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* Omron Healthcare Vietnam Co., LTD
Man. Address Binh Duong Province, Vietnam

Manufacturer* Omron Healthcare Co., Ltd.
Address 53, Kunotosubu, Terado-cho, Muko, KYOTO, 617-0002 Japan

Brand† Omron
Model‡ 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* Omron Healthcare Vietnam Co., LTD
Man. Address Binh Duong Province, Vietnam

Manufacturer* Omron Healthcare Co., Ltd.
Address 53, Kunotosubu, Terado-cho, Muko, KYOTO, 617-0002 Japan

Brand† Omron
Model‡ 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 ☒ No ☒ N/A* ☒
2 Algorithm for Auscultatory Measurements Yes ☒ No ☒ N/A† ☒
3 Artefact/Error Detection Yes ☒ No ☒
4 Microphone(s) Yes ☒ No ☒ N/A† ☒
5 Pressure Transducer Yes ☒ No ☒
6 Cuffs or Bladders Yes ☒ No ☒
7 Inflation Mechanism Yes ☒ No ☒
8 Deflation Mechanism Yes ☒ No ☒

Part II

9 Model Name or Number Yes ☒ No ☒
10 Casing Yes ☒ No ☒
11 Display Yes ☒ No ☒
12 Carrying/Mounting Facilities Yes ☒ No ☒
13 Software other than Algorithm Yes ☒ No ☒
14 Memory Capacity/Number of stored measurements Yes ☒ No ☒
15 Printing Facilities Yes ☒ No ☒ N/A‡ ☒
16 Communication Facilities Yes ☒ No ☒ N/A‡ ☒
17 Power Supply Yes ☒ No ☒
18 Other Facilities Yes ☒ No ☒ N/A‡ ☒

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@dableducational.org.

Signature of Director
Lucia Prada

Date
6 March, 2019

Signature of Witness
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)

<table>
<thead>
<tr>
<th>Devices – Item 9</th>
<th>Omron RS3 Intelli IT (HEM-6161T-E)</th>
<th>Omron RS4 (HEM-6181-E)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pictures</td>
<td><img src="image" alt="Omron RS3 Intelli IT" /></td>
<td><img src="image" alt="Omron RS4" /></td>
</tr>
<tr>
<td>Display Image</td>
<td><img src="image" alt="Display Image" /></td>
<td><img src="image" alt="Display Image" /></td>
</tr>
<tr>
<td>Validation</td>
<td><em>(equivalence)</em></td>
<td>ANSI/AAMI/ISO 81060-2:2013 and ESH 2010</td>
</tr>
<tr>
<td>Category</td>
<td>Wrist Devices for Self-measurement of Blood Pressure</td>
<td>Wrist Devices for Self-measurement of Blood Pressure</td>
</tr>
<tr>
<td>Casing – Item 10</td>
<td><strong>Casing</strong>&lt;br&gt;Dimensions&lt;br&gt;Approximately 84 mm (w) × 62 mm (h) × 21 mm (l) (not including the wrist cuff)</td>
<td><strong>Casing</strong>&lt;br&gt;Dimensions&lt;br&gt;Approximately 93 mm (w) × 62 mm (h) × 20 mm (l) (not including the wrist cuff)</td>
</tr>
<tr>
<td>Buttons/Switches</td>
<td>Buttons/Switches</td>
<td></td>
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<tr>
<td>-----------------</td>
<td>-----------------</td>
<td></td>
</tr>
<tr>
<td><strong>Power</strong></td>
<td><strong>Power</strong></td>
<td></td>
</tr>
<tr>
<td>On/Off with START/STOP button</td>
<td>On/Off with START/STOP button</td>
<td></td>
</tr>
<tr>
<td><strong>Communication</strong></td>
<td><strong>Measurement Records</strong></td>
<td></td>
</tr>
<tr>
<td>Connection button</td>
<td>Memory button</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Morning Average button</td>
<td></td>
</tr>
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<table>
<thead>
<tr>
<th>Display – Item 11</th>
<th>Display/Symbols/Indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Measurement Procedure</strong></td>
<td><strong>Measurement Procedure</strong></td>
</tr>
<tr>
<td>Deflation symbol</td>
<td>Deflation symbol</td>
</tr>
<tr>
<td>Heartbeat symbol</td>
<td>Heartbeat symbol</td>
</tr>
<tr>
<td><strong>Post Measurement</strong></td>
<td><strong>Post Measurement</strong></td>
</tr>
<tr>
<td>SBP, DBP and Pulse</td>
<td>SBP, DBP and Pulse</td>
</tr>
<tr>
<td>Irregular heartbeat symbol</td>
<td>Irregular heartbeat symbol</td>
</tr>
<tr>
<td>Cuff wrap guide symbol (OK, loose)</td>
<td>Cuff wrap guide symbol (OK, loose)</td>
</tr>
<tr>
<td>Measurement error “E1 E3 E4 E5 Er”</td>
<td>Measurement error “E1 E3 E4 E5 Er”</td>
</tr>
<tr>
<td><strong>Power</strong></td>
<td><strong>Power</strong></td>
</tr>
<tr>
<td>Battery symbol (low, depleted)</td>
<td>Battery symbol (low, depleted)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Software other than Algorithm – Item 13</th>
<th>Software other than Algorithm</th>
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<tr>
<td><strong>Software other than Algorithm</strong></td>
<td><strong>Software other than Algorithm</strong></td>
</tr>
<tr>
<td><strong>Averages and Differences</strong></td>
<td><strong>Averages and Differences</strong></td>
</tr>
<tr>
<td>Average (Last 3 measurements value within 10 min)</td>
<td>Average (Last 3 measurements value within 10 min)</td>
</tr>
<tr>
<td>Weekly Average (morning measurements value within 8 weeks)</td>
<td>Weekly Average (morning measurements value within 8 weeks)</td>
</tr>
</tbody>
</table>
### Diagnostic
- Irregular heartbeat detection

### Functions
- Correct cuff wrapping detection

### Communication
- The data (measurement result of blood pressure and pulse rate) transfer via Bluetooth

### Memory Capacity
<table>
<thead>
<tr>
<th>Item</th>
<th>Number of stored measurements</th>
</tr>
</thead>
<tbody>
<tr>
<td>14</td>
<td>30 measurements</td>
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<tr>
<td></td>
<td>60 measurements</td>
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</table>

### Same Criteria

#### Measurement
- **Accuracy**
  - Blood Pressure accuracy ± 3 mmHg
  - Pulse accuracy ± 5%
- **Method**
  - Oscillometric measurement method
  - Manually initiated measurements
- **Ranges**
  - Cuff Pressure range 0 to 299 mmHg
  - Blood Pressure measurement SYS 60 to 260 mmHg
  - Blood Pressure measurement DIA 40 to 215 mmHg
  - Pulse measurement 40 to 180 beats / min.
- **Inflation**
  - Inflation 0 to 299 mmHg
  - Automatic Inflation
- **Deflation**
  - Automatic Deflation
- **Cuffs (Please state sizes and materials used)**
  - Wrist Cuff (Wrist circumference 13.5 cm to 21.5 cm) Type BF
  - Sensors
  - The electric pressure sensor
- **Measurements other than Blood Pressure**
  - Pulse 40 to 180 beat / min.

#### Buttons/Switches
- **Power**
  - On/Off with START/STOP button

#### Display/Symbols/Indicators
- **Measurement Procedure**
  - Deflation symbol
  - Heartbeat symbol
  - During Measurement: Blood Pressure Level
- **Post Measurement**
  - SBP, DBP and Pulse
  - Cuff wrap guide symbol (OK, loose)
  - Measurement error "E1 E3 E4 E5 Er"

### Measurement
- **Accuracy**
  - Blood Pressure accuracy ± 3 mmHg
  - Pulse accuracy ± 5%
- **Method**
  - Oscillometric measurement method
  - Manually initiated measurements
- **Ranges**
  - Cuff Pressure range 0 to 299 mmHg
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  - The electric pressure sensor
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#### Buttons/Switches
- **Power**
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#### Display/Symbols/Indicators
- **Measurement Procedure**
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<tr>
<td>Functions</td>
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</tr>
<tr>
<td>Correct cuff wrapping detection</td>
<td>Correct cuff wrapping detection</td>
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<table>
<thead>
<tr>
<th>Comments</th>
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<tbody>
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<td>Recommendation</td>
<td>Recommended</td>
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<tr>
<td>Date</td>
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