dabl® Educational Trust — Declaration of Equivalence Form

Declaration of Blood Pressure Measuring Device Equivalence 2011

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

SECTION A - Please complete all items.

I Mike Mak, (Name of a Company Director) a Director of Zhongshan Transtek Electronics Co.,Ltd, (Company name)

hereby state that there are no differences that will affect blood pressure measuring accuracy between the

Manufacturer ZHONGSHAN TRANSTEK ELECTRONICS CO., LTD. Brand BRAUN Model BP6100

Blood pressure measuring device for which validation is claimed. If alternative model names are used, include all.

blood pressure measuring device and the

Manufacturer ZHONGSHAN TRANSTEK ELECTRONICS CO., LTD. Brand TRANSTEK Model TMB-986

Existing validated blood pressure measuring device. If alternative model names are used, include all.

blood pressure measuring device, which has previously passed the 2002 protocol, the results of which were published as follows:

Wen Jun Liu, Su Gang Li, Zhe Song and Wei Gong
Authors(s)

Validation of the TRANSTEK blood pressure monitor TMB-986 for home blood pressure monitoring according to the International Protocol
Title

Blood Pressure Monitoring (Publication) 2010, 15:278–2. (Year Volume Pages)

The only differences between the devices involve the following components:

When a component is not relevant, both Yes and No should be left blank. It is necessary to provide details on each item ticked "Yes" in Section C or on a separate sheet.

Part I	1	Algorithm for Oscillometric Measurements	Yes ☐	No ☒
	2	Algorithm for Auscultatory Measurements	Yes ☐	No ☐
	3	Artefact/Error Detection	Yes ☐	No ☒
	4	Microphone(s)	Yes ☐	No ☐
	5	Pressure Transducer	Yes ☐	No ☒
	6	Cuff or Bladder	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 ☒
	16	Communication Facilities	Yes ☐	No ☒
	17	Power Supply	Yes ☐	No ☒
	18	Other Facilities	Yes ☐	No ☐

An explanation of each item ticked "Yes" must be included in *Section C* on the next page

SECTION B 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 manuals and images for both devices to info@dableducational.org.

Signature of Director _____ Company Stamp/Seal

Name

Date Sept. 14, 2012

Signature of Witness Ryan ZHONG

Carraig Court, Georges Avenue, Blackrock, Co. Dublin, Ireland.
Form DET7 110110

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SECTION C of Upper arm blood pressure monitor

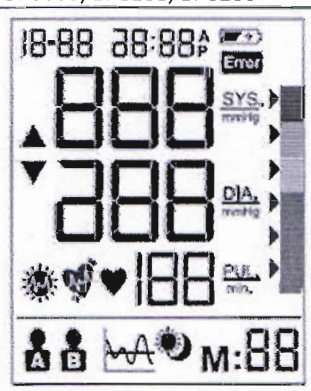
Model Name or Number

	TMB-986	Upper arm blood pressure monitor
Model Number	TMB-986	BP6000, BP6100, BP6200

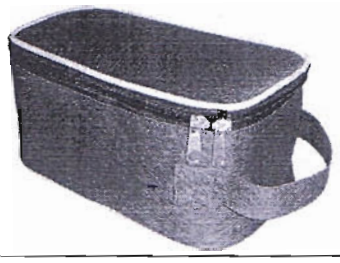
Casing

	TMB-986	BP6000, BP6100, BP6200
Casing		

Display

	TMB-986	BP6000, BP6100, BP6200
LCD Display Drawing		 LCD display size: 80x65mm

Carrying/Mounting Facilities

	TMB-986	BP6000, BP6100, BP6200
Carrying/Mounting Facilities		

Software Other than Alogrithm

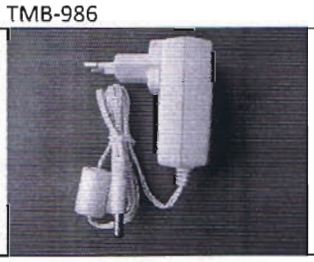
	TMB-986	BP6000	BP6100	BP6200
Software Other than Alogrithm	• Dual user	• Dual user	• Dual user	• Dual user
	• 2x60 memories	• 2x40 memories	• 2x50 memories	• 2x60 memories
	WHO indicator	• WHO indicator	• WHO indicator	• WHO indicator
	• Low battery indicator	• Low battery indicator	• Low battery indicator	• Low battery indicator
	• Day/time setting	• Day/time setting	• Day/time setting	• Day/time setting
	• Blood pressure & heart rate measurement	• Blood pressure & heart rate measurement	• Blood pressure & heart rate measurement	• Blood pressure & heart rate measurement
				• IHB detection
	• Blood pressure data memorized with date/time	• Blood pressure data memorized with date/time	• Blood pressure data memorized with date/time	• Blood pressure data memorized with date/time
	• Last 3 reading average	• Last 3 reading average	• Full day average of past 7 days	• Full day average of past 7 days • Morning average of past 7 days • Evening average of

				past 7 days
	•	•	•	• Morning hypertension
	•	•	•	• Display with back light
	• Error message indication	• Error message indication	• Error message indication	• Error message indication
	• Auto shut off when no operation for 1 min	• Auto shut off when no operation for 1 min	• Auto shut off when no operation for 1 min	• Auto shut off when no operation for 1 min

Memory Capacity/Number of Store Measurements

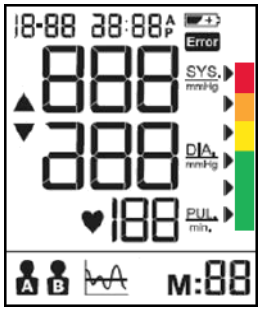
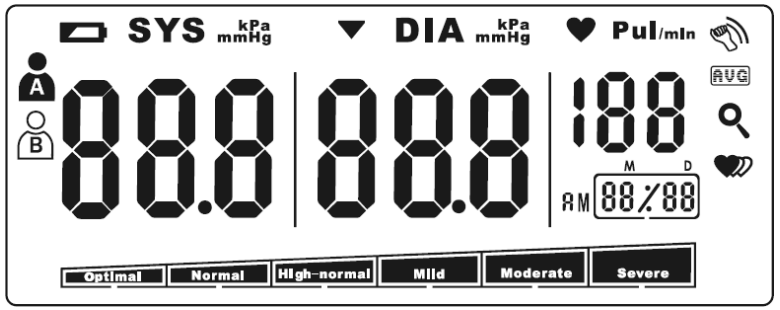
	TMB-986	BP6000	BP6100	BP6200
Memory Capacity/Number of Store Measurements	2x 60 sets (dual user, 60 measurements for each user)	2 x 40 sets (dual user, 40 measurements for each user)	2 x 50 sets (dual user, 50 measurements for each user)	2 x 60 sets (dual user, 60 measurements for each user)

Communication Faciilities

	TMB-986	BP6000	BP6100	BP6200
Communication Faciilities				

Ryan

Comparison of the Braun BP6100 with the Transtek TMB-986

Devices	Braun BP6100	Transtek TMB-986
Pictures		
Display		
Validation		ESH 2002
Device 1 Criteria	***Buttons/Switches*** *Settings* Mode 10 *Analysis* Average 10 ***Display/Symbols/Indicators*** *Measurement Procedure* Inflation symbol [Query 7] 11 ***Algorithms*** *Averages and Differences* 7-day mean 13	

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Devices	Braun BP6100		Transtek TMB-986	
Same Criteria	***Measurement***		***Measurement***	
	Accuracy		*Accuracy*	
	Pulse accuracy ± 5%	1, 5	Pulse accuracy ± 5%	1, 5
	Method		*Method*	
	Oscillometric measurement method	1, 5	Oscillometric measurement method	1, 5
	Pulse 40 bpm – 199 bpm	1, 5, 8	Pulse 40 bpm – 199 bpm	1, 5, 8
	Manually initiated measurements	13	Manually initiated measurements	13
	Measurements are from single inflations	13	Measurements are from single inflations	13
	Inflation		*Inflation*	
	Inflation 0 mmHg – 300 mmHg Query 2	1, 5, 7	Inflation 0 mmHg – 300 mmHg Query 2	1, 5, 7
	Automatic Inflation	7	Automatic Inflation	7
	Zero pressure check before inflation Query 5	7	Zero pressure check before inflation	7
	Deflation		*Deflation*	
	Automatic Deflation	8	Automatic Deflation	8
	Automatic safety release Query 3 & Response 2	8	Automatic safety release Query 3 & Response 2	8
	Sensors		*Sensors*	
	Pressure sensor: piezo-resistive Query 10	5	Pressure sensor: piezo-resistive Query 10	5
	Buttons/Switches		***Buttons/Switches***	
	Power		*Power*	
	On/Off with Start/Stop (Start Label) Query 8	10	On/Off with Start/Stop (Start/Stop Label)	10
	Measurement Records		*Measurement Records*	
	Memory	10	Memory	10
	User ID (A or B)	10	User ID (A or B)	10
	Display/Symbols/Indicators		***Display/Symbols/Indicators***	
	Measurement Procedure		*Measurement Procedure*	
	Deflation symbol Query 7	11	Deflation symbol	11
	During Measurement: BP Level & Heartbeat	11	During Measurement: BP Level & Heartbeat	11
	Post Measurement		*Post Measurement*	
	SBP, DBP and Pulse	11	SBP, DBP and Pulse	11
	BP classification (WHO)	10, 11, 13	BP classification (WHO)	10, 11, 13
	Measurement Records		*Measurement Records*	
	Memory recall number	11	Memory recall number	11
	User (A or B)	11	User (A or B)	11
	Date and Time		*Date and Time*	
	Date and Time (During memory recall)	11	Date and Time (During memory recall)	11
	Power		*Power*	
	Low battery	11, 17	Low battery	11, 17

Devices	Braun BP6100	Transtek TMB-986
Same Criteria (continued)	***Casing***	***Casing***
	Display	*Display*
	Single screen display 10	Single screen display 10
	Segment LCD 10	Segment LCD 10
	Power	*Power*
	Automatic switch-off when not used for 1 min 17	Automatic switch-off when not used for 1 min 17
Comparable Criteria	***Measurement***	***Measurement***
	Accuracy	*Accuracy*
	BP accuracy ± 3 mmHg (10°C-40°C) Query 1 1, 5	BP accuracy ± 3 mmHg (15°C-25°C) ± 6 mmHg otherwise Query 1 1, 5
	Cuffs	*Cuffs*
	Small/Medium (Arm circ. 22 cm to 32 cm) # TMB-1250-02 Query 6 6	Small/Medium (Arm circ. 22 cm to 32 cm) # AC2232-01 Query 6 6
	Large/XLarge (Arm circ. 32-42 cm) # TMB-1250-03 Query 6 6	Large/XLarge (Arm circ. 32-42 cm) # TMB-986-AC-05 Query 6 6
	Measurement Records	*Measurement Records*
	Memory: 50 measurements × 2 users 14	Memory: 60 measurements × 2 users 14
	Buttons/Switches	***Buttons/Switches***
	Settings	*Settings*
	Date/Time set 10	Set 10
	Display/Symbols/Indicators	***Display/Symbols/Indicators***
	Post Measurement	*Post Measurement*
	Measurement error E1, E2, E3, E4, Eexx Query 4 11	Measurement error E1, E2, E3, ~~(E10, E11)~~ → E4, ~~E20, E21~~, Eexx Query 4 11
	Hypertension (Indicator strip) 11, 13	Hypertension (Grading strip) 11, 13
	Average (Icon) 11, 13, 14	Average (AVG) 11, 13, 14
	Measurement Records	*Measurement Records*
	Memory “M” symbol 11	Memory icon (Magnifying glass) 11
	Date and Time	*Date and Time*
	Date and Time 11	Setting of Date and Time set but only display of Time 11
	Casing	***Casing***
	Power	*Power*
	4 “AA” batteries ~ 300 measurements 17	4 “AAA” batteries 17
Device 2 Criteria		***Display/Symbols/Indicators***
		Post Measurement
		Irregular heartbeat 11, 13, 18
		Body movement error 3, 11, 13, 18
		Measurement Records
		Memory, number of stored measurements 11
		Settings
		Current unit (kPa / mmHg) marker 11

Devices	Braun BP6100	Transtek TMB-986
Device 2 Criteria (continued)		***Algorithms*** *Averages and Differences* Last 3 measurements mean 13 *Diagnostic* Irregular heartbeat detection Query 11 13 Body movement error detection 3, 13 *Parameter Settings* Unit conversion (kPa / mmHg) 13 ***Casing*** *Power* AC adapter (Optional) 17

Comments	1	Query	In the specifications section of the Braun manual, blood pressure accuracy is described as being ± 3 mmHg whereas, in the Transtek TMB-986 manual, it is described as being ± 0.4 kPa (3 mmHg), when the temperature is between 15°C and 25°C, and ± 0.8 kPa (6 mmHg), when the temperature is outside that but between 10°C and 40°C. Both manuals state that the operating temperature range is 5°C and 40°C with a relative humidity up to 80%. It must, therefore, be inferred that the accuracy claimed for the Braun BP6100 applies to the full operating temperature range. Furthermore, no level of accuracy is claimed for the Transtek TMB-986 operating between 5°C and 9.9°C. While the Transtek TMB-986 has been validated, can you please explain the differences in the accuracy claims?
		Response	The device standard working condition is from 10 to 40°C, so if temperature is lower than 10°C, the device will work, but the value is not usable. For the Transtek device, they don't provide the accuracy between 5°C~9.9°C. We have corrected the Braun manual accordingly.
		Comment	According to this response, there are still differences in the manuals regarding the accuracy of the devices

	5°C – 9.9°C	10°C – 14.9°C	15°C – 25°C	25.1°C – 40°C
Braun BP6100	Results not usable	± 3 mmHg	± 3 mmHg	± 3 mmHg
Transtek TMB-986	No accuracy provided	± 6 mmHg (± 0.8 kPa)	± 3 mmHg (± 0.4 kPa)	± 6 mmHg (± 0.8 kPa)

Nevertheless, this is just an indication of accuracy; it is the validation procedures that are the true measured of accuracy and the Transtek device has been validated. The primary issue of the temperature range has been resolved.

2	Query	In the specifications sections, of both the manual for the Braun BP6100 and the manual for the Transtek TMB-986, the range of measurement for blood pressure is described as 0 mmHg to 300 mmHg. Is this the actual measurement range (whereby a value of 300 mmHg could be recorded for SBP and a value of 0 mmHg for DBP) or is 300 mmHg the maximum inflation with the actual measurement range being a narrow range within those limits?
	Response	300mmHg is for both devices the maximum inflation. Once it is reached, it will immediately deflate to a smaller value, to protect the user and the device. This safety function can be measured with the equipment BP 2, but is not described in any of the OM´s.
	Comment	The explanation clarifies this feature and also the presence of the safety release.
3	Query	In the specifications section of the Braun manual, an item “Exhaust” is described as “Automatic exhaust valve”. It is unclear as to whether this refers to automatic deflation or a safety exhaust valve. The manual for the Transtek TMB-986 does not contain any reference to deflation. Please clarify the safety exhaust provisions in both devices.
	Response	TMB-986 is using the principle of inflation measurement. The item “Exhaust” was a mistake in the OM. We have now corrected the Braun manual accordingly.
	Comment	The item is removed from the manual
4	Query	Eight error codes (E1, E2, E3, E10, E11, E20, E21, Eexx) are described for the Transtek TMB-986 whereas none is described for the Braun BP6100, for which a simple error symbol is shown regardless of the error. Please explain.
	Response	On page 13 (in the Attachment), you find the error codes which are explained in the OM for BP6000 series. E1 up to E4 is explained in details. All other error codes are for the service technicians and therefore they are only mentioned as Eexx. Both Transtek TMB-986 and Braun BP6000 series will show E1, E2, E3, E4, and Eexx only. Therefore, Transtek will modify there I/M accordingly.
	Comment	The new error codes are described in the manual. E1, E2 and E3 are identical in both manuals. E4 corresponds to E10 and E11 in the current Transtek manual. It is assumed that E20 and E21 will be assumed into the Eexx set in the new Transtek manual.
5	Query	A zero pressure check, prior to inflation, appears to be described for the Transtek TMB-986. (The actual sentence is “Adjust the zero automatically.”) No such check is described for the Braun BP6100. Please explain.
	Response	Transtek TMB-986 model will “Adjust the zero automatically” before inflation. Braun BP6000 series will be same as TMB-986. We have now corrected the Braun manual accordingly.
	Comment	The explanation clarifies this function.

6	Query	According to the manual for the Transtek TMB-986, only one cuff is supplied (AC2232-01). However, in the validation paper [Liu WJ, Li SG, Song Z, Gong W. Validation of the Transtek blood pressure monitor TMB-986 for home blood pressure monitoring according to the International Protocol. *Blood Press Monit* 2010;**15**(5):278-80], two cuffs are used. Can you please explain this anomaly? Are both cuffs supplied with the device or is one available as an optional extra? What is the part number for the other cuff? No part numbers for cuffs are provided for the cuffs in the Braun manual. What are the part numbers used for the BP6100 cuffs?
	Response	The Braun BP6000 series will be the same as the TMB-986 and it will have the 2 cuffs supplied for each model. For TMB-986, the part number for the big cuff is TMB-986-AC-05 (32-42cm). For the BP6100, the part numbers from supplier for the cuffs are TMB-1250-02 (22-32cm) and TMB-1250-03 (32-42cm). All cuff bladders are exactly the same. The only difference is the outside material. For the TMB-986, it is polyester and for the BP6100, it is nylon.
	Comment	The fact that the cuff bladders are the same is sufficient. Previous studies have shown that outside materials do not have any effect on the accuracy of readings.
7	Query	There are two triangles on the left hand side of the screen for the Braun BP6100. No explanation of their use is provided in the manual. Please explain their uses, if any.
	Response	The two triangles indicate only the inflation (upper triangle) and the open valve and release pressure (lower triangle). There is no other function behind these triangles. We have now added a short explanation of these 2 symbols in the Braun OM.
	Comment	The explanations clarify their uses
8	Query	In the Braun BP6100, how are measurements be aborted before completion? This is not described in the manual.
	Response	It is described in the chapter “taking a measurement” last line.
	Comment	The last line states, “After taking blood pressure measurement, turn off the device by pressing the “start” (1) button or automatically after 1 minute.” It is taken that this button can also be used to abort a reading if required.
9	Query	The Transtek TMB-986 is manufactured in China by Zhongshan Transtek Electronics Co. Ltd. While the declaration form also states that they manufacture the Braun BP6100, according to the manual, it is manufactured in Switzerland by Kaz Europe SA. Can you please explain this anomaly?
	Response	According to your definition the Manufacturer is Transtek because they “manufacture” all the single component of the BP6000. However, according to the directive 93/42/CE the legal manufacturer is Kaz. This means that Transtek is the actual manufacturer of the BP6000, but once the product is onto the market, the legal manufacturer is Kaz: we have the legal responsibility in case of any issues with customers. To make it short, if we want to have the CE mark we need to be the Legal Manufacturer for this product. This is requested by the directive 93/42/CE.
	Comment	This explanation, along with supporting documentation, prove both devices are manufactured Transtek. It is also understood that the reference to the BP6000 refers to the BP6000 series which includes the BP6100.

	10	Note	Evidence was supplied to dablEducational Ltd. to prove that the key components of both devices are identical.
	11	Query	Is BP error detection in the Transtek TMB-986 independent of the IHB feature?
		Response	The BP error detection has nothing to do with the IHB detection.
		Comment	This explanation is accepted.
Recommendation	Equivalence is Recommended		
Date	28/11/2012		