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 Omron Healthcare Europe B.V. (Company name)

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

Omron M6 (HEM-7211-E8)
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Omron 705IT (HEM-759-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

El Assaad, Mohamed A.; Topouchian, Jirar A.; Asmar, Roland G
Authors(s)

Evaluation of two devices for self-measurement of blood pressure according to the international protocol: the Omron M5-I and the Omron 705IT
Title

Blood pressure monitoring
Publication

2003;8(3):127-133
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 power button (the start button is used for power on and measurement start.). No adjust button. The up button and down button are added. No USB port.

11) No symbol for inflation. The symbol for average value, the symbol for irregular heart beat, the symbol for body motion, the symbol for cuff wrapping guide and the indicator for blood pressure level are added.

The dual check system indicator (LED) is added.

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13) The function to detect irregular heat beat, the function to detect body motion, the function to average of memories (average of the latest 3 measurements), the function to guide cuff wrapping and the function to check the pressure sensor ("the dual check system") are included.

14) Stores 90 readings instead of 28.

15) No Printing Facilities.

16) No communication facilities.

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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 29. June 2011.

Signature of Witness J. Meijer

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Comparison of the Omron M6 (HEM-7211-E8) with the Omron 705IT (HEM-759-E)

Devices	Omron M6 (HEM-7211-E8)	Omron 705IT (HEM-759-E)
Pictures		
Display		
Validation		ESH-IP 2002
Device 1 Criteria	***Measurement*** *Sensors* Pressure sensor: 2nd sensor for dual check 5 ***Buttons/Switches*** *Settings* Up and down 10 ***Display/Symbols/Indicators*** *Preparation* Correct cuff wrapping indicator 11, 13, 18 *Post Measurement* Hypertension (Indicator strip) 11, 13 Average icon 11, 13, 14 Body movement error 3, 11, 13, 18 Irregular heartbeat 11, 13, 18	

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Devices	Omron M6 (HEM-7211-E8)		Omron 705IT (HEM-759-E)	
Device 1 Criteria (continued)	***Display/Symbols/Indicators (continued)***			
	Settings			
	Sensor cross check (LED)	5, 18		
	Algorithms			
	Averages and Differences			
	Last 3 measurements (within 10 min of each other) mean	13		
	Diagnostic			
	Normotension/Hypertension	13		
	135 / 85 mmHg thresholds	13		
	Irregular heartbeat detection	13		
	Body movement error detection	3, 13		
	Parameter Settings			
	Correct cuff wrapping detection	13		
	Sensor cross check	5, 18		
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
	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	7	Fuzzy Logic	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
	Cuffs		*Cuffs*	
	Large (Arm circ. 32-42 cm) (Optional) Note 2	6	Large (Arm circ. 32-42 cm) (Optional) Note 2	6
	Small (Arm circ. 17-22 cm) (Optional) Note 2	6	Small (Arm circ. 17-22 cm) (Optional) Note 2	6

Devices	Omron M6 (HEM-7211-E8)		Omron 705IT (HEM-759-E)	
Same Criteria (continued)	***Buttons/Switches***		***Buttons/Switches***	
	Measurement Records		*Measurement Records*	
	Memory	10	Memory	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
	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
	Case		***Case***	
	Display		*Display*	
	Segment LCD	10	Segment LCD	10
	Power		*Power*	
	AC adapter (Optional)	17	AC adapter (Optional)	17
Comparable Criteria	***Measurement***		***Measurement***	
	Cuffs		*Cuffs*	
	Medium 146 mm × 446 mm (Arm circ. 22 to 32 cm) Note 2	6	Medium 140 mm × 480 mm (Arm circ. 22 to 32 cm) Note 2	6
	Sensors		*Sensors*	
	Pressure sensor: piezo-resistive Note 1	5	Pressure sensor: capacitive Note 1	5
	Measurement Records		*Measurement Records*	
	Memory: 90 measurements	14	Memory: 28 measurements	14
	Buttons/Switches		***Buttons/Switches***	
	Power		*Power*	
	On/Off with Start/Stop (O/I Label)	10	On/Off with Stop (O/I Label)	10
			Start	10
	Settings		*Settings*	
	Date/Time set	10	Adjust	10
			Set	10
	Display/Symbols/Indicators		***Display/Symbols/Indicators***	
	Post Measurement		*Post Measurement*	
	Measurement error E 1, E2, E3, E4, E5 and Er Note 3	11	Measurement error E and Er Note 3	11
	Measurement Records		*Measurement Records*	
	Memory icon	11	Memory “M” symbol	11

Devices	Omron M6 (HEM-7211-E8)	Omron 705IT (HEM-759-E)
Comparable Criteria (continued)	***Case*** *Display* Single screen display 10 *Power* 4 "AA" batteries ~ 1500 measurements 17 Automatic switch-off when not used for 2 min 17	***Case*** *Display* Dual screen display 10 *Power* 4 "AA" (LR6) batteries ~ 300 measurements 17 Automatic switch-off when not used for 5 min 17
Device 2 Criteria		***Display/Symbols/Indicators*** *Measurement Procedure* Inflation symbol 11 ***Case*** *Ports* USB/Printer port 15 USB port, cable and PC software 16, 18 *Features* Optional printer 15

Query	1	Query a) The cuffs for the Omron M6 (HEM-7211-E8) are the same as those for the Omron M6 (HEM-7211-E). In the equivalence application for the Omron M6 (HEM-7211-E) on 17/02/2010, a change in the cloth was declared. Tables and figures were supplied in response to a query at that time. The equivalence for the Omron M6 (HEM-7211-E8) is against the same device. Yet this difference is not included. Please explain. b) The dual check system (function and LED) is not included in the declaration. c) The fact that a printing facility is included in the Omron 705IT (HEM-759-E) but not in the Omron M6 (HEM-7211-E8) is not included in the declaration Response a) *This was mistake. Please confirm the revised application.* b) *This was mistake. Please confirm the revised application.* c) *This was mistake. Please confirm the revised application.* Comment The revised application is OK.
Notes	1	The Omron M6 (HEM-7211-E) was approved as equivalent to the Omron 705IT (HEM-759-E) on 26/08/2010. The Omron M6 (HEM-7211-E8) is identical to the M6 (HEM-7211-E) device except that the current pressure sensor (CPSU), a capacitive type, is changed to a new pressure sensor (NPS), a piezoelectric semiconductor type. Details of comparatives tests 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.

The manual for the HEM-7211-E was updated to refer to the HEM-7211-E and HEM-7211-E8. The main difference was the removal of the pressure detection item in the technical data section. The optional AC adapter has also changed.

2

This query from the equivalence application for the HEM-7211-E is also applicable to the HEM-7211-E8.

Query There appear to be some differences in the cuffs supplied with the monitors.

a) There are different part numbers between those listed for the devices. These match the declaration of the different cloth covers. No difference is made in the declaration. It is taken that there are no changes.

b) It is understood that the cloth changes apply to the large cuffs also.

c) The dimensions of the cuff supplied with the Omron M6 (HEM-7211-E) differ from that supplied with the Omron 705IT (HEM-759-E), with which it is being compared. However, the declaration declares only a change in the outer cloth and that there is no change in size. Please explain.

Response a) *These cuffs have no differences except cloth covers. The parts number difference comes from different cloth covers.*

b) *These cuffs have no differences except cloth covers.*

c) *Please confirm chart1 which explains the relation between the models and dimensions.*

Models and cuff dimensions

Models	Dimensions (in manual)
705IT	140 mm x 480 mm
M6	146 mm x 446 mm

The actual size of these cuffs is same (Fig1).

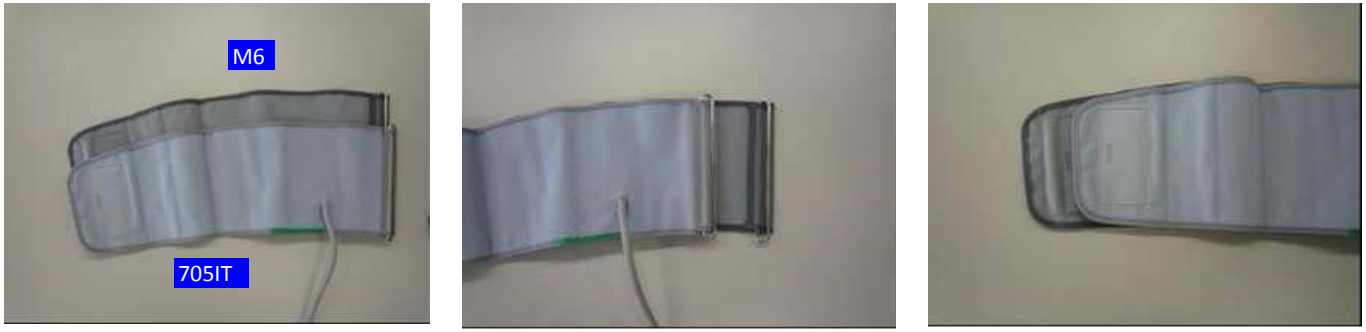


Fig1 Size comparison

The dimensions in manual were different because the measurement point was different. (Fig4)

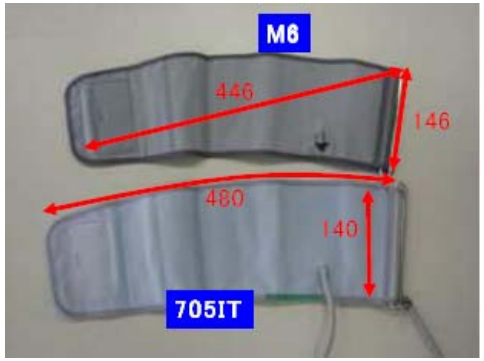


Fig2 Measurement point

However, this does not make any difference to measurement accuracy because the dimensions of bladder are all the same. In order not to confuse users, we will standardize the measurement point of cuff and describe the standardize dimensions in the manual.

Comment The explanation is accepted

3

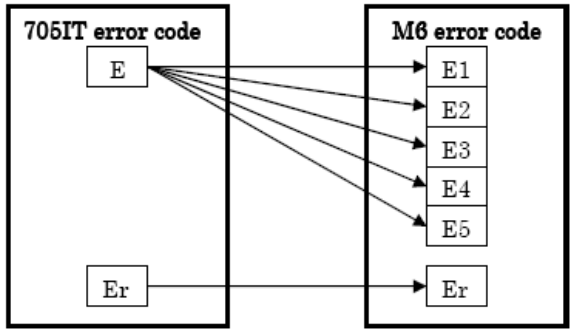
This query from the equivalence application for the HEM-7211-E is also applicable to the HEM-7211-E8.

Query There appear to be some differences in the error codes (apart from the extra features) which would not be expected if there were no algorithm changes. In the list, a slash indicates a line break where the error code is on two lines. Please explain.

Response *Regarding to Group 3, the 705IT error code E had subdivide to E1, E2, E3, E4 and E5. 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 3 Error Codes

Model	Error codes					
705IT	E					Er
M6	E1	E2	E3	E2	E5	Er

		 Comment The explanation is accepted
Recommendation	Equivalence is recommended.	
Date	02/07/2012	