

**DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE**

A SIGNED COPY WILL BE POSTED ON THE [www.dableducational.org](http://www.dableducational.org) WEBSITE

**SECTION A** - Please complete all items.

I **KI-CHUL CHA,** a Director of **InBody 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 <sup>a</sup>	InBody CO., LTD.	Address	625, Eonju-ro, Gangnam-gu, Seoul 06106 KOREA
Manufacturer <sup>b</sup>	InBody CO., LTD.	Address	625, Eonju-ro, Gangnam-gu, Seoul 06106 KOREA
Brand <sup>c</sup>	InBody	Model <sup>d</sup>	BPBIO320S

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>	InBody CO., LTD.	Address	625, Eonju-ro, Gangnam-gu, Seoul 06106 KOREA
Manufacturer <sup>b</sup>	InBody CO., LTD.	Address	625, Eonju-ro, Gangnam-gu, Seoul 06106 KOREA
Brand <sup>c</sup>	InBody	Model <sup>d</sup>	BPBIO320

Existing validated blood pressure measuring device.

which has previously passed the ESH-IP2(2010) protocol, the results of which were published as follows:  
 Anastasios Kollias, Emelina Stambolliu, Konstantinos G. Kyriakoulis, Stamatis S. Papadatos and George S. Stergiou.  
 Validation of the single-cuff oscillometric blood pressure monitor InBody BPBIO320 for public use according to the  
 2010 European Society of Hypertension International Protocol Blood Pressure Monitoring 2018, 00:000–000

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 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 checked="" type="checkbox"/>	No <input 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 checked="" type="checkbox"/>	N/A <sup>g</sup> <input type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A <sup>g</sup> <input 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.

- 9) Model name is changed to BPBIO320S from BPBIO320
10) BPBIO320S added SUB DISPLAY PORT(Communicate with the multi-display device)
13) BPBIO320S added Elbow detect sensor and Human detect sensor facilities.



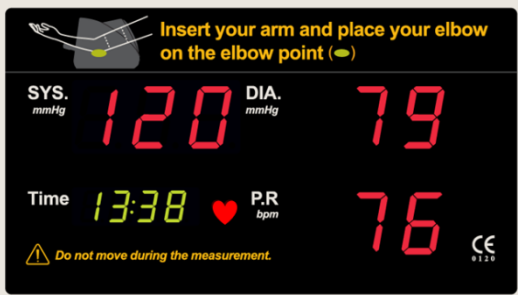
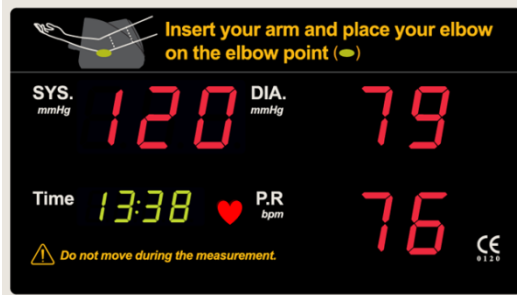
SECTION C Please check that the following are included with the application
A manual for the validated device [X]
A manual for the device for which equivalence is being sought [X]
Completed DET9 Form [X]
An image of the device for which equivalence is being sought [X]
An image of the screen layout of validated device\* [X]
An image of the screen layout of the device for which equivalence is being sought\* [X]
\* 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 [Handwritten Signature]
Name KI-CHUL CHA
Date 02/05/2019
Signature of Witness [Handwritten Signature]
Name DAE-SEOK KIM
Address 625, Eonju-ro, Gangnam-gu, Seoul 06106 KOREA

Company Stamp/Seal
InBody Co., Ltd.
625, Eonju-ro, Gangnam-gu, Seoul 06106 KOREA
TEL: (82-2)501-3939 FAX: (82-2)501-3978

Comparison of the InBody BPBIO320S with the InBody BPBIO320

Devices – Item 9	BPBIO320S	BPBIO320
Pictures		
DisplayImage		
Validation	Equivalence	ESH IP2010
Category	Blood pressure monitor	Blood pressure monitor
Casing – Item 10	<p><i>Dimensions</i> 489(W) x 409(D) x 284(H) mm</p> <p><i>Ports</i> RS-232C D-Sub terminal 2EA AC Inlet SUB DISPLAY port(Communicate with the multi-display device)</p> <p><i>Features</i> Measurement guide panel is separate. Fully automatic device. (The Cuff is built inside the device)</p>	<p><i>Dimensions</i> 489(W) x 409(D) x 284(H) mm</p> <p><i>Ports</i> RS-232C D-Sub terminal 2EA AC Inlet</p> <p><i>Features</i> Measurement guide panel is separate. Fully automatic device. (The Cuff is built inside the device)</p>

<b>Display – Item 11</b>	<i>Type</i> 3-digit display LED(7-Segment LED)	<i>Type</i> 3-digit display LED(7-Segment LED)
<b>Carrying/Mounting Facilities – Item 12</b>	Dedicated Desk	Dedicated Desk
<b>Software other than Algorithm – Item 13</b>	Voice guidance on measurement methods and results. Print the result value and Pulse graph and other information.	Voice guidance on measurement methods and results. Print the result value and Pulse graph and other information.
<b>Memory Capacity Item 14</b>	N/A	N/A
<b>Printing Facilities Item 15</b>	2.5” Thermal Printer	2.5” Thermal Printer
<b>Communication Facilities – Item 16</b>	PC connection function for data transfer via RS232 Cable	PC connection function for data transfer via RS232 Cable
<b>Power Supply Item 17</b>	Switching AC Power supply unit, 100-240V AC 50-60Hz	Switching AC Power supply unit, 100-240V AC 50-60Hz
<b>Other differences</b>	<i>Other Details on Equivalent device that are different to Validated device</i> Added the Elbow detect Sensor. Added the Human detect Sensor. Measurement Records Save the last 5 measurement results.	<i>Other Details on Validated device that are different to Equivalent device</i> N/A
<b>Same Criteria</b>	<p><b>Measurement</b></p> <p><i>Accuracy</i> Pressure: <math>\pm 2</math> mmHg Pulse: <math>\pm 1.5</math> % of reading</p> <p><i>Method</i> Oscillometric measurement method</p> <p><i>Ranges</i> Pressure: 0 - 300 mmHg Pulse: 30 - 240 beats/minute</p> <p><i>Inflation</i> Automatic inflation by air pump</p> <p><i>Deflation</i> Automatic deflation by solenoid valve</p>	<p><b>Measurement</b></p> <p><i>Accuracy</i> Pressure: <math>\pm 2</math> mmHg Pulse: <math>\pm 1.5</math> % of reading</p> <p><i>Method</i> Oscillometric measurement method</p> <p><i>Ranges</i> Pressure: 0 - 300 mmHg Pulse: 30 - 240 beats/minute</p> <p><i>Inflation</i> Automatic inflation by air pump</p> <p><i>Deflation</i> Automatic deflation by solenoid valve</p>

	<p><i>Cuffs (Please state sizes and materials used)</i>  Winding mechanism operated by geared motor  Bladder size: 125(w) x 310(L) mm  Applicable arm circumference  :7 inches(18.0 cm) to 16.5 inches(42.0 cm)</p> <p><i>Sensors</i>  Pressure sensor: Gauge type pressure transducer</p> <p><i>Measurements other than Blood Pressure</i>  PULSE( = Heart rate)</p> <p><b>Buttons/Switches</b>  <i>Power</i>  ON/OFF Power Switch</p> <p><i>Measurement Records</i>  Start/Stop  Print</p> <p><i>Function</i>  [▲]button: used to change function  [▼]button: used to change function  Emergency stop: All function are stopped</p> <p><i>Analysis</i>  N/A</p> <p><i>Event Marking</i>  N/A</p> <p><i>Communication</i>  N/A</p> <p><b>Display/Symbols/Indicators</b>  <i>Preparation</i>  “0” lighting</p>	<p><i>Cuffs(Please state sizes and materials used)</i>  Winding mechanism operated by geared motor  Bladder size: 125(w) x 310(L) mm  Applicable arm circumference  :7 inches(18.0 cm) to 16.5 inches(42.0 cm)</p> <p><i>Sensors</i>  Pressure sensor: Gauge type pressure transducer</p> <p><i>Measurements other than Blood Pressure</i>  PULSE( = Heart rate)</p> <p><b>Buttons/Switches</b>  <i>Power</i>  ON/OFF Power Switch</p> <p><i>Measurement Records</i>  Start/Stop  Print</p> <p><i>Function</i>  [▲]button: used to change function  [▼]button: used to change function  Emergency stop: All function are stopped</p> <p><i>Analysis</i>  N/A</p> <p><i>Event Marking</i>  N/A</p> <p><i>Communication</i>  N/A</p> <p><b>Display/Symbols/Indicators</b>  <i>Preparation</i>  “0” lighting</p>
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	<p><i>Measurement Procedure</i>                  Display the pressure value during measurement.                  The Heart LED twinkle synchronized to the Heartbeat.</p> <p><i>Post Measurement</i>                  Systolic blood pressure(SYS)                  Diastolic blood pressure(DIA)                  Pulse(P.R)</p> <p><i>Measurement Records</i>                  Systolic blood pressure(SYS)                  Diastolic blood pressure(DIA)                  Pulse(P.R)</p> <p><i>Date and Time</i>                  Display Time                  Print date and time</p> <p><i>Power</i>                  N/A</p> <p><i>Function</i>                  N/A</p> <p><i>Communication</i>                  N/A</p> <p><i>Not described</i>                  N/A</p> <p><b>Algorithms</b>  <i>Averages and Differences</i>                  N/A</p> <p><i>Diagnostic</i>                  N/A  <i>Communication</i>                  N/A</p>	<p><i>Measurement Procedure</i>                  Display the pressure value during measurement.                  The Heart LED twinkle synchronized to the Heartbeat.</p> <p><i>Post Measurement</i>                  Systolic blood pressure(SYS)                  Diastolic blood pressure(DIA)                  Pulse(P.R)</p> <p><i>Measurement Records</i>                  Systolic blood pressure(SYS)                  Diastolic blood pressure(DIA)                  Pulse(P.R)</p> <p><i>Date and Time</i>                  Display Time                  Print date and time</p> <p><i>Power</i>                  N/A</p> <p><i>Function</i>                  N/A</p> <p><i>Communication</i>                  N/A</p> <p><i>Not described</i>                  N/A</p> <p><b>Algorithms</b>  <i>Averages and Differences</i>                  N/A</p> <p><i>Diagnostic</i>                  N/A  <i>Communication</i>                  N/A</p>
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<p><b>Comparable Criteria</b></p>	<p><b>Measurement</b>  <i>Measurements other than Blood Pressure</i>                  MAP( = DIA + (SYS-DIA)/3 )                  PP( = SYS - DIA )                  RPP( = SYS x PULSE )  <i>Measurement Records</i>                  Save the last 5 measurement results.</p> <p><b>Algorithms</b>  <i>Functions</i>                  Motion Sensor to Automatically switch from sleep to standby mode.                  Detect the elbow(sensor) for correct examination posture.</p>	
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**Office use only.**

<p><b>Comments</b></p>	
<p><b>Recommendation</b></p>	<p><b>Recommended</b></p>
<p><b>Date</b></p>	<p><b>21 May 2019</b></p>