dabl®Educational Trust

Declaration of Equivalence Form

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]	InBody Co., LTD.	*Address*	625, Eonju-ro, Gangnam-gu, Seoul, Republic of Korea
Manufacturer[b]	InBody Co., LTD.	*Address*	625, Eonju-ro, Gangnam-gu, Seoul, Republic of Korea
Brand[c]	InBody Co., LTD.	Model[d]	InBody BPBIO480KV

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]	KOROT Co., LTD	*Address*	5F, 54, Nonhyeon-ro 2-gil, Gangnam-gu, Seoul, Republic of Korea
Manufacturer[b]	KOROT Co., LTD	*Address*	5F, 54, Nonhyeon-ro 2-gil, Gangnam-gu, Seoul, Republic of Korea
Brand[c]	KOROT Co., LTD	Model[d]	KOROT P3 Accurate

Existing validated blood pressure measuring device.

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

Ntineri, A., Theodosiadi, A., Menti, A., Kyriakoulis, K. G., Ntousopoulos, V., Kollias, A., & Stergiou, G. S. (2023). A novel professional automated auscultatory blood pressure monitor with visual display of Korotkoff sounds: InBody BPBIO480KV

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 ☐	No ☒	N/A[e] ☐
	2	Algorithm for Auscultatory Measurements	Yes ☐	No ☒	N/A[f] ☐
	3	Artefact/Error Detection	Yes ☐	No ☒	
	4	Microphone(s)	Yes ☐	No ☒	N/A[f] ☐
	5	Pressure Transducer	Yes ☐	No ☒	
	6	Cuffs or Bladders	Yes ☐	No ☒	
	7	Inflation Mechanism	Yes ☐	No ☒	
	8	Deflation Mechanism	Yes ☐	No ☒	
Part II	9	Model Name or Number	Yes ☒	No ☐	
	10	Casing	Yes ☐	No ☒	
	11	Display	Yes ☒	No ☐	
	12	Carrying/Mounting Facilities	Yes ☐	No ☒	
	13	Software other than Algorithm	Yes ☒	No ☐	
	14	Memory Capacity/Number of stored measurements	Yes ☒	No ☐	
	15	Printing Facilities	Yes ☒	No ☐	N/A[g] ☐
	16	Communication Facilities	Yes ☒	No ☐	N/A[g] ☐
	17	Power Supply	Yes ☐	No ☒	
	18	Other Facilities	Yes ☐	No ☒	N/A[g] ☐

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.

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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.

KOROT is a subsidiary company of InBody, therefore, the model name has been changed accordingly.

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 _____

Name KI-CHULA CHA

Date 2023/08/04

Signature of Witness _____

Name JONGHEUN SHIN

Address 5F, 54, Nonhyeon-ro 2-gil, Gangnam-gu, Seoul, Republic of Korea

Company Stamp/Seal

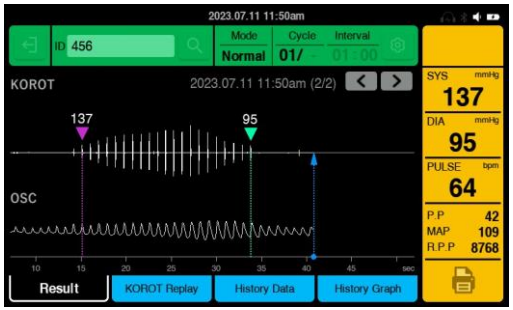
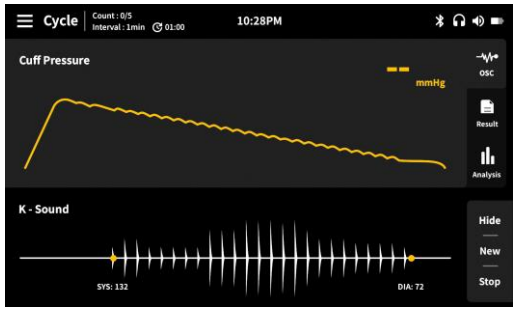
KOROT Co.,Ltd.

President, Ki Chul Cha

KOROT Co.,Ltd.

54, Nonhyeon-ro 2-gil, Gangnam-gu,
Seoul, 06313 Republic of Korea

Comparison of the KOROT P3 Accurate with the InBody BPBIO480KV

Devices – Item 9	KOROT P3 Accurate	InBody BPBIO480KV
Pictures		
Display Image		
Validation	Equivalence	AAMI/ISO/ESH Universal protocol (ISO 81060-2:2018)
Category	Blood pressure monitor	Blood pressure monitor
Casing – Item 10	*Dimensions* Same *Ports* Same *Features* Same	*Dimensions* 200(W) x 180(D) x 210(H) mm *Ports* - USB port - Audio port - AC Inlet *Features* - The cuff is connected to the main body and can be separated. - The MIC (KOROT sensor) attached to the cuff detects Korotkoff sound and displays the Korotkoff sound graph
Display – Item 11	*Type*	*Type*

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	Same	7 inch TFT LCD
Carrying/Mounting Facilities – Item 12	Same	Has handle on the top
Software other than Algorithm – Item 13	- Shows Korotkoff sound graph and Oscillometirc graph while measuring - Detects irregular pulse wave, movement while measuring, incorrect cuff wearing, ambient noise and artrial fibrillation - Can send the result data including graphs, SYS, DIA, Pulse, PP, MAP, RPP, etc. to the KOROT printing program	- Shows Korotkoff sound graph and Oscillometirc graph while measuring - Detects irregular pulse wave, movement while measuring and incorrect cuff wearing
Memory Capacity Item 14	*Number of stored measurements* 10,000 results	*Number of stored measurements* 1,000 results
Printing Facilities Item 15	Can be connected to the KOROT printing program in the PC or tablet via Bluetooth and print the result sheet	N/A
Communication Facilities – Item 16	- USB A-type Port - Bluetooth 5.0	USB A-type Port
Power Supply Item 17	Same	- Rechargeable Li-ion battery - AC adaptor: 100-240 V~, 50-60 Hz
Other differences	*Other Details on Equivalent device that are different to Validated device* GUI design, requires password to enter the menu, proper pressurization function, etc.	*Other Details on Validated device that are different to Equivalent device* N/A
Same Criteria	***Measurement*** *Accuracy* Same *Method* Same *Ranges* Same *Inflation* Same	***Measurement*** *Accuracy* - Pressure: ±3 mmHg - Pulse: ±2 % of reading *Method* Auto auscultation + Oscillometric *Ranges* - Pressure: 0 - 300 mmHg - Pulse: 30 - 240 beats/minute *Inflation* Automatic inflation by air pump

	Deflation Same *Cuffs (Please state sizes and materials used)* Same *Sensors* Same *Measurements other than Blood Pressure* Same ***Buttons/Switches*** *Power* Same *Function* Same *Analysis* N/A *Event Marking* N/A	*Deflation* Automatic deflation by solenoid valve *Cuffs(Please state sizes and materials used)* - M-size cuff: 22.0 cm to 32.0 cm - L-size cuff: 32.0 cm to 42.0 cm - Cuff-1: 23 cm to 28.0 cm - Cuff-2: 28.0 cm to 35.0 cm - Cuff-3: 33.0 cm to 42.0 cm *Sensors* - Pressure sensor: gauge type pressure transducer - MIC (KOROT sensor): microphone which detects Korotkoff sound *Measurements other than Blood Pressure* - Pulse rate (PUL) - Pulse Pressure (PP) - Mean Arterial Pressure (MAP) - Rate Pressure Product (RPP) ***Buttons/Switches*** *Power* - Short press of Start/Stop button: Start measuring - Short press of Start/Stop button while measuring: Stop measuring - Pressing Start/Stop button for 5 seconds: Turning on or off *Function* Wheel button for volume control *Analysis* N/A *Event Marking* N/A

	Communication N/A ***Display/Symbols/Indicators*** *Preparation* Same *Measurement Procedure* Same *Post Measurement* Same *Measurement Records* Same *Date and Time* Same *Power* N/A *Features* N/A	*Communication* N/A ***Display/Symbols/Indicators*** *Preparation* Turns off after 60 seconds (Keep power on when adaptor is connected) *Measurement Procedure* Displays pressure, Korotkoff sound graph and Oscillometric graph *Post Measurement* - Systolic blood pressure (SYS) - Diastolic blood pressure (DIA) - Pulse rate (PUL) - Pulse Pressure (PP) - Mean Arterial Pressure (MAP) - Rate Pressure Product (RPP) *Measurement Records* - Systolic blood pressure (SYS) - Diastolic blood pressure (DIA) - Pulse rate (PUL) - Pulse Pressure (PP) - Mean Arterial Pressure (MAP) - Rate Pressure Product (RPP) - measured Korotkoff sound graph - measured Oscillometric graph *Date and Time* Displays date and time *Power* N/A *Features* N/A

	Not described N/A ***Algorithms*** *Averages and Differences* Same *Diagnostic* N/A *Functions* N/A *Communication* N/A	*Not described* N/A ***Algorithms*** *Averages and Differences* Auto auscultation + Oscillometric *Diagnostic* N/A *Functions* N/A *Communication* N/A
Comparable Criteria	***Measurement*** *Measurement Records* - The result data is saved and sorted by patient ID - Without the patient ID, the data is saved to the guest section ***Buttons/Switches*** *Measurement Records* Touch screen: - The result data is saved and sorted by patient ID - Without the patient ID, the data is saved to the guest section ***Display/Symbols/Indicators*** *Function* Other symbols (irregular pulse wave, movement while measuring, incorrect cuff wearing, ambient noise and artrial fibrillation) *Communication* Bluetooth symbol ***Algorithms*** *Functions* N/A	***Measurement*** *Measurement Records* The result data is saved and sorted by the date and time ***Buttons/Switches*** *Measurement Records* Touch screen: - The result data is saved and sorted by the date and time ***Display/Symbols/Indicators*** *Function* Other symbols (irregular pulse wave, movement while measuring, incorrect cuff wearing) *Communication* N/A ***Algorithms*** *Functions* N/A

Comments		
Recommendation	**Recommended**	
Date	September 2023	