

## DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2011

A SIGNED COPY WILL BE POSTED ON THE [www.dablededucational.org](http://www.dablededucational.org) WEBSITE

### SECTION A - Please complete all items.

I, \_\_\_\_\_, a Director of **Artsana s.p.a.**,  
Name of a Company Director Company name

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

Manufacturer **Artsana spa** Brand **PiC Solution** Model **Help Check**  
Blood pressure measuring device for which validation is claimed. If alternative model names are used, include all.

blood pressure measuring device and the

Manufacturer **Artsana spa** Brand **PiC Solution** Model **My Check**  
Existing validated blood pressure measuring device. If alternative model names are used, include all.

blood pressure measuring device, which has previously passed the ESH protocol, the results of which were published as follows:

**Gruseppe Germano; Angelos Psimenos; Francesco Sarullo; Alessandro Venditti; Valerio Pecchioli; Roland Asmar**  
Authors(s)

Validation of four automatic devices for self-measurement of blood pressure according to the international Protocol:  
**The PiC Indolor Personal Check, Comfort Check, My Check and Travel Check.**  
Title

**Blood Pressure** 2009 - 18:1,15 - 23.  
Publication Year Volume Pages

The only differences between the devices involve the following components:

When a component is not relevant, both Yes and No should be left blank. It is necessary to provide details on each item ticked "Yes" in Section C or on a separate sheet.

Part	Item	Yes	No
Part I	1 Algorithm for Oscillometric Measurements	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	2 Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <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 type="checkbox"/>
	5 Pressure Transducer	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	6 Cuff or Bladder	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 checked="" type="checkbox"/>	No <input type="checkbox"/>
	12 Carrying/Mounting Facilities	Yes <input type="checkbox"/>	No <input checked="" 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 type="checkbox"/>	No <input checked="" type="checkbox"/>
	15 Printing Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	16 Communication Facilities	Yes <input type="checkbox"/>	No <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 checked="" type="checkbox"/>

An explanation of each item ticked "Yes" must be included in Section C on the next page

### SECTION B 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 manuals and images for both devices to [info@dablededucational.org](mailto:info@dablededucational.org).

Signature of Director \_\_\_\_\_

Company Stamp/Seal

Name **Mario Merlo**

Date **14.12.2011**

Signature of Witness \_\_\_\_\_



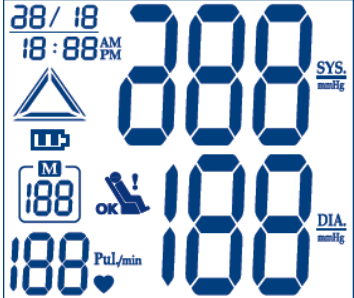
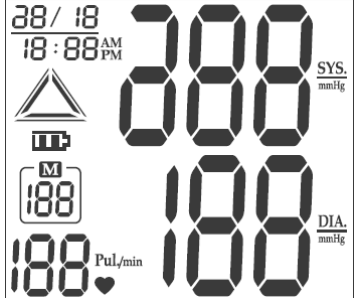
Name **Francesco Lo Piccolo**

Address **Artsana s.p.a. Via Saldarini Catelli 1, 22070, Grandate (Como), Italy**

**SECTION C** 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.

The device is almost the same, the only differences are the name, the display layout and the software (different from algorithm) that detects if the patient took enough rest to have a proper measurement.

Comparison of the Artsana Pic Solution Help Check with the Artsana Pic Solution My Check

Devices	Artsana Pic Solution Help Check	Artsana Pic Solution My Check
Pictures		
Display		
Validation		ESH
Device 1 Criteria	<p><b>Display/Symbols/Indicators</b>  <i>Post Measurement</i>                      Haemodynamic stability indicator 11, 13, 18</p> <p><b>Algorithms</b>  <i>Diagnostic</i>                      Haemodynamic stability detection 13</p>	
Same Criteria	<p><b>Measurement</b>  <i>Accuracy</i>                      BP accuracy ± 3 mmHg 1, 5                      Pulse accuracy ± 5% 1, 5</p> <p><i>Method</i>                      Oscillometric measurement method 1, 5                      BP 30 mmHg – 260 mmHg 1, 5, 7, 8                      Pulse 40 bpm – 199 bpm 1, 5, 8</p>	<p><b>Measurement</b>  <i>Accuracy</i>                      BP accuracy ± 3 mmHg 1, 5                      Pulse accuracy ± 5% 1, 5</p> <p><i>Method</i>                      Oscillometric measurement method 1, 5                      BP 30 mmHg – 260 mmHg 1, 5, 7, 8                      Pulse 40 bpm – 199 bpm 1, 5, 8</p>

Devices	Artsana Pic Solution Help Check	Artsana Pic Solution My Check	
<b>Same Criteria (continued)</b>	<b>Measurement (continued)</b>	<b>Measurement (continued)</b>	
	<i>Method (continued)</i>	<i>Method (continued)</i>	
	Manually initiated measurements	13	Manually initiated measurements 13
	Measurements are from single inflations	13	Measurements are from single inflations 13
	<i>Inflation</i>		<i>Inflation</i>
	Inflation 0 mmHg – 300 mmHg	1, 5, 7	Inflation 0 mmHg – 300 mmHg 1, 5, 7
	Automatic Inflation	7	Automatic Inflation 7
	Fuzzy Logic	7	Fuzzy Logic 7
	Zero pressure check before inflation	7	Zero pressure check before inflation 7
	<i>Deflation</i>		<i>Deflation</i>
	Automatic Deflation	8	Automatic Deflation 8
	Automatic safety release valve	8	Automatic safety release valve 8
	<i>Cuffs</i>		<i>Cuffs</i>
	Large (Arm circ. 34-46 cm) (Optional)	6	Large (Arm circ. 34-46 cm) (Optional) 6
	Medium (Arm circ. 24 to 36 cm)	6	Medium (Arm circ. 24 to 36 cm) 6
	Small (Arm circ. 18-26 cm) (Optional)	6	Small (Arm circ. 18-26 cm) (Optional) 6
	<i>Sensors</i>		<i>Sensors</i>
	Pressure sensor: semi conductor	5	Pressure sensor: semi conductor 5
	<i>Measurement Records</i>		<i>Measurement Records</i>
	Memory: 120 measurements	14	Memory: 120 measurements 14
	<b>Buttons/Switches</b>		<b>Buttons/Switches</b>
	<i>Power</i>		<i>Power</i>
	On/Off with Start/Stop (O/I Label)	10	On/Off with Start/Stop (O/I Label) 10
	<i>Measurement Records</i>		<i>Measurement Records</i>
	Memory (shows average on first press)	10	Memory (shows average on first press) 10
	<i>Settings</i>		<i>Settings</i>
	Date/Time set (2 buttons: Mode & Plus)	10	Date/Time set (2 buttons: Mode & Plus) 10
	<b>Display/Symbols/Indicators</b>		<b>Display/Symbols/Indicators</b>
<i>Measurement Procedure</i>		<i>Measurement Procedure</i>	
Beeps before measurement	18	Beeps before measurement 18	
During Measurement: BP Level & Heartbeat	11	During Measurement: BP Level & Heartbeat 11	
Beeps after measurement	18	Beeps after measurement 18	
<i>Post Measurement</i>		<i>Post Measurement</i>	
SBP, DBP and Pulse	11	SBP, DBP and Pulse 11	
Measurement error $EE$ , $E1$ , $E2$ , $E3$ & $E_r$	11	Measurement error $EE$ , $E1$ , $E2$ , $E3$ & $E_r$ 11	
Hypertension (triangle)	11, 13	Hypertension (triangle) 11, 13	
Average ( $\bar{R}$ symbol)	11, 13, 14	Average ( $\bar{R}$ symbol) 11, 13, 14	

Devices	Artsana Pic Solution Help Check	Artsana Pic Solution My Check
<p><b>Same Criteria (continued)</b></p>	<p><b>Display/Symbols/Indicators (continued)</b></p> <p><i>Measurement Records</i></p> <p>Memory “M” symbol 11</p> <p>Memory recall number 11</p> <p>Delete memory (Press memory button for 5 s) 11</p> <p><i>Date and Time</i></p> <p>Date and Time 11</p> <p>Date and Time (During memory recall) 11</p> <p><i>Power</i></p> <p>Charged battery 11, 17</p> <p>Low battery 11, 17</p> <p><i>Settings</i></p> <p>Recalibrate (⌘A displayed) 11, 18</p> <p><b>Algorithms</b></p> <p><i>Averages and Differences</i></p> <p>Last 3 measurements mean 13</p> <p><i>Diagnostic</i></p> <p>135 / 85 mmHg thresholds 13</p> <p><b>Casing</b></p> <p><i>Display</i></p> <p>Single screen display 10</p> <p>Segment LCD 10</p> <p><i>Ports</i></p> <p>Data port (Optional USB cable and PC software) 16, 18</p> <p><i>Power</i></p> <p>4 “AA” batteries 17</p> <p>AC adapter (Optional) 17</p> <p>Automatic switch-off when not used for 4 min 17</p>	<p><b>Display/Symbols/Indicators (continued)</b></p> <p><i>Measurement Records</i></p> <p>Memory “M” symbol 11</p> <p>Memory recall number 11</p> <p>Delete memory (Press memory button for 5 s) 11</p> <p><i>Date and Time</i></p> <p>Date and Time 11</p> <p>Date and Time (During memory recall) 11</p> <p><i>Power</i></p> <p>Charged battery 11, 17</p> <p>Low battery 11, 17</p> <p><i>Settings</i></p> <p>Recalibrate (⌘A displayed) 11, 18</p> <p><b>Algorithms</b></p> <p><i>Averages and Differences</i></p> <p>Last 3 measurements mean 13</p> <p><i>Diagnostic</i></p> <p>135 / 85 mmHg thresholds 13</p> <p><b>Casing</b></p> <p><i>Display</i></p> <p>Single screen display 10</p> <p>Segment LCD 10</p> <p><i>Ports</i></p> <p>Data port (Optional USB cable and PC software) 16, 18</p> <p><i>Power</i></p> <p>4 “AA” batteries 17</p> <p>AC adapter (Optional) 17</p> <p>Automatic switch-off when not used for 4 min 17</p>
<p><b>Comparable Criteria</b></p>		
<p><b>Device 2 Criteria</b></p>		<p><b>Case</b></p> <p><i>Features</i></p> <p>Lid 10</p>

<b>Comments</b>	The “Help Check” is the same as the “My Check” with the addition of a haemodynamic stability indicator. (The symbol with the “OK” part is shown if the patient is fully relaxed. The symbol with the “!” part is shown if the patient is not fully relaxed and the reading may not be accurate; it is suggested that the patient rest and then take another measurement).
<b>Recommendation</b>	Equivalence is recommended
<b>Date</b>	11/01/2011