

Aktiia Receives Regulatory Approval for the **World's First Optical Blood Pressure System** Without the Need for Calibration with a Regular Cuff

Neuchâtel, Switzerland – June 12, 2024 – Aktiia, the Swiss startup revolutionizing Blood Pressure (BP) monitoring and management, announces it has received regulatory approval (CE mark) for its next-generation optical technology that does not require calibration with a traditional cuff. The CE mark allows market access to potentially over 40 countries. The underlying groundbreaking calibration-free technology, known as CALFREE™, uses input from optical sensors commonly found in either smartwatches or the cameras of commercial smartphones. This is a crucial first step towards integrating Aktiia's CALFREE technology into various third-party devices.

Since its inception in 2018, Aktiia has been an innovative pioneer of blood pressure technology, known for its scientific rigor, visionary team, and initial breakthrough product – the first continuous BP monitoring device worn on the wrist, which currently requires monthly calibration. Today's announcement represents a significant advancement in BP data collection and hypertension management, enabling the development of optical systems that do not require any calibration while meeting the stringent BP performance thresholds for regulatory approval.

The healthcare industry is already taking note:

“The ability to monitor blood pressure without using a cuff is a game-changer. This achievement has the potential to greatly improve hypertension care, from better patient motivation to more efficient medication regimens,”

said **Adrian James, former President of Omada Health**

Aktiia's blood pressure dataset is growing exponentially, with over 10 billion signals from more than 70,000 users worldwide, creating countless opportunities for discoveries that advance our collective understanding of blood pressure and provide predictive insights on a global scale. This extensive

dataset has enabled Aktiia to create unprecedented Foundation Models of blood pressure, previously unattainable without the size and richness of this extensive dataset.

Transforming Wearables and Smartphones into Medical-Grade Devices

Approval of the CALFREE technology sets the stage for Aktiia to transform BP monitoring and management by enabling the integration of a medical-grade blood pressure system into a wide range of consumer devices (smartwatches, smartbands, and smartphone cameras), dramatically changing the ease and convenience of collecting data on one of the most impactful vital signs – blood pressure.

“This regulatory approval of Aktiia’s CALFREE technology is the realization of a lifetime of work and a crucial step towards achieving our ultimate dream – to improve BP management and reduce the impact of hypertension on global health,”

said Dr. Josep Sola, CTO and Co-founder of Aktiia

Addressing a Global Health Crisis

Hypertension, often referred to as a "silent killer," is the leading cause of cardiovascular diseases worldwide. The World Health Organization (WHO) reports that the number of adults with hypertension has doubled from 650 million in 1990 to 1.3 billion in 2019, with projections reaching 1.5 billion by 2025. The current methods of blood pressure monitoring, still reliant on 19th Century technology, involve cumbersome and often inaccurate cuff-based devices, and are inadequate for the growing need for effective hypertension management in the modern age.

Aktiia’s CALFREE technology extends its position of offering the most accessible, comfortable, and convenient method for long-term blood pressure monitoring. Improved data collection is a cornerstone to significantly improving blood pressure management and helping reduce the economic and health burdens associated with hypertension.

"Aktiia's innovative approach to data collection is transforming blood pressure management. By harnessing the power of our vast and rich dataset, predictive, precision BP care can be delivered on the scale required for impactful blood pressure management,"

said Dr. Jay Shah, CMO of Aktiia

About Aktiia

Founded in Switzerland in May 2018, Aktiia was created out of a passion to develop the best products for diagnosing and treating hypertension. Founders Drs. Mattia Bertschi (CEO) and Josep Solà (CTO) spent 15 years at the prestigious Swiss research institute CSEM, deciphering the language of the heart to deepen our understanding of blood pressure. Today, Aktiia's diverse team of over 50 extraordinary individuals is transforming years of innovative research into a global healthcare solution, offering the most complete and intuitive blood pressure monitoring and management tools on the market.

The company's first product, the Aktiia G1, gained CE-marking in December 2020, offering continuous blood pressure monitoring with monthly calibrations. The newly CALFREE technology represents the next generation, providing on-demand blood pressure readings without the need for calibration. This approval marks the first time a device of this kind has been recognized by regulatory authorities.

The full media package can be downloaded [here](#).

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