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DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2006

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SECTION A - Please complete all items online.

I Takefumi Nakanishi (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 i-C10 (HEM-7070-E)
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Omron M7 (HEM-780-E)
Existing validated blood pressure measuring device

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

Andrew Coleman, Stephen Steel, Paul Freeman, Annemarie de Greeff and Andrew Shennan
Authors(s)
Validation of the Omron M7 (HEM-780-E) oscillometric blood pressure monitoring device according to the British Hypertension Society protocol
Title
Blood Pressure Monitoring
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:

10) includes 1 Start button instead of 2 buttons (Power ON and Start), includes 1 memory button (to see the individual readings) instead of 2 memory button, includes memory button for Morning time and Evening time, includes 2 user button, includes cuff compartment

11) includes symbol for Irregular Heartbeat detection, includes symbol for the indicator of Hypertension, includes error symbol for the indicator of Body movement, no symbol for the inflation status, includes symbol for 2 user, includes symbol for the high blood pressure in morning, includes symbol for the weekly average readings in Moring and Evening, includes symbol for Auto-mode (3 continuous measurements)

13) includes the function of weekly average in Morning and Evening, includes Auto-mode (3 continuous measurements), includes Irregular Heartbeat detection function, includes Hypertension indicator function, includes Body movement error indicator

14) 84 x 2 user readings in memory instead of 90 readings

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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 _____

Name Takefumi Nakanishi

Date 30 July. 2008

Signature of Witness _____

Name Janet Meijer

Address Omron Healthcare Europe B.V., Kruisweg 577, 2132NA Hoofddorp, The Netherlands

Company Stamp/Seal

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Comparison of the Omron i-C10 with the Omron M7

Devices	Omron i-C10 (HEM-7070-E)	Omron M7 (HEM-780-E)
Pictures		
Validation		BHS
Device 1 Criteria	Body movement error indicator 3, 11, 13 Cuff Compartment 10 User ID switch, symbol 10, 11 Auto mode (3 continuous measurements) 10, 11, 13 Morning/Evening Average buttons and algorithms 10, 11, 13 Hypertension indicator 11, 13 Irregular heartbeat detection 11, 13 Morning hypertension symbol 11, 13	
Same Criteria	Accuracy ± 3 mmHg 1, 5 BP 0 mmHg to 299 mmHg, Pulse 40-180 bpm 1, 5, 7, 8 Pressure detection by “capacitive” pressure sensor 5 Date/Time Display 11 Last 3 measurements averages 13	Accuracy ± 3 mmHg 1, 5 BP 0 mmHg to 299 mmHg, Pulse 40-180 bpm 1, 5, 7, 8 Pressure detection by “capacitive” pressure sensor 5 Date/Time Display 11 Last 3 measurements averages 13
Comparable Criteria	Cuff: 152 mm × 600 mm (Arm circ. 22 to 42 cm) 6 O/I Start button 10 Set Button 10 Single screen display 10 Memory button, memory symbol 10, 11 During Measurement: Deflation & Heartbeat Symbols 11 Memory: 84 measurements × 2 users 11, 14 Power: 4 “AA” batteries ~ 1400 measurements 17 Power: Optional AC adapter 17	Cuff: 150 mm × 582 mm (Arm circ. 22 to 42 cm) 6 On and Start buttons 10 Date/Time setting button 10 Two screen display 10 Two memory buttons (previous/next) , memory symbol 10, 11 During Measurement: Inflation, Deflation & Heart Symbols 11 Memory: 90 measurements 11, 14 Power: 4 “AA” batteries ~ 300 measurements 17 Power: Optional AC adapter (In Tech. Specs/Not in Diagram) 17
Device 2 Criteria		
Web link		http://www.omron-healthcare.com/sitepreview.php?SiteID=221

Comments	Bar the removal of the USB facility, the i-C10 appears to be almost identical to the M-10IT with the casing extended to be a built-in carry case, including the cuff compartment and cover. Issues relating to the Declaration of Equivalence for the M-10IT can also ne reasonably applied to the i-C10 as the technology appears to be identical. Some queries were sent to Omron and were answered adequately on that occasion and the responses are included here. 1 Pressure sensor: A query was sent to Omron concerning "capacitive" and "electrostatic" sensors when comparing the M10-IT to the M7. *The pressure sensor in the M10-IT is described as "capacitive" whereas that of the M7 is described as "electrostatic". No references to these differences are made in the declaration form in which Item 5 (Pressure Transducer) is marked as indicating no differences between the devices.* Their reply was accepted *We can say that the sensor is completely same on both M10-IT and M7, though there are a bit different description in the instruction manuals. The sensor is "capacity" type, we normally say "Capacitive pressure sensor". We have put the "Electrostatic capacity pressure sensor" on the instruction manual of M7 accidentally. If this difference can not allow us to say that the pressure sensor is same, we are going to revise our description on M7 instruction manual immediately.* 2 Body movement error detection: A query was sent to Omron concerning possible issues relating to artefact detection. *This is declared under Item 13 (Software other than Algorithm) rather than Item 3 (Artefact/Error Detection) which is marked as indicating no differences between the devices.* Their reply was accepted *Both M10-IT and M7 has completely same function on Item 3 (Artefact/Error Detection). Our "Body movement error" on M10-IT is the additional function on Item 3. M10-IT can show the error same as M7 in case there are some artefact during the measurement and M10-IT can show Body movement mark on its display in case it is estimated there are especially arm movement. This Body movement function can not give any factor to the measurement result. We have thought we should say "Body movement detection function" in the equivalent form.* 3 Cuffs: The description of the cuffs in the manual for the M7 is slightly different from in the manuals for the M10-IT, the M6 Comfort and i-C10. On their website, they are described as the ML ComfortCuff® for the M7, the M10-IT and the M6 Comfort. The i-C10 is not yet listed on the website but the description matches that in the manuals for the M10-IT and the M6 Comfort. It appears to be the same cuff. 4 Batteries: Batteries appear to last 4 to 5 times longer in the i-C10 than in the M7. This may be due to improvements in battery technology reflected in the newer manual.
Recommendation	Equivalence is recommended
Date	06/10/2008