

Validation of the RisingSun RS-651 Blood Pressure Monitor Based on Auscultation in Adults According to the ANSI/AAMI/ISO 81060-2:2013 Standard

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This study validated the RisingSun RS-651 blood pressure (BP) monitor based on auscultation in adults according to the American National Standards Institute/Association for the Advancement of Medical Instrumentation/International Organization for Standardization (ANSI/AAMI/ISO) 81060-2:2013 standard. The RS-651 device was evaluated in a study of 97 participants. The same arm simultaneous method, as defined in the ANSI/AAMI/ISO standard, was used. The mean differences±standard deviation for criterion 1 were 0.8±2.3 mm Hg for systolic BP (SBP) and

−0.1±2.9 mm Hg for diastolic BP (DBP). Analysis for criterion 2 resulted in values of 0.8±1.5 mm Hg for SBP and −0.1±2.1 mm Hg for DBP. All of the data fulfilled the ANSI/AAMI/ISO 81060-2:2013 standard requirements to pass the validation. The RisingSun RS-651 device can be recommended for both clinical and self/home use in adults according to the ANSI/AAMI/ISO 81060-2:2013 standard. *J Clin Hypertens (Greenwich)*. 2016;18:1279–1283. © 2016 The Authors. *The Journal of Clinical Hypertension* Published by Wiley Periodicals, Inc.

Fully automated blood pressure (BP) monitors are increasingly replacing standard mercury sphygmomanometers^{1–5} because they do not require specific training and do not have observer error.^{6–8} However, replacing mercury sphygmomanometers with automated devices may lead to an inappropriate diagnosis or hypertension management because of inaccurate BP measurements.^{1,9} Hence, the accuracy of a BP monitor is of prime importance.¹⁰ It is recommended that BP measurement devices be validated according to an internationally recognized standard to confirm their accuracy.^{10–12}

Although the auscultation method has been accepted as a gold standard for BP measurements, most automated BP monitors, which have been validated according to a recognized standard, assess BP using the oscillometric technique.^{1,9,13,14} With these oscillometric BP monitors, systolic BP (SBP) and diastolic BP (DBP) are estimated by oscillations using different algorithms that are proprietary to different devices.^{13,15} Therefore, the oscillometric method is not as reliable as the auscultation method.^{16–18}

Previous studies have shown that a few automated BP monitors that are based on the auscultation method to measure BP values use a microphone with high

sensitivity.^{19,20} In recent years, improvements in the transducer and sensor have led to better microphone performance, but there is still a potential mistake in recording and identifying Korotkoff sounds.¹³ Therefore, automated BP monitors using the auscultation method also require validation to ensure their accuracy.

In the present study, we validated the accuracy of the RisingSun RS-651 automated auscultation BP monitor device (RisingSun Company, Beijing, China) in adults according to international protocols of the American National Standards Institute/Association for the Advancement of Medical Instrumentation/International Organization for Standardization (ANSI/AAMI/ISO) 81060-2:2013 standard guidelines.²¹

METHODS

Ethics Statement

All participants enrolled in the study provided informed written consent before the start of the validation experiment. The study protocol was approved by the ethics committee of Chinese People's Liberation Army (PLA) General Hospital (Beijing, China).

RisingSun RS-651 Device

The RS-651 device is an automated electronic noninvasive BP monitor designed primarily for BP measurements in a clinic. It can also be used for self/home BP measurements.

The RS-651 device measures BP values using auscultation on the upper arm during the continuous linear deflation period at a rate of 2 mm of mercury per second. The mean arterial pressure (MAP) and the heart rate (HR) values are calculated by oscillometry during the same period. The SBP, DBP, MAP, and HR are shown on a digital display. All data mentioned above in

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addition to the beat-to-beat pulse waveform can be displayed on a PC or laptop via a USB cable. These indices could help the RS-651 device reduce or remove artifacts for further accuracy. Users can analyze and manage data using the software provided by the manufacturer.

The RS-651 device has a cuff that is compliant with the ANSI/AAMI/ISO 81060-1 standard. The standard cuff for adults that is provided with the device is suitable for upper arm circumferences ranging between 20 and 40 cm. The power supply is provided by built-in rechargeable batteries or through an AC adapter. If no operations occur within 3 minutes, the device automatically turns off to save power.

The manufacturer provided three devices, one of which was randomly selected and used throughout the validation experiment.

Participant Selection

A total of 97 adults (12 years and older) were included in this validation study. The participants were recruited to ensure that number, sex, age, arm circumference, and BP reading distributions were in accordance with the ANSI/AAMI/ISO 81060-2:2013 standard requirements. All participants were recruited as inpatients or outpatients from the Chinese PLA General Hospital. No patients had atrial fibrillation, cardiac arrhythmia, peripheral arterial disease, or other known heart disease per the ANSI/AAMI/ISO 81060-2:2013 standard requirements.

Familiarization

Two weeks before the start of the validation study, more than 50 test measurements were performed for observers and supervisors, and no problems occurred.

BP Measurements

The validation team consisted of three persons: two observers and one independent supervisor. The two observers received formal training in mercury BP measurements after the training program of the Chinese Hypertension League and passing an inspection. SBP was recorded at the appearance of Korotkoff sounds (phase I) and DBP was recorded coincident with the disappearance (phase V) of Korotkoff sounds, as required by the ANSI/AAMI/ISO 81060-2:2013 standard. These readings were recorded independently by each of the two observers. The supervisor recorded all of the device readings and oversaw the entire procedure. The two observers were blinded to each other's measurements as well as to the readings.

The participants were required to sit in a quiet room without disturbing noises and to avoid any loud talking during the measurements. The participants sat with both feet flat on the floor, knees flexed to 90°, and the arm placed in a comfortable position at heart level on a table.²²

The "same arm simultaneous method" that was defined in the ANSI/AAMI/ISO 81060-2:2013 standard was performed in this validation study. The RS-651

device was connected in parallel to the cuff and mercury sphygmomanometer with a double stethoscope via a Y-shaped tube. Manual and device BP measurements were performed simultaneously on the same upper arm by utilizing the same cuff and same inflation/deflation cycle. The RS-651 device automatically inflated the cuff to approximately 20 mm Hg higher than the actual SBP value and deflated to approximately 20 mm Hg below the actual DBP value.

An initial manual BP value was taken for BP screening and classification and was not used in the calculation of the accuracy of the RS-651 device. Each participant underwent three pairs of manual and device measurements. A 1-minute rest was taken between each measurement.

Data Analysis

The data, including SBP, DBP, age, and arm circumference, were noted on paper forms and subsequently entered and analyzed using Matlab (The MathWorks Inc., Natick, MA). Data analysis was performed according to both criteria 1 and 2 as required in the ANSI/AAMI/ISO 81060-2:2013 standard.

The limits of agreement between the readings using a mercury sphygmomanometer (reference method) and the RS-651 device were plotted using the Bland-Altman method²³ plot to assess how the differences related to the reference BP value.

RESULTS

Participants

In this validation experiment, the 97 participants (mean age, 44±16 years; range, 20–81 years) were comprised of 50 (51.5%, criteria ≥30%) men and 47 (48.5%, criteria ≥30%) women. The mean arm circumference was 28.3±3.7 cm (range, 22.0–36.5 cm). The numbers (percentages) of patients were 23 (23.7%, criteria ≥20%), 53 (54.6%, criteria ≥40%), 44 (45.3%, criteria ≥40%), and 21 (21.6%, criteria ≥20%) in the arm circumference ranges of 22.0 to 25.5 cm, 25.6 to 29.0 cm, 29.1 to 32.5 cm, and 32.5 to 36.5 cm, respectively. All of the values of sex, age, and arm circumference distributions met or exceeded the ANSI/AAMI/ISO 81060-2:2013 standard.

BP Measurements

The mean BP value of the 97 participants obtained by the initial auscultation method were 126.9±23.7 mm Hg (range, 88–217 mm Hg) for SBP and 78.4±13.3 mm Hg (range, 50–118 mm Hg) for DBP. The distributions of the initial SBP and DBP reference readings are as follows:

The numbers (percentages) of high SBP (≥160 mm Hg), medium SBP (≥140 mm Hg), and low SBP (≤100 mm Hg) were 20 (10.3%, criteria ≥5%), 40 (20.6%, criteria ≥20%), and 24 (12.4%, criteria ≥5%), respectively. The numbers (percentages) of high DBP (≥100 mm Hg), medium DBP (≥85 mm Hg), and low

DBP (≤ 60 mm Hg) were 18 (9.2%, criteria $\geq 5\%$), 44 (22.7%, criteria $\geq 20\%$), and 20 (10.3%, criteria $\geq 5\%$), respectively.

The mean BP for all 291 measurements with the mercury sphygmomanometer was 125.6 ± 24.0 mm Hg (range, 85–217 mm Hg) for SBP and 78.2 ± 13.6 mm Hg (range, 49–119 mm Hg) for DBP. The mean BP for all the measurements with the RS-651 device was 126.4 ± 24.2 mm Hg (range, 86–216 mm Hg) and 78.1 ± 13.4 mm Hg (range, 47–120 mm Hg) for SBP and DBP, respectively.

According to criterion 1, the mean difference of 291 separate BP data pairs were 0.8 ± 2.3 mm Hg for SBP and -0.1 ± 2.9 mm Hg for DBP. These data were within the ANSI/AAMI/ISO 81060-2:2013 standard requirements (5 ± 8 mm Hg). According to criterion 2, the calculated standard deviation (SD) for SBP was 1.5 mm Hg and for DBP was 2.1 mm Hg, which is in accordance with the acceptance of 6.89 mm Hg for SBP and 6.95 mm Hg for DBP.

Bland-Altman plots²³ of the data set are presented in Figure 1 and Figure 2 for SBP and DBP, respectively. These figures showed no underestimation or overestimation of BP at either low or high BP levels by the RS-651 device.

DISCUSSION

The accuracy of the RisingSun RS-651 BP monitor based on auscultation was assessed in adults for SBP and DBP according to the ANSI/AAMI/ISO 81060-2:2013 standard. The results showed that the RS-651 device achieved both the criteria 1 and 2 of the ANSI/AAMI/ISO 81060-2:2013 standard requirement. No pattern of BP overestimation or underestimation was discernible over the measured BP ranges.

The significantly low mean \pm SD values indicate close agreement between the RS-651 device and the gold-standard mercury sphygmomanometer, with no significant bias. It may be because we simultaneously measured the BP in the same arm with the RS-651 device and the mercury sphygmomanometer. BP fluctuates every moment depending on the autonomic nervous system.²⁴ The same arm simultaneous method can reduce the impact of these fluctuations, depending on one's activity level and emotions.

DEVICE STRENGTHS AND LIMITATIONS

A major advantage of the RS-651 device is the improved auscultatory method. It uses a micromechanical vibration sensor array to assist the high-sensitivity microphone in detecting the Korotkoff sounds, and it has an

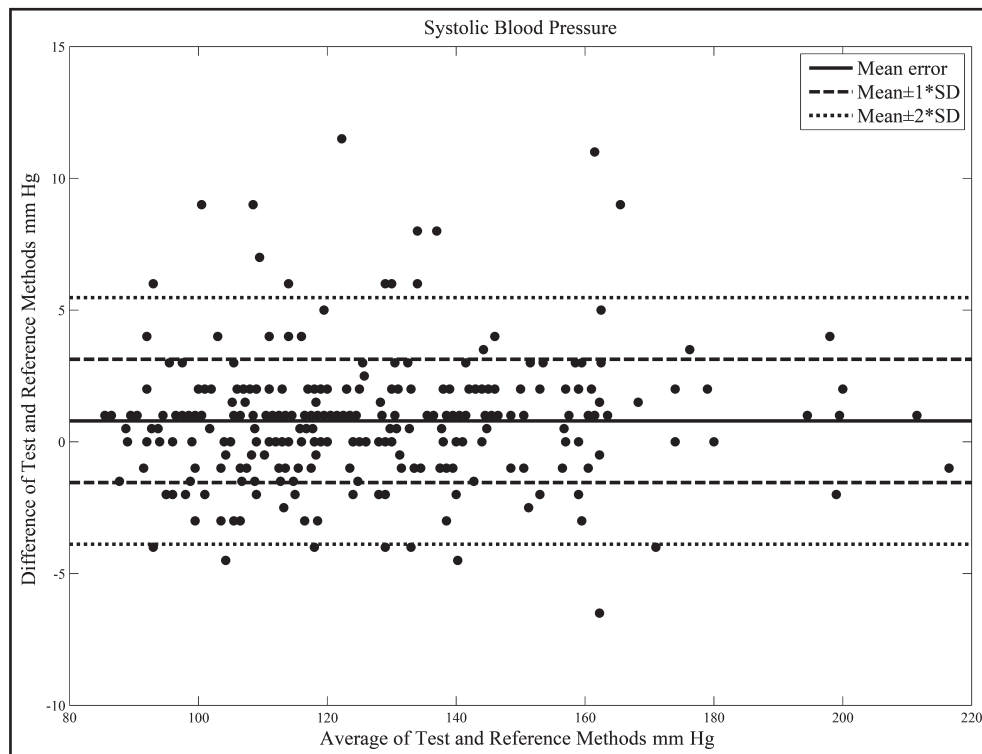


FIGURE 1. Bland-Altman plots for the differences between the RS-651 readings and the observers' measurements for systolic blood pressure. The x-axis represents the average of systolic blood pressure measured by the RS-651 device (test) and the mercury sphygmomanometer (reference). The y-axis represents the difference between the systolic blood pressure obtained by the RS-651 device and the mercury sphygmomanometer. A positive value indicates that the device measurement is greater than the observer's measurement.

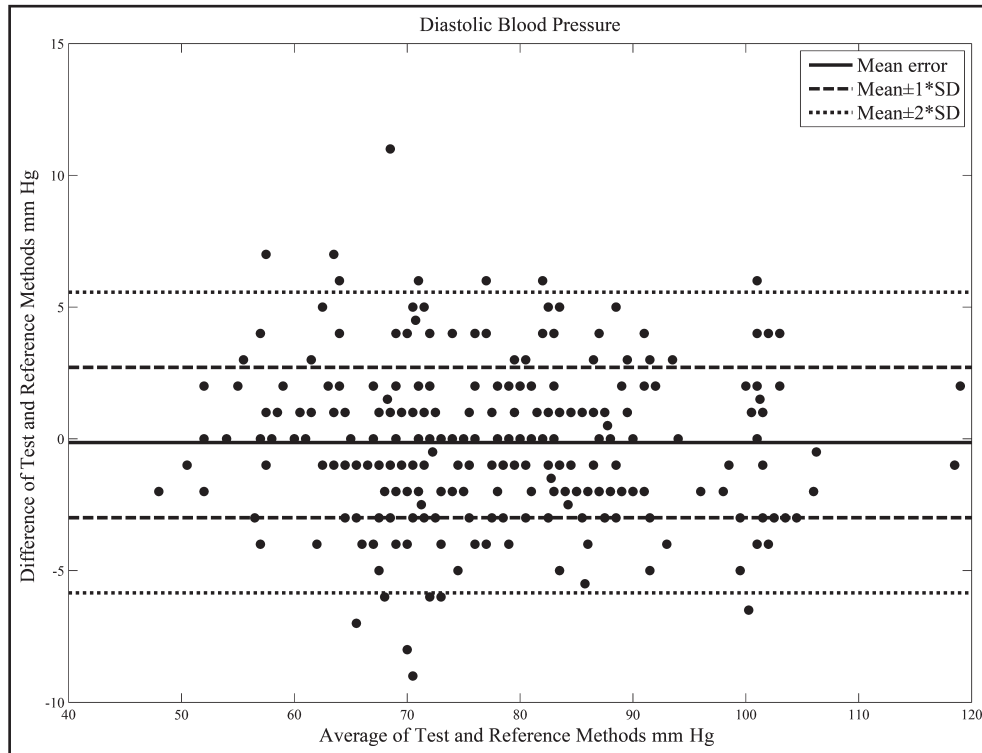


FIGURE 2. Bland-Altman plots for the differences between the RS-651 readings and the observers' measurements for diastolic blood pressure. The x-axis represents the average of diastolic blood pressure measured by the RS-651 device (test) and the mercury sphygmomanometer (reference). The y-axis represents the difference between the diastolic blood pressure obtained by the RS-651 device and the mercury sphygmomanometer. A positive value indicates that the device measurement is greater than the observer's measurement.

improved algorithm that can reduce sound artifacts recorded by the microphone.

One novel feature of the RS-651 device is that it can estimate the SBP values during the inflation period and then inflate the cuff to approximately 20 mm Hg higher than the estimated SBP values automatically, without needing to inflate to an excessive suprasystolic BP to obtain the SBP values. The RS-651 device could decrease the measurement time without sacrificing accuracy and could reduce discomfort, especially in the geriatric population and hypotensive patients.

A major limitation of this study is that we mainly focused on validating the device in adults. As the ANSI/AAMI/ISO 81060-2:2013 standard requires, because the device will be intended for use in special patient groups, such as obese patients, diabetic patients, and pregnant women,²⁵⁻²⁷ it should undergo specific validation studies in those special populations. Previous works also suggest that a BP monitor validated in adults is not always accurate in children²⁸; therefore, studies in children younger than 12 years will also be required. These will be studied in the future.

Another limitation is related to the cuff that was provided by the manufacturer. The cuff was intended for arm circumferences between 20 and 40 cm; thus, this cuff is not suitable for participants with an arm

circumference outside of this range. Previous work suggests that an accurate BP assessment requires the selection of an appropriate cuff size according to the participant's arm circumference.²⁹ Hence, a separate validation study specifically including participants with very large arm circumferences is needed.^{13,30,31}

CONCLUSIONS

The RisingSun RS-651 BP monitor passed the ANSI/AAMI/ISO 81060-2:2013 standard requirements and proved to be accurate across the entire BP range. We can recommend this device for both clinical use and self/home BP measurements in the adult population.

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