

## 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 R6  
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Omron R7  
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

Topouchian JA, El Assaad MA, Orobinskaia LV, El Feghali RN, Asmar RG. Validation of two automatic devices for self-measurement of blood pressure according to the International Protocol of the European Society of Hypertension: the Omron M6 (HEM-7001-E) and the Omron R7 (HEM 637-IT)

Title  
Blood Pressure Monitoring 2006; 11:165-171  
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 type="checkbox"/>	No <input checked="" type="checkbox"/>
	15	Printing Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	16	Communication Facilities	Yes <input checked="" 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 "GRAPH" button, no two of "allow" buttons to select the setting and to view the graph display.

11) segment LCD display instead of dot matrix LCD display, no graph display, no symbol of alarm function, includes the symbol of irregular heartbeat detection.

13) no graph display function, no alarm function, includes irregular heartbeat detection function, includes the memory average function (average of the latest 3 measurements)

16) no USB data communication port

**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>T. Nakanishi</u>	Company Stamp/Seal
Name	<u>Takefumi Nakanishi</u>	OMRON HEALTHCARE EUROPE B.V.
Date	<u>21 Aug. 2008</u>	Kruisweg 577
Signature of Witness	<u>J. Meijer</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>	Tel. +31 - 20 354 82 00
		Fax +31 - 20 354 82 01

## Comparison of the Omron R6 with the Omron R7

Devices	Omron R6	Omron R7
Pictures		
Validation	ESH	
Device 1 Criteria	Irregular heartbeat detection and symbol 11, 13 Last 3 measurements averages 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 “electrostatic capacity” pressure sensor 5 Cuff: For wrist circumference 13.5 to 21.5 cm 6 Automatic inflation, rapid deflation 7, 8 O/I Start button 10 Set Button 10 Date/Time Display 11 Wrist positioning sensor 11, 13 Memory: 90 measurements 11, 14 Power: 2 “AAA” batteries ~ 300 measurements 17	Accuracy ± 3 mmHg 1, 5 BP 0 mmHg to 299 mmHg, Pulse 40-180 bpm 1, 5, 7, 8 Pressure detection by “electrostatic capacity” pressure sensor 5 Cuff: For wrist circumference 13.5 to 21.5 cm 6 Automatic inflation, rapid deflation 7, 8 O/I Start button 10 Set Button 10 Date/Time Display 11 Wrist positioning sensor 11, 13 Memory: 90 measurements 11, 14 Power: 24 “AAA” batteries ~ 300 measurements 17
Comparable Criteria	Segment LCD display 10 Memory button, memory icon 10, 11 Date/Time (with Set and Memory buttons) 10 During Measurement: Heartbeat Symbol 11	Dot matrix LCD display 10 Memory button, memory “M” symbol 10, 11 Date/Time (with Set, Forward and Back buttons) 10 During Measurement: Inflation, Deflation & Heartbeat Symbols 11
Device 2 Criteria		Forward & Back control buttons 10 Graph Button 10 Screen font size adjustment 11 Graph Display 11, 13 Alarm (for same time each day measurements) 11, 13 USB port, cable and PC software 16, 18
Web link	<a href="http://www.omron-healthcare.com/sitepreview.php?SiteID=234">http://www.omron-healthcare.com/sitepreview.php?SiteID=234</a>	<a href="http://www.omron-healthcare.com/sitepreview.php?SiteID=235">http://www.omron-healthcare.com/sitepreview.php?SiteID=235</a>

<b>Comments</b>	<p>The R6 and R7 appear to differ only in the extra features provided.</p> <p>The forward and back control buttons are mainly there to leaf through individual measurements in the graph though they are used when setting the date and time. Without the graph, they are not needed in the R6 and the Mem button us used as a “forward” button that cycles through the values.</p> <p>The arm positioning and blood pressure measurement instructions are almost identical for both devices. The cuffs are the same.</p>
<b>Recommendation</b>	Equivalence is Recommended
<b>Date</b>	17/12/2008