

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** clearRAPID

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 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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A ^e <input type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^f <input checked="" type="checkbox"/>
	3	Artefact/Error Detection	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	4	Microphone(s)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^f <input checked="" type="checkbox"/>
	5	Pressure Transducer	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	6	Cuffs or Bladders	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	7	Inflation Mechanism	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	8	Deflation Mechanism	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
Part II	9	Model Name or Number	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	10	Casing	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	11	Display	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	12	Carrying/Mounting Facilities	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	13	Software other than Algorithm	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	14	Memory Capacity/Number of stored measurements	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	15	Printing Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input checked="" type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input checked="" type="checkbox"/>
	17	Power Supply	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	18	Other Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input checked="" type="checkbox"/>

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.

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

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



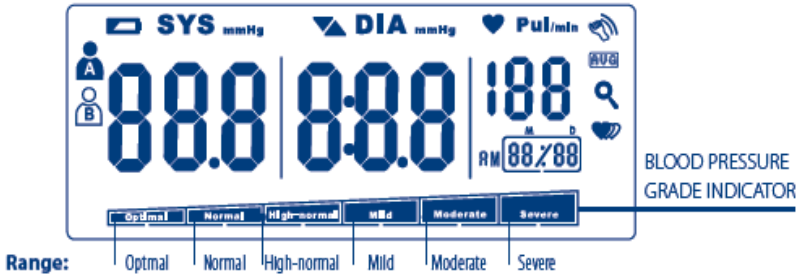
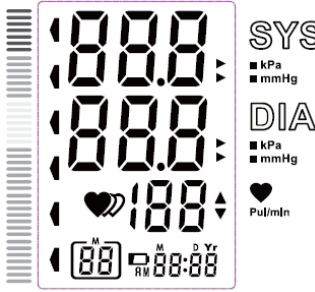


SECTION B of Declaration of Blood Pressure Measuring Device Equivalence

	Existing Validated Device	Device applied for Validation
Model Name or Number	TMB-1491	clearRAPID
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

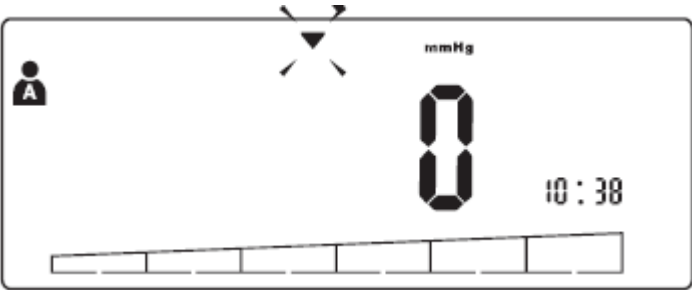
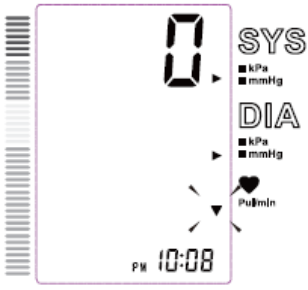
	<ul style="list-style-type: none"> • Low battery indicator 	<ul style="list-style-type: none"> • Low battery indicator
	<ul style="list-style-type: none"> • Day/Time setting 	<ul style="list-style-type: none"> • Day/Time setting
	<ul style="list-style-type: none"> • Blood pressure & heart rate measurement 	<ul style="list-style-type: none"> • Blood pressure & heart rate measurement
	<ul style="list-style-type: none"> • Kpa / mmHg unit 	<ul style="list-style-type: none"> • mmHg unit
	<ul style="list-style-type: none"> • Blood pressure data memorized with date/time 	<ul style="list-style-type: none"> • Blood pressure data memorized with date/time
	<ul style="list-style-type: none"> • Last 3 reading average 	<ul style="list-style-type: none"> • Last 3 reading average
	<ul style="list-style-type: none"> • Error message indication 	<ul style="list-style-type: none"> • Error message indication
	<ul style="list-style-type: none"> • Auto shut off when no operation for 1 min 	<ul style="list-style-type: none"> • Auto shut off when no operation for 1 min
Memory Capacity/ Number of stored measurements	60 sets(single user)	100 sets per user(two user)
Power Supply	4 x AAA	4x AAA or AC adaptor, output: 6VDC, 1A


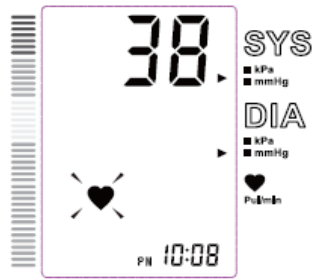
Comparison of the PIC clearRAPID Automatic Blood Pressure Monitor with the Transtek TMB-1491

<p>Devices</p>	<p>PIC clearRAPID Automatic Blood Pressure Monitor</p>	<p>Transtek TMB-1491</p>
<p>Pictures</p>		
<p>Display</p>		
<p>Validation</p>		<p>ESH 2010</p>
<p>Device 1 Criteria</p>		<p>Measurement <i>Cuffs(Please state sizes and materials used)</i> 22-32cm and 22-42cm</p> <p><i>Measurement Records</i> 60 (single user)</p>

		<p>Buttons/Switches Three buttons, mechanical buttons Start/stop button SET button MEM button</p> <p>Casing <i>Appearance</i> 110mm*110mm*41mm, color and shape different</p> <p><i>Ports</i> Cuff port</p> <p><i>Power</i> 4 x AAA battery only</p>
<p>Device 2 Criteria</p>	<p>Measurement <i>Cuffs(Please state sizes and materials used)</i> 22-42cm</p> <p><i>Measurement Records</i> 100 per user (two user)</p> <p>Buttons/Switches One switch and three buttons, touch buttons User selection switch Start/stop button SET button MEM button</p> <p>Casing <i>Appearance</i> 100mm*186mm*35mm, color and shape different</p> <p><i>Ports</i> Cuff port and AC adaptor port</p>	

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

	<p><i>Function</i></p> <p>User selection switch SET button MEM button</p> <p><i>Analysis</i></p> <p>N/A</p> <p><i>Event Marking</i></p> <p>N/A</p> <p><i>Communication</i></p> <p>N/A</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i></p> <p>Adjust to zero pressure</p> 	<p><i>Function</i></p> <p>SET button MEM button</p> <p><i>Analysis</i></p> <p>N/A</p> <p><i>Event Marking</i></p> <p>N/A</p> <p><i>Communication</i></p> <p>N/A</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i></p> <p>Adjust to zero pressure</p> 
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	<p><i>Measurement Procedure</i> Display the cuff pressure, heart rate symbol and measurement time</p>  <p><i>Post Measurement</i> Upper arm</p> <p><i>Date and Time</i> Display measurement time in the lower right corner of LCD</p> <p><i>Power</i> Low battery</p> <p><i>Function</i> Measure blood pressure and heart rate Recall measurement records Delete measurement records</p> <p><i>Communication</i> N/A</p> <p><i>Features</i> Measuring during inflation</p> <p>Algorithms <i>Averages and Differences</i> Recall the average value of the last measurement</p>	<p><i>Measurement Procedure</i> Display the cuff pressure, heart rate symbol and measurement time</p>  <p><i>Post Measurement</i> Upper arm</p> <p><i>Date and Time</i> Display measurement time in the lower right corner of LCD</p> <p><i>Power</i> Low battery</p> <p><i>Function</i> Measure blood pressure and heart rate Recall measurement records Delete measurement records</p> <p><i>Communication</i> N/A</p> <p><i>Features</i> Measuring during inflation</p> <p>Algorithms <i>Averages and Differences</i> Recall the average value of the last measurement</p>
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	<p><i>Diagnostic</i> N/A, indicate WHO blood pressure classification</p> <p><i>Functions</i> Measure blood pressure and heart rate</p> <p><i>Communication</i> N/A</p> <p>Casing</p> <p><i>Display</i> LCD</p> <p><i>Ports</i> Cuff port and AC adaptor port</p> <p><i>Power</i> 4xAAA battery, or AC adaptor, 6V 1A.</p> <p><i>Features</i> ABS, trapezoid</p>	<p><i>Diagnostic</i> N/A, indicate WHO blood pressure classification</p> <p><i>Functions</i> Measure blood pressure and heart rate</p> <p><i>Communication</i> N/A</p> <p>Casing</p> <p><i>Display</i> LCD</p> <p><i>Ports</i> Cuff port</p> <p><i>Power</i> 4xAAA battery</p> <p><i>Features</i> ABS, trapezoid</p>
<p>Comparable Criteria</p>	<p><i>Appearance</i> 100mm*186mm*35mm, color different</p> <p><i>Measurement Records</i> 100 per user (two user)</p> <p><i>Power</i> Except 4xAAA battery, also can be supplied by authorized AC adaptor</p> <p><i>Cuff size</i> 22-42cm</p> <p><i>Button</i> Touch buttons</p>	<p><i>Appearance</i> 110mm*110mm*41mm, color different</p> <p><i>Measurement Records</i> 60 (single user)</p> <p><i>Power</i> Just supplied by 4xAAA battery</p> <p><i>Cuff size</i> 22-32cm and 22-42cm</p> <p><i>Button</i> Mechanical buttons</p>

Comments		<i>Home Use Only, Self-measurement</i>
Recommendation		<i>Recommended</i>
Date		18 November 2015