

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE

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

SECTION A - Please complete all items.

I **KI-CHUL CHA,**
Name of a Company Director

a Director of **InBody Co., LTD. ,,**
Company name

hereby state that there are no differences that will affect blood pressure measuring accuracy between the

Maker^a InBody CO., LTD. **Address** 625, Eonju-ro, Gangnam-gu, Seoul 06106 KOREA
Manufacturer^b InBody CO., LTD. **Address** 625, Eonju-ro, Gangnam-gu, Seoul 06106 KOREA
Brand^c InBody **Model^d** BPBIO330N

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 InBody CO., LTD. **Address** 625, Eonju-ro, Gangnam-gu, Seoul 06106 KOREA
Manufacturer^b InBody CO., LTD. **Address** 625, Eonju-ro, Gangnam-gu, Seoul 06106 KOREA
Brand^c InBody **Model^d** BPBIO320

Existing validated blood pressure measuring device.

which has previously passed the ESH-IP2 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 Societ

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

- 9) Model name is changed to BPBIO330N from BPBIO320.
- 10) BPBIO330N added SUB DISPLAY PORT(Communicate with the multi-display device)
- 15) BPBIO330N has not print facility
- 16) BPBIO330N provide blood pressure management PC program(Hard copy)

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
- Completed DET9 Form
- 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 *Ki-Chul Cha* ✓ Company Stamp/Seal

Name KI-CHUL CHA



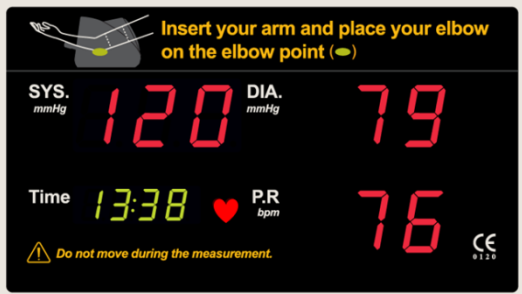
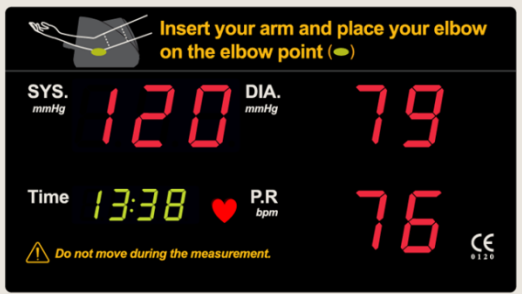
Date 04/14/2020

Signature of Witness *DAE-SEOK KIM*

Name DAE-SEOK KIM

Address 625, Eonju-ro, Gangnam-gu, Seoul 06106 KOREA


Comparison of the BPBIO330N with the BPBIO320

Devices – Item 9	InBody BPBIO330N	InBody BPBIO320
Pictures		
Display Image		
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 AC Inlet</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 AC Inlet</p> <p><i>Features</i> Measurement guide panel is separate. Fully automatic device. (The Cuff is built inside the device)</p>

Display – Item 11	<i>Type</i> 3-digit display LED(7-Segment LED)	<i>Type</i> 3-digit display LED(7-Segment LED)
Carrying/Mounting Facilities – Item 12	Dedicated Desk	Dedicated Desk
Software other than Algorithm – Item 13	Voice guidance on measurement methods and results.	Voice guidance on measurement methods and results. Print the result value and Pulse graph and other information.
Memory Capacity Item 14	<i>Number of stored measurements</i> Save the last measurement counters (MAX 999,999) Save the last 5 measurement results	<i>Number of stored measurements</i> Save the last measurement counters (MAX 999,999)
Printing Facilities Item 15	N/A	2.5” Thermal Printer
Communication Facilities – Item 16	PC connection function for data transfer via RS232 Cable	PC connection function for data transfer via RS232 Cable
Power Supply Item 17	Switching AC Power supply unit, 100-240V AC 50-60Hz	Switching AC Power supply unit, 100-240V AC 50-60Hz
Other differences	<i>Other Details on Equivalent device that are different to Validated device</i> Measurement Records Save the last 5 measurement results. Program Provide blood pressure management Program.	<i>Other Details on Validated device that are different to Equivalent device</i> Print function
Same Criteria	Measurement <i>Accuracy</i> Pressure: ± 2 mmHg Pulse: ± 1.5 % of reading <i>Method</i> Oscillometric measurement method <i>Ranges</i> Pressure: 0 - 300 mmHg Pulse: 30 - 240 beats/minute <i>Inflation</i> Automatic inflation by air pump	Measurement <i>Accuracy</i> Pressure: ± 2 mmHg Pulse: ± 1.5 % of reading <i>Method</i> Oscillometric measurement method <i>Ranges</i> Pressure: 0 - 300 mmHg Pulse: 30 - 240 beats/minute <i>Inflation</i> Automatic inflation by air pump

<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>Measurement Records</i> Last Measurement</p> <p><i>Measurements other than Blood Pressure</i> PULSE(= Heart rate)</p> <p>Buttons/Switches <i>Power</i> ON/OFF Power Switch</p> <p><i>Measurement Records</i> Start/Stop</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>Display/Symbols/Indicators</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>Measurement Records</i> Last Measurement</p> <p><i>Measurements other than Blood Pressure</i> PULSE(= Heart rate)</p> <p>Buttons/Switches <i>Power</i> ON/OFF Power Switch</p> <p><i>Measurement Records</i> Start/Stop</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>Display/Symbols/Indicators</p>
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	<p><i>Preparation</i> "0" lighting</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</p> <p><i>Power</i> N/A</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> N/A</p> <p>Algorithms <i>Averages and Differences</i> N/A</p>	<p><i>Preparation</i> "0" lighting</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 data 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>Features</i> N/A</p> <p><i>Not described</i> N/A</p> <p>Algorithms <i>Averages and Differences</i> N/A</p>
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	<p><i>Diagnostic</i> N/A</p> <p><i>Functions</i> N/A</p> <p><i>Communication</i> N/A</p>	<p><i>Diagnostic</i> N/A</p> <p><i>Functions</i> N/A</p> <p><i>Communication</i> N/A</p>
Comparable Criteria	<p>Measurement <i>Button/Switch</i></p> <p>Press the  button to display the last measurement on the display unit.</p> <p><i>Measurements other than Blood Pressure</i> $MAP(= DIA + (SYS-DIA)/3)$ $PP(= SYS - DIA)$ $RPP(= SYS \times PULSE)$</p> <p><i>Measurement Records</i> Save the last 5 measurement results.</p> <p>Algorithms <i>Communication</i> Communication with the blood pressure management program. Measurement time, minute, day, month, year, SYS, DIA, PR Transport Protocol.</p>	<p>Printing function</p> <p>Press the Print button to print the result.</p>

Comments	
Recommendation	Recommended
Date	June 2020