dabl® Educational Trust

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2006

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SECTION A - Please complete all items online.

I Tomohiro Kukita (Name of a Company Director) Director of (Company name) Omron Healthcare Europe B.V.

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

Omron M2 (HEM-7119-E)
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Omron M3 Intellisense (HEM-7051-E)
Existing validated blood pressure measuring device

blood pressure measuring device, which has previously passed the International protocol, the results of which were published as follows

Asmar R, Khabouth J, Topouchian J, El Feghali R, Mattar J
Authors(s)

Validation of three automatic devices for self-measurement of blood pressure according to the International Protocol: The Omron M3 Intellisense (HEM-7051-E), the Omron M2 Compact (HEM 7102-E), and the Omron R3-I Plus (HEM 6022-E)
Title

Blood pressure monitoring
Publication

2010;15(1):49-54
Year Volume Pages

The only differences between the devices involve the following components:
(When a component is not relevant, both Yes and No should be left blank. Please provide details on any differences below.)

Part I	1	Algorithm for Oscillometric Measurements	Yes ☐	No ☒
	2	Algorithm for Auscultatory Measurements	Yes ☐	No ☐
	3	Artefact/Error Detection	Yes ☐	No ☒
	4	Microphone(s)	Yes ☐	No ☐
	5	Pressure Transducer	Yes ☒	No ☐
	6	Cuff or Bladder	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 ☐
	16	Communication Facilities	Yes ☐	No ☐
	17	Power Supply	Yes ☐	No ☒
	18	Other Facilities	Yes ☐	No ☒

Brief explanation of differences and further relevant details:

5) The pressure sensor is replaced to a piezo electric sensor (NPS) from a capacitive sensor (CPSU), but the accuracy of blood pressure measurement is equivalent between NPS and CPSU.

6) Outer cloth is changed, no change on the size, shape and material on bladder.

10) No Set button (Date and Time setting, Beeper ON/OFF setting).

11) No symbol for average of 3 readings in memory, no symbol for beeper ON/OFF, no symbol for date and time. Blood pressure level indicator and Cuff wrapping guide function are added.

13) No average function (average of the latest 3 readings in memory), no beeper control function, no date and time function.

14) 21 memories instead of 42 memories.

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SECTION B - Complete all items, bar signatures and seal, online and print. Sign and seal it then send the original along with manuals for both devices to our address below.

Signature of Director Tomohiro Kukita

Company Stamp/Seal

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Name Tomohiro Kukita

Date 28 June, 2012.

Signature of Witness M. Yoshimura

Name Minoru Yoshimura

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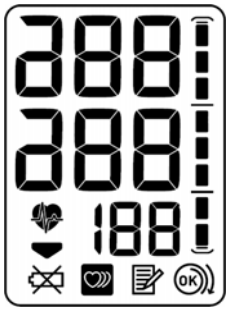
Comparison of the Omron M2 (HEM-7119-E) with the Omron M3 Intellisense (HEM-7051-E)

Devices	M2 (HEM-7119-E)	M3 Intellisense (HEM-7051-E)
Pictures		
Display		
Validation		ESH-IP 2002
Device 1 Criteria	***Measurement*** *Cuffs* Universal (Arm circ. 22-42 cm) (Optional) Note 2 — 6 ***Display/Symbols/Indicators*** *Preparation* Correct cuff wrapping indicator — 11, 13 ***Algorithms*** *Parameter Settings* Correct cuff wrapping detection — 13	
Same Criteria	***Measurement*** *Accuracy* BP accuracy ± 3 mmHg — 1, 5 Pulse accuracy ± 5% — 1, 5 *Method* Oscillometric measurement method — 1, 5	***Measurement*** *Accuracy* BP accuracy ± 3 mmHg — 1, 5 Pulse accuracy ± 5% — 1, 5 *Method* Oscillometric measurement method — 1, 5

Devices	M2 (HEM-7119-E)		M3 Intellisense (HEM-7051-E)	
Same Criteria (continued)	***Measurement (continued)***		***Measurement (continued)***	
	Method (continued)		*Method (continued)*	
	Pulse 40 bpm -180 bpm	1, 5	Pulse 40 bpm -180 bpm	1, 5
	Measurements are from single inflations	13	Measurements are from single inflations	13
	Manually initiated measurements	13, 14	Manually initiated measurements	13, 14
	Inflation		*Inflation*	
	Inflation 0 mmHg - 299 mmHg	1, 5, 7	Inflation 0 mmHg - 299 mmHg	1, 5, 7
	Automatic Inflation	7	Automatic Inflation	7
	Fuzzy Logic Query 1, Note 3	7	Fuzzy Logic Query 1, Note 3	7
	Press button if BP > 220 mmHg	7	Press button if BP > 220 mmHg	7
	Manually adjustable inflation pressure	7	Manually adjustable inflation pressure	7
	Deflation		*Deflation*	
	Automatic Deflation	8	Automatic Deflation	8
	Automatic safety release valve Query 1, Note 4	8	Automatic safety release valve Query 1, Note 4	8
	Cuffs		*Cuffs*	
	Medium 146 mm × 446 mm (Arm circ. 22 to 32 cm) Note 2	6	Medium 146 mm × 446 mm (Arm circ. 22 to 32 cm) Note 2	6
	Large (Arm circ. 32-42 cm) (Optional) Note 2	6	Large (Arm circ. 32-42 cm) (Optional) Note 2	6
	Buttons/Switches		***Buttons/Switches***	
	Power		*Power*	
	On/Off with Start/Stop (O/I Start Label)	10	On/Off with Start/Stop (O/I Start Label)	10
	Measurement Records		*Measurement Records*	
	Memory	10	Memory	10
	Display/Symbols/Indicators		***Display/Symbols/Indicators***	
	Measurement Procedure		*Measurement Procedure*	
	Deflation symbol	11	Deflation symbol	11
	Heartbeat symbol during deflation	11	Heartbeat symbol during deflation	11
	Post Measurement		*Post Measurement*	
	SBP, DBP and Pulse	11	SBP, DBP and Pulse	11
	Irregular heartbeat	11, 13	Irregular heartbeat	11, 13
	Measurement Records		*Measurement Records*	
	Memory icon Query 6	11	Memory icon Query 6	11
	Power		*Power*	
	Low battery	11, 17	Low battery	11, 17
	Algorithms		***Algorithms***	
	Diagnostic		*Diagnostic*	
	Normotension/Hypertension	13	Normotension/Hypertension	13
	135 / 85 mmHg thresholds	13	135 / 85 mmHg thresholds	13

Devices	M2 (HEM-7119-E)	M3 Intellisense (HEM-7051-E)
Same Criteria (continued)	***Algorithms (continued)***	***Algorithms (continued)***
	Diagnostic (continued)	*Diagnostic (continued)*
	Irregular heartbeat detection 13	Irregular heartbeat detection 13
	Case	***Case***
	Display	*Display*
	Single screen display 10	Single screen display 10
	Segment LCD 10	Segment LCD 10
	Power	*Power*
	AC adapter (Optional) 17	AC adapter (Optional) 17
	Automatic switch-off when not used for 5 min 17	Automatic switch-off when not used for 5 min 17
Comparable Criteria	***Measurement***	***Measurement***
	Measurement Records	*Measurement Records*
	Memory: 21 measurements 14	Memory: 42 measurements 14
	Sensors	*Sensors*
	Pressure sensor: piezo-resistive Note 1 5	Pressure sensor: capacitive Note 1 5
	Display/Symbols/Indicators	***Display/Symbols/Indicators***
	Post Measurement	*Post Measurement*
	Measurement error EE, E, E/E and Er Query 1, Note 5 11	Measurement error EE, E, E/E and E/o25 Query 1, Note 5 11
	Hypertension (Indicator strip) 11, 13	Hypertension (Blinking heartbeat) 11, 13
	Measurement Records	*Date and Time*
	Memory recall number (Replaces pulse rate momentarily) 11	Date and Time (During memory recall) 11
	Case	***Case***
	Power	*Power*
	4 “AAA” batteries ~ 300 measurements 17	4 “AA” batteries ~ 1500 measurements 17
Device 2 Criteria		***Buttons/Switches***
		Settings
		Set 10
		Display/Symbols/Indicators
		Measurement Procedure
		Audible pulse indicator during deflation (Optional) 18
		Beeps after measurement (Optional) 18
		Post Measurement
		Average symbol 11, 13
		Date and Time
		Date and Time 11
		Settings
		Audible pulse indicator mode active 11, 18

Devices	M2 (HEM-7119-E)	M3 Intellisense (HEM-7051-E)
Device 2 Criteria (continued)		***Algorithms*** *Averages* Last 3 measurements (within 10 min of each other) mean 13

Query	1	Query	There are differences in the descriptions of the rapid air release, fuzzy logic and error codes between the manuals. Similar queries were raised previously but it is not possible to infer scientifically that answers can be applied in these instances also. Can you confirm that the rapid air release and fuzzy logic are used in both devices and that the mapping of the errors, as described previously for specific devices also applies to these? Rapid Air Release — Fuzzy Logic — Error Codes[2] M2 (HEM-7119-E): No — No — E EE E/E Er/? M3 Intellisense (HEM-7051-E): Yes[1] — Yes — E EE E/E E/o*P* Note 1 This is not included in the manual but stated in a previous communication. Note 2 From previous communications, the errors are equivalent and grouped as shown and *P* refers to a pressure level. It is unclear from the manuals whether or not a pressure is shown for the HEM-7119-E.
		Response	*We confirm that rapid air release function and fuzzy logic are applied for all devices. Regarding to the error codes, please refer the document which we sent previously. For equivalent models of M3 Intellisense, a group1 error codes apply but we change the device error code from "Eo25" to "Er" in order to avoid confusion form our customers. ("25" is not pressure).*
		Comment	The explanation is accepted
	2	Query	The declaration states that there is "No symbol for memory" but a memory symbol is present.
		Response	*This is an error. We will correct the declaration.*
		Comment	The revised application is OK.
Notes	1		The Omron M2 (HEM-7117-E) was approved as equivalent to the Omron M3 Intellisense (HEM-7051-E) on 26/08/2010. The Omron M2 (HEM-7119-E) is similar to the M2 (HEM-7117-E) device except that a) The current pressure sensor (CPSU), a capacitive type, is changed to a new pressure sensor (NPS), a piezoelectric semiconductor type, b) An indicator is used to show hypertension rather than a blinking heartbeat and c) A feature for indicating when the cuff is correctly wrapped is added. Details of comparatives tests between the sensors have been reviewed by dabl®Educational. Furthermore, the Omron M6 Comfort (HEM-7221-E8), which is the same as the Omron M6 Comfort (HEM-7221-E) except for a similar change in sensor, has been validated using the ESH-IP 2010 protocol and is recommended for use. Following a review of these documents, it was concluded that the change in sensor would not have a detrimental effect on the accuracy of the device.

<table>
<tr><td rowspan="6"></td><td>2</td><td>There is a change in the cloth used for the cuffs between those used for the Omron M2 (HEM-7119-E) [CM2-9513256-6 Medium, CL2-9513255-8 Large and CW-9520534-2 Universal] and those used for the Omron M3 Intellisense (HEM-7051-E) [CM-4997086-7 & CM1-7935058-8 Medium and CL-4997065-4 Large]. The Omron M2 Basic (HEM-7116-E), approved for equivalence 26/08/2010 used CM2-9513256-6 & CM1-9997578-9 Medium and CL2-9513255-8 & CL1-9996760-3 Large.</td></tr>
<tr><td rowspan="2">3</td><td>This note from the equivalence application for the HEM-7117-E is also applicable to the HEM-7119-E.</td></tr>
<tr><td>The equivalent group of M3 Intellisense (HEM-7051-E) has the function of "Fuzzy logic", then M2 also has Fuzzy logic as well in this case. However, in our recent marketing approach some of models mention Fuzzy logic in the manual, some models do not mention, although all models in this group have Fuzzy logic. However, we put the explanation of automatic inflation in each instruction manual for users to understand the function in spite of using the word of Fuzzy logic. As Fuzzy logic is related to Inflation mechanism, we checked "no differences" on the Part I - Item 7 of declaration forms.</td></tr>
<tr><td rowspan="2">4</td><td>This note from the equivalence application for the HEM-7117-E is also applicable to the HEM-7119-E.</td></tr>
<tr><td>The fact we have is that the group of M3 Intellisense (HEM-7051-E) have same deflation mechanism. They have same valves for deflation system, as you mentioned, which are the regular deflation valve (slow deflation during measurement) and the rapid exhaust valve (release pressure rapidly from air system in the device after measurement to make comfortable and safe patients). Also these 2 valves are operated by automatic. In some device's manual e.g. M3 Intellisense (HEM-7051-E), we mention only "Deflation: Automatic pressure release valve" as one function of automatic deflation so that we could provide easy explanation to end users.</td></tr>
<tr><td rowspan="2">5</td><td>This note from the equivalence application for the HEM-7117-E is also applicable to the HEM-7119-E.</td></tr>
<tr><td>Regarding to Group1, when error appears in the device, the number in 2nd line indicates current air pressure. Therefore, EE and EE/0 indicates same error "cuff is under inflated" and also E and E/38 for measurement error. The number “0” and “38” means for “0mmHg” and “38mmHg”. These are no more than example description for manual. However, in order not to confuse users, we are not using this description in manual any more. Regarding to Eo25 and Er25, these indicates same error "device error". These differences come from hardware limitation from LCD display. We consider these error codes have no difference and there is no algorithm change.
Group 1 Error Codes
<table>
<tr><th>Models</th><th colspan="4">Error codes</th><th>Ref</th></tr>
<tr><td>M3 Intellisense</td><td>EE</td><td>E</td><td>E/E</td><td>Eo25</td><td>Z</td></tr>
<tr><td>M2</td><td>EE</td><td>E</td><td>E/E</td><td>Eo25</td><td>Z</td></tr>
<tr><td>M3</td><td>EE</td><td>E/38</td><td>E/E</td><td>Er25</td><td>Y</td></tr>
</table>
</td></tr>
<tr><td>Recommendation</td><td colspan="2">Equivalence is recommended.</td></tr>
<tr><td>Date</td><td colspan="2">02/07/2012</td></tr>
</table>