

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2011

A SIGNED COPY WILL BE POSTED ON THE www.dableducational.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 **Classic 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 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 checked="" type="checkbox"/>	No <input 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, add 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@dableducational.org.

Signature of Director MERLO MARIO Company Stamp/Seal

Name MARIO MERLO

Date

Signature of Witness [Signature]

Name FRANCESCO W ACCOLO

Address Artsana S.p.A, via Soldatini Catelli 1, 22070 GRANDATE (CO) ITALY

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Carriga Court, Georges Avenue, Blackrock, Co. Dublin, Ireland.

Form [EN 17 110110]

Tel + 353 1 278 0247

Fax + 353 1 278 3835

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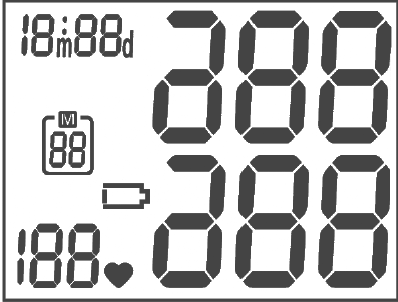
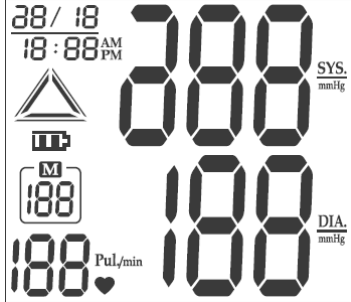
Email info@dableducational.org

Web www.dableducational.org

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 Classic Check model has the same algorithm and cone cuff of the My Check model for performing the measurement. In the Classic Check model some features are not activated (High Pressure icon and Average) and the memory sectors are 30 instead 120.

Comparison of the Artsana Pic Solution Classic Check (200) with the Artsana Pic Solution My Check

Devices	Artsana Pic Solution Classic Check (200)	Artsana Pic Solution My Check
Pictures		
Display		
Validation		ESH
Device 1 Criteria		
Same Criteria	<p>Measurement</p> <p><i>Accuracy</i></p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p>Pulse accuracy ± 5% 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</p> <p>Pulse 40 bpm -199 bpm 1, 5, 8</p> <p>Manually initiated measurements 13</p> <p>Measurements are from single inflations 13</p> <p><i>Inflation</i></p> <p>Inflation 0 mmHg - 300 mmHg 1, 5, 7</p> <p>Automatic Inflation 7</p> <p>Fuzzy Logic 7</p>	<p>Measurement</p> <p><i>Accuracy</i></p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p>Pulse accuracy ± 5% 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</p> <p>Pulse 40 bpm -199 bpm 1, 5, 8</p> <p>Manually initiated measurements 13</p> <p>Measurements are from single inflations 13</p> <p><i>Inflation</i></p> <p>Inflation 0 mmHg - 300 mmHg 1, 5, 7</p> <p>Automatic Inflation 7</p> <p>Fuzzy Logic 7</p>

Devices	Artsana Pic Solution Classic Check (200)	Artsana Pic Solution My Check
Same Criteria	<p>Measurement</p> <p><i>Inflation</i></p> <p>Zero pressure check before inflation 7</p> <p><i>Deflation</i></p> <p>Automatic Deflation 8</p> <p>Automatic safety release valve 8</p> <p><i>Cuffs</i></p> <p>Large (Arm circ. 34-46 cm) (Optional) 6</p> <p>Medium (Arm circ. 24 to 36 cm) 6</p> <p>Small (Arm circ. 18-26 cm) (Optional) 6</p> <p><i>Sensors</i></p> <p>Pressure sensor: semi conductor 5</p> <p>Buttons/Switches</p> <p><i>Power</i></p> <p>On/Off with Start/Stop (O/I Label) 10</p> <p><i>Measurement Records</i></p> <p>Memory 10</p> <p><i>Settings</i></p> <p>Date/Time set (2 buttons: Mode & Plus) 10</p> <p>Display/Symbols/Indicators</p> <p><i>Measurement Procedure</i></p> <p>During Measurement: BP Level & Heartbeat^{Query 2} 11</p> <p><i>Post Measurement</i></p> <p>SBP, DBP and Pulse 11</p> <p>Measurement error EE, $E1$, $E2$, $E3$ & E_r 11</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>Low battery 11, 17</p> <p><i>Settings</i></p> <p>Recalibrate ($\square H$ displayed) 11, 18</p> <p>Casing</p> <p><i>Display</i></p>	<p>Measurement</p> <p><i>Inflation</i></p> <p>Zero pressure check before inflation 7</p> <p><i>Deflation</i></p> <p>Automatic Deflation 8</p> <p>Automatic safety release valve 8</p> <p><i>Cuffs</i></p> <p>Large (Arm circ. 34-46 cm) (Optional) 6</p> <p>Medium (Arm circ. 24 to 36 cm) 6</p> <p>Small (Arm circ. 18-26 cm) (Optional) 6</p> <p><i>Sensors</i></p> <p>Pressure sensor: semi conductor 5</p> <p>Buttons/Switches</p> <p><i>Power</i></p> <p>On/Off with Start/Stop (O/I Label) 10</p> <p><i>Measurement Records</i></p> <p>Memory (shows average on first press) 10</p> <p><i>Settings</i></p> <p>Date/Time set (2 buttons: Mode & Plus) 10</p> <p>Display/Symbols/Indicators</p> <p><i>Measurement Procedure</i></p> <p>During Measurement: BP Level & Heartbeat^{Query 2} 11</p> <p><i>Post Measurement</i></p> <p>SBP, DBP and Pulse 11</p> <p>Measurement error EE, $E1$, $E2$, $E3$ & E_r 11</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>Low battery 11, 17</p> <p><i>Settings</i></p> <p>Recalibrate ($\square H$ displayed) 11, 18</p> <p>Casing</p> <p><i>Display</i></p>

Devices	Artsana Pic Solution Classic Check (200)	Artsana Pic Solution My Check
	Single screen display 10 Segment LCD 10 <i>Power</i> 4 “AA” batteries 17 AC adapter (Optional) 17	Single screen display 10 Segment LCD 10 <i>Power</i> 4 “AA” batteries 17 AC adapter (Optional) 17
Comparable Criteria	<p>Measurement</p> <p><i>Method</i> BP 40 mmHg - 250 mmHg^{Query 1} 1, 5, 7, 8</p> <p><i>Measurement Records</i> Memory: 30 measurements 14</p> <p>Casing</p> <p><i>Power</i> Automatic switch-off when not used for 1 min 17</p> <p><i>Ports</i> Data port (Optional USB cable and PC software) 16, 18</p>	<p>Measurement</p> <p><i>Method</i> BP 30 mmHg - 260 mmHg^{Query 1} 1, 5, 7, 8</p> <p><i>Measurement Records</i> Memory: 120 measurements 14</p> <p>Casing</p> <p><i>Power</i> Automatic switch-off when not used for 4 min 17</p> <p><i>Ports</i> Data port (Optional USB cable and PC software) 16, 18</p>
Device 2 Criteria		<p>Display/Symbols/Indicators</p> <p><i>Measurement Procedure</i> Beeps before measurement 18 Beeps after measurement 18</p> <p><i>Post Measurement</i> Hypertension (triangle) 11, 13 Average (F symbol) 11, 13, 14</p> <p><i>Power</i> Charged battery 11, 17</p> <p>Algorithms</p> <p><i>Averages and Differences</i> Last 3 measurements mean 13</p> <p><i>Diagnostic</i> 135 / 85 mmHg thresholds 13</p> <p>Case</p> <p><i>Features</i> Lid 10</p>

Comments	Artsana Pic Solution are producing a new "Classic Check" to replace their existing "Classic Check". Though quite different, each is a stripped down version of the "My Check". Some minor queries were clarified satisfactorily.	
	1	<p>Query According to the respective manuals, the measurement range for the Artsana PiC Solution My Check is 30 mmHg to 260 mmHg while that for the Artsana PiC Solution Classic Check is 40 mmHg to 250 mmHg. Given that the blood pressure measurement algorithms are identical for both devices, why is there a difference?</p> <p>Reply The Pic Solution "My Check" and the "Classic Check" BPMs use the same measurement algorithm. For marketing strategies we choose to have a narrower visualization range in the "Classic Check" BPM than in the "My Check" BPM. That means that we set different measurement range to display to the end user the blood pressure between 40mmHg and 250 mmHg instead of 30 mmHg and 260 mmHg, but the "Classic Check" BPM measures in the same manner as the "My Check" BPM.</p> <p>We have validated the "My Check" BPM with the ESH protocol in order to demonstrate the clinical accuracy by covering the measurement range from 30~260 mmHg so this range covers also the "Classic Check" range 40~250 mmHg.</p> <p>Comment Clarification is accepted.</p>
	2	<p>Query The use of the pulse indicator symbol is unclear in both manuals. Is it simply shown beside the pulse when the measurement is being displayed or is it also used during deflation to indicate the occurrence of a pulse?</p> <p>Reply The pulse indicator symbol shows the occurrence of a pulse during the deflation and when the measurement is done it is lighted on to indicate the pulse rate per minute.</p> <p>Comment Clarification is accepted.</p>
	3	<p>Query The name "Classic Check" is identical to that of another model in the Artsana PiC Solution range which is still advertised online and which is recommended on dablEducational.org. We understand the item number of this currently available model is 00 022012 000 100 while that for the model for which this equivalence is sought is 00 022012 000 200. This difference alone is too subtle to be noticed easily by consumers. When the new model is made available, how is it going to be clearly distinguishable from the current model for the consumer and, should equivalence be approved, for display on dablEducational.org?</p> <p>Reply The new Classic Check is going to be clearly distinguishable from the consumer, because the current Classic Check will be replaced by the new model.</p> <p>Comment This is essentially a marketing issue. However, the models will be distinguished clearly on the dablEducational.org website.</p>
Recommendation	Equivalence is recommended	
Date	03/11/2011	