

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 HEM-SOLAR (HEM-4500-SOLE)

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, Therese 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

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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), no Memory button. Solar panel is added.

11) No symbol for memory, no symbol for average of 3 readings in memory, no symbol for beeper ON/OFF, no symbol for date and time, no symbol for irregular heartbeat symbol. The symbol for rechargeable battery indicator is added.

13) No average function (average of the latest 3 readings in memory), no beeper control function, no date and time function, no function to detect irregular heartbeat. The function to detect outside standard range of systolic or diastolic blood pressure is added.

14) No memory instead of 21 memories.

17) The rechargeable battery is added. The rechargeable battery is charged by the AC adapter or the solar battery.



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	<u><i>T. Nakanishi</i></u>	Company Stamp/Seal
Name	<u>Takefumi Nakanishi</u>	OMRON HEALTHCARE EUROPE B.V.
Date	<u>29 June 2009</u>	Kruisweg 577
Signature of Witness	<u><i>J. Meijer</i></u>	NL-2132 NA Hoofddorp
Name	<u>Janet Meijer</u>	P.O. Box 2150 NL- 2130 GL Hoofddorp
Address	<u>Omron Healthcare Europe B.V., Kruisweg 577 , 2132NA Hoofddorp, The Netherlands</u>	

Comparison of the New with the Old

Devices	Omron HEM-Solar (HEM-4500-SOLE)	Omron M1 Plus (HEM-4011C-E)
Pictures		
Validation		ESH
Device 1 Criteria	Power: AC adapter (Charges rechargeable battery) 17 Power: Solar Panel (Charges rechargeable battery) 17 Power: Rechargeable battery ~ 280 uses x 300 charges 17 Recharging LED 10, 17	
Same Criteria	Accuracy ± 3 mmHg 1, 5 Oscillometric measurement method 1, 5 BP 0 mmHg to 299 mmHg, Pulse 40-180 bpm 1, 5, 7, 8 Pressure detection by “capacitive” pressure sensor 5 Cuff (Med): 146 mm \times 446 mm (Arm circ. 22 to 32 cm) 6 Optional small (AC 17-22 cm) and large (AC 32-42 cm) cuffs 6 Inflation: Manual by inflation bulb 7 Manual Inflation/Automatic Deflation 7, 8 Re-inflation symbol 7, 11 Deflation: Automatic release valve 8 I/O Start button 10 Single screen display 10 During Measurement: Deflation & Heartbeat Symbols 11 Hypertension indicator 11, 13 Power: Automatic switch-off when not used for 5 min 17	Accuracy ± 3 mmHg 1, 5 Oscillometric measurement method 1, 5 BP 0 mmHg to 299 mmHg, Pulse 40-180 bpm 1, 5, 7, 8 Pressure detection by “capacitive” pressure sensor 5 Cuff (Med): 146 mm \times 446 mm (Arm circ. 22 to 32 cm) 6 Optional small (AC 17-22 cm) and large (AC 32-42 cm) cuffs 6 Inflation: Manual by inflation bulb 7 Manual Inflation/Automatic Deflation 7, 8 Re-inflation symbol 7, 11 Deflation: Automatic release valve 8 I/O Start button 10 Single screen display 10 During Measurement: Deflation & Heartbeat Symbols 11 Hypertension indicator 11, 13 Power: Automatic switch-off when not used for 5 min 17
Comparable Criteria	Low battery/Rechargeable Battery symbol 11, 17 Power: Optional 2 “AAA” batteries ~ 1500 measurements 17	Low battery symbol 11, 17 Power: 4 “AAA” batteries ~ 1500 measurements 17

Device 2 Criteria		Set Button 10 Memory button, memory symbol 10, 11 Date/Time Display 11 Irregular heartbeat detection, symbol 11, 13 Optional audible indicator during deflation, “buzzer” symbol 11, 13 Memory: 21 measurements 11, 14 Last 3 measurements averages 13
Web link	http://www.omron-healthcare.com/sitepreview.php?SiteID=694	http://www.omron-healthcare.com/sitepreview.php?SiteID=226
Comments	The main blood pressure determinations components, including the cuffs, appear to be the same. The HEM-Solar does not have the arrhythmia, averaging and “buzzer” features and does not store the results. However it does have three optional power supply methods – the back of the device is a solar panel for charging a rechargeable battery which can also be recharged by an AC adapter. Finally, a standard battery option is provided but this is regarded as an emergency option.	
Recommendation	Equivalence is recommended.	
Date	22/07/09	