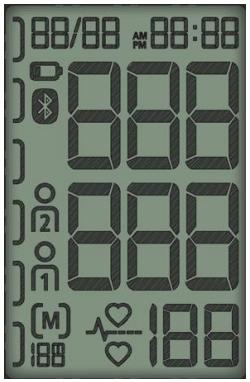
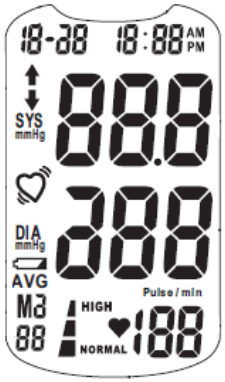
Comparison of the wrist blood pressure monitor HARTMANN Veroval BPW26 with the AViTA BPM15S

Devices	HARTMANN Veroval BPW26	AViTA BPM15S
Pictures		
Display		
Validation	Equivalence	ESH 2010
Category	Wrist Type Blood Pressure Monitor	Wrist Type Blood Pressure Monitor
Casing – Item 10	*Dimension* 70 * 85 * 24 mm (W * H * D) *Ports* *Cuff Port* *Features* *ABS plastic part* *Printing*	*Dimension* 64.9 * 86.6 * 27.8 mm (W * H * D) *Ports* *Cuff Port* *Features* *ABS plastic part* *Printing*

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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	*N/A*	*N/A*
Communication Facilities – Item 16	*Bluetooth*	*N/A*
Power Supply Item 17	*2* AAA Batteries*	*2* AAA Batteries*
Other differences	*N/A*	*N/A*
Same Criteria	***Measurement*** *Accuracy* Blood Pressure Accuracy ± 3 mmHg Pulse Accuracy ± 4% *Method* Oscillometric *Ranges* Cuff pressure 0 -300 mmHg Systolic 50 mmHg – 280 mmHg Diastolic 30 mmHg – 200 mmHg *Inflation* Automatic inflation by internal pump *Deflation* Automatic speed deflation system *Cuffs (Please state sizes and materials used)* approx. 12.5 X 21 cm Bladder dimension: 138x64mm *Sensors*	***Measurement*** *Accuracy* Blood Pressure Accuracy ± 3 mmHg Pulse Accuracy ± 4% *Method* Oscillometric *Ranges* Cuff pressure 0 -300 mmHg Systolic 50 mmHg – 280 mmHg Diastolic 30 mmHg – 200 mmHg *Inflation* Automatic inflation by internal pump *Deflation* Automatic speed deflation system *Cuffs(Please state sizes and materials used)* approx. 12.5 X 21 cm Bladder dimension: 138x64mm *Sensors*

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	Pressure Sensor *Measurements other than Blood Pressure* Pulse rate ***Buttons/Switches*** *Power* START/POWER Button (on / off) *Measurement Records* Memory Recall Buttons – User 1 / User 2 *Function* Date and Time Setting– combination of button user 1+user2 ***Display/Symbols/Indicators*** *Preparation* N/A *Measurement Procedure* Inflation symbol Deflation symbol Heartbeat symbol during deflation Irregular Heartbeat symbol *Post Measurement* Systolic blood pressure Diastolic blood pressure Pulse rate WHO indicator *Measurement Records* Memory recall number *Date and Time* Date and Time *Power* Low Battery detection symbol *Function* Average	Pressure Sensor *Measurements other than Blood Pressure* Pulse rate ***Buttons/Switches*** *Power* START/POWER Button (on / off) *Measurement Records* Memory Recall Button - MEM *Function* Date and Time Set Button – SET Mode (Alarm) Button - Mode ***Display/Symbols/Indicators*** *Preparation* N/A *Measurement Procedure* Inflation symbol Deflation symbol Heartbeat symbol during deflation Irregular Heartbeat symbol *Post Measurement* Systolic blood pressure Diastolic blood pressure Pulse rate WHO indicator *Measurement Records* Memory recall number *Date and Time* Date and Time *Power* Low Battery detection symbol *Function* Average

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	Alarm *Features* N/A *Not described* *N/A* ***Algorithms*** *Averages and Differences* 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 *Diagnostic* *N/A*	Alarm *Features* N/A *Not described* *N/A* ***Algorithms*** *Averages and Differences* Average of the last 3 measurements *Diagnostic* *N/A*
Comparable Criteria		

Comments		
Recommendation	**RECOMMENDED**	
Date	**April 2023**	

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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, (Name of a Company Director) a Director of AVITA Corporation, (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]	BPW26

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 BPM15S 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 ☐	No ☒	N/A[e] ☐
	2	Algorithm for Auscultatory Measurements	Yes ☐	No ☐	N/A[f] ☒
	3	Artefact/Error Detection	Yes ☐	No ☒	
	4	Microphone(s)	Yes ☐	No ☐	N/A[f] ☒
	5	Pressure Transducer	Yes ☐	No ☒	
	6	Cuffs or Bladders	Yes ☐	No ☒	
	7	Inflation Mechanism	Yes ☐	No ☒	
	8	Deflation Mechanism	Yes ☐	No ☒	
Part II	9	Model Name or Number	Yes ☒	No ☐	
	10	Casing	Yes ☒	No ☐	
	11	Display	Yes ☒	No ☐	
	12	Carrying/Mounting Facilities	Yes ☒	No ☐	
	13	Software other than Algorithm	Yes ☐	No ☒	
	14	Memory Capacity/Number of stored measurements	Yes ☒	No ☐	
	15	Printing Facilities	Yes ☐	No ☐	N/A[g] ☒
	16	Communication Facilities	Yes ☒	No ☐	N/A[g] ☐
	17	Power Supply	Yes ☐	No ☒	
	18	Other Facilities	Yes ☐	No ☒	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 model name is different. The new device is BPW26 and the validated device is BPM15S.

10) The casing designs are different.

11) The LCD size and displayed data are different.

12) Carrying/Mounting Facilities are different.

14) BPW26 has 2*100 memories and BPM15S has 1*90 memories.

16) BPW26 has bluetooth function and BPM15S doesn't have bluetooth function.

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.

AVITA CORPORATION

Signature of Director Bill Kwang 4/11, 2023 Company Stamp/Seal

Name ~~Bill Kuang~~ Authorized Signature

Date

AVITA CORPORATION

Signature of Witness Johnny Chuang 4/11, 2023

Name ~~Johnny Chuang~~ Authorized Signature

Address 9F, NO.78, SEC.1, KWANG-FU RD , SAN-Chung District, New Taipei City 24158 Taiwan R.O.C.