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]	M3 (HEM-7131-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]	M6 AC (HEM-7322-E)

Existing validated blood pressure measuring device.

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

dablEducational Trust; 2014 Jan 22. 4 p. Available from: http://www.dableducational.org/Publications/2014/ESH-IP 2010 Validation of Omron M6 AC (HEM-7322-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) The model number is changed to M3 (HEM-7131-E) from M6 AC (HEM-7322-E).

10) The weekly average button is removed from the M3.

11) The morning average symbol, the evening average symbol and the morning hypertension symbol are removed from the M3.

13) The average at morning and night function and the morning hypertension detection function are removed from the M3.

14) The memory capacity has 2 users each 60 sets.

17) The M3 has AC adapter as optional parts.

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 Tomohiro Kukita

Date 17 Mar, 2014

Signature of Witness _____

Name Anita Kecskes

Address 17 Mar, 2014

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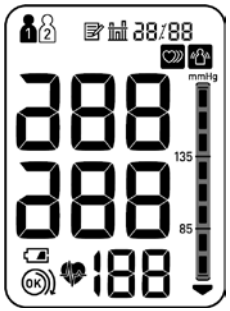
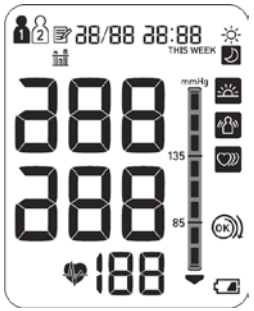
Comparison of the Omron M3 (HEM-7131-E) with the Omron M6 AC (HEM-7322-E)

Devices	Omron M3 (HEM-7131-E)	Omron M6 AC (HEM-7322-E)
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
	Prevent storing of result (Guest mode) 13, 14	Prevent storing of result (Guest mode) 13, 14
	Inflation	*Inflation*
	Inflation 0 mmHg to 299 mmHg 1, 5, 7	Inflation 0 mmHg to 299 mmHg 1, 5, 7

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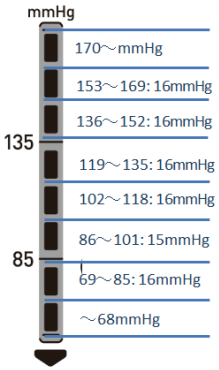
Devices	Omron M3 (HEM-7131-E)		Omron M6 AC (HEM-7322-E)	
Same Criteria (continued)	***Measurement (continued)***		***Measurement (continued)***	
	Inflation (continued)		*Inflation (continued)*	
	Automatic Inflation	7	Automatic Inflation	7
	Fuzzy Logic	7	Fuzzy Logic	7
	Press button if BP > 210 mmHg	7	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	6	Large (Arm circ. 22 cm to 42 cm) No. HEM-RML31	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
	User ID slider	10	User ID slider	10
	Function		*Function*	
	Date/Time set	10	Date/Time set	10
	Up and down	10	Up and down	10
	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
	Hypertension (Indicator strip) Query 2	11, 13	Hypertension (Indicator strip) Query 2	11, 13
	Hypertension (Indicator LEDs)	11, 13	Hypertension (Indicator LEDs)	11, 13
	Memory zone average	11, 13, 14	Memory zone average	11, 13, 14
	Body movement error	3, 11, 13, 18	Body movement error	3, 11, 13, 18
	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
	User (1, 2 and Guest)	11	User (1, 2 and Guest)	11
	Date and Time		*Date and Time*	
	Date and Time (During memory recall)	11	Date and Time (During memory recall)	11

Devices	Omron M3 (HEM-7131-E)	Omron M6 AC (HEM-7322-E)
Same Criteria (continued)	***Display/Symbols/Indicators(continued)*** *Power* Low & Exhausted battery 11, 17 ***Algorithms*** *Averages and Differences* Last 3 measurements (within 10 min) memory zone mean 13 *Diagnostic* BP classification Query 2 13 135 / 85 mmHg thresholds 13 Irregular heartbeat detection 13 Body movement error detection 3, 13 *Functions* Correct cuff wrapping detection 13 ***Casing*** *Display* Single screen display 10 Segment LCD 10 *Power* 4 “AA” batteries ~ 1000 measurements 17 AC adapter (S-9515336-9 or UK-9983666-5) (Optional) 17 Automatic switch-off when not used for 2 min 17 Rechargeable batteries not permitted 17	***Display/Symbols/Indicators(continued)*** *Power* Low & Exhausted battery 11, 17 ***Algorithms*** *Averages and Differences* Last 3 measurements (within 10 min) memory zone mean 13 *Diagnostic* BP classification Query 2 13 135 / 85 mmHg thresholds 13 Irregular heartbeat detection 13 Body movement error detection 3, 13 *Functions* Correct cuff wrapping detection 13 ***Casing*** *Display* Single screen display 10 Segment LCD 10 *Power* 4 “AA” batteries ~ 1000 measurements 17 AC adapter (S-9515336-9 or UK-9983666-5) (Optional) 17 Automatic switch-off when not used for 2 min 17 Rechargeable batteries not permitted 17
Comparable Criteria	***Measurement*** *Measurement Records* Memory: 60 measurements × 2 users (Guest not recorded) 14 ***Display/Symbols/Indicators*** *Post Measurement* Correct cuff wrapping indicator (icon + LED) 11, 13, 18 *Date and Time* Date and Time (alternating) 11	***Measurement*** *Measurement Records* Memory: 100 measurements × 2 users (Guest not recorded) 14 ***Display/Symbols/Indicators*** *Post Measurement* Correct cuff wrapping indicator (icon + 2 LEDs) 11, 13, 18 *Date and Time* Date and Time 11
Device 2 Criteria		***Buttons/Switches*** *Analysis* Average 10 ***Display/Symbols/Indicators*** *Post Measurement* Morning hypertension 11, 13 7-day morning memory zone average 11, 13, 14

Devices	Omron M3 (HEM-7131-E)	Omron M6 AC (HEM-7322-E)
Device 2 Criteria (continued)		***Display/Symbols/Indicators(continued)*** *Post Measurement (continued)* 7-day evening memory zone average 11, 13, 14 ***Algorithms*** *Averages and Differences* 7-day morning and evening memory zone means (8 weeks) 13 *Diagnostic* Morning hypertension 13

Queries	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	Both devices have vertical indicator strips. Each strip 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 manuals, their 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 either manual. What range of pressure does each section represent and are they the same for both devices?
		Response	Please find the range of the pressure for each section as shown. These are same for both devices.
		Comment	The reply answers the query fully.



Note	1	The main difference between these devices is that the averaging features provided on the M6 AC (HEM-7322-E) are not provided on the M3 (HEM-7131-E). The M3 (HEM-7131-E) stores 60 measurements per user, as distinct from 100 per user for the M6 AC (HEM-7322-E) and also uses the same segments to display an alternating date and time whereas the M6 AC (HEM-7322-E) can display both together. Both devices have a green LED symbol to indicate if the cuff was wrapped correctly The M6 AC (HEM-7322-E) has an extra separate orange LED symbols to indicate if the cuff was wrapped too loosely; no light is shown on the M3 (HEM-7131-E) in this instance. The feature is duplicated on the screen of both devices where the cuff wrap symbol is shown with either the “OK” or “tighten it” arrow sections to indicate correct or loose cuff wrapping.
Recommendation	Equivalence is Recommended	
Date	21 March 2014	