

## DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2006

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

### SECTION A - Please complete all items online.

I Liu Yi Director of Andon Health Co., Ltd  
Name of a Company Director Company name

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

BEURER BM 44

Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Andon KD-5915

Existing validated blood pressure measuring device

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

Qi-Fang Huang, Jie Wang, Chang-Sheng Sheng, Na-Na Zhang, Yan 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

2010;volume15;pp232-234

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. Please provide details on any differences below.)

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 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 type="checkbox"/>
	17	Power Supply	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	18	Other Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Brief explanation of differences and further relevant details:

- (10) Just has 1 button <Start/stop> ;
- (11) No date and time .
- (13) No voice function.
- (14) No memory

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**SECTION B** - Complete all items, bar signatures and seal, online and print. Sign and seal it then send the original along with manuals for both devices to our address below.

Signature of Director 刘子

Name Liu yi

Date 10 December 2010

Signature of Witness 刘智军

Name Liu zhijun

Address Andon Health Co.,Ltd . No.3 Jin Ping Street, Ya An Road,Nankai District,Tianjin 300790,China



**ANDON HEALTH CO., LTD.**

**No. 3 Jinping Road, Ya An Street, Nankai District, Tianjin, China**



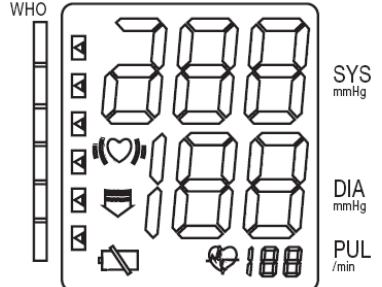
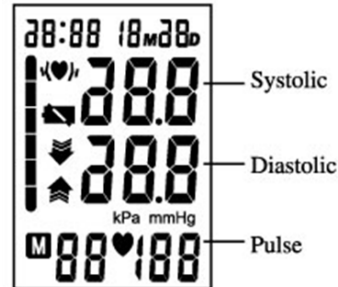
## **DECLARATION**

**DATE: DEC.15,2010**

**THIS IS TO DECLARE THAT THE MEASUREMENT ALGORITHM OF  
BLOOD PRESSURE MONITOR BM 44 IS THE SAME AS KD-5915.**

**ANDON HEALTH CO., LTD.**  
**ANDON HEALTH CO., LTD.**

Comparison of the Beurer BM44 with the Andon KD-5915

Devices	Beurer BM44	Andon KD-5915
Pictures		
Display		
Validation		ESH
Device 1 Criteria		
Same Criteria	<p><b>Measurement</b></p> <p><i>Accuracy</i></p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</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>Automatic Inflation 7</p> <p>Zero pressure check before inflation<sup>Query 2</sup> 7</p> <p><i>Deflation</i></p> <p>Automatic Deflation 8</p>	<p><b>Measurement</b></p> <p><i>Accuracy</i></p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</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>Automatic Inflation 7</p> <p>Zero pressure check before inflation<sup>Query 2</sup> 7</p> <p><i>Deflation</i></p> <p>Automatic Deflation 8</p>

Devices	Beurer BM44	Andon KD-5915
<b>Same Criteria (Continued)</b>	<b>Measurement (continued)</b>	<b>Measurement (continued)</b>
	<i>Cuffs</i>	<i>Cuffs</i>
	Medium (Arm circ. 22 to 30 cm) 6	Medium (Arm circ. 22 to 30 cm) 6
	Large (Arm circ. 30-42 cm) (Optional) 6	Large (Arm circ. 30-42 cm) (Optional) 6
	Extra Large (Arm circ. 42-48 cm) (Optional) <sup>Query 3</sup> 6	Extra Large (Arm circ. 42-48 cm) (Optional) <sup>Query 3</sup> 6
	<i>Sensors</i>	<i>Sensors</i>
	Pressure sensor: KD-2107-006G or KD-2107-006GR <sup>Query 1</sup> 5	Pressure sensor: KD-2107-006G or KD-2107-006GR <sup>Query 1</sup> 5
	<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 (Start Label) 10
	<b>Display/Symbols/Indicators</b>	<b>Display/Symbols/Indicators</b>
	<i>Preparation</i>	<i>Preparation</i>
	Previous result displayed on BP start 11, 14	Previous result displayed on BP start 11, 14
	<i>Measurement Procedure</i>	<i>Measurement Procedure</i>
	Heartbeat symbol during deflation 11	Heartbeat symbol during deflation 11
	<i>Post Measurement</i>	<i>Post Measurement</i>
	SBP, DBP and Pulse 11	SBP, DBP and Pulse 11
	Measurement error (0, 1, 2, 3, 4, 5, 6, 7, 8, A) 11	Measurement error (0, 1, 2, 3, 4, 5, 6, 7, 8, A) 11
	Hypertension (Indicator strip) 11, 13	Hypertension (Indicator strip) 11, 13
	BP classification (WHO) 10, 11, 13	BP classification (WHO) 10, 11, 13
	Irregular heartbeat 11, 13, 18	Irregular heartbeat 11, 13, 18
	<i>Power</i>	<i>Power</i>
	Low battery 11, 17	Low battery 11, 17
	<b>Algorithms</b>	<b>Algorithms</b>
	<i>Diagnostic</i>	<i>Diagnostic</i>
	WHO Guidelines 13	WHO Guidelines 13
	Irregular heartbeat detection 13	Irregular heartbeat detection 13
<b>Case</b>	<b>Case</b>	
<i>Display</i>	<i>Display</i>	
Single screen display 10	Single screen display 10	
Segment LCD 10	Segment LCD 10	
<i>Power</i>	<i>Power</i>	
4 "AA" batteries ~ 600 measurements 17	4 "AA" batteries 17	
AC adapter (Optional) 17	AC adapter (Optional) 17	
Automatic switch-off when not used for 1 min 17	Automatic switch-off when not used for 1 min 17	
Rechargeable batteries not permitted 17	Rechargeable batteries not permitted 17	

Devices	Beurer BM44	Andon KD-5915
<b>Comparable Criteria</b>	<p><b>Measurement</b> <i>Inflation</i> Inflation 0 mmHg - 300 mmHg 1, 5, 7</p> <p><b>Measurement (continued)</b> <i>Measurement Records</i> Memory: 1 measurement 14</p>	<p><b>Measurement</b> <i>Inflation</i> Inflation 0 mmHg - 295 mmHg 1, 5, 7</p> <p><b>Measurement (continued)</b> <i>Measurement Records</i> Memory: 60 measurements 14</p>
<b>Device 2 Criteria</b>		<p><b>Buttons/Switches</b> <i>Measurement Records</i> Memory 10</p> <p><b>Display/Symbols/Indicators</b> <i>Measurement Procedure</i> Beeps before measurement 18 Optional voiced assistance 18</p> <p><i>Post Measurement</i> Optional voiced results 18</p> <p><i>Measurement Records</i> Memory "M" symbol 11 Memory recall number 11 Delete memory 11 Optional voiced records 18</p> <p><i>Date and Time</i> Date and Time 11 Date and Time (During memory recall) 11</p> <p><i>Settings</i> Current unit (kPa / mmHg) marker <sup>Note 1</sup> 11</p>
<b>Web link</b>	<a href="http://www.beurer.com/web/en/product/blood_pressure/upper_arm/detail.php?pk=31&amp;id=13514&amp;bek=112&amp;bct=%26nbsp%3B%26gt%3B%26nbsp%3Bproduct+details%26nbsp%3B%26gt%3B%26nbsp%3BBM44">http://www.beurer.com/web/en/product/blood_pressure/upper_arm/detail.php?pk=31&amp;id=13514&amp;bek=112&amp;bct=%26nbsp%3B%26gt%3B%26nbsp%3Bproduct+details%26nbsp%3B%26gt%3B%26nbsp%3BBM44</a>	<a href="http://andon.manufacturer.globalsources.com/si/6008800800032/pdf/Wrist-blood/1032471456/Blood-Pressure-Monitor.htm">http://andon.manufacturer.globalsources.com/si/6008800800032/pdf/Wrist-blood/1032471456/Blood-Pressure-Monitor.htm</a>

<b>Comments</b>	<p>Andon is an OEM manufacturer for the BM-44.</p> <p>The BM44 is a more basic device than the Andon KD-5915. There are no date and time facilities and only the last reading is stored.</p> <p>There were three queries which were answered satisfactorily.</p> <p>Query 1        Is the pressure sensor KD-2107-006G or KD-2107-006GR used in the BM44?</p> <p>Response 1    <i>Yes, this pressure sensor is used in BM44</i></p> <p>Query 2        Is the zero pressure check used in the BM44?</p> <p>Response 2    <i>Yes, zero pressure check is used in BM44</i></p> <p>Query 3        Can the extra large cuff be used with the BM44?</p> <p>Response 3    <i>Yes, BM44 can use an extra large cuff</i></p> <p>A previous query to Andon is relevant</p> <p>Query 4        On the display screen of the KD-5915, there are units for mmHg and kPa that seem to indicate a conversion facility. No such ability is described. Can you please confirm this facility either way?</p> <p>Response 4    <i>When the "START" button is pressed, all display characters are shown for self-test. The kPa is only displayed at the moment. It's a reserved function that the result is displayed for kPa. The function doesn't open, so the Operation Guide of the KD-5915 doesn't mention it.</i></p> <p>Response 4a   <i>The displayed "kPa" is just a reserved functionality. It is not used in the BM44.</i></p>
<b>Recommendation</b>	Equivalence is recommended.
<b>Date</b>	31/01/2011