

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2006

A SIGNED COPY WILL BE POSTED ON THE 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-5031
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
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 explanation of differences and further relevant details:

(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

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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 



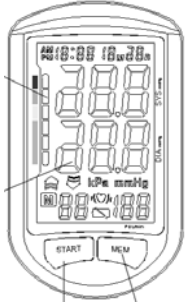
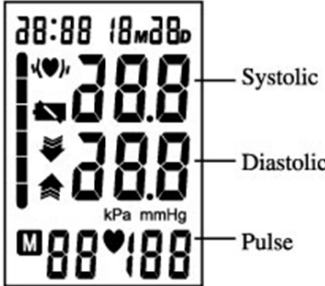
Name Wang renda

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-5031 with the Andon KD-5915

| Devices | Andon KD-5031 | 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-5031 | Andon KD-5915 |
|--------------------------------------|---|---|
| Same Criteria (Continued) | <p>Measurement (continued)</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>Automatic Inflation 7</p> <p>Zero pressure check before inflation 7</p> <p><i>Deflation</i></p> <p>Automatic Deflation 8</p> <p><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> <p>Medium (Arm circ. 22 to 30 cm) 6</p> <p>Buttons/Switches</p> <p><i>Power</i></p> <p>On/Off with Start/Stop (Start Label) 10</p> <p><i>Measurement Records</i></p> <p>Memory 10</p> <p>Display/Symbols/Indicators</p> <p><i>Measurement Procedure</i></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>Hypertension (Indicator strip) 11, 13</p> <p>BP classification (WHO) 10, 11, 13</p> <p>Irregular heartbeat 11, 13, 18</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>Measurement (continued)</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>Automatic Inflation 7</p> <p>Zero pressure check before inflation 7</p> <p><i>Deflation</i></p> <p>Automatic Deflation 8</p> <p><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> <p>Medium (Arm circ. 22 to 30 cm) 6</p> <p>Buttons/Switches</p> <p><i>Power</i></p> <p>On/Off with Start/Stop (Start Label) 10</p> <p><i>Measurement Records</i></p> <p>Memory 10</p> <p>Display/Symbols/Indicators</p> <p><i>Measurement Procedure</i></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>Hypertension (Indicator strip) 11, 13</p> <p>BP classification (WHO) 10, 11, 13</p> <p>Irregular heartbeat 11, 13, 18</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> |

| Devices | Andon KD-5031 | Andon KD-5915 |
|------------------------------|---|---|
| Same Criteria (Continued) | <p>Display/Symbols/Indicators (continued)</p> <p><i>Power</i></p> <p>Low battery 11, 17</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> <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>Power</i></p> <p>Low battery 11, 17</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> <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 | <p>Measurement</p> <p><i>Inflation</i></p> <p>Inflation 0 mmHg - 300 mmHg 1, 5, 7</p> <p><i>Sensors</i></p> <p>Pressure sensor: KD-2107-006GR 5</p> <p><i>Measurement Records</i></p> <p>Memory: 60 measurements × 2 zones 14</p> | <p>Measurement</p> <p><i>Inflation</i></p> <p>Inflation 0 mmHg - 295 mmHg 1, 5, 7</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> |
| 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> |
| Web link | http://andon.manufacturer.globalsources.com/si/6008800800032/pdf/Wrist-blood/1030876756/Electronic-Blood-Pressure-Monitor.htm | http://andon.manufacturer.globalsources.com/si/6008800800032/pdf/Wrist-blood/1032471456/Blood-Pressure-Monitor.htm |

| | |
|-----------------------|---|
| Comments | There was just one query Query On the display screen of the KD-5915 and the KD-5031, 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 Guides of the KD-5915 and the KD-5031 don't mention it.</i> |
| Recommendation | Equivalence is recommended |
| Date | 20/07/2010 |