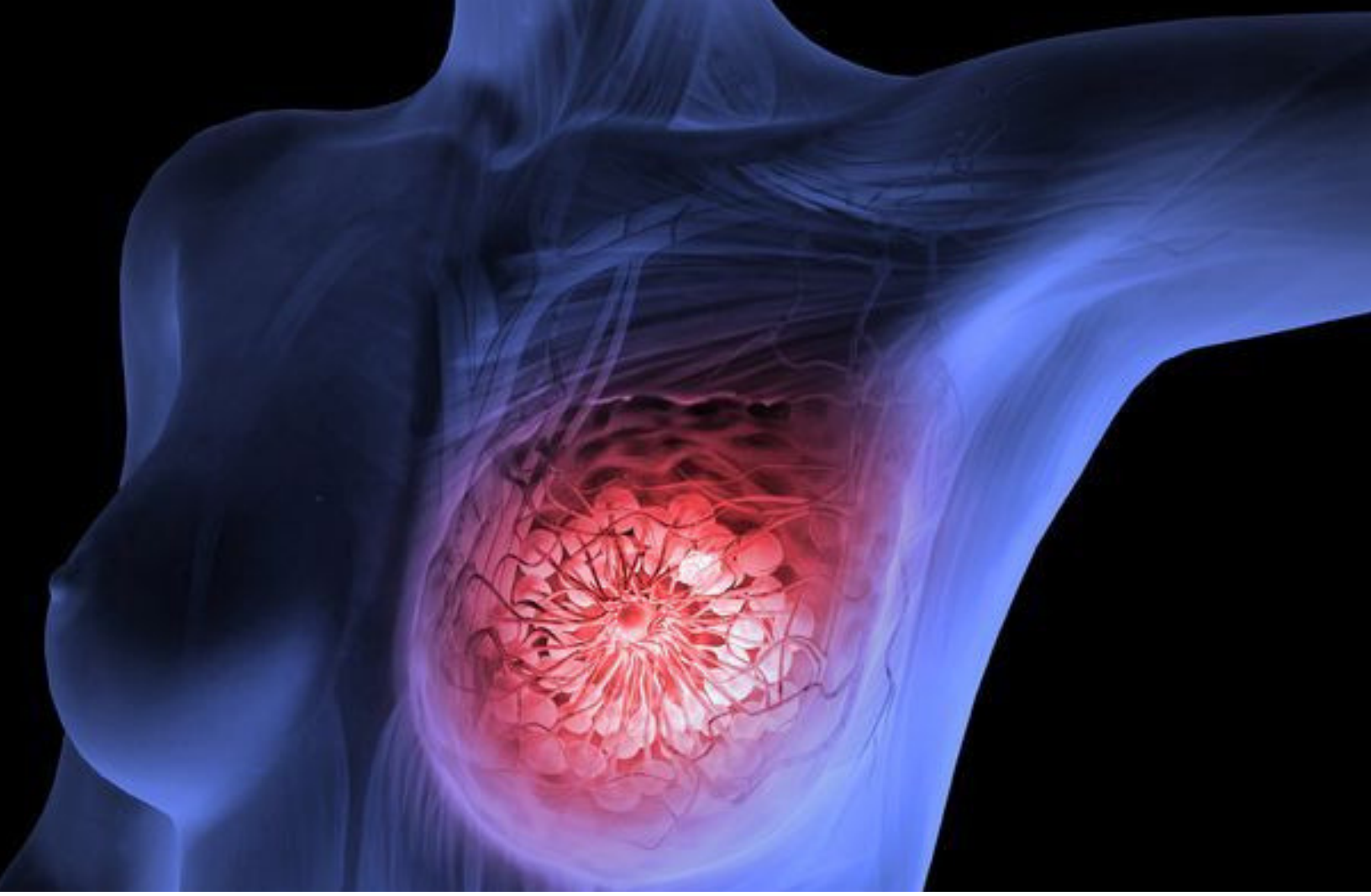
THERMA CAN

INFRARED IMAGING SERVICES

YOUR TRUSTED CHOICE FOR BREAST HEALTH SCREENING



LEARNING ABOUT

BREAST THERMOGRAPHY

Medical infrared imaging is the process of obtaining highly detailed and sensitive infrared images of the human body. The word thermology involves the diagnostic analysis of those images by a Board-Certified medical specialist using a scientific method.

- Thermology is accepted by the US Dept of Health and Human Services as an adjunctive diagnostic procedure for breast disease.
- Thermology is derived from more than fifty (50) years of extensive clinical development and has a sound basis in medical science.
- Thermology evaluates tissue function and is distinctly different from structure-based diagnostic methods, such as X-ray mammography, MRI and ultrasound.

Thermology does not replace these other diagnostic methods but rather they add to thermology's diagnostic value and complement it as part of a comprehensive program. Breast thermology is particularly effective in instances where X-ray mammography is compromised; such as in women who are not menopausal, have used hormone replacement therapy (HRT), have glandular or dense breasts, have fibrocystic disease, had prior biopsies, have implants or surgical reductions, are pregnant, are lactating or have small or large breasts.

EARLY DETECTION IS THE BEST DEFENSE

Breast thermology has a very high (approximately 97%) sensitivity identifying the specific tissue features associated with breast cancer. A normal thermology report does not eliminate all possibility of breast cancer and atypical or abnormal results of other means of evaluation should not be disregarded.

The diagnostic power of thermology can be diminished by tissue inflammation, infection or hormone imbalances. The presence of these conditions can cause false-positive findings, especially on initial studies of an individual. Over time and with repeated studies, thermology can usually distinguish non-cancerous conditions from evolving breast cancer. A questionable thermology feature will resolve, demonstrate stability or evolve to reveal thermology features distinctive of breast ca

False-negative errors are rare and usually a consequence of a latent (resting, non-active) stage in the development of breast cancer. The internationally standardized thermology classification (Marseille System) defines five (5) conventional and distinct reporting categories, ranging from TH-1 (normal) through TH-5 (severely abnormal) and two (2) specialized reporting categories; TH-0 (incomplete or technically defective) and TH-6 (evaluating thermology features in cases of biopsy-proven cancer).

These numbers DO NOT relate to the classification system used to stage breast cancer.

See a sample study of breast thermography on pg. 5

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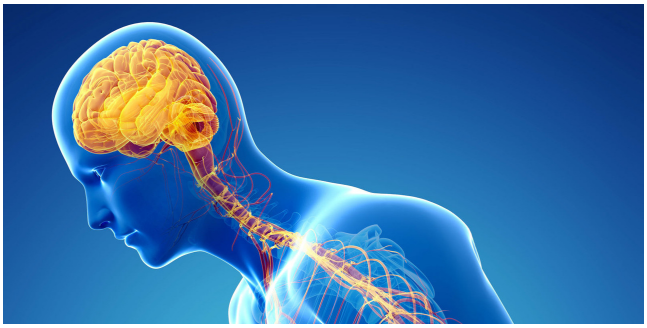
AUTONOMIC CHALLENGE



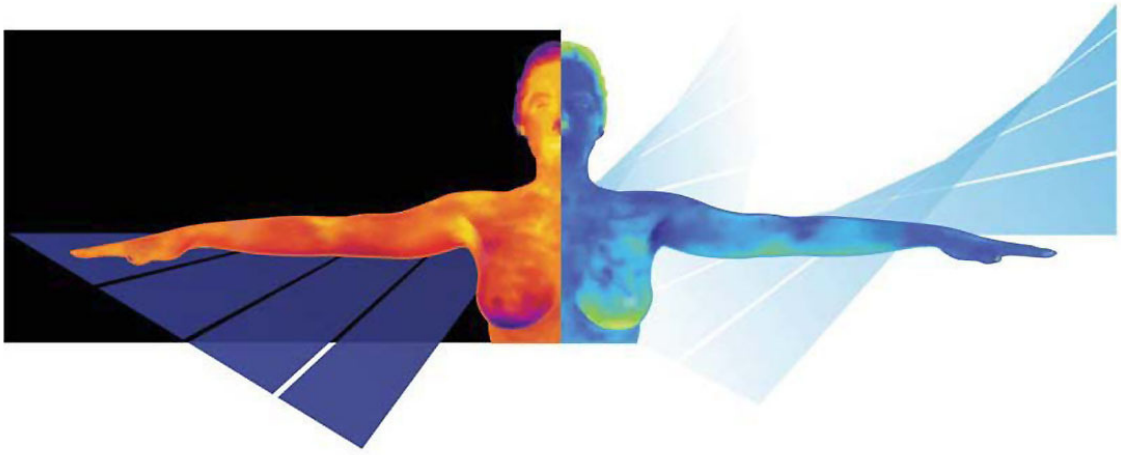
The autonomic challenge (cold water challenge) involves the patient immersing both hands in cold (approximately 11°C) water. This procedure is a deliberate and simple dynamic functional challenge involving the autonomic nervous system that anticipates the adaptive constriction of normal blood vessels with consequent cooling of the skin. The challenge is intended to differentially indicate regions of unregulated hyperemia that are reliably and proximally associated with significant proliferative disorders.

While there is a wide recognition that diagnostic infrared imaging is a physiologic process, there is not an equally wide understanding of the underlying physiologic principles. Over fifty years ago, Lawson developed an empirical relationship linking unusually hot skin patterns with underlying cancer in the female breast and with that link founded the modern era of medical thermography (1). The basis for the elevated skin temperatures and breast cancer were the subject of considerable speculation and, as often occurs, the observations preceded the understanding. Interested individuals as well as serious investigators have speculated the heat of focal inflammation, an immune response or the inefficiencies of cancer's metabolism as the basis for the hot patterns proximal to breast cancer (2, 3). A simple calculation of the energy requirements to maintain the increased temperatures commonly encountered with breast cancer effectively eliminated locally-generated metabolic heat as a possible mechanism for the hot patterns related to breast cancer (4)

Folkman formalized a theory of neo-angiogenesis (the development of new blood vessels) as a requirement for any malignant tumor to grow larger than 0.15mm in diameter (5). Konerding and Steinberg published a study of the ultra-structure of cancer's neo-angiogenic blood vessels that described their structural and functional abnormalities as to exclude any effective modulation by the autonomic nervous system (6).

In the past twenty years, medical scientists have discovered the very high concentrations of Nitric Oxide (a readily diffusible gas) produced by pre-cancerous and cancerous cells. Among its properties is a profound dilatory effect on regional blood vessels. These two abnormal mechanisms, structurally defective neo-angiogenic blood vessels and the strong dilatory effect of Nitric Oxide are almost certainly the basis for the high thermal energy patterns associated with cancer in the female breast as the dis-regulated hypaeremia of core body-temperature blood flows to a relatively superficial area in the female breast (7, 8, 9).

The adult female breast will present a variety of high thermal energy patterns based upon many vascular and metabolic conditions unrelated to cancer or any other pathology, such as typically occurs in the later third of the menstrual cycle, during pregnancy or lactation. On prima facie, these non-cancerous high thermal energy patterns can emulate the "hot spots" empirically associated with breast cancer with the important exception of the specific patho-physiologic dis-regulated hyperemia of core body-temperature blood associated with cancer. A simple (as in single variant) functional challenge is necessary to distinguish the hot patterns of breast cancer from the hot patterns of non-cancerous conditions with good reliability (10). The acclimation of a patient in a very cold room (17°C) will dissipate latent heat of the skin but not effectively distinguish the hot patterns associated with breast cancer by temperature levels alone.



The complex three-dimensional structure of the female chest prevents a uniform application of sprayed alcohol, cold water or a draft of cold air used to cool the skin and creates a complex thermal artifact rather than a simple physiologic challenge to distinguish the characteristic dis-regulated blood flow of cancer.

While the use of vaso-active drugs or the administration of pure oxygen have the potential to provide a single variant physiologic challenge capable of distinguishing the dis-regulated blood flow in the female breast associated with cancer; cooling a patient's hands by immersing them wrist-deep into a temperature-defined water bath for a specified time-span provides that consistent and simple physiologic challenge, provided the analytic parameters are derived from a substantive database. Therma-Scan developed that database from trials involving the detailed quantitative analysis of thousands of patient studies and different temperatures of the water bath and time-spans. A large-scale clinical outcome study was presented at the 2004 Congress of the American Academy of Thermology that documented the significant contribution of the cold-challenge technique for substantially increasing the diagnostic specificity of breast thermology (10). A review of the cold-challenge protocols utilized by some thermographers reveals a significant variance in technique with poor application of physiologic principles, such as allowing five to ten minutes to elapse between the cold challenge and subsequent imaging and no specified temperature of the water bath (11).

Lawson R. Canad Med Assn J. Implications of surface temperatures in the diagnosis of breast cancer. 1956;75:309- 310.
Lawson RN: Thermography-A new tool in the investigation of breast cancer. Can Serv Med J.1957;13:517-518.
Head J.F., Elliott R.L. Thermography. Its relation to pathologic characteristics, vascularity, proliferation rate, and survival of patients with invasive ductal carcinoma of the breast. Cancer 1997;79:186–188.
Anbar M. Hyperthermia of the cancerous breast: analysis of mechanism. Cancer Letters, 1994.
Folkman, J. Tumor Angiogenesis: Therapeutic Implications. N Engl J Med. 1971;285(21):1182-1186.
Konerding MA & Steinberg F. Computerized infrared thermographic and ultrastructure studies of xenotransplanted human tumors on nude mice. Thermology 1988;3:7-14.
Loibl, S. Buck A, Strank C et al. The role of early expression of inducible nitric oxide synthase in human breast cancer. European Journal of Cancer (1990)Y. 2005;41(2):265-271.
Thornsen LL, Miles DW, Happerfield L, Bobrow LG, Knowles RG, Moncada S. Nitric oxide synthese activity in human breast cancer. Br J Cancer. 1995(July);72(1):41-44.
Martin JHJ, Begum S, Alalami O, Harrison A, Scott KWM. Endothelial nitric oxide synthase: correlation with histologic grade, lymph node status and estrogen receptor expression in human breast cancer. Tumor Biol. 2000;21:90-97.
Hoekstra P, The autonomic challenge and analytic breast thermology. Thermology International, 2004(14);3:106.
Amalu W.C. (Sept 2004) Nondestructive testing of the human breast: the validity of dynamic stress testing in medical infrared breast imaging. In Engineering in Medicine and Biology Society. pp 1174-1177

THERMOLOGY: THE TECHNIQUE

The practical application of this challenge procedure involves placing a woman's hands into a basin of cold (approximately 11 degrees C) water for one minute between two sets of identically positioned images. The cold water acts as an intentional challenge to the autonomic nervous system. The expected response to this challenge is a vaso-constrictive effect that will provide a uniform and bilaterally symmetrical cooling effect to the skin. The pre- and post-challenge images can be compared in order to evaluate a decrease in skin temperature as a result of an adaptive physiologic constriction in the caliber of normal blood vessels. This technique, then, contrasts the normal and reactive blood vessels from the non-responding blood vessels that are an important means of identifying neo-angiogenic and nitric oxide-dilated blood vessels characteristic of cancer.

Other techniques that blow cold air or spray cold water or alcohol onto a woman's breasts produce significant and complicated artifact rather than a single variable physiologic challenge; we consider these techniques as unsound. It is our experience that the autonomic challenge greatly improves the specificity of breast thermology, diminishing the number of false-positive errors by differentiating non-cancerous inflammation or mastitis as a basis for atypical high-energy blood vessels (1). The autonomic challenge procedure also diminishes the number of false-negative errors by contrasting non-modulating blood vessels from other prominent blood vessels in the same or contralateral breast.

Hoekstra P, The autonomic challenge and analytic breast thermology. Thermology International, 2004(14);3:106.

BREAST THERMOGRAPHY: A SAMPLE STUDY

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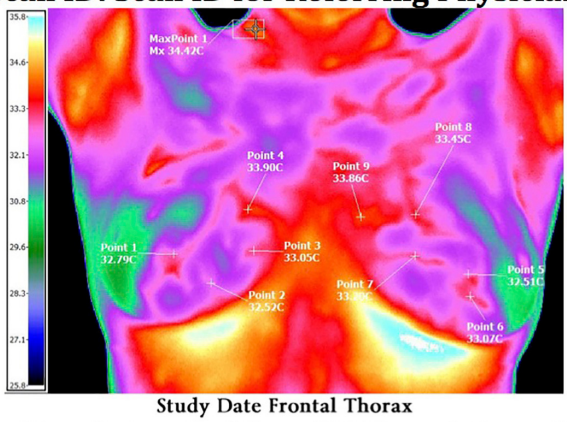
Study Date

ANALYSIS OF BREAST THERMOLOGY

Sample Patient, DOB: Date of Birth
Scan ID: Scan ID for Referring Physician



Study Date Frontal Thorax

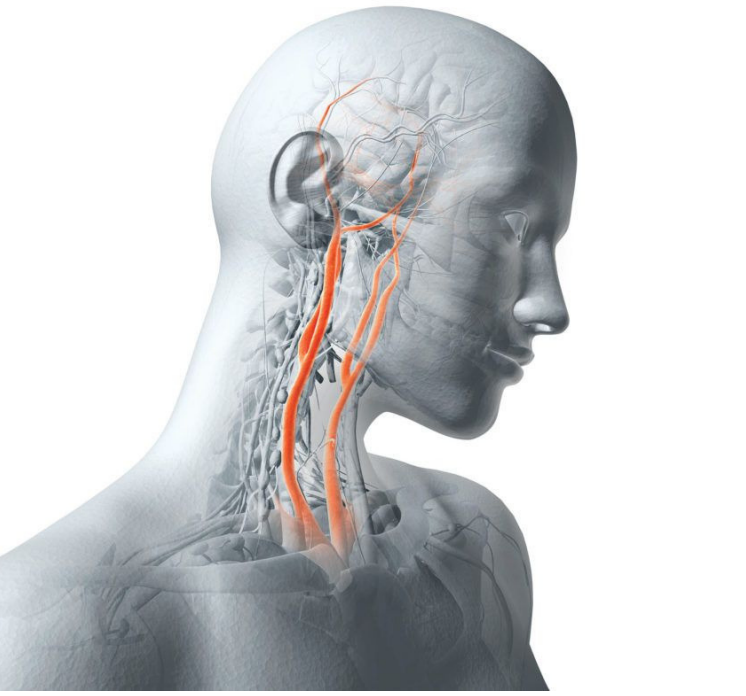
BACKGROUND: Two (2) replicate sets of three (3) high-resolution radiometric infrared images were made of the anterior and the right and left lateral aspects of the thorax to feature the breasts. The second set of images was made immediately after the patient withdrew both hands from a one-minute immersion in cold (approx. 11°C) water. This procedure is a deliberate and simple dynamic functional challenge that anticipates the adaptive constriction of normal blood vessels with consequent cooling of the skin. The challenge is intended to differentially indicate regions of unregulated hyperemia that are reliably and proximally associated with solid cancerous neoplasm. The results of this challenge are coupled with specific features of vascular configuration, quantitative thermal differentials and, when available, time-based evolution of thermal patterns and levels to provide a multi-parametric risk assessment for breast cancer. The patient's related history includes a familial and two (2) personal risk factor(s) for breast cancer. The patient's related history includes no symptom(s) associated with breast disease.

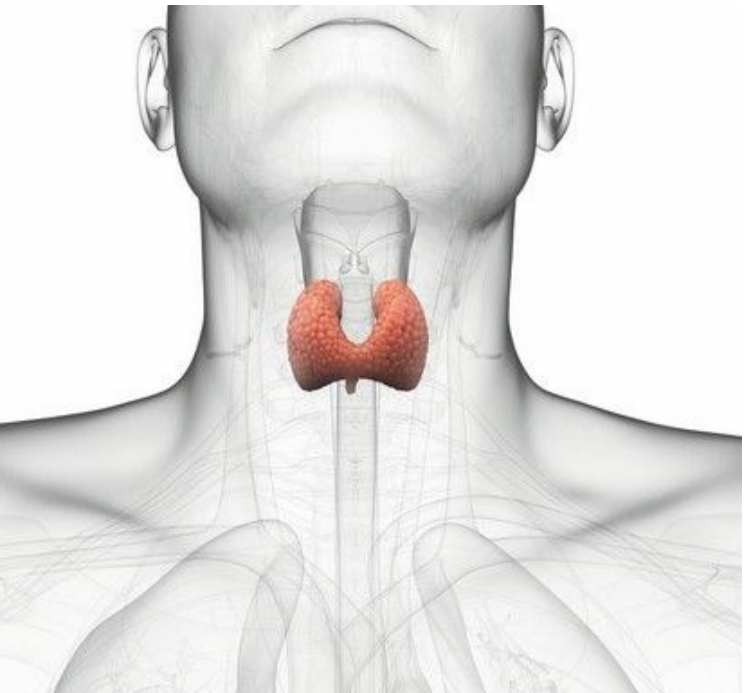
Study Date(s)	Right Breast TH Score	Left Breast TH Score
Study Date	TH-2	TH-2
None		

ANALYSIS: The infrared images of the right and left breasts demonstrate essentially symmetric, distinct, large-caliber, hyperthermic and vascular-like patterns in the peri-areolar area (please refer to the Study Date Frontal Thorax thermogram above for specific features locations). None of the vascular-like patterns demonstrate asymmetric complexity. No significantly hyperthermic (+2.0°CΔ) and asymmetric foci or vascular-like patterns, asymmetric global emission levels, asymmetric complex vascular-like patterns or asymmetric physical distortions are discerned from the right or left breast. The post-challenge images demonstrate symmetric and adaptive attenuation of the emission levels from all of the thermal features of the right and left breasts.

RISK ASSESSMENT: Quantitative analysis of the infrared images does **not** indicate any thermology signs or criteria that establish risk for breast cancer of the right or left breasts. However, the hyperthermic and vascular-like patterns are consistent with estrogen-promoted benign glandular hyperplasia and related moderate to high tissue density of the right and left breasts.

SUMMARY: Benign-type atypical thermology; graded TH-2 for the right breast and TH-2 for the left breast. We recommend annual thermology for comparative analysis.





WHAT WE OFFER

As a Canadian based company, our mission is to provide accessibility to medical-grade diagnostic infrared imaging for early detection and prevention. Therma-Can was formed using the model developed by its predecessor, MTI which provided excellence in breast thermology from 2001 to 2012. Our on-going dedication in the field of medical thermology is to educate, support and inspire those within our communities. Therma-Can's enhanced capabilities utilizes the most experienced and finest source for analysis and reporting in the world. There are two divisions within Canada, Therma-Can East and Therma-Can West.

Therma-Can partners with Therma-Scan Reference Laboratory. Therma-Scan was founded in 1972 with unrelenting commitment to innovation, integrity and the highest ethical, technical and professional standards in the practice of diagnostic infrared imaging, Therma-Scan is the most experienced and accomplished provider of medical thermology in the world. They are proficient and certified by the American Board of Thermology in oncology, neuroscience and vascular thermology. For more information on Therma-Scan please visit thermascan.com

SERVICES

- **BREAST THERMOGRAPHY:**

  No-touch, non-invasive, radiation-free breast health screening. Compatible with breasts of all shapes, sizes and density

- **THYROID THERMOGRAPHY:**

  Evaluates the functional condition of the thyroid structure. Thermography estimates functional cellular activity

- **CAROTID THERMOGRAPHY:**

  Evaluates the competence of the right and left carotid artery network as a means to indicate risk for stroke and/or cerebrovascular insufficiency.

COLLABORATE WITH US?

More and more people are choosing digital infrared imaging (thermography) as a means of preventative health-care, yet knowledge of this type of modality still falls short for those who subscribe to only one facet of the health care industry.

A collaboration with Therma-Can can provide your organization with an opportunity to educate and promote awareness in your community, driving more traffic to your facility of care while offering a new service to your existing clientele.

THE BENEFITS OF HOSTING A CLINIC

- Therma-Can will provide the necessary marketing material for you to host a clinic at your facility.
- Therma-Can will pay you up to $250.00 (The number of participants per clinic will determine the appropriate payment scale).
- Your business will be advertised on Therma-Can's website and social media with link attached to your website / contact information.
- Clients with a moderate to high TH scale score will be encouraged to seek your guidance to create a lifestyle plan that best works for them.
- You may choose to host as many clinics as you deem necessary.

THERMOLOGY: SUBSTANTIATION

There are well over eight hundred peer-reviewed clinical studies on diagnostic infrared imaging for breast cancer in the Index Medicus with a data-base in excess of 300,000 women participating in these studies, often in large cohorts and some followed for up to twelve years. In 1972, Acting Secretary Thomas Tierney of the US Dept of Health, Education and Welfare released an official position paper that stated "The medical consultants indicate that thermography, in its present state of development, is beyond the experimental stage as a diagnostic procedure in the following 4 areas: (1) Pathology of the female breast. (2)". On January 29, 1982, the US Food and Drug Administration published its formal listing and classification of thermography as an adjunctive diagnostic device for breast cancer. In 2005 the FDA reaffirmed this position and classification (1).

The US National Cancer Institute states "The use of thermography, also known as digital infrared imaging, is based on the principle that chemical and blood vessel activity in both precancerous and the area surrounding a developing breast cancer is almost always higher than in normal tissue. This activity frequently results in an increase in the regional surface temperature of the breast. Thermography uses ultra-sensitive infrared cameras and sophisticated computers to detect, analyze and produce high-resolution of these temperature variations, which may be among the earliest signs of breast cancer." (2). There are ICD-9, ICD-10 and CPT procedure codes for breast thermology.

1. Code of Federal Regulations, Title 21, Vol. 8, 21 CFR884.2980.
2. US NCI official website.

THERMOGRAPHY VS. MAMMOGRAPHY

- Breast thermography has been FDA approved as an '**adjunct** ' diagnostic tool to mammograms since 1982.
- There have been 800 peer-reviewed breast thermography studies in which over a quarter million women have participated in large-scale studies over 12 years. These studies show thermography to be 90% accurate.
- Mammograms in pre-menopausal women can be up to 89% inaccurate, leading to unnecessary procedures, as well as emotional and physical trauma.
- Many false negatives occur with mammograms since tumors are frequently located in the upper outer aspects of the breasts where the scans do not reach.
- In Europe, Canada, & Australia healthy breasts are routinely screened with thermography and mammograms are used as a second line of diagnosis.
- For earliest detection and prevention, it is recommended that women receive baseline breast thermography at age 20, every three years between ages 20-30, and annually from age 30.
- Starting breast thermography at any age gives you the safest and earliest detection possible.

BE A PART OF OUR TEAM AND HELP SAVE LIVES ONE SCAN AT A TIME

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Therma-Scan is certified facility by the American Academy of Thermology