

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2006

A SIGNED COPY WILL BE POSTED ON THE www.dableducational.org WEBSITE

SECTION A - Please complete all items online.

I Takefumi Nakanishi 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 i-C10 (HEM-7070-E)

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

Jalil Belghazi, Ramzi N El Feghali, Thérèse Moussalem, Maya Rejdych, Roland G Asmar

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) 1-12

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

Brief explanation of differences and further relevant details:

10) 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 2 user, includes symbol for the high blood pressure in morning, includes symbol for the weekly average readings in Morning 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)

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 T. Nakanishi

Name Takefumi Nakanishi

Date 30 July, 2008

Signature of Witness J. Meijer

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 M6 Comfort

Devices	Omron i-C10 (HEM-7070-E)	Omron M6 Comfort (HEM-7000-E)
Pictures		
Validation		ESH
Device 1 Criteria	Cuff Compartment 10 User ID switch, symbol 10, 11 Auto mode (3 continuous measurements - button, symbol) 10, 11, 13 Morning/Evening weekly Average buttons and algorithms 10, 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 Body movement error indicator 3, 11, 13 Pressure detection by “capacitive” pressure sensor 5 Cuff: 152 mm × 600 mm (Arm circ. 22 to 42 cm) 6 O/I Start button 10 Single screen display 10 Date/Time Display 11 During Measurement: Deflation & Heartbeat Symbols 11 Hypertension indicator 11, 13 Irregular heartbeat detection 11, 13 Last 3 measurements averages 13 Power: Optional AC adapter 17	Accuracy ± 3 mmHg 1, 5 BP 0 mmHg to 299 mmHg, Pulse 40-180 bpm 1, 5, 7, 8 Body movement error indicator 3, 11, 13 Pressure detection by “capacitive” pressure sensor 5 Cuff: 152 mm × 600 mm (Arm circ. 22 to 42 cm) 6 O/I Start button 10 Single screen display 10 Date/Time Display 11 During Measurement: Deflation & Heartbeat Symbols 11 Hypertension indicator 11, 13 Irregular heartbeat detection 11, 13 Last 3 measurements averages 13 Power: Optional AC adapter 17
Comparable Criteria	Set Button 10 Memory button, memory symbol 10, 11 Memory: 84 measurements × 2 users 11, 14 Power: 4 “AA” batteries ~ 1400 measurements 17	Date/Time setting button 10 2 memory buttons, memory symbol 10, 11 Memory: 90 measurements 11, 14 Power: 4 “AA” batteries ~ 1500 measurements 17
Device 2 Criteria		

Web link	http://www.omron-healthcare.com/sitepreview.php?SiteID=537
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Comments	<p>The i-C10 essentially has extra averaging facilities not available on the M6 Comfort. Weekly morning and evening averages are included with a special symbol if the morning average is elevated. While both devices provide averages for the last three readings, the i-C10 has a facility for automatically taking three readings in sequence. Readings can be stored separately for 2 people. Date and time settings on the i-C10 are provided using the set (auto mode) and memory buttons.</p> <p>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.</p> <p>All of the additions are calculated extras There appears to be no differences in any aspects concerned with BP detection.</p> <p>The i-C10 is not yet listed on the Omron website.</p>
Recommendation	Equivalence is recommended
Date	06/10/2008