

Medaval Accreditation Assessment

Volume 2016

Report 1626

05 August 2016

Accreditation assessment of the blood pressure measurement technology used in the A&D UB-543 wrist monitor, as validated according to the European Society of Hypertension International Protocol revision 2010

Approved by the Medaval Advisory Board

| | | |
|-----------------------------------|-------------------|------------------|
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Reference

Medaval Ltd. Accreditation assessment of the blood pressure measurement technology used in the A&D UB-543 wrist monitor, as validated according to the European Society of Hypertension International Protocol revision 2010. *Medical Device Assessment*. 2016 Aug 5;**2016**(1626). 5 p. Epub: 2019 Jan 31. Available from: <https://www.medaval.ie/MDA/2016/MDA1626.pdf>.

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Accreditation assessment of the blood pressure measurement technology used in the A&D UB-543 wrist monitor, as validated according to the European Society of Hypertension International Protocol revision 2010

Medaval Accreditation-Assessment Report – 5th August 2016

Test Device Details

| | | Assessment |
|-------------------------------|--|--|
| Full Name | A&D UB-543 | Requirement satisfactory |
| Model | UB-543 | Requirement satisfactory |
| Measurement Site | Wrist | Requirement satisfactory |
| Client Use | Suitable for self-measurement. | Requirement satisfactory |
| Operation Method | Oscillometry, automatic during deflation | Requirement satisfactory |
| Measurement Occurrence | Single Measurements Only | Requirement satisfactory |
| Device Photograph |  | Modification: No photograph in paper. Standard image shown in report. |
| Manufacturer(s) | Sole: A&D Company Ltd., 3-23-14 Higashi-Ikebukuro, Toshima-Ku, 170-0013 Tokyo, JAPAN | Requirement satisfactory |
| Cuffs | Integrated 15.5 cm to 21.5 cm | Cuffs Listed: Requirement satisfactory Wrist Circumferences: Requirement satisfactory |

Study Details

| | | |
|-----------------------------|---|--|
| Original Publication | Fania C, Benetti E, Palatini P. Validation of the A&D BP UB-543 wrist device for home blood pressure measurement according to the European Society of Hypertension International Protocol revision 2010. <i>Blood Press Monit.</i> 2015 Aug; 20 (4):237-40. Epub: 2015 Mar 12. doi: 10.1097/MBP.000000000000117. PMID: 25768063. | |
| Protocol | The European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults ¹ | |

| | | Assessment |
|---------------------------------|------------------------------|--------------------------|
| Adherence | Followed Precisely | Requirement satisfactory |
| Adjustments | None | Requirement satisfactory |
| Study Meas. Method | Oscillometric | Requirement satisfactory |
| Study Measurement Site | Wrist | Requirement satisfactory |
| Observers | | |
| Supervisor + 2 Observers | Yes | Requirement satisfactory |
| Observer Training | By expert in BP measurement | Requirement satisfactory |
| Observer Familiarisation | 40 test measurements | Requirement satisfactory |
| Observers Blinded | From device and each other | Requirement satisfactory |
| Sample | | |
| Population | A general population | Requirement satisfactory |
| Circumstances | None | Requirement satisfactory |
| HBP Subjects Selection | Inpatients and outpatients | Requirement satisfactory |
| NBP Subjects Selection | Accompanying persons & staff | Requirement satisfactory |

| | | |
|---|--------------------------------|----|
| Test Device Details and Study Details Assessment | Checks | 22 |
| | Permitted Modifications | 1 |
| | Violations | 0 |

Procedure

Table 1: Screening and Recruitment Details

| Screening and Recruitment | | | | Assessment |
|----------------------------------|-----------------------|----------------|-----------|----------------------------------|
| Total Screened | | | 34 | Value within requirements |
| Total Excluded | | | 1 | Value within requirements |
| | Ranges Complete | | 1 | Value within requirements |
| | Range Adjustment | | 0 | Value within requirements |
| | Arrhythmias | | 0 | Value within requirements |
| | Device Failure | | 0 | Value within requirements |
| | Poor Quality Sounds | | 0 | Value within requirements |
| | Cuff Size Unavailable | | 0 | Value within requirements |
| | Observer Disagreement | | 0 | Value within requirements |
| | Distribution | | 0 | Value within requirements |
| | Other Reasons* | | 0 | Value within requirements |
| Total Recruited | | | 33 | Value within requirements |
| *Explanation Summary | | | | No details required |
| Recruitment Ranges | | | | |
| SBP | Total | | 33 | Value within requirements |
| | Low | | 11 | Value within requirements |
| | | < 90 mmHg | 1 | Value within requirements |
| | | 90 – 129 mmHg | 10 | Value within requirements |
| | Medium | 130 – 160 mmHg | 11 | Value within requirements |
| | High | | 11 | Value within requirements |
| | | 161 – 180 mmHg | 10 | Value within requirements |
| | | > 180 mmHg | 1 | Value within requirements |
| DBP | Total | | 33 | Value within requirements |
| | Low | | 11 | Value within requirements |
| | | < 40 mmHg | 1 | Value within requirements |
| | | 40 – 79 mmHg | 10 | Value within requirements |
| | Medium | 80 – 100 mmHg | 11 | Value within requirements |
| | High | | 11 | Value within requirements |
| | | 101 – 130 mmHg | 10 | Value within requirements |
| | | > 130 mmHg | 1 | Value within requirements |
| Total Extremes | | | 4 | Value within requirements |
| On Treatment Ranges | | | | |
| SBP | Low | < 130 mmHg | 2 | Value within requirements |
| | Medium | 130 – 160 mmHg | 7 | Value within requirements |
| | High | > 160 mmHg | 4 | Value within requirements |
| DBP | Low | < 80 mmHg | 2 | Value within requirements |
| | Medium | 80 – 100 mmHg | 6 | Value within requirements |
| | High | > 100 mmHg | 5 | Value within requirements |
| Table 1 Assessment | | | | Checks 36 |
| | | | | Permitted Modifications 0 |
| | | | | Violations 0 |

Study Results

Table 2: Subject Details

| | | | Assessment | |
|---------------------------|----------------------|---------------------|--------------------------------|---------------------------|
| Sex | Male:Female | 17:16 | Value within requirements | Value within requirements |
| Age (years) | Range (Low:High) | 25:83 | Value within requirements | Value within requirements |
| | Mean (SD) | 53.1 (16.4) | Value within requirements | Value within requirements |
| Arm Circumference (cm) | Range (Low:High) | 21:38 | Value within requirements | Value within requirements |
| | Mean (SD) | 29.0 (3.6) | Value within requirements | Value within requirements |
| Wrist Circumference (cm) | Range (Low:High) | 15:20 | Value within requirements | Value within requirements |
| | Mean (SD) | 17.5 (1.4) | Value within requirements | Value within requirements |
| Cuff for Test Device (cm) | Wrist (13.5 to 21.5) | 33 | | |
| | Total | 33 | Value within requirements | |
| Recruitment SBP (mmHg) | Range (Low:High) | 84:196 | Value within requirements | Value within requirements |
| | Mean (SD) | 141.8 (25.1) | Value within requirements | Value within requirements |
| Recruitment DBP (mmHg) | Range (Low:High) | 34:132 | Value within requirements | Value within requirements |
| | Mean (SD) | 88.2 (14.5) | Value within requirements | Value within requirements |
| Table 2 Assessment | | | Checks | 23 |
| | | | Permitted Modifications | 0 |
| | | | Violations | 0 |

Table 3: Observer Measurements in each Recruitment Range

| | | | Assessment | |
|---------------------------|-------------------------------|---------------|--------------------------------|---------------------------|
| SBP | Overall Range mmHg (Low:High) | 84:189 | Value within requirements | Value within requirements |
| | Low (< 130 mmHg) | 42 | Value within requirements | |
| | Medium (130 – 160 mmHg) | 33 | Value within requirements | |
| | High (> 160 mmHg) | 24 | Value within requirements | |
| | Maximum Difference | 18 | Value within requirements | |
| DBP | Overall Range mmHg (Low:High) | 50:126 | Value within requirements | Value within requirements |
| | Low (< 80 mmHg) | 30 | Value within requirements | |
| | Medium (80 – 100 mmHg) | 43 | Value within requirements | |
| | High (> 100 mmHg) | 26 | Value within requirements | |
| | Maximum Difference | 17 | Value within requirements | |
| Table 3 Assessment | | | Checks | 12 |
| | | | Permitted Modifications | 0 |
| | | | Violations | 0 |

Table 4: Observer Differences

| | | | Assessment | |
|---------------------------|------------------|-------------------|--------------------------------|---------------------------|
| Observer 2 – Observer 1 | | | | |
| SBP (mmHg) | Range (Low:High) | -4:+4 | Value within requirements | Value within requirements |
| | Mean (SD) | +0.2 (2.4) | Value within requirements | Value within requirements |
| DBP (mmHg) | Range (Low:High) | -4:+4 | Value within requirements | Value within requirements |
| | Mean (SD) | +0.6 (2.5) | Value within requirements | Value within requirements |
| Repeated Measurements | | 0 | Value within requirements | |
| Table 4 Assessment | | | Checks | 9 |
| | | | Permitted Modifications | 0 |
| | | | Violations | 0 |

Table 5: Validation Results

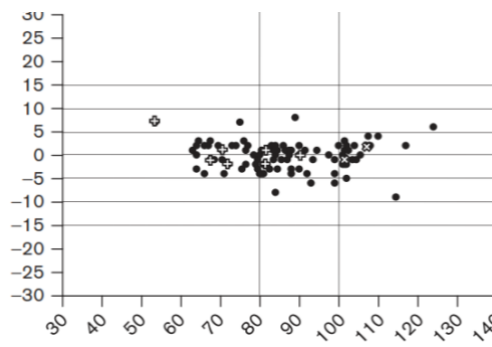
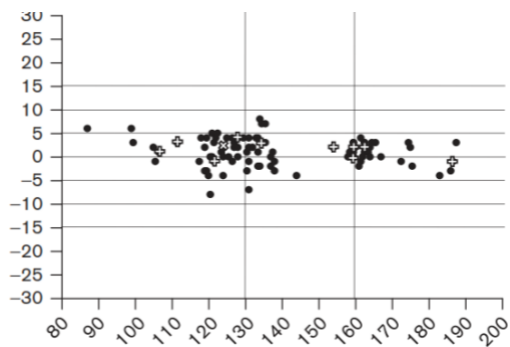
| Part 1 | Pass Req. | | Achieved | | Assessment | |
|-----------|-----------|--------|-------------|-------------|-------------------------------|-------------------------------|
| | Two of | All of | SBP | DBP | | |
| ≤ 5 mmHg | 73 | 65 | 92 | 90 | Value within passing criteria | Value within passing criteria |
| ≤ 10 mmHg | 87 | 81 | 99 | 99 | Value within passing criteria | Value within passing criteria |
| ≤ 15 mmHg | 96 | 93 | 99 | 99 | Value within passing criteria | Value within passing criteria |
| Grade 1 | | | Pass | Pass | Value within passing criteria | Value within passing criteria |
| Mean mmHg | | | +1.1 | -0.1 | Value within requirements | Value within requirements |
| SD mmHg | | | 2.9 | 3.0 | Value within requirements | Value within requirements |

| Part 2 | Pass Req. | Achieved | | Assessment | |
|--------------|-----------|-------------|-------------|-------------------------------|-------------------------------|
| | | SBP | DBP | | |
| 2/3 ≤ 5 mmHg | ≥ 24 | 33 | 33 | Value within passing criteria | Value within passing criteria |
| 0/3 ≤ 5 mmHg | ≤ 3 | 0 | 0 | Value within passing criteria | Value within passing criteria |
| Grade 2 | | Pass | Pass | Value within passing criteria | Value within passing criteria |
| Grade 3 | | Pass | Pass | Value within passing criteria | Value within passing criteria |

| Part 3 | Result | Pass | Value within passing criteria |
|--------------------|--------|------|-------------------------------|
| Table 5 Assessment | | | |

| | | |
|---------------------------|--------------------------------|----|
| Table 5 Assessment | Checks | 21 |
| | Permitted Modifications | 0 |
| | Violations | 0 |

Plots



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

| Assessment | |
|--------------------------|--|
| Requirement satisfactory | |
| Requirement satisfactory | |

| | | |
|-------------------------|--------------------------------|---|
| Plots Assessment | Checks | 2 |
| | Permitted Modifications | 0 |
| | Violations | 0 |

Recommendations

Overall Summary

Number of checks 125
 Number of permitted modifications 1
 Number of violations 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 A&D UB-543 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 International Protocol of the European Society of Hypertension 2010 Revision.

Date of Advisory Board Approval: 29th July 2016.

Reference

- O'Brien E, Atkins N, Stergiou G, Karpettas N, Parati G, Asmar R, Imai Y, Wang J, Mengden T, Shennan A; Working Group on Blood Pressure Monitoring of the European Society of Hypertension. European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults. *Blood Press Monit.* 2010;**15**:23-38. doi: 10.1097/MBP.0b013e3283360e98. PMID: 20110786. Erratum in *Blood Press Monit.* 2010;**15**(3):171-2.