DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2013

A SIGNED COPY WILL BE POSTED ON THE www.dableducational.org WEBSITE

SECTION A - Please complete all items.

I Minoru Yoshimura, a Director of OMRON Healthcare Europe B.V.,
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] OMRON Healthcare Co., Ltd. Address 53 Kunotsubo, Terado-cho, Muko, Kyoto 617-0002, Japan

Manufacturer[b] OMRON Healthcare Co., Ltd Address 53 Kunotsubo, Terado-cho, Muko, Kyoto 617-0002, Japan

Brand[c] OMRON Model[d] RS2 (HEM-6121-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 Co., Ltd. Address 53 Kunotsubo, Terado-cho, Muko, Kyoto 617-0002, Japan

Manufacturer[b] OMRON Healthcare Co., Ltd. Address 53 Kunotsubo, Terado-cho, Muko, Kyoto 617-0002, Japan

Brand[c] OMRON Model[d] RS3 (HEM-6130-E)

Existing validated blood pressure measuring device.

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

Takahashi H, Yokoi T, Yoshika M. Validation of the OMRON RS3 (HEM-6130-E) wrist blood pressure monitor, in oscillometry mode, for clinic use and self measurement in a general population, according to the European Society of Hypertension International Protocol revision 2010 [Internet]. Dublin: dablEducational Trust; 2013 Feb 01 [cited 2013 Feb 14]. 4 p. Available from: http://www.dableducational.org/Publications/2013/ESH-IP 2010 Validation of Omron RS3 (HEM-6130-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.

9. Model name RS2 (HEM-6121-E)

10. No Memory button and Date/Time setting button.

11. No Average value symbol, Date/Time display and movement error symbol. The Hearbeat symbol will blink when measurement is outside the standard range.

13. No function of Average value, Date/Time and movement error detection.

14. 30 memories.

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	☒
An image of the validated device	☒
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 Minoru Yoshimura

Date 14 Feb 2013

Signature of Witness _____

Name Tomohiro Kukita

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Comparison of the Omron RS2 (HEM-6121-E) with the Omron RS3 (HEM-6130-E)

Devices	Omron RS2 (HEM-6121-E)	Omron RS3 (HEM-6130-E)
Pictures		
Display		
Validation		ESH 2010
Device 1 Criteria		
Same Criteria	***Measurement*** *Accuracy* BP accuracy ± 3 mmHg 1, 5 Pulse accuracy ± 5% 1, 5 *Method* Oscillometric measurement method 1, 5 Pulse 40 bpm to 180 bpm 1, 5, 8 Manually initiated measurements 13 Measurements are from single inflations 13 *Inflation* Inflation 0 mmHg to 299 mmHg 1, 5, 7 Automatic Inflation 7	***Measurement*** *Accuracy* BP accuracy ± 3 mmHg 1, 5 Pulse accuracy ± 5% 1, 5 *Method* Oscillometric measurement method 1, 5 Pulse 40 bpm to 180 bpm 1, 5, 8 Manually initiated measurements 13 Measurements are from single inflations 13 *Inflation* Inflation 0 mmHg to 299 mmHg 1, 5, 7 Automatic Inflation 7

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Devices	Omron RS2 (HEM-6121-E)		Omron RS3 (HEM-6130-E)	
Same Criteria (continued)	***Measurement (continued)***		***Measurement (continued)***	
	Deflation		*Deflation*	
	Automatic Deflation	8	Automatic Deflation	8
	Cuffs		*Cuffs*	
	Wrist circ. ~ 13.5 cm to ~ 21.5 cm	6	Wrist circ. ~ 13.5 cm to ~ 21.5 cm	6
	Buttons/Switches		***Buttons/Switches***	
	Power		*Power*	
	On/Off with Start/Stop (Start/Stop Label)	10	On/Off with Start/Stop (Start/Stop Label)	10
	Measurement Records		*Measurement Records*	
	Memory	10	Memory	10
	Display/Symbols/Indicators		***Display/Symbols/Indicators***	
	Preparation		*Preparation*	
	Correct cuff wrapping indicator	11, 13, 18	Correct cuff wrapping indicator	11, 13, 18
	Measurement Procedure		*Measurement Procedure*	
	Deflation symbol	11	Deflation symbol	11
	During Measurement: BP Level & Heartbeat	11	During Measurement: BP Level & Heartbeat	11
	Post Measurement		*Post Measurement*	
	SBP, DBP and Pulse	11	SBP, DBP and Pulse	11
	Measurement error E 1, E3, E4, E5, Er	11	Measurement error E 1, E3, E4, E5, Er	11
	BP classification (Thresholds exceeded)	10, 11, 13	BP classification (Thresholds exceeded)	10, 11, 13
	Irregular heartbeat	11, 13, 18	Irregular heartbeat	11, 13, 18
	Measurement Records		*Measurement Records*	
	Memory icon	11	Memory icon	11
	Memory recall number (Replaces pulse rate momentarily)	11	Memory recall number (Replaces pulse rate momentarily)	11
	Power		*Power*	
	Low battery	11, 17	Low battery	11, 17
	Algorithms		***Algorithms***	
	Diagnostic		*Diagnostic*	
	135 / 85 mmHg thresholds	13	135 / 85 mmHg thresholds	13
	Irregular heartbeat detection	13	Irregular heartbeat detection	13
	Parameter Settings		*Parameter Settings*	
	Correct cuff wrapping detection	13	Correct cuff wrapping detection	13
	Case		***Case***	
	Display		*Display*	
	Single screen display	10	Single screen display	10
	Segment LCD	10	Segment LCD	10
	Power		*Power*	
	2 “AAA” batteries ~ 300 measurements	17	2 “AAA” batteries ~ 300 measurements	17
	Automatic switch-off when not used for 2 min	17	Automatic switch-off when not used for 2 min	17

Devices	Omron RS2 (HEM-6121-E)	Omron RS3 (HEM-6130-E)
Comparable Criteria	***Measurement*** *Measurement Records* Memory: 30 measurements 14 ***Display/Symbols/Indicators*** *Post Measurement* Hypertension (Blinking heartbeat) 11, 13	***Measurement*** *Measurement Records* Memory: 60 measurements 14 ***Display/Symbols/Indicators*** *Post Measurement* Hypertension (Indicator strip) 11, 13
Device 2 Criteria		***Buttons/Switches*** *Settings* Set 10 ***Display/Symbols/Indicators*** *Post Measurement* Average 11, 13, 14 Body movement error 3, 11, 13, 18 *Date and Time* Date and Time 11 Date and Time (During memory recall) 11 ***Algorithms*** *Averages and Differences* Last 3 measurements (within 10 min of each other) mean 13 *Diagnostic* Body movement error detection 3, 13

Comments	1	Note	These devices are clearly equivalent and from the same family. The RS2 contains fewer extra features than the RS3 and a simpler method of indicating hypertension.
Recommendation	Equivalence is Recommended		
Date	15/02/2013		