

## DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2011

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### SECTION A - Please complete all items.

I **Mario Merlo**,  
Name of a Company Director

a Director of **Artsana s.p.a.**,  
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 **Digit Extra**

Blood pressure measuring device for which validation is claimed. If alternative model names are used, include all.

blood pressure measuring device and the

Manufacturer **Andon Health Co., Ltd.** Brand **Andon** Model **KD-5915**

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:

**Oi-Fang Huang, Jie Wang, Chang-Sheng Sheng, Na-Na Zhang, Van Li and Ji-Guang Wang**

Authors(s)

**Validation of the ANDON KD-5915 blood pressure monitor for home blood pressure monitoring according to the European Society of Hypertension International Protocol.**

Title

**Blood Pressure Monitoring**

**August 2010.**

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 checked="" type="checkbox"/>	No <input 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 checked="" 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@dableducational.org](mailto:info@dableducational.org).

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

Company Stamp/Seal

Name **Mario Merlo**

Date **GRANDATE, 6.09.2012**

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

Name **Francesco Lo Piccolo**

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

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**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.

9) Model name is different

(10) Case shape, colors and brand logo are different.





(11) LCD layout is different but all the information shown on the KD-5915 are present on the Digit Extra display.

(13) Digit Extra can also calculate and show the average reading of the last three measurements. No voice function is implemented.

(14) Digit Extra stores 30\*3 readings instead of 60 readings

Α.Κ.Σ. ΑΝΑΣΤΑΣΙΑ

Comparison of the Artsana Pic Solution Digit Extra with the Andon KD-5915

Devices	Artsana Pic Solution Digit Extra	Andon KD-5915
Pictures		
Display		
Validation		ESH 2002
Device 1 Criteria	<p><b>Display/Symbols/Indicators</b></p> <p><i>Preparation</i></p> <p>Previous memory zone (U1 or U2) displayed on BP start 11, 14</p> <p>Option to change memory zone before measurement 11, 14</p> <p><i>Post Measurement</i></p> <p>Average "A" 11, 13, 14</p> <p><b>Algorithms</b></p> <p><i>Averages and Differences</i></p> <p>Last 3 measurements memory zone mean 13</p>	
Same Criteria	<p><b>Measurement</b></p> <p><i>Accuracy</i></p> <p>BP accuracy <math>\pm 3</math> mmHg 1, 5</p> <p>Pulse accuracy <math>\pm 5\%</math> 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</p>	<p><b>Measurement</b></p> <p><i>Accuracy</i></p> <p>BP accuracy <math>\pm 3</math> mmHg 1, 5</p> <p>Pulse accuracy <math>\pm 5\%</math> <sup>Query 5</sup> 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</p>

Devices	Artsana Pic Solution Digit Extra	Andon KD-5915
<b>Same Criteria (Continued)</b>	<p><b>Measurement (continued)</b></p> <p><i>Method</i></p> <p>BP 30 mmHg – 280 mmHg (0 mmHg – 300 mmHg)<sup>Query 6</sup> 1, 5, 7, 8</p> <p>Pulse 40 bpm – 180 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 – 295 mmHg 1, 5, 7</p> <p>Automatic Inflation 7</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>Small (Arm circ. 22 to 30 cm) 6</p> <p>Medium (Arm circ. 30 to 42 cm) (Optional) 6</p> <p>Large (Arm circ. 42 to 48 cm) (Optional) 6</p> <p><i>Sensors</i></p> <p>Pressure sensor: KD-2107-006GRA<sup>Query 2</sup> 5</p> <p><b>Buttons/Switches</b></p> <p><i>Power</i></p> <p>On/Off with Start/Stop (Start symbol label) 10</p> <p><i>Measurement Records</i></p> <p>Memory 10</p> <p><b>Display/Symbols/Indicators</b></p> <p><i>Measurement Procedure</i></p> <p>Beeps before measurement 18</p> <p>Deflation symbol (Zero pressure check)<sup>Query 4</sup> 11</p> <p>Inflation symbol<sup>Query 3</sup> 11</p> <p><i>Post Measurement</i></p> <p>SBP, DBP and Pulse 11</p> <p>Measurement error (0, 1, 2, 3, 4, 5, 6, 7, 8, A) 11</p> <p>Hypertension (Indicator strip) 11, 13</p> <p>BP classification (WHO) 10, 11, 13</p> <p>Irregular heartbeat 11, 13, 18</p>	<p><b>Measurement (continued)</b></p> <p><i>Method</i></p> <p>BP 0 mmHg – 300 mmHg<sup>Query 6</sup> 1, 5, 7, 8</p> <p>Pulse 40 bpm – 180 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 – 295 mmHg 1, 5, 7</p> <p>Automatic Inflation 7</p> <p>Zero pressure check before inflation 7</p> <p><i>Deflation</i></p> <p>Automatic Deflation 8</p> <p>Automatic safety release valve<sup>Query 7</sup> 8</p> <p><i>Cuffs</i></p> <p>Small (Arm circ. 22 to 30 cm) 6</p> <p>Medium (Arm circ. 30 to 42 cm) (Optional) 6</p> <p>Large (Arm circ. 42 to 48 cm) (Optional) 6</p> <p><i>Sensors</i></p> <p>Pressure sensor: KD-2107-006G or KD-2107-006GR 5</p> <p><b>Buttons/Switches</b></p> <p><i>Power</i></p> <p>On/Off with Start/Stop (Start label) 10</p> <p><i>Measurement Records</i></p> <p>Memory 10</p> <p><b>Display/Symbols/Indicators</b></p> <p><i>Measurement Procedure</i></p> <p>Beeps before measurement 18</p> <p>Deflation symbol (Zero pressure check)<sup>Query 4</sup> 11</p> <p>Inflation symbol<sup>Query 3</sup> 11</p> <p><i>Post Measurement</i></p> <p>SBP, DBP and Pulse 11</p> <p>Measurement error (0, 1, 2, 3, 4, 5, 6, 7, 8, A) 11</p> <p>Hypertension (Indicator strip) 11, 13</p> <p>BP classification (WHO) 10, 11, 13</p> <p>Irregular heartbeat 11, 13, 18</p>

Devices	Artsana Pic Solution Digit Extra	Andon KD-5915
<b>Same Criteria (Continued)</b>	<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 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>Current unit (kPa / mmHg) marker 11</p> <p><b>Algorithms</b></p> <p><i>Diagnostic</i></p> <p>WHO Guidelines 13</p> <p>Irregular heartbeat detection 13</p> <p><b>Case</b></p> <p><i>Display</i></p> <p>Single screen display 10</p> <p>Segment LCD 10</p> <p><i>Power</i></p> <p>4 “AA” batteries (~6 months @ 3 min/d) 17</p> <p>AC adapter (Optional) 17</p> <p>Automatic switch-off when not used for 1 min 17</p> <p>Rechargeable batteries not permitted 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 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>Current unit (kPa / mmHg) marker 11</p> <p><b>Algorithms</b></p> <p><i>Diagnostic</i></p> <p>WHO Guidelines 13</p> <p>Irregular heartbeat detection 13</p> <p><b>Case</b></p> <p><i>Display</i></p> <p>Single screen display 10</p> <p>Segment LCD 10</p> <p><i>Power</i></p> <p>4 “AA” batteries (~2 months @ 3 min/d) 17</p> <p>AC adapter (Optional) 17</p> <p>Automatic switch-off when not used for 1 min 17</p> <p>Rechargeable batteries not permitted 17</p>
<b>Comparable Criteria</b>	<p><b>Measurement</b></p> <p><i>Measurement Records</i></p> <p>Memory: 30 measurements × 2 users 14</p>	<p><b>Measurement</b></p> <p><i>Measurement Records</i></p> <p>Memory: 60 measurements 14</p>
<b>Device 2 Criteria</b>		<p><b>Display/Symbols/Indicators</b></p> <p><i>Measurement Procedure</i></p> <p>Optional voiced assistance 18</p> <p><i>Post Measurement</i></p> <p>Optional voiced results 18</p> <p><i>Measurement Records</i></p> <p>Optional voiced records 18</p>

Comments	
1	<p><b>Query</b> According to the manuals, the Digit Extra is manufactured by Artsana S.p.A. in Italy but made in China whereas the Andon KD-5915 is manufactured by Andon Health Co., Ltd. in China. Can you please clarify if both devices are manufactured by the one company?</p> <p><b>Response</b> Both products mentioned above, Digit Extra and Andon KD-5915 are produced and assembled in Andon Health factory in Tianjin (China) by Andon Health Co., Ltd. Artsana Spa. is buying Digit Extra from Andon, and this blood pressure monitor is an aesthetic customized version of Andon KD-5915. Since Artsana Spa applied and obtained the CE mark for Digit Extra, Artsana Spa can claim to be the manufacturer for Digit Extra.</p> <p><b>Comment</b> In order to obtain a CE mark, the legal manufacturer, who is not necessarily the maker, must be registered in Europe. The makers must be the same for equivalence and, this is accepted as being Andon Health Co., Ltd., Tianjin, China for both devices.</p>
	<p><b>Query</b> Item 16 in the Specifications section of the manual is a heading for a list of components but no list is provided. Can you provide the list, in particular for the pressure sensor item?</p> <p><b>Response</b> Item 16 in the Specifications section represents a simple list of components that concur in performing the blood pressure measurement. The list is already included in item 16 and comprises the following components: the pump, the valve, the cuff, the sensor and the LCD (for displaying the value of the blood pressure to the users).</p> <p><b>Query</b> Query 2 related to the list of components. In the manual for the Andon KD-5915, they are listed as follows:</p> <ol style="list-style-type: none"> <li>18. A list of all components belonging to the pressure measuring system, including accessories <ol style="list-style-type: none"> <li>1) Pump: KPM27C-6B1 or CJP37-C06A1 or MPDC6V</li> <li>2) Value [sic]: KSV05B-6A or CJV13-A06A1 or VLDC6V</li> <li>3) LCD: KD-598-L01</li> <li>4) Cuff: 22cm-30cm, 30cm-42cm(Optional), 42cm-48cm(Optional)</li> <li>5) Sensor: KD-2107-006G or KD-2107-006GR</li> </ol> </li> </ol> <p>The reason for the query was to check if the sensor in the Digit Extra was also KD-2107-006G or KD-2107-006GR. Is this the case?</p> <p><b>Response</b> The pressure sensor used on Digit Extra is KD-2107-006GRA. The letter "A" at the end of the pressure sensor code for Digit Extra identifies the "packing method" of the sensor. "Packing method" means how the manufacturer packs the sensors to ship them to the customers but the sensors are perfectly the same.</p> <p><b>Comment</b> The sensors are accepted as being identical.</p>

3	Query	An up-arrow symbol is described in the Display Indicators sections of the Digit Extra manual as “need to measure again” and similarly, in the Andon KD-5915 manual, as “find an error, please re-inflate”. However, it is not described elsewhere nor shown on any of the example screens in either manual. When is it shown?
	Response	The up-arrow symbol is only shown and described in the Display Indicators sections of Digit Extra and Andon KD-5915. It has been evaluated that there is no real need to use example screens to further explain the up-arrow symbol. From the display indicators sections, the user is aware of the symbol meaning and doesn’t need to take any action while the monitor is completing the measurement.
	Comment	While this does not entirely answer the question, it does clarify that this symbol is not related to the blood pressure measurement mechanism but appears to be shown when there is an error to remind the user to try again.
4	Query	A down-arrow symbol is described in the Display Indicators sections of the Digit Extra manual as “deflate the remnant air” and similarly, in the Andon KD-5915 manual, as “the pressure in the cuff is instable, or much remnant air in cuff”. However, it is not described elsewhere nor shown on any of the example screens in either manual. When is it shown?
	Response	The down-arrow symbol is only shown and described in the Display Indicators Sections of Digit Extra and Andon KD-5915 instruction manual. Similarly as above, It has been evaluated that since the user is not required to take any action when the down-arrow symbol occurs, there is no real need to further explain the symbol using example screens.
	Comment	While this does not entirely answer the question, it does clarify that this symbol is not related to the blood pressure measurement mechanism and that it is used to indicate the zero-pressure-check procedure. However, the query was raised as the descriptions are badly worded; in particular, that in the Digit Extra manual suggests that this procedure requires to be initiated manually by the user.
5	Query	There is no pulse accuracy entry in the Specifications section in the manual for the Andon KD-5915. What is the pulse accuracy for this device?
	Response	Andon KD-5915 declared accuracy for the pulse rate is +/- 5%.
	Comment	The accuracy is accepted.
6	Query	There is no blood pressure range entry in the Specifications section in the manual for the Andon KD-5915. What is the blood pressure range for this device?
	Response	Andon KD–5915 is designed to measure blood pressure values ranging from 0 – 300 mmHg. Digit Extra is designed to measure exactly the same pressure range, although the manual shows a precautionary smaller pressure range: 30 - 280 mmHg.
	Comment	The explanation is accepted.

	7	<p>Query The Digit Extra provides rapid deflation if the cuff pressure reaches 300 mmHg. Is this feature also provided with the Andon KD-5915?</p> <p>Response Rapid deflation feature is also provided with Andon KD-5915: for all mentioned blood pressure monitors the internal air circuit is the same and the mechanic valve that guarantees the rapid deflation feature is the same component.</p> <p>Comment The explanation is accepted.</p>
<b>Recommendation</b>	Equivalence is Recommended	
<b>Date</b>	26/10/2012	