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, 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]	Andon	*Address*	Andon Health Co.,Ltd.No.3 Jin Ping Street,Ya An Road,Nankai District,Tianjin 300190,China
Manufacturer[b]	Artsana S.p.A.	*Address*	Via Saldarini Catelli 1, 22070, Grandate (CO), Italy
Brand[c]	Pic Solution	Model[d]	CARDIOSimple

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 ☐	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.

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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 Pic Solutions CARDIOSimple from Andon KD-5917;

(11) No symbols for "AM" and "PM".No symbol for "inflate to measure".Blood pressure and pulse rate are displayed on the LCD separately.Date and time are displayed on the LCD separately;

(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 Jan. 2016

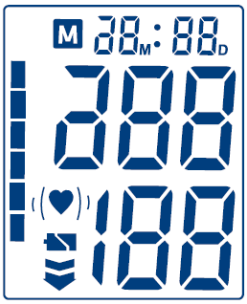
Signature of Witness Zhang Fei

Name Zhang Fei

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

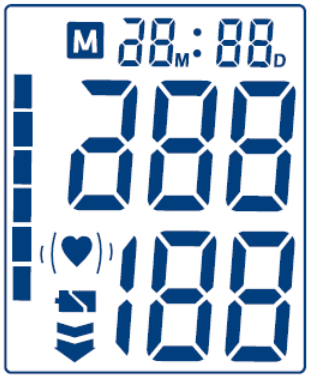
ANDON HEALTH CO.,LTD. 天津 九安医疗电子股份有限公司

SECTION B of Declaration of Blood Pressure Measuring Device Equivalence

	Existing Validated Device	Device applied for Validation
Model Name or Number	Andon KD-5917	Pic Solution CARDIOSimple
Casing		
Display		
Carrying/ Mounting Facilities		
Software other than Algorithm	Setting date and time	Setting date and time
	The result is automatically stored	The result is automatically stored
	Can show the average reading of the last three measurements	Can show the average reading of the last three measurements
	Turn off automatically after 1 minute of no operation	Turn off automatically after 1 minute of no operation
	Keeping on pressing button “MEM” for three seconds, all results will be deleted after three “beep”	Keeping on pressing button “MEM” for three seconds, all results will be deleted after three “beep”
	WHO indicator	WHO indicator
Memory Capacity/ Number of stored	2*60 times with time and date stamp	2*60 times with time and date stamp

measure ments		
Power Supply	4 AA batteries or DC 6V	4 AA batteries or DC 6V

Comparison of the Pic Solutions CARDIOSimple with the Andon KD-5917

Devices	Pic Solutions CARDIOSimple (Device 2)	Andon KD-5917(Device 1)
Pictures		
Display		
Validation		ESH 2010
Category	Automated Device for clinical or at home use	Automated Device for clinical or at home use

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Device 1 Criteria		*Voice Function* Yes *Dimension* 125mm x 130mm x 62mm *Weight* 323g(Excluding batteries) *Buttons* Memory buttons MEM *Display* Blood pressure and pulse rate are displayed on the LCD simultaneously; Date and time are displayed on the LCD simultaneously.
Device 2 Criteria	*Voice Function* No *Dimension* 132 mm x 96 mm x 44.6 mm *Weight* 205g(Excluding batteries) *Buttons* Memory buttons M1/M2 *Display* Blood pressure and pulse rate are displayed on the LCD separately; Date and time are displayed on the LCD separately.	

Same Criteria	***Measurement*** *Accuracy* Pressure: ±3mmHg Pulse rate: ±5% *Method* Oscillometric *Ranges* Cuff pressure 0 – 300 mmHg systolic 60 – 260 mmHg diastolic 40 –199 mmHg Pulse rate: 40-180 beats/minute *Inflation* Automatic inflation by internal pump *Deflation* Automatic speed deflation system *Cuffs* 22-42cm *Sensors* KD-2107-006G or KD-2017-006GR *Measurement Records* 2*60 times with time and date stamp *Measurements other than Blood Pressure* Heart rate ***Buttons/Switches*** *Power* Start/stop button	***Measurement*** *Accuracy* Pressure: ±3mmHg Pulse rate: ±5% *Method* Oscillometric *Ranges* Cuff pressure 0 – 300 mmHg systolic 60 – 260 mmHg diastolic 40 –199 mmHg Pulse rate: 40-180 beats/minute *Inflation* Automatic inflation by internal pump *Deflation* Automatic speed deflation system *Cuffs* 22-42cm *Sensors* KD-2107-006G or KD-2017-006GR *Measurement Records* 2*60 times with time and date stamp *Measurements other than Blood Pressure* Heart rate ***Buttons/Switches*** *Power* Start/stop button

	Measurement Records N/A *Analysis* N/A *Event Marking* N/A *Communication* N/A ***Display/Symbols/Indicators*** *Preparation* N/A *Measurement Procedure* Measuring during deflation *Post Measurement* Upper arm *Measurement Records* 2*60 times with time and date stamp *Power* 4 AA batteries or DC 6V *Function* N/A *Communication* N/A	*Measurement Records* N/A *Analysis* N/A *Event Marking* N/A *Communication* N/A ***Display/Symbols/Indicators*** *Preparation* N/A *Measurement Procedure* Measuring during deflation *Post Measurement* Upper arm *Measurement Records* 2*60 times with time and date stamp *Power* 4 AA batteries or DC 6V *Function* N/A *Communication* N/A

	Features N/A *Not described* N/A ***Algorithms*** *Averages and Differences* Can show the average reading of the last three measurements *Diagnostic* N/A *Functions* Measure blood pressure and heart rate *Communication* N/A ***Casing*** *Display* LCD *Ports* Cuff port *Power* 4 AA batteries or DC 6V *Features* N/A	*Features* N/A *Not described* N/A ***Algorithms*** *Averages and Differences* Can show the average reading of the last three measurements *Diagnostic* N/A *Functions* Measure blood pressure and heart rate *Communication* N/A ***Casing*** *Display* LCD *Ports* Cuff port *Power* 4 AA batteries or DC 6V *Features* N/A
Comparable Criteria	N/A	N/A

Comments		
Recommendation	***Recommended***	
Date	8th February 2016	