

Thermography Clinic Inc.

Thermal Breast Imaging Report

Brief Historical Overview: Last mammogram performed in January 2016, reported with normal findings.
Breast ultrasound was performed in January 2020, reported with normal findings.
Most recent breast examination performed in January 2021 both breasts reported as normal.

Subjective Complaints: ROUTINE THERMAL BREAST ASSESSMENT.

Preface:

Thermography is utilized to view the amount of heat emitted from the skin's surface. This provides a territorial analysis of the temperatures with specific quantitative measurements taken of questionable regions. As a general note, the radiation wave length observed is at the infrared end of the light spectrum. Special instrumentation is required for this examination, noting that infrared rays are invisible to the unaided human eye. The thermograms demonstrate these heat emissions as colors or as black and white images. The colors or shades of black and white will differ in various parts of the body, but in a normal healthy individual, the temperature changes should be relatively symmetrical.

This patient was evaluated with FLIR A-320 Infra Red Camera, with examination guidelines followed, as set forth by the International Academy of Clinical Thermology. Multiple series were performed providing a provocative challenge to aid in the physiological assessment of the breasts.

Explanation of Delta-T Measurements: The breasts are compared right to left in identical locations. The difference in temperature for each area is termed Delta-T (ΔT) and is reported in degrees Celsius. Relative values for rating purposes have been established as follows:

Delta-T	1.0 °C or higher at the nipple
Delta-T	1.5 °C or higher in the periareolar area
Delta-T	2.0 °C or higher in the area of clinical finding
Delta-T	3.0 °C or higher in isolated areas without clinical finding

FDA Cleared & Important Safety Information: Caution:

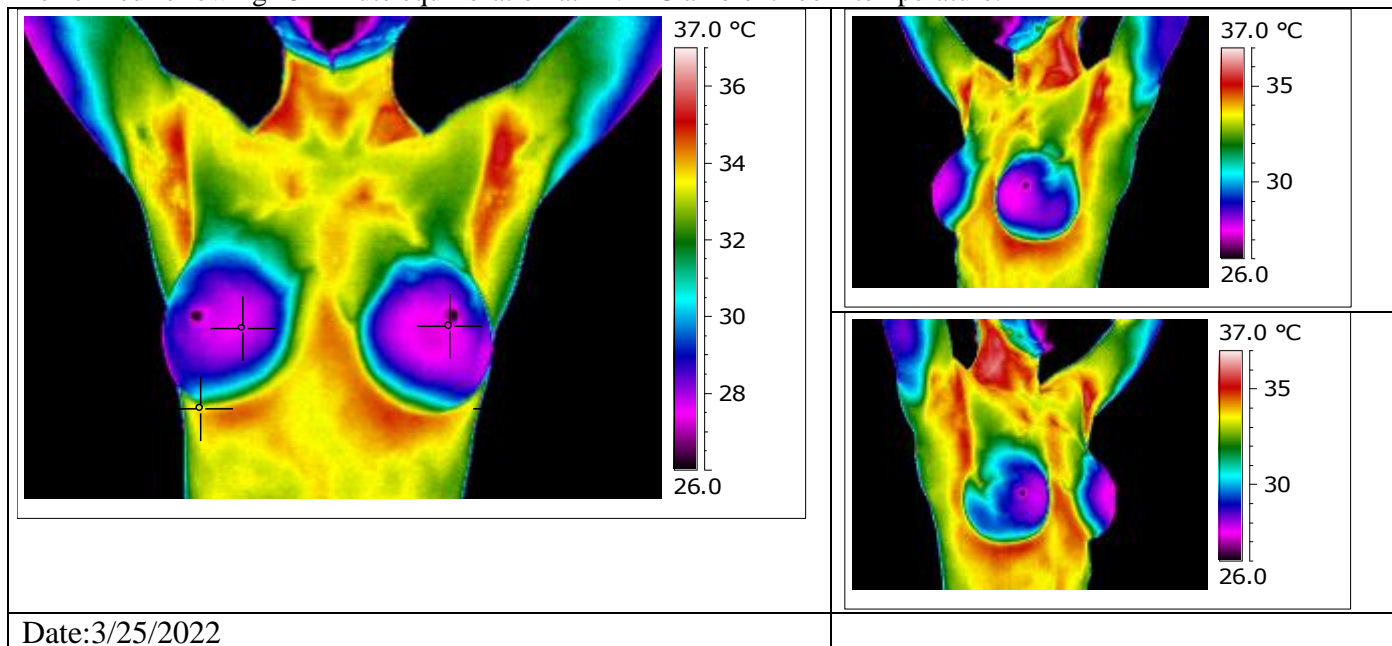
The United States Food and Drug Administration has cleared breast thermal imaging as an adjunct (complement) test to breast screening, and diagnostic imaging studies (such as Mammography, MRI, or Ultrasound), and recommends that patients follow the recommendations of their healthcare provider for routine screenings as well as for diagnostic imaging and/or additional work-up.

For further information see Title 21, Chapter 1, Part 884, Subpart C, Section 884.2980(a) of the United States Code of Federal Regulations.

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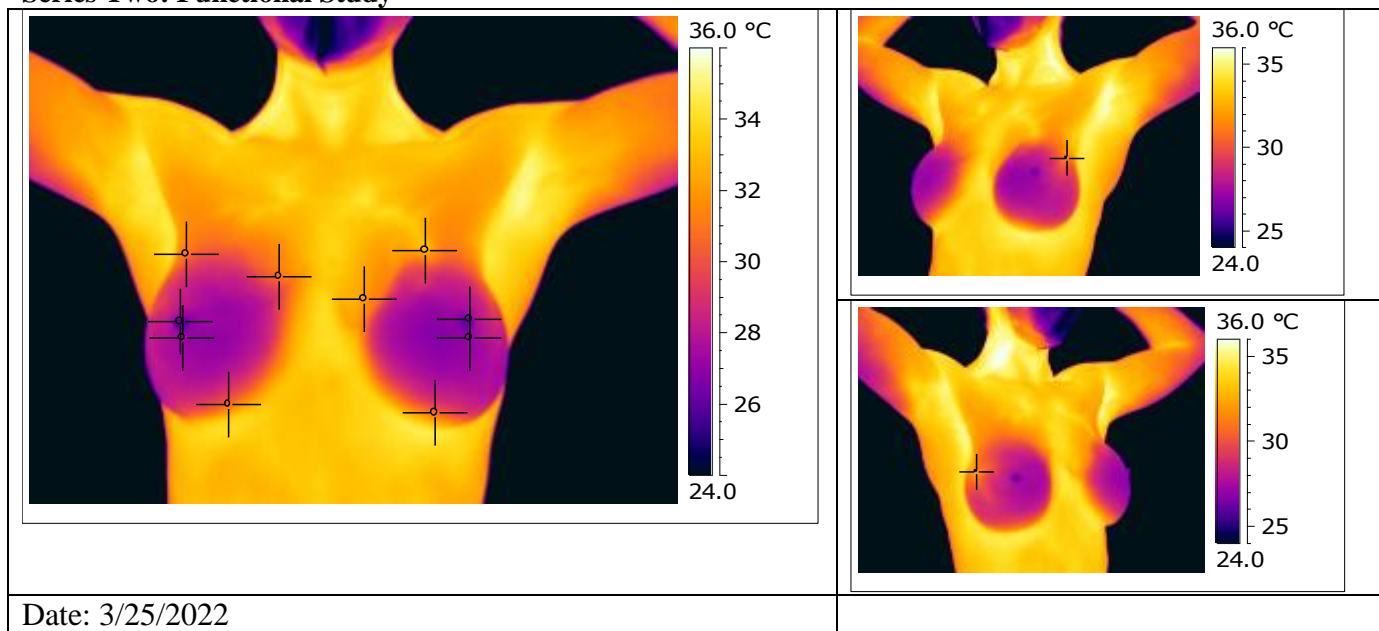
Thermographic Findings: Series One: Baseline Study

Performed following 15 minute equilibration at 21.4 °C ambient room temperature.



Nipple	Right	=	33.8 °C	Left	=	22.1 °C	ΔT	=	11.64 °C
Periareolar	Right	=	27.7 °C	Left	=	27.5 °C	ΔT	=	0.23 °C

Series Two: Functional Study



Nipple	Right	=	25.5 °C	Left	=	26.1 °C	ΔT	=	0.62 °C
Periareolar	Right	=	27.3 °C	Left	=	27.2 °C	ΔT	=	0.08 °C

Series 2 Quantitative analysis of temperature in degrees Celsius compared to baseline images:

Performed 25 minutes post onset of examination and following a 60 second hand soak in 10°C water. This provides an autonomic challenge and a response of sympathetic vaso-constriction. The skin's microcirculation is further shut down and we are able to contrast any non-responsive blood vessels that may be associated with malignant neoplasms. This includes the neo-angiogenic blood vessels and those that are dilated because of nitric oxide. Ambient room temperature remained at 21.4 °C .

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Observational Note: The Delta T between the right and left nipple is less than 1.0°C and remains within limits for this study. The Delta T between the right and left periareolar region is less than 1.5°C which remains within normal limits.

Impression:

Right Breast: TH-2, Score = 45

- Curvilinear Thermovascular Pattern Upper Breast Score = 25
- Regional Hyperthermia Score = 20

Left Breast: TH-2, Score = 65

- Curvilinear Thermovascular Pattern Upper Breast Score = 25
- Regional Hyperthermia $\Delta T \geq 2.0$ °C (Contra Lateral) Score = 25
- Asymmetrical Thermal Pattern Score = 15

Discussion:

Right Breast TH-2 –Within normal limits regarding thermal emission. Numerical values of 30-74, statistically, most frequently associated with benign disorders such as cystic and fibrocystic breasts.

Left Breast TH-2–Within normal limits regarding thermal emission. Numerical values of 30-74, statistically, most frequently associated with benign disorders such as cystic and fibrocystic breasts.

Clinical Comment:

These thermographic findings are all within normal limits but should be kept under observation and routinely monitored for any future changes. Continued close clinical and thermographic monitoring is advised.

Thermography provides a physiological assessment of the microcirculation and is quite sensitive for the detection of risk factors regarding several pathological conditions. This test, however, does not replace or discourage clinical findings or mammography and any suspicious lesions should be followed up with additional testing or medical evaluation.

Follow-up: The patient should have follow-up thermographic evaluation for comparison to this examination in nine to twelve months.

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Board Certified Clinical Thermographer

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TH Report System: Standard Qualitative and Quantitative Analysis

The thermographic findings presented in this study were evaluated based on 32 standard thermological signs and quantification changes, during the course of the examination. Each of these were provided with numerical values (scores), which were developed based on the statistical frequency of occurrence and its association with breast pathology. Scores of 0-29 presents relatively symmetrical and avascular patterns and are considered statistical normals. Scores of 30-74, were also considered within normal limits, but usually displayed some thermovascular patterns and statistically appeared to be associated mainly with benign breast distortions. It is noted, that the higher the score appears in this group, the incidence of pathology increases



TH-1	Score	0-29	Within normal limits regarding thermal emission
TH-2	Score	30-74	Within normal limits regarding thermal emission. Most frequently associated with benign disorders such as cystic and fibrocystic breasts.
TH-3	Score	75-119	Equivocal regarding thermal emission. Finding is possibly benign but is considered at risk and should be followed closely.
TH-4	Score	120-149	Abnormal regarding thermal emission. Finding is considered high risk.
TH-5	Score	≥ 150	Abnormal regarding thermal emission. Finding is considered very high risk.

Regarding carcinoma, regardless of tumor size and histological type, the average thermal score was found to be higher than 80. The in situ carcinomas, the microinvasive carcinomas (< 5mm), and T1 Cancer (< 2cm) had average scores of 87, 92 and 129 respectively. (Gautherie)

* TH scoring system is based on original research conducted by M. Gauthrie, A. Kotewicz and P. Gueblez. Study presented in Thermal Assessment of Breast Health, entitled “Accurate and objective evaluation of breast thermograms: basic principles and new advances with special reference to an improved computer-assisted scoring system.” Published by MTP Press Limited, Lancaster/Boston. Since Gautherie’s original research, additional signs and numerical values have been added, to establish the present scoring system (as used for in this report). These additional signs and values are based in extensive imaging and clinical work, separately performed by Dr’s G. Chapman, B. Hobbins and A. Mostovoy.