

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE

A SIGNED COPY WILL BE POSTED ON THE www.dableducational.org WEBSITE

SECTION A - Please complete all items.

I **Kevin Tan**, 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<sup>a</sup> **Guangdong Transtek Medical Electronics Co.,Ltd** Address **Zone A, No.105 ,Dongli Road, Torch Development District, Zhongshan,528437,Guangdong,China**

Manufacturer<sup>b</sup> **Guangdong Transtek Medical Electronics Co.,Ltd** Address **Zone A, No.105 ,Dongli Road, Torch Development District, Zhongshan,528437,Guangdong,China**

Brand<sup>c</sup> **Kinetik Wellbeing** Model<sup>d</sup> **TMB-1970**

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<sup>a</sup> **Guangdong Transtek Medical Electronics Co.,Ltd** Address **Zone A, No.105 ,Dongli Road, Torch Development District, Zhongshan,528437,Guangdong,China**

Manufacturer<sup>b</sup> **Guangdong Transtek Medical Electronics Co.,Ltd** Address **Zone A, No.105 ,Dongli Road, Torch Development District, Zhongshan,528437,Guangdong,China**

Brand<sup>c</sup> **TRANSTEK** Model<sup>d</sup> **TMB-986**

Existing validated blood pressure measuring device.

which has previously passed the **2002** protocol, the results of which were published as follows:

Title: Validation of the Transtek blood pressure monitor TMB-986 for self-measurement according to the European Society of Hypertension international Protocol.

Authors: Wen Jun Liua, Su Gang Lia, Zhe Songa and Wei Gongb

Publication: Blood Press Monit 2010;15(5):278-80 doi: 10.1097/MBP.0b013e32833e43ca

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 <sup>e</sup> <input type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>f</sup> <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 <sup>f</sup> <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 <sup>g</sup> <input checked="" type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>g</sup> <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 <sup>g</sup> <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 Kevin Tan

Company Stamp/Seal

Name Kevin Tan

Date 9 September 2021





Signature of Witness Jie Zhu



Name Jie.Zhu

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

Comparison of the Kinetic Wellbeing TMB-1970 with the TRANSTEK TMB-986

Devices – Item 9	Kinetic Wellbeing TMB-1970	TRANSTEK TMB-986
Pictures		
Display Image		
Validation	Arm device for self measurement of blood pressure	ESH 2002
Category	Arm device for self measurement of blood pressure	Arm device for self measurement of blood pressure
Casing – Item 10	<p><i>Dimensions</i> 102mm*107mm*40mm</p> <p><i>Ports</i></p> <p><i>Cuff port</i></p> <p><i>Features</i> Kinetik Wellbeingprinting Button printing</p>	<p><i>Dimensions</i> 182mm*100mm*40mm</p> <p><i>Ports</i></p> <p><i>Cuff port</i></p> <p><i>Features</i> Transtek printing Button printing</p>
Display – Item 11	Type LCD	Type LCD

<b>Carrying/Mounting Facilities – Item 12</b>	None <i>Dimensions</i> 52mm*58mm	None
<b>Software other than Algorithm – Item 13</b>	<i>One User</i> 90 sets memories/per user 1 grade indicator mmHg unit	<i>Dual Users</i> 60 sets memories/per user 2 grade indicator mmHg unit
<b>Memory Capacity Item 14</b>	90 sets memories/per user	60 sets memories/per user
<b>Printing Facilities Item 15</b>	N/A	N/A
<b>Communication Facilities – Item 16</b>	N/A	N/A
<b>Power Supply Item 17</b>	4dry cells 1.5V AAA	4dry cells 1.5V AAA & 6V/1A power adapter
<b>Other differences</b>	<i>Other Details on Equivalent device that are different to Validated device</i> N/A	<i>Other Details on Validated device that are different to Equivalent device</i> N/A
<b>Same Criteria</b>	<p><b>Measurement</b></p> <p><i>Accuracy</i> Pressure: within <math>\pm 3</math>mmHg Pulse value: <math>\pm 5\%</math> Max</p> <p><i>Method</i> Oscillographic testing mode</p> <p><i>Ranges</i> Rated cuff pressure: Pressure: 0mmHg~299mmHg Pulse value: (40-199)beat/minute</p> <p><i>Inflation</i> Automatic inflation</p> <p><i>Deflation</i> Automatic deflation</p> <p><i>Cuffs (Please state sizes and materials used)</i> 22CM-42CM, nylon</p> <p><i>Sensors</i> Piezo-resistive</p>	<p><b>Measurement</b></p> <p><i>Accuracy</i> Pressure: 5°C-40°C within <math>\pm 3</math>mmHg(0.4kPa) Pulse value: <math>\pm 5\%</math></p> <p><i>Method</i> Oscillographic testing mode</p> <p><i>Ranges</i> Rated cuff pressure: 0kpa – 39.9kpa (0mmHg~299mmHg) pulse value: (40-199) beat/minute</p> <p><i>Inflation</i> Automatic inflation</p> <p><i>Deflation</i> Automatic deflation</p> <p><i>Cuffs(Please state sizes and materials used)</i> 22CM-42CM polyester</p> <p><i>Sensors</i> Piezo-resistive</p>

	<p><i>Measurement Records</i></p> <p><i>Measurements other than Blood Pressure</i>  <i>Pulse rate</i></p> <p><b>Buttons/Switches</b>  <i>power button</i>  <i>Memory button</i></p> <p><b>Display/Symbols/Indicators</b>  <i>Preparation</i>  <i>Automatic Zero setting</i></p> <p><i>Measurement Procedure</i>  <i>Inflation symbol</i>  <i>Pressure value indication</i>  <i>Current time</i></p> <p><i>Measurement Records</i>  <i>Systolic blood pressure (SYS)</i>  <i>Diastolic blood pressure (DIA)</i>  <i>Pulse rate</i>  <i>Measurement time</i>  <i>Memory Query symbol</i></p> <p><i>Power</i>  <i>Low power</i></p> <p><i>Features</i>  <i>Measuring during inflation</i></p> <p><b>Algorithms</b>  <i>Equivalent device has the identical measurement algorithm as the validated device.</i></p>	<p><i>Measurement Records</i></p> <p><i>Measurements other than Blood Pressure</i>  <i>Pulse rate</i></p> <p><b>Buttons/Switches</b>  <i>Power button</i>  <i>Memory button</i>  <i>Set button</i></p> <p><b>Display/Symbols/Indicators</b>  <i>Preparation</i>  <i>Automatic Zero setting</i></p> <p><i>Measurement Procedure</i>  <i>Inflation symbol</i>  <i>Pressure value indication</i>  <i>Current time</i></p> <p><i>Measurement Records</i>  <i>Systolic blood pressure (SYS)</i>  <i>Diastolic blood pressure (DIA)</i>  <i>Pulse rate</i>  <i>Measurement time</i>  <i>Memory Query symbol</i></p> <p><i>Power</i>  <i>Low power</i></p> <p><i>Features</i>  <i>Measuring during inflation</i></p> <p><b>Algorithms</b>  <i>Equivalent device has the identical measurement algorithm as the validated device.</i></p>
<p><b>Comparable Criteria</b></p>	<p><b>Measurement</b>  <i>Cuffs (Please state sizes and materials used)</i>  <i>About 22CM-42CM,nylon</i></p> <p><i>Measurement Records</i>  <i>90 sets/per user,total one user</i></p> <p><b>Display/Symbols/Indicators</b>  <i>Post Measurement</i>  <i>Systolic blood pressure (SYS)</i></p>	<p><b>Measurement</b>  <i>Cuffs (Please state sizes and materials used)</i>  <i>About 22CM-42CM,polyester</i></p> <p><i>Measurement Records</i>  <i>60 sets/per user,total two users</i></p> <p><b>Display/Symbols/Indicators</b>  <i>Post Measurement</i>  <i>Systolic blood pressure (SYS)</i></p>

	<i>Diastolic blood pressure (DIA)</i> <i>Pulse rate</i>	<i>Diastolic blood pressure (DIA)</i> <i>Pulse rate</i>
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<b>Comments</b>		
<b>Recommendation</b>	<b>Recommended</b>	
<b>Date</b>	<b>November 2021</b>	