

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 Check (92187)
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

Blood Pressure Monitoring 2010;volume15;pp232-234
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 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) No <MEM> button, but has <T3> button;

(11) No date and time display;

(13) The monitor can show the average reading of the last three measurements within 15 minutes; No voice function; No BP classification(WHO).

(14) The most recent 1 measurements can be stored in the memory

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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 9 September 2010

Signature of Witness 刘智军



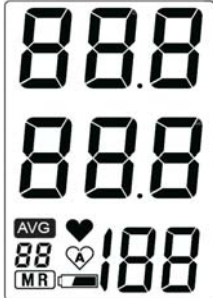

Name Liu zhijun

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

Company Stamp/Seal



Comparison of the Medel Check (92187) with the Andon KD-5915

Devices	Medel Check (92187)	Andon KD-5915
Pictures		
Display		 <p style="margin-left: 750px;">Systolic</p> <p style="margin-left: 750px;">Diastolic</p> <p style="margin-left: 750px;">Pulse</p>
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>Post Measurement</i></p> <p>Average 11, 13, 14</p> <p>Algorithms</p> <p><i>Averages and Differences</i></p> <p>Last 3 measurements (within 15 min of each other) mean 13</p> <p>Casing</p> <p><i>Features</i></p> <p>Lid 10</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	Medel Check (92187)	Andon KD-5915
Same Criteria (Continued)	<p>Measurement (continued)</p> <p><i>Accuracy</i></p> <p>Pulse accuracy ± 5% 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</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>Inflation 0 mmHg - 295 mmHg 1, 5, 7</p> <p>Automatic Inflation 7</p> <p>Zero pressure check before inflation/Self test 7</p> <p><i>Deflation</i></p> <p>Automatic Deflation 8</p> <p><i>Cuffs</i></p> <p>Extra Large (XXL) (Arm circ. 42-48 cm) (Optional) 6</p> <p>Large (XL) (Arm circ. 30-42 cm) (Optional) 6</p> <p>Medium (Standard) (Arm circ. 22 to 30 cm) 6</p> <p><i>Sensors</i></p> <p>Pressure sensor: KD-2107-006G or KD-2107-006GR 5</p> <p>Buttons/Switches</p> <p><i>Power</i></p> <p>On/Off with Start/Stop (O/I Label) 10</p> <p>Display/Symbols/Indicators</p> <p><i>Measurement Procedure</i></p> <p>During Measurement: BP Level & Heartbeat 11</p> <p>Beeps before measurement 18</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>Irregular heartbeat 11, 13, 18</p> <p><i>Measurement Records</i></p> <p>Memory "MR" symbol 11</p> <p><i>Power</i></p> <p>Low battery 11, 17</p>	<p>Measurement (continued)</p> <p><i>Accuracy</i></p> <p>Pulse accuracy ± 5% 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</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>Inflation 0 mmHg - 295 mmHg 1, 5, 7</p> <p>Automatic Inflation 7</p> <p>Zero pressure check before inflation/Self test 7</p> <p><i>Deflation</i></p> <p>Automatic Deflation 8</p> <p><i>Cuffs</i></p> <p>Extra Large (Arm circ. 42-48 cm) (Optional) 6</p> <p>Large (Arm circ. 30-42 cm) (Optional) 6</p> <p>Medium (Arm circ. 22 to 30 cm) 6</p> <p><i>Sensors</i></p> <p>Pressure sensor: KD-2107-006G or KD-2107-006GR 5</p> <p>Buttons/Switches</p> <p><i>Power</i></p> <p>On/Off with Start/Stop (Start Label) 10</p> <p>Display/Symbols/Indicators</p> <p><i>Measurement Procedure</i></p> <p>During Measurement: BP Level & Heartbeat 11</p> <p>Beeps before measurement 18</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>Irregular heartbeat 11, 13, 18</p> <p><i>Measurement Records</i></p> <p>Memory "M" symbol 11</p> <p><i>Power</i></p> <p>Low battery 11, 17</p>

Devices	Medel Check (92187)	Andon KD-5915
Same Criteria (Continued)	<p>Algorithms <i>Diagnostic</i></p> <p>Irregular heartbeat detection 13</p> <p>Case <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>Algorithms <i>Diagnostic</i></p> <p>Irregular heartbeat detection 13</p> <p>Case <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>Measurement <i>Measurement Records</i></p> <p>Memory: 1 measurement 14</p> <p>Case <i>Power</i></p> <p>Automatic switch-off when not used for 3 min 17</p>	<p>Measurement <i>Measurement Records</i></p> <p>Memory: 60 measurements 14</p> <p>Case <i>Power</i></p> <p>Automatic switch-off when not used for 1 min 17</p>
Device 2 Criteria		<p>Buttons/Switches <i>Measurement Records</i></p> <p>Memory 10</p> <p>Display/Symbols/Indicators <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>Memory recall number 11</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>Settings</i></p> <p>Current unit (kPa / mmHg) marker 11</p>

Devices	Medel Check (92187)	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>This model appears to be identical to the Andon MD-534 for which equivalence was approved in August 2010.</p> <p>The single query that applied to the Andon MD-534, and the reply, are also included 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 Check (92187)?</p> <p>Response 2 <i>Yes</i></p> <p>Query 3 The Andon KD-5915 sounds warning beeps before each measurement. Is this feature present in the Medel Check (92187)?</p> <p>Response 3 <i>Yes</i></p>
Recommendation	Equivalence is recommended
Date	12/11/2010