Pulse: 40 - 180 beats/minute</p> <p><i>Inflation</i> Automatic inflation</p> <p><i>Deflation</i> Automatic deflation</p> <p><i>Cuffs(Please state sizes and materials used)</i> 16-24cm, 22-32cm, 23-37cm, 31-45cm Nylon</p> <p><i>Sensors</i> Capacitance sensor</p> <p><i>Measurement Records</i> SYS,DIA,PUL</p> <p><i>Measurements other than Blood Pressure</i> Heart rate WHO classification</p> <p><b>Buttons/Switches</b> <i>Power</i> Start button</p> <p><i>Measurement Records</i> Memory recall button – ▲button or ▼button</p> <p><i>Function</i> Date and time setting - set button</p> <p><i>Analysis</i></p>
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	<p>N/A</p> <p><i>Event Marking</i> N/A</p> <p><i>Communication</i> N/A</p> <p><b><i>Display/Symbols/Indicators</i></b> <i>Preparation</i> Zero is blinking</p> <p><i>Measurement Procedure</i> Pressure value Heart mark Pressure bar indicator</p> <p><i>Post Measurement</i> Systolic blood pressure Diastolic blood pressure Pulse rate WHO classification</p> <p><i>Measurement Records</i> Systolic blood pressure Diastolic blood pressure Pulse rate WHO classification Memory mark symbol Memory number</p> <p><i>Date and Time</i> N/A</p> <p><i>Power</i> Battery detection symbol</p>	<p>N/A</p> <p><i>Event Marking</i> N/A</p> <p><i>Communication</i> N/A</p> <p><b><i>Display/Symbols/Indicators</i></b> <i>Preparation</i> Zero is blinking</p> <p><i>Measurement Procedure</i> Pressure value Heart mark Pressure bar indicator</p> <p><i>Post Measurement</i> Systolic blood pressure Diastolic blood pressure Pulse rate WHO classification Date and Time</p> <p><i>Measurement Records</i> Systolic blood pressure Diastolic blood pressure Pulse rate WHO classification Date and Time Memory mark symbol Memory number</p> <p><i>Date and Time</i> Year, Month, Day, Hour, Minute</p> <p><i>Power</i> Battery detection symbol</p>
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	<p><i>Function</i> Average data</p> <p><i>Communication</i> N/A</p> <p><i>Features</i> N/A</p> <p><i>Not described</i> N/A</p> <p><b>Algorithms</b> <i>Averages and Differences</i> N/A</p> <p><i>Diagnostic</i> N/A</p> <p><i>Functions</i> N/A</p> <p><i>Communication</i> N/A</p>	<p><i>Function</i> Average data TriCheck™ mode MyPressure Setting mode (AUTO/180/210/240) Cuff Fit Error detection Body Movement Error detection</p> <p><i>Communication</i> N/A</p> <p><i>Features</i> N/A</p> <p><i>Not described</i> N/A</p> <p><b>Algorithms</b> <i>Averages and Differences</i> N/A</p> <p><i>Diagnostic</i> N/A</p> <p><i>Functions</i> N/A</p> <p><i>Communication</i> N/A</p>
<b>Comparable Criteria</b>		

<b>Comments</b>	Satisfactory explanations received for cuff connectors and sensor/transducer.
<b>Recommendation</b>	<b>Recommended</b>
<b>Date</b>	<b>05 July 2019</b>