

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 M1 Compact (HEM-4022-E)

Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Omron M1 Plus (HEM-4011C-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

Publication

2007:3(4) 1-12

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 checked="" type="checkbox"/>

Brief explanation of differences and further relevant details:

10) no Set button (Date and Time setting, Beeper ON/OFF setting)

11) no symbol for average of 3 reading in memory, no symbol for beeper ON/OFF, no symbol for date and time

13) no average function (average of the latest 3 reading in memory), no beeper control function, no date and time function.

14) 14 readings in memory instead of 21 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 29 Jan. 2008
Signature of Witness Helen Demeny
Name Helen Demeny
Address Omron Healthcare Europe B.V., Kruisweg 577, 2132NA Hoofddorp, The Netherlands

Company Stamp/Seal
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Comparison of the Omron M1 Compact with the Omron M1 Plus

Devices	Omron M1 Compact (HEM-4022-E)	Omron M1 Plus (HEM-4011C-E)
Pictures		
Validation		ESH
Device 1 Criteria		
Same Criteria	BP 0 mmHg to 299 mmHg, Pulse 40-180 bpm 1, 5, 7, 8 Accuracy ± 3 mmHg 1, 5 Pressure detection by “capacitive” pressure sensor 5 Cuff (Medium 146 mm \times 446 mm – Arm Circ. 22 cm to 32 cm) 6 Manual Inflation/Automatic Deflation 7, 8 On/Off button 10 Memory button 10 Irregular heartbeat detection 11, 13 Hypertension indicator 11, 13 4 \times 1.5 V “AAA” Batteries (1500 measurements) 17	BP 0 mmHg to 299 mmHg, Pulse 40-180 bpm 1, 5, 7, 8 Accuracy ± 3 mmHg 1, 5 Pressure detection by “capacitive” pressure sensor 5 Cuff (Medium 146 mm \times 446 mm – Arm Circ. 22 cm to 32 cm) 6 Manual Inflation/Automatic Deflation 7, 8 On/Off button 10 Memory button 10 Irregular heartbeat detection 11, 13 Hypertension indicator 11, 13 4 \times 1.5 V “AAA” Batteries (1500 measurements) 17
Comparable Criteria	Single screen display (small) 10 Memory: 14 measurements 14	Single screen display (large) 10 Memory: 21 measurements 14
Device 2 Criteria		Date/Time Set button 10 Date/Time 11, 13 “Buzzer Mode” (Audible pulse indicator during deflation) 11, 13 Average algorithm (3 most recent measurements) 11, 13
Web link	http://www.omron-healthcare.com/sitepreview.php?SiteID=579	http://www.omron-healthcare.com/sitepreview.php?SiteID=226

Comments	The Omron M1 Compact is essentially a “scaled down version” of the M1 Plus. It does not contain the Date/Time, “Buzzer Mode” and averaging features. It retains fewer measurement in memory.
Recommendation	Equivalence is recommended.
Date	10/03/2008