

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, 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^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 HBP170

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 BP170

Existing validated blood pressure measuring device.

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

Validation of the InBody BP170 oscillometric upper-arm home blood pressure monitor in general population according to AAMI/ESH/ISO Universal Standard (ISO 81060-2:2018)

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 type="checkbox"/>	No <input checked="" 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 type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input checked="" 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 HBP170 from BP170.

16) HBP170 has Bluetooth facility.

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@dablededucational.org.

Signature of Director 

Company Stamp/Seal

Name KI-CHUL CHA





Date 04/14/2020

Signature of Witness 

Name DAE-SEOK KIM

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

Comparison of the InBody HBP170 with the InBody BP170

Devices – Item 9	InBody HBP170	InBody BP170
Pictures		
Display Image		
Validation	Equivalence	AAMI/ESH/ISO Protocol, 2018
Category	Blood pressure monitor	Blood pressure monitor
Casing – Item 10	<p><i>Dimensions</i> 99(W) x 191(H) x 26(L) mm</p> <p><i>Ports</i> AC adaptor connection Cuff connection</p> <p><i>Features</i> The Cuff is separated (The Cuff must connect Main Body)</p>	<p><i>Dimensions</i> 99(W) x 191(H) x 26(L) mm</p> <p><i>Ports</i> AC adaptor connection Cuff connection</p> <p><i>Features</i> The Cuff is separated (The Cuff must connect Main Body)</p>
Display – Item 11	<i>Type</i>	<i>Type</i>

Carrying/Mounting Facilities – Item 12	Custom LCD	Custom LCD
Software other than Algorithm – Item 13	N/A	N/A
Memory Capacity Item 14	<i>Number of stored measurements</i> M1 and M2 can each store up to 100 measurement values.	<i>Number of stored measurements</i> M1 and M2 can each store up to 100 measurement values.
Printing Facilities Item 15	N/A	N/A
Communication Facilities – Item 16	<i>Bluetooth Function</i>	N/A
Power Supply Item 17	Switching AC Power supply unit, Input : 100-240V AC 50-60Hz Output : DC 6V	Switching AC Power supply unit, Input : 100-240V AC 50-60Hz Output : DC 6V
Other differences	<i>Other Details on Equivalent device that are different to Validated device</i> <i>Bluetooth Function</i>	<i>Other Details on Validated device that are different to Equivalent device</i> N/A
Same Criteria	<p>Measurement</p> <p><i>Accuracy</i> Pressure: ±3 mmHg Pulse: ±3 % 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> M-size cuff Applicable arm circumference :22.0 cm to 32.0 cm</p>	<p>Measurement</p> <p><i>Accuracy</i> Pressure: ±3 mmHg Pulse: ±3 % 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> M-size cuff Applicable arm circumference :22.0 cm to 32.0 cm</p>

	<p>L-size cuff Applicable arm circumference :32.0 cm to 42.0 cm</p> <p><i>Sensors</i> Pressure sensor: Gauge type pressure transducer</p> <p><i>Measurement Records</i> Memory Capacitor M1 and M2 can each store up to 100 measurement values.</p> <p><i>Measurements other than Blood Pressure</i> PULSE(= Heart rate)</p> <p>Buttons/Switches</p> <p><i>Power</i> Start/Stop</p> <p><i>Measurement Records</i> [M1]button: Enter the memory mode 1 [M2]button: Enter the memory mode 2</p> <p><i>Function</i> [▲]button: used to change function [▼]button: used to change function</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> “0” lighting</p>	<p>L-size cuff Applicable arm circumference :32.0 cm to 42.0 cm</p> <p><i>Sensors</i> Pressure sensor: Gauge type pressure transducer</p> <p><i>Measurement Records</i> Memory Capacitor M1 and M2 can each store up to 100 measurement values.</p> <p><i>Measurements other than Blood Pressure</i> PULSE(= Heart rate)</p> <p>Buttons/Switches</p> <p><i>Power</i> Start/Stop</p> <p><i>Measurement Records</i> [M1]button: Enter the memory mode 1 [M2]button: Enter the memory mode 2</p> <p><i>Function</i> [▲]button: used to change function [▼]button: used to change function</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> “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 Date and Time</p> <p><i>Power</i> Display AC Adapter Icon while connect the AC Adapter Display Remaining battery indicator</p> <p><i>Function</i> Display Mute Icon Display Storing location Icon(M1/M2) Display Average Blood pressure Icon when show the average blood pressure for the last three times Display Manual Pressurization Icon if user adjust pressurization Display Morning Surge Hypertension Icon if user has high blood pressure in the morning Display Irregular heartbeat detection Icon Display Motion detection Icon if detected motion during the measurement Display Faulty in cuff worn state Icon or Normal in cuff worn state</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 Date and Time</p> <p><i>Power</i> Display AC Adapter Icon during connect the AC Adapter Display Remaining battery indicator</p> <p><i>Function</i> Display Mute Icon Display Storing location Icon(M1/M2) Display Average Blood pressure Icon when show the average blood pressure for the last three times Display Manual Pressurization Icon if user adjust pressurization Display Morning Surge Hypertension Icon if user has high blood pressure in the morning Display Irregular heartbeat detection Icon Display Motion detection Icon if detected motion during the measurement Display Faulty in cuff worn state Icon or Normal in cuff worn state</p>
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	<p>Icon</p> <p><i>Communication</i> Display Bluetooth Icon while connect the Bluetooth</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>Diagnostic</i> N/A</p> <p><i>Functions</i> N/A</p> <p><i>Communication</i> N/A</p>	<p>Icon</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>Diagnostic</i> N/A</p> <p><i>Functions</i> N/A</p> <p><i>Communication</i> N/A</p>
Comparable Criteria		

Comments	
Recommendation	Recommended
Date	June 2020