

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 **Patrick Chow,** a Director of **Grandway Technology (Shenzhen) Limited,**
 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 **Grandway** Address **Block 7, Zhu Keng Industrial Zone, Ping Shan District, 518118 Shenzhen, PEOPLE'S REPUBLIC OF CHINA**

Manufacturer^b **Grandway** Address **Block 7, Zhu Keng Industrial Zone, Ping Shan District, 518118 Shenzhen, PEOPLE'S REPUBLIC OF CHINA**

Brand^c **G.LAB** Model^d **MD4180**

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 **Grandway** Address **Block 7, Zhu Keng Industrial Zone, Ping Shan District, 518118 Shenzhen, PEOPLE'S REPUBLIC OF CHINA**

Manufacturer^b **Grandway** Address **Block 7, Zhu Keng Industrial Zone, Ping Shan District, 518118 Shenzhen, PEOPLE'S REPUBLIC OF CHINA**

Brand^c **Grandway** Model^d **MD2301**

Existing validated blood pressure measuring device.

which has previously passed the **ESH 2010** protocol, the results of which were published as follows:

Validation of the Grandway MD2301 digital automatic blood pressure monitor according to the European Society of Hypertension International Protocol.

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 checked="" type="checkbox"/>	N/A ^g <input 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.

(10) 4 buttons: START/STOP button, Memory button, Forward button and Backward button;

(11) LCD can display User 3 and User 4 ;

(13) Increasing Alarm clock, User 3 and User 4

(14) Stores 240 * 4 readings

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 Patrick Chow

Date 23 May, 2016




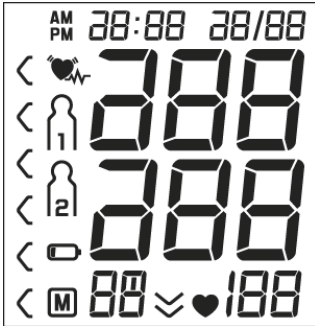
Signature of Witness _____

Name Eric Wong

Address Block 7, Zhu Keng Industrial Zone, Ping Shan District, 518118 Shenzhen, PEOPLE'S REPUBLIC OF CHINA




























Comparison of the New with the Old

Devices – Item 9	G.LAB MD4180	GRANDWAY MD2301
Pictures		
Display Image		
Validation		ESH-IP 2010
Category	Blood Pressure Monitor Device	Blood Pressure Monitor Device
Casing – Item 10	<p><i>Dimensions</i> 164 (L) x 99 (W) x 46 (H)cm</p> <p><i>Ports</i> N/A</p> <p><i>Features</i> Systolic and diastolic blood pressure measurement</p>	<p><i>Dimensions</i> 165 (L) x 107 (W) x 50 (H)cm</p> <p><i>Ports</i> N/A</p> <p><i>Features</i> Systolic and diastolic blood pressure measurement</p>

	Pulse rate measurement Irregular heartbeat (IHB) detection and indication WHO blood pressure classification scale (WHO Guidelines 1999) Alarm clock	Pulse rate measurement Irregular heartbeat (IHB) detection and indication WHO blood pressure classification scale (WHO Guidelines 1999)
Display – Item 11	<i>Type</i> Single Screen Display Segment LCD <i>Measurement Procedure</i> During Measurement: BP level & Heartbeat <i>Post Measurement</i> SBP, DBP and Pulse Measurement error: E1, E2, E3, E4, E5 and E6 Memory-Zone mean (A symbol) 7- day morning memory-zone mean (AM symbol) 7- day evening memory-zone mean (AM symbol)	<i>Type</i> Single Screen Display Segment LCD <i>Measurement Procedure</i> During Measurement: BP level & Heartbeat <i>Post Measurement</i> SBP, DBP and Pulse Measurement error: E1, E2, E3, E4, E5 and E6 Memory-Zone mean (A symbol) 7- day morning memory-zone mean (AM symbol) 7- day evening memory-zone mean (AM symbol)
Carrying/Mounting Facilities – Item 12	N/A	N/A
Software other than Algorithm – Item 13	Memory zone means 7- day morning memory-zone mean 7- day evening memory-zone mean Alarm clock WHO Guidelines 1999	Memory zone means 7- day morning memory-zone mean 7- day evening memory-zone mean WHO Guidelines 1999
Memory Capacity Item 14	240 memories x 4 users	60 memories x 2 users
Printing Facilities Item 15	N/A	N/A
Communication Facilities – Item 16	N/A	N/A
Power Supply Item 17	Alkaline Battery (DC 6V 600mA, LR03 (AAA) 1.5V x 4 pcs) Battery Life ~ 300 measurements	Alkaline Battery (DC 6V 600mA, LR06 (AA) 1.5V x 4 pcs) Battery Life ~ 500 measurements

Other differences	Memory Capacity: 240 memories x 4 users Alarm Function	Memory Capacity: 60 memories x 2 users
Same Criteria	<p>Measurement</p> <p><i>Accuracy</i></p> <p>BP accuracy \pm 3mmHg Pulse accuracy \pm 5%</p> <p><i>Method</i></p> <p>Oscillometric method made during cuff inflation</p> <p><i>Ranges</i></p> <p>Systolic pressure: 50 – 250 mmHg Diastolic pressure: 30 – 200 mmHg Pulse rate: 40 – 180 pulse/minute Manually initiated measurements Measurements are from single inflations</p> <p><i>Inflation</i></p> <p>Inflation 0mmHg – 300mmHg Automatic Inflation Zero pressure check before inflation</p> <p><i>Deflation</i></p> <p>Automatic Deflation</p> <p><i>Cuffs (Please state sizes and materials used)</i></p> <p>Nylon Material Standard Type: 22 – 36 cm (Original), Nylon Material Large: 35 – 44 cm (Optional) Nylon Material Universal: 22 – 44 cm (Optional)</p> <p><i>Sensors</i></p> <p>US9111 Resistance Type Pressure Sensors</p> <p><i>Measurement Records</i></p> <p>Memory Capacity: 240 memories x 4 users</p> <p><i>Measurements other than Blood Pressure</i></p> <p>N/A</p>	<p>Measurement</p> <p><i>Accuracy</i></p> <p>BP accuracy \pm 3mmHg Pulse accuracy \pm 5%</p> <p><i>Method</i></p> <p>Oscillometric method made during cuff inflation</p> <p><i>Ranges</i></p> <p>Systolic pressure: 60 – 250 mmHg Diastolic pressure: 40 – 199 mmHg Pulse rate: 40 – 180 pulse/minute Manually initiated measurements Measurements are from single inflations</p> <p><i>Inflation</i></p> <p>Inflation 0mmHg – 300mmHg Automatic Inflation Zero pressure check before inflation</p> <p><i>Deflation</i></p> <p>Automatic Deflation</p> <p><i>Cuffs(Please state sizes and materials used)</i></p> <p>Nylon Material Standard Type: 22 – 36 cm (Original), Nylon Material Large: 35 – 44 cm (Optional) Nylon Material Universal: 22 – 44 cm (Optional)</p> <p><i>Sensors</i></p> <p>US9111 Resistance Type Pressure Sensors</p> <p><i>Measurement Records</i></p> <p>Memory Capacity: 60 memories x 2 users</p> <p><i>Measurements other than Blood Pressure</i></p> <p>N/A</p>

	<p>Buttons/Switches</p> <p><i>Power</i> Start/Stop ( Symbol)</p> <p><i>Measurement Records</i> Memory ( Symbol) Forward ( Symbol) Backward ( Symbol)</p> <p><i>Function</i> Start/Stop ( Symbol) - Start/Stop Measurement Memory ( Symbol) - Enter Memory Mode Forward ( Symbol) - Increase value or goes forward Backward ( Symbol) - Decrease value or goes backward</p> <p><i>Analysis</i> N/A</p> <p><i>Event Marking</i> Start/Stop ( Symbol) Memory ( Symbol) Forward ( Symbol) Backward ( Symbol)</p> <p><i>Communication</i> N/A</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i>  Start to inflate  Zero pressure check used</p> <p><i>Measurement Procedure</i> During Measurement: BP Level, Heartbeat,  and User icon</p> <p><i>Post Measurement</i> SBP, DBP and Pulse Measurement error: E1, E2, E3, E4, E5 and E6 Memory-Zone mean (A symbol)</p>	<p>Buttons/Switches</p> <p><i>Power</i> Start/Stop ( Symbol)</p> <p><i>Measurement Records</i> Memory 1 ( 1 Symbol) Memory 2 ( 2 Symbol)</p> <p><i>Function</i> Start/Stop ( Symbol) - Start/Stop Measurement Memory 1 ( 1 Symbol) - Enter User 1 Memory Mode Memory 2 ( 2 Symbol) - Enter User 2 Memory Mode</p> <p><i>Analysis</i> N/A</p> <p><i>Event Marking</i> Start/Stop ( Symbol) Memory 1 ( 1 Symbol) Memory 2 ( 2 Symbol)</p> <p><i>Communication</i> N/A</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i>  Zero pressure check used</p> <p><i>Measurement Procedure</i> During Measurement: BP Level and Heartbeat</p> <p><i>Post Measurement</i> SBP, DBP and Pulse Measurement error: E1, E2, E3, E4, E5 and E6 Memory-Zone mean (A symbol)</p>
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	<p>7- day morning memory-zone mean (AM symbol) 7- day evening memory-zone mean (AM symbol) WHO blood pressure classification scale (WHO Guidelines 1999) Irregular heartbeat (IHB) detection and indication</p> <p><i>Measurement Records</i> Memory Capacity: 240 memories x 4 users</p> <p><i>Date and Time</i> Date and Time Date and Time (During memory recall and measuring)</p> <p><i>Algorithms</i> <i>Averages and Differences</i> Memory Zone Means</p> <p><i>Diagnostic</i> WHO blood pressure classification scale (WHO Guidelines 1999) Irregular heartbeat (IHB) detection</p>	<p>7- day morning memory-zone mean (AM symbol) 7- day evening memory-zone mean (AM symbol) WHO blood pressure classification scale (WHO Guidelines 1999) Irregular heartbeat (IHB) detection and indication</p> <p><i>Measurement Records</i> Memory Capacity: 60 memories x 2 users</p> <p><i>Date and Time</i> Date and Time Date and Time (During memory recall)</p> <p><i>Algorithms</i> <i>Averages and Differences</i> Memory Zone Means</p> <p><i>Diagnostic</i> WHO blood pressure classification scale (WHO Guidelines 1999) Irregular heartbeat (IHB) detection</p>
<p>Comparable Criteria</p>	<p>Casing Power Alkaline Battery (DC 6V 600mA, LR03 (AAA) 1.5V x 4 pcs) Battery Life ~ 300 measurements</p> <p><i>Display/Symbols/Indicators</i> <i>Preparation</i> ▲ Start to inflate ▼ Zero pressure check used</p>	<p>Casing Power Alkaline Battery (DC 6V 600mA, LR06 (AA) 1.5V x 4 pcs) Battery Life ~ 500 measurements</p> <p><i>Display/Symbols/Indicators</i> <i>Preparation</i> ∨ Zero pressure check used</p>

Comments		
Recommendation	Recommended	
Date	6 June 2016	