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 Mike Mai, a Director of Guangdong Transtek Medical Electronics 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]	Guangdong Transtek Medical Electronics Co.,Ltd	*Address*	Zone A, No.105, Dongli Rd., Torch Development District, Zhongshan, Guangdong, China, 528437
Manufacturer[b]	Artsana S.P.A	*Address*	Via Saldarini Catelli, 122070, Grandate(C)), Italy
Brand[c]	Pic	Model[d]	CARDIO maxi

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]	Guangdong Transtek Medical Electronics Co.,Ltd	*Address*	Zone A, No.105, Dongli Rd., Torch Development District, Zhongshan, Guangdong, China, 528437
Manufacturer[b]	Guangdong Transtek Medical Electronics Co.,Ltd	*Address*	Zone A, No.105, Dongli Rd., Torch Development District, Zhongshan, Guangdong, China, 528437
Brand[c]	TRANSTEK	Model[d]	TMB-1491

Existing validated blood pressure measuring device.

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

Hui Yong Tian, Si Jian Zeng, Xiao Yan Zhong ,Wei Gong and Wen Jun Liu; Validation of TRANSTEK blood blood pressure monitor TMB-1491 for self-measurement according to the European Society of Hypertension International Protocol reversion 2010, Blood Pressure Monitoring, 2015:280-282

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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Form DET7 130102

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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.

See attached document

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 Mike Mai

Company Stamp/Seal

Name Mike Mai

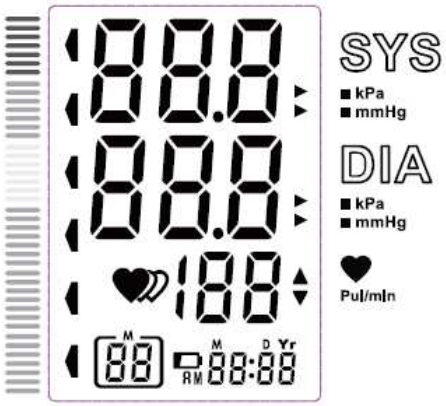
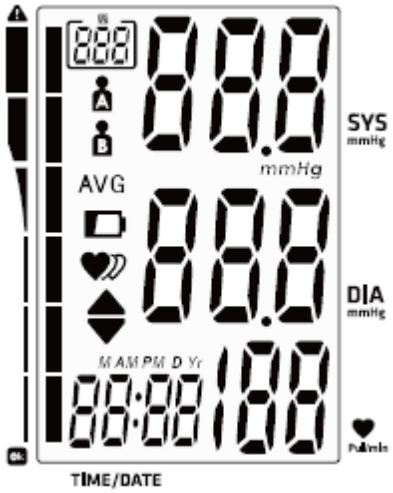
Date Oct. 29st,2015

Signature of Witness Ada Zhang

Name Ada Zhang

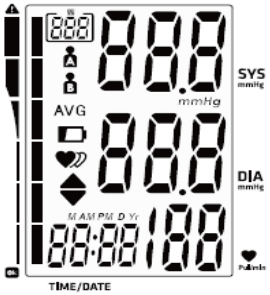
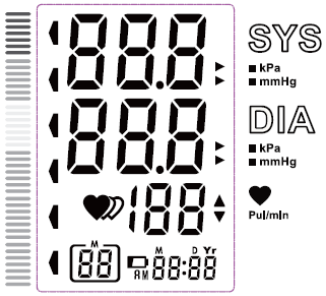
Address Zone A, No.105, Dongli Rd., Torch Development District, Zhongshan, Guangdong, China, 528437

SECTION B of Declaration of Blood Pressure Measuring Device Equivalence

	Existing Validated Device	Device applied for Validation
Model Name or Number	TMB-1491	CARDIO maxi
Casing		
Display		
Carrying/ Mounting Facilities	NO	
Software other than Algorithm	• Single User	• Two Users
	• 60 sets memories	• 100 sets memories per user
	• WHO indicator	• WHO indicator

	• Low battery indicator	• Low battery indicator
	• Day/Time setting	• Day/Time setting
	• Blood pressure & heart rate measurement	• Blood pressure & heart rate measurement
	• Kpa / mmHg unit	• mmHg unit
	• Blood pressure data memorized with date/time	• Blood pressure data memorized with date/time
	• Last 3 reading average	• Last 3 reading average
	• Error message indication	• Error message indication
	• Auto shut off when no operation for 1 min	• Auto shut off when no operation for 1 min
Memory Capacity/ Number of stored measure ments	60 sets(single user)	100 sets per user(two user)
Power Supply	4 x AAA	4x AAA or AC adaptor, output: 6VDC, 1A

Comparison of the PIC CARDIOmaxi with the Transtek TMB-1491

Devices	*CARDIOmaxi Authomatic Blood Pressure Monitor*	*Blood Pressure Monitor Transtek TMB-1491*
Pictures		
Display		
Validation		ESH 2010
Device 1 Criteria		***Measurement*** *Cuffs(Please state sizes and materials used)* 22-32cm and 22-42cm *Measurement Records* 60 (single user)

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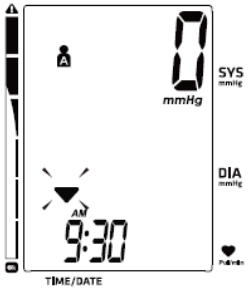
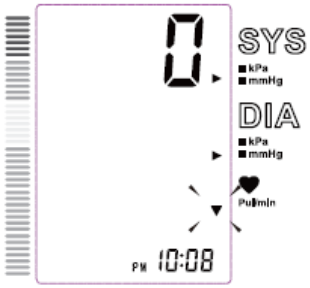
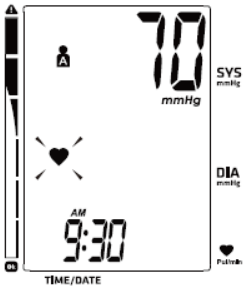
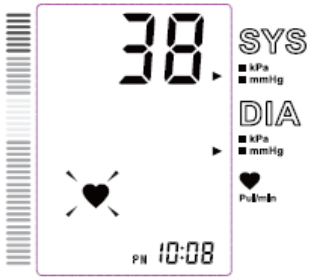
		Buttons/Switches Three buttons Start/stop button SET button MEM button ***Casing*** *Appearance* 110mm*110mm*41mm, color and shape different *Ports* Cuff port *Power* 4 x AAA battery
Device 2 Criteria	***Measurement*** *Cuffs(Please state sizes and materials used)* 22-42cm *Measurement Records* 100 per user (two user) ***Buttons/Switches*** One switch and three buttons User selection switch Start/stop button SET button MEM button ***Casing*** *Appearance* 123.5mm*140mm*58.5mm, color and shape different *Ports* Cuff port and AC adaptor port	

	Power 4 x AAA battery, or AC adaptor, 6V 1A.	
Same Criteria	***Measurement*** *Accuracy* Pressure: 5℃-40℃ within±0.4kPa(3mmHg) Pulse value:±5% *Method :* Oscillographic *Ranges* Rated cuff pressure: 0mmHg~300mmHg Measurement pressure: 40mmHg-230mmHg pulse value: (40-199) beat/minute *Inflation* Automatic Inflation Zero pressure check before inflation *Deflation* Automatic Deflation Automatic safety release *Cuffs (Please state sizes and materials used)* 22-42cm, Polyester *Sensors* Piezo-resistive *Measurements other than Blood Pressure* Heart rate ***Buttons/Switches*** *Power* Start/stop	***Measurement*** *Accuracy* Pressure: 5℃-40℃ within±0.4kPa(3mmHg) Pulse value:±5% *Method:* Oscillographic *Ranges* Rated cuff pressure: 0mmHg~300mmHg Measurement pressure: 40mmHg-230mmHg pulse value: (40-199) beat/minute *Inflation* Automatic Inflation Zero pressure check before inflation *Deflation* Automatic Deflation Automatic safety release *Cuffs(Please state sizes and materials used)* 22-32cm and 22-42cm, Polyester *Sensors* Piezo-resistive *Measurements other than Blood Pressure* Heart rate ***Buttons/Switches*** *Power* Start/stop

	Function User selection switch SET button MEM button *Analysis* The average of last three measurements Irregular heartbeat *Event Marking* N/A *Communication* N/A ***Display/Symbols/Indicators*** *Preparation* Adjust to zero pressure  	*Function* SET button MEM button *Analysis* The average of last three measurements Irregular heartbeat *Event Marking* N/A *Communication* N/A ***Display/Symbols/Indicators*** *Preparation* Adjust to zero pressure 

	Measurement Procedure Display the cuff pressure, heart rate symbol and measurement time  *Post Measurement* Upper arm *Date and Time* Display measurement time in the lower left corner of LCD *Power* Low battery *Function* Measure blood pressure and heart rate Recall measurement records Delete measurement records *Communication* N/A *Features* Measuring during inflation	*Measurement Procedure* Display the cuff pressure, heart rate symbol and measurement time  *Post Measurement* Upper arm *Date and Time* Display measurement time in the lower left corner of LCD *Power* Low battery *Function* Measure blood pressure and heart rate Recall measurement records Delete measurement records *Communication* N/A *Features* Measuring during inflation

	Algorithms *Averages and Differences* Recall the average value of the last measurement *Diagnostic* N/A, indicate WHO blood pressure classification *Functions* Measure blood pressure and heart rate *Communication* N/A ***Casing*** *Display* LCD *Ports* Cuff port and AC adaptor port *Power* 4 x AAA battery, or AC adaptor, 6V 1A. *Features* ABS, trapezoid	***Algorithms*** *Averages and Differences* Recall the average value of the last measurement *Diagnostic* N/A, indicate WHO blood pressure classification *Functions* Measure blood pressure and heart rate *Communication* N/A ***Casing*** *Display* LCD *Ports* Cuff port *Power* 4 x AAA battery *Features* ABS, trapezoid
Comparable Criteria	*Appearance* 123.5mm*140mm*58.5mm, color different *Measurement Records* 100 per user (two user) *Power* Except 4xAAA battery, also can be supplied by authorized AC adaptor *Cuff size* 22-42cm	*Appearance* 110mm*110mm*41mm, color different *Measurement Records* 60 (single user) *Power* Just supplied by 4 x AAA battery *Cuff size* 22-32cm and 22-42cm

Comments		
Recommendation	**Recommended - Home Use Only, Self-measurement**	
Date	**7th December 2015**	