

FRAUNHOFER INSTITUTE FOR PHOTONIC MICROSYSTEMS IPMS

PRESS RELEASE

"ThrombUS+" project funded with € 9.5 million

EU project develops portable diagnostic device for the early detection of deep vein thrombosis

Deep vein thrombosis (DVT) is a significant health risk. In about half of patients, the blood clot breaks away from the vein wall and travels to the lungs, where it can cause a pulmonary embolism. Approximately 25% of people who suffer a pulmonary embolism die as a result. This makes it the third leading cause of cardiovascular death worldwide, after stroke and heart attack. The danger: In up to two-thirds of all cases of thrombosis, people have no symptoms. This makes early detection a major challenge. The EU project "ThrombUS+" brings together 18 European partners to develop a new, portable diagnostic device. The EU is funding the project with €9.5 million as part of the Horizon Europe Innovation Action.

The ThrombUS+ project plans a portable cuff with an integrated ultrasound transducer for continuous vascular imaging of the lower limbs to detect venous thrombosis as soon as it occurs. In the project, Fraunhofer IPMS and VERMON are developing ultrasound transducer arrays for the portable component, which will enable continuous monitoring of DVT directly on site. Fraunhofer IPMS focuses on MEMS-based ultrasound transducers, so-called CMUTs (Capacitive Micromachined Ultrasonic Transducers). They are considered to be the next generation of medical ultrasound sensors. The low-cost mass production of CMUTs makes them widely available. Their advantages, such as miniaturization with a high number of channels, high bandwidth and sensitivity, open up the possibility of developing a completely new diagnostic system.

"There are many challenges in developing a portable solution for the diagnosis and prevention of thrombosis," said Prof. Kaldoudi, coordinator of the project and a scientist at the Athena Research Center in Greece. "We are addressing these challenges not only from a technological perspective. One of the strengths of the consortium lies in the application of a compliance-by-design approach, which integrates legal, regulatory and safety requirements for complex medical devices as early as possible in the development process, thus shortening the innovation's path to the patient".

The clinical, technical and regulatory experience gained in the ThrombUS+ project will therefore create new opportunities for market access of future complex AI-based

PRESS RELEASE June 18, 2024 || Page 1 | 3

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medical devices. The project paves the way for a new era in which wearable devices and artificial intelligence can be used to transform diagnostics into continuous and autonomous point-of-care services. This will reduce the burden on physicians. The interdisciplinary and international composition of the consortium is crucial to its success.

PRESS RELEASE June 18, 2024 || Page 2 | 3

About Fraunhofer IPMS

Fraunhofer IPMS is one of the leading international research and development service providers for electronic and photonic microsystems in the application fields of intelligent industrial solutions and manufacturing, medical technology and health, and mobility. In two state-of-the-art clean rooms and with a total of four development sites in Dresden, Cottbus and Erfurt, the institute develops innovative MEMS components and microelectronic devices on 200 mm and 300 mm wafers. Services range from consulting and process development to pilot production.

About the ThrombUS+ project

The <u>ThrombUS+ project</u> brings together 18 European partners. With a duration of 42 months, it will end in June 2027. The EU is funding ThrombUS+ with €9.5 million under grant number HORIZON-HLTH-2023-TOOL-05-101137227. The project will use large data sets collected in three large-scale clinical trials to train artificial intelligence. Validation will take place in the clinical setting through an early feasibility study and a multicenter clinical trial.

Project partners:

- Athena Research Center (Coordinator)
- Fraunhofer-Institut f
 ür Photonische Mikrosysteme IPMS
- Kaunas Technical University
- VERMON SA
- Telemed
- EchoNous Inc
- medis Medizinische Messtechnik GmbH
- ComfTech SLR
- Tampere University
- Lithuanian University of Health Sciences

- General Hospital Papageorgiou
- Foundation Casa Sollievo della Sofferenza
- Simon Veil Hospital
- VDE Association of Electrical, Electronics, and Information Technology EV
- MEDEA SLR
- Phaze Clinical Research & Pharma Consulting SA
- PREDICTBY Research and Consulting SL
- SciGen Technologies SA



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Images



Illustration of a pulmonary embolism, a potentially fatal complication caused by a venous thrombosis. © *Fraunhofer IPMS*



Close-up of a CMUT chip on a wafer. © Fraunhofer IPMS



CMUT array on rewiring carrier for connection to discrete electronics. © Fraunhofer IPMS

The **Fraunhofer-Gesellschaft**, based in Germany, is the world's leading applied research organization. By prioritizing key technologies for the future and commercializing its findings in business and industry, it plays a major role in the innovation process. A trailblazer and trendsetter in innovative developments and research excellence, it is helping shape our society and our future. Founded in 1949, the Fraunhofer-Gesellschaft currently operates 76 institutes and research units throughout Germany. Around 30,800 employees, predominantly scientists and engineers, work with an annual research budget of roughly \in 3.0 billion, \notin 2.6 billion of which is designated as contract research.

PRESS RELEASE

June 18, 2024 || Page 3 | 3