Validation of the A&D UA-651 Plus/UA-651SL Plus automated sphygmomanometer according to the ISO 81060–2, 2018 and ISO 81060–2 Amendment 1, 2020, which resulted in the currently pending Amendment to Amendment 1

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Abstract
In 2020 the ANSI/AAMI/ISO published Amendment 1 to the 81060–2 Standard. The purpose was to try to address issues relating to the distribution of subjects with respect to limb size ranges. It also required a new plot showing the limb circumferences on the x-axis and the device minus reference errors on the y-axis (Alpert plot). The study reported here showed inadequacies of the Amendment if significantly overlapping cuffs were to be tested. The innovative approach led to the testing of 135 subjects. Requirements for blood pressure (BP), arm circumference, and gender were fulfilled. The standard same arm sequential protocol was used. Criterion 1 calculations gave a mean ± standard deviation (SD) device minus manual BP values of 0.22 ± 7.90 mmHg for systolic BP and -0.68 ± 7.36 mmHg for diastolic BP. The maximum allowed mean value for either measurement is 5.0 mmHg. The SD values for Criterion 2 were 6.03 mmHg for systolic BP (maximum allowed 6.95) and 6.47 mmHg for diastolic BP (maximum allowed 6.90). All results passed the Standard requirements. This study demonstrated inadequacies of Amendment 1 and led to the development of an Amendment 2, still in the process of finalization. The new Amendment corrects the issues with significantly overlapping cuffs and “wide-range” cuffs. The A&D UA-651 Plus/UA-651SL Plus BP monitors and the five cuffs not only passed the requirements of 81060–2:2018 and Amendment 1 but also a revised and more rigorous protocol with more subjects involved. These devices and cuffs can be used with confidence.

KEYWORDS
2020 ISO amendment, ISO validation, overlapping cuffs

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1 | INTRODUCTION

The current worldwide Standard for the validation of automated sphygmomanometers is the American National Standards Institute/Association for the Advancement of Medical Instrumentation/International Standards Organization (ANSI/AAMI/ISO) 81060–2:2018.1 In 2020 an Amendment was published2 attempting to address perceived shortcomings related to, for example, the testing of wide-range cuffs, that might otherwise cause inadequate limb size distribution. In addition, the Amendment tried to ensure adequate testing in all ranges of the limb circumference within individual cuffs. The Amendment requires fixed percentages of subjects in the highest and lowest octiles of the total limb circumference range of the cuffs to be tested, and percentages in the four quartiles of this range. The requirements also dictated the minimal subject numbers for each cuff if multiple cuffs were to be tested. Another new feature was a modification of the usual Bland-Altman plot in which the x-axis displays the actual arm circumferences for the entire range and the y-axis the usual device minus reference blood pressures (BP) for each accepted reading (Alpert plot).3

When the Amendment was written the authors did not take into consideration the possibility that a manufacturer might request, for business purposes, the testing of multiple overlapping cuffs in the same validation study. The Amendment, unfortunately, did not make provisions for that study design. When the request for this validation study was received by the author, he tried to comply with the 2020 Amendment but found inadequacies in the current requirements. The interpretation of the current language led to widely ranging subject numbers per cuff; some cuffs would be significantly “under-tested.”

Dr Alpert presented the proposed study to numerous Sphygmonanometer Committee members for advice as how to ensure optimal testing of each of the cuffs and satisfy the requirements of the Amendment as well as possible. To ensure adherence to the standard, the study was designed to try to address the current Amendment and to adjust for subject numbers per cuff.

2 | MATERIALS AND METHODS

A&D is a global company that specializes in BP monitoring. A&D has developed a BP monitor that is ISO Cuff Connector compliant and contains an electrical controlled exhaust valve (ECEV). The ECEV optimizes deflation by controlling the actual size of the exhaust opening, allowing for a constant deflation speed. The ECEV allows the monitor to operate optimally with five different overlapping cuffs sizes. The devices tested were designated as the UA-651 Plus and the UA-651 SL Plus. These are the same device with different model numbers based on geographic marketing regions.

The procedures required by the ISO 81060–2 and Amendment were performed by the research staff of the Stern Cardiovascular Foundation, Germantown, TN. The staff members have performed validation studies previously. Written informed consent was obtained from all subjects. The study was approved by the Baptist Healthcare Independent IRB. There were 135 subjects in the final analyses.

Table 1 shows the final study design developed by Dr Alpert after numerous consultations with other ISO Committee members. For each cuff both quartile and octile requirements were designed to be met, although this is not strictly required. The design tried to fulfill all of the requirements of Amendment 1, despite that the Amendment lacked provisions for overlapping cuffs.

The subjects were ≥18 years with arm circumferences ranging from 16 to 45 cm. A total of 135 subjects were eligible for final data analyses. Twenty-six subjects were excluded from the final data analyses. In 17 the cell for needed BP values was already full. For one subject the arm circumference was out of the range for the study. In two there was excessive variation of DBP values. In three there were critical data omitted on the data forms. In three others the auscultation values were not heard within 4 mmHg. The Standard requires at least 30% of the subjects to be female and ≥30% to be male. We enrolled 74 females (55%) and 60 males (45%).

The procedure followed the protocol described in 81060–2. Briefly, the sequence was as follows: consent was obtained; arm circumference measured; proper cuffs selected for both auscultation and device under test; subject seated quietly for 5 minutes with feet flat on floor, back supported, and arm utilized supported at the level of the heart. The cuffs used for auscultation had the following arm circumference ranges (cm): 15–21, 20–27, 26–35, 32–43. The first reading was performed by auscultation by two blinded observers. The values were recorded by a third observer. The cuff was changed and a second reading was done with the device after a 1 min pause. The 3rd, 5th, 7th, and 9th readings were by auscultation, and the 4th, 6th, and 8th from the device. Requirements for observer BP agreement and drift of BP values were enforced.

2.1 | Analyses

Each individual device reading was compared to the average of the two auscultatory readings before and the two after the device reading. The means and standard deviations were calculated as described in 81060–2, termed Criterion 1 and Criterion 2. Criterion 1 calculations gave a mean ± standard deviation (SD) device minus manual BP values of 0.22 ± 7.90 mmHg for systolic BP (SBP) and -0.68 ± 7.36 mmHg for diastolic BP (DBP). The maximum allowed mean value for either systolic or diastolic BP is 5.0 mmHg. The SD values for Criterion 2 were 6.03 mmHg for systolic BP (maximum allowed 6.95) and 6.47 mmHg for diastolic BP (maximum allowed 6.90). All results passed the Standard requirements. Bland-Altman and Alpert plots were done as required by the Standard and Amendment 1.

3 | RESULTS

The device passed the SBP and DBP requirements (Table 2). There were no adverse events experienced. Table 1 shows the study design. As can
TABLE 1  Subject distribution and cuff distribution (135 subjects)

| Cuff size       | Small adult | Adult | Semi large | Wide range | Large adult |
|-----------------|-------------|-------|------------|------------|-------------|
| Cuff range      | 16-24 cm    | 22-32 cm | 23-37 cm | 22-42 cm | 31-45 cm |
| Total for cuff  | 18          | 16    | 21         | 31         | 23         |
| 16.0            |             |       |            |            |             |
| 16.5            |             |       |            |            |             |
| 17.0            |             |       |            |            |             |
| 17.5            |             |       |            |            |             |
| 18.0            |             |       |            |            |             |
| 18.5            |             |       |            |            |             |
| 19.0            |             |       |            |            |             |
| 19.5            |             |       |            |            |             |
| 20.0            |             |       |            |            |             |
| 20.5            |             |       |            |            |             |
| 21.0            |             |       |            |            |             |
| 21.5            |             |       |            |            |             |
| 22.0            |             |       |            |            |             |
| 22.5            |             |       |            |            |             |
| 23.0            |             |       |            |            |             |
| 23.5            |             |       |            |            |             |
| 24.0            |             |       |            |            |             |
| 24.5            |             |       |            |            |             |
| 25.0            |             |       |            |            |             |
| 25.5            |             |       |            |            |             |
| 26.0            |             |       |            |            |             |
| 26.5            |             |       |            |            |             |
| 27.0            |             |       |            |            |             |
| 27.5            |             |       |            |            |             |
| 28.0            |             |       |            |            |             |
| 28.5            |             |       |            |            |             |
| 29.0            |             |       |            |            |             |
| 29.5            |             |       |            |            |             |
| 30.0            |             |       |            |            |             |
| 30.5            |             |       |            |            |             |
| 31.0            |             |       |            |            |             |
| 31.5            |             |       |            |            |             |
| 32.0            |             |       |            |            |             |
| 32.5            |             |       |            |            |             |
| 33.0            |             |       |            |            |             |
| 33.5            |             |       |            |            |             |
| 34.0            |             |       |            |            |             |
| 34.5            |             |       |            |            |             |
| 35.0            |             |       |            |            |             |
| 35.5            |             |       |            |            |             |
| 36.0            |             |       |            |            |             |
| 36.5            |             |       |            |            |             |

(Continues)
TABLE 1  (Continued)

| Cuff size | Small adult | Adult | Semi large | Wide range | Large adult |
|-----------|-------------|-------|------------|------------|-------------|
| Cuff range | 16-24 cm    | 22-32 cm | 23-37 cm | 22-42 cm | 31-45 cm |
| Total for cuff | 18 | 16 | 21 | 31 | 23 |
| 37.0      |             |        |            |            |            |
| 37.5      |             |        |            |            | 1          |
| 38.0      |             |        |            | 4          | 0          |
| 38.5      |             |        |            |            | 5          |
| 39.0      |             |        |            |            |            |
| 39.5      |             |        |            |            |            |
| 40.0      |             |        |            |            | 2          |
| 40.5      |             |        |            |            |            |
| 41.0      |             |        |            |            |            |
| 41.5      |             |        |            |            | 3          |
| 42.0      |             |        |            |            | 3          |
| 42.5      |             |        |            |            |            |
| 43.0      |             |        |            |            |            |
| 43.5      |             |        |            |            |            |
| 44.0      |             |        |            |            |            |
| 44.5      |             |        |            |            |            |
| 45.0      |             |        |            |            |            |

TABLE 2  ANSI/AAMI/ISO 81060–2 standard criteria testing results

| Criterion 1                              | Criterion 2                              |
|------------------------------------------|------------------------------------------|
| Mean SD                                  | Mean SD                                  |
| Systolic pressure 0.22 mmHg (maximum allowed 5.0) 7.90 | 6.03 (maximum allowed 6.95) |
| Diastolic pressure −0.68 mmHg (maximum allowed 5.0) 7.36 | 6.47 (maximum allowed 6.90) |

Circumference of the arm

| n | %  |
|----|----|
| Small adult | 21 | 16%  |
| Adult | 16 | 12%  |
| Semi-large | 28 | 21%  |
| Wide-range | 39 | 29%  |
| Large adult | 30 | 22%  |
| Total | 134 |     |

Blood pressure

| n | %  |
|----|----|
| SYS ≤ 100 mmHg (≥5%) | 29 | 7%  |
| SYS ≥ 160 mmHg (≥5%) | 28 | 7%  |
| SYS ≥ 140 mmHg (≥20%) | 121 | 30%  |
| DIA ≤ 60 mmHg (≥5%) | 54 | 14%  |
| DIA ≥ 100 mmHg (≥5%) | 19 | 5%  |
| DIA ≥ 85 mmHg (≥20%) | 88 | 22%  |
Figure 1  (A) Bland-Altman plot of systolic blood pressure; (B) Bland-Altman plot of diastolic blood pressure; (C) Alpert plot of systolic blood pressure differences across the range of arm circumference values; (D) Alpert plot of diastolic blood pressure differences across the range of arm circumference values
be observed, the wider range cuffs had greater subject numbers as outlined in the Amendment. The Bland-Altman plots are shown in panels A and B of Figure 1. The Alpert plots are in panels C and D. The errors from the smallest to the largest arm circumferences are generally equally distributed.

4 DISCUSSION

The author was given a complex task to design the validation study of five cuffs with very significant overlap. The authors of the ISO 2020 Amendment had not considered this scenario when the Amendment was developed and approved. Dr Alpert involved many ISO Committee members in the design of this innovative study. A core of AAMI Committee members began the process of developing an Amendment to the 2020 Amendment to try to address the observed shortcomings highlighted by this study. Many drafts were written and re-written. Members of the European Society of Hypertension were shown the 7th draft and they are in agreement. The entire ISO Committee has required multiple meetings to refine the AAMI document so that it can become an approved ISO document. Currently that draft is entering final Committee voting status.

Not only did the A&D UA-651 Plus/UA-651SL Plus pass a protocol significantly more stringent than the ISO “requirements” but also led to the realization that Amendment 1 had not been written to be able to meet the business needs of companies/manufacturers who had global markets to satisfy. The current draft of the Amendment to the 2020 Amendment has now addressed the study design needed for both overlapping cuffs and, in particular, “wide-range” cuffs. Final publication is expected in 2022. Healthcare providers can be confident that their patients can use the A&D device with any of the tested cuffs and obtain clinically actionable BP values.

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CONFLICTS OF INTEREST

There are no conflicts of interest to report. Written informed consent was obtained from all subjects.

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