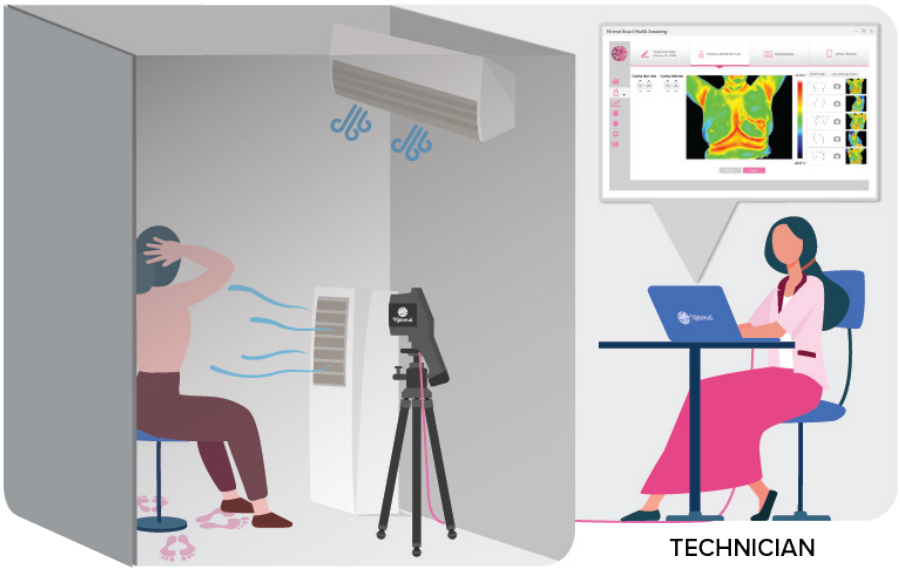
A NOVEL BREAST CANCER SCREENING TEST

Niramai™

NIRAMAI™ is a health tech company with a mission to save lives by enabling early detection of breast cancer in a privacy aware manner, through an AI-based technique called Thermalytix®

- No Touch
- No See
- No Pain
- No Radiation
- Rapid Test
- Works for all ages



SCREENING AREA

TECHNICIAN

Niramai receives U.S. FOOD & DRUG ADMINISTRATION for their medical device SMILE-100

ISO 13485:2016

MDSAP

MAKE IN INDIA

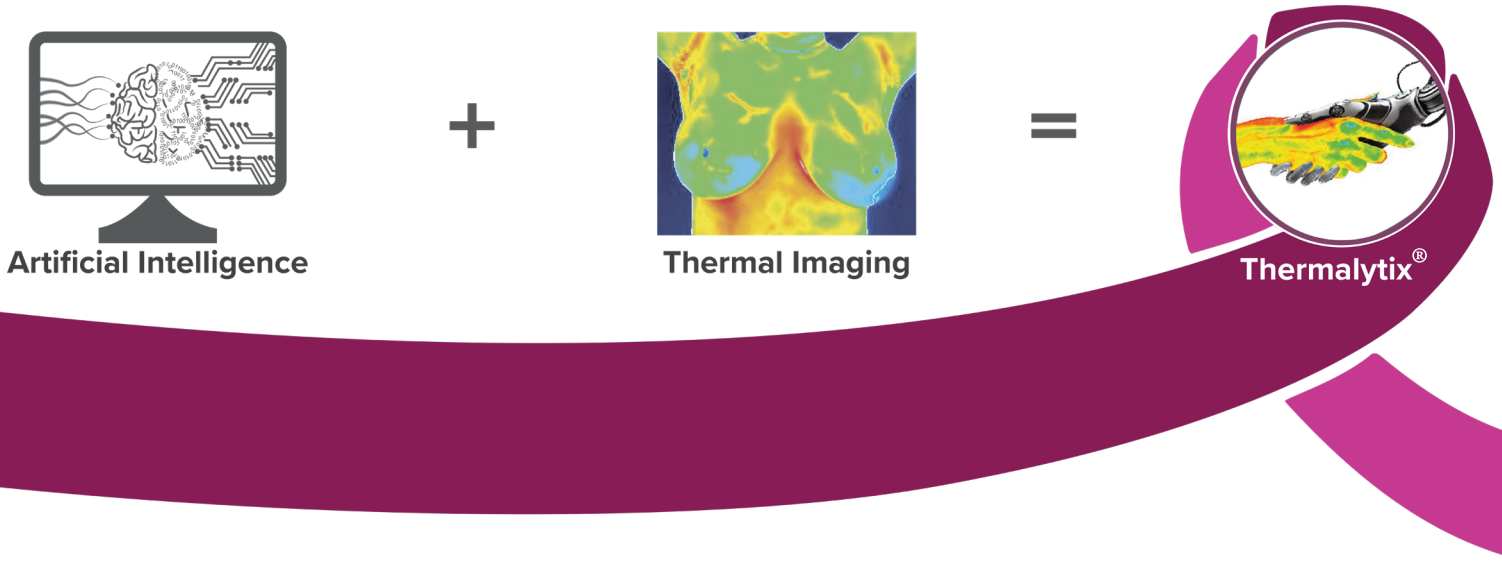
CE
0297

THERMALYTIX®
The Novel Breast Cancer Screening Test by NIRAMAI™

Thermalytix® is a computer-aided diagnostic software medical device intended to aid medical doctors, in detection and localization of malignant lesions in breast tissue using thermal imaging coupled with Artificial Intelligence

1,25,000+ Screenings completed	10,000+ Screenings camps	160+ Locations in 32 Cities	8+ Countries

NIRAMAI's Thermalytix® is a non-invasive breast health screening test that employs innovative proprietary machine learning and deep learning algorithms to analyze temperature distribution on the chest, to automatically generate a quantitative report showing a breast health score and assist doctors in identifying abnormal breast lesions.



How is THERMALYTIX® DIFFERENT FROM THERMOGRAPHY?

Thermography or Infrared Imaging is approved by USFDA as an adjunct modality for breast cancer screening detection. However, interpretation of breast thermography requires special expertise and is very complex and error prone as visual analysis of 400,000 temperature points is hard. Thermography is therefore a subjective interpretation of thermal data and so far has seen limited adoption. Thermalytix technology however, takes thermal sensing to a whole new level by automating the analysis and eliminating subjective interpretation. Thermalytix® is an AI-based software that considerably improves clinical diagnosis by automating detection of abnormal thermal patterns and generating quantitative health scores that can assist radiologists in cancer diagnosis. With the improved accuracy and ease of interpretation brought in, Thermalytix® is now being used by medical practitioners in many leading hospitals in India and other countries.

Benefits of THERMALYTIX®

For Patients:

Age-agnostic:

It is age and breast density agnostic and works even for women below 40 years for whom Mammography is not recommended

Early Detection:

It detects tumors significantly smaller (5mm) than what can be detected with physical examination (25mm).

Low cost per screening:

Niramai technology cost per screening is significantly lower compared to other modalities.

No side effects:

Thermalytix® does not use radiation of any form & measures temperatures on the body.

Portable equipment:

The thermal sensor used by Niramai can be carried to any location in an ordinary backpack increasing accessibility of screening test.

Non-contact, private screening:

The equipment is placed at 3ft from the patient. It is no-touch, no-see screening which makes it a painless procedure.The private screening experience is appreciated by women.

For Radiologist:

Ease of interpretation:

Niramai's Thermalytix® analyzes 400000 temperature values per person and generates a real-time and quantified report. Our studies show that use of Thermalytix® can improve the radiologist sensitivity by more than 20%.

Complements Sono-Mammography:

Since Thermalytix® provides information about the location of possible lesions, the annotated images can help to perform targeted breast ultrasound, which saves upto 10-15 minutes of precious radiologist time.

Complements Mammography:

Interpretation of mammography images for dense breasts is somewhat difficult. Use of Thermalytix® in combination with mammography can improve the sensitivity of cancer detection by 16.7% when compared to the interpretation of raw mammography alone.

The Most Awarded Healthtech Startup

33+ Multi-national Patents Granted

Winners of Commonwealth Digital Health Award 2022

Winner of National Startup Award in Healthcare - Diagnostics

Winners of the World Bank Award for Women Health 2022

Winners of Eurasante Bio Accelerator Program in France

Winners of PHC Tech Challenge 2021

Research Grant

Top Cancer Startup

Inception Program

BIRAC Winner Award

Gold Prize 2019 Winner

CLINICAL EVALUATION RESULTS OF THERMALYTIX®

42 International Peer Reviewed Publications

Check out http://niramai.com/publications

Formal prospective and retrospective clinical studies of Thermalytix has resulted in publications in leading scientific venues

1. Frontiers in Artificial Intelligence
2. International Journal Of Community Medicine And Public Health
3. British Medical Journal Open
4. Thermology International
5. Journal of Clinical Oncology Global Oncology (JCO GO) from American Society of Clinical Oncology (ASCO)
6. **San Antonio Breast Cancer Symposium;** San Antonio, Texas, USA.
7. **European Breast Cancer Conference,** Barcelona, Spain
8. **UK Imaging and Oncology, UKIO Liverpool UK**
9. **The Lancet Oncology**
10. **ASCO Breakthrough Summit**
11. **ASCO Annual Meeting**, Chicago, IL
12. **Global Breast Cancer Conference, Seoul,** Korea
13. **International Conference on Advances in Breast Cancer Treatments,** Kyoto, Japan
14. **International Conference on Breast Cancer Management,** Amsterdam
15. Artificial Intelligence in Medicine
16. Asia Pacific Journal of Cancer Prevention.
17. Indian Cancer Congress, ICC
18. Annual Conference of IRIA Indian Radiological Imaging Association

THERMALYTIX® CLINICAL STUDIES

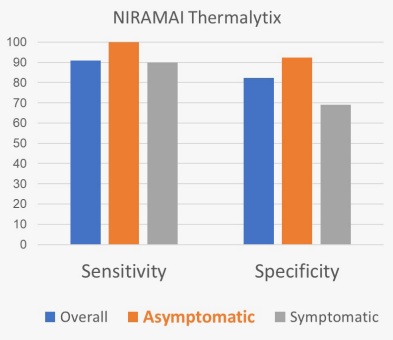
NIRAMAI Thermalytix® has been evaluated in multiple clinical settings by expert radiologists and these results have been published in PubMed-indexed peer-reviewed journals and international conferences. Below are the details of five such studies for quick reference:

Study 1: Observational Study to Evaluate the Clinical Efficacy of Thermalytix for Detecting Breast Cancer in Symptomatic and Asymptomatic Women

Journal of Clinical Oncology Global Oncology (JCO GO), Oct 2020.

Objective: To evaluate the sensitivity and specificity of Thermalytix, an artificial intelligence–based computer-aided diagnostics (CADx) engine, to detect breast malignancy by comparing the CADx output with the final diagnosis derived using standard screening modalities.

Method: This multisite observational study recruited 470 symptomatic and asymptomatic women who presented for a breast health checkup in two centers. All participants underwent a Thermalytix test and one or more standard-of-care tests for breast cancer screening, as recommended by the radiologist. Results from Thermalytix were compared with final diagnoses given by expert clinician based on the symptoms and the available reports of standard modalities (mammography, ultrasonography, elastography, biopsy, fine-needle aspiration cytology, and so on) in a blinded fashion.



Results:

- Thermalytix resulted in a sensitivity of 91.02% and specificity of 82.39% in detection of breast malignancy.
- Thermalytix showed an overall area under the curve (AUC) of 0.90.
- The sensitivity and NPV of Thermalytix in screening population was 100% with 7.6% False Positive rate.

Conclusion: Thermalytix is an excellent screening tool and a companion diagnostic tool.

Study 2: A prospective evaluation of breast thermography enhanced by a novel machine learning technique for screening breast abnormalities in a general population of women presenting to a secondary care hospital.

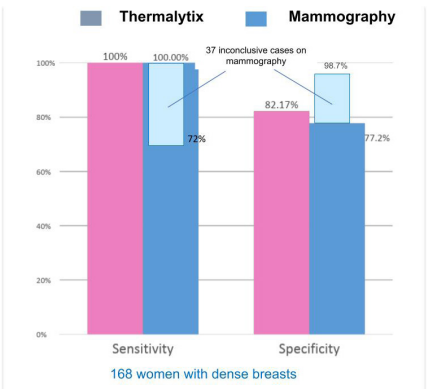
Frontiers in Artificial Intelligence, Jan 2023.

Objective: To evaluate the clinical performance of Thermalytix, a CE-marked, AI-based thermal imaging test, with respect to conventional mammography.

Method: A prospective, single blinded comparative study was performed to evaluate the performance of Thermalytix in 459 women with both dense and nondense breast tissue. Both symptomatic and asymptomatic women, aged 30–80 years, presenting to the hospital underwent Thermalytix followed by 2-D mammography if any one of them or both showed suspicious malignancy, ultrasound and guided biopsy was performed for confirmatory diagnosis. Thermalytix and Mammography results were compared in a blinded fashion all the statistical analysis was performed by a third party.

Results:

- Twenty-one women were histopathologically confirmed with breast malignancy (21/459, 4.6%).
- The overall sensitivity of Thermalytix was 95.24% , and the specificity was 88.58%.
- In women with dense breasts (n = 168, 36.6%), the sensitivity was of Thermalytix 100% and the specificity was 81.65%.
- Among these 168 women, 37 women (22%) were reported as BI-RADS 0 on mammography; in this subset, the sensitivity of Thermalytix was 100%.



Conclusion: Thermalytix showed high sensitivity in women with dense breast and outperformed mammography in women with dense breasts and those reported as BI-RADS 0. Thus has the potential to supplement mammographic screening in women with dense breasts.

THERMALYTIX® CLINICAL STUDIES

Study 3: Performance of artificial intelligence-based breast cancer screening in a community setting: a real-world evaluation study

The Lancet Oncology, 1 Jul 2022.

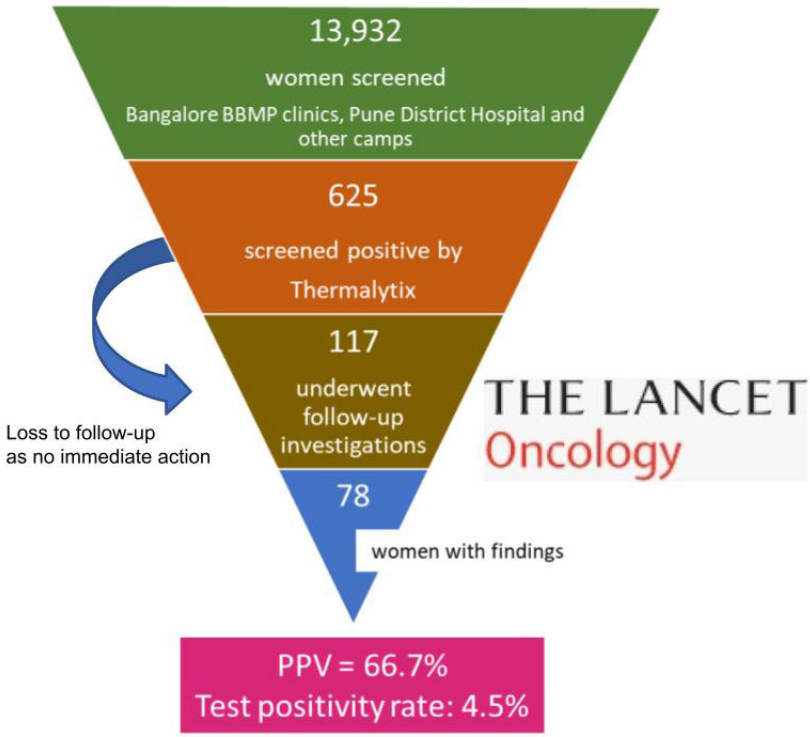
Objective: To assess the performance of the Thermalytix test in identifying women suspicious of breast cancer in community settings.

Method: A total of 13,932 women who underwent Thermalytix tests in community-based screening camps in the Indian states of Karnataka and Maharashtra between Aug 12, 2017, and May 31, 2021, were included in this study. Participants with Thermalytix B-scores of 4 or 5 were followed-up with a telephone call to obtain information about their subsequent tests, such as mammography, ultrasonography, or histopathological examination. Women with a follow-up report were categorised as having "Normal", "Abnormal–Benign", or "Abnormal–Malignant" findings

Results:

- 13,932 women were included in the analysis. 625 of these women showed Thermalytix B-scores of 4 or 5
- 117 of these 625 women underwent standard follow-up investigations.
- Abnormalities were detected in 74 benign pathologies and 4 malignant of the 117 followed-up women.
- Thermalytix has a positive predictive value of 66·7% in detecting benign and malignant breast lesions.

Conclusion: It is feasible to conduct Thermalytix test in remote locations with minimal infrastructure and minimal training. The Thermalytix test can be used to triage women for referral which makes it a logistically and economically feasible option for breast cancer screening in LMICs.



THERMALYTIX® CASE STUDIES

Case Study 1:

Case Presentation: Shanti (58 years) was facing some discomfort in her breast. She learnt that there was a free screening camp being conducted in a nearby hospital where the Niramai test was being offered. She underwent Niramai breast health check up which was carried out in an enclosed, cool room where no one would see or touch the women – with the technician seated outside providing necessary instructions. Shanti recalls being very comfortable during the test which lasted less than 15 minutes. The Niramai test detected suspicious thermal activity and recommended that an ultra-sonography (USG) be conducted in the left breast. The results were generated in real-time and shared with the doctor. The USG revealed the case as “more in favour of malignancy”. Doctor then proceeded to conduct a biopsy immediately and found Grade III Infiltrating Ductal Carcinoma with moderate lymphoid infiltrate in the same location as indicated by Niramai test. Detection at an early stage and immediate follow-up treatment made all the difference for Shanti. She has since undergone surgery and followed up with chemotherapy. Her recovery has been smooth and the family is relieved to have put the worst behind them.

Conclusion: The Niramai test could detect suspicious thermal activity and detect malignancy on the left breast before recommending ultra-sonography (USG).

Case Study 2:

Case Presentation: Kaveri (name changed) had expressed pain in her right breast and consulted multiple experts. There was a great deal of uncertainty about presence of malignant lump in her breast. She was advised to get X-ray Mammography done at a diagnostic center which noted the evidence of soft tissues density lesion. Kaveri was also asked to undergo MRI. The combined results of MRI and Mammography showed a lesion with 29% to 77% chances of malignancy. As a result, Kaveri and her family were in a dilemma as they were advised to proceed with surgery for removal of the lump, followed by biopsy to ascertain whether or not it is cancerous. The family decided to get the NIRAMAI test as well. The report from the test showed minimal thermal activity and suggested a low thermalogical score. The test concluded absence of malignancy and recommended regular check-up. Patient’s family was still concerned and decided to go ahead with the follow-up treatment plan based on findings of Mammography, Ultrasound and MRI. The patient underwent excision surgery where breast region sized 7.5mm x 5mm x 2.5 mm was removed. Biopsy test found calcified nodule with no malignancy, proving NIRAMAI analysis to be correct.

Conclusion: The Thermalytix test detected the benign lesion accurately and prevented the patient from undergoing invasive procedures when used as an adjunct to mammography

HEAR FROM THE EXPERTS

Dr Sudhakar Sampangi

Breast Imaging Specialist, HCG Hospital

"Mammogram and ultrasound, the most common modalities used for the diagnosis of the disease, have their limitations. For instance, with a mammogram it's difficult to detect the micro calcification in dense breasts (common in the case of young women), while ultrasound scans are largely subjective, wherein the results vary from radiologist to radiologist. Now, with Thermalytix, bringing together the dual advantages of thermography and artificial intelligence, it's possible to do away with errors of manual interpretation. It's a highly accurate and effective way of detecting malignant tumours or lesions at an early stage, thereby preventing a majority of cancer deaths. Unlike traditional diagnostic modalities, here the patient doesn't have to endure any pain, touch, or radiation. It's completely non-invasive, yet highly accurate. We can repeat the process any number of times; it's as easy and quick as taking a photograph. Besides, there are no side-effects. Patients appreciate the fact that they are not exposed to additional pain, discomfort, or unnecessary biopsies, while medical practitioners are able to make early and accurate breast cancer diagnosis. In my clinical practice, I see immense value in a health-tech innovation like Thermalytix that makes healthcare more accessible to people".

Dr H V Ramprakash

Senior Radiologist and Expert Thermographer

"Thermography can detect breast cancer in ways that are non-invasive, non-ionizing and non-traumatizing. In addition to detecting tumor growth earlier, this innovation can bring breast cancer screening to the doorsteps of women all over the world. I am happy to partner with NIRAMAI on this journey".

Dr Kiran Mazumdar-Shaw

Chairperson and Managing Director, Biocon Limited

"I congratulate Team NIRAMAI for developing an innovative thermal analytics based Breast Cancer Test for early stage detection. This Non-Invasive Risk Assessment with Machine Intelligence (NIRAMAI) is relevant for women of all ages and poses minimal health hazard since it is contact and radiation free. I believe NIRAMAI will enable easy adoption for early cancer screening and will play a key role in improving outcomes in our ongoing battle against breast cancer. I am delighted to support this initiative".

CUSTOMERS AND PARTNERS WE SERVED

CONTACT US

For more details on Thermalytix® & access to our research studies, please contact:

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