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]	easyRAPID

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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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

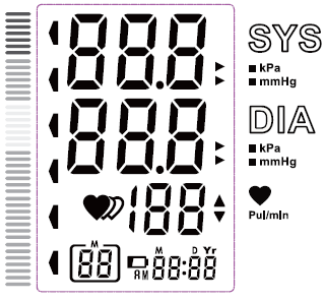
Address Zone A, No.105, Dongli Rd., Torch Development District, Zhongshan, Guangdong, China, 528437

SECTION B of Declaration of Blood Pressure Measuring Device Equivalence

	Existing Validated Device	Device applied for Validation
Model Name or Number	TMB-1491	easyRAPID
Casing		
Display		
Carrying/ Mounting Facilities	NO	
Software other than Algorithm	• Single User	• Single User
	• 60 sets memories	• 60 sets memories
	• 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)	60 sets(single user)
Power Supply	4 x AAA	4x AAA or AC adaptor, output: 6VDC, 1A

Comparison of the PIC easyRAPID Automatic Blood Pressure Monitor with the Transtek *TMB-1491*

Devices	*PIC easyRAPID Automatic 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

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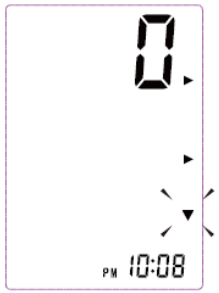
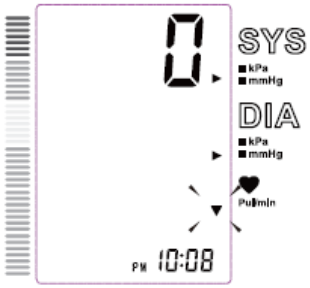
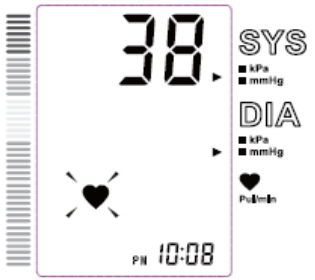
		Casing *Appearance* color and shape different *Ports* Cuff port *Power* 4 x AAA battery only
Device 2 Criteria	***Measurement*** *Cuffs(Please state sizes and materials used)* 22-42cm ***Casing*** *Appearance* color and shape different *P orts* Cuff port and AC adaptor port *Power* 4 x AAA battery, or 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	***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 *Measurement Records* 60 *Measurements other than Blood Pressure* Heart rate ***Buttons/Switches*** *Power* Start/stop *Function* SET button MEM button *Analysis* N/A *Event Marking* N/A *Communication* N/A	*Deflation* Automatic Deflation Automatic safety release *Cuffs(Please state sizes and materials used)* 22-32cm and 22-42cm, Polyester *Sensors* Piezo-resistive *Measurement Records* 60 *Measurements other than Blood Pressure* Heart rate ***Buttons/Switches*** *Power* Start/stop *Function* SET button MEM button *Analysis* N/A *Event Marking* N/A *Communication*

	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 right corner of LCD *Power* Low battery	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 right 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*AAA battery, or AC adaptor, 6V 1A. *Features* ABS, trapezoid	*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 *Power* 4*AAA battery *Features* ABS, trapezoid

Comparable Criteria	*Appearance* 110mm*110mm*40mm, color different *Power* Except 4*AAA battery, also can be supplied by authorized AC adaptor *Cuff size* 22-42cm	*Appearance* 110mm*110mm*41mm, color different *Power* Just supplied by 4*AAA battery *Cuff size* 22-32cm and 22-42cm

Comments		***Home Use Only, Self-measurement***
Recommendation	***Recommended***	
Date	18 November 2015	