

## DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2006

A SIGNED COPY WILL BE POSTED ON THE [www.dableducational.org](http://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 Classic (HEM-442-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 checked="" type="checkbox"/>	No <input 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)

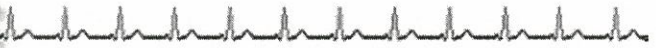
11) no symbol for average of 3 reading in memory, no symbol for beeper ON/OFF, no symbol for date and time, no symbols of hypertension indicator and irregular heartbeat detection.

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

14) 14 readings in memory instead of 21 readings.

17) 4 x AA batteries instead of 4 x AAA batteries

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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

Company Stamp/Seal

Name Takefumi Nakanishi

OMRON HEALTHCARE EUROPE B.V.

Date 29 Jan. 2008

Kruisweg 577

Signature of Witness H. Demeny

NL-2132 NA Hoofddorp

Name Helen Demeny



P.O. Box 2150 NL- 2130 GL Hoofddorp

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

Tel. +31 - 20 354 82 00

Fax +31 - 20 354 82 01

## Comparison of the Omron M1 Classic with the Omron M1 Plus

Devices	Omron M1 Classic (HEM-442-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 $\pm 3$ mmHg 1, 5 Pressure detection by “capacitive” pressure sensor 5 Manual Inflation/Automatic Deflation 7, 8 On/Off button 10 Memory button 10	BP 0 mmHg to 299 mmHg, Pulse 40-180 bpm 1, 5, 7, 8 Accuracy $\pm 3$ mmHg 1, 5 Pressure detection by “capacitive” pressure sensor 5 Manual Inflation/Automatic Deflation 7, 8 On/Off button 10 Memory button 10
Comparable Criteria	Cuff (Medium 145 mm $\times$ 480 mm – Arm Circ. 22 cm to 32 cm) 6 Single screen display (small) 10 Memory: 14 measurements 14 4 $\times$ 1.5 V “AA” Batteries (1000 measurements) 17	Cuff (Medium 146 mm $\times$ 446 mm – Arm Circ. 22 cm to 32 cm) 6 Single screen display (large) 10 Memory: 21 measurements 14 4 $\times$ 1.5 V “AAA” Batteries (1500 measurements) 17
Device 2 Criteria		Date/Time Set button 10 Irregular heartbeat detection 11, 13 Hypertension indicator 11, 13 Date/Time 11, 13 “Buzzer Mode” (Audible pulse indicator during deflation) 11, 13 Average algorithm (3 most recent measurements) 11, 13
Web link	<a href="http://www.omron-healthcare.com/sitepreview.php?SiteID=229">http://www.omron-healthcare.com/sitepreview.php?SiteID=229</a>	<a href="http://www.omron-healthcare.com/sitepreview.php?SiteID=226">http://www.omron-healthcare.com/sitepreview.php?SiteID=226</a>

Comments	The Omron M1 Classic is essentially a “scaled down version” of the M1 Plus. There appears to be a difference in the size of the cuff but, diagrammatically, they appear to be the same. No information on the bladder size is provided but both are recommended for the same range of arm circumferences. Because of the mechanism, even if the bladder supplied with the M1 Classic is slightly larger, it is unlikely to make a difference.
Recommendation	Equivalence is recommended.
Date	10/03/2008