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 ElectronicsCo.,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]	PIKDARE S.r.l.	*Address*	Via Saldarini Catelli, 10 - 22070, Casnate con Bernate (CO), Italy
Brand[c]	PIC Solution	Model[d]	mobileRAPID

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]	LS808-B

Existing validated blood pressure measuring device.

which has previously passed the ESH2010 protocol, the results of which were published as follows:

Zhong HuaLiu, Xian Yue Liu, Wen Jun Wu Validation of Transtek LS808-B for self/home measurement according to the European Society of Hypertension International Protocol reversion 2010

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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Declaration of Equivalence Form

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 _____ Company Stamp/Seal

Name Mike Mai

Date 2017. 05. 27

Signature of Witness _____

Name

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

Comparison of the PIKDARE PiC Solution mobileRAPID with the Transtek LS808-B

Devices – Item 9	PIKDARE PiC Solution mobileRAPID	Transtek LS808-B
Pictures		
Display Image		
Validation		ESH 2010 ESH 2002 BHS AAMI

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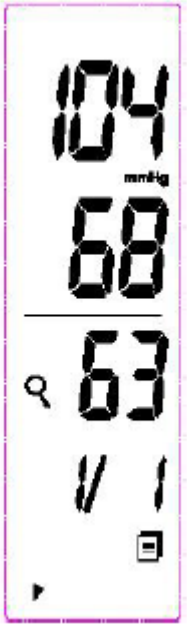
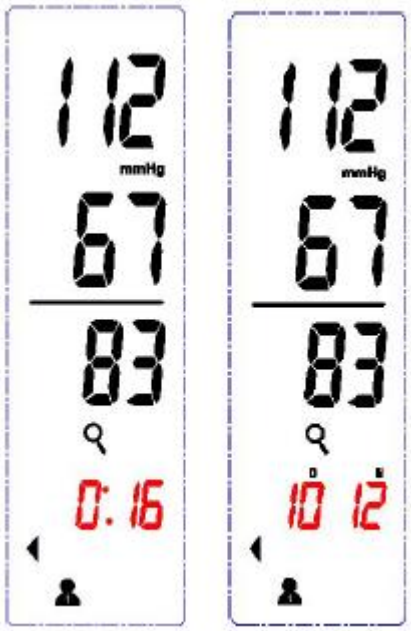
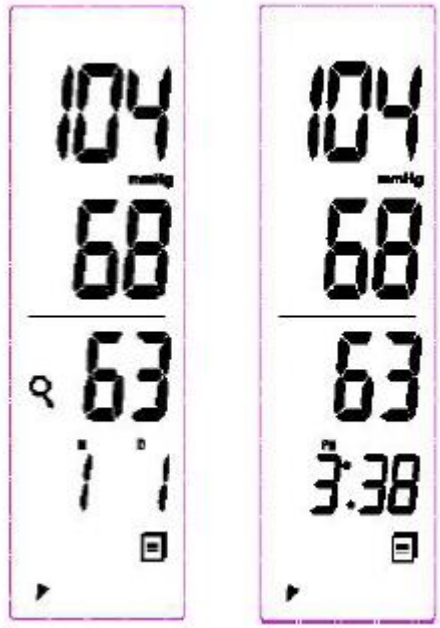
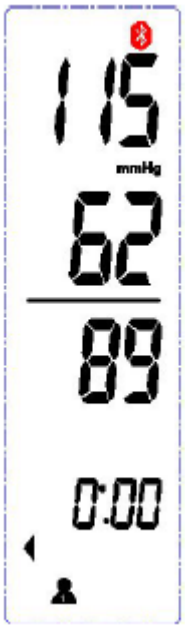
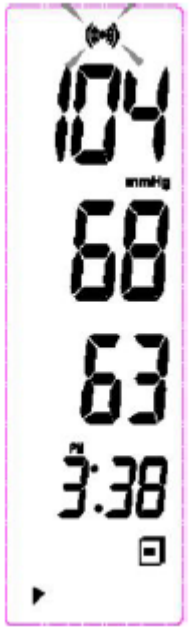
Category		
Casing – Item 10	*Dimensions* *133.0mm*74.3mm*25.4mm* *Ports* *Cuff port and DC power port* *Features* *133.0mm*74.3mm*25.4mm* 22-42cm	*Dimensions* *130.9mm*73mm*29.4mm* *Ports* *Cuff port and DC power port* *Features* *130.9mm*73mm*29.4mm* 22-42cm
Display – Item 11	*Indication* *Unit: mmHg unit* *ESH indicator* *Measurement records:* *Maximum 100 records per each user(dual users)* *If the measurement results beyond the measuring range.*	*Indication* *Unit: Kpa / mmHg unit* *WHO indicator* *Measurement records:* *Maximum 60 records per each user(dual users)* *If the measurement results beyond the measuring range ,display shows OUT.*
Carrying/Mounting Facilities – Item 12	*Blue-black bag*	*NA*
Software other than Algorithm – Item 13	*Dual Users* *200 sets memories* *ESH indicator* *mmHg unit*	*Dual Users* *120sets memories* *WHO indicator*
Memory Capacity Item 14	*200 sets memories*	*120 sets memories*
Printing Facilities Item 15	NA	NA
Communication Facilities – Item 16	NA	NA
Power Supply Item 17	1. *lithium battery* 2. 6V DC Jack	1. *lithium battery* *2.* 6V DC Jack
Other differences	*Other Details on Equivalent device that are different to Validated device* N/A	*Other Details on Validated device that are different to Equivalent device* N/A
Same Criteria	***Measurement*** *Accuracy*	***Measurement*** *Accuracy*

	Pressure: ±3 mmHg Pulse value:±5% *Method* *Oscillography* *Ranges* *Rated cuff pressure:0mmHg~300mmHg* *Measurement pressure:40mmHg~230mmHg* *Pulse value:(40-199) beat/minute* *Inflation* *Automatic Deflation* *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* *Last 3 reading average* ***Buttons/Switches*** *Power* *User 1 / User 2/ MEM* *Function* *User 1 / User 2/ MEM/"lock" button* ***Casing*** *Ports* *Cuff port and DC power port* *Power* *3.7V lithium battery*	*Power*
	Pressure: ±3 mmHg Pulse value:±5% *Method* *Oscillography* *Ranges* *Rated cuff pressure:0mmHg~300mmHg* *Measurement pressure:40mmHg~230mmHg* *Pulse value:(40-199) beat/minute* *Inflation* *Automatic Deflation* *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* *Last 3 reading average* ***Buttons/Switches*** *Power* *User 1 / User 2/ MEM* *Function* *User 1 / User 2/ MEM/"lock" button* ***Casing*** *Ports* *Cuff port and DC power port* *Power* *3.7V lithium battery*	

	Display/Symbols/Indicators *Preparation*  *Measurement Procedure*  *Measurement Records*	***Display/Symbols/Indicators*** *Preparation*  *Measurement Procedure*  *Measurement Records*

	 *Date and Time*	 *Date and Time*

	 *Power* *Low power* *Function* *Measure blood pressure and heart rate* *Recall measurement records* *Delete measurement records* *Communication*	 *Power* *Low power* *Function* *Measure blood pressure and heart rate* *Recall measurement records* *Delete measurement records* *Communication*

	 *Features* *Measuring during inflation* *Not described* ***Algorithms*** *Averages and Differences* *Averages and Differences* *Recall the average value of last measurement* *Diagnostic* *N/A* *Functions* *Measure blood pressure and heart rate*	 *Features* *Measuring during inflation* *Not described* ***Algorithms*** *Averages and Differences* *Averages and Differences* *Recall the average value of last measurement* *Diagnostic* *N/A* *Functions* *Measure blood pressure and heart rate*

	Communication	*Communication*
Comparable Criteria		

Comments		
Recommendation	**Recommended**	
Date	**12 June 2017**	