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 Li Hui Jun (Name of a Company Director) a Director of Shenzhen Pango Electronic Co., Ltd, (Company name)

hereby state that there are no differences that will affect blood pressure measuring accuracy between the

Maker[a]	Inventum Huishoudelijke Apparaten B.V.	*Address*	Meander 861 6825 MH Arnhem The Netherlands
Manufacturer[b]	Shenzhen Pango Electronic Co., Ltd	*Address*	No.25, 1st Industry zone, FengHuangRd, XiKen Village, HengGang Town, LongGang District, Shenzhen., China
Brand[c]	Inventum	Model[d]	BDP619

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]	Shenzhen Pango Electronic Co., Ltd	*Address*	No.25, 1st Industry zone, FengHuangRd, XiKen Village, HengGang Town, LongGang District, Shenzhen., China
Manufacturer[b]	Shenzhen Pango Electronic Co., Ltd	*Address*	No.25, 1st Industry zone, FengHuangRd, XiKen Village, HengGang Town, LongGang District, Shenzhen., China
Brand[c]	Pangao	Model[d]	PG-800A11

Existing validated blood pressure measuring device.

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

Validation of the Pangao PG-800A11 wrist device assessed according to the European Society of Hypertension and the British Hypertension Society protocols. Blood Press Monit. 2015 April; 20(2):108-111 doi: 10.1097/MBP.0000000000000095.

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.

See attached document

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

Date

Signature of Witness _____ 30, June, 2016

Name HE BAOZHU

Address No.25, 1st Industry zone, FengHuangRd, XiKen Village, HengGang Town, LongGang District, Shenzhen., China

深圳市攀高电子有限公司
Shenzhen Pango Electronic Co.,Ltd

Comparison of the Inventum BDP619 with the Pangao PG-800A11

Devices – Item 9	Inventum BDP619	Pangao PG-800A11
Pictures	*Image height: Picture 3.2 cm* 	*Image height: Picture 3.2 cm* 
Display Image	*Image height: Picture 4 cm* 	*Image height: Picture 4 cm* 
Validation	-	ESH 2010
Category	Wrist Devices for Self-measurement of Blood Pressure	*Wrist Devices for Self-measurement of Blood Pressure*
Casing – Item 10	*Dimensions 75 x 72 x 65 mm* *Ports: none* *Features: 90 memory places, 13.5 – 19,5 cm cuff, Irregular heartbeat detection, WHO indicator*	*Dimensions 75 x 72 x 65 mm* *Ports: none* *Features: 90 memory places, 13.5 – 19,5 cm cuff, Irregular heartbeat detection, WHO indicator*
Display – Item 11	*Type: LCD display* No differences	*Type: LCD display* No differences
Carrying/Mounting Facilities – Item 12	*Storage case (PP)*	*Storage case (PP)*

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Software other than Algorithm – Item 13	No differences	No differences
Memory Capacity Item 14	*Number of stored measurements: 90*	*Number of stored measurements: 90*
Printing Facilities Item 15	n/a.	n/a.
Communication Facilities – Item 16	n/a.	n/a.
Power Supply Item 17	2 x AAA	2 x AAA
Other differences	*Other Details on Equivalent device that are different to Validated device:* - *Control panel colour, text colour + knobs colour, rating label, giftbox design, User manual*	*Other Details on Validated device that are different to Equivalent device* - *Control panel colour, text colour + knobs colour, rating label, giftbox design, User manual*
Same Criteria	***Measurement*** *Accuracy* No differences *Method* No differences *Ranges* No differences *Inflation* No differences	***Measurement*** *Accuracy* No differences *Method* No differences *Ranges* No differences *Inflation* No differences

	Deflation No differences *Cuffs (Please state sizes and materials used)* No differences *Sensors* No differences *Measurement Records* No differences *Measurements other than Blood Pressure* No differences ***Buttons/Switches*** *Power*  The color and symbols are different *Measurement Records* No differences *Function* No differences *Analysis* No differences *Event Marking* No differences *Communication* N/A ***Display/Symbols/Indicators***	*Deflation* No differences *Cuffs (Please state sizes and materials used)* No differences *Sensors* No differences *Measurement Records* No differences *Measurements other than Blood Pressure* No differences ***Buttons/Switches*** *Power*  The color and symbols are different *Measurement Records* No differences *Function* No differences *Analysis* No differences *Event Marking* No differences *Communication* N/A ***Display/Symbols/Indicators***

	Preparation No differences *Measurement Procedure* No differences *Post Measurement* No differences *Measurement Records* No differences *Date and Time* No differences *Power* No differences *Function* No differences *Communication* No differences *Features* No differences *Not described* None ***Algorithms*** *Averages and Differences* No differences *Diagnostic* No differences *Functions* No differences *Communication*	*Preparation* No differences *Measurement Procedure* No differences *Post Measurement* No differences *Measurement Records* No differences *Date and Time* No differences *Power* No differences *Function* No differences *Communication* No differences *Features* No differences *Not described* None ***Algorithms*** *Averages and Differences* No differences *Diagnostic* No differences *Functions* No differences *Communication*

	No differences	No differences
Comparable Criteria	- Everything except of: *Control panel colour, text colour + knobs colour, rating label, giftbox design, User manual*	- Everything except of: *Control panel colour, text colour + knobs colour, rating label, giftbox design, User manual*

Comments		none
Recommendation	**Recommended**	
Date	**4th August 2016**	