

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.

hereby state that there are no differences that will affect blood pressure measuring accuracy between the Victiman Co., LTD Manufacture	I Andre van Gils, Name of a Company Director					a Director of Omron Healthcare Europe B.V.,				
Name	hereby stat	hereby state that there are no differences that will affect blood pressure measuring accuracy between the								
Brand's Omron	Makera			Man.	Address	Binh Duong Province, \	/ietnam			
Brand* Omron Model* X3 Comfort (HEM-7155-EC) 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* Omron Healthcare Man. Address Binh Duong Province, Vietnam Vietnam Co., LTD Manufacturer* Omron Healthcare Co., Ltd. Address Sinh Duong Province, Vietnam Vietnam Co., LTD Manufacturer* Omron Healthcare Co., Ltd. Address Sinh Duong Province, Vietnam Vietnam Co., LTD Manufacturer* Omron Healthcare Co., Ltd. Address Sinh Duong Province, Vietnam Vietnam Co., LTD Manufacturer* Omron Healthcare Co., Ltd. Address Sinh Duong Province, Vietnam Vietnam Vietnam Vietnam Co., LTD Manufacturer* Omron Healthcare Co., Ltd. Address Sinh Duong Province, Vietnam	Manufacturer ^b	Omro	n Healthcare Co., L	td.	Address	53, Kunotsubo, Terado	-cho, Muko, k	(YOTO, 617-0	002 Japan	
blood pressure measuring device and the validated blood pressure measuring device Maker* Omron Healthcare Man. Address Binh Duong Province, Vietnam Vietnam Co., LTD Manufacture* Omron Healthcare Co., Ltd. Address 53, Kunotsubo, Terado-cho, Muko, KYOTO, 617-0002 Japan Brand* Omron Model* M6 Comfort (HEM-7321-E) Eisting validated blood pressure measuring device. which has previously passed the ESH 2010 protocol, the results of which were published as follows: dablEducational Trust; 2014 Jan 22. 4 p. Available from: ESH-IP 2010 Validation of Omron M6 Comfort (HEM-7321-E), pdf 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 No N/A* Arefact/Error Detection Yes No No N/A* On N/A* Arefact/Error Detection Yes No No No N/A* On						X3 Comfort (HEM-7155	5-EO)			
Maker* Omron Healthcare Man. Address Binh Duong Province, Vietnam Vietnam Co., LTD Manufacture* Omron Healthcare Co., Ltd. Address 53, Kunotsubo, Terado-cho, Muko, KYOTO, 617-0002 Japan Brand* Omron Model* M6 Comfort (HEM-7321-E) Easting validated blood pressure measuring device. which has previously passed the ESH 2010 protocol, the results of which were published as follows: dablEducational Trust; 2014 Jan 22. 4 p. Available from: ESH-IP 2010 Validation of Omron M6 Comfort (HEM-7321-E), pdf Full reference The only differences between the devices involve the following components: Tick one box for each frem 1-18. Part I 1 Algorithm for Oscillometric Measurements Yes No No N/A* N/A* Artefact/Error Detection Yes No No N/A* Artefact/Error Detection Yes No No N/A* Artefact/Error Detection Yes No No N/A* Artefact/Error Bladders Yes No No No N/A* For Inflation Mechanism Yes No										
Nanufacture* Vietnam Co., LTD Manufacture* Omron Healthcare Co., Ltd. Address 53, Kunotsubo, Terado-cho, Muko, KYOTO, 617-0002 Japan Brand* Omron Model* M6 Comfort (HEM-7321-E) Existing validated blood pressure measuring device. which has previously passed the ESH 2010 protocol, the results of which were published as follows: dablEducational Trust; 2014 Jan 22. 4 p. Available from: ESH-IP 2010 Validation of Omron M6 Comfort (HEM-7321-E).pdf 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 No N/A* Salary No No No N/A* Salary No No No No Salary No No No Salary No No No Salary No No Salary No Sa		sure me	asuring device and	the vali	dated bl	ood pressure measuring	device			
Brand* Omro Model* M6 Comfort (HEM-7321-E) Existing validated blood pressure measuring device. which has previously passed the ESH 2010 protocol, the results of which were published as follows: dablEducational Trust; 2014 Jan 22. 4 p. Available from: ESH-IP 2010 Validation of Omron M6 Comfort (HEM-7321-E).pdf 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 No N/A* 2 Algorithm for Auscultatory Measurements Yes No No N/A* 3 Artefact/Error Detection Yes No No N/A* 4 Microphone(s) Yes No No N/A* 5 Pressure Transducer Yes No No No N/A* 7 Inflation Mechanism Yes No	Maker ^a		on meantifeare wan.		Address	Binh Duong Province, Vietnam				
Existing validated blood pressure measuring device. which has previously passed the ESH 2010 protocol, the results of which were published as follows: dablEducational Trust; 2014 Jan 22. 4 p. Available from: ESH-IP 2010 Validation of Omron M6 Comfort (HEM-7321-E).pdf Full references 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/A¹ Algorithm for Auscultatory Measurements Yes No N/A¹ Algorithm Yes No	Manufacturer ^b	Omroi	on Healthcare Co., Ltd. Address 53, Kunotsubo, Terado-cho, Muko, KYOTO, 617-0002 J			002 Japan				
dablEducational Trust; 2014 Jan 22. 4 p. Available from: ESH-IP 2010 Validation of Omron M6 Comfort (HEM-7321-E).pdf Full reference The only differences between the devices involve the following components: Tick one box for each item 1–18. Part I					Model ^d	M6 Comfort (HEM-732	1-E)			
E).pdf Full references The only differences between the devices involve the following components: Tick one box for each item 1–18. Part I	which has p	revious	ly passed the ESH	2010 pr	rotocol,	the results of which wer	e published as	follows:		
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 ⋈ 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 ⋈ N/A ^g ⋈	Full reference The only differences between the devices involve the following components:									
2 Algorithm for Auscultatory Measurements Yes \ No \ N/A^f \ 3 3 Artefact/Error Detection Yes \ No \ NO \ N/A^f \ 4 4 Microphone(s) Yes \ No \ NO \ N/A^f \ 5 5 Pressure Transducer Yes \ NO \ NO \ 7 6 Cuffs or Bladders Yes \ NO \ 7 8 Deflation Mechanism Yes \ NO \ 8 9 Deflation Mechanism Yes \ NO \ NO \ 7 10 Casing Yes \ NO \ NO \ 10 11 Display Yes \ NO \ NO \ 11 12 Carrying/Mounting Facilities Yes \ NO \ 13 3 Software other than Algorithm Yes \ NO \ NO \ 15 14 Memory Capacity/Number of stored measurements Yes \ NO \ NO \ N/A^g \ 16 16 Communication Facilities Yes \ NO \ NO \ N/A^g \ 17 17 Power Supply Yes \ NO \ NO \ N/A^g \ 17 18				rillomet	ric Meas	surements	Yes 🖂	No 🖂	N/Ae 🖂	
Artefact/Error Detection Microphone(s) Pressure Transducer Cuffs or Bladders Inflation Mechanism Deflation Mechanism Part II 9 Model Name or Number Casing Carrying/Mounting Facilities Software other than Algorithm Memory Capacity/Number of stored measurements Perul Memory Capacities Yes No No No NA® No No NA® No No NA® No No NA® NA® No No NA® NA® No No NA® NA® No NA® No NA® No NA® NA® NA® No NA®			1771						-	
4 Microphone(s) 5 Pressure Transducer 6 Cuffs or Bladders 7 Inflation Mechanism 8 Deflation Mechanism Yes No No Part II 9 Model Name or Number 10 Casing 11 Display 12 Carrying/Mounting Facilities 13 Software other than Algorithm 14 Memory Capacity/Number of stored measurements 15 Printing Facilities Yes No No N/Ag No			-		,				.,	
5 Pressure Transducer 6 Cuffs or Bladders 7 Inflation Mechanism 8 Deflation Mechanism 9 Model Name or Number 10 Casing 11 Display 12 Carrying/Mounting Facilities 13 Software other than Algorithm 14 Memory Capacity/Number of stored measurements 15 Printing Facilities 16 Communication Facilities 17 Power Supply 18 No □ 19 No □ 10 N/Ag □ 10 No □ 11 No □ 12 No □ 13 No □ 14 Memory Capacity/Number of stored measurements 15 Printing Facilities 16 Communication Facilities 17 Power Supply 18 □ No □ 19 No □ 10 N/Ag □ 10 N/Ag □ 11 No □ 12 N/Ag □ 13 No □ 14 No □ 15 Printing Facilities 16 Communication Facilities 17 Power Supply 18 □ No □ 19 No □ 10 N/Ag □ 10 N/Ag □ 11 No □ 12 N/Ag □ 13 No □ 14 N/Ag □ 15 Printing Facilities 16 No □ 17 Power Supply									N/A ^f ⊠	
7 Inflation Mechanism 8 Deflation Mechanism Yes □ No ☒ Part II 9 Model Name or Number 10 Casing 11 Display 12 Carrying/Mounting Facilities 13 Software other than Algorithm 14 Memory Capacity/Number of stored measurements 15 Printing Facilities Yes ☒ No □ 16 Communication Facilities Yes ☒ No □ N/A ^g ☒ No □ N/A ^g ☒ No □ N/A ^g ☒ No □ N/A ^g ☒ No □ N/A ^g ☒ No □ N/A ^g ☒		5	Pressure Transdu	cer			Yes 🗌	No 🖂	. –	
8 Deflation Mechanism Part II 9 Model Name or Number 10 Casing 11 Display 12 Carrying/Mounting Facilities 13 Software other than Algorithm 14 Memory Capacity/Number of stored measurements 15 Printing Facilities 16 Communication Facilities 17 Power Supply Yes □ No □ N/Ag □ No □ N/Ag		6	Cuffs or Bladders				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/Ag ⋈ 16 Communication Facilities Yes □ No □ N/Ag ⋈ 17 Power Supply Yes □ No ⋈		7	Inflation Mechan	ism			Yes 🗌	No 🖂		
10 Casing Yes No No 1 11 Display Yes No No 1 12 Carrying/Mounting Facilities Yes No 1 13 Software other than Algorithm Yes No 1 14 Memory Capacity/Number of stored measurements Yes No No 1 15 Printing Facilities Yes No No N/Ag No No No N/Ag No No No N/Ag No No No N/Ag No		8	Deflation Mechan	nism			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 No □ N/A	Part II	9	Model Name or N	lumber			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/Ag ☑ 16 Communication Facilities Yes ☐ No ☐ N/Ag ☑ 17 Power Supply Yes ☐ No ☑		10	Casing				Yes 🖂	No 🗌		
13 Software other than Algorithm 14 Memory Capacity/Number of stored measurements 15 Printing Facilities 16 Communication Facilities 17 Power Supply Yes □ No □ N/A ^g ⋈ N/A ^g ⋈ N/A ^g ⋈ N/A ^g ⋈		11	Display				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 ☑		12	Carrying/Mountir	ng Facili	ties		Yes 🛛	No 🗌		
		13	Software other th	nan Algo	rithm		Yes 🛛	No 🗌		
16 Communication Facilities Yes ☐ No ☐ N/A ^g ☒ 17 Power Supply Yes ☐ No ☒		14	Memory Capacity	/Numb	er of sto	red measurements	Yes 🖂	No 🗌		
17 Power Supply Yes ☐ No ⊠		15	Printing Facilities				Yes 🗌	No 🗌	N/A ^g 🖂	
		16	Communication F	acilities	i		Yes 🗌	No 🗌	N/A ^g 🖂	
18 Other Facilities Yes ☐ No ☐ N/A ^g ☒							Yes 🗌	No 🖂		
		18	Other Facilities				Yes 🗌	No 🗌	N/A ^g 🖂	

An explanation of each item ticked. Tes must be included in section b of on a separate

- 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.

Fax + 353 1 278 3835

- 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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Declaration of Equivalence Form

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.

In an attached document. DET9 Form.

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	\boxtimes			
Completed DET9 Form	\boxtimes			
An image of the device for which equivalence is being sought				
An image of the screen layout of validated device*	\boxtimes			
An image of the screen layout of the device for which equivalence is being sought*	\boxtimes			

^{*} 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 Lucia Prada

Date 16 September, 2019

Signature of Witness

Name Hideki Kondo

Address 16 September, 2019

Company Stamp/Seal

OMRON HEALTHCARE EUROPE BV Scorpius 33

NL-2132 LR Hoofddorp P.O.BOX 2050 NL-2130 GL Hoofddorp

TEL +31-23 5544700 FAX +31-23 5544701

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Device Equivalence Evaluation Form

Comparison of the Omron X3 Comfort (HEM-7155-EO) with the Omron M6 Comfort (HEM-7321-E)

Devices – Item 9	Omron X3 Comfort (HEM-7155-EO)	Omron M6 Comfort (HEM-7321-E)
Pictures	OMRON OMRON SES 130 DUA 78 CO PRESE 730 OMRON OMRON	OMRON OMRON
Display Image	BYS BEAR PM SYS BYS BYS BYS BYS BYS BYS BYS BYS BYS	188 38:88 * THIS WEEK THIS WEEK TO THIS WEEK TO THIS WEEK TO THE THE THIS WEEK TO THE THIS WEEK TO THE THIS WEEK TO THE
Validation	Equivalence	ESH 2010
Category	Upper Arm Devices for Self-measurement of Blood Pressure	Upper Arm Devices for Self-measurement of Blood Pressure
Casing – Item 10	Casing Dimensions Approximately 105 mm (w) × 85 mm (h) × 152 mm (l) (not including the Arm cuff) Buttons/Switches Power On/Off with START/STOP	Casing Dimensions Approximately 124 mm (w) × 90 mm (h) × 161 mm (l) (not including the Arm cuff) Buttons/Switches Power On/Off with START/STOP

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Device Equivalence Evaluation Form

	Measurement Records	Measurement Records
	Memory	Memory
	Functions	Functions
	Back/Forward	Back/Forward
	User ID select	User ID select
	Date/Time setting	Date/Time setting
		Weekly average
Display – Item 11	Display/Symbols/Indicators	Display/Symbols/Indicators
	Measurement Procedure	Measurement Procedure
	Deflation symbol	Deflation symbol
	Heartbeat symbol	Heartbeat symbol
	User ID symbol	User ID symbol
		During Measurement: Blood Pressure Level
	Post Measurement	Post Measurement
	SBP, DBP and Pulse	SBP, DBP and Pulse
	Date and Time	Date and Time
	Irregular heartbeat symbol	Irregular heartbeat symbol
	<u> </u>	
	Cuff wrap guide symbol (OK, loose)	Cuff wrap guide symbol (OK, loose) and Cuff wrap OK lamp
	Body Movement error symbol	Body Movement error symbol
	Measurement error "E1 E2 E3 E4 E5 Er"	Measurement error "E1 E2 E3 E4 E5 Er"
	Power	Power
	Battery symbol (low, depleted)	Battery symbol (low, depleted)
	Measurement Records	Measurement Records
	Memory symbol	Memory symbol
	Memory recall number (replaces pulse rate momentarily)	Memory recall number (replaces pulse rate momentarily)
	Date and Time	Date and Time
	Date and Time (During memory recall)	Date and Time (During memory recall)
	Function	Function
	Blood pressure level symbol	Blood pressure level indicator
	Average value symbol	Average value symbol
	The age value symbol	Morning average symbol
		Evening average symbol
		Blood pressure colour indicator
		Morning hypertension symbol
Carrying/Mounting	Carrying/Mounting Facilities	Carrying/Mounting Facilities
Facilities – Item 12	Storage Case	Storage Case
Software other than	Software other than Algorithm	Software other than Algorithm
Algorithm – Item 13	Averages and Differences	Averages and Differences
	Average (Last 3 measurements value within 10 min)	Average (Last 3 measurements value within 10 min)
		Morning/Evening Weekly Average
	Diagnostic	Diagnostic
	Irregular heartbeat detection	Irregular heartbeat detection
	Blood Pressure classification	Blood Pressure classification
	Functions	Functions
	Correct cuff wrapping detection	Correct cuff wrapping detection
	Body movement error detection	Body movement error detection
	body movement entit detection	Body movement error detection

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Device Equivalence Evaluation Form

Memory Capacity	Number of stored measurements		Number of stored measurements	
Item 14	60 measurements per user	100 measurements per user		
Same Criteria	Measurement	Measurement		
	Accuracy	Accuracy		
	Blood Pressure accuracy ± 3 mmHg	1,5	Blood Pressure accuracy ± 3 mmHg	1,5
	Pulse accuracy ± 5%	1,5	Pulse accuracy ± 5%	1,5
	Method		Method	
	Oscillometric measurement method	1,5	Oscillometric measurement method	1,5
	Manually initiated measurements	13	Manually initiated measurements	13
	Ranges		Ranges	
	Cuff Pressure range 0 to 299 mmHg	1,5,7,8	Cuff Pressure range 0 to 299 mmHg	1,5,7,8
	Blood Pressure measurement SYS 60 to 260 mmHg	1,5,7,8	Blood Pressure measurement SYS 60 to 260 mmHg	1,5,7,8
	Blood Pressure measurement DIA 40 to 215 mmHg	1,5,7,8	Blood Pressure measurement DIA 40 to 215 mmHg	1,5,7,8
	Pulse measurement 40 to 180 beats / min.	1,5,7,8	Pulse measurement 40 to 180 beats / min.	1,5,7,8
	Inflation		Inflation	
	Inflation 0 to 299 mmHg	1,5,7	Inflation 0 to 299 mmHg	1,5,7
	Automatic Inflation	7	Automatic Inflation	7
	Deflation		Deflation	
	Automatic Deflation	8	Automatic Deflation	8
	Cuffs		Cuffs	
	Arm Cuff HEM-FL31 (Arm circumference 22 cm to 44 cm) Type BF	6	Arm Cuff HEM-FL31 (Arm circumference 22 cm to 44 cm) Type BF	6
	Sensors		Sensors	
	The electric pressure sensor	5	The electric pressure sensor	5
	Measurements other than Blood Pressure		Measurements other than Blood Pressure	
	Pulse 40 to 180 beat / min.	1,5,8	Pulse 40 to 180 beat / min.	1,5,8
	Display/Symbols/Indicators		Display/Symbols/Indicators	
	Measurement Procedure		Measurement Procedure	
	Heartbeat symbol	11	Heartbeat symbol	11
	During Measurement: Blood Pressure Level	11	During Measurement: Blood Pressure Level	11
	Post Measurement		Post Measurement	
	SBP, DBP and Pulse	11	SBP, DBP and Pulse	11
	Irregular heartbeat symbol	11	Irregular heartbeat symbol	11
	Cuff wrap guide symbol (OK, loose)	11	Cuff wrap guide symbol (OK, loose)	11
	Measurement error "E1 E2 E3 E4"	11	Measurement error "E1 E2 E3 E4"	11
	Power		Power	
	Battery symbol (low, depleted)	11	Battery symbol (low, depleted)	11
	Software other than Algorithm		Software other than Algorithm	
	Diagnostic		Diagnostic	
	Irregular heartbeat detection	13	Irregular heartbeat detection	13
	Functions		Functions	
	Correct cuff wrapping detection	13	Correct cuff wrapping detection	13
	Body movement error detection	13	Body movement error detection	13
	Power Supply		Power Supply	
	Power		Power	
	4 "AA" batteries	17	4 "AA" batteries	17
	AC adapter (HHP-CM01 / HHP-BFH01)	17	AC adapter (HHP-CM01 / HHP-BFH01)	17

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Device Equivalence Evaluation Form

Comments			l
Recommendation	Reco	Recommended	
Date	Septe	ember 2019	l

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