

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 **Simon Ouyang,** a Director of **AViTA Corporation,**
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 **AViTA Corporation** Address **9F, NO.78, SEC.1, KWANG-FU RD., SAN-Chung District, New Taipei City 24158 TAIWAN R.O.C.**

Manufacturer^b **PIKDARE S.r.l** Address **Via Saldarini Catelli, 10
22070 Casnate con Bernate (CO)-ITALY**

Brand^c **Pic solution** Model^d **mobileRAPID WRIST**
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 **AViTA Corporation** Address **9F, NO.78, SEC.1, KWANG-FU RD., SAN-Chung District, New Taipei City 24158 TAIWAN R.O.C.**

Manufacturer^b **AViTA Corporation** Address **9F, NO.78, SEC.1, KWANG-FU RD., SAN-Chung District, New Taipei City 24158 TAIWAN R.O.C.**

Brand^c **AViTA** Model^d **BPM17**
Existing validated blood pressure measuring device.

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

Kang Y-Y, Chen Qi, Liu C-Y, Li Y, and Wang J-G. Validation of the AViTA BPM17 wrist blood pressure monitor for home blood pressure monitoring 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 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 type="checkbox"/>	N/A ^B <input checked="" type="checkbox"/>
	16	Communication Facilities	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A ^B <input type="checkbox"/>
	17	Power Supply	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	18	Other Facilities	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A ^B <input type="checkbox"/>

An explanation of each item ticked "Yes" must be included in Section B or on a separate sheet.

- Notes:
- Provide the name and address of the actual maker of the device.
 - Provide the name and address of the legal manufacturer of the device, even if it is the same as that of the maker.
 - Provide the name of the brand under which it is sold, even if it is the same as that of the manufacturer or maker.
 - Provide the model name. If alternative or internal model names are used, include all. Each device must be uniquely identifiable.
 - Only tick N/A (Not Applicable) if neither device measures blood pressure using the oscillometric method.

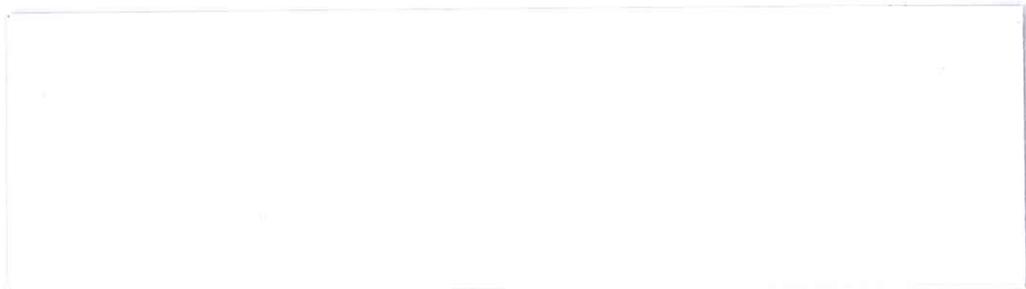
SECTION B An explanation for each item, 1 to 18, ticked "Yes" in Section A must be provided here or in an attached document. All differences between the devices must be described.

- 9) The model name is different. mobileRAPID WRIST for new device and validated device is BPM17.
10) The designs of the case are different.
11) The size and displayed data are different.
12) Carrying/Mounting Facilities are different.
13) Software other than algorithm is different.
16) mobileRAPID WRIST has BLE module. When device finish measuring, the measurement data will be sent to receiver by BLE module.
18) Other Facilities are different.

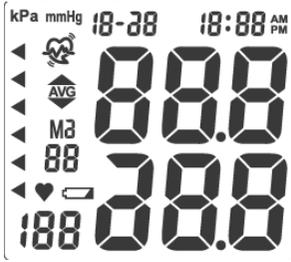
SECTION C Please check that the following are included with the application
A manual for the validated device
A manual for the device for which equivalence is being sought
An image of the validated device
An image of the device for which equivalence is being sought
An image of the screen layout of validated 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 [Signature] Company Stamp/Seal [Red Seal]
Name Simon Ouyang
Date
Signature of Witness [Signature]
Name Jonathan Chen
Address 9F, NO.78, SEC.1, KWANG-FU RD., SAN-Chung District, New Taipei City 24158 TAIWAN R.O.C.



Comparison of the PIC solution mobileRAPID Wrist with the AViTA BPM17

Devices – Item 9	PIC solution mobileRAPID Wrist	AViTA BPM17
<p>Pictures</p>	<p>Image height: Picture 3.2 cm</p>  <p>The image shows the PIC solution mobileRAPID Wrist device. It has a white face with a red PIC logo at the top. The display shows 'mmHg 18-28 18:88 AM'. Below the display are buttons for 'SYS mmHg', 'START STOP', and 'SET'. There are also two user selection buttons labeled '1' and '2'.</p>	<p>Image height: Picture 3.2 cm</p>  <p>The image shows the AViTA BPM17 device. It is a white wrist-worn device with a digital display showing '9-23 10:38 AM'. The display also shows 'M3 08' and '6.8'. There are buttons for 'SET', 'M1', and 'M2'.</p>
<p>Display Image</p>	<p>Image height: Picture 4 cm</p>  <p>The image shows a close-up of the PIC solution mobileRAPID Wrist display. It displays 'mmHg 18-28 18:88 AM'. Below the main display are 'AVG', 'M3 88', and '188' readings. There are also heart rate and pulse icons.</p>	<p>Image height: Picture 4 cm</p>  <p>The image shows a close-up of the AViTA BPM17 display. It displays 'kPa mmHg 18-28 18:88 AM'. Below the main display are 'AVG', 'M3 88', and '188' readings. There are also heart rate and pulse icons.</p>
<p>Validation</p>	<p>ESH 2010</p>	<p>ESH 2010</p>
<p>Category</p>	<p>Wrist Type Blood Pressure Monitor</p>	<p>Wrist Type Blood Pressure Monitor</p>
<p>Casing – Item 10</p>	<p>Dimensions approx. 91 x 74.5 x 15mm (W x H x D)</p> <p>Ports Cuff Port</p> <p>Features N/A</p>	<p>Dimensions 94.5 x 68 x 15mm (W x H x D)</p> <p>Ports Cuff Port</p> <p>Features N/A</p>

Display – Item 11	Type LCD	Type LCD
Carrying/Mounting Facilities – Item 12		
Software other than Algorithm – Item 13		
Memory Capacity Item 14	Number of stored measurements 2x90	Number of stored measurements 2x90
Printing Facilities Item 15		
Communication Facilities – Item 16	BLE 4.2	N/A
Power Supply Item 17	2*AAA Batteries	2*AAA Batteries
Other differences	Other Details on Equivalent device that are different to Validated device Measuring Range: Blood Pressure- 40~255mmHg	Other Details on Validated device that are different to Equivalent device Measuring Range: Blood Pressure- 30~280mmHg
Same Criteria	<p>Measurement Accuracy Blood Pressure : ± 3 mmHg Pulse rate : ± 4% of reading</p> <p>Method Oscillometric</p> <p>Ranges Pulse Rate: 40~199 beat/min.</p> <p>Inflation Yes</p> <p>Deflation N/A</p> <p>Cuffs (Please state sizes and materials used) approx. 12.5~21 cm</p>	<p>Measurement Accuracy Blood Pressure : ± 3 mmHg Pulse rate : ± 4% of reading</p> <p>Method Oscillometric</p> <p>Ranges Pulse Rate: 40~199 beat/min.</p> <p>Inflation Yes</p> <p>Deflation N/A</p> <p>Cuffs(Please state sizes and materials used)</p>

	<p><i>Sensors</i> US9111-006-S</p> <p><i>Measurement Records</i> Memory recall number</p> <p><i>Measurements other than Blood Pressure</i> Pulse rate</p> <p>Buttons/Switches</p> <p><i>Power</i> START/POWER Button (on/off)</p> <p><i>Measurement Records</i> Memory Recall Button – MEM1 & MEM2</p> <p><i>Function</i> Date and Time Set Button - SET</p> <p><i>Analysis</i> N/A</p> <p><i>Event Marking</i> N/A</p> <p><i>Communication</i> BLE 4.0</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i> N/A</p> <p><i>Measurement Procedure</i> Inflation symbol Deflation symbol Heartbeat symbol during inflation Irregular heartbeat symbol</p> <p><i>Post Measurement</i> Systolic blood pressure Diastolic blood pressure</p>	<p>approx. 12.5~21 cm</p> <p><i>Sensors</i> US9111-006-S</p> <p><i>Measurement Records</i> Memory recall number</p> <p><i>Measurements other than Blood Pressure</i> Pulse rate</p> <p>Buttons/Switches</p> <p><i>Power</i> START/POWER Button (on/off)</p> <p><i>Measurement Records</i> Memory Recall Button – MEM1 & MEM2</p> <p><i>Function</i> Date and Time Set Button - SET</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</p> <p><i>Preparation</i> N/A</p> <p><i>Measurement Procedure</i> Inflation symbol Deflation symbol Heartbeat symbol during inflation Irregular heartbeat symbol</p> <p><i>Post Measurement</i> Systolic blood pressure</p>
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	<p>Pulse rate 2013 ESH/ESC</p> <p><i>Measurement Records</i> Memory recall number</p> <p><i>Date and Time</i> Date and Time</p> <p><i>Power</i> Low Battery detection symbol</p> <p><i>Function</i> Backlight</p> <p><i>Communication</i> BLE 4.2</p> <p><i>Features</i> N/A</p> <p><i>Not described</i></p> <p>Algorithms <i>Averages and Differences</i> No Average function</p> <p><i>Diagnostic</i> N/A</p> <p><i>Functions</i> N/A</p> <p><i>Communication</i> N/A</p>	<p>Diastolic blood pressure Pulse rate WHO indicator</p> <p><i>Measurement Records</i> Memory recall number</p> <p><i>Date and Time</i> Date and Time</p> <p><i>Power</i> Low Battery detection symbol</p> <p><i>Function</i> Average</p> <p><i>Communication</i> N/A</p> <p><i>Features</i> N/A</p> <p><i>Not described</i></p> <p>Algorithms <i>Averages and Differences</i> Average of the last 3 measurement</p> <p><i>Diagnostic</i> N/A</p> <p><i>Functions</i> N/A</p> <p><i>Communication</i> N/A</p>
<p>Comparable Criteria</p>		

Comments		Blood Pressure Measuring Range for mobileRAPID is 40~255mmHg, whereas the validated AVITA BPM17 has a range of 30~280mmHg.
		Manufacturer reply; The measurement algorithm is the same. The only difference is that AVITA added the logical verification to limit the range.
Recommendation	Recommended	
Date	23 July 2018	