

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2013

A SIGNED COPY WILL BE POSTED ON THE www.dableducational.org WEBSITE

SECTION A - Please complete all items.

I Liu Yi, a 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

Maker^a CITIZEN Address 6-1-12 Tanashi-cho,Nishi-Tokyo-shi,Tokyo188-8511,Japan
 Manufacturer^b Andon Address Andon Health Co.,Ltd.No.3 Jin Ping Street,Ya An Road,Nankai District,Tianjin 300190,China
 Brand^c CITIZEN Model^d CHU305

Blood pressure measuring device for which validation is claimed. If alternative model names are used, include all.

blood pressure measuring device and the validated blood pressure measuring device

Maker^a Andon Address Andon Health Co.,Ltd.No.3 Jin Ping Street,Ya An Road,Nankai District,Tianjin 300190,China
 Manufacturer^b Andon Address Andon Health Co.,Ltd.No.3 Jin Ping Street,Ya An Road,Nankai District,Tianjin 300190,China
 Brand^c Andon Model^d KD-5917

Existing validated blood pressure measuring device.

which has previously passed the ESH2010 protocol, the results of which were published as follows:

Guo WG, Li BL, He Y, Xue YS, Wang HY, Zheng QS, Xiang DC. Validation of the Andon KD-5917 automatic upper arm blood pressure monitor, for clinic use and self-measurement, according to the European Society of Hypertension International Protocol revision 2010. Blood Press Monit. Blood Press Monit 2014;19(4):242-5

Full reference

The only differences between the devices involve the following components:

Tick one box for each item 1-18.

Part I	1	Algorithm for Oscillometric Measurements	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A ^e <input type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^f <input type="checkbox"/>
	3	Artefact/Error Detection	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
	4	Microphone(s)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^f <input checked="" type="checkbox"/>
	5	Pressure Transducer	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
	6	Cuffs or Bladders	Yes <input type="checkbox"/>	No <input 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 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 checked="" type="checkbox"/>	
	13	Software other than Algorithm	Yes <input type="checkbox"/>	No <input checked="" 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"/>	N/A ^g <input type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <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"/>	N/A ^g <input type="checkbox"/>

An explanation of each item ticked "Yes" must be included in Section B or on a separate sheet.

- Notes:
- a. Provide the name and address of the actual maker of the device.
 - b. Provide the name and address of the legal manufacturer of the device, even if it is the same as that of the maker.
 - c. Provide the name of the brand under which it is sold, even if it is the same as that of the manufacturer or maker.
 - d. Provide the model name. If alternative or internal model names are used, include all. Each device must be uniquely identifiable.
 - e. Only tick N/A (Not Applicable) if neither device measures blood pressure using the oscillometric method.
 - f. Only tick N/A (Not Applicable) if neither device measures blood pressure using the auscultatory method.
 - g. Only tick N/A (Not Applicable) if neither device provides printing, communication or other facilities, as appropriate.

SECTION B An explanation for each item, 1 to 18, ticked "Yes" in Section A must be provided here or in an attached document. All differences between the devices must be described.

- (9) The Model Name is changed to CITIZEN CHU305 from Andon KD-5917;
- (10) They have the same botton but in the different position;
- (11)No symbol for "inflate to measure";
- (14)Stores 99 readings instead of 2*60 readings;
- (18) No voice function;

SECTION C Please check that the following are included with the application

- A manual for the validated device
- A manual for the device for which equivalence is being sought
- An image of the validated device
- An image of the device for which equivalence is being sought
- An image of the screen layout of validated device*
- An image of the screen layout of the device for which equivalence is being sought*

* Screen layouts shown complete, and without obscuring labels or lines, in manuals need not be included separately.

SECTION D Complete all items, bar signatures and seal, online and print. Sign and seal it then send the original to our address below. Please email a signed copy of this form, together with the manuals and images for both devices, to info@dableducational.org.

Signature of Director Liu Yi

Company Stamp/Seal



Name Liu Yi



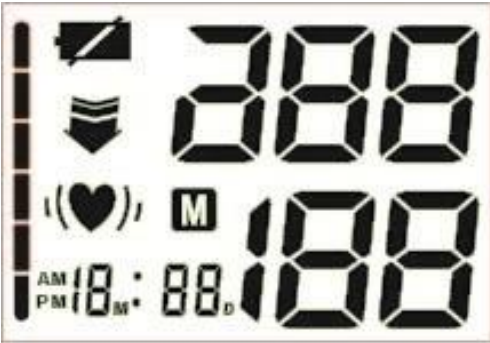

Date 22 Dec. 2014

Signature of Witness Zhangfei

Name Zhang Fei

Address Andon Health Co.,Ltd.No.3 Jin Ping Street,Ya An Road,Nankai District,Tianjin 300190,China

Comparison of the Andon KD-5917 with the Citizen CHU305

Devices	Citizen CHU305 (Device 2)	Andon KD-5917 (Device 1)
Pictures		
Display		
Validation		ESH 2010
Device 1 Criteria		<p><i>Memory</i> 2*60 Readings</p> <p><i>Voice Function</i> Yes</p> <p><i>Dimension</i> Approximately 125mm x 130mm x 62mm</p> <p><i>Weight</i> Approximately 323g (Excluding batteries)</p>

<p>Device 2 Criteria</p>	<p><i>Memory</i> 99 Readings</p> <p><i>Voice Function</i> None</p> <p><i>Dimension</i> Approximately 138mm x 54mm x 95mm</p> <p><i>Weight</i> Approximately 211g (Excluding batteries)</p>	
<p>Same Criteria</p>	<p>Measurement</p> <p><i>Accuracy</i> BP Accuracy ±3mmHg Pulse accuracy ±5mmHg</p> <p><i>Method</i> Oscillometric SBP Range 60-260 mmHg DBP Range 40-199 mmHg Pulse Rate Range 40-180 pulse/min Cuff Pressure 0-300 mmHg</p> <p><i>Inflation</i> Automatic inflation by internal pump</p> <p><i>Deflation</i> Automatic speed deflation system</p> <p><i>Cuffs</i> 22cm-30cm Upper Arm Location</p> <p><i>Sensors</i> KD-2107-006G or KD-2107-006GR</p>	<p>Measurement</p> <p><i>Accuracy</i> BP Accuracy ±3mmHg Pulse accuracy ±5mmHg</p> <p><i>Method</i> Oscillometric SBP Range 60-260 mmHg DBP Range 40-199 mmHg Pulse Rate Range 40-180 pulse/min Cuff Pressure 0-300 mmHg</p> <p><i>Inflation</i> Automatic inflation by internal pump</p> <p><i>Deflation</i> Automatic speed deflation system</p> <p><i>Cuffs</i> 22cm-30cm Upper Arm Location</p> <p><i>Sensors</i> KD-2107-006G or KD-2107-006GR</p>

	<p>Display/Symbols/Indicators <i>Power</i> 4 AA Batteries</p> <p>Casing <i>Display</i> LCD</p>	<p>Display/Symbols/Indicators <i>Power</i> 4 AA Batteries</p> <p>Casing <i>Display</i> LCD</p>
Comparable Criteria		
Device 2 Criteria		

Recommendation	<i>Recommended</i>
Date	27 January 2015