dabl®Educational Trust — Declaration of Equivalence Form

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 Tomohiro Kukita, (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 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]	M2 Basic(HEM-7120-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]	HEM-7130

Existing validated blood pressure measuring device.

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

dablEducational Trust; 2013 Nov 14. 4 p. Available from: http://www.dableducational.org/Publications/2013/ESH-IP 2010 Validation of Omron HEM-7130.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) The model number is changed to M2 Basic(HEM-7120-E) from HEM-7130.

10) The memory button, the Up/Down buttons and the Date/Time setting button are removed from the M2 Basic.

11) The Average value symbol, the Date/Time display, the movement error symbol, the irregular heartbeat symbol, the blood pressure level indicator, the cuff warp guide symbol and the memory number are removed from the M2 Basic.

13) The average reading recently 3times with 10minutes function, the body movement detection function, the irregular heart beat detection function, the cuff wrap guide function, the blood pressure indicator function and the clock function are removed from the M2 Basic.

14) The memory capacity has the last measurement value.

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 Tomohiro Kukita

Company Stamp/Seal

Name Tomohiro Kukita

Date 17 Mar, 2014

Signature of Witness Anita Kecskes

Name Anita Kecskes

Address 17 Mar, 2014

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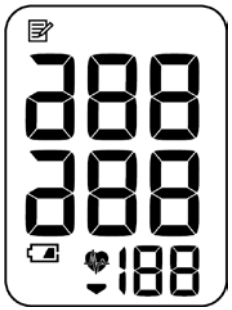
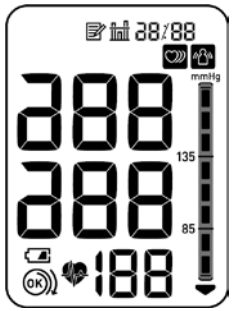
Comparison of the Omron M2 Basic (HEM-7120-E) with the Omron HEM-7130 (Japanese model)

Devices	Omron M2 Basic (HEM-7120-E)	Omron HEM-7130 (Japanese model) [Query 4]
Pictures		
Display		
Validation		ESH 2010
Device 1 Criteria		
Same Criteria	***Measurement***	***Measurement***
	Accuracy	*Accuracy*
	BP accuracy ± 3 mmHg 1, 5	BP 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
	BP 0 mmHg to 299 mmHg [Query 1] 1, 5, 7, 8	BP 0 mmHg to 299 mmHg [Query 1] 1, 5, 7, 8
	Pulse 40 bpm to 180 bpm 1, 5, 8	Pulse 40 bpm to 180 bpm 1, 5, 8
	Manually initiated measurements 13	Manually initiated measurements 13
	Measurements are from single inflations 13	Measurements are from single inflations 13
	Inflation	*Inflation*
	Inflation 0 mmHg to 299 mmHg 1, 5, 7	Inflation 0 mmHg to 299 mmHg 1, 5, 7
	Automatic Inflation 7	Automatic Inflation 7

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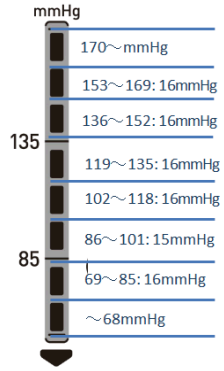
Devices	Omron M2 Basic (HEM-7120-E)	Omron HEM-7130 (Japanese model) [Query 4]
Same Criteria (continued)	***Measurement (continued)***	***Measurement (continued)***
	Inflation (continued)	*Inflation (continued)*
	Fuzzy Logic 7	Fuzzy Logic 7
	Press button if BP > 210 mmHg 7	Press button if BP > 210 mmHg 7
	Deflation	*Deflation*
	Automatic Deflation 8	Automatic Deflation 8
	Cuffs	*Cuffs*
	Large (Arm circ. 22 cm to 42 cm) No. HEM-RML31 (Optional) 6	Large (Arm circ. 22 cm to 42 cm) No. HEM-RML31 (Optional) [Query 2] 6
	Medium (Arm circ. 22 cm to 32 cm) No. HEM-CR24 6	Medium (Arm circ. 22 cm to 32 cm) No. HEM-CR24 [Query 2] 6
	Small (Arm circ. 17 cm to 22 cm) No. HEM-CS24 (Optional) [Query 2] 6	Small (Arm circ. 17 cm to 22 cm) No. HEM-CS24 (Optional) [Query 2] 6
	Display/Symbols/Indicators	***Display/Symbols/Indicators***
	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 E1 E2 E3 E4 E5 Er 11	Measurement error E1 E2 E3 E4 E5 Er 11
	Measurement Records	*Measurement Records*
	Memory icon 11	Memory icon 11
	Power	*Power*
	Low & Exhausted battery 11, 17	Low & Exhausted battery 11, 17
	Casing	***Casing***
	Display	*Display*
	Single screen display 10	Single screen display 10
	Segment LCD 10	Segment LCD 10
	Power	*Power*
	4 “AA” batteries ~ 1000 measurements 17	4 “AA” batteries ~ 1000 measurements 17
	AC adapter (S-9515336-9 or UK-9983666-5) (Optional) 17	AC adapter (S-9515336-9 or UK-9983666-5) (Optional) 17
	Automatic switch-off when not used for 2 min 17	Automatic switch-off when not used for 2 min 17
	Rechargeable batteries not permitted 17	Rechargeable batteries not permitted 17
Comparable Criteria	***Measurement***	***Measurement***
	Measurement Records	*Measurement Records*
	Memory: 1 measurement 14	Memory: 60 measurements (Guest not recorded) 14
	Buttons/Switches	***Buttons/Switches***
	Power/Measurement Records	*Power/Measurement Records*
	On/Off including Memory 10	On/Off with Start/Stop (Start/Stop Label) 10
		Memory 10

Devices	Omron M2 Basic (HEM-7120-E)	Omron HEM-7130 (Japanese model) [Query 4]
Device 2 Criteria		***Measurement***
		Method
		Prevent storing of result (Guest mode) 13, 14
		Buttons/Switches
		Function
		Date/Time set 10
		Up and down 10
		Display/Symbols/Indicators
		Post Measurement
		Hypertension (Indicator strip) [Query 3] 11, 13
		Average 11, 13, 14
		Body movement error 3, 11, 13, 18
		Irregular heartbeat 11, 13, 18
		Correct cuff wrapping indicator 11, 13, 18
		Measurement Records
		Memory recall number (Replaces pulse rate momentarily) 11
		Date and Time
		Date and Time (alternating) 11
		Date and Time (During memory recall) 11
		Algorithms
		Averages and Differences
		Last 3 measurements (within 10 min of each other) mean 13
		Diagnostic
		BP classification [Query 3] 13
		Irregular heartbeat detection 13
		Body movement error detection 3, 13
		Functions
		Correct cuff wrapping detection 13

Comments	1	Query	Each of the manuals states that the blood pressure measurement range is 0 mmHg to 299 mmHg. They also state that the monitor will not inflate above 299 mmHg. This means that the measurement ranges must be below this. According to ISO 80601-2-30 (2009), the device must be capable (in non-neonatal mode) of indicating at least 60 mmHg to 230 mmHg for SBP and 40 mmHg to 130 mmHg for DBP (201.12.1.103), so specifying these separately is necessary. It also requires that the pressure ranges provided are the rated pressures (201.7.9.2.9 h and 201.12.1.101) and that those measurements that are outside of these ranges trigger a technical alarm (201.12.1.106). a) What are the SBP and DBP rated ranges for each of the devices? b) Are there technical alarm ranges for each of the devices?
		Response	a) There is no SBP and DBP rated ranges because we have not defined the rated range of cuff pressure which is actually limited by measurement range of the pressure (not blood pressure) 0 to 299 mmHg. The capability to measure the required SBP and DBP range (201.12.1.103) are confirmed by technical validation test. b) There is no technical alarm because of the reason above.
		Query	The rated ranges for SBP and DBP are simply the ranges, within the inflation range, for which SBP and DBP values are displayed. Where a pulse is detected close to the maximum inflation pressure or the wave envelope suggests SBP as being close to the maximum inflation pressure, it may be rejected an unreliable estimate of SBP. DBP estimates close to zero can be similarly rejected. These are the technical alarm conditions. The reply suggests that there are no upper or lower limits to either SBP or DBP i.e. 299 mmHg ≥ SBP > DBP ≥ 0 mmHg. Is this correct?
		Response	Yes, this is correct.
		Comment	The reply answers the query fully.
	2	Query	a) What are the numbers of the cuffs supplied with the HEM-7130? b) Why is the small cuff (HEM-CS24; arm circ. 17 cm to 32 cm) not provided as an option for the M2 Basic (HEM-7120-E)? c) Why is the large cuff (arm circ. 32 cm to 42 cm), optionally available for the HEM-7130, different from the large cuff large cuff (No. HEM-RML31; arm circ. 22 cm to 42 cm) optionally available for the M2 Basic (HEM-7120-E)?
		Response	a) The HEM-7130 is supplied with a medium cuff (HEM-CR24; arm circ. 22 cm to 32 cm). A large cuff (HEM-RML31; arm circ. 22 cm to 42 cm) is optional. b) The small cuff option is currently missing from the manual. We are now working to add it. c) It is the same large cuff (No. HEM-RML31; arm circ. 22 cm to 42 cm) that is available for both devices. However, in Japan, it is marketed as being for arm circumferences 32 cm to 42 cm.
		Comment	The reply answers the query fully.

	3	Query	The HEM-7130 has a vertical indicator strip. It contains 8 sections with a 135 mmHg mark between the 3rd and 4th sections and an 85 mmHg mark between the 6th and 7th sections. From the diagrams in the respective manual, its function appears to be to display the pulse pressure, with a series of sections lit from one indicating a range of SBP values to one indicating a range of DBP values. However, no explanation is provided in the manual. What range of pressure does each section represent? 
		Response	Please find the range of the pressure for each section as shown.
		Comment	The reply answers the query fully.
	4	Query	The image of the HEM-7130 available from www.healthcare.omron.co.jp matches that in the validation paper and in the manuals available from www.healthcare.omron.co.jp and healthcare.omron.co.in. However, the images available from omronhealthcare.com.au and healthcare.omron.co.in have an extra OK LED on the case. Please explain. 
		Response	The model in www.healthcare.omron.co.jp is the correct one to which we are referring. This is Japan model. The model in omronhealthcare.com.au has the same model name but is a different regional model for Australia and India.
		Query	Have they distinguishing names or alternative names?
		Response	These have the same model name but we distinguish them by a rating label on the unit. For example, there is “IN” for the rating label of the India model and “AU” for the Australia model. Please find the rating labels as shown. From the top, it is Japan, India, and Australia. 
		Comment	The query relates to how we distinguish the particular HEM-7130 model in the assessments and on the website. Given that they are distinguished by rating labels only, we will simply use *HEM-7130 (Japanese model)*.

Note	1	The M2 Basic (HEM-7120-E) has the same blood pressure measuring facilities as the HEM-7130 (Japanese model). However, other than the display of pressure or error, it contains none of the post-measurement features of the HEM-7130.
Recommendation	Equivalence is Recommended	
Date	20 March 2014	