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] RS2 (HEM-6161-E)

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] RS4 (HEM-6181-E)

Existing validated blood pressure measuring device.

which has previously passed the ESH2010 protocol, the results of which were published as follows:

Validation of two automatic devices, Omron HEM-6232T and HEM-6181, for self-measurement of blood pressure at the wrist according to the ANSI/AAMI/ISO 81060-2:2013 protocol and the European Society of Hypertension International Protocol revision 2010

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 _____ Company Stamp/Seal

Name Lucia Prada

Date 6 March, 2019

Signature of Witness _____

Name Janet Meijer

Address 6 March, 2019

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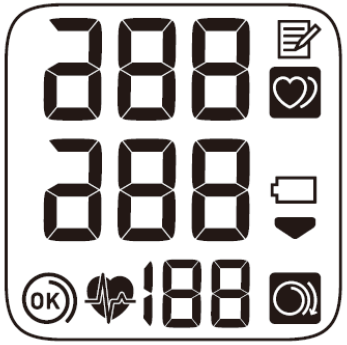
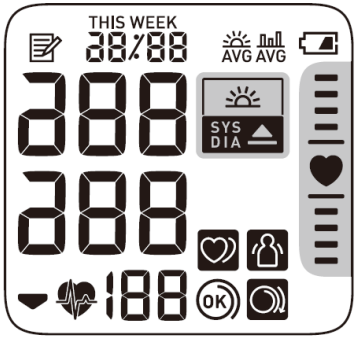
Comparison of the Omron RS2 (HEM-6161-E) with the Omron RS4 (HEM-6181-E)

Devices – Item 9	Omron RS2 (HEM-6161-E)	Omron RS4 (HEM-6181-E)
Pictures		
Display Image		
Validation	*(equivalence)*	ANSI/AAMI/ISO 81060-2:2013 and ESH 2010
Category	Wrist Devices for Self-measurement of Blood Pressure	Wrist Devices for Self-measurement of Blood Pressure
Casing – Item 10	***Casing*** *Dimensions* Approximately 84 mm (w) × 62 mm (h) × 21 mm (l) (not including the wrist cuff)	***Casing*** *Dimensions* Approximately 93 mm (w) × 62 mm (h) × 20 mm (l) (not including the wrist cuff)

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	Buttons/Switches *Power* On/Off with START/STOP button *Measurement Records* Memory button	***Buttons/Switches*** *Power* On/Off with START/STOP button *Measurement Records* Memory button Morning Average button
Display – Item 11	***Display/Symbols/Indicators*** *Measurement Procedure* Deflation symbol Heartbeat symbol During Measurement: Blood Pressure Level *Post Measurement* SBP, DBP and Pulse Irregular heartbeat symbol Cuff wrap guide symbol (OK, loose) Measurement error “E1 E3 E4 E5 Er“ *Measurement Records* Memory symbol Memory recall number (replaces pulse rate momentarily) *Power* Battery symbol (low, depleted)	***Display/Symbols/Indicators*** *Preparation* Positioning indicator *Measurement Procedure* Deflation symbol Heartbeat symbol During Measurement: Blood Pressure Level *Post Measurement* SBP, DBP and Pulse Irregular heartbeat symbol Cuff wrap guide symbol (OK, loose) Measurement error “E1 E3 E4 E5 Er“ Body Movement error Measurement error “E7” (Wrist is moved up and down during a measurement) *Measurement Records* Memory symbol Memory recall number (replaces pulse rate momentarily) *Power* Battery symbol (low, depleted) *Date and Time* Date and Time (During memory recall) *Function* Morning average symbol Average value symbol Hypertension symbol Morning hypertension symbol
Software other than Algorithm – Item 13	***Software other than Algorithm*** *Diagnostic* Irregular heartbeat detection *Functions* Correct cuff wrapping detection	***Software other than Algorithm*** *Averages and Differences* Average (Last 3 measurements value within 10 min) Weekly Average (morning measurements value within 8 weeks) *Diagnostic* Irregular heartbeat detection Blood Pressure classification *Functions* Correct cuff wrapping detection Body movement error detection
Memory Capacity Item 14	*Number of stored measurements* 30 measurements	*Number of stored measurements* 60 measurements

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 (Please state sizes and materials used)		*Cuffs (Please state sizes and materials used)*	
	Wrist Cuff (Wrist circumference 13.5 cm to 21.5 cm) Type BF	6	Wrist Cuff (Wrist circumference 13.5 cm to 21.5 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
	Buttons/Switches		***Buttons/Switches***	
	Power		*Power*	
	On/Off with START/STOP button	10	On/Off with START/STOP button	10
	Measurement Records		*Measurement Records*	
	Memory button	10	Memory button	10
	Display/Symbols/Indicators		***Display/Symbols/Indicators***	
	Measurement Procedure		*Measurement Procedure*	
	Deflation symbol	11	Deflation symbol	11
	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 E3 E4 E5 Er“	11	Measurement error “E1 E3 E4 E5 Er“	11
	Measurement Records		*Measurement Records*	
	Memory symbol	11	Memory symbol	11
	Memory recall number (replaces pulse rate momentarily)	11	Memory recall number (replaces pulse rate momentarily)	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

Comments		
Recommendation	**Recommended**	
Date	28 March 2019	