DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2006

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SECTION A - Please complete all items online.

I   **Tomohiro Kukita**   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

Omron M2 Basic (HEM-7116-E2)
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   **2010;15(1):49-54**
Publication   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.)

			Yes	No
Part I	1	Algorithm for Oscillometric Measurements	☐	☒
	2	Algorithm for Auscultatory Measurements	☐	☐
	3	Artefact/Error Detection	☐	☒
	4	Microphone(s)	☐	☐
	5	Pressure Transducer	☒	☐
	6	Cuff or Bladder	☒	☐
	7	Inflation Mechanism	☐	☒
	8	Deflation Mechanism	☐	☒
Part II	9	Model Name or Number	☒	☐
	10	Casing	☒	☐
	11	Display	☒	☐
	12	Carrying/Mounting Facilities	☐	☐
	13	Software other than Algorithm	☒	☐
	14	Memory Capacity/Number of stored measurements	☒	☐
	15	Printing Facilities	☐	☐
	16	Communication Facilities	☐	☐
	17	Power Supply	☐	☒
	18	Other Facilities	☐	☒

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), no Memory button.

11) No symbol for average of 3 readings in memory, no symbol for beeper ON/OFF, no symbol for date and time, no symbol for irregular heartbeat symbol. Blood pressure level indicator is added.

13) No average function (average of the latest 3 readings in memory), no beeper control function, no date and time function, no function to detect irregular heartbeat.
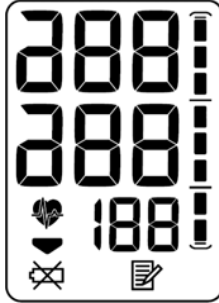
14) Previous memory instead of 42 memories.

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Signature of Director _Tomohiro Kukita_

Name   Tomohiro Kukita

Date   28 June, 20/2.

Signature of Witness _M. ..._

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Comparison of the Omron M2 Basic (HEM-7116-E2) with the Omron M3 Intellisense (HEM-7051-E)

Devices	M2 Basic (HEM-7116-E2)	M3 Intellisense (HEM-7051-E)
Pictures		
Display		
Validation		ESH-IP 2002
Device 1 Criteria	**Measurement** *Cuffs* Universal (Arm circ. 22-42 cm) (Optional)　　6	

Same Criteria	**Measurement**
	Accuracy
	  BP accuracy ± 3 mmHg　　1, 5
	  Pulse accuracy ± 5%　　1, 5
	Method
	  Oscillometric measurement method　　1, 5
	  Pulse 40 bpm -180 bpm　　1, 5
	  Measurements are from single inflations　　13
	  Manually initiated measurements　　13, 14
	Inflation
	  Inflation 0 mmHg - 299 mmHg　　1, 5, 7
		Measurement
		Accuracy
		  BP accuracy ± 3 mmHg　　1, 5
		  Pulse accuracy ± 5%　　1, 5
		Method
		  Oscillometric measurement method　　1, 5
		  Pulse 40 bpm -180 bpm　　1, 5
		  Measurements are from single inflations　　13
		  Manually initiated measurements　　13, 14
		Inflation
		  Inflation 0 mmHg - 299 mmHg　　1, 5, 7

Devices	M2 Basic (HEM-7116-E2)		M3 Intellisense (HEM-7051-E)	
Same Criteria (continued)	***Measurement (continued)***		***Measurement (continued)***	
	Inflation (continued)		*Inflation (continued)*	
	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)	6	Large (Arm circ. 32-42 cm) (Optional)	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
	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
	Measurement Records		*Measurement Records*	
	Memory icon	11	Memory icon	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	10, 11, 13	135 / 85 mmHg thresholds	10, 11, 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

Devices	M2 Basic (HEM-7116-E2)		M3 Intellisense (HEM-7051-E)	
Comparable Criteria	***Measurement***		***Measurement***	
	Sensors		*Sensors*	
	Pressure sensor: piezo-resistive [Note 1]	5	Pressure sensor: capacitive [Note 1]	
	Measurement Records		*Measurement Records*	
	Memory: 1 measurement	14	Memory: 42 measurements	14
	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
	Case		***Case***	
	Power		*Power*	
	4 "AAA" batteries ~ 300 measurements	17	4 "AA" batteries ~ 1500 measurements	17
Device 2 Criteria			***Buttons/Switches***	
			Measurement Records	
			Memory	10
			Settings	
			Set	10
			Display/Symbols/Indicators	
			Measurement Procedure	
			Audible pulse indicator during deflation (Optional)	18
			Beeps after measurement (Optional)	18
			Post Measurement	
			Irregular heartbeat	11, 13
			Average symbol	11, 13
			Date and Time	
			Date and Time	11
			Date and Time (During memory recall)	11
			Settings	
			Audible pulse indicator mode active	11, 18
			Algorithms	
			Averages	
			Last 3 measurements (within 10 min of each other) mean	13
			Diagnostic	
			Irregular heartbeat detection	13

Query			
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 Basic (HEM-7116-E2) 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-7116-E2.
		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 Basic (HEM-7116-E) was approved as equivalent to the Omron M3 Intellisense (HEM-7051-E) on 26/08/2010. The Omron M2 Basic (HEM-7116-E2) is similar to the M2 Basic (HEM-7116-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 and b) An indicator is used to show hypertension rather than a blinking heartbeat.
			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.
	2		There is a change in the cloth used for the cuffs between those used for the Omron M2 Basic (HEM-7116-E2) [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.

	3	This note from the equivalence application for the HEM-7116-E is also applicable to the HEM-7116-E2.
		The equivalent group of M3 Intellisense (HEM-7051-E) has the function of "Fuzzy logic", then M2 Basic (HEM-7116-E) 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.
	4	This note from the equivalence application for the HEM-7116-E is also applicable to the HEM-7116-E2.
		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.
	5	This note from Omron is applicable to the HEM-7116-E2.
		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

Models	Error codes				Ref
M3 Intellisense	EE	E	E/E	Eo25	Z
M2 Basic	EE	E	E/E	Eo25	Z
M3	EE	E/38	E/E	Er25	Y

Recommendation	Equivalence is recommended.
Date	02/07/2012