

## Medaval Accreditation Assessment

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### **Accreditation assessment of the blood pressure measurement technology used in the Omron BP765 (HEM-7311-ZSA) upper arm monitor, as validated according to the AAMI/ANSI/ISO 81060-2:2013 standard for a general study in adults**

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#### **Reference**

Medaval Ltd. Accreditation assessment of the blood pressure measurement technology used in the Omron BP765 (HEM-7311-ZSA) upper arm monitor, as validated according to the AAMI/ANSI/ISO 81060-2:2013 standard for a general study in adults. *Medical Device Assessment*. 2016 Aug 5;2016(1625). 5 p. Epub: 2019 Jan 31. Available from: <https://www.medaval.ie/MDA/2016/MDA1625.pdf>.

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# Accreditation assessment of the blood pressure measurement technology used in the Omron BP765 (HEM-7311-ZSA) upper arm monitor, as validated according to the AAMI/ANSI/ISO 81060-2:2013 standard for a general study in adults

*Medaval Accreditation-Assessment Report – 5<sup>th</sup> August 2016*

## Test Device Details

|                               |   | Assessment   |
|-------------------------------|---|--|
| <b>Full Name</b>              | Omron BP765   | Requirement satisfactory   |
| <b>Model</b>                  | HEM-7311-ZSA  | Requirement satisfactory   |
| <b>Measurement Site</b>       | Upper Arm   | Requirement satisfactory   |
| <b>Client Use</b>             | Suitable for self-measurement.  | Requirement satisfactory   |
| <b>Operation Method</b>       | Oscillometry, automatic during deflation  | Requirement satisfactory   |
| <b>Measurement Occurrence</b> | Single Measurements Only  | Requirement satisfactory   |
| <b>Device Photograph</b>      |                  |  |
| <b>Manufacturer(s)</b>        | Sole: Omron Healthcare, Kyoto Head Office, Shiokoji Horikawa, Shimogyo ku, Kyoto 600 8530, JAPAN. | Requirement satisfactory   |
| <b>Cuffs</b>                  | Omron HEM-RML31: Medium-Large 22 cm to-42 cm  | Cuffs Listed: Requirement satisfactory<br>Arm Circumferences: Requirement satisfactory |

## Study Details

|                                 |   |                            |
|---------------------------------|---|----------------------------|
| <b>Original Publication</b>     | Takahashi H, Yoshika M, Yokoi T. Validation of two automatic devices for the self-measurement of blood pressure according to the ANSI/AAMI/ISO81060-2:2009 guidelines: the Omron BP765 (HEM-7311-ZSA) and the Omron BP760N (HEM-7320-Z). <i>Vasc Health Risk Manag.</i> 2015 Jan;9(11):49-53. doi: 10.2147/VHRM.S72438. PMID: 25657587. |                            |
| <b>Protocol</b>                 | Followed: The AAMI/ANSI/ISO 81060-2:2009 standard for a general study in adults. <sup>1</sup><br>Fulfils: The AAMI/ANSI/ISO 81060-2:2013 standard for a general study in adults. <sup>1</sup>   |                            |
| <b>Assessment</b>               |   |                            |
| <b>Reference Determination</b>  | Sequential same-arm   | Requirement satisfactory   |
| <b>Adherence</b>                | 81060-2:2009 covers 2013  | Optional data satisfactory |
| <b>Adjustments</b>              | None  | Optional data satisfactory |
| <b>Study Meas. Method</b>       | Oscillometric   | Requirement satisfactory   |
| <b>Study Measurement Site</b>   | Upper Arm   | Requirement satisfactory   |
| <b>Observers</b>                |   |                            |
| <b>Supervisor + 2 Observers</b> | Yes   | Optional data satisfactory |
| <b>Observer Training</b>        | BHS online training   | Optional data satisfactory |
| <b>Observer Familiarisation</b> | Not specified   | Optional data not provided |
| <b>Observers Blinded</b>        | From device and each other  | Optional data satisfactory |
| <b>Sample</b>                   |   |                            |
| <b>Population</b>               | A general population  | Requirement satisfactory   |
| <b>Circumstances</b>            | None  | Requirement satisfactory   |
| <b>HBP Subjects Selection</b>   | Hospital outpatients  | Optional data satisfactory |
| <b>NBP Subjects Selection</b>   | Hospital staff  | Optional data satisfactory |

|   |                                |    |
|---|--------------------------------|----|
| <b>Test Device Details and Study Details Assessment</b> | <b>Checks</b>                  | 22 |
|   | <b>Permitted Modifications</b> | 0  |
|   | <b>Violations</b>              | 0  |

**Procedure**

**Table 1: Screening and Recruitment Details**

| Screening and Recruitment  |  |           | Assessment                   |  |
|--|--|-----------|------------------------------|--|
| Total Screened   |  | <b>99</b> | Value within requirements    |  |
| Total Excluded   |  | <b>14</b> | Value within requirements    |  |
| Device Failure   |  | <b>0</b>  | Optional detail not provided |  |
| Poor Quality Sounds  |  | <b>0</b>  | Optional detail not provided |  |
| Cuff Size Unavailable  |  | <b>0</b>  | Optional detail not provided |  |
| Observer Disagreement  |  | <b>0</b>  | Optional detail not provided |  |
| Bigeminy   |  | <b>0</b>  | Optional detail not provided |  |
| Trigeminy  |  | <b>0</b>  | Optional detail not provided |  |
| Isolated VPB   |  | <b>0</b>  | Optional detail not provided |  |
| Atrial Fibrillation  |  | <b>0</b>  | Optional detail not provided |  |
| Other Reasons*   |  | <b>0</b>  | Optional detail not provided |  |
| Total Recruited  |  | <b>85</b> | Value within requirements    |  |
| *Explanation Summary   |  |           | Optional detail not provided |  |
| Subjects < 20 years old, arm circumference outside 22 cm to 42 cm, with arrhythmias, who moved their arms during measurements or had unclear K5 were excluded. |  |           |                              |  |

|                           |                                |           |
|---------------------------|--------------------------------|-----------|
| <b>Table 1 Assessment</b> | <b>Checks</b>                  | <b>13</b> |
|                           | <b>Permitted Modifications</b> | <b>0</b>  |
|                           | <b>Violations</b>              | <b>0</b>  |

**Study Results**

**Table 2: Subject Details**

|                           |                  |                   | Assessment                    |   |
|---------------------------|------------------|-------------------|-------------------------------|---|
| Sex                       | Male:Female      | <b>39:46</b>      | Value within requirements     | Value within requirements               |
| Age (years)               | Range (Low:High) | <b>21:78</b>      | Value within requirements     | Value within requirements               |
|                           | Mean (SD)        | <b>49 (12.6)</b>  | Optional data satisfactory    | Optional data satisfactory              |
| Arm Circumference (cm)    | Range (Low:High) | <b>22.2:41.9</b>  | Optional data satisfactory    | Optional data satisfactory              |
|                           | Mean (SD)        | <b>32.3 (5.8)</b> | Optional data satisfactory    | Optional data satisfactory              |
|                           | Adults:Children  | <b>85:0</b>       | Value within requirements     | Value within requirements               |
| Cuff for Test Device (cm) | ML (22- 42)      | <b>85</b>         | Value within requirements     |   |
|                           | Q1 (22 – 27)     | <b>26</b>         | Value within requirements     |   |
|                           | Q2 (27.1 – 32)   | <b>11</b>         | Value within requirements     |   |
|                           | Q3 (32.1 – 37)   | <b>29</b>         | Value within requirements     |   |
|                           | Q4 (37.1 – 42)   | <b>19</b>         | Value within requirements     |   |
| Recruitment SBP (mmHg)    | Range (Low:High) | <b>84:188</b>     | Control data provided instead | Control data provided instead           |
|                           | Mean (SD)        | <b>130 (9.7)</b>  | Control data provided instead | Incorrect control data provided instead |
| Recruitment DBP (mmHg)    | Range (Low:High) | <b>55:122</b>     | Control data provided instead | Control data provided instead           |
|                           | Mean (SD)        | <b>83 (13.6)</b>  | Control data provided instead | Control data provided instead           |

|                           |                                |           |
|---------------------------|--------------------------------|-----------|
| <b>Table 2 Assessment</b> | <b>Checks</b>                  | <b>25</b> |
|                           | <b>Permitted Modifications</b> | <b>0</b>  |
|                           | <b>Violations</b>              | <b>0</b>  |

**Table 3: Observer Measurements Range-Requirements**

|                           |                  |             | <b>Assessment</b>              |                           |
|---------------------------|------------------|-------------|--------------------------------|---------------------------|
| SBP                       | ≤ 100 mmHg       | <b>7%</b>   | Value within requirements      |                           |
|                           | 101 – 139 mmHg   | <b>59%</b>  | Value within requirements      |                           |
|                           | 140 – 159 mmHg   | <b>29%</b>  | Value within requirements      |                           |
|                           | ≥ 160 mmHg       | <b>5%</b>   | Value within requirements      |                           |
| DBP                       | ≤ 60 mmHg        | <b>6%</b>   | Value within requirements      |                           |
|                           | 61 – 84 mmHg     | <b>49%</b>  | Value within requirements      |                           |
|                           | 85 – 99 mmHg     | <b>34%</b>  | Value within requirements      |                           |
|                           | ≥ 100 mmHg       | <b>11%</b>  | Value within requirements      |                           |
| DBP sounds used           | K4:K5 (subjects) | <b>0:85</b> | Value within requirements      | Value within requirements |
| <b>Table 3 Assessment</b> |                  |             | <b>Checks</b>                  | 10                        |
|                           |                  |             | <b>Permitted Modifications</b> | 0                         |
|                           |                  |             | <b>Violations</b>              | 0                         |

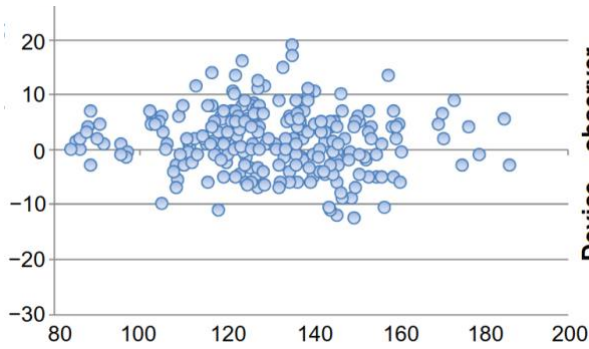
**Table 4: Observer Differences**

|                           |                  |                | <b>Assessment</b>                                    |                            |
|---------------------------|------------------|----------------|--|----------------------------|
| Observer 2 – Observer 1   |                  |                |  |                            |
| SBP (mmHg)                | Range (Low:High) | ?:?            | Optional data not provided                           | Optional data not provided |
|                           | Mean (SD)        | <b>0 (1,3)</b> | Optional data provided                               | Optional data provided     |
| DBP (mmHg)                | Range (Low:High) | ?:?            | Optional data not provided                           | Optional data not provided |
|                           | Mean (SD)        | <b>0 (1,3)</b> | Optional data provided                               | Optional data provided     |
| Repeated Measurements     |                  | ?              | Modification: Missing value accepted by paper review |                            |
| <b>Table 4 Assessment</b> |                  |                | <b>Checks</b>  | 9                          |
|                           |                  |                | <b>Permitted Modifications</b>                       | 1                          |
|                           |                  |                | <b>Violations</b>                                    | 0                          |

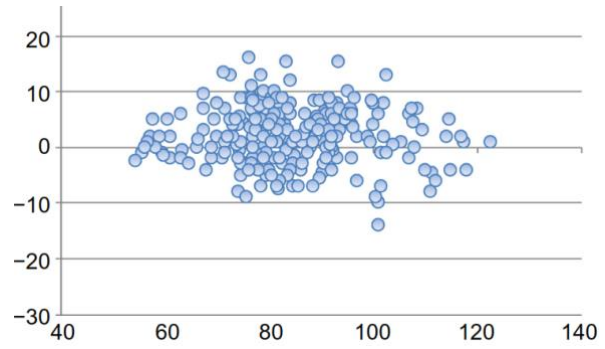
**Table 5: Validation Results**

| Criterion 1               | Pass Req.   | Achieved    |                                | <b>Assessment</b>             |                               |
|---------------------------|-------------|-------------|--------------------------------|-------------------------------|-------------------------------|
|                           |             | SBP         | DBP                            |                               |                               |
| Measurement pairs         |             | <b>255</b>  |                                | Value within requirements     |                               |
| Mean mmHg                 | ≤ 5         | <b>+1.5</b> | <b>+2.2</b>                    | Value within passing criteria | Value within passing criteria |
| SD mmHg                   | ≤ 8         | <b>5.5</b>  | <b>5.1</b>                     | Value within passing criteria | Value within passing criteria |
| Grade 1                   |             | <b>Pass</b> | <b>Pass</b>                    | Value within passing criteria | Value within passing criteria |
| <b>Criterion 2</b>        |             |             |                                |                               |                               |
| Number of subjects        |             | <b>85</b>   |                                | Value within requirements     |                               |
| Mean mmHg                 |             | <b>+1.5</b> | <b>+2.2</b>                    | Value within passing criteria | Value within passing criteria |
| SD mmHg                   | ≤ 6.78:6.58 | <b>4.4</b>  | <b>4.4</b>                     | Value within passing criteria | Value within passing criteria |
| Grade 2                   |             | <b>Pass</b> | <b>Pass</b>                    | Value within passing criteria | Value within passing criteria |
| <b>Result</b>             |             | <b>Pass</b> |                                | Value within passing criteria |                               |
| <b>Table 4 Assessment</b> |             |             | <b>Checks</b>                  | 15                            |                               |
|                           |             |             | <b>Permitted Modifications</b> | 0                             |                               |
|                           |             |             | <b>Violations</b>              | 0                             |                               |

**Plots**



SBP Plot Provided **Yes**  
 DBP Plot Provided **Yes**



Optional data provided  
 Optional data provided

|                         |                                |   |
|-------------------------|--------------------------------|---|
| <b>Plots Assessment</b> | <b>Checks</b>                  | 2 |
|                         | <b>Permitted Modifications</b> | 0 |
|                         | <b>Violations</b>              | 0 |

**Recommendations**

**Overall Summary**

|  |    |
|--|----|
| <i>Number of checks</i>                  | 96 |
| <i>Number of permitted modifications</i> | 1  |
| <i>Number of violations</i>              | 0  |

**Assessment Summary**

The validation has been checked and is verified as having been conducted in accordance with the protocol requirements. Therefore, the results are considered to be valid, the null hypothesis, that the device is inaccurate in measuring blood pressure, is rejected and the conclusion, that the device is accurate for self-measurement in adults, is correct.

**Certification Decision**

The Omron BP765 (HEM-7311-ZSA), with the HEM-RML31 22 cm to-42 cm cuff, is certified by Medaval Ltd., for blood pressure measurement in adults, as it fulfilled the conditions required for a pass in a validation study carried out in accordance with the requirements of the AAMI/ANSI/ISO 81060-2:2013 standard.

Date of Advisory Board Approval: 29th July 2016.

**References**

1. American National Standards Institute, Association for the Advancement of Medical Instrumentation, International Electrotechnical Commission. ANSI/AAMI/IEC 80601-2-30:2009 & A1:2013, Medical electrical equipment - Part 2-30: Particular requirements for basic safety and essential performance of automated type non-invasive sphygmomanometers and Amendment 1. Geneva, Switzerland: IEC Central Office; 2009.
2. Association for the Advancement of Medical Instrumentation, American National Standards Institute, International Organization for Standardization. AAMI/ANSI/ISO 81060-2:2013, Non-invasive Sphygmomanometers - Part 2: Clinical Investigation of Automated Measurement Type. Geneva, Switzerland: ISO; 2013.