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 Mr. Bülent Tek, (Name of a Company Director) a Director of PAR Medizintechnik GmbH & Co. KG, (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 ☐	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.
Form DET7 130102

(dabl®Educational Trust Limited is a not-for-profit organisation)
Tel +353 1 278 0247
Fax +353 1 278 3835
Email info@dableducational.org
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.

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

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

	Size: 31 x 11 mm (w x h)	Size: 27 x 58 mm (w x h)
Carrying/Mounting Facilities – Item 12	Carrying Facilities: Wearable pouch for PHYSIO-PORT with belt	Carrying Facilities: 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	USB: HID-Protocol	USB: 1.1, 2.0 RS-232: 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	*No other differences between the devices*	*No other differences between the devices*
Same Criteria	***Measurement*** Accuracy: Uses the same algorithm for the deflation and the inflation mode like TONOPORT VI. Method: Oscillometric Ranges: SYS: 60 to 260 mmHg DIA: 40 to 220 mmHg HF: 35 to 240 min^{-1} Inflation: Same Algorithm like Tonoport VI	***Measurement*** Accuracy: Inflation Method: Systolic: ± 2,8 mmHg Diastolic: ± 2,9 mmHg Deflation Method: Systolic: ± 3,6 mmHg Diastolic: ± 2,4 mmHg Method: Oscillometric Ranges: SYS: 60 to 260 mmHg DIA: 40 to 220 mmHg HR: 35 to 240 min^{-1} Inflation: Yes (selectable)

	Deflation: Same Algorithm like Tonoport VI Cuffs: Cuff material: Nylon / Tubing material: PVC Small (Arm circumference: 17 - 26 cm) Standard (Arm circumference: 24 - 32 cm) Large (Arm circumference: 32 - 42 cm) Sensors: Two piezoresistive pressure transducer Measurement Records: Systolic, diastolic blood pressure and heartrate Measurements other than Blood Pressure: No ***Buttons/Switches*** Power: Power switch in the battery compartment Measurement Records: Press the START STOP Button Function: 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. Analysis: The device does not analyse the measured data. Event Marking: The device safes the error codes of failed measurements.	Deflation: Yes (selectable) Cuffs: 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) Sensors: Two piezoresistive pressure transducer Measurement Records: Systolic, diastolic blood pressure and heartrate Measurements other than Blood Pressure: No ***Buttons/Switches*** Power: Press the START STOP Button Measurement Records: Press the START STOP Button Function: 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. Analysis: The device does not analyse the measured data. Event Marking: The device safes the error codes of failed measurements.

	Display/Symbols/Indicators Preparation: Displays the current time. Measurement Procedure: Displays the current cuff pressure. Post Measurement: Displays the result (SYS, DIA and HR) of the measurement. Measurement Records: Saves the systolic, diastolic blood pressure, the heartrate, time and date of the measurement. Date and Time: DD.MM.JJJJ HH:MM ***Algorithms*** Averages and Differences The device does not analyse the measured data. Diagnostic: Diagnosis of pathological blood pressure values. Functions: Stores the measured values	***Display/Symbols/Indicators*** Preparation: Displays the current time. Measurement Procedure: Displays the current cuff pressure. Post Measurement: Displays the result (SYS, DIA and HR) of the measurement. Measurement Records: Saves the systolic, diastolic blood pressure, the heartrate, time and date of the measurement. Date and Time: DD.MM.JJJJ HH:MM ***Algorithms*** Averages and Differences The device does not analyse the measured data. Diagnostic: Diagnosis of pathological blood pressure values. Functions: Stores the measured values
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	9th March 2017