

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 R6 (HEM-6052-E)
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 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 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 "left arrow" button to select the setting and to view the graph display. No USB data communication port. The "user ID selection" switch is added.

11) Segment LCD display instead of dot matrix LCD display, no graph display, no symbol of alarm function, includes the symbols of irregular heartbeat detection, movement error, memory average, user ID and buzzer, includes the blood pressure level indicator.

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

14) Stores 90 readings each for two users instead of 90 readings for one user.

16) No communication facilities.

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



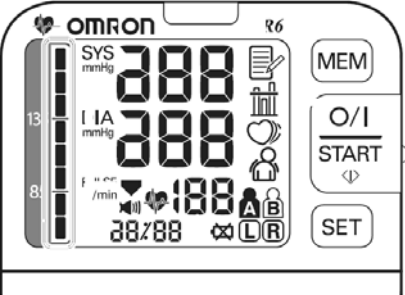
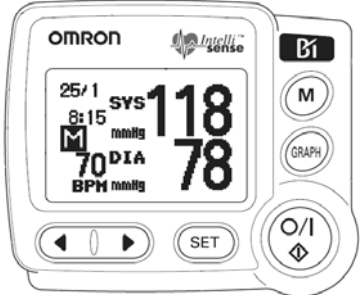
Date 6 September, 2010

Signature of Witness _____

Name Janet Meijer

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

Comparison of the Omron R6 (HEM-6052-E) with the Omron R7 (HEM-637-IT)

Devices	Omron R6 (HEM-6052-E)	Omron R7 (HEM-637-IT)
Picture		
Display		
Validation		ESH
Device 1 Criteria	<p>Buttons/Switches</p> <p><i>Settings</i></p> <p>User ID switch (A, B and Guest) 10</p> <p>Two date/time setting buttons 10</p> <p>Display/Symbols/Indicators</p> <p><i>Post Measurement</i></p> <p>Hypertension (Indicator strip) 11, 13</p> <p>Average icon 11, 13, 14</p> <p>Body movement error 3, 11, 13, 18</p> <p>Irregular heartbeat 11, 13, 18</p> <p><i>Settings</i></p> <p>User A or B 11</p> <p>Selected wrist 11</p> <p>Audible pulse indicator mode active 11, 18</p>	

Devices	Omron R6 (HEM-6052-E)	Omron R7 (HEM-637-IT)
Device 1 Criteria	<p>Algorithms <i>Averages and Differences</i></p> <p>Last 3 measurements (within 10 min of each other) mean 13</p> <p><i>Diagnostic</i></p> <p>Normotension/Hypertension 13</p> <p>135 / 85 mmHg thresholds 13</p> <p>Irregular heartbeat detection 13</p> <p>Body movement error detection 3, 13</p>	
Same Criteria	<p>Measurement <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><i>Deflation</i></p> <p>Automatic Deflation 8</p> <p><i>Cuffs</i></p> <p>Wrist circ. 13.5-21.5 cm 6</p> <p><i>Sensors</i></p> <p>Pressure sensor: Electrostatic capacitive semiconductor 5</p> <p>Wrist positioning sensor (disabled/enabled options) 13, 18</p> <p>Buttons/Switches <i>Power</i></p> <p>On/Off with Start/Stop (O/I Start Label) 10</p> <p><i>Measurement Records</i></p> <p>Memory 10</p> <p><i>Settings</i></p> <p>Set 10</p> <p>Display/Symbols/Indicators <i>Measurement Procedure</i></p> <p>Deflation symbol 11</p>	<p>Measurement <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><i>Deflation</i></p> <p>Automatic Deflation 8</p> <p><i>Cuffs</i></p> <p>Wrist circ. 13.5-21.5 cm 6</p> <p><i>Sensors</i></p> <p>Pressure sensor: Electrostatic capacitive semiconductor 5</p> <p>Wrist positioning sensor (disabled/enabled options) 13, 18</p> <p>Buttons/Switches <i>Power</i></p> <p>On/Off with Start/Stop (O/I or Start/Stop Label) 10</p> <p><i>Measurement Records</i></p> <p>Memory 10</p> <p><i>Settings</i></p> <p>Set 10</p> <p>Display/Symbols/Indicators <i>Measurement Procedure</i></p> <p>Deflation symbol 11</p>

Devices	Omron R6 (HEM-6052-E)	Omron R7 (HEM-637-IT)
Same Criteria (Continued)	<p>Display/Symbols/Indicators (continued) <i>Measurement Procedure (continued)</i></p> <p>During Measurement: BP Level & Heartbeat 11</p> <p><i>Post Measurement</i></p> <p>SBP, DBP and Pulse 11</p> <p><i>Date and Time</i></p> <p>Date and Time 11</p> <p>Date and Time (During memory recall) 11</p> <p><i>Power</i></p> <p>Low battery 11, 17</p> <p>Algorithms <i>Parameter Settings</i></p> <p>Right or left wrist 1</p> <p>Case <i>Display</i></p> <p>Single screen display 10</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) <i>Measurement Procedure (continued)</i></p> <p>During Measurement: BP Level & Heartbeat 11</p> <p><i>Post Measurement</i></p> <p>SBP, DBP and Pulse 11</p> <p><i>Date and Time</i></p> <p>Date and Time 11</p> <p>Date and Time (During memory recall) 11</p> <p><i>Power</i></p> <p>Low battery 11, 17</p> <p>Algorithms <i>Parameter Settings</i></p> <p>Right or left wrist 1</p> <p>Case <i>Display</i></p> <p>Single screen display 10</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 <i>Measurement Records</i></p> <p>Memory: 90 measurements each A & B (None for Guest) 14</p> <p>Display/Symbols/Indicators <i>Measurement Procedure</i></p> <p>Wrist position – adjust with lights and beep when OK 11, 13, 18 Orange light to blue lights and beeps when OK</p> <p><i>Post Measurement</i></p> <p>Measurement error (E, E + flashing light, E/E, Er nnn) 11</p> <p><i>Measurement Records</i></p> <p>Memory icon 11</p> <p>Case <i>Display</i></p> <p>Segment LCD 10</p>	<p>Measurement <i>Measurement Records</i></p> <p>Memory: 90 measurements (Can be disabled/enabled) 14</p> <p>Display/Symbols/Indicators <i>Measurement Procedure</i></p> <p>Wrist position – adjust with symbol and beep when OK 11, 13, 18 Arrows to symbol and beep when OK</p> <p><i>Post Measurement</i></p> <p>Measurement error (E ▼, E HEIGHT ▼, E/E, E 0nn) 11</p> <p><i>Measurement Records</i></p> <p>Memory “M” symbol 11</p> <p>Case <i>Display</i></p> <p>Dot matrix LCD 10</p>
Device 2 Criteria		<p>Buttons/Switches <i>Settings</i></p> <p>Forward (for date/time setting and graph details) 10</p> <p>Backward (for date/time setting and graph details) 10</p>

Devices	Omron R6 (HEM-6052-E)	Omron R7 (HEM-637-IT)
Device 2 Criteria		<p>Buttons/Switches (continued)</p> <p><i>Analysis</i></p> <p>Graph 10</p> <p>Display/Symbols/Indicators</p> <p><i>Measurement Procedure</i></p> <p>Inflation symbol 11</p> <p><i>Post Measurement</i></p> <p>Graphs (Morning/Evening/All measurements) 11, 13</p> <p><i>Date and Time</i></p> <p>Alarm reminder (2 alarms/day) 18</p> <p><i>Settings</i></p> <p>Screen font size adjustment 11</p> <p>Case</p> <p><i>Ports</i></p> <p>Data port (Optional USB cable and PC software) 16, 18</p>
Web link		

Comments	<p>The R6 (HEM-6052-E) (not to be confused with the R6 (HEM-6000-E)), provides very different extra features to the R7 (HEM-637-IT). The R6 provides blood pressure diagnostic information, irregular heartbeat and body movement errors whereas the R7 provides graphs and PC linking features. The R6 provides records to be kept on two users with both devices providing a facility for not recording measurements. The R7 provides an alarm facility.</p> <p>Buttons and switches are provided accordingly. The arm positioning and blood pressure measurement instructions are similar in outcome though they differ in presentation with the R6 providing a light that changes from orange to blue while the R7 provides arrows that change to a heart symbol. The light is also used in the R6 to indicate an error where the wrist moves out of position during the measurement whereas the R7 indicates this by displaying the word “height” with the error.</p> <p>The segment display in the R6 also allows icons to be displayed more readily. The cuffs are the same.</p> <p>The fundamental measurement aspects of both devices, however, appear to be the same.</p>
Recommendation	Equivalence is recommended.
Date	16/09/2010