

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 **KOROT 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 **KOROT Co.,LTD.** Address **54, Nonhyeon-ro 2-gil, Gangnam-gu, Seoul, 06106, KOREA**
 Manufacturer^b **KOROT Co.,LTD** Address **54, Nonhyeon-ro 2-gil, Gangnam-gu, Seoul, 06106, KOREA**
 Brand^c **KOROT Co.** Model^d **KOROT V1**

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 **AAMI/ESH/ISO 81060-2:2018** protocol, the results of which were published as follows:

Validation of the InBody BP170 oscillometric home blood pressure monitor in general population according to the Association for the Advancement of Medical Instrumentation/European Society of Hypertension/ International Organization for Standardization

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 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 ^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) The model name is different. KOROT V1 for new device and validated device is InBody BP170.
10) The Arrow Buttons and the M1/M2 buttons have been replaced with the User button and the M Button.
11) The size of the display and the layout of each component have been changed.
13) A function has been added to display the most recently measured value together.
14) Memory capacity is 120 times x 2 way instead of 100 times x 2 way.
16) KOROT V1 has Bluetooth facility.

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.



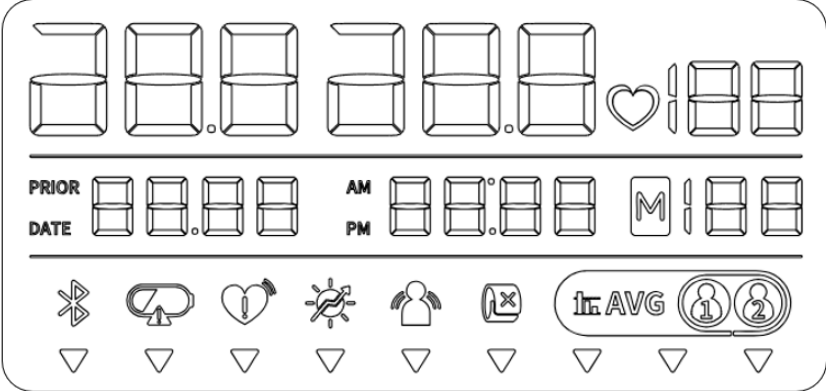
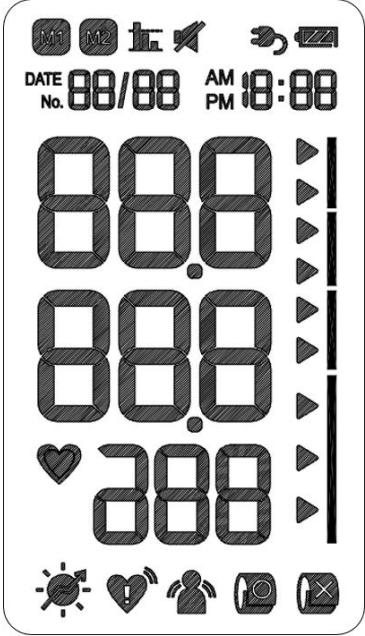
SECTION D Complete all items, bar signatures and seal, online and print. Sign and seal it then send the original to our address below. Please email a signed copy of this form, together with the manuals and images for both devices, to info@dableducational.org.

Signature of Director _____
Name KI-CHUL CHA
Date 2025/01/23
Signature of Witness _____
Name DAE-SEOK KIM
Address 54, Nonhyeon-ro 2-gil, Gangnam-gu, Seoul, 06106, KOREA

Company Stamp/Seal
KOROT Co.,Ltd.
Ki Chul Cha
President, Ki Chul Cha

KOROT Co.,Ltd.
54, Nonhyeon-ro 2-gil, Gangnam-gu,
Seoul, 06313 Republic of Korea

Comparison of the KOROT V1 with the InBody BP170

Devices – Item 9	KOROT V1	InBody BP170
Pictures		
Display Image		
Validation	Equivalence	AAMI/ESH/ISO Protocol, 81060-2: 2018

Category	Blood pressure monitor	Blood pressure monitor
Casing – Item 10	<p><i>Dimensions</i> 66(W) x 50(H) x 190(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 with backlight	Custom LCD
Software other than Algorithm – Item 13	N/A	N/A
Memory Capacity Item 14	<p><i>Number of stored measurements</i> M1 and M2 can each store up to 120 measurement values.</p>	<p><i>Number of stored measurements</i> M1 and M2 can each store up to 100 measurement values.</p>
Printing Facilities Item 15	N/A	N/A
Communication Facilities – Item 16	<i>Bluetooth Function</i>	N/A
Power Supply Item 17	4 “AAA” Batteries, AC adapter (Optional, DC 5V_2A)	4 “AA” Batteries, AC adapter (Optional, DC 6V_2A)
Other differences	<p><i>Other Details on Equivalent device that are different to Validated device</i> <i>Bluetooth Function</i></p>	<p><i>Other Details on Validated device that are different to Equivalent device</i> N/A</p>
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>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</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 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>Measurements other than Blood Pressure</i> PULSE(= Heart rate)</p> <p>Buttons/Switches <i>Power</i> Start/Stop</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 <i>Preparation</i> “0” lighting</p> <p><i>Measurement Procedure</i> Display the pressure value during measurement.</p>	<p><i>Ranges</i> Pressure: 0 - 300 mmHg</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 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>Measurements other than Blood Pressure</i> PULSE(= Heart rate)</p> <p>Buttons/Switches <i>Power</i> Start/Stop</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 <i>Preparation</i> “0” lighting</p> <p><i>Measurement Procedure</i> Display the pressure value during measurement.</p>
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	<p>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 Remaining battery indicator</p> <p><i>Function</i> Display Storing location Icon(M1/M2) Display Average Blood pressure Icon when show the average blood pressure for the last three times 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</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>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 Remaining battery indicator</p> <p><i>Function</i> Display Storing location Icon(M1/M2) Display Average Blood pressure Icon when show the average blood pressure for the last three times 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</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>Ranges</i> Pulse: 30 - 199 beats/minute</p> <p><i>Measurement Records</i> Memory Capacitor M1 and M2 can each store up to 120 measurement values.</p> <p>Buttons/Switches <i>Measurement Records</i> [M]button: Enter the memory mode 1 or 2</p> <p><i>Function</i> [Person]button: used to change function [M]button: used to change function</p> <p>Display/Symbols/Indicators <i>Communication</i> Display Bluetooth Icon while connect the Bluetooth</p>	<p>Measurement <i>Ranges</i> Pulse: 30 - 240 beats/minute</p> <p><i>Measurement Records</i> Memory Capacitor M1 and M2 can each store up to 100 measurement values.</p> <p>Buttons/Switches <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>Display/Symbols/Indicators <i>Communication</i> N/A</p>

Comments	
Recommendation	RECOMMENDED
Date	February 2026