

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 **Bill Huang,** 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 **Kaz Europe Sàrl** Address **Place Chauderon 18, 1003 Lausanne, Switzerland**
 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 **Braun** Model^d **BUA7200**
 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 (Wellex)** Model^d **BPM64**
 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 Q., Liu C.Y., Li Y. and Wang J.G. Validation of the AViTA BPM64 upper-arm 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 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 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 type="checkbox"/>	N/A ^g <input checked="" 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.

(6) Cuff

New device has the same cuff size and same bladder but different colors (white / blue) and different materials on outside of cuff (white "faux leather" - PVC)

(9) Model Name or Number

Braun BUA7200 (marketing name ActivScan 9), including regional (language) versions BUA7200WE and BUA7200CEME

(10) Casing

New model has a different housing design and different buttons configuration: dial knob (scroll wheel) with touch sensing buttons

(11) Display

New Device has a color graphic display (dot matrix) based on TFT-LCD technology

(13) SW other than algorithm

New device has advanced functions like 7,14 & 30 days average calculation, graphical and calendar views of memorized readings and embedded tutorials. Visuals on display are also different due to graphic dot-matrix display

(14) Memory capacity/Number of stored measurements

New device has 2x200 readings which are only available for on-device display and also for download thru Bluetooth connection with smartphone

(16) Communication Facilities

New device has Bluetooth Low Energy (BT Smart) communication facility for download of stored readings and automatic date/time settings when connected to smartphone (dedicated APP required).

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.



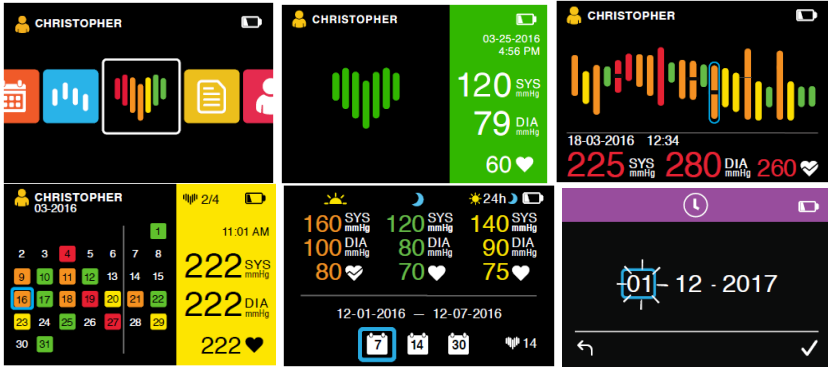
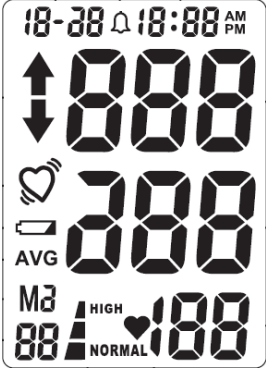
Signature of Director _____ Company Stamp/Seal
Name Bill Huang **AVITA CORPORATION**

Date 15-March-2018 
Authorized Signature

Signature of Witness _____
Name Jonathan Chen **AVITA CORPORATION**


Address 9F, NO.78, SEC.1, KWANG-FU RD., SAN CHING DISTRICT, NEW TAIPEI CITY 24158 Taiwan R.O.C. 

Comparison with BRAUN BUA7200 and AViTA BPM64

Devices – Item 9	BRAUN BUA7200	AViTA BPM64
Pictures		
Display image	<p>Full-colour TFT-LCD dot matrix display with bitmap graphics that change with context. Some examples given below:</p> 	<p>Classic B&W LCD display:</p> 
Validation		ESH 2010 (IP2)
Category	Arm Type Blood Pressure Monitor	Arm Type Blood Pressure Monitor
Casing – Item 10	<p><i>Dimensions</i> 99.5 * 99 * 141.5 mm (W * H *D)</p> <p><i>Ports</i></p>	<p><i>Dimensions</i> 113 * 140 * 57 mm (W * H *D)</p> <p><i>Ports</i></p>

	<p>Cuff Port</p> <p><i>Features</i> 2 buttons, 2 touch buttons, 1 dial knob (navigation scroll wheel)</p>	<p>Cuff Port</p> <p><i>Features</i> 4 buttons</p>
Display – Item 11	<p><i>Type</i> Full-colour dot matrix TFT LCD</p>	<p><i>Type</i> TN Segment LCD</p>
Carrying/Mounting Facilities – Item 12	N/A	N/A
Software other than Algorithm – Item 13	<p>New device has a Graphic User Interface (GUI) with a main menu based on icons and dial knob (scroll wheel) navigation. Main functions “measurement” and “home” available with touch buttons. Advanced functions like 7,14 & 30 days average calculation. Graphical and calendar views of memorized readings. Embedded tutorials for accurate measurement and WHO colour chart. Visuals on display are different due to graphic dot-matrix display</p>	<p>Average 3 last measurements Alarms</p>
Memory Capacity Item 14	<p><i>Number of stored measurements</i> 200 memories x 2 users (2*200)</p>	<p><i>Number of stored measurements</i> 90 memories x 2 users (2*90)</p>
Printing Facilities Item 15	N/A	N/A
Communication Facilities – Item 16	Bluetooth LE (BT Smart 4.0) to transfer measurement data to smartphone (with dedicated APP)	N/A
Power Supply Item 17	4 * AA Batteries (6V)	4 * AA Batteries (6V)
Other differences	N/A	N/A
Same Criteria	<p>Measurement <i>Accuracy</i> Blood Pressure Accuracy ± 3 mmHg Pulse Accuracy $\pm 4\%$</p> <p><i>Method</i> Oscillometric</p>	<p>Measurement <i>Accuracy</i> Blood Pressure Accuracy ± 3 mmHg Pulse Accuracy $\pm 4\%$</p> <p><i>Method</i> Oscillometric</p>

	<p><i>Ranges</i> Blood Pressure: 40~255mmHg Pulse Rate: 40~199 beat/min.</p> <p><i>Inflation</i> Automatic inflation by internal pump Zero pressure check before inflation</p> <p><i>Deflation</i> Automatic by exhaust valve</p> <p><i>Cuffs (Please state sizes and materials used)</i> Cuff size: 22-42 cm Bladder dimension: 120 x 235 mm Materials:</p> <ul style="list-style-type: none"> • PVC « faux-leather » in white color on cuff outside • Stretchy polyester in blue/purple color inside cuff • Velcro loop and hook in grey color <p><i>Sensors</i> US-9111-006-S (semiconductor)</p> <p><i>Measurement Records</i> YES: SYS, DIA, Pulse, IHB, Date & time</p> <p><i>Measurements other than Blood Pressure</i> Pulse (heart rate) Irregular heartbeat Date & time</p> <p>Buttons/Switches <i>Power</i> POWER Button (On / Off). Also used to abort measurement</p> <p><i>Measurement Records</i> Records access from GUI menu (History/Graph view)</p> <p><i>Function</i></p>	<p><i>Ranges</i> Blood Pressure: 40~255mmHg Pulse Rate: 40~199 beat/min.</p> <p><i>Inflation</i> Automatic inflation by internal pump Zero pressure check before inflation</p> <p><i>Deflation</i> Automatic by exhaust valve</p> <p><i>Cuffs (Please state sizes and materials used)</i> Cuff size: 22-42 cm Bladder dimension: 120 x 235 mm Materials:</p> <ul style="list-style-type: none"> • Polyester in black color on cuff outside • Stretchy polyester in black color inside cuff • Velcro loop and hook in black color <p><i>Sensors</i> US-9111-006-S (semiconductor)</p> <p><i>Measurement Records</i> YES: SYS, DIA, Pulse, IHB, Date & time</p> <p><i>Measurements other than Blood Pressure</i> Pulse (heart rate) Irregular heartbeat Date & time</p> <p>Buttons/Switches <i>Power</i> POWER (On / Off) & START Button. Also used to abort measurement</p> <p><i>Measurement Records</i> Memory Recall Buttons – User 1 / User 2</p> <p><i>Function</i></p>
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	<p>Start measurement Button (touch button)</p> <p><i>Analysis</i> N/A</p> <p><i>Event Marking</i> N/A</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i> Zero pressure check: during “3-2-1 countdown” animation on LCD</p> <p><i>Measurement Procedure</i> Inflation: show progress bar animation Deflation Display Results</p> <p><i>Post Measurement</i> Systolic blood pressure Diastolic blood pressure Pulse (heart rate) WHO indicator Irregular Heartbeat indicator (IHB) Errors, if any (ERROR 0, 1, 2, 3)</p> <p><i>Measurement Records</i> YES: SYS, DIA, Pulse, IHB, Date & time</p> <p><i>Date and Time</i> Yes (visible when measurement completes)</p> <p><i>Power</i> Low Battery symbol</p> <p><i>Features</i> Average page view</p> <p><i>Not described</i> N/A</p>	<p>Average of last 3 measurements for User 1 or User 2 Alarm setting</p> <p><i>Analysis</i> N/A</p> <p><i>Event Marking</i> N/A</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i> Zero pressure check: Up/Down arrow symbol </p> <p><i>Measurement Procedure</i> Inflation: show cuff pressure in numerical value and pulse symbol Deflation Display Results</p> <p><i>Post Measurement</i> Systolic blood pressure Diastolic blood pressure Pulse (heart rate) WHO indicator Irregular Heartbeat indicator (IHB) Errors, if any (Err 0, 1, 2, 3)</p> <p><i>Measurement Records</i> YES: SYS, DIA, Pulse, IHB, Date & time</p> <p><i>Date and Time</i> Yes (always visible)</p> <p><i>Power</i> Low Battery symbol</p> <p><i>Features</i> AVG symbol</p> <p><i>Not described</i></p>
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	<p>Algorithms Averages and Differences N/A</p> <p><i>Diagnostic</i> WHO scale with colour-coded background on display</p> <p><i>Functions</i> N/A</p>	<p>N/A</p> <p>Algorithms Averages and Differences N/A</p> <p><i>Diagnostic</i> WHO scale</p> <p><i>Functions</i> N/A</p>
<p>Comparable Criteria</p>	<p><i>Measurement Records</i> Memory capacity: 200 measurements for 2 users (2*200)</p> <p>Buttons/Switches Home Button (touch button) – for GUI Navigator Dial knob (scroll wheel) for function selection in GUI Enter Button (for confirmation in GUI) in centre of dial knob.</p> <p><i>Measurement Records</i> Access thru menu in GUI</p> <p><i>Function</i> Navigation with dial knob and centre button to access all functions from GUI menu</p> <p><i>Analysis</i> Averages functions accessible from GUI menu</p> <p><i>Event Marking</i> Delete individual reading from GUI menu (History)</p> <p><i>Communication</i> Bluetooth connection (pairing) menu</p> <p>Display/Symbols/Indicators</p> <p><i>Post Measurement</i> WHO indicator in 4 colours, with ESH 2013 hypertension level for</p>	<p><i>Measurement Records</i> Memory capacity: 90 measurements for 2 users (2*90)</p> <p>Buttons/Switches N/A</p> <p><i>Measurement Records</i> Memory Recall Buttons–User 1 / User 2</p> <p><i>Function</i> Time & Date Setting (SET button) + Alarm Memory view for User 1 or User 2</p> <p><i>Analysis</i> Last 3 readings average, in memory mode</p> <p><i>Event Marking</i> N/A</p> <p><i>Communication</i> N/A</p> <p>Display/Symbols/Indicators</p> <p><i>Post Measurement</i> WHO indicator, 3-levels (Normal, High-Normal, High)</p>

	<p>home use (135/85mmHg)</p> <p><i>Measurement Records</i> Measurements records visible in different views: history graph and monthly calendar</p> <p><i>Date and Time</i> Time and date in EU or US format – selectable by user</p> <p><i>Communication</i> Bluetooth pairing progress and status</p> <p><i>Features</i> All functions accessible in GUI menu:</p> <ul style="list-style-type: none"> • Graphical history view with colour bars • Averages (AM, PM and 24-hour) for past 7, 14 and 30 days. • Calendar view with colour-coded daily averages • User selection and user name. Add/delete user. • Device settings • Time & date setting and format (EU/US) • Bluetooth pairing function • Help Function (animated guide) and WHO colour chart 	<p><i>Measurement Records</i> Memory recall number</p> <p><i>Date and Time</i> US format only</p> <p><i>Communication</i> N/A</p> <p><i>Features</i> AVG symbol for last 3 measurements Alarms</p>
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Comments		
Recommendation	Recommended	
Date	23 March 2018	