Validation of a new automated device for blood pressure measurement as per the ISO81060-2:2013 International Standard: The Cordex SmartCuff™ Device.

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Background: We tested the Cordex SmartCuff device, an innovative, non-invasive automated blood pressure (BP) measurement system that incorporates an operator-independent methodology which will also assess vascular endothelial function utilizing the same BP cuff. This instrument will provide key individual information that assesses cardiovascular disease risk and will have great clinical utility. In this clinical investigation, we validated the BP function of the Cordex Device to determine whether it meets the ISO81060-2:2013 guideline, the accepted standard for non-invasive BP testing performance. The International Organization for Standardization (ISO) is a worldwide federation that creates standards to ensure that products are safe, reliable and of good quality. Blood pressure cuffs must meet this rigorous standard to be used in patient care and this standard is required by the FDA.

Methods: The clinical investigation protocol and informed consent form were approved by the Johns Hopkins IRB and all subjects gave written informed consent prior to enrollment. Under the direction of the study investigators, a team of three highly trained medical technicians validated the performance of the device by comparing it to a marketed reference BP cuff using the same arm sequential method. Using a double stethoscope and an American Diagnostic Corporation sphygmomanometer, for any given subject, two of the medical technicians independently, and in a blind fashion, determined the reference BP. We waited 60 seconds and then obtained BP with the Cordex device. In order for a measurement pair to be valid, the medical technicians' BP determinations needed to be within 4 mmHg of one another's measurements. These measurements are allowed to be repeated up to 8 times to reach the goal of obtaining 3 valid pairs per subject. A minimum of 255 valid pairs and 85 subjects are required to meet this standard. The ISO standard allows for no more than 10% of the subjects having 2 valid pairs. Additional determinations are allowable to meet this latter requirement. For BP pairs, the permissible standard deviation (SD) of the difference between the reference BP and Cordex BP must be less than 8 SD for both systolic and diastolic BP (ISO standard statistical criteria I). For the average BP of individual subjects, there a maximum permissible SD for reference and Cordex BP difference as specified in the ISO guidelines, which varies by the difference between the BP methods (ISO standard statistical criteria II). Both criteria I and II must be met to pass the ISO Standard.

Results: We met the ISO Standard for the validation of the Cordex SmartCuff device based on the testing of 89 subjects yielding 259 valid BP pairs. For the differences between the 259 total pairs, the difference (mean ± SD) between the reference and Cordex BP was SBP: -1.62 ± 7.50 mm Hg; DBP: 0.34 ± 7.08 mm Hg. Thus, the SD was below the allowable maximum of 8 SD. For the BP measurements among the 89 subjects, the difference for SBP was -1.71 ± 6.48 mm Hg; DBP was 0.39± 6.55 mm Hg. Thus, these SD's met the guidelines for the maximum permissible levels for differences between the reference and Cordex BP devices for Criteria I and II. We also met the ISO Standard requirement for having the required number of subjects for each of the 3 cuff sizes that were used and for all of the required categories of subjects across the BP range of low (SBP<100, DBP<60 mmHg) to high (SBP>160, DBP> 100mmHg).

Conclusion: The Cordex SmartCuff Device, an automated, operator independent instrument for assessing vascular health, demonstrated performance that satisfied all of the ISO 81060-2:2013 International Standard requirements for the non-invasive assessment of BP.