

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2013

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SECTION A - Please complete all items.

I **Mr. Bülent Tek,** a Director of **PAR Medizintechnik GmbH & Co. KG,**
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 PAR Medizintechnik GmbH & Co. KG **Address** Sachsendamm 6, 10829 Berlin, Germany

Manufacturer^b PAR Medizintechnik GmbH & Co. KG **Address** Sachsendamm 6, 10829 Berlin, Germany

Brand^c PAR Medizintechnik **Model^d** PHYSIO-PORT

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 PAR Medizintechnik GmbH & Co. KG **Address** Sachsendamm 6, 10829 Berlin, Germany

Manufacturer^b PAR Medizintechnik GmbH & Co. KG **Address** Sachsendamm 6, 10829 Berlin, Germany

Brand^c PAR Medizintechnik **Model^d** TONOPORT VI

Existing validated blood pressure measuring device.

which has previously passed the ESH-IP2010 protocol, the results of which were published as follows:

M. Abou-Dakn, C. Döhmen and S. Wenzel Validation of the TONOPORT VI ambulatory blood pressure monitor in adults according to the European Society of Hypertension International Protocol revision 2010. Journal of Human Hypertension, 14 July 2016.

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

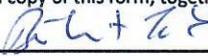
An explanation of the differences in part II between the PHYSIO-PORT and the TONOPORT VI are described in the attached document 'DET9 Device Equivalence Comparison Form PHYSIO-PORT and TONOPORT VI'.

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.

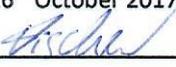
SECTION D Complete all items, bar signatures and seal, online and print. Sign and seal it then send the original to our address below. Please email a signed copy of this form, together with the manuals and images for both devices, to info@dableducational.org.

Signature of Director 

Company Stamp/Seal

Name Mr. Bülent Tek

Date 16th October 2017

Signature of Witness 

Name Mr. Thomas Fischer

Address PAR Medizintechnik GmbH & Co. KG, Sachsendamm 6, 10829 Berlin, Germany

PAR Medizintechnik GmbH & Co.KG
Sachsendamm 6
10829 Berlin

Comparison of the PAR Medizintechnik PHYSIO-PORT with the PAR Medizintechnik TONOPORT VI

Devices – Item 9	PHYSIO-PORT	TONOPORT VI
Pictures		
Display Image	 <p>The complete screen layout is shown on page 13 of the PHYSIO-PORT operator's manual.</p>	 <p>The complete screen layout is shown on page 15 of the TONOPORT VI operator's manual.</p>
Validation		ESH 2010
Category	Sphygmomanometer for Ambulatory Blood Pressure Measurement	Sphygmomanometer for Ambulatory Blood Pressure Measurement
Casing – Item 10	<p><u>Dimensions:</u> Width: 80mm Height: 27 mm Depth: 105 mm</p> <p><u>Ports:</u> Cuff-Connector, USB</p>	<p><u>Dimensions:</u> Width: 73 mm Height: 27 mm Depth: 108 mm</p> <p><u>Ports:</u> Cuff-Connector, USB, RS-232</p>
Display – Item 11	<p><u>Type:</u> LCD (reflective)</p>	<p><u>Type:</u> LCD (reflective)</p>

	<u>Size:</u> 31 x 11 mm (w x h)	<u>Size:</u> 27 x 58 mm (w x h)
Carrying/Mounting Facilities – Item 12	<u>Carrying Facilities:</u> Wearable pouch for PHYSIO-PORT with belt	<u>Carrying Facilities:</u> Wearable pouch for TONOPORT VI with belt
Software other than Algorithm – Item 13	Uses the same firmware like the TONOPORT VI.	No additional software on the device.
Memory Capacity Item 14	Up to 400 blood pressure measurements	Up to 400 blood pressure measurements
Printing Facilities Item 15	No printing facilities	No printing facilities
Communication Facilities – Item 16	<u>USB:</u> HID-Protocol	<u>USB:</u> 1.1, 2.0 <u>RS-232:</u> 9600 Bd, 8N1
Power Supply Item 17	2 AA size NiMH batteries or 2 AA size alkaline batteries	2 AA size NiMH batteries or 2 AA size alkaline batteries
Other differences	<i>No other differences between the devices</i>	<i>No other differences between the devices</i>
Same Criteria	<p>Measurement</p> <p><u>Accuracy:</u> Uses the same algorithm for the deflation and the inflation mode like TONOPORT VI.</p> <p><u>Method:</u> Oscillometric</p> <p><u>Ranges:</u> SYS: 60 to 260 mmHg DIA: 40 to 220 mmHg HF: 35 to 240 min⁻¹</p> <p><u>Inflation:</u> Same Algorithm like Tonoport VI</p>	<p>Measurement</p> <p><u>Accuracy:</u> Inflation Method: Systolic: ± 2,8 mmHg Diastolic: ± 2,9 mmHg Deflation Method: Systolic: ± 3,6 mmHg Diastolic: ± 2,4 mmHg</p> <p><u>Method:</u> Oscillometric</p> <p><u>Ranges:</u> SYS: 60 to 260 mmHg DIA: 40 to 220 mmHg HR: 35 to 240 min⁻¹</p> <p><u>Inflation:</u> Yes (selectable)</p>

	<p><u>Deflation:</u> Same Algorithm like Tonoport VI</p> <p><u>Cuffs:</u> Cuff material: Nylon / Tubing material: PVC Small (Arm circumference: 17 - 26 cm) Standard (Arm circumference: 24 - 32 cm) Large (Arm circumference: 32 - 42 cm)</p> <p><u>Sensors:</u> Two piezoresistive pressure transducer</p> <p><u>Measurement Records:</u> Systolic, diastolic blood pressure and heartrate</p> <p><u>Measurements other than Blood Pressure:</u> No</p> <p>Buttons/Switches</p> <p><u>Power:</u> Power switch in the battery compartment</p> <p><u>Measurement Records:</u> Press the START STOP Button</p> <p><u>Function:</u> The INFO Button is used to display the results of the last measurement or the last error message and to enter the calibration mode. The SUN MOON Button toggles between day and night phase.</p> <p><u>Analysis:</u> The device does not analyse the measured data.</p> <p><u>Event Marking:</u> The device safes the error codes of failed measurements.</p>	<p><u>Deflation:</u> Yes (selectable)</p> <p><u>Cuffs:</u> Cuff material: Nylon / Tubing material: PVC Small (Arm circumference: 17 - 26 cm) Standard (Arm circumference: 24 - 32 cm) Large (Arm circumference: 32 - 42 cm) Extra-Large (Arm circumference: 38 - 46 cm)</p> <p><u>Sensors:</u> Two piezoresistive pressure transducer</p> <p><u>Measurement Records:</u> Systolic, diastolic blood pressure and heartrate</p> <p><u>Measurements other than Blood Pressure:</u> No</p> <p>Buttons/Switches</p> <p><u>Power:</u> Press the START STOP Button</p> <p><u>Measurement Records:</u> Press the START STOP Button</p> <p><u>Function:</u> The INFO Button is used to display the results of the last measurement, clear the memory, set date and time, select a measurement protocol, enter the calibration mode, display the firmware version, select the energy source, enable/disable the audio signal, select the pressure unit, toggle between day and night phase and select measurement method.</p> <p><u>Analysis:</u> The device does not analyse the measured data.</p> <p><u>Event Marking:</u> The device safes the error codes of failed measurements.</p>
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	<p>Display/Symbols/Indicators</p> <p><u>Preparation:</u> Displays the current time.</p> <p><u>Measurement Procedure:</u> Displays the current cuff pressure.</p> <p><u>Post Measurement:</u> Displays the result (SYS, DIA and HR) of the measurement.</p> <p><u>Measurement Records:</u> Saves the systolic, diastolic blood pressure, the heartrate, time and date of the measurement.</p> <p><u>Date and Time:</u> DD.MM.JJJJ HH:MM</p> <p>Algorithms</p> <p><u>Averages and Differences</u> The device does not analyse the measured data.</p> <p><u>Diagnostic:</u> Diagnosis of pathological blood pressure values.</p> <p><u>Functions:</u> Stores the measured values</p>	<p>Display/Symbols/Indicators</p> <p><u>Preparation:</u> Displays the current time.</p> <p><u>Measurement Procedure:</u> Displays the current cuff pressure.</p> <p><u>Post Measurement:</u> Displays the result (SYS, DIA and HR) of the measurement.</p> <p><u>Measurement Records:</u> Saves the systolic, diastolic blood pressure, the heartrate, time and date of the measurement.</p> <p><u>Date and Time:</u> DD.MM.JJJJ HH:MM</p> <p>Algorithms</p> <p><u>Averages and Differences</u> The device does not analyse the measured data.</p> <p><u>Diagnostic:</u> Diagnosis of pathological blood pressure values.</p> <p><u>Functions:</u> Stores the measured values</p>
Comparable Criteria	-	-

Comments	Both devices are manufactured by PAR Medizintechnik GmbH & Co. KG and both devices uses the same hardware with an identically firmware for the blood pressure measurement. All modifications do not affect the accuracy of the results.
Recommendation	RECOMMENDED
Date	9 th March 2017