

## DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2006

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

### 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-5963  
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 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.)

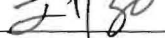
Part I	1	Algorithm for Oscillometric Measurements	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	3	Artefact/Error Detection	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	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 checked="" type="checkbox"/>	No <input type="checkbox"/>
	15	Printing Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	16	Communication Facilities	Yes <input checked="" type="checkbox"/>	No <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"/>

Brief explanation of differences and further relevant details:

- (10) The touch screen instead of the button.
- (13) The monitor can show the average reading of the last three measurements; mutle-language are selected.Download the records to the computer.
- (14) Stores 66\*3 readings instead of 60 readings
- (16) USB port
- (18) USB cable and CD for data download to PC.

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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 21 Jun. 2010

Signature of Witness 



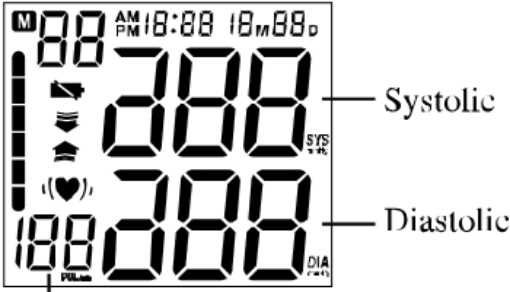
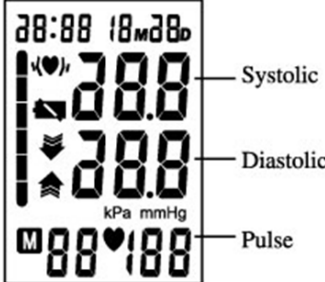
Name Wang renda

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

Company Stamp/Seal



Comparison of the Andon KD-5963 with the Andon KD-5915

Devices	Andon KD-5963	Andon KD-5915
Pictures		
Display	 <p>Systolic</p> <p>Diastolic</p>	 <p>Systolic</p> <p>Diastolic</p> <p>Pulse</p>
Validation		ESH
Device 1 Criteria	<p><b>Buttons/Switches</b></p> <p><i>Power</i></p> <p>On/Off switch for touch screen 10</p> <p><b>Display/Symbols/Indicators</b></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>Optional voiced average 18</p>	

Devices	Andon KD-5963	Andon KD-5915
<b>Device 1 Criteria (Continued)</b>	<p><b>Algorithms</b> <i>Averages and Differences</i> Last 3 measurements memory zone mean 13</p> <p><b>Case</b> <i>Ports</i> USB port, cable and PC software 16, 18</p>	
<b>Same Criteria</b>	<p><b>Measurement</b> <i>Accuracy</i> BP accuracy <math>\pm 3</math> mmHg 1, 5</p> <p><i>Method</i> Oscillometric measurement method 1, 5 Pulse 40 bpm -180 bpm 1, 5, 8 Manually initiated measurements 13 Measurements are from single inflations 13</p> <p><i>Inflation</i> Inflation 0 mmHg - 295 mmHg 1, 5, 7 Automatic Inflation 7 Zero pressure check before inflation 7</p> <p><i>Deflation</i> Automatic Deflation 8</p> <p><i>Cuffs</i> Medium (Arm circ. 22 to 30 cm) 6</p> <p><b>Display/Symbols/Indicators</b> <i>Measurement Procedure</i> Beeps before measurement 18 Optional voiced assistance 18</p> <p><i>Post Measurement</i> SBP, DBP and Pulse 11 Measurement error (0, 1, 2, 3, 4, 5, 6, 7, 8, A) 11 Hypertension (Indicator strip) 11, 13 BP classification (WHO) 10, 11, 13 Irregular heartbeat 11, 13, 18 Optional voiced results 18</p> <p><i>Measurement Records</i> Memory "M" symbol 11 Memory recall number 11</p>	<p><b>Measurement</b> <i>Accuracy</i> BP accuracy <math>\pm 3</math> mmHg 1, 5</p> <p><i>Method</i> Oscillometric measurement method 1, 5 Pulse 40 bpm -180 bpm 1, 5, 8 Manually initiated measurements 13 Measurements are from single inflations 13</p> <p><i>Inflation</i> Inflation 0 mmHg - 295 mmHg 1, 5, 7 Automatic Inflation 7 Zero pressure check before inflation 7</p> <p><i>Deflation</i> Automatic Deflation 8</p> <p><i>Cuffs</i> Medium (Arm circ. 22 to 30 cm) 6</p> <p><b>Display/Symbols/Indicators</b> <i>Measurement Procedure</i> Beeps before measurement 18 Optional voiced assistance 18</p> <p><i>Post Measurement</i> SBP, DBP and Pulse 11 Measurement error (0, 1, 2, 3, 4, 5, 6, 7, 8, A) 11 Hypertension (Indicator strip) 11, 13 BP classification (WHO) 10, 11, 13 Irregular heartbeat 11, 13, 18 Optional voiced results 18</p> <p><i>Measurement Records</i> Memory "M" symbol 11 Memory recall number 11</p>

Devices	Andon KD-5963	Andon KD-5915
<b>Same Criteria (Continued)</b>	<p><b>Display/Symbols/Indicators (continued)</b> <i>Measurement Records (continued)</i></p> <p>Delete memory 11</p> <p>Optional voiced records 18</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><b>Algorithms</b> <i>Diagnostic</i></p> <p>WHO Guidelines 13</p> <p>Irregular heartbeat detection 13</p> <p><b>Case</b> <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><b>Display/Symbols/Indicators (continued)</b> <i>Measurement Records (continued)</i></p> <p>Delete memory 11</p> <p>Optional voiced records 18</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><b>Algorithms</b> <i>Diagnostic</i></p> <p>WHO Guidelines 13</p> <p>Irregular heartbeat detection 13</p> <p><b>Case</b> <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>
<b>Comparable Criteria</b>	<p><b>Measurement</b> <i>Sensors</i></p> <p>Pressure sensor: KD-2107-006G 5</p> <p><i>Measurement Records</i></p> <p>Memory: 66 measurements × 3 zones 14</p> <p><b>Buttons/Switches</b> <i>Power</i></p> <p>On/Off with Start/Stop (On/Off Label) from touch screen 10</p> <p><i>Measurement Records</i></p> <p>Memory from touch screen 10</p>	<p><b>Measurement</b> <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><b>Buttons/Switches</b> <i>Power</i></p> <p>On/Off with Start/Stop (Start Label) 10</p> <p><i>Measurement Records</i></p> <p>Memory 10</p>
<b>Device 2 Criteria</b>		<p><b>Measurement</b> <i>Cuffs</i></p> <p>Extra Large (Arm circ. 30-42 cm) (Optional) 6</p> <p>Large (Arm circ. 30-42 cm) (Optional) 6</p>

Devices	Andon KD-5963	Andon KD-5915
Device 2 Criteria (Continued)		<b>Display/Symbols/Indicators Settings</b> Current unit (kPa / mmHg) marker 11
Web link		<a href="http://andon.manufacturer.globalsources.com/si/6008800800032/pdf/Wrist-blood/1032471456/Blood-Pressure-Monitor.htm">http://andon.manufacturer.globalsources.com/si/6008800800032/pdf/Wrist-blood/1032471456/Blood-Pressure-Monitor.htm</a>

Comments	<p>There were three minor queries</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>Query 2      The declaration for the KD-5963 claims it has 2 memory zones of 60 readings. The Operation Guide states 3 zones of 66 readings.</p> <p>Response 2    <i>60*2 memories, which is from the declaration for the KD-5963, is written wrong.66*3 memories from the Operation Guide is right. I modified the declaration and attached it. Please update the declaration.</i></p> <p>Comment 2    The declaration attached is the updated one.</p> <p>Query 3      Are not multiple language voice functions are available for both the KD-5963 and the KD-5915?</p> <p>Response 3    <i>Both the KD-5915 and KD-5963 are multiple language voice functions.</i></p>
Recommendation	Equivalence is recommended
Date	20/07/2010