

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-5913
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 type="checkbox"/>	No <input checked="" 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:

(10) 3 buttons, <I/O><MEM><AVG>

(13) The monitor can also show the average reading of the last three measurements; No voice function; No BP classification(WHO).

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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 _____

Name _____ Liu yi

Date _____ 4 August 2010

Signature of Witness _____

Name _____ Liu zhijun

Address _____



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

Comparison of the Andon KD-5913 with the Andon KD-5915

Devices	Andon KD-5913	Andon KD-5915
Pictures		
Display		
Validation		ESH
Device 1 Criteria	<p>Buttons/Switches</p> <p><i>Analysis</i></p> <p>Average (AVG Label) 10</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i></p> <p>Previous result displayed on BP start 11, 14</p> <p><i>Post Measurement</i></p> <p>Average 11, 13, 14</p> <p>Algorithms</p> <p><i>Averages and Differences</i></p> <p>Last 3 measurements 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-5913	Andon KD-5915		
Same Criteria (Continued)	Measurement (continued)	Measurement (continued)		
	<i>Method</i>	<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. 42-48 cm) (Optional)	6	Extra Large (Arm circ. 42-48 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
	<i>Sensors</i>		<i>Sensors</i>	
	Pressure sensor: KD-2107-006G or KD-2107-006GR	5	Pressure sensor: KD-2107-006G or KD-2107-006GR	5
	<i>Measurement Records</i>		<i>Measurement Records</i>	
	Memory: 60 measurements	14	Memory: 60 measurements	14
	Buttons/Switches		Buttons/Switches	
	<i>Power</i>		<i>Power</i>	
	On/Off with Start/Stop (O/I 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>		
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	
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	

Devices	Andon KD-5913	Andon KD-5915
Same Criteria (Continued)	<p>Display/Symbols/Indicators (continued)</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>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>	<p>Display/Symbols/Indicators (continued)</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>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		
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>Hypertension (Indicator strip) 11, 13</p> <p>BP classification (WHO) 10, 11, 13</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>Algorithms</p> <p><i>Diagnostic</i></p> <p>WHO Guidelines 13</p>
Web link		http://andon.manufacturer.globalsources.com/si/6008800800032/pd/tl/Wrist-blood/1032471456/Blood-Pressure-Monitor.htm

Comments	There was just one query 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? 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>
Recommendation	Equivalence is recommended
Date	17/08/2010