

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 ^a	GuangdongTranstek Medical Electronics Co.,Ltd	<i>Address</i>	Zone A, No.105 ,Dongli Road, Torch Development District, Zhongshan,528437,Guangdong,China
Manufacturer ^b	Guangdong Transtek Medical Electronics Co.,Ltd	<i>Address</i>	Zone A, No.105 ,Dongli Road, Torch Development District, Zhongshan,528437,Guangdong,China
Brand ^c	Kinetik Wellbeing	Model ^d	TMB-2088

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	<i>Address</i>	Zone A, No.105 ,Dongli Road, Torch Development District, Zhongshan,528437,Guangdong,China
Manufacturer ^b	Guangdong Transtek Medical Electronics Co.,Ltd	<i>Address</i>	Zone A, No.105 ,Dongli Road, Torch Development District, Zhongshan,528437,Guangdong,China
Brand ^c	TRANSTEK	Model ^d	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 home blood pressure monitoring according to the International

Authors: Liu WJ, Li SG, Song Z, Gong W.

Publication:BloodPressMonit 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 ^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 type="checkbox"/>	No <input checked="" 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 type="checkbox"/>	No <input checked="" 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.

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
 - Completed DET9 Form
 - 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 October 14, 2021 *Jie Zhu*



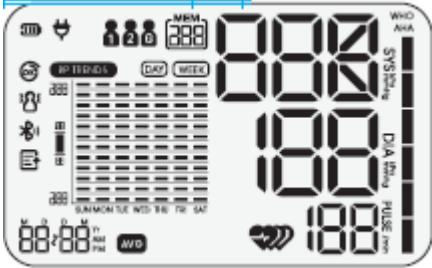
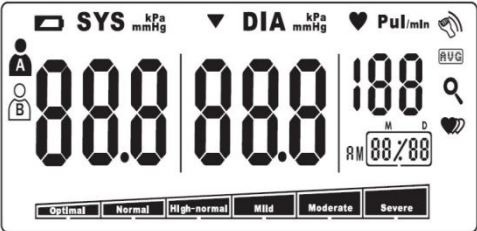
Signature of Witness _____

Name Jie.Zhu

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



Comparison of the Kinetik Wellbeing TMB-2088 with the TRANSTEK TMB-986

Devices – Item 9	Kinetik Wellbeing TMB-2088	TRANSTEK TMB-986
<p>Pictures</p>		
<p>Display Image</p>		
<p>Validation</p>	<p>Arm device for self measurement of blood pressure</p>	<p>ESH 2002</p>
<p>Category</p>	<p>Arm device for self measurement of blood pressure</p>	<p>Arm device for self measurement of blood pressure</p>
<p>Casing – Item 10</p>	<p>Dimensions 174*100*41mm</p> <p>Ports Cuff port and DC power port</p> <p>Features kinetik Wellbeing printing Button printing</p>	<p>Dimensions 182mm*100mm*39mm</p> <p>Ports Cuff port and DC power port</p> <p>Features Cuff and AC adaptor connectors Model name printing Button printing</p>
<p>Display – Item 11</p>	<p>Type LCD</p>	<p>Type LCD</p>

	LCD V.A.124 mm × 76 mm	LCD V.A.128*50mm
Carrying/Mounting Facilities – Item 12	None	None
Software other than Algorithm – Item 13	<i>Dual Users 250 sets memories/per user 2 grade indicator mmHg unit</i>	<i>Dual Users 60 sets memories/per user WHO indicator mmHg unit</i>
Memory Capacity Item 14	<i>250 sets memories/per user</i>	<i>60 sets memories/per user</i>
Printing Facilities Item 15	N/A	N/A
Communication Facilities – Item 16	N/A	N/A
Power Supply Item 17	<i>1、 4*AAA batteries 2、 AC adaptor</i>	<i>1. 4*AAA batteries 2. AC adaptor</i>
Other differences	<i>Other Details on Equivalent device that are different to Validated device N/A</i>	<i>Other Details on Validated device that are different to Equivalent device N/A</i>
Same Criteria	<p>Measurement <i>Accuracy Pressure:within±3mmHg Pulse value:±5% Max</i></p> <p>Method <i>Oscillographic testing mode</i></p> <p>Ranges <i>Rated cuff pressure: Pressure:0mmHg~299mmHg Pulse value: (40-199)beat/minute</i></p> <p>Inflation <i>Automatic inflation</i></p> <p>Deflation <i>Automatic deflation</i></p> <p>Cuffs (Please state sizes and materials used) <i>About 22CM-42CM,Nylon</i></p> <p>Sensors <i>Piezo-resistive</i></p>	<p>Measurement <i>Accuracy Pressure:5°C-40°C within±3mmHg(0.4kPa) Pulse value:±5%</i></p> <p>Method <i>Oscillographic testing mode</i></p> <p>Ranges <i>Rated cuff pressure: 0kpa - 40kpa (0mmHg~300mmHg) Measurement pressure: 5.33kPa-30.67kPa (40mmHg-230mmHg) pulse value: (40-199) beat/minute</i></p> <p>Inflation <i>Automatic inflation</i></p> <p>Deflation <i>Automatic deflation</i></p> <p>Cuffs(Please state sizes and materials used) <i>About 22CM-32cm or 32CM-42CM polyester</i></p> <p>Sensors <i>Piezo-resistive</i></p>

	<p><i>Measurements other than Blood Pressure</i> <i>Pulse rate</i></p> <p>Buttons/Switches <i>power button</i> <i>Memory button</i></p> <p>Display/Symbols/Indicators <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>Algorithms <i>Equivalent device has the identical measurement algorithm as the validated device.</i></p>	<p>Buttons/Switches <i>Power button</i> <i>Memory button</i> <i>Set button</i></p> <p>Display/Symbols/Indicators <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>Algorithms <i>Equivalent device has the identical measurement algorithm as the validated device.</i></p>
<p>Comparable Criteria</p>	<p>Measurement <i>Cuffs (Please state sizes and materials used)</i> <i>About 22cm-42cm, Nylon</i></p> <p><i>Measurement Records</i> <i>250 sets/per user,total two users</i></p> <p>Display/Symbols/Indicators <i>Post Measurement</i> <i>Systolic blood pressure (SYS)</i> <i>Diastolic blood pressure (DIA)</i> <i>Pulse rate</i></p>	<p>Measurement <i>Cuffs (Please state sizes and materials used)</i> <i>About 22CM-32cm or 22CM-42CM polyester</i> <i>Measurement Records</i> <i>60 sets/per user,total two users</i></p> <p>Display/Symbols/Indicators <i>Post Measurement</i> <i>Systolic blood pressure (SYS)</i> <i>Diastolic blood pressure (DIA)</i> <i>Pulse rate</i></p>

Comments		
Recommendation	Recommended	
Date	November 2021	