

## DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2013

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

### SECTION A - Please complete all items.

I **Liu Yi,** a 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

Maker <sup>a</sup>	Beurer	Address	Soeflinger Strasse 218 * 89077 Ulm / Germany
Manufacturer <sup>b</sup>	Andon	Address	Andon Health Co.,Ltd.No.3 Jin Ping Street,Ya An Road,Nankai District,Tianjin 300190,China
Brand <sup>c</sup>	Beurer	Model <sup>d</sup>	BM45

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 <sup>a</sup>	Andon	Address	Andon Health Co.,Ltd.No.3 Jin Ping Street,Ya An Road,Nankai District,Tianjin 300190,China
Manufacturer <sup>b</sup>	Andon	Address	Andon Health Co.,Ltd.No.3 Jin Ping Street,Ya An Road,Nankai District,Tianjin 300190,China
Brand <sup>c</sup>	Andon	Model <sup>d</sup>	KD-5917

Existing validated blood pressure measuring device.

which has previously passed the ESH2010 protocol, the results of which were published as follows:

Guo WG, Li BL, He Y, Xue YS, Wang HY, Zheng QS, Xiang DC. Validation of the Andon KD-5917 automatic upper arm blood pressure monitor, for clinic use and self-measurement, according to the European Society of Hypertension International Protocol revision 2010. Blood Press Monit. Blood Press Monit 2014;19(4):242-5

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 <sup>e</sup> <input type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>f</sup> <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"/>	N/A <sup>f</sup> <input type="checkbox"/>
	5	Pressure Transducer	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
	6	Cuffs or Bladders	Yes <input checked="" type="checkbox"/>	No <input 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 type="checkbox"/>	No <input type="checkbox"/>	
	10	Casing	Yes <input 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 type="checkbox"/>	No <input type="checkbox"/>	
	15	Printing Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>g</sup> <input type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>g</sup> <input type="checkbox"/>
	17	Power Supply	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	18	Other Facilities	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>g</sup> <input 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.

(6)The bladders of the two Model are same. Cuff size for KD-5917 is 22cm-42cm,cuff size for BM45 is 22cm-36cm. The cuff size is different,but the range of the cuff size BM45 is included in the cuff size KD-5917.

(9) The Model Name is changed to Beurer BM45 from Andon KD-5917;

(10) 3buttons: START/STOP button, Memory buttonM1 and M2;

(11)Have symbols for "User memory". No symbol for "inflate to measure";

(13)The monitor can show the average reading of the morning/evening measurements for the last 7 days (morning: 5:00 a.m -9:00 a.m; evening: 6:00 p.m-8:00 p.m);

(18) No voice function;

**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@dablededucational.org](mailto:info@dablededucational.org).

Signature of Director \_\_\_\_\_ Company Stamp/Seal

Name Liu Yi

Date 2 Dec. 2015

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



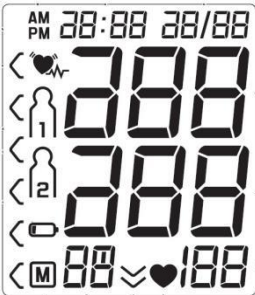
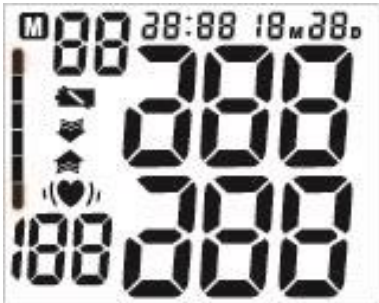
Name Zhang Fei

Address Andon Health Co.,Ltd.No.3 Jin Ping Street,Ya An Road,Nankai District,Tianjin 300190,China





Comparison of the Beurer BM 45 with the Andon KD-5917

Devices	Beurer BM 45(Device 2)	Andon KD-5917(Device 1)
Pictures		
Display		
Validation		ESH 2010
Category	SBPM & CBPM	SBPM & CBPM
Device 1 Criteria		<p><i>Cuff size</i> 22-42cm</p> <p><i>Voice Function</i> Yes</p> <p><i>Dimension</i> 125mm x 130mm x 62mm</p> <p><i>Weight</i> 323g(Excluding batteries)</p> <p><i>Buttons</i> Memory buttons MEM</p> <p><i>Software other than algorithm</i> No average reading measurements function</p>

<p><b>Device 2 Criteria</b></p>	<p><i>Cuff size</i> 22-36cm</p> <p><i>Voice Function</i> No</p> <p><i>Dimension</i> 165 mm x 107 mm x 50 mm</p> <p><i>Weight</i> 284g(Excluding batteries)</p> <p><i>Buttons</i> Memory buttons M1/M2</p> <p><i>Software other than algorithm</i> The monitor can show the average reading of the morning/evening measurements for the last 7 days (morning: 5:00 a.m -9:00 a.m; evening: 6:00 p.m-8:00 p.m)</p>	
<p><b>Same Criteria</b></p>	<p><b>Measurement</b></p> <p><i>Accuracy</i> Pressure: <math>\pm 3</math>mmHg Pulse rate: <math>\pm 5\%</math></p> <p><i>Method</i> Oscillometric</p> <p><i>Ranges</i> Cuff pressure 0 – 300 mmHg systolic 60 – 260 mmHg diastolic 40 –199 mmHg</p> <p><i>Inflation</i> Automatic inflation by internal pump</p> <p><i>Deflation</i> Automatic speed deflation system</p> <p><i>Cuffs</i> 22-36cm</p> <p><i>Sensors</i> KD-2107-006G or KD-2017-006GR</p>	<p><b>Measurement</b></p> <p><i>Accuracy</i> Pressure: <math>\pm 3</math>mmHg Pulse rate: <math>\pm 5\%</math></p> <p><i>Method</i> Oscillometric</p> <p><i>Ranges</i> Cuff pressure 0 – 300 mmHg systolic 60 – 260 mmHg diastolic 40 –199 mmHg</p> <p><i>Inflation</i> Automatic inflation by internal pump</p> <p><i>Deflation</i> Automatic speed deflation system</p> <p><i>Cuffs</i> 22-42cm</p> <p><i>Sensors</i> KD-2107-006G or KD-2017-006GR</p>

	<p><i>Measurement Records</i> 2*60 times with time and date stamp</p> <p><i>Measurements other than Blood Pressure</i> Heart rate</p> <p><b>Buttons/Switches</b> <i>Power</i> Start/stop button</p> <p><i>Measurement Records</i> N/A</p> <p><i>Analysis</i> N/A</p> <p><i>Event Marking</i> N/A</p> <p><i>Communication</i> N/A</p> <p><b>Display/Symbols/Indicators</b> <i>Preparation</i> N/A</p> <p><i>Measurement Procedure</i> Measuring during deflation</p> <p><i>Post Measurement</i> Upper arm</p> <p><i>Measurement Records</i> 2*60 times with time and date stamp</p> <p><i>Date and Time</i> Display the date and time in the up side of the LCD</p> <p><i>Power</i> 4 AA batteries</p>	<p><i>Measurement Records</i> 2*60 times with time and date stamp</p> <p><i>Measurements other than Blood Pressure</i> Heart rate</p> <p><b>Buttons/Switches</b> <i>Power</i> Start/stop button</p> <p><i>Measurement Records</i> N/A</p> <p><i>Analysis</i> N/A</p> <p><i>Event Marking</i> N/A</p> <p><i>Communication</i> N/A</p> <p><b>Display/Symbols/Indicators</b> <i>Preparation</i> N/A</p> <p><i>Measurement Procedure</i> Measuring during deflation</p> <p><i>Post Measurement</i> Upper arm</p> <p><i>Measurement Records</i> 2*60 times with time and date stamp</p> <p><i>Date and Time</i> Display the date and time in the up side of the LCD</p> <p><i>Power</i> 4 AA batteries</p>
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	<p><i>Function</i> N/A</p> <p><i>Communication</i> N/A</p> <p><i>Features</i> N/A</p> <p><i>Not described</i> N/A</p> <p><b>Algorithms</b> <i>Diagnostic</i> N/A</p> <p><i>Functions</i> Measure blood pressure and heart rate</p> <p><i>Communication</i> N/A</p> <p><b>Casing</b> <i>Display</i> LCD</p> <p><i>Ports</i> Cuff port</p> <p><i>Power</i> 4 AA batteries</p> <p><i>Features</i> N/A</p>	<p><i>Function</i> N/A</p> <p><i>Communication</i> N/A</p> <p><i>Features</i> N/A</p> <p><i>Not described</i> N/A</p> <p><b>Algorithms</b> <i>Diagnostic</i> N/A</p> <p><i>Functions</i> Measure blood pressure and heart rate</p> <p><i>Communication</i> N/A</p> <p><b>Casing</b> <i>Display</i> LCD</p> <p><i>Ports</i> Cuff port</p> <p><i>Power</i> 4 AA batteries</p> <p><i>Features</i> N/A</p>
<p><b>Comparable Criteria</b></p>	<p>N/A</p>	<p>N/A</p>

<b>Comments</b>		
<b>Recommendation</b>	<b>Recommended</b>	
<b>Date</b>	<b>17 December 2015</b>	