

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2013

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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 <sup>a</sup>	Beurer	Address	Beurer GmbH, Söflinger Strasse 218, 89077 Ulm/ Germany
Manufacturer <sup>b</sup>	Grandway	Address	No.5, the Second Industrial Zone, Zhukeng Community, Longtian Street, Pingshan District, Shenzhen
Brand <sup>c</sup>	Beurer	Model <sup>d</sup>	BM81

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 <sup>a</sup>	Grandway	Address	No.5, the Second Industrial Zone, Zhukeng Community, Longtian Street, Pingshan District, Shenzhen
Manufacturer <sup>b</sup>	Grandway	Address	No.5, the Second Industrial Zone, Zhukeng Community, Longtian Street, Pingshan District, Shenzhen
Brand <sup>c</sup>	Grandway	Model <sup>d</sup>	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 MD2301(Grandway Technology Limited, Shenzhen, China) 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 <sup>e</sup> <input type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>f</sup> <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 <sup>f</sup> <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 <sup>g</sup> <input checked="" type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>g</sup> <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 <sup>g</sup> <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) Button arrangement: Start/Stop button, M button, Forward button and Backward button

(11) LCD Full screen re-designed and BLE icon built-in

(13) BLE transmission, All measuring record will transmit to mobile phone

(14) Stores 120\*2 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

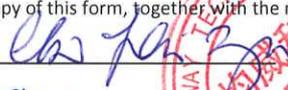
An image of the device for which equivalence is being sought

An image of the screen layout of validated device\*

An image of the screen layout of the device for which equivalence is being sought\*

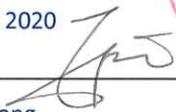
\* Screen layouts shown complete, and without obscuring labels or lines, in manuals need not be included separately.

**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](mailto:info@dableducational.org).

Signature of Director \_\_\_\_\_  Company Stamp/Seal

Name Patrick Chow

Date 3-Nov, 2020

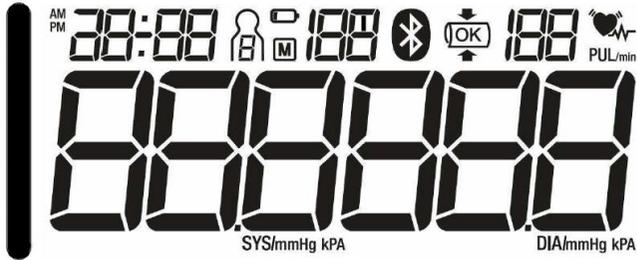
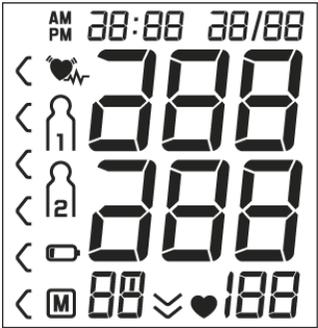
Signature of Witness \_\_\_\_\_ 

Name Eric Wong

Address No.5, the Second Industrial Zone, Zhukeng Community, Longtian Street, Pingshan District, Shenzhen



Comparison of the Beurer BM81 with the GRANDWAY MD2301

Devices – Item 9	Beurer BM81	GRANDWAY MD2301
Pictures		
Display Image		
Validation		ESH-IP 2010, BHS and AAMI
Category	Blood Pressure Monitor Device	Blood Pressure Monitor Device
Casing – Item 10	<p><i>Dimensions</i> 143 (L) x 91 (W) x 22 (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>

	<b>Pulse rate measurement</b> <b>Irregular heartbeat (IHB) detection and indication</b> <b>WHO blood pressure classification scale (WHO Guidelines 1999)</b>	<b>Pulse rate measurement</b> <b>Irregular heartbeat (IHB) detection and indication</b> <b>WHO blood pressure classification scale (WHO Guidelines 1999)</b>
<b>Display – Item 11</b>	<i>Type</i> <b>Single Screen Display</b> <b>Segment LCD</b> <i>Measurement Procedure</i> <b>During Measurement: BP level &amp; Heartbeat</b> <i>Post Measurement</i> <b>SBP, DBP and Pulse</b> <b>Measurement error: E1, E2, E3, E4, E5, E6, E7</b> <b>Memory-Zone mean (A symbol)</b> <b>7- day morning memory-zone mean (AM symbol)</b> <b>7- day evening memory-zone mean (PM symbol)</b>	<i>Type</i> <b>Single Screen Display</b> <b>Segment LCD</b> <i>Measurement Procedure</i> <b>During Measurement: BP level &amp; Heartbeat</b> <i>Post Measurement</i> <b>SBP, DBP and Pulse</b> <b>Measurement error: E1, E2, E3, E4, E5 and E6</b> <b>Memory-Zone mean (A symbol)</b> <b>7- day morning memory-zone mean (AM symbol)</b> <b>7- day evening memory-zone mean (AM symbol)</b>
<b>Carrying/Mounting Facilities – Item 12</b>	N/A	N/A
<b>Software other than Algorithm – Item 13</b>	<b>Memory zone means</b> <b>7- day morning memory-zone mean</b> <b>7- day evening memory-zone mean</b> <b>WHO Guidelines 1999</b>	<b>Memory zone means</b> <b>7- day morning memory-zone mean</b> <b>7- day evening memory-zone mean</b> <b>WHO Guidelines 1999</b>
<b>Memory Capacity Item 14</b>	120 memories x 2 users	60 memories x 2 users
<b>Printing Facilities Item 15</b>	N/A	N/A
<b>Communication Facilities – Item 16</b>	N/A	N/A
<b>Power Supply Item 17</b>	<b>Alkaline Battery (DC 6V 600mA, LR03 (AAA) 1.5V x 4 pcs)</b> <b>Battery Life ~ 300 measurements</b>	<b>Alkaline Battery (DC 6V 600mA, LR06 (AA) 1.5V x 4 pcs)</b> <b>Battery Life ~ 500 measurements</b>
<b>Other differences</b>	<b>BLE Transmission Function</b>	<b>Nil</b>

<p><b>Same Criteria</b></p>	<p><b>Measurement</b></p> <p><i>Accuracy</i>  <b>BP accuracy ± 3mmHg</b>  <b>Pulse accuracy ± 5%</b></p> <p><i>Method</i>  <b>Oscillometric method made during cuff inflation</b></p> <p><i>Ranges</i>  <b>Systolic pressure: 60 – 250 mmHg</b>  <b>Diastolic pressure: 30 – 200 mmHg</b>  <b>Pulse rate: 40 – 180 pulse/minute</b>  <b>Manually initiated measurements</b>  <b>Measurements are from single inflations</b></p> <p><i>Inflation</i>  <b>Inflation 0mmHg – 300mmHg</b>  <b>Automatic Inflation</b>  <b>Zero pressure check before inflation</b></p> <p><i>Deflation</i>  <b>Automatic Deflation</b></p> <p><i>Cuffs (Please state sizes and materials used)</i>  <b>Nylon Material Standard Type: 24 – 40 cm (Original),</b></p> <p><i>Sensors</i>  <b>US9111 Resistance Type Pressure Sensors</b></p> <p><i>Measurement Records</i>  <b>Memory Capacity: 120 memories x 2 users</b></p> <p><i>Measurements other than Blood Pressure</i>  <b>N/A</b></p> <p><b>Buttons/Switches</b></p>	<p><b>Measurement</b></p> <p><i>Accuracy</i>  <b>BP accuracy ± 3mmHg</b>  <b>Pulse accuracy ± 5%</b></p> <p><i>Method</i>  <b>Oscillometric method made during cuff inflation</b></p> <p><i>Ranges</i>  <b>Systolic pressure: 60 – 250 mmHg</b>  <b>Diastolic pressure: 40 – 199 mmHg</b>  <b>Pulse rate: 40 – 180 pulse/minute</b>  <b>Manually initiated measurements</b>  <b>Measurements are from single inflations</b></p> <p><i>Inflation</i>  <b>Inflation 0mmHg – 300mmHg</b>  <b>Automatic Inflation</b>  <b>Zero pressure check before inflation</b></p> <p><i>Deflation</i>  <b>Automatic Deflation</b></p> <p><i>Cuffs(Please state sizes and materials used)</i>  <b>Nylon Material Standard Type: 22 – 36 cm (Original),</b>  <b>Nylon Material Large: 35 – 44 cm (Optional)</b>  <b>Nylon Material Universal: 22 – 44 cm (Optional)</b></p> <p><i>Sensors</i>  <b>US9111 Resistance Type Pressure Sensors</b></p> <p><i>Measurement Records</i>  <b>Memory Capacity: 60 memories x 2 users</b></p> <p><i>Measurements other than Blood Pressure</i>  <b>N/A</b></p> <p><b>Buttons/Switches</b></p>
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	<p><i>Power</i>  <b>Start/Stop ( ⓘ Symbol)</b></p> <p><i>Measurement Records</i>  <b>Memory ( M Symbol)</b>  <b>Forward ( + Symbol)</b>  <b>Backward ( - Symbol)</b></p> <p><i>Function</i>  <b>Start/Stop ( ⓘ Symbol) - Start/Stop Measurement</b>  <b>Memory ( M Symbol) - Enter Memory Mode</b>  <b>Forward ( + Symbol) - Increase value or goes forward</b>  <b>Backward ( - Symbol) - Decease value or goes backward</b></p> <p><i>Analysis</i>  <b>N/A</b></p> <p><i>Event Marking</i>  <b>Start/Stop ( ⓘ Symbol)</b>  <b>Memory ( M Symbol)</b>  <b>Forward ( + Symbol)</b>  <b>Backward ( - Symbol)</b></p> <p><i>Communication</i>  <b>N/A</b></p> <p><b><i>Display/Symbols/Indicators</i></b></p> <p><i>Preparation</i>  <b>Full Screen for Zero pressure check used</b></p> <p><i>Measurement Procedure</i>  <b>During Measurement: BP Level, Heartbeat, Memory Record number and User icon</b></p> <p><i>Post Measurement</i>  <b>SBP, DBP and Pulse</b>  <b>Measurement error: E1, E2, E3, E4, E5, E6, and E7</b>  <b>Memory-Zone mean (A symbol)</b>  <b>7- day morning memory-zone mean (AM symbol)</b></p>	<p><i>Power</i>  <b>Start/Stop ( ⓘ Symbol)</b></p> <p><i>Measurement Records</i>  <b>Memory 1 ( ⓘ1 Symbol)</b>  <b>Memory 2 ( ⓘ2 Symbol)</b></p> <p><i>Function</i>  <b>Start/Stop ( ⓘ Symbol) - Start/Stop Measurement</b>  <b>Memory 1 ( ⓘ1 Symbol) - Enter User 1 Memory Mode</b>  <b>Memory 2 ( ⓘ2 Symbol) - Enter User 2 Memory Mode</b></p> <p><i>Analysis</i>  <b>N/A</b></p> <p><i>Event Marking</i>  <b>Start/Stop ( ⓘ Symbol)</b>  <b>Memory 1 ( ⓘ1 Symbol)</b>  <b>Memory 2 ( ⓘ2 Symbol)</b></p> <p><i>Communication</i>  <b>N/A</b></p> <p><b><i>Display/Symbols/Indicators</i></b></p> <p><i>Preparation</i>   <b>Zero pressure check used</b></p> <p><i>Measurement Procedure</i>  <b>During Measurement: BP Level and Heartbeat</b></p> <p><i>Post Measurement</i>  <b>SBP, DBP and Pulse</b>  <b>Measurement error: E1, E2, E3, E4, E5 and E6</b>  <b>Memory-Zone mean (A symbol)</b>  <b>7- day morning memory-zone mean (AM symbol)</b></p>
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	<p><b>7- day evening memory-zone mean (PM symbol)</b>  <b>WHO blood pressure classification scale (WHO Guidelines 1999)</b>  <b>Irregular heartbeat (IHB) detection and indication</b></p> <p><i>Measurement Records</i>  <b>Memory Capacity: 120 memories x 2 users</b></p> <p><i>Date and Time</i>  <b>Date and Time</b>  <b>Date and Time (During memory recall and measuring)</b></p> <p><i>Algorithms</i>  <i>Averages and Differences</i>  <b>Memory Zone Means</b></p> <p><i>Diagnostic</i>  <b>WHO blood pressure classification scale (WHO Guidelines 1999)</b>  <b>Irregular heartbeat (IHB) detection</b></p>	<p><b>7- day evening memory-zone mean (AM symbol)</b>  <b>WHO blood pressure classification scale (WHO Guidelines 1999)</b>  <b>Irregular heartbeat (IHB) detection and indication</b></p> <p><i>Measurement Records</i>  <b>Memory Capacity: 60 memories x 2 users</b></p> <p><i>Date and Time</i>  <b>Date and Time</b>  <b>Date and Time (During memory recall)</b></p> <p><i>Algorithms</i>  <i>Averages and Differences</i>  <b>Memory Zone Means</b></p> <p><i>Diagnostic</i>  <b>WHO blood pressure classification scale (WHO Guidelines 1999)</b>  <b>Irregular heartbeat (IHB) detection</b></p>
<b>Comparable Criteria</b>	<p><b>Casing</b>                  Power  <b>Alkaline Battery (DC 6V 600mA, LR03 (AAA) 1.5V x 4 pcs)</b>  <b>Battery Life ~ 300 measurements</b></p> <p><i>Display/Symbols/Indicators</i>  <i>Preparation</i>  <b>Full Screen for Zero pressure check used</b></p>	<p><b>Casing</b>                  Power  <b>Alkaline Battery (DC 6V 600mA, LR06 (AA) 1.5V x 4 pcs)</b>  <b>Battery Life ~ 500 measurements</b></p> <p><i>Display/Symbols/Indicators</i>  <i>Preparation</i>   <b>Zero pressure check used</b></p>

<b>Comments</b>	
<b>Recommendation</b>	<b>Recommended</b>
<b>Date</b>	<b>January 2021</b>