Validation of the Aktiia Blood Pressure Cuff for Clinical Use According to the ANSI/AAMI/ISO 81060-2:2013 Protocol

Jérémy Alexandre[1]; Kevin Tan[2]; Tiago P Almeida[1]; Josep Sola[1]; Bruce S Alpert[3]; Jay Shah[1]

[1]Aktiia SA, Neuchâtel, Switzerland; [2]Guangdong Transtek Medical Electronics, Zhongshan, China; [3]Retired from Department of Pediatrics, University of Tennessee Health Science Center, Memphis, USA

Supplementary Materials

Address for correspondence:

Jay Shah

Aktiia SA

Rue du Bassin 8a, 2000 Neuchâtel, Switzerland

Email: publication@aktiia.com

Tel: +41 32 552 20 52

Fax: +41 31 4159 2653

Methods

Statistical Analysis

In addition to the ISO 81060-2 protocol, population-level differences in BP measurements between Aktiia cuff and the reference double-auscultation were investigated with scatter plots and Pearson correlation (R^2).

Here, we also included the 95% confidence interval (CI) of BP differences between Aktiia cuff and reference double-auscultation, and the Student's paired t-tests. P-values of less than 0.05 were considered statistically significant.

Results

Significant differences – albeit well within the limits delineated by ISO 81060-2 [1] – were found between Aktiia cuff and reference double-auscultation for SBP ($\mu \pm \sigma$ [95% CI]: 1.3±7.11 [0.4, 2.2] mmHg, P=0.0034). Conversely, non-significant bias were found for DBP (-0.16±5.46 [-0.8, 0.5] mmHg, P=0.6467).

SBP and DBP measurements performed by the Aktiia cuff were highly correlated with the reference double-auscultation (Figure S1, $R^2 = 0.93$ and $R^2 = 0.91$, respectively).

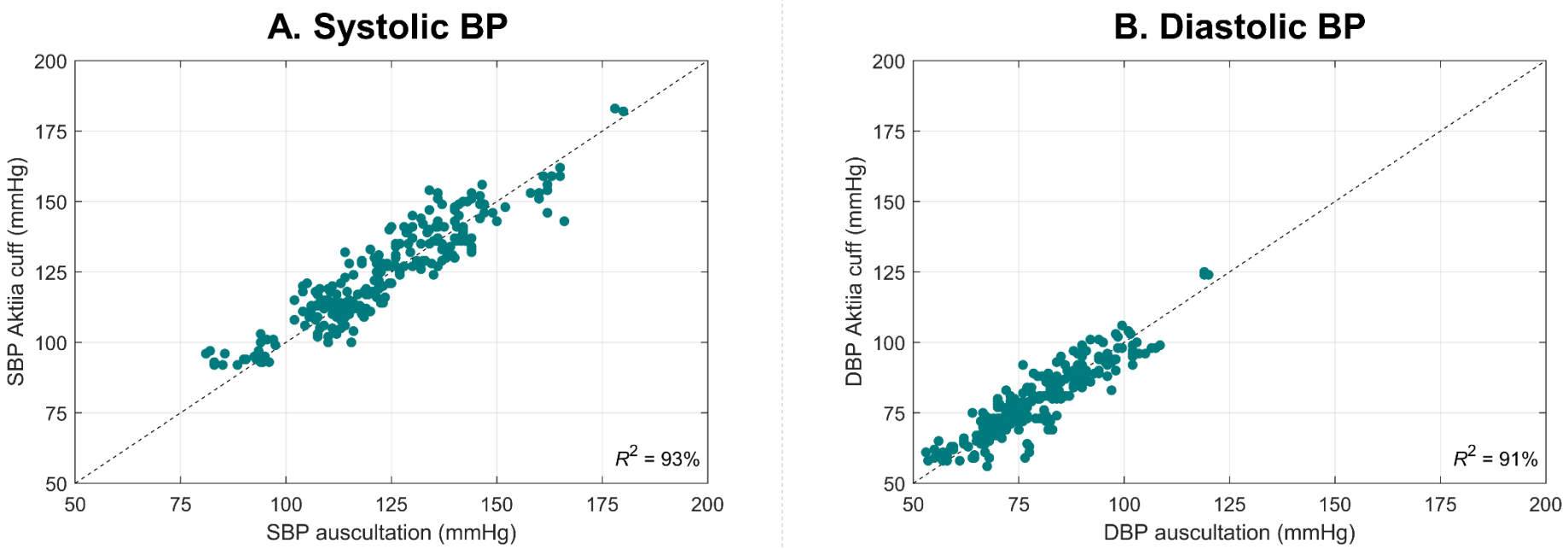

Figure S1. Scatter plots comparing BP measurements performed by the Aktiia cuff and the reference double-auscultation.

REFERENCES

[1] 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. 2013.