# POSITION STATEMENT ON THERMOGRAPHY

The Indian Radiological & Imaging Association-Indian College of Radiology & Imaging (IRIA-ICRI), Breast Imaging Society, India (BISI) & Association of Breast Surgeons INDIA (ABSI):

1. Do not extend their support for using breast thermography/infrared imaging with or without AI of the breast as a screening tool for the primary detection of breast cancer or as an adjunctive diagnostic tool for detection of breast cancer.
2. Discourages its use in routine clinical practice for the above indications.
3. Encourages the use of other alternative, evidence based and cost-effective methods for the screening and diagnosis of breast cancer.
4. Request its members and members of other allied medical professional specialties to widely disseminate this information to patients and caregivers in order that they can take informed decisions about their illness.

***Thermalytix by Niramai***

The Breast Imaging Society, India and Association of Breast Surgeons India and IRIA-ICRI has the main goal of supporting research and education in the field of breast cancer within the medical community and beyond- to publicize these procedures to patients, for them to take an informed decision. Recently, it has been brought to our notice that Breast Thermography with Artificial Intelligence (Thermalytix) is being promoted as being a viable alternative screening tool for the primary detection of breast cancer or as an adjunctive diagnostic tool for detection of breast cancer.

Breast cancer is one of the leading causes of cancer deaths among women accounting for 11.6% of total deaths of 9.6 million due to all types of cancer every year all over the world. Therefore, cost-effective tools for screening and early detection have a significant role in reducing the disease burden. Currently X-ray mammography in isolation or in combination with Breast Ultrasound & Breast MRI are the mainstay modalities for screening and early diagnosis. Histopathology remains the gold standard for confirmation of breast cancer.

Thermography detected lesions, will invariably require mammography and breast ultrasound for characterization and biopsy localization for pathological confirmation.

While we agree that the use of a particular technique or procedure is a matter of autonomy and professional judgement, we believe that use of this technique in clinical practice is not warranted as it is not supported by the current state of research and evidence. We believe that the injudicious promotion of this technique may result in more harms than benefits especially in a country like ours where health education and access to healthcare is limited and cost is an important consideration.

**Infrared Breast Thermography**

Infrared Breast Thermography has often been discussed as a cost-effective alternative for early breast cancer detection in resource constrained settings. It is a medical imaging technique in which infra-red images of a patient's breasts are used to detect physiological abnormalities associated with breast cancer. In the recent years, Infrared Systems have evolved from static to dynamic systems that record a series of IR images and augmented by Artificial Intelligence (AI) for image assessment.

Thermalytix by Niramai is a solution that offer thermography combined with AI-enabled software, patient's demographic data and a novel vascularity analysis that gives objective assessment of the thermal analysis as per their claims. Niramai claims to have received approvals from US FDA, European CE and regulatory clearance from Ministry of Health & Family welfare, Government of India.

**Evidence through published literature and reports about utility and concerns**

Few review articles have opined that AI and Computer Aided Diagnostics (CAD) can potentially improve the accuracy of Thermography (1)(2). Some experimental studies have found promising results with AI augmented Thermography (3)(4). However, all of these studies have a small sample size and they recommend larger Randomized Controlled Trials (RCTs) for further clarity.

A review done by Lozano et al (2019) from The University of Texas found that, based on mixed findings from researchers over the years and exacerbated by the degree of subjectivity in assessing thermograms, infrared thermography lost considerable research interest and credibility within the medical community (5).

This also reflects in various international guidelines and position statements of various professional bodies. USFDA has stated that Thermograms are not substitutes for Mammograms (6). The Society of Breast Imaging, USA also does not currently support the use of thermography/infrared imaging of the breast as a screening tool in the detection of breast cancer (7). The Canadian Cancer Society states that thermography has not been shown to be an effective tool for medical imaging for cancer (8). NHS (UK), Cancer Australia & TGA (Therapeutic Goods Administration) and other national breast radiology bodies have also opined on similar lines.

Besides, the approvals given by USFDA, European CE are for the safety of the equipment and not for its clinical efficacy per-se. There are also concerns about the datasets used to design and train the AI models in Thermalytix, where more clarity is required.

The guidelines under the Medical Devices Rules 2017 issued by Government of India vide File No.X.11035/656/2017-DRS dated 19th April 2018 mandates clinical evaluation & clinical investigation of all medical devices (Section 5 sub-section 14) to clearly establish favorable risk-benefit ratio and clinical evidence before deploying in patient care (9). Multi-centric RCTs, systematic reviews of RCTs and Meta-Analysis are essential to derive Level I or Level II clinical evidence (10). As on date, Thermalytix by Niramai does not have sufficient studies/ data to unequivocally establish its clinical efficacy and also does not appear in the list of approved Medical Devices in India by CDSCO (11).

There have been concerns about False positives, which can trigger anxiety and lead to unnecessary cascading investigations. These will not only cause financial burden but also mental anguish in patients. There are also concerns about False Negatives, which are a bigger danger. These can lead to a false sense of security among patients who might actually be at risk. This can potentially deprive patients of early diagnosis and intervention. In both case scenarios, there can be serious medico- legal implications.

Thermalytix by Niramai certainly is an interesting innovation for augmenting screening of Breast Cancer. However, there are unanswered questions like the datasets used and actual clinical efficacy vis-à-vis current gold standard investigations. Therefore, more studies and Randomized Controlled Trials (RCTs) need to be undertaken to ascertain its accuracy before it can be used in mainstream patient care.

**References:**


1. Gonzalez-Hernandez, Jose-Luis, et al. "Technology, application and potential of dynamic breast thermography for the detection of breast cancer." International Journal of Heat and Mass Transfer 131 (2019): 558-573.
2. Al Husaini, Mohammed Abdulla Salim, et al. "A systematic review of breast cancer detection using thermography and neural networks." IEEE Access 8 (2020): 208922-208937.
3. Fernández-Ovies, Francisco Javier, et al. "Detection of breast cancer using infrared thermography and deep neural networks." International Work-Conference on Bioinformatics and Biomedical Engineering. Springer, Cham, 2019.
4. Torres-Galvan, Juan Carlos, et al. "Deep convolutional neural networks for classifying breast cancer using infrared thermography." Quantitative InfraRed thermography journal 19.4 (2022): 283-294.
5. Lozano III, Adolfo, and Fatemeh Hassanipur. "Infrared imaging for breast cancer detection: An objective review of foundational studies and its proper role in breast cancer screening." Infrared Physics & Technology 97 (2019): 244-257.
6. https://www.fda.gov/consumers/consumer-updates/breast-cancer-screening-thermogramno-substitute-mammogram
7. https://www.sbi-online.org/RESOURCES/PolicyPositionStatements/Breast Thermography.aspx
8. https://cancer.ca/en/cancer-information/resources/glossary/t/thermography
9. https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medicaldevice/Essentialprinciples.pdf
10. https://guides.library.stonybrook.edu/evidence-based-
11. medicine/levels_of_evidence#:~:text=Level%20III%3A%20Evidence%20from%20evidence,o f%20descriptive%20or%20qualitative%20studies
12. https://cdscomdonline.gov.in/NewMedDev/ListOfApprovedDevices (As on 7th December 2022)

Dr. Pushpraj Bhatele
President IRIA

Dr. Varaprasad Vemuri
Chairman ICRI

Dr. Bagyam Raghavan
President BISI

Dr. S V S Deo
President ABSI

Dr. Somashekhar S P
Immediate Past President ABSI

Dr. Varshas Hardas
Secretary BISI

Dr. Rohit Kumar C
Secretary ABSI

Dated: 28/12/22