

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2013

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

SECTION A - Please complete all items.

I Gary Hung,
Name of a Company Directora Director of Rossmax International Ltd.,
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	Rossmax Swiss GmbH	Address	Tramstrasse 16, CH-9442 Berneck, Switzerland
Brand ^c	Alvita	Model ^d	Blood Pressure Monitor – Wrist (S150)

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	S150

Existing validated blood pressure measuring device.

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

Zeng WF, Huang QF, Sheng CS, Li Y, Wang JG. Validation of the Rossmax S150 wrist blood pressure monitor, for self measurement, 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 <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 type="checkbox"/>	No <input checked="" type="checkbox"/>	
	11	Display	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	12	Carrying/Mounting Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	13	Software other than Algorithm	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	14	Memory Capacity/Number of stored measurements	Yes <input type="checkbox"/>	No <input checked="" 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.

9. The validated model is S150 and the claimed model is Blood Pressure Monitor – Wrist.

SECTION C Please check that the following are included with the application

A manual for the validated device	<input checked="" type="checkbox"/>
A manual for the device for which equivalence is being sought	<input checked="" type="checkbox"/>
An image of the validated device	<input checked="" type="checkbox"/>
An image of the device for which equivalence is being sought	<input checked="" type="checkbox"/>
An image of the screen layout of validated device*	<input checked="" type="checkbox"/>
An image of the screen layout of the device for which equivalence is being sought*	<input checked="" type="checkbox"/>

* 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

Name Gary Hung

Date May 12, 2015



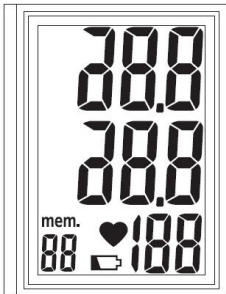
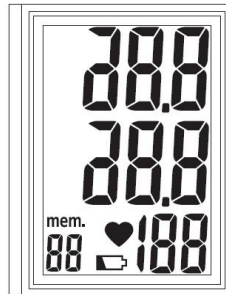
Signature of Witness Mark Lin





ROSSMAX INTERNATIONAL LTD.

Name Mark Lin

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

Comparison of the Alvita Blood Pressure Monitor – Wrist with the Rossmax S150

Devices	Alvita Blood Pressure Monitor – Wrist(S150)	Rossmax S150
Pictures		
Display		
Validation		ESH 2010
Device 1 Criteria		
Device 2 Criteria		
Same Criteria	Measurement <i>Accuracy</i> Pressure: ± 3 mmHg Pulse: $\pm 5\%$ of reading <i>Method</i> Oscillometric measurement method <i>Inflation</i> Automatic inflation Inflation: 0 mmHg - 299 mmHg Measurement Range; Pressure:30-260mmHg Pulse: 40-199 beats/minute	Measurement <i>Accuracy</i> Pressure: ± 3 mmHg Pulse: $\pm 5\%$ of reading <i>Method</i> Oscillometric measurement method <i>Inflation</i> Automatic inflation Inflation: 0 mmHg - 299 mmHg Measurement Range; Pressure:30-260mmHg Pulse: 40-199 beats/minute

	<p><i>Deflation</i> Automatic deflation</p> <p><i>Cuffs</i> Wrist circumference: 13.5~22cm(5.3"~8.7")</p> <p><i>Sensors</i> Semi-conductor</p> <p><i>Measurement Records</i> Memory capacity: 90</p> <p>Buttons/Switches <i>Power</i> On/Off/Start ( symbol)</p> <p><i>Measurement Records</i> Memory(M symbol)</p> <p>Display/Symbols/Indicators <i>Preparation</i> "0" blinking</p> <p><i>Measurement Procedure</i> Heartbeat symbol during deflation</p> <p><i>Post Measurement</i> systolic blood pressure, diastolic blood pressure, and pulse</p> <p><i>Measurement Records</i>  symbol</p> <p>Memory Sequence <i>Power</i> Weak Battery Mark</p> <p>Casing <i>Display</i> Single screen display Segment LCD</p> <p><i>Power</i> Two AAA batteries</p>	<p><i>Deflation</i> Automatic deflation</p> <p><i>Cuffs</i> Wrist circumference: 13.5~22cm(5.3"~8.7")</p> <p><i>Sensors</i> Semi-conductor</p> <p><i>Measurement Records</i> Memory capacity: 90</p> <p>Buttons/Switches <i>Power</i> On/Off/Start( symbol)</p> <p><i>Measurement Records</i> Memory(M symbol)</p> <p>Display/Symbols/Indicators <i>Preparation</i> "0" blinking</p> <p><i>Measurement Procedure</i> Heartbeat symbol during deflation</p> <p><i>Post Measurement</i> systolic blood pressure, diastolic blood pressure, and pulse</p> <p><i>Measurement Records</i>  symbol</p> <p>Memory Sequence <i>Power</i> Weak Battery Mark</p> <p>Casing <i>Display</i> Single screen display Segment LCD</p> <p><i>Power</i> Two AAA batteries</p>
Comparable Criteria		

Comments		
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Recommendation	<i>Recommended</i>
Date	21 May 2015