

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2013

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SECTION A - Please complete all items.

I **Minoru Yoshimura,**
Name of a Company Director

a Director of **OMRON Healthcare Europe B.V.,**
Company name

hereby state that there are no differences that will affect blood pressure measuring accuracy between the

Maker^a **OMRON Healthcare Co., Ltd.** Address **53 Kunotsubo, Terado-cho, Muko, Kyoto 617-0002, Japan**
 Manufacturer^b **OMRON Healthcare Co., Ltd** Address **53 Kunotsubo, Terado-cho, Muko, Kyoto 617-0002, Japan**
 Brand^c **OMRON** Model^d **HEM-7250-IT**

Blood pressure measuring device for which validation is claimed. If alternative model names are used, include all.

blood pressure measuring device and the validated blood pressure measuring device

Maker^a **OMRON Healthcare Co., Ltd.** Address **53 Kunotsubo, Terado-cho, Muko, Kyoto 617-0002, Japan**
 Manufacturer^b **OMRON Healthcare Co., Ltd.** Address **53 Kunotsubo, Terado-cho, Muko, Kyoto 617-0002, Japan**
 Brand^c **OMRON** Model^d **HEM-7251G**

Existing validated blood pressure measuring device.

which has previously passed the **ESH-IP** protocol, the results of which were published as follows:

Takahashi H, Yokoi T, Yoshika M. Validation of the OMRON HEM-7251G upper arm blood pressure monitor, in oscillometry mode, for clinic use and self measurement in a general population, according to the European Society of Hypertension International Protocol revision 2010 [Internet]. Dublin: dablEducational Trust; 2013 Feb 01 [cited 2013 Feb 15]. 4 p. Available from: http://www.dableducational.org/Publications/2013/ESH-IP_2010_Validation_of_Omron_HEM-7251G.pdf

Full reference

The only differences between the devices involve the following components:

Tick one box for each item 1–18.

Part I	1	Algorithm for Oscillometric Measurements	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A ^e <input type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^f <input checked="" 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"/>	N/A ^f <input checked="" type="checkbox"/>
	5	Pressure Transducer	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	6	Cuffs or Bladders	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 checked="" 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"/>	N/A ^g <input checked="" type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input checked="" type="checkbox"/>
	17	Power Supply	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	18	Other Facilities	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input type="checkbox"/>

An explanation of each item ticked "Yes" must be included in Section B or on a separate sheet.

- Notes: a Provide the name and address of the actual maker of the device.
 b Provide the name and address of the legal manufacturer of the device, even if it is the same as that of the maker.
 c Provide the name of the brand under which it is sold, even if it is the same as that of the manufacturer or maker.
 d Provide the model name. If alternative or internal model names are used, include all. Each device must be uniquely identifiable.
 e Only tick N/A (Not Applicable) if neither device measures blood pressure using the oscillometric method.
 f Only tick N/A (Not Applicable) if neither device measures blood pressure using the auscultatory method.
 g Only tick N/A (Not Applicable) if neither device provides printing, communication or other facilities, as appropriate.

SECTION B An explanation for each item, 1 to 18, ticked "Yes" in Section A must be provided here or in an attached document. All differences between the devices must be described.

9) Model number HEM-7250-IT

10) No Transfer button. The Start/Stop button is added instead of the Start/Stop button 1 and the Start/Stop 2 button. The User ID button, the Date/Time setting button and the USB cable connector are added. The Transfer area mark for the Near field communication is added.

11) No symbol for transferred, symbol for unsent and symbol for out of translation service area. The symbol of "WellnessLINK", the symbol for average value and the indicator of blood pressure level are added. The Icon of the transferring symbol is changed.

13) The average function (average of the latest 3 readings in memory) is added.

16) The Near field communication to connect with personal computer and smartphone and the USB interface to connect with personal computer are added, instead of the 3G mobile telecommunications technology to connect with the dedicated server.

17) The AC adapter model is changed.

18) No room temperature measurement function.

SECTION C Please check that the following are included with the application

- A manual for the validated device
- A manual for the device for which equivalence is being sought
- An image of the validated device
- An image of the device for which equivalence is being sought
- An image of the screen layout of validated device*
- An image of the screen layout of the device for which equivalence is being sought*

* Screen layouts shown complete, and without obscuring labels or lines, in manuals need not be included separately.

SECTION D Complete all items, bar signatures and seal, online and print. Sign and seal it then send the original to our address below. Please email a signed copy of this form, together with the manuals and images for both devices, to info@dableducational.org.

Signature of Director 

Name Minoru Yoshimura

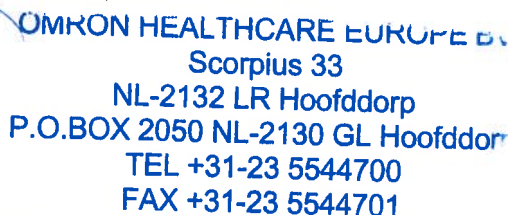
Date 15 Feb 2013

Signature of Witness 



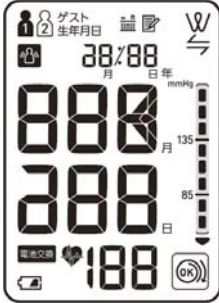
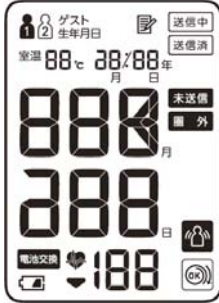
Name Tomohiro Kukita

Address Scorpion 33, 2132 LR Hoofddorp, The Netherlands

Company Stamp/Seal


OMRON HEALTHCARE EUROPE B.V.
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Comparison of the Omron HEM-7250-IT with the Omron HEM-7251G

Devices	Omron HEM-7250-IT	Omron HEM-7251G
Pictures		
Display		
Validation		ESH 2010
Device 1 Criteria	<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><i>Communication</i></p> <p>“WellnessLINK” transmit data reminder 11, 16</p> <p>Algorithms</p> <p><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>135 / 85 mmHg thresholds 13</p> <p>Casing</p> <p><i>Ports</i></p> <p>USB port, cable and PC software 16, 18</p> <p>Near field communications link 16, 18</p>	

Devices	Omron HEM-7250-IT	Omron HEM-7251G
Same Criteria	Measurement	Measurement
	<i>Accuracy</i>	<i>Accuracy</i>
	BP accuracy ± 3 mmHg 1, 5	BP accuracy ± 3 mmHg 1, 5
	Pulse accuracy $\pm 5\%$ 1, 5	Pulse accuracy $\pm 5\%$ 1, 5
	<i>Method</i>	<i>Method</i>
	Oscillometric measurement method 1, 5	Oscillometric measurement method 1, 5
	Pulse 40 bpm – 180 bpm 1, 5, 8	Pulse 40 bpm – 180 bpm 1, 5, 8
	Manually initiated measurements 13	Manually initiated measurements 13
	Measurements are from single inflations 13	Measurements are from single inflations 13
	<i>Inflation</i>	<i>Inflation</i>
	Inflation 0 mmHg to 299 mmHg 1, 5, 7	Inflation 0 mmHg to 299 mmHg 1, 5, 7
	Automatic Inflation 7	Automatic Inflation 7
	Press button if BP > 220 mmHg 7	Press button if BP > 220 mmHg 7
	<i>Deflation</i>	<i>Deflation</i>
	Automatic Deflation 8	Automatic Deflation 8
	<i>Cuffs</i>	<i>Cuffs</i>
	Single 120 mm \times 480 mm (Arm circ. 17 to 32 cm) HEM-CUFF-R22 6	Single 120 mm \times 480 mm (Arm circ. 17 to 32 cm) HEM-CUFF-R22 6
	<i>Measurement Records</i>	<i>Measurement Records</i>
	Memory: 90 measurements \times 2 users (Guest not recorded) 14	Memory: 90 measurements \times 2 users (Guest not recorded) 14
	Buttons/Switches	Buttons/Switches
	<i>Measurement Records</i>	<i>Measurement Records</i>
	Memory 10	Memory 10
	<i>Settings</i>	<i>Settings</i>
	Up and down 10	Up and down 10
	Display/Symbols/Indicators	Display/Symbols/Indicators
	<i>Preparation</i>	<i>Preparation</i>
	Correct cuff wrapping indicator 11, 13, 18	Correct cuff wrapping indicator 11, 13, 18
	<i>Measurement Procedure</i>	<i>Measurement Procedure</i>
	Date of Birth during inflation 18	Date of Birth during inflation 18
	Deflation symbol 11	Deflation symbol 11
During Measurement: BP Level & Heartbeat 11	During Measurement: BP Level & Heartbeat 11	
<i>Post Measurement</i>	<i>Post Measurement</i>	
SBP, DBP and Pulse 11	SBP, DBP and Pulse 11	
Measurement error E1, E2, E3, E4 & E5 11	Measurement error E1, E2, E3, E4 & E5 11	
Body movement error 3, 11, 13, 18	Body movement error 3, 11, 13, 18	
<i>Measurement Records</i>	<i>Measurement Records</i>	
Memory icon 11	Memory icon 11	

Devices	Omron HEM-7250-IT	Omron HEM-7251G
Same Criteria (continued)	<p>Display/Symbols/Indicators (continued) <i>Measurement Records (continued)</i></p> <p>Memory recall number (Replaces pulse rate momentarily) 11</p> <p>User (1, 2 and Guest) 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>Date of Birth 18</p> <p><i>Power</i></p> <p>Low battery 11, 17</p> <p>Replace battery 11, 17</p> <p>Algorithms <i>Diagnostic</i></p> <p>Body movement error detection 3, 13</p> <p><i>Parameter Settings</i></p> <p>Correct cuff wrapping detection 13</p> <p>Casing <i>Display</i></p> <p>Single screen display 10</p> <p>Segment LCD 10</p> <p><i>Power</i></p> <p>4 “AA” batteries ~ 300 measurements 17</p> <p>Automatic switch-off when not used for 2 min 17</p>	<p>Display/Symbols/Indicators (continued) <i>Measurement Records (continued)</i></p> <p>Memory recall number (Replaces pulse rate momentarily) 11</p> <p>User (1, 2 and Guest) 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>Date of Birth 18</p> <p><i>Power</i></p> <p>Low battery 11, 17</p> <p>Replace battery 11, 17</p> <p>Algorithms <i>Diagnostic</i></p> <p>Body movement error detection 3, 13</p> <p><i>Parameter Settings</i></p> <p>Correct cuff wrapping detection 13</p> <p>Case <i>Display</i></p> <p>Single screen display 10</p> <p>Segment LCD 10</p> <p><i>Power</i></p> <p>4 “AA” batteries ~ 300 measurements 17</p> <p>Automatic switch-off when not used for 2 min 17</p>
Comparable Criteria	<p>Buttons/Switches <i>Power</i></p> <p>On/Off with Start/Stop (Measurement/Stop Label – 測定/停止) 10</p> <p><i>Measurement Records</i></p> <p>Memory 10</p> <p>User ID slider 10</p> <p><i>Settings</i></p> <p>Date/Time set 10</p> <p>Display/Symbols/Indicators <i>Communication</i></p> <p>Transmitting data symbol 11, 16</p> <p>Case <i>Power</i></p> <p>AC adapter (HEM-AC-W5J 60100W5SW) 17</p>	<p>Buttons/Switches <i>Power</i></p> <p>2 × On/Off with Start/Stop (User Number Labels) 10</p> <p><i>Measurement Records</i></p> <p>Memory 10</p> <p>(User ID incorporated into Start/Stop buttons) 10</p> <p><i>Settings</i></p> <p>(Date/Time set incorporated into Data Transfer button) 10</p> <p>Display/Symbols/Indicators <i>Communication</i></p> <p>Transmitting data (text symbol 送信中) 11, 16</p> <p>Case <i>Power</i></p> <p>AC adapter (HEM-AC-U 60100CL1000-J) 17</p>

Devices	Omron HEM-7250-IT	Omron HEM-7251G
Device 2 Criteria		<p>Buttons/Switches</p> <p>Data Transfer 10</p> <p>Display/Symbols/Indicators</p> <p><i>Communication</i></p> <p>Data transmission successful (text symbol 送信済) 11, 16</p> <p>Data transmission unsuccessful (text symbol 未送信) 11, 16</p> <p>Data transmission signal out of range (text symbol 圏外) 11, 16</p> <p><i>Features</i></p> <p>Ambient temperature 11, 18</p> <p>Case</p> <p><i>Ports</i></p> <p>3G mobile communications link 16, 18</p>

Comments	1	Note	<p>These devices are clearly equivalent, from a BP measurement perspective, and from the same family. As regards differences in features provided on the devices, the HEM-7250-IT provides a hypertension indicator strip and the mean of the last three readings for Users 1 and 2. The HEM-7251G provides ambient temperature.</p> <p>Omron provides two centralised recording facilities, known as “WellnessLINK” and “MedicalLINK”, to which users can register. Data recorded on the HEM-7250-IT system can be transmitted to the WellnessLINK system either automatically, using a near field communications link via a mobile phone or a PC, or directly, by connecting the device to the PC using the USB cable. The WellnessLINK symbol reminds the user that at least 72 measurements are awaiting transmission.</p> <p>Data recorded on the HEM-7251-G system is transmitted to the MedicalLINK system, using 3G mobile communications, automatically but a manual transmission can be initiated using the <i>Data Transfer</i> button.</p>																												
	2	Note	<p>Translation of Japanese symbols (top down)</p> <table border="0"> <thead> <tr> <th colspan="2">HEM-7250-IT and HEM-7251G</th> <th colspan="2">HEM-7251G only</th> </tr> </thead> <tbody> <tr> <td>ゲスト</td> <td>Guest</td> <td>送信中</td> <td>Being transmitted</td> </tr> <tr> <td>生年月日</td> <td>Date of birth</td> <td>送信済</td> <td>Transmitted</td> </tr> <tr> <td>月</td> <td>Month</td> <td>室温</td> <td>Room temperature</td> </tr> <tr> <td>日</td> <td>Day</td> <td>未送信</td> <td>Not transmitted</td> </tr> <tr> <td>年</td> <td>Year</td> <td>圏外</td> <td>Outside (transmission) range</td> </tr> <tr> <td>電池交換</td> <td>Battery replacement</td> <td></td> <td></td> </tr> </tbody> </table>	HEM-7250-IT and HEM-7251G		HEM-7251G only		ゲスト	Guest	送信中	Being transmitted	生年月日	Date of birth	送信済	Transmitted	月	Month	室温	Room temperature	日	Day	未送信	Not transmitted	年	Year	圏外	Outside (transmission) range	電池交換	Battery replacement		
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Date	27/02/2013																														