

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 Gao Wendong, a Director of Sejoy Electronics & Instruments Co., 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 Sejoy Electronics&Instruments Co., Ltd Address Building 2, No.202, Zhengzhong Rd., Westlake Econmy & Technology Zone, 310030, Hangzhou, China
 Manufacturer^b Sejoy Electronics&Instruments Co., Ltd Address Building 2, No.202, Zhengzhong Rd., Westlake Econmy & Technology Zone, 310030, Hangzhou, China
 Brand^c SEJOY Model^d BP-1209
 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 Sejoy Electronics&Instruments Co., Ltd Address Building 2, No.202, Zhengzhong Rd., Westlake Econmy & Technology Zone, 310030, Hangzhou, China
 Manufacturer^b Sejoy Electronics&Instruments Co., Ltd Address Building 2, No.202, Zhengzhong Rd., Westlake Econmy & Technology Zone, 310030, Hangzhou, China
 Brand^c SEJOY Model^d BP-1307
 Existing validated blood pressure measuring device.

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

Validation of the Sejoy BP-1307 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 <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 checked="" 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 type="checkbox"/>	No <input checked="" 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 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.

- (6) The bladders of two Model are same. Cuff size for BP-1307 is 22cm~42cm, cuff size for BP-1209 is 22cm~36. The cuff size is different, but the range of the cuff size BP-1209 is included in the cuff size BP-1307.
- (9) The model name is changed to BP-1209 from BP-1307
- (10) The casing of the device is with different appearance
- (11) The size of LCD display is different and the icons are different
- (14) Stores 120 readings instead of 2*60.

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 Gao Wendong

Company Stamp/Seal

Name Gao Wendong

Date 07 Feb, 2018

Signature of Witness Han Dongzheng

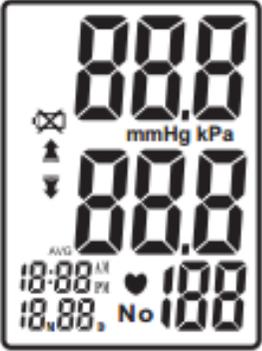
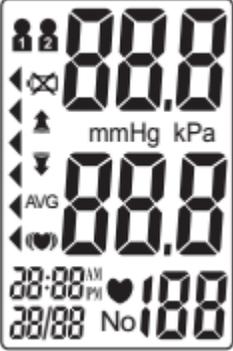
Name Han Dongzheng

Address Building 2, No.202, Zhenzhong Road, Westlake Economy & Technology Zone, 310030, Hangzhou, China

杭州世佳电子有限公司
HANGZHOU SEJOY ELECTRONICS & INSTRUMENTS CO.,LTD

任云华

Comparison of the SEJOY BP-1209 with the SEJOY BP-1307

Devices – Item 9	SEJOY BP-1209	SEJOY BP-1307
Pictures		
Display Image		
Validation		ESH 2010
Category	Upper arm blood pressure monitor for home blood pressure monitoring	Upper arm blood pressure monitor for home blood pressure monitoring
Casing – Item 10	<p><i>Dimensions</i> Approx.134x99x66mm</p> <p><i>Ports</i> Cuff port</p>	<p><i>Dimensions</i> Approx.166x114x72mm</p> <p><i>Ports</i> Cuff port</p>

	<p>AC adapter port</p> <p><i>Features</i></p> <p>Blood pressure measurement</p> <p>Heart rate</p>	<p>AC adapter port</p> <p><i>Features</i></p> <p>Blood pressure measurement</p> <p>Heart rate</p> <p>WHO Classification</p>
Display – Item 11	<p><i>Type</i></p> <p>LCD</p>	<p><i>Type</i></p> <p>LCD</p>
Carrying/Mounting Facilities – Item 12	no	no
Software other than Algorithm – Item 13	no	no
Memory Capacity Item 14	<p><i>Number of stored measurements</i></p> <p>120 measurements with date and time</p>	<p><i>Number of stored measurements</i></p> <p>2x60 measurements with date and time</p>
Printing Facilities Item 15	no	no
Communication Facilities – Item 16	no	no
Power Supply Item 17	no	no
Other differences	ECG measurement, PC software	N/A
Same Criteria	<p>Measurement</p> <p><i>Accuracy</i></p> <p>Pressure :±3mmHg</p> <p>Pulse rate: ±5%</p> <p><i>Method</i></p> <p>Oscillometric</p> <p><i>Ranges</i></p> <p>Cuff pressure 0-300mmHg</p> <p>Pulse 30-180 beats/min</p> <p><i>Inflation</i></p> <p>Automatic inflation by internal pump</p>	<p>Measurement</p> <p><i>Accuracy</i></p> <p>Pressure :±3mmHg</p> <p>Pulse rate: ±5%</p> <p><i>Method</i></p> <p>Oscillometric</p> <p><i>Ranges</i></p> <p>Cuff pressure 0-300mmHg</p> <p>Pulse 30-180 beats/min</p> <p><i>Inflation</i></p> <p>Automatic inflation by internal pump</p>

	<p><i>Deflation</i> Automatic speed deflation system</p> <p><i>Cuffs(Please state sizes and materials used)</i> 22-36cm PVC, Polyester</p> <p><i>Sensors</i> Semi-conductive pressure</p> <p><i>Measurement Records</i> 120 measurements with date and time</p> <p><i>Measurements other than Blood Pressure</i> Heart rate</p> <p>Buttons/Switches</p> <p><i>Power</i> Start/Stop button</p> <p><i>Measurement Records</i> Memory recall button – M button</p> <p><i>Function</i> Date and time Setting– Setting button” Start/Stop” for 3 sec</p> <p><i>Analysis</i> N/A</p> <p><i>Event Marking</i> N/A</p> <p><i>Communication</i> N/A</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i> N/A</p>	<p><i>Deflation</i> Automatic speed deflation system</p> <p><i>Cuffs(Please state sizes and materials used)</i> 22-42 cm PVC, Polyester</p> <p><i>Sensors</i> Semi-conductive pressure</p> <p><i>Measurement Records</i> 2x60 measurements with date and time</p> <p><i>Measurements other than Blood Pressure</i> Heart rate WHO Classification</p> <p>Buttons/Switches</p> <p><i>Power</i> Start/Stop button</p> <p><i>Measurement Records</i> Memory recall button – M button</p> <p><i>Function</i> Date and time setting– SET button</p> <p><i>Analysis</i> N/A</p> <p><i>Event Marking</i> N/A</p> <p><i>Communication</i> N/A</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i> N/A</p>
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	<p><i>Measurement Procedure</i> Inflation symbol Deflation symbol Heartbeat symbol during deflation</p> <p><i>Post Measurement</i> Systolic blood pressure Diastolic blood pressure Pulse rate</p> <p><i>Measurement Records</i> Memory recall number</p> <p><i>Date and Time</i> Date and Time</p> <p><i>Power</i> Low battery detection symbol</p> <p><i>Function</i> N/A</p> <p><i>Communication</i> N/A</p> <p><i>Features</i> N/A</p> <p><i>Not described</i></p> <p>Algorithms <i>Averages and Differences</i> N/A</p> <p><i>Diagnostic</i> N/A</p> <p><i>Functions</i> N/A</p>	<p><i>Measurement Procedure</i> Inflation symbol Deflation symbol Heartbeat symbol during deflation Irregular Heartbeat symbol</p> <p><i>Post Measurement</i> Systolic blood pressure Diastolic blood pressure Pulse rate WHO indicator</p> <p><i>Measurement Records</i> Memory recall number</p> <p><i>Date and Time</i> Date and Time</p> <p><i>Power</i> Low battery detection symbol</p> <p><i>Function</i> Average</p> <p><i>Communication</i> N/A</p> <p><i>Features</i> N/A</p> <p><i>Not described</i></p> <p>Algorithms <i>Averages and Differences</i> N/A</p> <p><i>Diagnostic</i> N/A</p>
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	<i>Communication</i> N/A	<i>Functions</i> N/A <i>Communication</i> N/A
Comparable Criteria		

Comments		This equivalence relates to the blood pressure measurement characteristics of both devices.
Recommendation	Recommended	
Date	21 February 2018	