

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2006

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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 SBM 45

- 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
Publication

2010; volume 15; pp232-234
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) Touch Button ;

(13) No voice function; display the average value of all the results which is measured from 5 o'clock to 9 o'clock in last 7 days; display the average value of all the results which is measured from 18 o'clock to 20 o'clock in last 7 days.

(14) 2*60

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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 刘毅

Name Liu yi

Date 15 December 2011

Signature of Witness 刘治军





Name Liu zhijun

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

Company Stamp/Seal



Comparison of the Beurer (Sanitas) SBM 45 with the Andon KD-5915

Devices	Beurer (Sanitas) SBM 45	Andon KD-5915
Pictures		
Display		
Validation		ESH
Device 1 Criteria	<p>Buttons/Switches</p> <p><i>Power</i></p> <p>Touch Screen Activation Switch 10</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation and Measurement Records</i></p> <p>User number (U1 or U2) 11, 14</p> <p><i>Post Measurement</i></p> <p>All measurements average (A symbol) 11, 13, 14</p> <p>7-day morning average (AM symbol) 11, 13, 14</p> <p>7-day evening average (PM symbol) 11, 13, 14</p> <p>Algorithms</p> <p><i>Averages and Differences</i></p> <p>All measurements mean 13</p> <p>7-day morning mean 13</p> <p>7-day evening mean 13</p>	

Devices	Beurer (Sanitas) SBM 45	Andon KD-5915
Device 1 Criteria <i>Continued</i>	Casing <i>Features</i> Cuff Holder 10	
Same Criteria	<p>Measurement</p> <p><i>Accuracy</i></p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p>Pulse accuracy $\pm 5\%$ ^{Query 1} 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</p> <p>BP 30 mmHg – 280 mmHg ^{Query 2} 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>Automatic Inflation 7</p> <p>Zero pressure check before inflation ^{Query 3} 7</p> <p><i>Deflation</i></p> <p>Automatic Deflation 8</p> <p><i>Cuffs</i></p> <p>Medium (Arm circ. 22 to 30 cm) 6</p> <p>Large (Arm circ. 30-42 cm) (Optional) 6</p> <p>Extra Large (Arm circ. 42-48 cm) (Usable but not supplied) ^{Query 4} 6</p> <p><i>Sensors</i></p> <p>Pressure sensor: KD-2107-006G or KD-2107-006GR ^{Query 5} 5</p> <p>Buttons/Switches</p> <p><i>Power</i></p> <p>On/Off with Start/Stop (Touch screen, Ⓜ symbol) 10</p> <p><i>Measurement Records</i></p> <p>Memory (Touch screen, MEM symbol) 10</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i></p> <p>Previous result displayed on BP start (U1 or U2) 11, 14</p> <p>Release air (⬇ symbol) ^{Query 6} 11, 14</p> <p><i>Measurement Procedure</i></p> <p>Heartbeat symbol during deflation 11</p>	<p>Measurement</p> <p><i>Accuracy</i></p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p>Pulse accuracy $\pm 5\%$ ^{Query 1} 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</p> <p>BP 30 mmHg – 280 mmHg ^{Query 2} 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>Automatic Inflation 7</p> <p>Zero pressure check before inflation ^{Query 3} 7</p> <p><i>Deflation</i></p> <p>Automatic Deflation 8</p> <p><i>Cuffs</i></p> <p>Medium (Arm circ. 22 to 30 cm) 6</p> <p>Large (Arm circ. 30-42 cm) (Optional) 6</p> <p>Extra Large (Arm circ. 42-48 cm) (Optional) ^{Query 4} 6</p> <p><i>Sensors</i></p> <p>Pressure sensor: KD-2107-006G or KD-2107-006GR ^{Query 5} 5</p> <p>Buttons/Switches</p> <p><i>Power</i></p> <p>On/Off with Start/Stop (START label) 10</p> <p><i>Measurement Records</i></p> <p>Memory (MEM label) 10</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i></p> <p>Previous result displayed on BP start 11, 14</p> <p>Remnant air in cuff (⬇ symbol) ^{Query 6} 11, 14</p> <p><i>Measurement Procedure</i></p> <p>Heartbeat symbol during deflation 11</p>

Devices	Beurer (Sanitas) SBM 45	Andon KD-5915
Same Criteria <i>Continued</i>	<p>Display/Symbols/Indicators</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>Pump up (↑ symbol) ^{Query 7} 11, 14</p> <p><i>Measurement Records</i></p> <p>Memory “M” symbol 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>Algorithms</p> <p><i>Diagnostic</i></p> <p>WHO Guidelines 13</p> <p>Irregular heartbeat detection 13</p> <p>Case</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 ~ 500 measurements 17</p> <p>AC adapter (Optional) 17</p> <p>Auto switch-off when not used for 1 min (2 min Memory mode) 17</p> <p>Rechargeable batteries not permitted 17</p>	<p>Display/Symbols/Indicators</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>Error re-inflate (↑ symbol) ^{Query 7} 11, 14</p> <p><i>Measurement Records</i></p> <p>Memory “M” symbol 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>Algorithms</p> <p><i>Diagnostic</i></p> <p>WHO Guidelines 13</p> <p>Irregular heartbeat detection 13</p> <p>Case</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 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>
Comparable Criteria	<p>Measurement</p> <p><i>Inflation</i></p> <p>Inflation 0 mmHg - 300 mmHg 1, 5, 7</p> <p><i>Measurement Records</i></p> <p>Memory: 2 × 60 measurements 14</p>	<p>Measurement</p> <p><i>Inflation</i></p> <p>Inflation 0 mmHg - 295 mmHg 1, 5, 7</p> <p><i>Measurement Records</i></p> <p>Memory: 60 measurements 14</p>

Devices	Beurer (Sanitas) SBM 45	Andon KD-5915
Device 2 Criteria		<p>Display/Symbols/Indicators</p> <p><i>Measurement Procedure</i></p> <p>Beeps before measurement 18</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>Memory recall number 11</p> <p>Optional voiced records 18</p> <p><i>Settings</i></p> <p>Current unit (kPa / mmHg) marker ^{Note 1} 11</p>
Web link	http://www.sanitas-online.de/web/en/products/bloodpressure/upperarm/SBM45.php	http://andon.manufacturer.globalsources.com/si/6008800800032/pdf/Wrist-blood/1032471456/Blood-Pressure-Monitor.htm

Comments	<p>Andon is an OEM manufacturer for the SBM 45.</p> <p>The SBM 45 is functionally the same as the Andon KD-5915 with added dual user, averaging and touch screen but without the voiced results.</p> <p>There were seven queries which were answered satisfactorily.</p>	
Queries	1	<p>Query A pulse accuracy of $\pm 5\%$ is described for the SBM 45. No information on pulse accuracy is provided for the KD-5915. What is the pulse accuracy for the KD-5915?</p> <p>Reply The pulse accuracy of KD-5915 is +/- 5%</p> <p>Comment Clarification is accepted.</p>
	2	<p>Query A measurement range of 30 mmHg - 280 mmHg for both SBP and DBP is described for the SBM 45. No information on measurement ranges is provided for the KD-5915. What is the blood pressure measurement range for the KD-5915?</p> <p>Reply The measurement range of KD-5915 is 30 – 280 mmHg</p> <p>Comment Clarification is accepted.</p>
	3	<p>Query Is the zero pressure check used in the SBM 45?</p> <p>Reply Yes, the zero pressure check is used in the SBM45</p> <p>Comment Clarification is accepted.</p>
	4	<p>Query An optional extra large cuff (Arm circ. 42-48 cm) is available for the KD-5915. There is no mention of it in the manual for the SBM 45. Can this cuff be used with the SBM 45?</p> <p>Reply Yes, this cuff can be used with SBM45 but it is not part of our sales offer.</p> <p>Comment Clarification is accepted.</p>
	5	<p>Query The pressure sensor for the KD-5915 is described as KD-2107-006G or KD-2107-006GR. No information is provided for the SBM 45. Are the same sensors used?</p> <p>Reply Yes, SBM45 also use the same sensors</p> <p>Comment Clarification is accepted.</p>

Queries (Continued)	6	Query	The ↓ symbol is described in the respective diagram legends as “Release Air” for the SBM 45 and as “the pressure in cuff is instable, or much remnant air in cuff” for the KD-5915. No other details are provided. What do these mean?
		Reply	“Release air” in SBM45 and “the pressure in cuff is instable, or much remnant air in cuff” in the KD-5915 have the same meaning
		Comment	Clarification is accepted.
	7	Query	The ↑ symbol is described in the respective diagram legends as “Pump up” for the SBM 45 and as “find an error, please re-inflate” for the KD-5915. No other details are provided. What do these mean?
		Reply	“Pump up” in SBM45 and “find an Error, please re-inflate” in KD-5915 have the same meaning.
		Comment	Clarification is accepted.
Notes	1	A previous query to Andon is relevant	
		Query	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?
		Reply	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. The displayed “kPa” is just a reserved functionality.
		Comment	Clarification is accepted.
Recommendation	Equivalence is recommended		
Date	02/05/2012		