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 Andre van Gils, (Name of a Company Director) a Director of Omron Healthcare Europe B.V., (Company name)

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

Maker[a] Omron Healthcare Man. Vietnam Co., LTD *Address* Binh Duong Province, Vietnam

Manufacturer[b] Omron Healthcare Co., Ltd. *Address* 53, Kunotsubo, Terado-cho, Muko, KYOTO, 617-0002 Japan

Brand[c] Omron Model[d] X7 Smart (HEM-7361T-ESL)

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] Omron Healthcare Man. Vietnam Co., LTD *Address* Binh Duong Province, Vietnam

Manufacturer[b] Omron Healthcare Co., Ltd. *Address* 53, Kunotsubo, Terado-cho, Muko, KYOTO, 617-0002 Japan

Brand[c] Omron Model[d] 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 ☒	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.

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	☒
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 Lucia Prada

Date 16 September, 2019

Signature of Witness _____

Name Hideki Kondo

Address 16 September, 2019

Company Stamp/Seal

OMRON HEALTHCARE EUROPE BV
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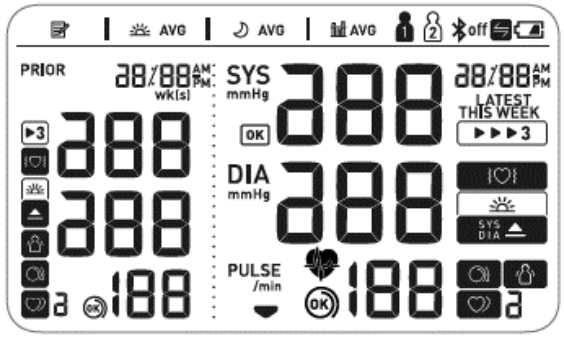
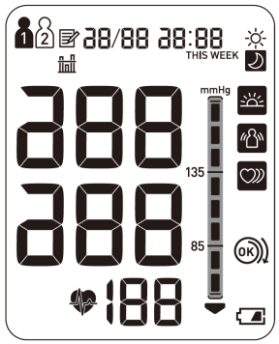
Comparison of the Omron X7 Smart (HEM-7361T-ESL) with the Omron M6 Comfort (HEM-7321-E)

Devices – Item 9	Omron X7 Smart (HEM-7361T-ESL)	Omron M6 Comfort (HEM-7321-E)
Pictures		
Display Image		
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 191 mm (w) × 85 mm (h) × 120 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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	Measurement Records Memory *Functions* Back/Forward User ID select Morning/Evening Weekly Average *Communication* Bluetooth button	*Measurement Records* Memory *Functions* Back/Forward User ID select Weekly average Date/Time setting
Display – Item 11	***Display/Symbols/Indicators*** *Measurement Procedure* Deflation symbol Heartbeat symbol User ID symbol *Post Measurement* SBP, DBP and Pulse Date and Time Irregular heartbeat symbol Cuff wrap guide symbol (OK, loose) Body Movement error symbol Measurement error "E1 E2 E3 E4 E5 E6 Er" *Power* Battery symbol (low, depleted) *Measurement Records* Memory symbol Memory recall number (replaces pulse rate momentarily) *Date and Time* Date and Time (During memory recall) *Function* Blood pressure level symbol Average value symbol Morning average symbol Evening average symbol AFib indicator symbol Prior Measurement reading SBP, DBP, Pulse, Date and Time, Irregular heart beat, Cuff wrap guide, Body movement, Blood pressure level and AFib indicator *Communication* Bluetooth ON symbol Bluetooth OFF symbol Sync symbol (Flashes/appears when data needs to be transferred because the stored memory is either almost, or completely full)	***Display/Symbols/Indicators*** *Measurement Procedure* Deflation symbol Heartbeat symbol User ID symbol During Measurement: Blood Pressure Level *Post Measurement* SBP, DBP and Pulse Date and Time Irregular heartbeat symbol Cuff wrap guide symbol (OK, loose) and Cuff wrap OK lamp Body Movement error symbol Measurement error "E1 E2 E3 E4 E5 Er" *Power* Battery symbol (low, depleted) *Measurement Records* Memory symbol Memory recall number (replaces pulse rate momentarily) *Date and Time* Date and Time (During memory recall) *Function* Blood pressure level indicator Average value symbol Morning average symbol Evening average symbol Blood pressure colour indicator Morning hypertension symbol

	Bluetooth pairing/transferring indicator Bluetooth connection error “Err”	
Carrying/Mounting Facilities – Item 12	*Carrying/Mounting Facilities* Storage Case	*Carrying/Mounting Facilities* Storage Case
Software other than Algorithm – Item 13	***Software other than Algorithm*** *Averages and Differences* Average (Last 3 measurements value within 10 min) Morning/Evening Weekly Average *Diagnostic* Irregular heartbeat detection Blood Pressure classification *Functions* Correct cuff wrapping detection Body movement error detection AFib detection *Communication* The data (measurement result of blood pressure and pulse rate) transfer via Bluetooth	***Software other than Algorithm*** *Averages and Differences* Average (Last 3 measurements value within 10 min) Morning/Evening Weekly Average *Diagnostic* Irregular heartbeat detection Blood Pressure classification *Functions* Correct cuff wrapping detection Body movement error detection
Same Criteria	***Measurement*** *Accuracy* Blood Pressure accuracy ± 3 mmHg 1,5 Pulse accuracy ± 5% 1,5 *Method* Oscillometric measurement method 1,5 Manually initiated measurements 13 *Ranges* 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 DIA 40 to 215 mmHg 1,5,7,8 Pulse measurement 40 to 180 beats / min. 1,5,7,8 *Inflation* Inflation 0 to 299 mmHg 1,5,7 Automatic Inflation 7 *Deflation* Automatic Deflation 8 *Cuffs* Arm Cuff HEM-FL31 (Arm circumference 22 cm to 44 cm) Type BF 6 *Sensors* The electric pressure sensor 5 *Measurements other than Blood Pressure* Pulse 40 to 180 beat / min. 1,5,8 ***Display/Symbols/Indicators*** *Measurement Procedure* Heartbeat symbol 11 During Measurement: Blood Pressure Level 11 *Post Measurement* SBP, DBP and Pulse 11	***Measurement*** *Accuracy* Blood Pressure accuracy ± 3 mmHg 1,5 Pulse accuracy ± 5% 1,5 *Method* Oscillometric measurement method 1,5 Manually initiated measurements 13 *Ranges* 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 DIA 40 to 215 mmHg 1,5,7,8 Pulse measurement 40 to 180 beats / min. 1,5,7,8 *Inflation* Inflation 0 to 299 mmHg 1,5,7 Automatic Inflation 7 *Deflation* Automatic Deflation 8 *Cuffs* Arm Cuff HEM-FL31 (Arm circumference 22 cm to 44 cm) Type BF 6 *Sensors* The electric pressure sensor 5 *Measurements other than Blood Pressure* Pulse 40 to 180 beat / min. 1,5,8 ***Display/Symbols/Indicators*** *Measurement Procedure* Heartbeat symbol 11 During Measurement: Blood Pressure Level 11 *Post Measurement* 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
	Memory Capacity		***Memory Capacity***	
	Number of stored measurements		*Number of stored measurements*	
	100 measurements per user	14	100 measurements per user	14
	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

Comments		
Recommendation	**Recommended**	
Date	**September 2019**	