dabl® Educational Trust

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 (Name of a Company Director) Director of (Company name) Andon Health Co. , Ltd

hereby state that there are no differences that will affect blood pressure measuring accuracy between the

Andon KD-931
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
Title

Blood Pressure Monitoring (Publication) 2010;volume15;pp232-234 (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 ☐	No ☒
	2	Algorithm for Auscultatory Measurements	Yes ☐	No ☐
	3	Artefact/Error Detection	Yes ☐	No ☒
	4	Microphone(s)	Yes ☐	No ☐
	5	Pressure Transducer	Yes ☐	No ☒
	6	Cuff or Bladder	Yes ☐	No ☒
	7	Inflation Mechanism	Yes ☐	No ☒
	8	Deflation Mechanism	Yes ☐	No ☒
Part II	9	Model Name or Number	Yes ☒	No ☐
	10	Casing	Yes ☒	No ☐
	11	Display	Yes ☒	No ☐
	12	Carrying/Mounting Facilities	Yes ☐	No ☐
	13	Software other than Algorithm	Yes ☒	No ☐
	14	Memory Capacity/Number of stored measurements	Yes ☐	No ☒
	15	Printing Facilities	Yes ☐	No ☐
	16	Communication Facilities	Yes ☒	No ☐
	17	Power Supply	Yes ☒	No ☐
	18	Other Facilities	Yes ☐	No ☐

Brief explanation of differences and further relevant details:

(10) Just has1 button <STOP> with LED lighting; an iPhone connector; a USB port for adapter power supply.
(11) As a display device, the iPhone instead the traditional LCD.
(13) No voice function.
(14) Stores 1000*4 readings instead of 60 readings
(16) Communication with iPhone
(17) DC:5V ⎓ 2.1A, batteries: 3.7V Li-ion 400mAh

© 2006 dabl® Educational Trust Limited
34 Main Street, Blackrock, Co. Dublin, Ireland.
Tel +353 1 278 0247
Fax +353 1 278 3835
(dabl® Educational Trust Limited is a not-for-profit organisation)
Email info@dableducational.org
Web www.dableducational.org

dabl® Educational Trust

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 Liu Yi

Company Stamp/Seal

Name Liu yi

Date 6 September 2010

Signature of Witness Liu zhijun

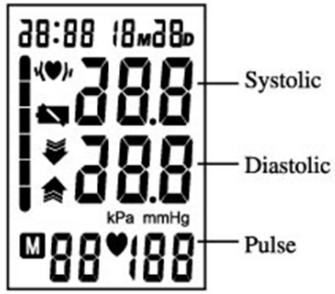
Name Liu zhijun

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

© 2006 dabl® Educational Trust Limited
34 Main Street, Blackrock, Co. Dublin, Ireland.

(dabl® Educational Trust Limited is a not-for-profit organisation)
Tel +353 1 278 0247
Fax +353 1 278 3835
Email info@dableducational.org
Web www.dableducational.org

Comparison of the Andon KD-931 with the Andon KD-5915

Devices	Andon KD-931	Andon KD-5915
Pictures		
Display		
Validation		ESH
Device 1 Criteria	***Buttons/Switches*** *Power* Stop button 10 ***Display/Symbols/Indicators*** *Preparation* Error on iPhone (ERROR: Communication Error) 11, 16 ***Case*** *Ports* iPhone connection port 15 *Power* Charging/Charged LED 17	
Same Criteria	***Measurement*** *Accuracy* BP accuracy ± 3 mmHg 1, 5	***Measurement*** *Accuracy* BP accuracy ± 3 mmHg 1, 5

© 2010 dabl® Educational Trust Limited – No reproduction of this document is permitted without the written authorisation of dabl® Educational Trust Limited dabl® Educational Trust Limited is a not-for-profit organisation.
Carraig Court, George's Avenue, Blackrock, Co. Dublin, Ireland Tel +353 1 278 0247 Fax +353 1 278 0882 Email info@dableducational.org Web www.dableducational.org

Devices	Andon KD-931		Andon KD-5915	
Same Criteria (continued)	***Measurement (continued)***		***Measurement (continued)***	
	Method		*Method*	
	Oscillometric measurement method	1, 5	Oscillometric measurement method	1, 5
	Pulse 40 bpm -180 bpm	1, 5, 8	Pulse 40 bpm -180 bpm	1, 5, 8
	Manually initiated measurements	13	Manually initiated measurements	13
	Measurements are from single inflations	13	Measurements are from single inflations	13
	Inflation		*Inflation*	
	Automatic Inflation	7	Automatic Inflation	7
	Inflation 0 mmHg - 295 mmHg	1, 5, 7	Inflation 0 mmHg - 295 mmHg	1, 5, 7
	Zero pressure check before inflation Query 1	7	Zero pressure check before inflation	7
	Deflation		*Deflation*	
	Automatic Deflation	8	Automatic Deflation	8
	Cuffs		*Cuffs*	
	Extra Large (Arm circ. 42-48 cm) (Optional)	6	Extra Large (Arm circ. 42-48 cm) (Optional)	6
	Large (Arm circ. 30-42 cm) (Optional)	6	Large (Arm circ. 30-42 cm) (Optional)	6
	Medium (Arm circ. 22 to 30 cm)	6	Medium (Arm circ. 22 to 30 cm)	6
	Display/Symbols/Indicators		***Display/Symbols/Indicators***	
	Measurement Procedure		*Measurement Procedure*	
	Beeps before measurement	18	Beeps before measurement	18
	Case		***Case***	
	Power		*Power*	
	Automatic switch-off when not used for 1 min	17	Automatic switch-off when not used for 1 min	17
Comparable Criteria	***Measurement***		***Measurement***	
	Sensors		*Sensors*	
	Pressure sensor: KD-2107-006GA Query 2	5	Pressure sensor: KD-2107-006G or KD-2107-006GR	5
	Case		***Case***	
	Power		*Power*	
	3.7V Li-ion 400 mAh battery (rechargeable)	17	4 “AA” batteries	17
	AC adapter	17	AC adapter (Optional)	17
iPhone-Device Same Criteria	***Display/Symbols/Indicators***		***Display/Symbols/Indicators***	
	Post Measurement		*Post Measurement*	
	SBP, DBP and Pulse	11	SBP, DBP and Pulse	11
	Hypertension (Indicator strip)	11, 13	Hypertension (Indicator strip)	11, 13
	BP classification (WHO)	10, 11, 13	BP classification (WHO)	10, 11, 13
	Irregular heartbeat	11, 13, 18	Irregular heartbeat	11, 13, 18

© 2010 dabl® Educational Trust Limited

Devices	Andon KD-931		Andon KD-5915	
iPhone-Device Same Criteria (continued)	***Display/Symbols/Indicators***		***Display/Symbols/Indicators***	
	Post Measurement		*Post Measurement*	
	SBP, DBP and Pulse	11	SBP, DBP and Pulse	11
	Hypertension (Indicator strip)	11, 13	Hypertension (Indicator strip)	11, 13
	BP classification (WHO)	10, 11, 13	BP classification (WHO)	10, 11, 13
	Irregular heartbeat	11, 13, 18	Irregular heartbeat	11, 13, 18
	Measurement Records		*Measurement Records*	
	Delete memory	11	Delete memory	11
	Date and Time		*Date and Time*	
	Date and Time	11	Date and Time	11
	Date and Time (During memory recall)	11	Date and Time (During memory recall)	11
	Algorithms		***Algorithms***	
	Diagnostic		*Diagnostic*	
	WHO Guidelines	13	WHO Guidelines	13
	Irregular heartbeat detection	13	Irregular heartbeat detection	13
iPhone-Device Comparable Criteria	***Measurement (continued)***		***Measurement (continued)***	
	Measurement Records		*Measurement Records*	
	Memory: 1000 measurements × 4 zones	14	Memory: 60 measurements	14
	Buttons/Switches		***Buttons/Switches***	
	Power		*Power*	
	On/Off and Start	10	On/Off with Start/Stop (Start Label)	10
	Display/Symbols/Indicators		***Display/Symbols/Indicators***	
	Post Measurement		*Post Measurement*	
	Measurement error	11	Measurement error	11
	ERROR: Pressure system is unstable before measurement		Er 0	
	ERROR: Fail to detect systolic pressure		Er 1	
	ERROR: Fail to detect diastolic pressure		Er 2	
	ERROR: Pneumatic system blocked or cuff is too tight during inflation		Er 3	
	ERROR: Pneumatic system leakage or cuff is too loose during inflation		Er 4	
	ERROR: Cuff pressure above 300mmHg		Er 5	
	ERROR: More than 160 seconds with cuff pressure above 15 mmHg		Er 6 *(3 minutes instead of 160 seconds)*	
	ERROR: EEPROM accessing error		Er 7	
	ERROR: Device parameter checking error		Er 8	
	ERROR: Span Error Query 3		Er A Query 3	
	Measurement Records		*Measurement Records*	
	“Database” option on iPhone	11	Memory “M” symbol	11
			Memory recall number	11

© 2010 dabl® Educational Trust Limited

Devices	Andon KD-931	Andon KD-5915
iPhone-Device Comparable Criteria (continued)	***Measurement (continued)*** *Measurement Records* Memory: 1000 measurements × 4 zones 14 ***Buttons/Switches*** *Power* On/Off and Start 10 ***Display/Symbols/Indicators*** *Post Measurement* Measurement error 11 ERROR: Pressure system is unstable before measurement ERROR: Fail to detect systolic pressure ERROR: Fail to detect diastolic pressure ERROR: Pneumatic system blocked or cuff is too tight during inflation ERROR: Pneumatic system leakage or cuff is too loose during inflation ERROR: Cuff pressure above 300mmHg ERROR: More than 160 seconds with cuff pressure above 15 mmHg ERROR: EEPROM accessing error ERROR: Device parameter checking error ERROR: Span Error Query 3 *Measurement Records* "Database" option on iPhone 11 *Power* Low battery with remaining capacity detail 11, 17 Measurement error (ERROR: Low battery) 11 ***Case*** *Display* iPhone screen 10	***Measurement (continued)*** *Measurement Records* Memory: 60 measurements 14 ***Buttons/Switches*** *Power* On/Off with Start/Stop (Start Label) 10 ***Display/Symbols/Indicators*** *Post Measurement* Measurement error 11 Er 0 Er 1 Er 2 Er 3 Er 4 Er 5 Er 6 *(3 minutes instead of 160 seconds)* Er 7 Er 8 Er A Query 3 *Measurement Records* Memory "M" symbol 11 Memory recall number 11 *Power* Low battery symbol 11, 17 ***Case*** *Display* Single screen display 10 Segment LCD 10
Device 2 Criteria		***Buttons/Switches*** *Measurement Records* Memory 10 ***Display/Symbols/Indicators*** *Measurement Procedure* Optional voiced assistance 18 *Post Measurement* Optional voiced results 18 *Measurement Records* Optional voiced records 18

© 2010 dabl® Educational Trust Limited

Devices	Andon KD-931	Andon KD-5915
Device 2 Criteria		***Display/Symbols/Indicators (continued)*** *Settings* Current unit (kPa / mmHg) marker [Query 4] 11 ***Case*** *Power* Rechargeable batteries not permitted 17
Web link		http://andon.manufacturer.globalsources.com/si/6008800800032/pdtl/Wrist-blood/1032471456/Blood-Pressure-Monitor.htm

Comments	
There were four queries	
Query 1	On the display screen of the KD-5915, there is a symbol indicating a zero pressure check. Does such a check happen with the KD-931?
Response 1	*"Zero pressure check" happens with the KD-931, but there is not a symbol indicating.*
Query 2	The pressure sensor on the KD-931 is the KD-2107-006GA but on the KD-5915 it is the KD-2107-006G or KD-2107-006GR. What is the difference between the KD-2107-006GA and the other two sensors?
Response 2	*KD-2107-006GA and KD-2107-006G: The pins of KD-2107-006GA are silvered, but KD-2107-006G's pins are not.* *KD-2107-006GA and KD-2107-006GR: The way of installation is different because of the pins' position.*
Query 3	The KD-5915 has an error ER A "Pressure sensor parameter error". There does not appear to be a corresponding error on the KD-931. Why not? The KD-931 has a "Span Error" that did not exist on the KD-5915. What causes this error?
Response 3	*"Pressure sensor parameter error" is equal to "Span Error".* *Span Value = Pressure sensor value on 300mmHg – Pressure sensor value on 0mmHg.* *If Span Value is too small, the precision will decline. If Pressure sensor parameter error, the span will error.*
Query 4	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?
Response 4	*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.*

© 2010 dabl® Educational Trust Limited

	Although this appears to be a very different device, the differences are purely on the presentation of the results. Andon provide hardware information on the pump, valve and sensor. The pumps and valves are the same for both devices and the differences in the sensors only concern the pin coatings and positions. The differences therefore concern the presentation and storage of the results. The KD-931 does not provide any display options on the device itself and it does not store the measurements. All that is provided is an interface for an Apple iPhone. An app for the iPhone is also provided. The iPhone must be sitting in the slot provided in the KD-931 with the app running for the device to work. Measurements are initiated from the iPhone and the result of the measurement is returned to it. An emergency stop button is provided on the KD-931. The facilities provided by the app and the iPhone screen allow more measurements to be stored, more analysis of the results, including plots, and clearer explanation of errors. The fundamental measurement functions of both devices appear to be identical. The hardware, cuff and the operating parameters are the same.
Recommendation	Equivalence is recommended
Date	16/09/2010

© 2010 dabl® Educational Trust Limited