

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 **Paul Hartmann AG** Address **Paul Hartmann AG, Paul-Hartmann-Strasse 12, 89522 Heidenheim, Germany**

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 **Hartmann** Model^d **HARTMANN Veroyal BPW22**

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 **BPM15S**

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, Zeng W-F, Liu M, Li Y, and Wang J-G. Validation of the AVITA BPM63S wrist blood pressure monitor for home blood pressure monitoring according to the European Society of Hypertension International Protocol revision 2010.

Blood Pressure M

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 type="checkbox"/> | No <input checked="" 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.

- 9) The model name is different. Veroval BPW22 for new device and validated device is BPM15S
10) The designs of the case are different.
11) The size and displayed data are different.
12) Carrying/Mounting Facilities are different.
14) Veroval BPW22 has 2*100 memories

SECTION C Please check that the following are included with the application

- A manual for the validated device [X]
A manual for the device for which equivalence is being sought [X]
An image of the validated device [X]
An image of the device for which equivalence is being sought [X]
An image of the screen layout of validated device* [X]
An image of the screen layout of the device for which equivalence is being sought* [X]



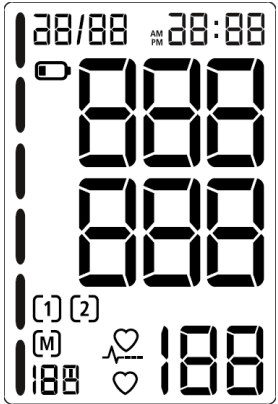
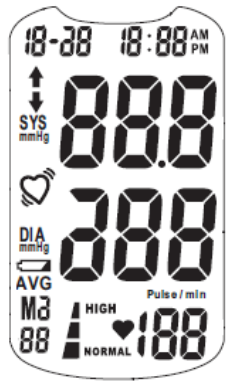
* Screen layouts shown complete, and without obscuring labels or lines, in manuals need not be included separately.

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 [Handwritten Signature] Company Stamp/Seal
Name Bill Huang
Date 2017.12.11

Signature of Witness [Handwritten 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 HARTMANN Veroval BPW22 with the AViTA BPM155

| Devices – Item 9 | HARTMANN Veroval BPW22 | AViTA BPM155 |
|------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Pictures |  |  |
| Display Image |  |  |
| Validation | Equivalence | ESH 2010 ESH 2002 BHS AAMI |
| Category | Wrist Type Blood Pressure Monitor | Wrist Type Blood Pressure Monitor |
| Casing – Item 10 | <p><i>Dimensions</i> 70 * 85 * 24 mm (W * H *D)</p> <p><i>Ports</i> Cuff Port</p> <p><i>Features</i> ABS plastic part Printing</p> | <p><i>Dimensions</i> 64.9 * 86.6 * 27.8 mm (W * H *D)</p> <p><i>Ports</i> Cuff Port</p> <p><i>Features</i> ABS Plastic part Printing</p> |

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| Display – Item 11 | LCD | LCD |
| Carrying/Mounting Facilities – Item 12 | Storage Box | Storage Box |
| Software other than Algorithm – Item 13 | N/A | N/A |
| Memory Capacity Item 14 | 2*100 times with date and time | 1*90 times with date and time |
| Printing Facilities Item 15 | Artwork logo, gift box and manual is different from AVITA BPM15S for different functions | Artwork logo, gift box and manual is different <i>for different functions</i> |
| Communication Facilities – Item 16 | N/A | N/A |
| Power Supply Item 17 | 2 * AAA Batteries | 2 * AAA Batteries |
| Other differences | N/A | N/A |
| Same Criteria | <p>Measurement</p> <p><i>Accuracy</i></p> <p>Blood Pressure Accuracy ± 3 mmHg</p> <p>Pulse Accuracy $\pm 4\%$</p> <p><i>Method</i></p> <p>Oscillometri</p> <p><i>Ranges</i></p> <p>Cuff pressure 0 -300 mmHg</p> <p>Systolic 50 mmHg – 280 mmHg</p> <p>Diastolic 30 mmHg – 200 mmHg</p> <p><i>Inflation</i></p> <p>Automatic inflation by internal pump</p> <p><i>Deflation</i></p> <p>Automatic speed deflation system</p> <p><i>Cuffs (Please state sizes and materials used)</i></p> <p>approx. 12.5 X 21 cm</p> | <p>Measurement</p> <p><i>Accuracy</i></p> <p>Blood Pressure Accuracy ± 3 mmHg</p> <p>Pulse Accuracy $\pm 4\%$</p> <p><i>Method</i></p> <p>Oscillometri</p> <p><i>Ranges</i></p> <p>Cuff pressure 0 -300 mmHg</p> <p>Systolic 50 mmHg – 280 mmHg</p> <p>Diastolic 30 mmHg – 200 mmHg</p> <p><i>Inflation</i></p> <p>Automatic inflation by internal pump</p> <p><i>Deflation</i></p> <p>Automatic speed deflation system</p> <p><i>Cuffs (Please state sizes and materials used)</i></p> <p>approx. 12.5 X 21 cm</p> |

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| | <p>Bladder dimension: 138x64mm</p> <p><i>Sensors</i> US-9111-006-S</p> <p><i>Measurement Records</i> 2*100 times with date and time</p> <p><i>Measurements other than Blood Pressure</i> Pulse rate</p> <p>Buttons/Switches <i>Power</i> START/POWER Button (on / off)</p> <p><i>Measurement Records</i> Memory Recall Buttons – User 1 / User 2</p> <p><i>Function</i> Date and Time Setting– combination of button user 1+user2</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> N/A</p> <p><i>Measurement Procedure</i> Inflation symbol Deflation symbol Heartbeat symbol during deflation Irregular Heartbeat symbol</p> <p><i>Post Measurement</i></p> | <p>Bladder dimension: 138x64mm</p> <p><i>Sensors</i> US-9111-006-S</p> <p><i>Measurement Records</i> 1*90 times with date and time</p> <p><i>Measurements other than Blood Pressure</i> Pulse rate</p> <p>Buttons/Switches <i>Power</i> START/POWER Button (on / off)</p> <p><i>Measurement Records</i> Memory Recall Button - MEM</p> <p><i>Function</i> Date and Time Set Button – SET Mode (Alarm) Button - Mode</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> N/A</p> <p><i>Measurement Procedure</i> Inflation symbol Deflation symbol Heartbeat symbol during deflation Irregular Heartbeat symbol</p> |
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| | <p>Systolic blood pressure 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> N/A</p> <p>Algorithms <i>Averages and Differences</i> Average of all measurement Average morning values of the last seven days measurements between 5:00AM and 9:00AM Average evening values of the last seven days measurements between 6:00PM and 8:00PM</p> <p><i>Diagnostic</i> N/A</p> <p><i>Functions</i></p> | <p><i>Post Measurement</i> Systolic blood pressure 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 Alarm</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 measurements</p> <p><i>Diagnostic</i> N/A</p> <p><i>Functions</i> N/A</p> <p><i>Communication</i> N/A</p> |
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|----------------------------|------------------------------------|--|
| | N/A <i>Communication</i> N/A | |
| Comparable Criteria | | |

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| Comments | | |
| Recommendation | Recommended | |
| Date | 26th January 2018 | |