dabl®Educational Trust — Declaration of Equivalence Form

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]	Globalcare	*Address*	A7th Building 39 Middle Industrial Main Road European Industrial Zone, Xiaolan Town, Zhongshan City Guangdong Province 52815 CHINA
Brand[c]	Hartmann	Model[d]	HARTMANN Veroval BPU22

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]	BPM63S

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 upper arm 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 ☐	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.

Carraig Court, Georges Avenue, Blackrock, Co. Dublin, Ireland.
(dabl®Educational Trust Limited is a not-for-profit organisation)
Tel + 353 1 278 0247 Email info@dableducational.org
Fax + 353 1 278 3835 Web www.dableducational.org

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. HARTMANN Veroval BPU22 for new device and validated device is BPM63S

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 are different

14) HARTMANN Veroval BPU22 has 2*100 memories

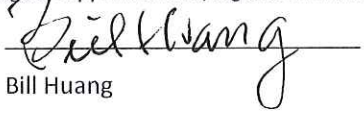
18)Other Facilities are different.

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  Company Stamp/Seal

Name Bill Huang

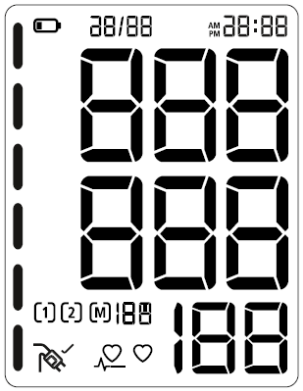
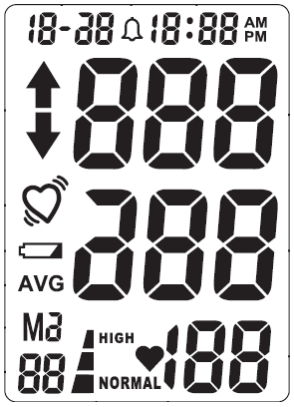
Date 2017. 12. 12

Signature of Witness 

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 BPU22 with the AViTA BPM63S

Devices – Item 9	HARTMANN Veroval BPU22	AViTA BPM63S
Pictures		
Display Image		
Validation	Equivalence	ESH 2010 ESH 2002 BHS AAMI
Category	Arm Type Blood Pressure Monitor	Arm Type Blood Pressure Monitor
Casing – Item 10	*Dimensions* 134 * 48 * 91 mm (W * H *D) *Ports*	*Dimensions* 113 * 140 * 57 mm (W * H *D) *Ports*

Carraig Court, George's Avenue, Blackrock, Co. Dublin, Ireland Tel +353 1 278 0247 Fax +353 1 278 0882 Email info@dableducational.org Web www.dableducational.org

	Cuff Port *Features* *NA*	Cuff Port *Features* *NA*
Display – Item 11	*Type* LCD	*Type* LCD
Carrying/Mounting Facilities – Item 12	NA	*NA*
Software other than Algorithm – Item 13	Different from AViTA BPM63S for different functions as 2 users, date and time setting, alarm, average	Different from bpu22 for different functions as 2 users, date and time setting, alarm, average
Memory Capacity Item 14	*Number of stored measurements* 2*100 times with date and time	*Number of stored measurements* 1*60 times with date and time
Printing Facilities Item 15	Artwork logo, gift box and manual is different from AViTA BPM63S for different functions	Artwork logo, gift box and manual is different for different functions
Communication Facilities – Item 16	NA	*NA*
Power Supply Item 17	4 * AA Batteries	4 * AA Batteries
Other differences	*Other Details on Equivalent device that are different to Validated device* *NA*	*Other Details on Validated device that are different to Equivalent device* NA
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	***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)* 22-42 cm Bladder dimension: 120x232mm *Sensors* US-9111-006-S *Measurement Records* 2*100 times with date and time *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 *Analysis* N/A *Event Marking* N/A *Communication* N/A ***Display/Symbols/Indicators***	Diastolic 30 mmHg – 200 mmHg *Inflation* Automatic inflation by internal pump *Deflation* Automatic speed deflation system *Cuffs(Please state sizes and materials used)* 22-33 cm Bladder dimension: 120x232mm *Sensors* US-9111-006-S *Measurement Records* 1*60 times with date and time *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 *Analysis* N/A *Event Marking* N/A *Communication* N/A ***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 *Communication* N/A *Features* N/A *Not described* ***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	*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 Alarm *Communication* N/A *Features* N/A *Not described* ***Algorithms*** *Averages and Differences* Average of the last 3 measurements

	Diagnostic N/A *Functions* N/A *Communication* N/A	*Diagnostic* N/A *Functions* N/A *Communication* N/A
Comparable Criteria		

Comments		**Query raised by dabl Educational;** "Declaration states that the pulse accuracy for the Veroval BPU22 is the same as the AViTA BPM63S, Pulse Accuracy ± 4%. However, the user manual for the Veroval BPU22 states a pulse accuracy of ± 5%. Which is correct please?
		Reply received; "± 4% is correct. ± 5% is our standard in other instruction manuals. So we would like to keep ± 5%, although it is technically better."
Recommendation	**Recommended**	
Date	**6th February 2018**	