

HeartBeam Joins European EXIT-CVD Research Consortium to Advance At-Home ECG Monitoring for Early Detection of Acute Coronary Syndrome (ACS) in High-Risk Patients

- *HeartBeam joins Philips, Medtronic, GE HealthCare and other global healthcare leaders in the EU-funded EXIT-CVD research consortium*
- *HeartBeam will lead the HEART-CHECK Study, one of the project's 22 studies*
- *HEART-CHECK will evaluate whether HeartBeam's at-home 3D ECG can help clinicians recognize recurrent events earlier in patients recently discharged after ACS*

SANTA CLARA, Calif.--(BUSINESS WIRE)-- [HeartBeam, Inc.](#) (NASDAQ: BEAT), a medical technology company focused on transforming cardiac care by providing powerful cardiac insights, today announced it is a contributing partner in the launch of the [EXIT-CVD](#) research project, co-funded by the European Union Innovative Health Initiative ([IHI](#)) and industry partners. The research consortium is led by University Medical Center Groningen ([UMCG](#)) and [Royal Philips](#), and aims to transform how cardiovascular disease is detected, monitored and treated.

Within EXIT-CVD, the HEART-CHECK study will evaluate the HeartBeam System for early detection and triage of cardiac events in high-risk patients recently discharged after an acute coronary syndrome (ACS), a group with well-documented risk of recurrent ischemic events, arrhythmias and hospital readmissions¹.

"Patients discharged after an ACS are in a vulnerable period, and their symptoms can be atypical and easily dismissed," said Branislav Vajdic, PhD, Founder and President of HeartBeam. "HEART-CHECK gives us the opportunity to evaluate whether a clinical-grade ECG recording outside of a medical facility can help clinicians recognize recurrent events earlier and get these patients to the right care sooner. Our priority remains FDA clearance for heart attack assessment. HEART-CHECK builds on our heart attack detection work, as we continue to advance opportunities for heart attack assessment outside of the healthcare facility. Being invited to contribute alongside some of the world's leading cardiovascular institutions and companies affirms the importance of acting at the right point along the cardiac care journey."

HeartBeam's role in the EXIT-CVD Consortium

HeartBeam is a contributing partner in the EXIT-CVD consortium and will lead the HEART-CHECK study, one of the project's 22 clinical studies. HeartBeam's contribution to the consortium is in-kind, including devices and clinical team expertise. The HEART-CHECK study is designed as a hybrid effectiveness-implementation study, assessing both the

HeartBeam System's clinical performance in the intended use population and its integration into real-world care pathways. The HeartBeam System is currently not CE marked and will be evaluated in HEART-CHECK for investigational purposes only.

The HeartBeam System captures the heart's electrical signals in three non-coplanar dimensions, delivering clinical-grade ECG data outside the hospital. Earlier this month, the U.S. Food and Drug Administration (FDA) granted Breakthrough Device Designation to the HeartBeam System as a tool for assessing potential heart attacks at home. The HeartBeam System is currently FDA cleared for arrhythmia assessment only. Its use for heart attack assessment is investigational only at this time.

EXIT-CVD aims to transform how cardiovascular disease is detected, monitored and treated. It will do so by identifying and acting on three key *exit points* along the cardiac care journey: preventing disease before it develops (*early exit*), reversing disease progression (*mid exit*), or halting progression in advanced stages (*late exit*). By combining diagnostics, digital tools and advanced therapeutic approaches, EXIT-CVD aims to deliver actionable, evidence-based strategies that can be implemented across diverse healthcare systems in Europe. The research project unites 42 public and private partners across 17 countries to conduct 22 clinical studies involving more than 14,000 patients. With a total budget of EUR 27.6 million, the project is co-funded by the European Union Innovative Health Initiative (IHI) and industry partners.

"Our vision is a future where heart disease is no longer an irreversible pathway," said Professor Pim van der Harst, Project Coordinator of EXIT-CVD and Head of Cardiology at the University Medical Center Groningen. "By understanding both the biological and social drivers of cardiovascular disease, and deploying integrated innovations across diagnostics, monitoring, and care, we can empower patients and clinicians to exit the disease continuum before it's too late."

"For more than 30 years, we have viewed cardiovascular disease as a continuous journey, from risk factors such as hypertension, to atherosclerosis, a first cardiac event and ultimately, for many patients, heart failure," said Robin Nijveldt, Chief of Cardiology at UMC Utrecht. "Yet most of us improve care within our own specialty and rarely have a complete view of the patient's experience. EXIT-CVD is an ambitious effort to build that holistic view together, helping transform cardiac care for millions of patients across Europe."

Clinical studies

The EXIT-CVD research consortium will conduct a total of 22 clinical studies involving more than 14,000 patients across Europe, including:

- Remote Cardiac Monitoring After Acute Coronary Syndrome (**HEART-CHECK** study): Hybrid effectiveness-implementation study evaluating the HeartBeam System for early detection and triage of acute coronary syndrome in high-risk cardiovascular patients.
- Camera-Based In-Hospital Monitoring (**CARDIO-CAM** study): Deployment and evaluation of an unobtrusive, video-based patient monitoring system that continuously captures cardiorespiratory signals and relevant clinical context.
- Spectral CT for Early Detection, Risk Stratification and Personalized Patient Care Pathways (**LEADER-PAD** study): Development and validation of new approaches for the early detection of cardiovascular disease in asymptomatic and low risk

symptomatic patients using spectral CT.

- Nurse/HCP-Led Remote Heart Failure Monitoring (**REMODEL-HF** study): Multinational randomized study evaluating the Heart Failure Management System ([HFMS](#)), a non-invasive remote monitoring technology, in patients recently hospitalized for heart failure, with the objective of improving outcomes and optimizing guideline-directed medical therapy.
- Imaging-Guided PCI Randomized Trial (**GUIDANCE-PCCT** study): Evaluation of clinical and procedural outcomes of PCI guided by photon counting CT versus standard angiography-guided PCI.
- Advanced Imaging in Infiltrative Cardiomyopathies (**NOTIFY-2** study): Validation of AI-driven image and ECG analysis algorithms to improve early diagnosis of Left Ventricular Hypertrophy (LVH) and underlying disease risk stratification.

Consortium partners

The IHI EXIT-CVD public-private partnership comprises 42 partner organizations from 17 countries:

- **Clinical and academic partners:** Hospital de la Santa Creu i Sant Pau (Spain), Politecnico di Milano (Italy), University of Pavia (Italy), Centro Cardiologico Monzino (Italy), EOC (Switzerland), KU Leuven (Belgium), NIKARD (Poland), UMC Utrecht (Netherlands), UMC Groningen (Netherlands), Technical University Eindhoven (Netherlands), Universitätsklinikum Köln (Germany), King's College London (UK), London School of Economics and Political Science (UK), and Varsinais-Suomen Hyvinvointialue (Finland)
- **Industry partners:** Philips, Circle CVI, GE HealthCare, Siemens Healthineers, **HeartBeam**, Medtronic, Huawei, XVIVO Perfusion, AstraZeneca, Cardiomed, Megi Health, Viatris, Cordys, Novartis, Corbotics, ZOLL, Sanofi, Repairon, Johnson & Johnson MedTech Heart Recovery, Onsentia, and CogStack
- **Healthcare consultancy:** Bridg Ou and IQVIA Solutions
- **Patient organization:** Stichting VrouwenHart
- **Medical association:** European Society of Cardiology (ESC)

More information can be viewed on the [EXIT-CVD](#) website.

This project is supported by the Innovative Health Initiative Joint Undertaking (IHI JU) under grant agreement No 101253160. The JU receives support from the European Union's Horizon Europe research and innovation program and COCIR, EFPIA, Europa Bio, MedTech Europe, and Vaccines Europe. Funded by the European Union, the private members, and those contributing partners of the IHI JU. Views and opinions expressed are those of the author(s) only and do not necessarily reflect those of the aforementioned parties. Neither of the aforementioned parties can be held responsible for them.

About HeartBeam, Inc.

HeartBeam, Inc. (NASDAQ: BEAT) is a medical technology company dedicated to transforming the detection and monitoring of critical cardiac conditions. The Company has developed the first-ever cable-free device capable of collecting ECG signals in 3D, from three non-coplanar directions, and synthesizing the signals into a 12-Lead ECG. This platform technology is designed for portable devices that can be used wherever the patient is

to deliver actionable heart intelligence. Physicians will be able to identify cardiac health trends and acute conditions and direct patients to the appropriate care – all outside of a medical facility, thus redefining the future of cardiac health management. HeartBeam's 3D ECG technology received FDA clearance for arrhythmia assessment in December 2024, and the 12-Lead ECG synthesis software received FDA clearance for arrhythmia assessment in December 2025¹. The Company holds over 25 issued patents related to technology enablement. For additional information, visit [HeartBeam.com](https://www.heartbeam.com).

Forward-Looking Statements

All statements in this release that are not based on historical fact are "forward-looking statements." While management has based any forward-looking statements included in this release on its current expectations, the information on which such expectations were based may change. Forward-looking statements involve inherent risks and uncertainties which could cause actual results to differ materially from those in the forward-looking statements, as a result of various factors including those risks and uncertainties described in the Risk Factors and in Management's Discussion and Analysis of Financial Condition and Results of Operations sections of our Forms 10-K, 10-Q and other reports filed with the SEC and available at www.sec.gov. We urge you to consider those risks and uncertainties in evaluating our forward-looking statements. We caution readers not to place undue reliance upon any such forward-looking statements, which speak only as of the date made. Except as otherwise required by the federal securities laws, we disclaim any obligation or undertaking to publicly release any updates or revisions to any forward-looking statement contained herein (or elsewhere) to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

¹Cleared Indications for Use

The HeartBeam System with 12-Lead ECG synthesis software for arrhythmia assessment received FDA clearance in December 2025. Refer to the Company's Cleared Indications for Use at <https://www.heartbeam.com/indications> for details on the intended use of its technology.

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