

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

Medel Elite (92125)
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

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 explanations 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 刘怡

Company Stamp/Seal

Name Liu Yi

Date 9 September 2010



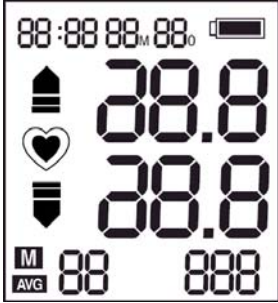
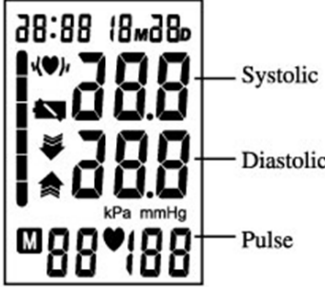
Signature of Witness 刘智军

Name Liu zhijun

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



Comparison of the Medel Elite (92125) with the Andon KD-5915

Devices	Medel Elite (92125)	Andon KD-5915
Pictures		
Display		
Validation		ESH
Device 1 Criteria	<p>Buttons/Switches</p> <p><i>Analysis</i></p> <p>Average (T3 Label) 10</p> <p>Display/Symbols/Indicators</p> <p><i>Measurement Procedure</i></p> <p>Inflation symbol 11</p> <p>Deflation symbol 11</p> <p><i>Post Measurement</i></p> <p>Average "AVG" symbol 11, 13, 14</p> <p>Algorithms</p> <p><i>Averages and Differences</i></p> <p>Last 3 measurements mean 13</p> <p>Case</p> <p><i>Display</i></p> <p>Backlight 10</p>	

Devices	Medel Elite (92125)	Andon KD-5915
Same Criteria (Continued)	Measurement (continued)	Measurement (continued)
	<i>Accuracy</i>	<i>Accuracy</i>
	BP accuracy ± 3 mmHg	BP accuracy ± 3 mmHg
	Pulse accuracy ± 5%	Pulse accuracy ± 5%
	<i>Method</i>	<i>Method</i>
	Oscillometric measurement method	Oscillometric measurement method
	Pulse 40 bpm -180 bpm	Pulse 40 bpm -180 bpm
	Manually initiated measurements	Manually initiated measurements
	Measurements are from single inflations	Measurements are from single inflations
	<i>Inflation</i>	<i>Inflation</i>
	Inflation 0 mmHg - 295 mmHg	Inflation 0 mmHg - 295 mmHg
	Automatic Inflation	Automatic Inflation
	Zero pressure check before inflation/Self test	Zero pressure check before inflation/Self test
	<i>Deflation</i>	<i>Deflation</i>
	Automatic Deflation	Automatic Deflation
	<i>Cuffs</i>	<i>Cuffs</i>
	Extra Large (XXL) (Arm circ. 42-48 cm) (Optional)	Extra Large (Arm circ. 42-48 cm) (Optional)
	Large (XL) (Arm circ. 30-42 cm) (Optional)	Large (Arm circ. 30-42 cm) (Optional)
	Medium (Standard) (Arm circ. 22 to 30 cm)	Medium (Arm circ. 22 to 30 cm)
	<i>Sensors</i>	<i>Sensors</i>
	Pressure sensor: KD-2107-006G or KD-2107-006GR	Pressure sensor: KD-2107-006G or KD-2107-006GR
	<i>Measurement Records</i>	<i>Measurement Records</i>
	Memory: 60 measurements	Memory: 60 measurements
	Buttons/Switches	Buttons/Switches
	<i>Power</i>	<i>Power</i>
	On/Off with Start/Stop (O/I Label)	On/Off with Start/Stop (Start Label)
	<i>Measurement Records</i>	<i>Measurement Records</i>
Memory	Memory	
Display/Symbols/Indicators	Display/Symbols/Indicators	
<i>Measurement Procedure</i>	<i>Measurement Procedure</i>	
During Measurement: BP Level & Heartbeat	During Measurement: BP Level & Heartbeat	
Beeps before measurement	Beeps before measurement	
<i>Post Measurement</i>	<i>Post Measurement</i>	
SBP, DBP and Pulse	SBP, DBP and Pulse	
Measurement error (0, 1, 2, 3, 4, 5, 6, 7, 8, A)	Measurement error (0, 1, 2, 3, 4, 5, 6, 7, 8, A)	
Irregular heartbeat	Irregular heartbeat	

Devices	Medel Elite (92125)	Andon KD-5915
Same Criteria (Continued)	<p>Display/Symbols/Indicators (continued)</p> <p><i>Measurement Records</i></p> <p>Memory “M” symbol 11</p> <p>Memory recall number 11</p> <p>Delete memory 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>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>Rechargeable batteries not permitted 17</p>	<p>Display/Symbols/Indicators (continued)</p> <p><i>Measurement Records</i></p> <p>Memory “M” symbol 11</p> <p>Memory recall number 11</p> <p>Delete memory 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>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>Rechargeable batteries not permitted 17</p>
Comparable Criteria	<p>Display/Symbols/Indicators</p> <p><i>Power</i></p> <p>Low/Full battery 11, 17</p> <p>Case</p> <p><i>Power</i></p> <p>Automatic switch-off when not used for 2 min 17</p>	<p>Display/Symbols/Indicators</p> <p><i>Power</i></p> <p>Low battery 11, 17</p> <p>Case</p> <p><i>Power</i></p> <p>Automatic switch-off when not used for 1 min 17</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>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>

Devices	Medel Elite (92125)	Andon KD-5915
Device 2 Criteria (Continued)		Algorithms Diagnostic WHO Guidelines 13
Web link		http://andon.manufacturer.globalsources.com/si/6008800800032/pdf/Wrist-blood/1032471456/Blood-Pressure-Monitor.htm

Comments	<p>Although appearance wise, these seem to be quite different, all of the core elements are identical.</p> <p>The previous query and the reply, is applicable here.</p> <p>Query 1 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 1 <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>There were two further queries due to differences in the manuals.</p> <p>Query 2 The pressure sensor for the Andon KD-5915 is the KD-2107-006G or the KD-2107-006GR. Is this the same for the Medel Elite (92125)?</p> <p>Response 2 Yes</p> <p>Query 3 The Andon KD-5915 sounds warning beeps before each measurement. Is this feature present in the Medel Elite (92125)?</p> <p>Response 3 Yes</p>
Recommendation	Equivalence is recommended
Date	12/11/2010