

AKTi!A

PUBLICATION

Blood Pressure Monitoring Journal
Coming Soon

LOCATION

Lausanne University Hospital, CHUV

CITATION

Vybornova, E. Polychronopoulou, A. Wurzner-Ghajarzadeh, S. Fallet, J. Sola, Gregoire Wuerzner, MD. C. Pellaton, A. Vybornova, S. Fallet, L. Marques, O. Grossenbacher, B. De Marco, V. Chapuis, M. Bertschi, B. Alpert, J. Solà. "Blood pressure from the optical Aktiia Bracelet: a one-month validation study using extended ISO81060-2 protocol adapted for a cuffless wrist device" *ClinicalTrials.gov* NCT04027777.

Aktiia Pivotal Clinical Trial

**AKTiA OPTICAL BLOOD PRESSURE MONITOR ACCURATE
COMPARED TO DOUBLE AUSCULTATION OVER A MONTH**

“ *After initialization and during one month, the overall accuracy of Aktiia Bracelet satisfied validation criteria 1 and 2 of ISO81060-2 in the sitting position. The Aktiia Bracelet can be recommended for BP measurement in the adult population.* ”

STUDY SUMMARY

The objective of this study was to compare the systolic (S) and diastolic (D) blood pressure (BP) estimations from the Aktiia optical device at the wrist against double auscultation over the period of one month, with subjects measured in multiple body positions.

KEY DEMOGRAPHICS

n=86

study participants

43/43

male/female

21-63 (38)

Age: Range (Mean)

18-41 (24)

BMI: Range (Mean)

1-2: 62%

3-4: 20%

5-6: 18%

Skin Color (Fitzpatrick Scale)

KEY FINDINGS

ISO81060-2

Aktiia meets requirements of the standard:

< 5 mmHg

Target: mean difference of test vs. reference for both SBP and DBP

< 8 mmHg

Target: standard deviation of difference

Full results to be published soon.

TAKEAWAY

Aktiia's pivotal trial built upon prior trials to demonstrate that Aktiia's Optical Blood Pressure Monitoring technology is able to accurately estimate blood pressure within the criteria of ISO81060-2 across a large, representative sample of people over the course of one month in different body positions, compared against double auscultation as a reference. The positive results show that Aktiia is an accurate and trustworthy method of measuring blood pressure across the adult population.