

## BREAKING NEW GROUND IN BREAST CANCER DIAGNOSTICS: THERMOBREAST WELCOMES THE FIRST PATIENTS IN THE PIONEERING CLINICAL TRIAL

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ThermoBreast is an ambitious project that aims to revolutionise breast cancer detection by developing a dynamic thermal imaging screening using infrared sensors and Artificial Intelligence (AI). ThermoBreast has launched its diagnostic trial and has already welcomed more than 400 participants. The 4-year Horizon Europe project, funded by the European Commission, aims to validate the next-generation Vision One thermal imaging device developed by project coordinator ThermoMind Ltd. Following a recent successful feasibility trial with 100 participants at Klinik Sankt Elisabeth in Heidelberg, Germany, ThermoBreast is now expanding to 11 other clinical centres around the world. In December 2023, the first patient was recruited within the main trial at University Hospital Heidelberg, which is also leading the clinical trial. To date, several devices have been successfully deployed at partner clinical sites at University Hospital Heidelberg and Klinik Sankt Elisabeth (Heidelberg, Germany) and Assuta Medical Centers in Haifa and Tel Aviv (Israel). Recruiting the first patients for this groundbreaking clinical trial marks a significant milestone for ThermoBreast in its goal to develop safe, pain-free, and accurate breast cancer diagnostics applicable to women of any age and breast density. Since December 2023, more than 400 patients have undergone the ThermoBreast screening procedure in the aforementioned clinical sites, paving the way for the ultimate goal of recruiting 28,000 patients for the study. Several other clinics and hospitals in France (Institute Gustav Roussy), Ireland (University College Cork), Italy (Azienda Ospedaliero-Universitaria Città della Salute e della Scienza di Torino), Slovenia (Univerzitetni Klinični Center Maribor), Lithuania (Hospital of Lithuanian University of Health Sciences Kaunas Clinics), and the US (MD Anderson Cancer Center) are also preparing to begin patient recruitment for the ThermoBreast trial. As a consortium partner, Cancer Patients Europe (CPE) is committed to enhancing a credible and reliable alternative to mammography for breast cancer screening. ThermoBreast is well set to provide this alternative. This is why CPE is actively exploring the necessary level of explainability for the ThermoBreast solution to ensure a patient-centred approach in the trial process.

### ThermoBreast partner clinics and hospitals



1 Feasibility studies are designed to see if it is possible to do the main study

## ThermoBreast Groundbreaking Study to Revolutionise Breast Cancer Detection

ThermoBreast performs an international trial that aims to revolutionise the detection and monitoring of breast cancer through the use of dynamic thermal imaging and advanced AI analysis. Its primary objective is to compare the diagnostic performance of advanced AI models with routine breast cancer screening. This innovative study, conducted at multiple centres worldwide, is designed as a prospective, blinded, and three-cohort diagnostic trial. This means that women will be recruited into three cohorts: Screening, High-Risk Screening, and Diagnostics. There will be no randomisation within this study, and the results of thermal screening will not be disclosed to participants or physicians to avoid any undue anxiety or influence on the physicians' decision-making. As the proposed method is still under development, the ThermoBreast system will only record thermal images and does not influence routine clinical practice for breast cancer diagnosis. This study is believed to provide valuable insights and advancements in the field of breast cancer diagnosis, ultimately leading to better outcomes for patients in terms of breast cancer early detection.

## ThermoBreast – safe and pain-free breast cancer screening

The ThermoBreast screening procedure offers a pain-free, radiation-free, and non-invasive alternative to traditional screening methods. Unlike other screening methods, ThermoBreast requires no direct contact with the body, making it safe and comfortable for both patients and technicians. Patient-centred care is at the core of the ThermoBreast procedure. A specially trained medical staff undergoes rigorous training to ensure a smooth and efficient screening process for all patients. Each individual undergoes a screening process, beginning with a consent form and a brief questionnaire related to their breast cancer history. The screening room is carefully controlled for temperature and privacy. The ThermoBreast procedure itself consists of three phases, each designed to capture the dynamic thermal patterns of the chest and armpit area with highly sensitive infrared sensors. The first phase allows the body to acclimate to the room temperature, while the second phase involves gentle cooling through fans to reveal more accurate thermal patterns. Finally, the third phase records the recovery of the body's temperature for further analysis. The captured thermal streams are then processed by innovative AI technology, which can identify patterns and potential abnormalities associated with breast cancer. While mammography and ultrasound depend primarily on structural and anatomical variation of the tumor from the surrounding breast tissue, thermography detects pathophysiological changes within the breast such as metabolic and vascular changes caused by cancer and the increase in vascularisation. As a volunteer for the ThermoBreast trial, patients have the chance to contribute to the development of a unique screening method for early breast cancer detection and make an impact on the future of breast cancer screenings for themselves, their loved ones, and future generations.

The ThermoBreast consortium is confident that the data gathered from this study will help gain valuable insights into the effectiveness of this technology and its role in breast cancer diagnosis, prevention, and monitoring. The technology has the potential to transform breast cancer diagnosis, introducing a new era in breast cancer screening. The start of patient recruitment in the ThermoBreast clinical study is a significant step towards a brighter tomorrow for breast cancer patients, aligning with the goals of European Union's Mission on Cancer and Beating Cancer Plan.

- To learn more about the ThermoBreast clinical trial, including its inclusion and exclusion criteria, please visit [ClinicalTrial.gov](https://clinicaltrials.gov).
- Follow the progress of ThermoBreast at [thermobreast.eu](https://thermobreast.eu) and on [LinkedIn](#), [Facebook](#), [X](#), and [YouTube](#) to stay up to date with the latest results.
- To learn more about the [ThermoMind](#) technology, please visit their [website](#).