dabl®Educational Trust — Declaration of Equivalence Form

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

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

Maker[a]	Beurer	*Address*	Soeflinger Strasse 218 * 89077 Ulm / Germany
Manufacturer[b]	Andon	*Address*	Andon Health Co.,Ltd.No.3 Jin Ping Street,Ya An Road,Nankai District,Tianjin 300190,China
Brand[c]	Beurer	Model[d]	BM55/BM66

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-5915

Existing validated blood pressure measuring device.

which has previously passed the ESH2002 protocol, the results of which were published as follows:

Huang QF, Wang J, Sheng CS, Zhang NN, Li Y, Wang JG. Validation of the ANDON KD-5915 blood pressure monitor for home blood pressure monitoring according to the European Society of Hypertension International Protocol. Blood Press Monit 2010;15(4)

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 ☐	No ☒	N/A[e] ☐
	2	Algorithm for Auscultatory Measurements	Yes ☐	No ☐	N/A[f] ☒
	3	Artefact/Error Detection	Yes ☐	No ☒	
	4	Microphone(s)	Yes ☐	No ☐	N/A[f] ☒
	5	Pressure Transducer	Yes ☐	No ☒	
	6	Cuffs or Bladders	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 ☐	N/A[g] ☒
	16	Communication Facilities	Yes ☐	No ☐	N/A[g] ☒
	17	Power Supply	Yes ☐	No ☒	
	18	Other Facilities	Yes ☐	No ☒	N/A[g] ☐

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.

Carraig Court, Georges Avenue, Blackrock, Co. Dublin, Ireland.
Form DET7 130102

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

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.

(10) 3buttons: START/STOP button, Memory buttonM1 and M2;

(11) Have the HSD symbol;

(13) The monitor can show the average reading of the morning/evening measurements for the last 7 days (morning: 5:00-9:00; evening: 18:00-20:00); Have the function of HSD;No voice function;

(14) Stores 60*2 readings instead of 60 readings;

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 _____ Company Stamp/Seal

Name Liu Yi

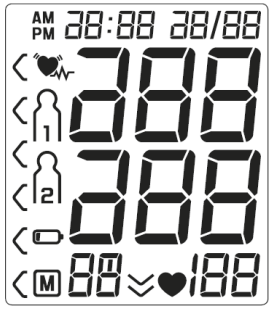
Date 23 Oct. 2013

Signature of Witness _____

Name Zhang Fei

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

Comparison of the Beurer BM55 with the Andon KD-5915

Devices	Beurer BM55	Andon KD-5915
Pictures		
Display		
Validation		ESH 2002
Device 1 Criteria	***Display/Symbols/Indicators*** *Post Measurement* Memory-zone mean (A symbol) 11, 13, 14 7-day morning memory-zone mean (AM symbol) 11, 13, 14 7-day evening memory-zone mean (PM symbol) 11, 13, 14 Haemodynamic stability indicator (Red/Green LED) 11, 13, 18 *Measurement Records* User (1 or 2) 11 *Communication* PC connection (PC symbol) 11, 16 ***Algorithms*** *Diagnostic* Haemodynamic stability detection 13 ***Casing*** *Ports*	

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	Beurer BM55		Andon KD-5915	
	USB port, cable and downloadable PC software	16, 18		
Same Criteria	***Measurement***		***Measurement***	
	Accuracy		*Accuracy*	
	BP accuracy ± 3 mmHg	1, 5	BP accuracy ± 3 mmHg	1, 5
	Pulse accuracy ± 5%	1, 5	Pulse accuracy ± 5% Note 2	1, 5
	Method		*Method*	
	Oscillometric during deflation	1, 5	Oscillometric during deflation	1, 5
	SBP 60 mmHg – 260 mmHg, DBP 40 mmHg – 199 mmHg Query 1	1, 5, 7,8	SBP 30 mmHg – 199 mmHg, DBP 60 mmHg – 180 mmHg Query1	1, 5, 7, 8
	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*	
	Inflation 0 mmHg – 300 mmHg	1, 5, 7	Inflation 0 mmHg – 295 mmHg	1, 5, 7
	Automatic Inflation	7	Automatic Inflation	7
	Press button if BP > 230 mmHg Query 4	7	Press button if BP > 230 mmHg	7
	Zero pressure check before inflation Query 3	7	Zero pressure check before inflation	7
	Deflation		*Deflation*	
	Automatic Deflation	8	Automatic Deflation	8
	Cuffs		*Cuffs*	
	Extra Large (Arm circ. 42 cm to 48 cm) (Optional) Query 2	6	Extra Large (Arm circ. 42 cm to 48 cm) (Optional)	6
	Large (Arm circ. 35 cm to 44 cm) (Optional Part 163.387) Query 2	6	Large (Arm circ. 30 cm to 42 cm) (Optional)	6
	Medium (Arm circ. 22 cm to 36 cm) Query 2	6	Medium (Arm circ. 22 cm to 30 cm)	6
	Sensors		*Sensors*	
	Pressure sensor: KD-2107-006G or KD-2107-006GR Query 5	5	Pressure sensor: KD-2107-006G or KD-2107-006GR	5
	Measurement Records		*Measurement Records*	
	Memory: 60 measurements × 2 users	14	Memory: 60 measurements	14
	Buttons/Switches		***Buttons/Switches***	
	Power		*Power*	
	On/Off with Start/Stop (❙ symbol)	10	On/Off with Start/Stop (START Label)	10
	Measurement Records		*Measurement Records*	
	Memory × 2 (M1 and M2 Labels)	10	Memory (MEM Label)	10
	Display/Symbols/Indicators		***Display/Symbols/Indicators***	
	Preparation		*Preparation*	
	Release air (≈ symbol) Query 3	11, 14	Remnant air in cuff (⬇ symbol)	11, 14

Devices	Beurer BM55	Andon KD-5915
	Measurement Procedure Heartbeat symbol during deflation 11 *Post Measurement* SBP, DBP and Pulse 11 Measurement error (Hi, Lo, Er *&* 0, 1, 2, 3, 4, 5, 6, 7, 8 *or* A) Query 1 11 Hypertension (Indicator strip) 11, 13 BP classification (WHO 1999) 10, 11, 13 Irregular heartbeat 11, 13, 18 *Measurement Records* Memory “M” symbol 11 Memory recall number 11 *Date and Time* Date and Time 11 Date and Time (During memory recall) 11 *Power* Low battery 11, 17 ***Algorithms*** *Diagnostic* WHO 1999 Guidelines 13 Irregular heartbeat detection 13 ***Casing*** *Display* Single screen display 10 Segment LCD 10 *Power* AC adapter (Optional Part 071.60) 17 Rechargeable batteries not permitted 17	*Measurement Procedure* Heartbeat symbol during deflation 11 *Post Measurement* SBP, DBP and Pulse 11 Measurement error (Er *&* 0, 1, 2, 3, 4, 5, 6, 7, 8 *or* A) 11 Hypertension (Indicator strip) 11, 13 BP classification (WHO 1999) 10, 11, 13 Irregular heartbeat 11, 13, 18 *Measurement Records* Memory “M” symbol 11 Memory recall number 11 *Date and Time* Date and Time 11 Date and Time (During memory recall) 11 *Power* Low battery 11, 17 ***Algorithms*** *Diagnostic* WHO 1999 Guidelines 13 Irregular heartbeat detection 13 ***Casing*** *Display* Single screen display 10 Segment LCD 10 *Power* AC adapter (Optional) 17 Rechargeable batteries not permitted 17
Comparable Criteria	***Casing*** *Power* 4 “AAA” batteries ~ 200 measurements 17 Automatic switch-off when not used for 3 min 17	***Casing*** *Power* 4 “AA” batteries 17 Automatic switch-off when not used for 1 min 17
Device 2 Criteria		***Display/Symbols/Indicators*** *Preparation* Previous result displayed on BP start 11, 14

Devices	Beurer BM55	Andon KD-5915
		Measurement Procedure Beeps before measurement 18 Optional voiced assistance 18 *Post Measurement* Error re-inflate (⬆ symbol) 11, 14 Optional voiced results 18 *Measurement Records* Optional voiced records 18 *Settings* Current unit (kPa / mmHg) marker Note 1 11

Comments		
Queries	1	Query: In reply to a previous query (01/08/2013 relating to the BM47), identical differences in measurement ranges were explained by the requirement to incorporate a technical alarm condition. This requirement is also stated the manual for the BM55. Therefore, does the following explanation, as applied to the BM47, also apply to the BM55? Both devices measure/calculate the same range of pressures. The KD-5915 was developed before ISO 80601-2 and, therefore, it simply displays blood pressures that occur within the full measurement range. Blood pressures outside that range are not measured at all and the result is an error. With the introduction of ISO 80601-2, some of the range had to be reserved in order to implement the technical alarm. Consequently, the maximum of the SBP rated range had to be reduced and the minimum of the DBP rated range increased. Blood pressures within the technical alarm ranges are measured but, to comply with ISO 80601-2, an error must be displayed. These errors are Hi and Lo, depending on which technical alarm condition is violated.

mmHg	Measurement Range				Display Range			
	TA Low Range	Rated Range		TA High Range	DBP		SBP	
		Min	Max		Min	Max	Min	Max
ISO 80601-2-30	< RR	≤ 40	300	> RR	≤ 40	≥ 130	≤ 60	≥ 230
BM55	30-39	40	260	261-280	40	199	60	260
KD-5915	N/A	30	280	N/A	30	199	60	280

Reply: Yes the explanations applied to the BM47 also apply for the BM55.

Comment: The explanation is accepted.

	2	Query	The cuff provided with the BM55 is for arm circumferences 22 cm to 36 cm. An optional large (arm circ. 35 cm to 44 cm) cuff (order no. 163.387) is also available. The cuff provided with the KD-5915 is for arm circumferences 22 cm to 30 cm. Optional large (arm circ. 30 cm to 42 cm) and extra large (arm circ. 42 cm to 48 cm) cuffs are also available. Despite the differences, item 6 "Cuffs or Bladders", in Part I, of Section A in the Declaration of Equivalence, is ticked as "No". a) Please supply the order numbers for all of the cuffs for each device. b) Please explain the differences in the cuffs provided, or available for, each device. c) Can the extra large cuff, optionally available for the KD-5915, be used with the BM55?
		Reply	a) KD-5915: 22-30cm included, no extra order number 30-42cm not included, no extra order number BM55: 22-30cm included, no extra order number 30-42cm order number 162.795 b) No differences c) Theoretical, it can be used but it will not be provided with the BM55
		Comment	Explanations are accepted
	3	Query	Is the zero pressure check used in the BM55 and is the ≯ symbol for this purpose? No information is provided in the manual.
		Reply	Yes, that symbol is designed for the zero pressure check in the BM55 The symbol is explained in the manual page 21 point 6. of the information on the display. It is explained as release air arrow, which informs the user about the process that air goes out of the system until zero.
		Comment	Explanation accepted.
	4	Query	Page 24 of the BM55 manual contains the sentences "The cuff's air pressure is slowly released. If you already recognise a tendency for high blood pressure, you should reinflate the cuff and increase the cuff's pressure again." a) Does this mean i) If fails to reach inflate sufficiently before deflating, it is possible to re-inflate it further during the deflation. If so, how is this done? ii) If it fails to record a reading due to insufficient inflation, it will inflate to a higher value on a subsequent attempt. or some other mechanism? b) To what values does the device inflate on each attempt?

			c) Is there a similar facility for the KD-5915?
		Response	a) The explanation is ii) b) About 40mmHg c) Yes, it's the same as KD-5915
		Comment	Explanations are accepted
	5	Query	The pressure sensor for the KD-5915 is described as KD-2107-006G or KD-2107-006GR. No information is provided for the BM55. Are the same sensors used?
		Reply	Yes, they are the same.
		Comment	Explanation accepted.
	6	Query	There are some errors in the Declaration of Equivalence. a) Item 16 "Communication Facilities", in Part II of Section A is ticked as "N/A". However, the BM55 does have a USB communications port and data can be transferred to a PC. This should be ticked "Yes" and should be described in Section B. b) The 2-user facility, in the BM55, is implied, rather than stated explicitly in Section B. It should be stated explicitly. Please resubmit the declaration with corrections resulting from any queries.
		Response	Revised Declaration of Equivalence Form submitted with corrections.
		Comment	Explanation accepted.
Notes	1	Previous queries relating to the KD-5915 are relevant	
		Query	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?
		Reply	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. The displayed "kPa" is just a reserved functionality.
		Comment	Clarification is accepted.

	2	Query No information on pulse accuracy is provided for the KD-5915. What is the pulse accuracy for the KD-5915? Reply The pulse accuracy of KD-5915 is +/- 5% Comment Clarification is accepted.
	3	In reply to a query (01/08/2013 relating to the BM47), the measurement range for the KD-5915 was stated as being 60 mmHg to 280 mmHg for SBP and 30 mmHg to 199 mmHg for DBP.
Recommendation	Recommended	
Date	23 February 2015	