

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2013

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SECTION A - Please complete all items.

I Li Rui 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 BDA632

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-800B11

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-800B11 blood pressure monitor according to the European Society of Hypertension and the British Hypertension Society protocols. Blood Press Monit.: 2014 December; 19(6):366-369 doi: 10.1097/MBP.0000000000000078.

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 type="checkbox"/>	No <input checked="" type="checkbox"/>	
	11	Display	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	12	Carrying/Mounting Facilities	Yes <input type="checkbox"/>	No <input checked="" 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 type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input checked="" type="checkbox"/>
	17	Power Supply	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	18	Other Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input checked="" 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.

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

Li Mad Jun



30, June, 2016



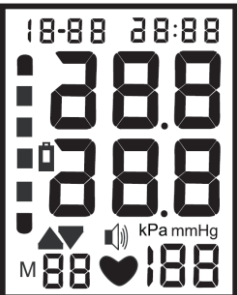
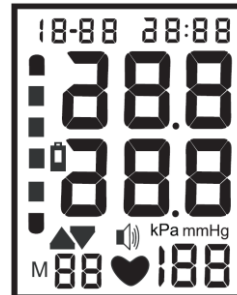
Name



HE BAO ZHU



Address

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

Comparison of the Inventum BDA632 with the Pangao PG-800B11

Devices – Item 9	Inventum BDA632	Pangao PG-800B11
<p>Pictures</p>	<p>Image height: Picture 3.2 cm</p> 	<p>Image height: Picture 3.2 cm</p> 
<p>Display Image</p>	<p>Image height: Picture 4 cm</p> 	<p>Image height: Picture 4 cm</p> 
<p>Validation</p>	<p>-</p>	<p>ESH 2010</p>
<p>Category</p>	<p>Upper Arm Devices for Self-measurement of Blood Pressure</p>	<p>Upper Arm Devices for Self-measurement of Blood Pressure</p>
<p>Casing – Item 10</p>	<p>Dimensions 140 x 110 x 56 mm</p> <p>Ports:</p> <ul style="list-style-type: none"> - Air outlet for cuff - DC 6V in. <p>Features: 90 memory places, 22-32 cm cuff, Irregular heartbeat detection, WHO indicator</p>	<p>Dimensions 140 x 110 x 56 mm</p> <p>Ports:</p> <ul style="list-style-type: none"> - Air outlet for cuff - DC 6V in. <p>Features: 90 memory places, 22-32 cm cuff, Irregular heartbeat detection, WHO indicator</p>
<p>Display – Item 11</p>	<p>Type: LCD display No differences</p>	<p>Type: LCD display No differences</p>
<p>Carrying/Mounting Facilities – Item 12</p>	<p>Zipper bag</p>	<p>Zipper bag</p>

		
Software other than Algorithm – Item 13	No differences	No differences
Memory Capacity Item 14	<i>Number of stored measurements: 90</i>	<i>Number of stored measurements: 90</i>
Printing Facilities Item 15	n/a.	n/a.
Communication Facilities – Item 16	n/a.	n/a.
Power Supply Item 17	4 x AA	4 x AA
Other differences	<i>Other Details on Equivalent device that are different to Validated device:</i> <ul style="list-style-type: none"> - Control panel colour, text colour + knobs colour, rating label, giftbox design, User manual 	<i>Other Details on Validated device that are different to Equivalent device</i> <ul style="list-style-type: none"> - Control panel colour, text colour + knobs colour, rating label, giftbox design, User manual
Same Criteria	<p>Measurement</p> <p><i>Accuracy</i> No differences</p> <p><i>Method</i> No differences</p> <p><i>Ranges</i> No differences</p> <p><i>Inflation</i> No differences</p>	<p>Measurement</p> <p><i>Accuracy</i> No differences</p> <p><i>Method</i> No differences</p> <p><i>Ranges</i> No differences</p> <p><i>Inflation</i> No differences</p>

	<p><i>Deflation</i> No differences</p> <p><i>Cuffs (Please state sizes and materials used)</i> No differences</p> <p><i>Sensors</i> No differences</p> <p><i>Measurement Records</i> No differences</p> <p><i>Measurements other than Blood Pressure</i> No differences</p> <p>Buttons/Switches <i>Power</i></p>  <p>The color and symbols are different</p> <p><i>Measurement Records</i> No differences</p> <p><i>Function</i> No differences</p> <p><i>Analysis</i> No differences</p> <p><i>Event Marking</i> No differences</p> <p><i>Communication</i> N/A</p> <p>Display/Symbols/Indicators</p>	<p><i>Deflation</i> No differences</p> <p><i>Cuffs (Please state sizes and materials used)</i> No differences</p> <p><i>Sensors</i> No differences</p> <p><i>Measurement Records</i> No differences</p> <p><i>Measurements other than Blood Pressure</i> No differences</p> <p>Buttons/Switches <i>Power</i></p>  <p>The color and symbols are different</p> <p><i>Measurement Records</i> No differences</p> <p><i>Function</i> No differences</p> <p><i>Analysis</i> No differences</p> <p><i>Event Marking</i> No differences</p> <p><i>Communication</i> N/A</p> <p>Display/Symbols/Indicators</p>
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	<p><i>Preparation</i> No differences</p> <p><i>Measurement Procedure</i> No differences</p> <p><i>Post Measurement</i> No differences</p> <p><i>Measurement Records</i> No differences</p> <p><i>Date and Time</i> No differences</p> <p><i>Power</i> No differences</p> <p><i>Function</i> No differences</p> <p><i>Communication</i> No differences</p> <p><i>Features</i> No differences</p> <p><i>Not described</i> None</p> <p>Algorithms <i>Averages and Differences</i> No differences</p> <p><i>Diagnostic</i> No differences</p> <p><i>Functions</i> No differences</p> <p><i>Communication</i></p>	<p><i>Preparation</i> No differences</p> <p><i>Measurement Procedure</i> No differences</p> <p><i>Post Measurement</i> No differences</p> <p><i>Measurement Records</i> No differences</p> <p><i>Date and Time</i> No differences</p> <p><i>Power</i> No differences</p> <p><i>Function</i> No differences</p> <p><i>Communication</i> No differences</p> <p><i>Features</i> No differences</p> <p><i>Not described</i> None</p> <p>Algorithms <i>Averages and Differences</i> No differences</p> <p><i>Diagnostic</i> No differences</p> <p><i>Functions</i> No differences</p> <p><i>Communication</i></p>
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	No differences	No differences
Comparable Criteria	- Everything except of: <i>Control panel colour, text colour + knobs colour, rating label, giftbox design, User manual</i>	- Everything except of: <i>Control panel colour, text colour + knobs colour, rating label, giftbox design, User manual</i>

Comments	none
Recommendation	Recommended
Date	4th August 2016