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 Gary Hung , a Director of Rossmax International 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]	Rossmax Swiss GmbH	*Address*	Tramstrasse 16, CH-9442 Berneck, Switzerland
Manufacturer[b]	PIKDARE S.r.l.	*Address*	via Saladarini Catelli, 10 - 22070 Casnate con Bernate - CO - Italy
Brand[c]	PiC Solution	Model[d]	CARDIOafib

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]	Rossmax Swiss GmbH	*Address*	Tramstrasse 16, CH-9442 Berneck, Switzerland
Manufacturer[b]	Rossmax Swiss GmbH	*Address*	Tramstrasse 16, CH-9442 Berneck, Switzerland
Brand[c]	Rossmax	Model[d]	CF175

Existing validated blood pressure measuring device.

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

Zhang, Lu; Kang, Yuan-Yuan; Zeng, W. Validation of the Rossmax CF175 upper-arm blood pressure monitor for home blood pressure monitoring according to the European Society of Hypertension International Protocol revision 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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Form DET7 130102

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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.

9. The validated model is CF175 and the claimed model is CARDIOafib

10. Button number. CF175 has 2 buttons , but CARDIOafib has 3 buttons.

11. CF175 has talking speaker mark, but CARDIOafib not.

11. CARDIOafib has Date/Time Indicator, Atrial fibrillation Detection, Arrhythmia Detection, Premature Contraction Detection, Cuff Wrap Detection,Morning and Nighttime Mark but CF175 not.

13. CF175 has talking speaker function, but CARDIOafib not.

13. CARDIOafib has Date/Time function,7 Day Average, Atrial fibrillation Detection, Arrhythmia Detection, Premature Contraction Detection but CF175 not.

14. CF175 has 90 of stored measurements, but CARDIOafib has 60 of stored measurements for 2 zones and guest mode .

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 Gary Hung

Company Stamp/Seal

ROSSMAX INTERNATIONAL LTD.

Name Gary Hung

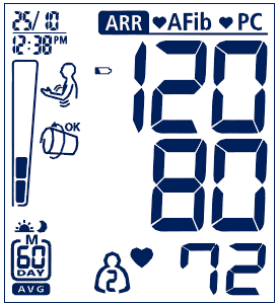
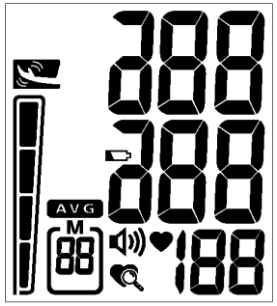
Date 2017/03/24

Signature of Witness Mark Lin

Name Mark Lin

Address 12F, No.189, Kang Chien Rd., Taipei, 114, Taiwan

Comparison of the Pikdare PiC Solution CARDIOafib with the Rossmax CF175

Devices – Item 9	*Pikdare PiC Solution CARDIOafib*	*Rossmax CF175*
Pictures		
Display Image		
Validation		ESH 2010
Category	Upper Arm Devices for Self Measurement of Blood Pressure	Upper Arm Devices for Self Measurement of Blood Pressure
Casing – Item 10	*Dimensions* 139.7mm X 96.0mm X 63.2mm *Ports* Data Link Socket AC Adaptor (Optional) *Features* 3 buttons	*Dimensions* 124mm X 85mm X 68.6mm *Ports* Data Link Socket AC Adaptor (Optional) *Features* 2 buttons
Display – Item 11	*Type* Date/Time Indicator, Atrial fibrillation Detection, Arrhythmia Detection, Premature Contraction Detection,	*Type* Talking speaker mark

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	Cuff Wrap Detection, Morning and Night-time Mark	
Carrying/Mounting Facilities – Item 12	Box	Box
Software other than Algorithm – Item 13	Date/Time Indicator, Atrial fibrillation Detection, Arrhythmia Detection, Premature Contraction Detection, Cuff Wrap Detection, Morning and Night-time Mark	Talking speaker mark
Memory Capacity Item 14	60 of stored measurements for 2 zones and guest mode	90 of stored measurements
Printing Facilities Item 15	N/A	N/A
Communication Facilities – Item 16	N/A	N/A
Power Supply Item 17	6V	6V
Other differences	N/A	N/A
Same Criteria	***Measurement*** *Accuracy* Pressure: ± 3 mmHg Pulse: ± 5% of reading *Method* Oscillometric measurement method *Ranges* Pressure:30-260 mmHg *Inflation* Automatic inflation Inflation: 0 mmHg - 299 mmHg *Deflation* Automatic deflation *Cuffs (Please state sizes and materials used)* Arm circumference: Adult: 24~40 cm (9.4”~15.7”) Materials: Nylon OXFORD	***Measurement*** *Accuracy* Pressure: ± 3 mmHg Pulse: ± 5% of reading *Method* Oscillometric measurement method *Ranges* Pressure:30-260 mmHg *Inflation* Automatic inflation Inflation: 0 mmHg - 299 mmHg *Deflation* Automatic deflation *Cuffs(Please state sizes and materials used)* Arm circumference: Adult: 24~40 cm (9.4”~15.7”) Materials: Nylon OXFORD

	Sensors Semi conductor *Measurement Records* Memory(M symbol) *Measurements other than Blood Pressure* Pluse ***Buttons/Switches*** *Power* START/STOP key *Measurement Records* Memory(M symbol) User-Switching button ***Display/Symbols/Indicators*** *Preparation* "0" blinking *Measurement Procedure* Heartbeat symbol during deflation *Post Measurement* systolic blood pressure, diastolic blood pressure, and pulse Movement Detector (once a body movement has been detected) *Measurement Records* M symbol and Memory Sequence Memory Average Symbol *Power* Weak Battery Indicator ***Algorithms*** *Averages and Differences* Average of the last 3 measurements *Diagnostic* Arrhythmia Detection Atrial Fibrillation Detection Premature Contraction Detection	*Sensors* Semi conductor *Measurement Records* Memory(M symbol) *Measurements other than Blood Pressure* Pluse ***Buttons/Switches*** *Power* On/Off/Start (⏻ symbol) *Measurement Records* Memory(M symbol) ***Display/Symbols/Indicators*** *Preparation* "0" blinking *Measurement Procedure* Heartbeat symbol during deflation *Post Measurement* systolic blood pressure, diastolic blood pressure, and pulse Movement Detector (once a body movement has been detected) *Measurement Records* M symbol and Memory Sequence Memory Average Symbol *Power* Weak Battery Indicator ***Algorithms*** *Averages and Differences* Average of the last 3 measurements *Diagnostic* Arrhythmia Detection Atrial Fibrillation Detection Premature Contraction Detection
Comparable Criteria	***Measurement*** *Measurement Records* Memory capacity: 60 x 2 zones and Guest mode (non-stored single measurement)	***Measurement*** *Measurement Records* Memory capacity: 90 *Post Measurement*

	Post Measurement Hypertension Risk Indicator (WHO)	Hypertension Risk Indicator (JNC-7)

Comments		None
Recommendation	***RECOMMENDED***	
Date	24th May 2017	