

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2013

A SIGNED COPY WILL BE POSTED ON THE www.dablededucational.org WEBSITE

SECTION A - Please complete all items.

I **Mr. Ronny Wegner,**
Name of a Company Directora Director of **PAUL HARTMANN AG,**
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-Strasse 12, 89522 Heidenheim, Germany
Manufacturer ^b	PAUL HARTMANN AG	Address	Paul-Hartmann-Strasse 12, 89522 Heidenheim, Germany
Brand ^c	HARTMANN	Model ^d	Veroval Duo Control

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	PAUL HARTMANN AG	Address	Paul Hartmann Strasse 12, 89522 Heidenheim, Germany
Manufacturer ^b	PAUL HARTMANN AG	Address	Paul Hartmann Strasse 12, 89522 Heidenheim, Germany
Brand ^c	HARTMANN	Model ^d	Tensoval Duo Control II

Existing validated blood pressure measuring device.

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

de Greeff A., Shennan AH.; Validation of the Tensoval Duo Control II blood pressure monitor for clinic use and self-measurement according to the British Hypertension Society protocol and 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 checked="" type="checkbox"/>	N/A ^f <input type="checkbox"/>
	3	Artefact/Error Detection	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	4	Microphone(s)	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A ^f <input type="checkbox"/>
	5	Pressure Transducer	Yes <input checked="" type="checkbox"/>	No <input 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 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 checked="" 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 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.

Brief explanation of differences: Further details are shown on the attached "Section B comparison sheet".

5) Pressure Transducer:

The 'Capacitive Pressure Sensor' used for the A/D (analog/digital) conversion function with the Tensoval duo control II, up to now, has been replaced by a state-of-the-art 'Piezoelectric Pressure Sensor' with the Veroval duo control.

The basic specification properties regarding the resolution capability and the sampling cycle (sampling rate) as well as in particular the accuracy of the pressure measurement are therefore equivalent for both sensors.

Both sensor models thus provide the same electronic pressure signals in identical manner to the electronic evaluation module and to the existing, unchanged evaluation algorithm, respectively.

9) Model name: HARTMANN Veroval Duo Control for new device and validated device is HARTMANN Tensoval Duo Control II.

10) The designs of casing (housing) are different. The number and kind of buttons are the same.

11) The size and displayed data are different.

12) The designs of carrying bag are different.

13) Software other than Algorithm: difference of memory function, difference of display indications.

14) HARTMANN Veroval Duo Control has 2 x 100 memories

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@dablededucational.org.

Signature of Director 

Name Ronny Wegner

Date 08.06.2018

Signature of Witness 



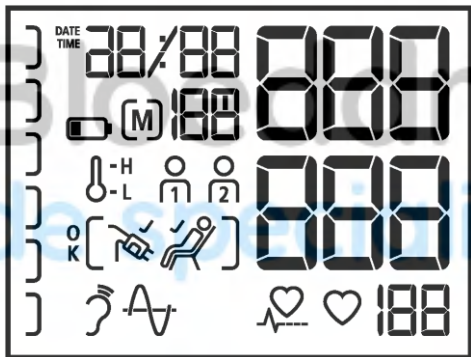
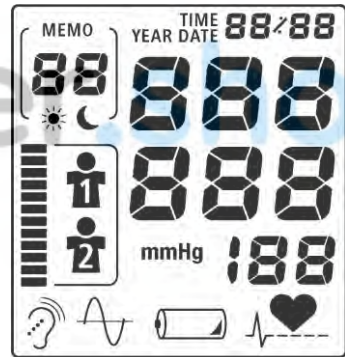
Name Katharina Wild

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

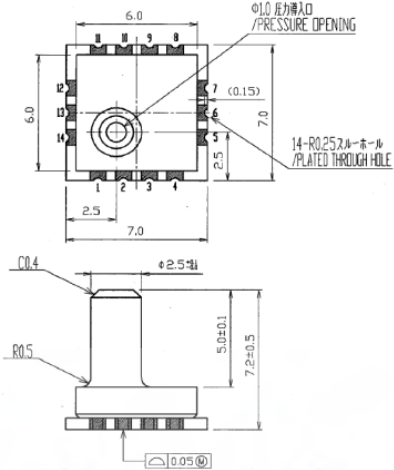
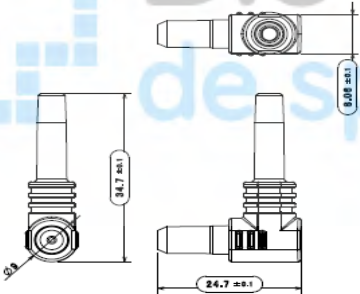
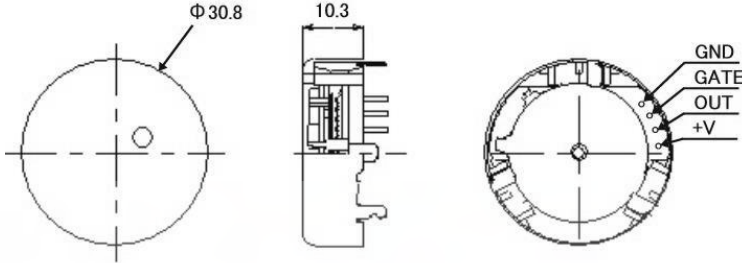
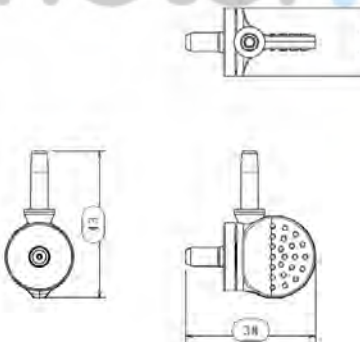
Company Stamp/Seal



Comparison of the HARTMANN Veroval Duo Control with the HARTMANN Tensoval Duo Control II

Devices – Item 9	HARTMANN Veroval Duo Control	HARTMANN Tensoval Duo Control II
Pictures		
Display Image		
Validation	Equivalence	BHS, ESH IP2010, AAMI, ISO 81060-2
Category	Upper arm device for self measurement of blood pressure	Upper arm device for self measurement of blood pressure
Casing – Item 10	<p><i>Dimensions</i> 158 mm (W) x 90mm (L) x 53mm (H)</p> <p><i>Ports</i> -USB socket -AC adaptor</p>	<p><i>Dimensions</i> 109 mm (W) x 179mm (D) x 65 mm (H)</p> <p><i>Ports</i> -USB socket -AC adaptor</p>

	<i>Features</i> Upper & bottom housing, blue frame, battery cover, display panel, 3 buttons (Start/Stop, Memory 1 & 2)	<i>Features</i> Upper & bottom housing, bottom housing cover, battery cover, display panel, 3 buttons (Start/Stop, Memory* 1 & 2) *Memory buttons are not separate components but parts of display panel.
Display – Item 11	<i>Type</i> LCD	<i>Type</i> LCD
Carrying/Mounting Facilities – Item 12	Carrying bag size: 230 mm (W) x 160mm (L) x 75mm (H)	Carrying bag size: 210 mm (W) x 140mm (L) x 100mm (H)
Software other than Algorithm – Item 13	Difference of LCD display symbols indication	Difference of LCD display symbols indication
Memory Capacity Item 14	100 x 2 (100 memory values for each of the 2 users) with date and time; Guest mode	60 x 2 (60 memory values for each of the 2 users) with date and time; Guest mode
Printing Facilities Item 15	N/A	N/A
Communication Facilities – Item 16	PC connection function for data transfer via USB cable.	PC connection function for data transfer via USB cable.
Power Supply Item 17	4 x 1.5V LR06 (size AA) alkaline batteries or AC adaptor (Output: DC6V, 600mA)	4 x 1.5V LR06 (size AA) alkaline batteries or AC adaptor (Output: DC6V, 600mA)
Other differences	<i>Display/Symbols/Indicators</i> -WHO classification (Traffic light system) -Cuff fit check -Rest indicator -Measurement OK indication -Temperature notification	<i>Display/Symbols/Indicators</i> -none

	<p>Pressure Sensor Model MMR901XA Pressure range: 0mmHg - 300 mmHg Safety over load: 600 mmHg Resolution: 0.05 mmHg</p> <p>Outline:</p>  <p>Cuff air plug Outline:</p> 	<p>Pressure Sensor Model CS-20A Pressure range: 0mmHg - 300 mmHg Safety over load: 390 mmHg Resolution: 0.05 mmHg</p> <p>Outline:</p>  <p>Cuff air plug Outline:</p> 
Same Criteria	<p>Measurement Accuracy Blood pressure accuracy ± 3 mmHg Pulse accuracy $\pm 5\%$</p> <p>Method Oscillometric measurement & auscultatory measurement (with integrated microphone) while deflation</p>	<p>Measurement Accuracy Blood pressure accuracy ± 3 mmHg Pulse accuracy $\pm 5\%$</p> <p>Method Oscillometric measurement & auscultatory measurement (with integrated microphone) while deflation</p>

<p><i>Ranges</i> Systolic blood pressure (SYS): 50 mmHg - 250 mmHg</p> <p><i>Inflation</i> Automatic inflation Inflation: 0 mmHg - 300 mmHg</p> <p><i>Deflation</i> Automatic deflation by electric valve</p> <p><i>Cuffs (Please state sizes and materials used)</i> Standard cuff M-size: Size: 226 x 520mm / Arm circumference: 22-32cm / Cuff cloth material: Nylon Standard cuff L-size: Size: 226 x 630mm / Arm circumference: 32-42cm / Cuff cloth material: Nylon Preformed cuff M-size: Size: 150 x 440mm / Arm circumference: 22-32cm / Cuff cloth material: Nylon</p> <p><i>Measurements other than Blood Pressure</i> Pulse rate</p> <p>Buttons/Switches Start / Stop key Memory 1 key Memory 2 key</p> <p>Display/Symbols/Indicators SYS mmHg, DIA mmHg, PUL/min are printed on housing.</p> <p><i>Preparation</i> Automatic Zero setting</p> <p><i>Measurement Procedure</i> -Inflation indication by pressure indication column -Pressure value indication -Oscillometric & auscultatory measurement symbol -Heart mark blinking at pulse detection</p>	<p><i>Ranges</i> Systolic blood pressure (SYS): 50 mmHg - 250 mmHg</p> <p><i>Inflation</i> Automatic inflation Inflation: 0 mmHg - 300 mmHg</p> <p><i>Deflation</i> Automatic deflation by electric valve</p> <p><i>Cuffs (Please state sizes and materials used)</i> Standard cuff M-size: Size: 226 x 520mm / Arm circumference: 22-32cm / Cuff cloth material: Nylon Standard cuff L-size: Size: 226 x 630mm / Arm circumference: 32-42cm / Cuff cloth material: Nylon Preformed cuff M-size: Size: 150 x 440mm / Arm circumference: 22-32cm / Cuff cloth material: Nylon</p> <p><i>Measurements other than Blood Pressure</i> Pulse rate</p> <p>Buttons/Switches Start / Stop key Memory 1 key Memory 2 key</p> <p>Display/Symbols/Indicators SYS mmHg, DIA mmHg, PUL/min are printed on housing.</p> <p><i>Preparation</i> Automatic Zero setting</p> <p><i>Measurement Procedure</i> -Inflation indication by pressure indication column -Pressure value indication -Oscillometric & auscultatory measurement symbol -Heart mark blinking at pulse detection</p>
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	<p><i>Post Measurement</i></p> <p>Systolic blood pressure (SYS) Diastolic blood pressure (DIA) Pulse rate Irregular pulse rhythm symbol Memory bank Measurement completion time</p> <p><i>Measurement Records</i></p> <p>Average of all stored data, average of morning/evening data for last 7 days, and individual data are indicated. Systolic blood pressure (SYS) Diastolic blood pressure (DIA) Pulse rate Irregular pulse rhythm symbol Memory bank Measurement date/time</p> <p><i>Date and Time</i></p> <p>Time indicated at power off, measurement completion and memory recall</p> <p><i>Power</i></p> <p>Low battery indication & empty battery indication Automatic switch-off after 3min. or 30sec. depending on the display</p> <p><i>Function</i></p> <p>Blood pressure measurement Pulse rate measurement Irregular pulse rhythm symbol Memory function Error indication</p> <p>Power</p> <p>4 x 1.5V LR06 (size AA) alkaline batteries</p> <p>Casing</p> <p><i>Features</i></p> <p>Cuff, AC adaptor, and USB cable connectors Company & Brand logo printing</p>	<p><i>Post Measurement</i></p> <p>Systolic blood pressure (SYS) Diastolic blood pressure (DIA) Pulse rate Irregular pulse rhythm symbol Memory bank Measurement completion time</p> <p><i>Measurement Records</i></p> <p>Average of all stored data, average of morning/evening data for last 7 days, and individual data are indicated. Systolic blood pressure (SYS) Diastolic blood pressure (DIA) Pulse rate Irregular pulse rhythm symbol Memory bank Measurement date/time</p> <p><i>Date and Time</i></p> <p>Time indicated at power off, measurement completion and memory recall</p> <p><i>Power</i></p> <p>Low battery indication & empty battery indication Automatic switch-off after 3min. or 30sec. depending on the display</p> <p><i>Function</i></p> <p>Blood pressure measurement Pulse rate measurement Irregular pulse rhythm symbol Memory function Error indication</p> <p>Power</p> <p>4 x 1.5V LR06 (size AA) alkaline batteries</p> <p>Casing</p> <p><i>Features</i></p> <p>Cuff, AC adaptor, and USB cable connectors Company & Brand logo printing</p>
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	<p>Model name printing Button printings SYS, DIA, PUL printing</p> <p>Algorithms Equivalent device (Veroval Duo Control) & validated device (Tensoval Duo Control II) have the identical measurement algorithm.</p>	<p>Model name printing Button printings SYS, DIA, PUL printing</p> <p>Algorithms Equivalent device (Veroval Duo Control) & validated device (Tensoval Duo Control II) have the identical measurement algorithm.</p>
Comparable Criteria	<p>Measurement range Diastolic blood pressure (DIA): 40 mmHg - 180 mmHg Pulse rate: 30 bpm - 199 bpm</p> <p>Display/Symbols/Indicators <i>Measurement Procedure</i> Cuff fit check</p> <p><i>Post Measurement</i> Cuff fit check Rest indicator Measurement OK indication Temperature notification WHO classification (Traffic light system) Measurement completion time & date</p> <p><i>Measurement Records</i> Cuff fit check Rest indicator Measurement OK indication Temperature notification WHO classification (Traffic light system)</p> <p>Measurement Records 100 x 2 memory storage</p> <p>Casing Upper & bottom housing, blue frame, battery cover, display panel, 3 buttons (Start/Stop, Memory 1 & 2)</p>	<p>Measurement range Diastolic blood pressure (DIA): 40 mmHg - 160 mmHg Pulse rate: 40 bpm - 160 bpm</p> <p>Display/Symbols/Indicators <i>Measurement Procedure</i> --</p> <p><i>Post Measurement</i> -- -- -- -- -- Measurement completion time</p> <p><i>Measurement Records</i> -- -- -- -- --</p> <p>Measurement Records 60 x 2 memory storage</p> <p>Casing Upper & bottom housing, bottom housing cover, battery cover, display panel, 3 buttons (Start/Stop, Memory* 1 & 2) *Memory buttons are not separate components but parts of display panel.</p>

Comments		
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Recommendation	Recommended	
Date	7 th July 2018	

