

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^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 **UA-654MR**

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 **UA-651**

Existing validated blood pressure measuring device.

which has previously passed the ESH 2010 protocol, the results of which were published as follows:

Elisabetta Benetti, Claudio Fania, Paolo Palatini. Validation of the A&D BP UA-651 device for home blood pressure measurement according to the European Society of Hypertension International Protocol revision 2010.

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 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 ^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)The equivalent device model name:UA-654MR

10)Difference of case design. Both devices have the different casing.

13)Difference of memory capacity

14)UA-654MR : 60 measurements, UA-651 : 30 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

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.

Signature of Director Yasuhiko Shinozaki Company Stamp/Seal

Name Yasuhiko Shinozaki

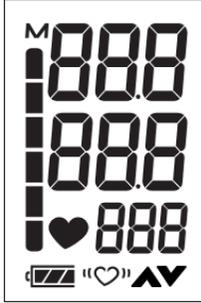
Date 18 June 2019

Signature of Witness Shinobu Ozaki

Name Shinobu Ozaki

Address 3-23-14 Higashi-ikebukuro Toshima-Ku, Tokyo 170-0013 JAPAN

Comparison of the AND UA-654MR with the AND UA-651

Devices – Item 9	AND UA-654MR	AND UA-651
Pictures		
Display Image		
Validation		ESH 2010
Category	Upper Arm Blood pressure monitor	Upper Arm Blood pressure monitor
Casing – Item 10	<p><i>Dimensions</i> Approx : 106 [W] × 67 [H] × 143 [D] mm Excluding the cuff holder</p> <p><i>Ports</i> Cuff port AC adaptor port</p> <p><i>Features</i> start Button Brand logo printing Model name printing SYS, DIA, PUL printing</p>	<p><i>Dimensions</i> Approx : 96 [W] × 68 [H] × 130 [D] mm</p> <p><i>Ports</i> Cuff port AC adaptor port</p> <p><i>Features</i> start button Brand logo printing Model name printing SYS, DIA, PUL printing</p>

	WHO Classification	WHO Classification
Display – Item 11	<i>Type</i> liquid crystal display	<i>Type</i> liquid crystal display
Carrying/Mounting Facilities – Item 12	N/A	N/A
Software other than Algorithm – Item 13	No	No
Memory Capacity Item 14	<i>Number of stored measurements</i> Last 60 measurements	<i>Number of stored measurements</i> Last 30 measurements
Printing Facilities Item 15	N/A	N/A
Communication Facilities – Item 16	N/A	N/A
Power Supply Item 17	4×1.5V batteries(R6P, LR6 or AA) or AC adapter(TB-233C) (optional)	4×1.5V batteries(R6P, LR6 or AA) or AC adapter(TB-233C) (optional)
Other differences	<i>Other Details on Equivalent device that are different to Validated device</i> <i>Sensors</i> Semiconductor sensor	<i>Other Details on Validated device that are different to Equivalent device</i> <i>Sensors</i> Capacitance sensor
Same Criteria	<p>Measurement</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>Measurement</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> Constant speed deflation</p> <p><i>Cuffs (Please state sizes and materials used)</i> 22-32cm 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>Buttons/Switches <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> N/A</p> <p><i>Event Marking</i> N/A</p> <p><i>Communication</i> N/A</p> <p>Display/Symbols/Indicators <i>Preparation</i> Zero is blinking</p>	<p><i>Deflation</i> Constant speed deflation</p> <p><i>Cuffs(Please state sizes and materials used)</i> 22-32cm 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>Buttons/Switches <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> N/A</p> <p><i>Event Marking</i> N/A</p> <p><i>Communication</i> N/A</p> <p>Display/Symbols/Indicators <i>Preparation</i> Zero is blinking</p>
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	<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><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>Algorithms <i>Averages and Differences</i></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><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>Algorithms <i>Averages and Differences</i></p>
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	<p>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>N/A</p> <p><i>Diagnostic</i> N/A</p> <p><i>Functions</i> N/A</p> <p><i>Communication</i> N/A</p>
Comparable Criteria		

Comments		Satisfactory explanation received for sensor/transducer.
Recommendation	Recommended	
Date	05 July 2019	