

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 Tomohiro Kukita 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 R7 (HEM-637-E7)
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
Authors(s)

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 checked="" type="checkbox"/>	No <input 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 type="checkbox"/>	No <input checked="" type="checkbox"/>
	11	Display	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	12	Carrying/Mounting Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	13	Software other than Algorithm	Yes <input type="checkbox"/>	No <input checked="" 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 type="checkbox"/>	No <input checked="" 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:

5) The pressure sensor is replaced to a piezo electric sensor (NPS) from an electrostatic capacitive sensor (CPS), but the accuracy of blood pressure measurement is equivalent between NPS and CPS.



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 _____

Company Stamp/Seal

Name Tomohiro Kukita



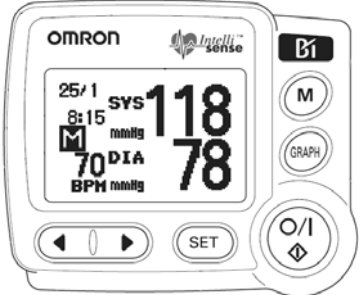
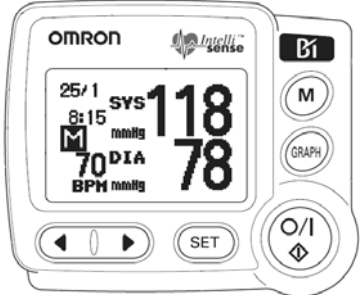
Date 6 September, 2010

Signature of Witness _____

Name Janet Meijer

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

Comparison of the Omron R7 (HEM-637-E7) with the Omron R7 (HEM-637-IT)

Devices	Omron R7 (HEM-637-E7)	Omron R7 (HEM-637-IT)
Pictures		
Display		
Validation		ESH
Device 1 Criteria		
Same Criteria	<p>Measurement</p> <p><i>Accuracy</i></p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p>Pulse accuracy ± 5% 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</p> <p>Pulse 40 bpm -180 bpm 1, 5</p> <p>Measurements are from single inflations 13</p> <p>Manually initiated measurements 13, 14</p> <p><i>Inflation</i></p> <p>Inflation 0 mmHg - 299 mmHg 1, 5, 7</p> <p>Automatic Inflation 7</p>	<p>Measurement</p> <p><i>Accuracy</i></p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p>Pulse accuracy ± 5% 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</p> <p>Pulse 40 bpm -180 bpm 1, 5</p> <p>Measurements are from single inflations 13</p> <p>Manually initiated measurements 13, 14</p> <p><i>Inflation</i></p> <p>Inflation 0 mmHg - 299 mmHg 1, 5, 7</p> <p>Automatic Inflation 7</p>

Devices	Omron R7 (HEM-637-E7)	Omron R7 (HEM-637-IT)
Same Criteria (Continued)	Measurement (continued)	Measurement (continued)
	<i>Deflation</i>	<i>Deflation</i>
	Automatic Deflation 8	Automatic Deflation 8
	<i>Cuffs</i>	<i>Cuffs</i>
	Wrist circ. 13.5-21.5 cm 6	Wrist circ. 13.5-21.5 cm 6
	<i>Sensors</i>	<i>Sensors</i>
	Wrist positioning sensor (Can be disabled/enabled) 13, 18	Wrist positioning sensor (Can be disabled/enabled) 13, 18
	<i>Measurement Records</i>	<i>Measurement Records</i>
	Memory: 90 measurements (Can be disabled/enabled) 14	Memory: 90 measurements (Can be disabled/enabled) 14
	Buttons/Switches	Buttons/Switches
	<i>Power</i>	<i>Power</i>
	On/Off with Start/Stop (O/I Label) 10	On/Off with Start/Stop (O/I or Start/Stop Label) 10
	<i>Measurement Records</i>	<i>Measurement Records</i>
	Memory 10	Memory 10
	<i>Settings</i>	<i>Settings</i>
	Set 10	Set 10
	Forward 10	Forward 10
	Backward 10	Backward 10
	<i>Analysis</i>	<i>Analysis</i>
	Graph 10	Graph 10
	Display/Symbols/Indicators	Display/Symbols/Indicators
	<i>Measurement Procedure</i>	<i>Measurement Procedure</i>
	Inflation symbol 11	Inflation symbol 11
	Deflation symbol 11	Deflation symbol 11
	During Measurement: BP Level & Heartbeat 11	During Measurement: BP Level & Heartbeat 11
	Wrist position – adjust and OK 11, 13, 18	Wrist position – adjust and OK 11, 13, 18
	<i>Post Measurement</i>	<i>Post Measurement</i>
	SBP, DBP and Pulse 11	SBP, DBP and Pulse 11
	Measurement error (E ▼, E HEIGHT ▼, E/E, E Onn) 11	Measurement error (E ▼, E HEIGHT ▼, E/E, E Onn) 11
	Graphs (Morning/Evening/All measurements) 11, 13	Graphs (Morning/Evening/All measurements) 11, 13
<i>Date and Time</i>	<i>Date and Time</i>	
Date and Time 11	Date and Time 11	
Date and Time (During memory recall) 11	Date and Time (During memory recall) 11	
Alarm reminder (2 alarms/day) 18	Alarm reminder (2 alarms/day) 18	
<i>Measurement Records</i>	<i>Measurement Records</i>	
Memory “M” symbol 11	Memory “M” symbol 11	

Devices	Omron R7 (HEM-637-E7)	Omron R7 (HEM-637-IT)
Same Criteria (Continued)	<p>Display/Symbols/Indicators (continued)</p> <p><i>Power</i></p> <p>Low battery 11, 17</p> <p><i>Settings</i></p> <p>Screen font size adjustment 11</p> <p>Algorithms</p> <p><i>Parameter Settings</i></p> <p>Right or left wrist 1</p> <p>Case</p> <p><i>Display</i></p> <p>Single screen display 10</p> <p>Dot matrix LCD 10</p> <p><i>Ports</i></p> <p>Data port (Optional USB cable and PC software) 16, 18</p> <p><i>Power</i></p> <p>2 “AAA” batteries ~ 300 measurements 17</p> <p>Automatic switch-off when not used for 2 min 17</p>	<p>Display/Symbols/Indicators (continued)</p> <p><i>Power</i></p> <p>Low battery 11, 17</p> <p><i>Settings</i></p> <p>Screen font size adjustment 11</p> <p>Algorithms</p> <p><i>Parameter Settings</i></p> <p>Right or left wrist 1</p> <p>Case</p> <p><i>Display</i></p> <p>Single screen display 10</p> <p>Dot matrix LCD 10</p> <p><i>Ports</i></p> <p>Data port (Optional USB cable and PC software) 16, 18</p> <p><i>Power</i></p> <p>2 “AAA” batteries ~ 300 measurements 17</p> <p>Automatic switch-off when not used for 2 min 17</p>
Comparable Criteria	<p>Measurement</p> <p><i>Sensors</i></p> <p>Pressure sensor: Piezoelectric semiconductor 5</p>	<p>Measurement</p> <p><i>Sensors</i></p> <p>Pressure sensor: Electrostatic capacitive semiconductor 5</p>
Device 2 Criteria		
Web link		

Comments	<p>The Omron R7 (HEM-637-E7) is identical to the HEM-637-IT device except that the current pressure sensor (CPS), an electrostatic capacitive semiconductor type, is changed to a new pressure sensor (NPS), a piezoelectric semiconductor type.</p> <p>This change in sensor was approved for the R6 (HEM-6000-E7), an equivalent device, by the advisory board on 09/04/2010. At that time, Omron supplied dabl® Educational with full details of tests carried out (in confidence), and a summary of these tests was provided to the advisory board. Further clarification on a number of queries was requested and provided. Following a review of these documents, it was concluded that the change in sensor would not affect the accuracy of the device and equivalence was recommended and was approved by the board.</p> <p>As this is the same change in sensor and the only difference between these devices, equivalence is recommended.</p>
Recommendation	Equivalence is recommended.
Date	16/09/2010