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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 M3 (HEM-7200-E8)
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

Journal of Hypertension (Publication) 2006;24(suppl 4):S278 (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) The up button and the down button are added.

11) The symbol for body motion, the symbol for cuff wrapping guide and the indicator for blood pressure level are added.

13) The function to detect body motion and the function to guide cuff wrapping are included.

14) 60 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 29 June 2011.

Signature of Witness J. Meijer-Due

Name Janet Meijer

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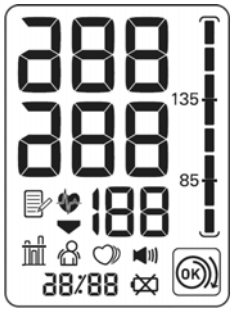
Comparison of the Omron M3 (HEM-7200-E8) with the Omron M3 Intellisense (HEM-7051-E)

Devices	M3 (HEM-7200-E8)	M3 Intellisense (HEM-7051-E)
Pictures		
Display		
Validation		ESH-IP 2002
Device 1 Criteria	***Buttons/Switches*** *Settings* Up and down 10 ***Display/Symbols/Indicators*** *Preparation* Correct cuff wrapping indicator 11, 13 *Post Measurement* Body movement error 3, 11, 13 ***Algorithms*** *Parameter Settings* Correct cuff wrapping detection 13 *Diagnostic* Body movement error detection 3, 13	

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Devices	M3 (HEM-7200-E8)		M3 Intellisense (HEM-7051-E)	
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	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	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
	Automatic safety release valve [Note 2]	8	Automatic safety release valve [Note 2]	8
	Cuffs		*Cuffs*	
	Medium 146 mm × 446 mm (Arm circ. 22 to 32 cm) [Note 3]	6	Medium 146 mm × 446 mm (Arm circ. 22 to 32 cm) [Note 3]	6
	Large (Arm circ. 32-42 cm) (Optional) [Note 3]	6	Large (Arm circ. 32-42 cm) (Optional) [Note 3]	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
	Settings		*Settings*	
	Set	10	Set	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
	Audible pulse indicator during deflation (Optional)	18	Audible pulse indicator during deflation (Optional)	18
	Beeps after measurement (Optional)	18	Beeps after measurement (Optional)	18
	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

Devices	M3 (HEM-7200-E8)		M3 Intellisense (HEM-7051-E)	
Same Criteria (continued)	***Display/Symbols/Indicators (continued)***		***Display/Symbols/Indicators (continued)***	
	Post Measurement		*Post Measurement*	
	SBP, DBP and Pulse	11	SBP, DBP and Pulse	11
	Irregular heartbeat	11, 13	Irregular heartbeat	11, 13
	Average symbol	11, 13	Average symbol	11, 13
	Measurement Records		*Measurement Records*	
	Memory icon	11	Memory icon	11
	Power		*Power*	
	Low battery	11, 17	Low battery	11, 17
	Settings		*Settings*	
	Audible pulse indicator mode active	11, 18	Audible pulse indicator mode active	11, 18
	Algorithms		***Algorithms***	
	Averages		*Averages*	
	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
	Case		***Case***	
	Display		*Display*	
	Single screen display	10	Single screen display	10
	Segment LCD	10	Segment LCD	10
	Power		*Power*	
	4 “AA” batteries ~ 1500 measurements	17	4 “AA” batteries ~ 1500 measurements	17
	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: 60 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/25 [Note 4]	11	Measurement error EE, E, E/E and E025 [Note 4]	11
	Hypertension (Indicator strip)	11, 13	Hypertension (Blinking heartbeat)	11, 13
Device 2 Criteria				

<table>
<tr><td rowspan="3">Queries</td><td rowspan="2">1</td><td>Query</td><td>Even though the application is for equivalence against the Omron M3 Intellisense (HEM-7051-E), the fact that the Omron M2 (HEM-7117-E) was previously approved against the same device is an important consideration. The only expected difference in the applications would therefore be the change in sensor.

There appears to be a change in the console weight according to the respective manuals

Weight (g)
Omron M3 (HEM-7200-E) 360
Omron M3 (HEM-7200-E8) 340</td></tr>
<tr><td>Response</td><td>We corrected the specification in the manual of Omron M3 (HEM-7200-E8) because we found that the previous Omron M3 (HEM-7200-E) was not correct.

Comment The explanation is accepted</td></tr>
<tr><td>2</td><td>Query</td><td>The cuffs for the Omron M3 (HEM-7200-E8) are the same as those for the Omron M3 (HEM-7200-E). In the equivalence application for the Omron M3 (HEM-7200-E) on 17/02/2010, a change in the cloth was declared. The equivalence for the Omron M3 (HEM-7200-E8) is against the same device. Yet this difference is not included. Please explain.

Response This was mistake. Please confirm the revised application.

Comment The revised application is OK.</td></tr>
<tr><td rowspan="3">Notes</td><td>1</td><td colspan="2">The Omron M3 (HEM-7200-E) was approved as equivalent to the Omron M3 Intellisense (HEM-7051-E) on 26/08/2010. The Omron M3 (HEM-7200-E8) is identical to the M3 (HEM-7200-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-7200-E was updated to refer to the HEM-7200-E and HEM-7200-E8. The manual for the HEM-7200-E was updated to refer to the HEM-7200-E and HEM-7200-E8. The main difference was the removal of the pressure detection item in the technical data section. The optional AC adapter has also changed.</td></tr>
<tr><td rowspan="2">2</td><td colspan="2">This note from the equivalence application for the HEM-7200-E is also applicable to the HEM-7200-E8.</td></tr>
<tr><td>Note</td><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</td></tr>
</table>

<table>
<tr><td></td><td></td><td>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></td><td>3</td><td>This query from the equivalence application for the HEM-7200-E is also applicable to the HEM-7200-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 1, when error appears in the device, the number in 2nd line indicates current air pressure. Regarding to Eo25 and Er25, these indicates same error "device error". These differences come from hardware limitation from LCD display.

Group 1 Error Codes
<table><tr><th>Model</th><th colspan="4">Error codes</th></tr><tr><td>M3 Intellisense</td><td>EE</td><td>E</td><td>E/E</td><td>Eo25</td></tr><tr><td>M3</td><td>EE</td><td>E</td><td>E/E</td><td>Er25</td></tr></table>
Comment The explanation is accepted</td></tr>
<tr><td></td><td>4</td><td>This query from the equivalence application for the HEM-7200-E is also applicable to the HEM-7200-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.

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.

Comment The explanation is accepted</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>