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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 Omron Healthcare Europe B.V. (Company name)

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

Omron BP785 (HEM-7222-Z)
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Omron M6 Comfort (HEM-7000-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

Belghazi J, El Feghali RN, Moussalem T, Rejdych M, Asmar RG
Authors(s)

Validation of four automatic devices for self-measurement of blood pressure according to the International Protocol of the European Society of Hypertension
Title

Vascular Health and Risk Management — 2007;3(4):389-400
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.)

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.

10) The "user ID selection" switch, the "Morning/Evening Average" switch and the "Memory" switch are added.

11) The symbol for cuff wrapping guide, the indicator for blood pressure level, the morning hypertension symbol, the morning average symbol, the evening average symbol, the week display, the user ID symbol and the TruRead™ symbol are added.

13) The function to guide cuff wrapping, the function to detect morning hypertension, the function to calculate a weekly averages for measurements taken in the morning and evening and the function to take three consecutive measurements (TruRead™) are included.

14) Stores 100 readings each for two users instead of 90 readings for one user.

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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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Date 8th June, 2011

Signature of Witness J. Meijer-Dijl

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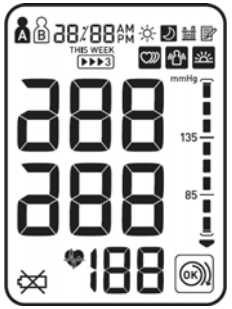
Comparison of the Omron BP785 (HEM-7222-Z) with the Omron M6 Comfort (HEM-7000-E)

Devices	Omron BP785 (HEM-7222-Z)	Omron M6 Comfort (HEM-7000-E)
Pictures		
Display		
Validation		ESH-IP 2002
Device 1 Criteria	***Measurement*** *Sensors* Pressure sensor: 2nd sensor for dual check 5 ***Buttons/Switches*** *Measurement Records* User ID 10 *Analysis* Morning/Evening Average 10 ***Display/Symbols/Indicators*** *Preparation* Correct cuff wrapping indicator 11, 13, 18 Multiple measurements (3) 11, 13 *Measurement Records* User (A or B) + Guest 11	

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Devices	Omron BP785 (HEM-7222-Z)		Omron M6 Comfort (HEM-7000-E)	
Device 1 Criteria (continued)	***Display/Symbols/Indicators (continued)***			
	Post Measurement			
	Morning hypertension (rising sun)	11, 13		
	Daytime weekly average (sun)	11, 13		
	Night-time weekly average (moon)	11, 13		
	Week indicator	11, 13		
	Settings			
	Sensor cross check (LED)	5, 18		
	Algorithms			
	Averages and Differences			
	Daytime weekly average × 8 weeks	13		
	Night weekly average × 8 weeks	13		
	Parameter Settings			
	Correct cuff wrapping detection	13		
	Sensor cross check	5, 18		
Same Criteria	***Measurement***		***Measurement***	
	Accuracy		*Accuracy*	
	BP accuracy ± 3 mmHg or ± 2% Query 1	1, 5	BP accuracy ± 3 mmHg Query 1	1, 5
	Pulse accuracy ± 5%	1, 5	Pulse accuracy ± 5%	1, 5
	Method		*Method*	
	Oscillometric measurement method	1, 5	Oscillometric measurement method	1, 5
	Pulse 40 bpm – 180 bpm	1, 5, 8	Pulse 40 bpm – 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 – 299 mmHg	1, 5, 7	Inflation 0 mmHg – 299 mmHg	1, 5, 7
	Automatic Inflation	7	Automatic Inflation	7
	Fuzzy Logic Query 2	7	Fuzzy Logic Query 2	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 2	8	Automatic safety release valve Query 2	8
	Cuffs		*Cuffs*	
	Single 152 mm × 600 mm (Arm circ. 22 to 42 cm)	6	Single 152 mm × 600 mm (Arm circ. 22 to 42 cm)	6

Devices	Omron BP785 (HEM-7222-Z)	Omron M6 Comfort (HEM-7000-E)
Same Criteria (continued)	***Buttons/Switches***	***Buttons/Switches***
	Power	*Power*
	On/Off with Start/Stop (Start/Stop Label) 10	On/Off with Start/Stop (O/I Start Label) 10
	Settings	*Settings*
	Date/Time set 10	Date/Time set 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
	Average icon 11, 13, 14	Average icon 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) Query 3 11	Memory recall number (Replaces pulse rate momentarily) Query 3 11
	Date and Time	*Date and Time*
	Date and Time 11	Date and Time 11
	Date and Time (During memory recall) 11	Date and Time (During memory recall) 11
	Power	*Power*
	Low battery 11, 17	Low battery 11, 17
	Algorithms	***Algorithms***
	Averages and Differences	*Averages and Differences*
	Last 3 measurements (within 10 min of each other) mean 13	Last 3 measurements (within 10 min of each other) mean 13
	Diagnostic	*Diagnostic*
	Normotension/Hypertension 13	Normotension/Hypertension 13
	135 / 85 mmHg thresholds 13	135 / 85 mmHg thresholds 13
	Irregular heartbeat detection 13	Irregular heartbeat detection 13
	Body movement error detection 3, 13	Body movement error detection 3, 13
	Case	***Case***
	Display	*Display*
	Single screen display 10	Single screen display 10
	Segment LCD 10	Segment LCD 10
	Power	*Power*
	4 “AA” batteries ~ 500 measurements 17	4 “AA” batteries ~ 1500 measurements 17
	AC adapter 17	AC adapter (Optional) 17

Devices	Omron BP785 (HEM-7222-Z)	Omron M6 Comfort (HEM-7000-E)
Comparable Criteria	***Measurement*** *Sensors* Pressure sensor: piezo-resistive [Note 1] 5 *Measurement Records* Memory: 100 measurements × 2 14 ***Buttons/Switches*** *Measurement Records* Memory 10 *Settings* Up and down 10 ***Display/Symbols/Indicators*** *Post Measurement* Measurement error E 1, E2, E3, E4, E5 and Er [Query 2, Note 2] 11 Hypertension (Indicator strip) 11, 13 ***Case*** *Power* Automatic switch-off when not used for 2 min 17	***Measurement*** *Sensors* Pressure sensor: capacitive [Note 1] 5 *Measurement Records* Memory: 90 measurements 14 ***Buttons/Switches*** *Measurement Records* Memory × 2 10 *S* U ***Display/Symbols/Indicators*** *Post Measurement* Measurement error EE/0, E and E/E [Query 2, Note 2] 11 Hypertension (Blinking heartbeat) 11, 13 ***Case*** *Power* Automatic switch-off when not used for 5 min 17
Device 2 Criteria		

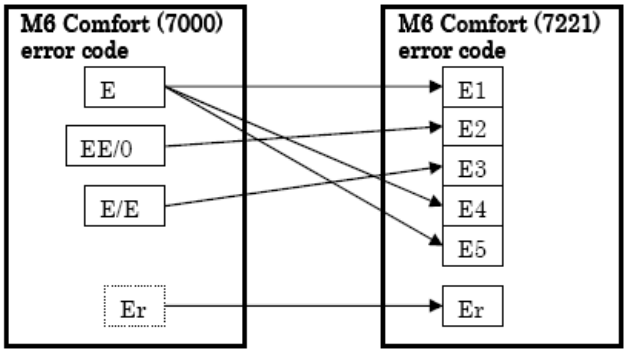
Queries			
	1	Query	BP accuracy is claimed to be ± 3 mmHg for the M6 Comfort (HEM-7000-E) but ± 3 mmHg or ± 2% for the BP785 (HEM-7222-Z). Can you clarify how these differ, both for pressures above and below 150 mmHg (where the 2% error equals 3 mmHg)?
		Response	*BP785 have as same BP accuracy as M6 Comfort (± 3 mmHg). The description "±3mmHg or 2% of reading" comes from the requirement of AAMI SP-10:2008 which is one of the standard for medical device in US. (BP785 are available in US market.) Please find the excerpt from the standard as following.* 4.4.4.B Pressure transducer accuracy At any single condition within the ambient temperature range of 50 °F to 104 °F (10 °C to 40 °C) and the relative humidity range of 15 % to 90 % (non-condensing), both for increasing and for decreasing pressure, the maximum error for the measurement of the cuff pressure at any point of the scale range shall be ± 3 mmHg (± 0.4 kPa) or 2 % of the reading above 200 mmHg.
		Comment	The explanation is accepted
	2	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]

		BP785 (HEM-7222-Z) Yes No E1 E4 E5 E2 E3 Er M6 Comfort (HEM-7000-E) No Yes E EE/P E/E 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. 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.* Comment The explanation is accepted
	3	Query On the respective diagrams for the unit display, the pulse display is also indicated as having a memory number function. This, latter function is not described elsewhere in the manuals. Is this an error in the description or, as described for other devices, does the memory number flash briefly when displaying previous measurements. If so, what is flashed when TruRead averages are shown? Response *As described for other devices, the memory number flash briefly when displaying previous measurements. For BP785, memory number is shown before the average is displayed. Memory number is not shown when the values for the individual measurement is displayed.* Comment The explanation is accepted
Notes	1	The sensors used in the Omron M6 Comfort (HEM-7000-E) is known as the "current pressure sensor" (CPSU), a capacitive type, which is being replaced by as new pressure sensor (NPS), a piezoelectric semiconductor type. This is used in the Omron BP785 (HEM-7222-Z). 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	This note from the equivalence application for the HEM-7221-E is also relevant to the HEM-7222-Z.
		Regarding to Group 4, M6 Comfort (7000) error code E had subdivide to M6 Comfort (7221) error code E1, E4 and E5. EE/0 is as same as E2. E/E is as same as E3. The background is explained below. For M6 Comfort (7000), EE/0 is as same as EE, 0 means 0mmHg, and this has the error code Er, but not described in manual. We consider there is no change in the error codes and algorithms among these devices. *For our software, error codes consist of several error judgment conditions. We had a limitation to show enough information on the display in the past due to technical restriction on hardware. For now, the hardware performance has advanced to display more error code. Therefore, we reconsidered the constitution of the error judgment conditions and changed the expression to make it more easy to*

understand for users, starting from M6 (HEM-7211-E) and M6 Comfort (HEM-7221-E).

Group 4 Error Codes

Model	Error codes					
M6 Comfort (7000)	EE/0	E	E/E			
M6 Comfort (7221)	E1	E2	E3	E2	E5	Er



Recommendation	Equivalence is recommended.
Date	02/07/2012