

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 **Masaki Furukoshi**, 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,Limited** Address **1-243 Asahi, Kitamoto-shi, Saitama, 364-8585 Japan**
 Manufacturer^b **A&D Company,Limited** Address **1-243 Asahi, Kitamoto-shi, Saitama, 364-8585 Japan**
 Brand^c **A&D** Model^d **TM-2657**

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,Limited** Address **1-243 Asahi, Kitamoto-shi, Saitama, 364-8585 Japan**
 Manufacturer^b **A&D Company,Limited** Address **1-243 Asahi, Kitamoto-shi, Saitama, 364-8585 Japan**
 Brand^c **A&D** Model^d **TM-2656**

Existing validated blood pressure measuring device.

which has previously passed the **BHS:1993** protocol, the results of which were published as follows:

Zeng WF, Liu M, Kang YY, Li Y, Wang JG. Validation of the fully automated A&D TM-2656 blood pressure monitor according to the British Hypertension Society Protocol. *Blood Press Monit* 2013;18(4):223-6.

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 type="checkbox"/>	No <input checked="" 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 type="checkbox"/>	No <input checked="" type="checkbox"/>	
	15	Printing Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A ^g <input type="checkbox"/>
	16	Communication Facilities	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input 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.

- 9) Model number is changed to TM-2657 from TM-2656.
- 10) Submitted device and validated device have difference case design, both devices have the different casing.
TM-2656 has two [START/STOP]button on both sides. TM-2657 has one[START/STOP] button on the top.
- 11) TM-2656 has IHB (Irregular heart beat) symbol mark,but TM-2657 not.
- 12) Both devices have the different bottom dimension.
- 13) TM-2657 added a printing function(print out Bar code or QR code on the paper).
- 16) TM-2657 added Bluetooth connection (option).

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 M. Furukoshi Company Stamp/Seal

Name Masaki Furukoshi

Date 3 July, 2015

Signature of Witness S. Osho

Name

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

Comparison of the A&D TM-2657 with the A&D TM-2656

Devices	TM-2657	TM-2656
Pictures		
Display		
Validation		BHS:1993
Device 1 Criteria		<p>Buttons/Switches</p> <p>each [START/STOP]button on the both sides</p> <p>Display/Symbols/Indicators</p> <p>indicators</p> <p>"AM/PM" indicator for time</p> <p>" Irregular Heart Beat(I.H.B.) " "♥" symbol mark indicator</p>
Device 2 Criteria	<p>Buttons/Switches</p> <p>one [START/STOP]button on the top</p> <p>Casing</p> <p>Communication: Bluetooth connection</p>	

<p>Same Criteria</p>	<p>Measurement</p> <p><i>Accuracy</i> Pressure: ±3 mmHg Pulse: ±5 % of reading</p> <p><i>Method</i> Oscillometric measurement method</p> <p><i>Ranges</i> Pressure: 0 - 299 mmHg Pulse: 30 - 240 beats/minute</p> <p><i>Inflation</i> Automatic inflation by air pump</p> <p><i>Deflation</i> Automatic deflation by mechanical exhaust</p> <p><i>Cuffs (Please state sizes and materials used)</i> Winding mechanism operated by geared motor Bladder size: 125(w) x 300(L) mm Applicable arm circumference :7 inches(18.0 cm) to 13.8 inches(35.0 cm)</p> <p><i>Sensors</i> Pressure sensor: Capacitance type pressure transducer</p> <p><i>Measurement Records</i> 3-digit display LED and thermal printer (SYS DIA PR)</p> <p>Buttons/Switches</p> <p><i>Power</i> Switching AC Power supply unit 100-240V AC 50-60Hz</p> <p><i>Function</i> [SELECT]button: used to select function [▲] button: use to change function [COUNT]button: display the number of measurements</p>	<p>Measurement</p> <p><i>Accuracy</i> Pressure: ±3 mmHg Pulse: ±5 % of reading</p> <p><i>Method</i> Oscillometric measurement method</p> <p><i>Ranges</i> Pressure: 0 - 299 mmHg Pulse: 30 - 240 beats/minute</p> <p><i>Inflation</i> Automatic inflation by air pump</p> <p><i>Deflation</i> Automatic deflation by mechanical exhaust</p> <p><i>Cuffs(Please state sizes and materials used)</i> Winding mechanism operated by geared motor Bladder size: 125(w) x 300(L) mm Applicable arm circumference :7 inches(18.0 cm) to 13.8 inches(35.0 cm)</p> <p><i>Sensors</i> Pressure sensor: Capacitance type pressure transducer</p> <p><i>Measurement Records</i> 3-digit display LED and thermal printer(SYS DIA PR)</p> <p>Buttons/Switches</p> <p><i>Power</i> Switching AC Power supply unit 100-240V AC 50-60Hz</p> <p><i>Function</i> [SELECT]button: used to select function [▲] button: use to change function [COUNT]button: display the number of measurements</p>
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	<p>Display/Symbols/Indicators</p> <p><i>Preparation</i> “0” lighting</p> <p><i>Measurement Procedure</i> Display the pressure value during measurement</p> <p><i>Post Measurement</i> systolic blood pressure, diastolic blood pressure, and pulse</p> <p><i>Date and Time</i> Display Time Printing date and time</p> <p><i>Function</i> Function number during the function changing mode</p> <p><i>Communication</i> RS-232C connection (Max 2channels, mini-DIN / D-Sub)</p> <p>Algorithms</p> <p><i>Diagnostic</i> "Irregular Heart Beat(I.H.B.)" "♥"symbol mark printing</p> <p>Casing</p> <p><i>Display</i> 3-digit display LED(SYS DIA PR) 2 LED lamp(measurement status)</p>	<p>Display/Symbols/Indicators</p> <p><i>Preparation</i> “0” lighting</p> <p><i>Measurement Procedure</i> Display the pressure value during measurement</p> <p><i>Post Measurement</i> systolic blood pressure, diastolic blood pressure, and pulse</p> <p><i>Date and Time</i> Display Time Printing date and time</p> <p><i>Function</i> Function number during the function changing mode</p> <p><i>Communication</i> RS-232C connection (Max 2 channels, mini-DIN / D-Sub)</p> <p>Algorithms</p> <p><i>Diagnostic</i> "Irregular Heart Beat(I.H.B.)" "♥"symbol mark printing</p> <p>Casing</p> <p><i>Display</i> 3-digit display LED(SYS DIA PR) 2 LED lamp(measurement status)</p>
<p>Comparable Criteria</p>	<p>Buttons/Switches</p> <p>A START/STOP button is on the top : Blood pressure measurement is started /stopped</p> <p>FAST STOP button: All functions are stopped (Change the name of the button)</p> <p><i>Communication</i> SD Card interface as standard equipment (For maintenance)</p>	<p>Buttons/Switches</p> <p>START/STOP buttons are on the both sides: Blood pressure measurement is started /stopped</p> <p>EMERGENCY STOP button: All functions are stopped</p> <p><i>Communication</i> Optional USB interface board (For maintenance)</p>

Comments		Both of these devices are intended for public use. The main difference is that TM-2657 model changed the apparent design. TM-2657 also is added a software function (print out bar-code or QR code included ID, date, and blood pressure measurement on the paper).
Recommendation	<i>Equivalence Recommended</i>	
Date	8 October 2015	