dabl®Educational Trust

Declaration of Equivalence Form

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,
Name of a Company Director

a Director of   A&D Compnay,Limited,
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 JAPAN	Higashi-ikebukuro	Toshima-Ku,Tokyo	170-0013
Manufacturer[b]	A&D Compnay,Limited	_Address_	3-23-14 JAPAN	Higashi-ikebukuro	Toshima-Ku,Tokyo	170-0013
Brand[c]	A&D	_Model[d]_	TM-2440			

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 JAPAN	Higashi-ikebukuro	Toshima-Ku,Tokyo	170-0013
Manufacturer[b]	A&D Compnay,Limited	_Address_	3-23-14 JAPAN	Higashi-ikebukuro	Toshima-Ku,Tokyo	170-0013
Brand[c]	A&D	_Model[d]_	TM-2441			

Existing validated blood pressure measuring device.

which has previously passed the ISO81060-2 protocol, the results of which were published as follows:

Kario.K, Hoshide.S, et al. Validation of the TM-2441 ambulatory blood pressure measurement device according to the ISO 81060-2:2013 standard
Full reference

The only differences between the devices involve the following components:
Tick one box for each item 1–18.

			Yes	No	N/A
Part I	1	Algorithm for Oscillometric Measurements	☐	☒	N/A[e] ☐
	2	Algorithm for Auscultatory Measurements	☐	☐	N/A[f] ☒
	3	Artefact/Error Detection	☐	☒	
	4	Microphone(s)	☐	☐	N/A[f] ☒
	5	Pressure Transducer	☐	☒	
	6	Cuffs or Bladders	☐	☒	
	7	Inflation Mechanism	☐	☒	
	8	Deflation Mechanism	☐	☒	
Part II	9	Model Name or Number	☒	☐	
	10	Casing	☒	☐	
	11	Display	☒	☐	
	12	Carrying/Mounting Facilities	☐	☒	
	13	Software other than Algorithm	☒	☐	
	14	Memory Capacity/Number of stored measurements	☐	☒	
	15	Printing Facilities	☐	☐	N/A[g] ☒
	16	Communication Facilities	☒	☐	N/A[g] ☐
	17	Power Supply	☐	☒	
	18	Other Facilities	☐	☒	N/A[g] ☐

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.

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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)The equivalent device model name:TM-2440

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

11)The display of TM-2440 is only OLED (display of TM-2441 is OLED and LCD).

13)Difference of switch function, sencing acceleration, Bluetooth communication, etc.

16)Bluetooth communication can not be used.

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   22 July 2019

Signature of Witness

Name   Shinobu Ozaki

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

Comparison of the A&D TM2440 with the A&D TM2441

Devices – Item 9	A&D TM2440	A&D TM2441
Pictures		
Display Image		
Validation		ISO80601-2:2013
Category	Ambulatory Blood Pressure Monitor	Ambulatory Blood Pressure Monitor
Casing – Item 10	*Dimensions* Approx：95【D】 × 66【W】 × 24.5【H】 mm *Ports* Cuff port USB connector port *Features* START/STOP switch for ABPM EVENT switch	*Dimensions* Approx：95【D】 × 66【W】 × 24.5【H】 mm *Ports* Cuff port USB connector port *Features* START/STOP switch for ABPM START/STOP switch for Self Measurement EVENT switch Exchange AUTO switch between ABPM and Self Measurement

Display – Item 11	*Type*
	    OLED display (dot matrix)
		Type
		    OLED display (dot matrix) + liquid crystal display

Carrying/Mounting Facilities – Item 12	N/A	N/A
Software other than Algorithm – Item 13	Auto blood pressure measurement USB communication	Auto blood pressure measurement Self blood pressure measurement Changing between ABPM and Self Acceleration sensing and memory Temperature and Barometric pressure sensing and memory Bluetooth communication USB communication

Memory Capacity Item 14	*Number of stored measurements*
	    600 blood pressure measurements
		Number of stored measurements
		    600 blood pressure measurements

Printing Facilities Item 15	N/A	N/A
Communication Facilities – Item 16	USB communication	Bluetooth® Ver.4.1 Low Energy USB communication
Power Supply Item 17	2×1.5V batteries(LR6 or AA) Alkaline battery or Nickel-hydrogen battery 1900mAh or more	2×1.5V batteries(LR6 or AA) Alkaline battery or Nickel-hydrogen battery 1900mAh or more

Other differences	*Other Details on Equivalent device that are different to Validated device*
	Sensors
	    N/A
		Other Details on Validated device that are different to Equivalent device
		Sensors
		    N/A

Same Criteria	***Measurement***
	Sensors
	  Semiconductor sensor
	
	Accuracy
	Pressure: ±3 mmHg
	Pulse: ±5 %
	
	Method
	Oscillometric measurement
		Measurement
		Sensors
		  Semiconductor sensor
		
		Accuracy
		Pressure: ±3 mmHg
		Pulse: ±5 %
		
		Method
		Oscillometric measurement

<table>
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Ranges
Pressure: 0 - 299 mmHg
Systolic pressure: 60 - 280 mmHg
Diastolic pressure: 30 - 160 mmHg
Pulse: 30 - 200 beats/minute

Inflation
  Rolling pump

Deflation
  Electromagnetic constant exhaust valve

Cuffs (Please state sizes and materials used)
  Small cuff: 15cm-22cm Nylon
  Adult cuff: 20cm-31cm Nylon
  Large cuff: 36cm-50cm Nylon
  Extra large cuff: 36cm-50cm Nylon

Measurement Records
  Date&Time, SYS,DIA,PUL

Measurements other than Blood Pressure
  Pulse rate(PUL)

Buttons/Switches
  Power
  N/A

  Analysis
  N/A

  Function
   EVENT switch

  Event Marking
  N/A

  Communication
  N/A

</td><td>

Ranges
Pressure: 0 - 299 mmHg
Systolic pressure: 60 - 280 mmHg
Diastolic pressure: 30 - 160 mmHg
Pulse: 30 - 200 beats/minute

Inflation
  Rolling pump

Deflation
  Electromagnetic constant exhaust valve

Cuffs(Please state sizes and materials used)
  Small cuff: 15cm-22cm Nylon
  Adult cuff: 20cm-31cm Nylon
  Large cuff: 36cm-50cm Nylon
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Measurement Records
  Date&Time, SYS,DIA,PUL

Measurements other than Blood Pressure
  Pulse rate(PUL)

Buttons/Switches
  Power
  N/A

  Analysis
  N/A

  Function
   EVENT switch

  Event Marking
  N/A

  Communication
  N/A

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	Display/Symbols/Indicators
	Preparation
	  Positioning indicator
	  Zero is blinking
	
	Date and Time
	  Year, Month, Day, Hour, Minute
	
	Power
	  Battery detection symbol
	
	Post Measurement
	  Systolic blood pressure
	  Diastolic blood pressure
	  Pulse rate
	  Date and Time
	
	Measurement Records
	  Systolic blood pressure
	  Diastolic blood pressure
	  Pulse rate
	  Date and Time
	  Memory number
	
	Not described
	  N/A
	
	Algorithms
	Averages and Differences
	  N/A
	
	Diagnostic
	  N/A
		Display/Symbols/Indicators
		Preparation
		  Positioning indicator
		  Zero is blinking
		
		Date and Time
		  Year, Month, Day, Hour, Minute
		
		Power
		  Battery detection symbol
		
		Post Measurement
		  Systolic blood pressure
		  Diastolic blood pressure
		  Pulse rate
		  Date and Time
		
		Measurement Records
		  Systolic blood pressure
		  Diastolic blood pressure
		  Pulse rate
		  Date and Time
		  Memory number
		
		Not described
		  N/A
		
		Algorithms
		Averages and Differences
		  N/A
		
		Diagnostic
		  N/A

Comparable Criteria	**Buttons/Switches**
	Measurement Records
	  START/STOP switch for ABPM
		Buttons/Switches
		Measurement Records
		  START/STOP switch for ABPM
		  START/STOP switch for Self Measurement

	Display/Symbols/Indicators *Measurement Procedure* Pressure value *Features* N/A *Function* ABPM setting *Communication* USB communication symbol **Algorithms** *Functions* IHB detection *Communication* USB communication	***Display/Symbols/Indicators*** *Measurement Procedure* Pressure value Heart mark (on LCD) *Features* Display the minutes until the measurement (on LCD) *Function* ABPM setting Self Measurement setting *Communication* USB communication symbol (on LCD) Bluetooth communication symbol (on LCD) **Algorithms** *Functions* IHB detection (display on LCD) *Communication* Bluetooth® Ver.4.1 Low Energy USB communication

Comments		
Recommendation	**Recommended**	
Date	**12ᵗʰ August 2019**	