



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

Andon KD-556
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

Blood Pressure Monitoring August 2010
Title Year Volume Pages

The only differences between the devices involve the following components:



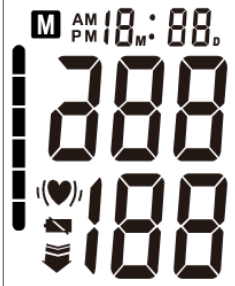
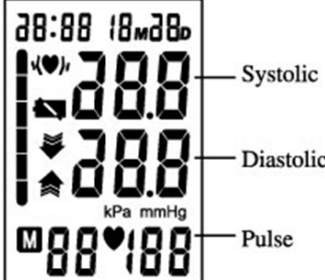
(When a component is not relevant, both Yes and No should be left blank. Please provide details on any differences below.)

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 checked="" type="checkbox"/>
	18	Other Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Brief explanation of differences and further relevant details:

- (11) the blood pressure and pulse rate will be displayed on the LCD screen separately.
- (13) The monitor can also show the average reading of the last three measurements.No voice function.
- (14) Stores 60*2 readings instead of 60 readings

Comparison of the Andon KD-556 with the Andon KD-5915

Devices	Andon KD-556	Andon KD-5915
Pictures		
Display		
Validation		ESH
Device 1 Criteria	<p>Display/Symbols/Indicators</p> <p><i>Preparation</i></p> <p>Previous memory zone result displayed on BP start 11, 14</p> <p>Option to change memory zone 11, 14</p> <p><i>Post Measurement</i></p> <p>Memory zone average 11, 13, 14</p> <p><i>Measurement Records</i></p> <p>Memory, number of stored measurements 11</p> <p>Memory zone 11</p> <p>Algorithms</p> <p><i>Averages and Differences</i></p> <p>Last 3 measurements memory zone mean 13</p>	
Same Criteria	<p>Measurement</p> <p><i>Accuracy</i></p> <p>BP accuracy ± 3 mmHg 1, 5</p>	<p>Measurement</p> <p><i>Accuracy</i></p> <p>BP accuracy ± 3 mmHg 1, 5</p>

Devices	Andon KD-556	Andon KD-5915		
Same Criteria (Continued)	Measurement (continued)			
	<i>Method</i>			
	Oscillometric measurement method	1, 5	Oscillometric measurement method	1, 5
	Pulse 40 bpm -180 bpm	1, 5, 8	Pulse 40 bpm -180 bpm	1, 5, 8
	Manually initiated measurements	13	Manually initiated measurements	13
	Measurements are from single inflations	13	Measurements are from single inflations	13
	<i>Inflation</i>		<i>Inflation</i>	
	Inflation 0 mmHg - 295 mmHg	1, 5, 7	Inflation 0 mmHg - 295 mmHg	1, 5, 7
	Automatic Inflation	7	Automatic Inflation	7
	Zero pressure check before inflation	7	Zero pressure check before inflation	7
	<i>Deflation</i>		<i>Deflation</i>	
	Automatic Deflation	8	Automatic Deflation	8
	<i>Cuffs</i>		<i>Cuffs</i>	
	Extra Large (Arm circ. 30-42 cm) (Optional)	6	Extra Large (Arm circ. 30-42 cm) (Optional)	6
	Large (Arm circ. 30-42 cm) (Optional)	6	Large (Arm circ. 30-42 cm) (Optional)	6
	Medium (Arm circ. 22 to 30 cm)	6	Medium (Arm circ. 22 to 30 cm)	6
	Buttons/Switches		Buttons/Switches	
	<i>Power</i>		<i>Power</i>	
	On/Off with Start/Stop (Start Label)	10	On/Off with Start/Stop (Start Label)	10
	<i>Measurement Records</i>		<i>Measurement Records</i>	
	Memory	10	Memory	10
	Display/Symbols/Indicators		Display/Symbols/Indicators	
	<i>Measurement Procedure</i>		<i>Measurement Procedure</i>	
	Beeps before measurement	18	Beeps before measurement	18
	<i>Post Measurement</i>		<i>Post Measurement</i>	
	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>Measurement Records</i>		<i>Measurement Records</i>		
Memory "M" symbol	11	Memory "M" symbol	11	
Memory recall number	11	Memory recall number	11	
Delete memory	11	Delete memory	11	
<i>Date and Time</i>		<i>Date and Time</i>		
Date and Time	11	Date and Time	11	
Date and Time (During memory recall)	11	Date and Time (During memory recall)	11	

Devices	Andon KD-556	Andon KD-5915
Same Criteria (Continued)	<p>Display/Symbols/Indicators (continued)</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><i>Parameter Settings</i></p> <p>Unit conversion (kPa / mmHg) 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>Automatic switch-off when not used for 1 min 17</p> <p>Rechargeable batteries not permitted 17</p>	<p>Display/Symbols/Indicators (continued)</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><i>Parameter Settings</i></p> <p>Unit conversion (kPa / mmHg) 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>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>Sensors</i></p> <p>Pressure sensor: KD-2107-006G 5</p> <p><i>Measurement Records</i></p> <p>Memory: 60 measurements × 2 zones 14</p> <p>Display/Symbols/Indicators</p> <p><i>Post Measurement</i></p> <p>SBP and DBP with separate Pulse 11</p>	<p>Measurement</p> <p><i>Sensors</i></p> <p>Pressure sensor: KD-2107-006G or KD-2107-006GR 5</p> <p><i>Measurement Records</i></p> <p>Memory: 60 measurements 14</p> <p>Display/Symbols/Indicators</p> <p><i>Post Measurement</i></p> <p>SBP, DBP and Pulse 11</p>
Device 2 Criteria		<p>Display/Symbols/Indicators</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> <p><i>Settings</i></p> <p>Current unit (kPa / mmHg) marker 11</p> <p>Case</p> <p><i>Power</i></p> <p>AC adapter (Optional) 17</p>

Devices	Andon KD-556	Andon KD-5915
Web link	http://andon.manufacturer.globalsources.com/si/6008800800032/pdf/Sphygmomanometer/1031197250/Blood-Pressure-Monitor.htm	http://andon.manufacturer.globalsources.com/si/6008800800032/pdf/Wrist-blood/1032471456/Blood-Pressure-Monitor.htm
Comments	<p>There was just one query</p> <p>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?</p> <p>Response <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>	
Recommendation	Equivalence is recommended	
Date	20/07/2010	