

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE

A SIGNED COPY WILL BE POSTED ON THE www.dableducational.org WEBSITE

SECTION A - Please complete all items.

I **Andre van Gils**, a 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

Maker^a **Omron Healthcare Man.** Address **Binh Duong Province, Vietnam Vietnam Co., LTD**
 Manufacturer^b **Omron Healthcare Co., Ltd.** Address **53, Kunotsubo, Terado-cho, Muko, KYOTO, 617-0002 Japan**
 Brand^c **Omron** Model^d **RS3 Intelli IT (HEM-6161T-E)**
 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 Man.** Address **Binh Duong Province, Vietnam Vietnam Co., LTD**
 Manufacturer^b **Omron Healthcare Co., Ltd.** Address **53, Kunotsubo, Terado-cho, Muko, KYOTO, 617-0002 Japan**
 Brand^c **Omron** Model^d **RS4 (HEM-6181-E)**
 Existing validated blood pressure measuring device.

which has previously passed the **ESH2010** protocol, the results of which were published as follows:

Validation of two automatic devices, **Omron HEM-6232T** and **HEM-6181**, for self-measurement of blood pressure at the wrist according to the **ANSI/AAMI/ISO 81060-2:2013** protocol and the **European Society of Hypertension International Protocol** revision

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 type="checkbox"/>	No <input checked="" type="checkbox"/>	
	18	Other Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input checked="" 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.

In an attached document. DET9 Form.

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
- Completed DET9 Form
- 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@dabieducational.org.

Signature of Director 

Company Stamp/Seal

Name Lucia Prada

Date 6 March, 2019

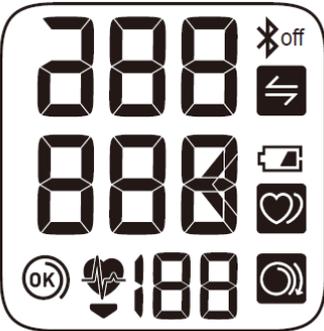
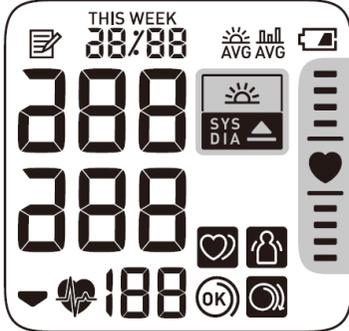
Signature of Witness 

Name Janet Meijer

Address 6 March, 2019

OMRON HEALTHCARE EUROPE BV
Scorpius 33
NL-2132 LR Hoofddorp
P.O.BOX 2050 NL-2130 GL Hoofddorp
TEL +31-23 5544700
FAX +31-23 5544701

Comparison of the Omron RS3 Intelli IT (HEM-6161T-E) with the Omron RS4 (HEM-6181-E)

Devices – Item 9	Omron RS3 Intelli IT (HEM-6161T-E)	Omron RS4 (HEM-6181-E)
Pictures		
Display Image		
Validation	<i>(equivalence)</i>	ANSI/AAMI/ISO 81060-2:2013 and ESH 2010
Category	Wrist Devices for Self-measurement of Blood Pressure	Wrist Devices for Self-measurement of Blood Pressure
Casing – Item 10	<p>Casing <i>Dimensions</i> Approximately 84 mm (w) × 62 mm (h) × 21 mm (l) (not including the wrist cuff)</p>	<p>Casing <i>Dimensions</i> Approximately 93 mm (w) × 62 mm (h) × 20 mm (l) (not including the wrist cuff)</p>

	<p>Buttons/Switches</p> <p><i>Power</i> On/Off with START/STOP button</p> <p><i>Communication</i> Connection button</p>	<p>Buttons/Switches</p> <p><i>Power</i> On/Off with START/STOP button</p> <p><i>Measurement Records</i> Memory button Morning Average button</p>
<p>Display – Item 11</p>	<p>Display/Symbols/Indicators</p> <p><i>Measurement Procedure</i> Deflation symbol Heartbeat symbol During Measurement: Blood Pressure Level</p> <p><i>Post Measurement</i> SBP, DBP and Pulse Irregular heartbeat symbol Cuff wrap guide symbol (OK, loose) Measurement error “E1 E3 E4 E5 Er”</p> <p><i>Power</i> Battery symbol (low, depleted)</p> <p><i>Communication</i> Bluetooth ON symbol Bluetooth OFF symbol Sync symbol (Flashes/appears when data needs to be transferred because the stored memory is either almost, or completely full) Bluetooth pairing/transferring indicator Bluetooth connection error “Err”</p>	<p>Display/Symbols/Indicators</p> <p><i>Preparation</i> Positioning indicator</p> <p><i>Measurement Procedure</i> Deflation symbol Heartbeat symbol During Measurement: Blood Pressure Level</p> <p><i>Post Measurement</i> SBP, DBP and Pulse Irregular heartbeat symbol Cuff wrap guide symbol (OK, loose) Measurement error “E1 E3 E4 E5 Er” Body Movement error Measurement error “E7” (Wrist is moved up and down during a measurement)</p> <p><i>Power</i> Battery symbol (low, depleted)</p> <p><i>Measurement Records</i> Memory symbol Memory recall number (replaces pulse rate momentarily)</p> <p><i>Date and Time</i> Date and Time (During memory recall)</p> <p><i>Function</i> Morning average symbol Average value symbol Hypertension symbol Morning hypertension symbol</p>
<p>Software other than Algorithm – Item 13</p>	<p>Software other than Algorithm</p>	<p>Software other than Algorithm</p> <p><i>Averages and Differences</i> Average (Last 3 measurements value within 10 min) Weekly Average (morning measurements value within 8 weeks)</p>

	<p><i>Diagnostic</i> Irregular heartbeat detection</p> <p><i>Functions</i> Correct cuff wrapping detection</p> <p><i>Communication</i> The data (measurement result of blood pressure and pulse rate) transfer via Bluetooth</p>	<p><i>Diagnostic</i> Irregular heartbeat detection Blood Pressure classification</p> <p><i>Functions</i> Correct cuff wrapping detection Body movement error detection</p>
Memory Capacity Item 14	<p><i>Number of stored measurements</i> 30 measurements</p>	<p><i>Number of stored measurements</i> 60 measurements</p>
Same Criteria	<p>Measurement</p> <p><i>Accuracy</i> Blood Pressure accuracy ± 3 mmHg 1,5 Pulse accuracy ± 5% 1,5</p> <p><i>Method</i> Oscillometric measurement method 1,5 Manually initiated measurements 13</p> <p><i>Ranges</i> Cuff Pressure range 0 to 299 mmHg 1,5,7,8 Blood Pressure measurement SYS 60 to 260 mmHg 1,5,7,8 Blood Pressure measurement DIA 40 to 215 mmHg 1,5,7,8 Pulse measurement 40 to 180 beats / min. 1,5,7,8</p> <p><i>Inflation</i> Inflation 0 to 299 mmHg 1,5,7 Automatic Inflation 7</p> <p><i>Deflation</i> Automatic Deflation 8</p> <p><i>Cuffs (Please state sizes and materials used)</i> Wrist Cuff (Wrist circumference 13.5 cm to 21.5 cm) Type BF 6</p> <p><i>Sensors</i> The electric pressure sensor 5</p> <p><i>Measurements other than Blood Pressure</i> Pulse 40 to 180 beat / min. 1,5,8</p> <p>Buttons/Switches</p> <p><i>Power</i> On/Off with START/STOP button 10</p> <p>Display/Symbols/Indicators</p> <p><i>Measurement Procedure</i> Deflation symbol 11 Heartbeat symbol 11 During Measurement: Blood Pressure Level 11</p> <p><i>Post Measurement</i> SBP, DBP and Pulse 11 Irregular heartbeat symbol 11 Cuff wrap guide symbol (OK, loose) 11 Measurement error “E1 E3 E4 E5 Er” 11</p>	<p>Measurement</p> <p><i>Accuracy</i> Blood Pressure accuracy ± 3 mmHg 1,5 Pulse accuracy ± 5% 1,5</p> <p><i>Method</i> Oscillometric measurement method 1,5 Manually initiated measurements 13</p> <p><i>Ranges</i> Cuff Pressure range 0 to 299 mmHg 1,5,7,8 Blood Pressure measurement SYS 60 to 260 mmHg 1,5,7,8 Blood Pressure measurement DIA 40 to 215 mmHg 1,5,7,8 Pulse measurement 40 to 180 beats / min. 1,5,7,8</p> <p><i>Inflation</i> Inflation 0 to 299 mmHg 1,5,7 Automatic Inflation 7</p> <p><i>Deflation</i> Automatic Deflation 8</p> <p><i>Cuffs (Please state sizes and materials used)</i> Wrist Cuff (Wrist circumference 13.5 cm to 21.5 cm) Type BF 6</p> <p><i>Sensors</i> The electric pressure sensor 5</p> <p><i>Measurements other than Blood Pressure</i> Pulse 40 to 180 beat / min. 1,5,8</p> <p>Buttons/Switches</p> <p><i>Power</i> On/Off with START/STOP button 10</p> <p>Display/Symbols/Indicators</p> <p><i>Measurement Procedure</i> Deflation symbol 11 Heartbeat symbol 11 During Measurement: Blood Pressure Level 11</p> <p><i>Post Measurement</i> SBP, DBP and Pulse 11 Irregular heartbeat symbol 11 Cuff wrap guide symbol (OK, loose) 11 Measurement error “E1 E3 E4 E5 Er” 11</p>

	<i>Power</i> Battery symbol (low, depleted) 11 Software other than Algorithm <i>Diagnostic</i> Irregular heartbeat detection 13 <i>Functions</i> Correct cuff wrapping detection 13		<i>Power</i> Battery symbol (low, depleted) 11 Software other than Algorithm <i>Diagnostic</i> Irregular heartbeat detection 13 <i>Functions</i> Correct cuff wrapping detection 13
--	--	--	--

Comments	
Recommendation	Recommended
Date	28 March 2019