

INTRODUCTION: According to the American Cancer Society, women diagnosed with stage-one breast disease have a 100% chance of survival. Yet in the United States, breast cancer is still the leading cause of cancer death among women between the ages of 20 and 59 and is the leading cause of cancer death for women worldwide.

Why? The most commonly used breast cancer screening methods are best at detecting mature cancers after years of growth and development. For patients with breast cancers identified in later stages, there are fewer treatment options and the survival rates are much lower.

The IMS breast cancer screening solution takes a different approach. By identifying and measuring metabolic changes in a patient's physiology, Infrared Mammography can see the effects of breast cancers while they are still in their earliest stages of development. Detecting breast cancer earlier gives patients a life saving head start on the road to a cure.

#### IMS SENIOR ANALYTIC LABORATORY STAFF:

Philip P. Hoekstra, III, PhD

The Chief Science Officer for Infrared Medical Solutions and a recognized authority in Infrared Mammography with thirty-seven years of experience and 750,000 clinical patient analyses completed. He is Board Certified in Neuro-Science, Oncology, and Vascular Thermology. Dr. Hoekstra is currently serving as President of the American Academy of Thermology and as Director of the American Board of Thermology.

Abigail Neal, MD

A Family and Urgent Care MD., graduated from Wayne State University School of Medicine, she completed her Family Medicine residency at William Beaumont Hospital - Troy. Upon completion of her residency, she practiced Family and Urgent Care Medicine before completing her Fellowship training in Infrared Mammography at Infrared Medical Solutions. Dr Neal is currently a member of the American Academy of Thermology and is a Diplomate of from the American Board of Thermology.

VISION: Save Women's Lives Through The Early Detection Of Breast Cancer Using Infrared Mammography.

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Patient's Name:  
Technician's Name: **Alison De Surra**  
Patient ID: **1351**  
Date Of Birth:

Thermologist: **Philip Hoekstra**  
Analyst: **Danielle Gotshaw**  
Study Date: **04 February 2011**  
Report Date: **09 February 2011**

SUMMARY: Atypical thermology sign with minor risk for malignant disease in the cranial-lateral quadrant of the right breast; graded TH-3. Atypical benign-type thermology of the left breast; graded TH-2. A comparative restudy is recommended in 120-180 days. Thank you for your referral. © Copyright 2001-2011. This report format, its text and image color pallet are copyrighted and may not be duplicated or replicated in any manner. All Rights Strictly Reserved. Therma-Scan Reference Laboratory, LLC. 34100 Woodward Ave. Suite 100 Birmingham, MI 48009 USA. 248.593.8700 [www.thermascan.com](http://www.thermascan.com)

TH-2 OR TH-2F: defines a thermal profile of breast features that are essentially uniform, regularly patterned and moderately large blood vessels. These thermal features are frequently associated with benign (non-cancerous) functional changes such as hormone imbalances, particularly estrogen-dominant imbalances that affect the glandular breast tissue. The TH-2 score does not indicate malignant (cancerous) disease. A classification of TH-2F indicates that distinct, low-energy (cold) patterns were identified in your analysis that are associated with benign cystic and/or fibroadenomas. These conditions often have symptoms of premenstrual tenderness or swelling, lumpy texture, feeling of excessive heaviness in the breast tissue and even breast pain. We recommend that you consult your personal physician to assess the health of your breasts and get treatment for any adverse or uncomfortable conditions. We also recommend an annual Thermology comparative restudy to monitor changes in the health of your breasts. In some cases, more frequent restudies may be indicated by your personal physician. Be sure to ask for their recommendation on restudy frequency.

TH-3: defines a profile of unusual breast tissue processes and/or blood vessels. This atypical category is classified TH-3 and is associated with a minor or equivocal (less than 10-20% as specified in your own report) risk of malignant breast disease. It is more likely that these features represent benign (non-cancerous) changes such as inflammation, acute cysts and/or fibroadenoma development, infection or a personal characteristic, especially on an initial study. A Thermology restudy in 45 to 180 days (as specified in your own report) provides the data necessary to compare and assess changes in the specific unusual Thermology feature. This comparison usually enables the differentiation of benign conditions from malignant disease. Please be sure to review your Thermology report with your personal physician and discuss a prudent course of action. Depending on familial or personal risk factors, physical examination and intangible concerns; that course of action may range from watchful waiting to prompt additional testing with other methods of evaluation. A personal commitment to vigilant follow-up is necessary as an unusual Thermology feature can precede abnormal results from other means of testing by 5-8 years. Clinical experience has determined that targeted ultrasound is the most effective means of follow-up to an atypical Thermology study. Your physician may learn more about breast Thermology by requesting literature through the IMS website or by contacting any of our knowledgeable clinical consultants.

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**BACKGROUND:** Two (2) replicate sets of three (3) high-resolution digital 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 one-minute immersion in cold (approx. 11Å°C) water. This procedure is a simple and deliberate autonomic challenge that anticipates the adaptive sympathetic-driven constriction of normal blood vessels with consequent cooling of the skin. The challenge is intended to differentially indicate unregulated core body-temperature hyperemia of defective blood vessels that is reliably and proximally associated with solid malignant neoplasm. Notice is made of this patient's related history that includes the current administration of estrogenic hormonal medication and a familial risk factor(s) for breast malignancy. The patient's related history includes no symptom(s) frequently associated with breast disease. This patient has a 10 September 2010 study of prior data available for comparative analysis.

**DATA:** The infrared images demonstrate certain patterns and emission differentials considered atypical. Specifically, an asymmetric, diffuse, large-caliber and vascular-like pattern is discerned in the cranial-lateral quadrant of the right breast (please refer to P16, P17 & P19 in the 04 February 2011 Right Aspect of Thorax thermogram above for specific features and locations). A moderately hyperthermic, non-complex and vascular-like pattern is discerned in the left breast (please refer to P74 & P75 in the 04 February 2011 Frontal Thorax the thermogram above for specific features and locations). Additionally, the post-challenge images demonstrate an adaptive attenuation in emission levels from all of the thermal features of both breasts. Comparative analysis with the prior study does not demonstrate any notable changes in the extent, caliber or relative emission levels of the described atypical vascular-like pattern discerned in the cranial-lateral quadrant of the right breast. However, comparative analysis with the prior study demonstrates adaptive attenuation in the emission levels of the described atypical vascular-like pattern discerned in the cranial-lateral quadrant of the right breast.

**IMPRESSION AND DISCUSSION:** Quantitative analysis of the infrared images indicates atypical metabolic and/or vascular processes in the cranial-lateral quadrant of the right breast that define a single thermology sign and establish minor (<10%) risk for confirming malignant disease at this time. However, in the absence of other specified risks, experience with similar findings demonstrate regional inflammation, personal variant or metaplasia as the more likely basis for the described atypical thermal features in the cranial-lateral quadrant of the right breast. Further, the lack of a positive evolution in the thermal features of the described atypical vascular-like pattern discerned in the cranial-lateral quadrant of the right breast, while favorable, is thought not of sufficient time-span to abate the risk for malignant disease. Other means of objective evaluation should be considered and are urged if clinically indicated. The risk specified by this analysis should be considered additive with other risk factors and other objective evaluations. Atypical metabolic and/or vascular processes are indicated in the left breast that do not define any thermology signs or criteria.

**SUMMARY:** Atypical thermology sign with minor risk for malignant disease in the cranial-lateral quadrant of the right breast; graded TH-3. Atypical benign-type thermology of the left breast; graded TH-2. A comparative restudy is recommended in 120-180 days. Thank you for your referral. Å© Copyright 2001-2011. This report format, its text and image color pallet are copyrighted and may not be duplicated or replicated in any manner. All Rights Strictly Reserved. Therma-Scan Reference Laboratory, LLC. 34100 Woodward Ave. Suite 100 Birmingham, MI 48009 USA. 248.593.8700 [www.thermascan.com](http://www.thermascan.com)



early detection. redefined.


## *Infrared Mammogram*

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A handwritten signature in black ink, appearing to read "Philip P. Hoekstra, III, Ph.D.", is written over a light gray signature line.

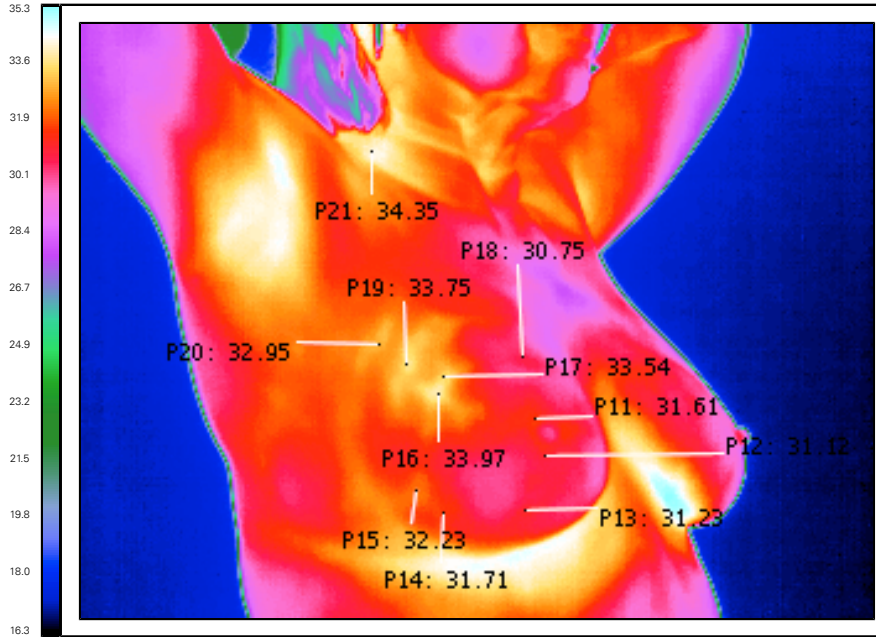
Philip P. Hoekstra, III **Ph.D., DABT, FAAT**

 American Academy of Thermology Certified

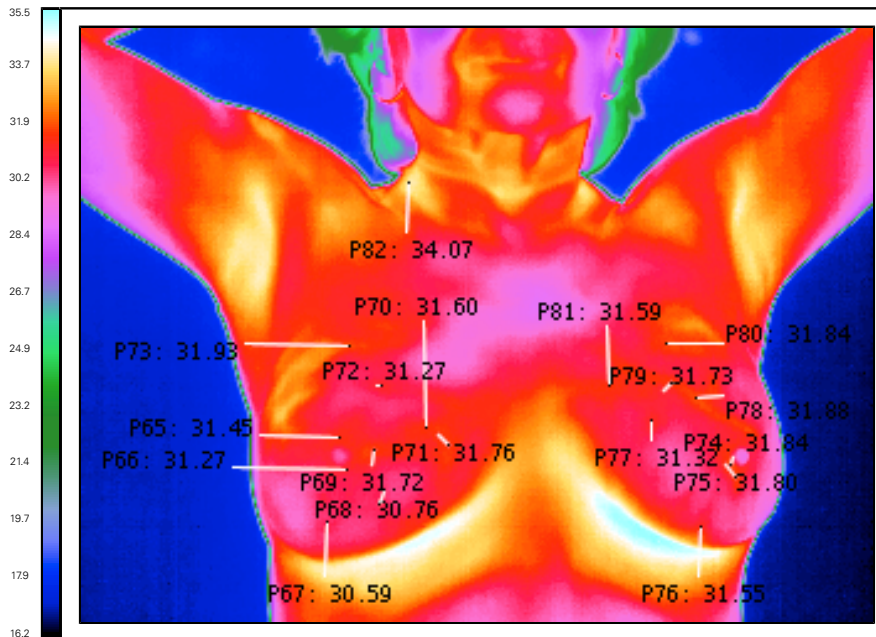
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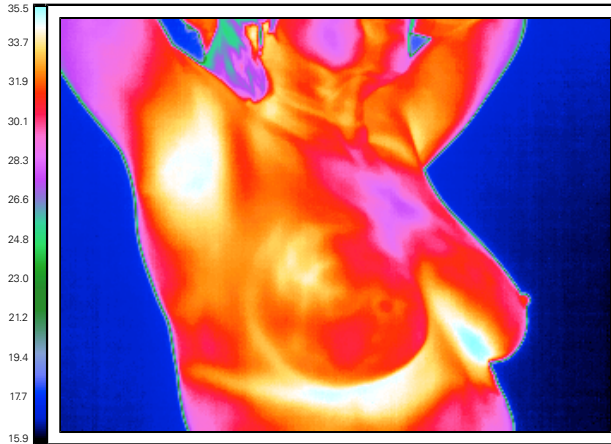
04 February 2011, Post-Challenge, Right Aspect of Thorax



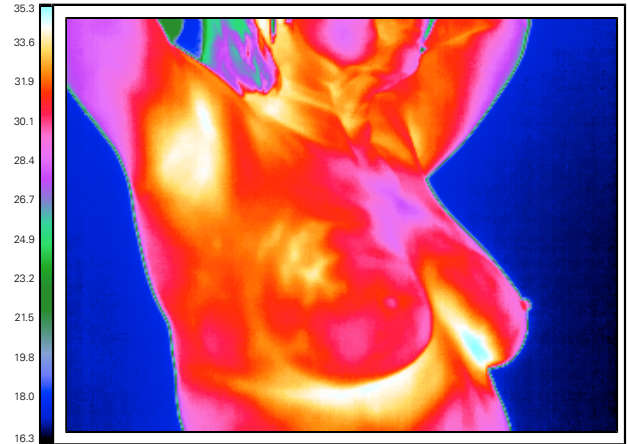
04 February 2011, Post-Challenge, Frontal Thorax

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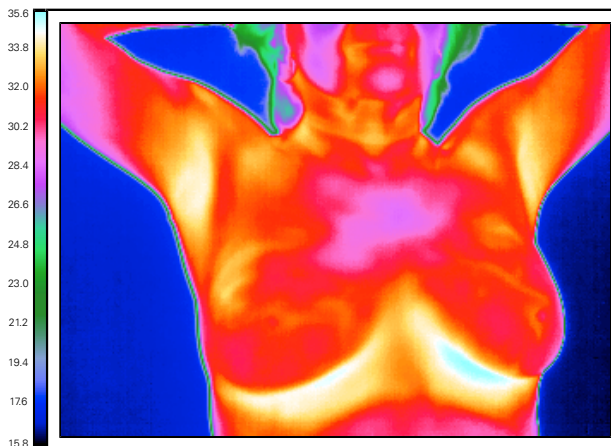
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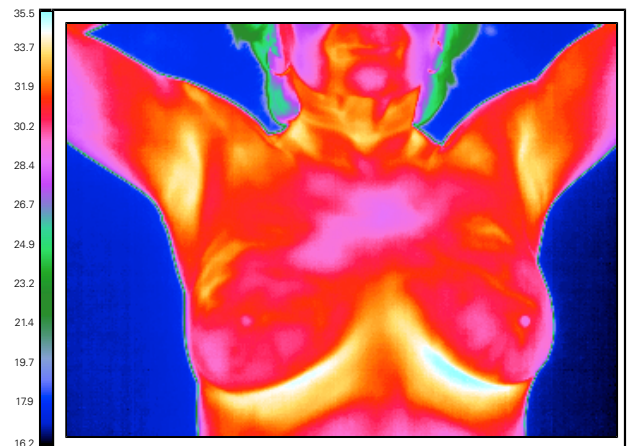
04 February 2011, Pre-Challenge, Right Aspect of Thorax



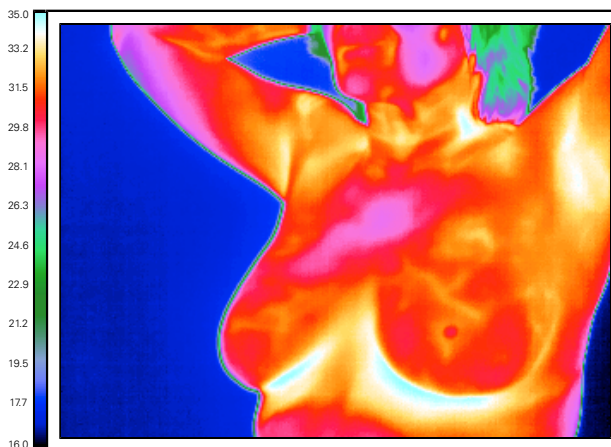
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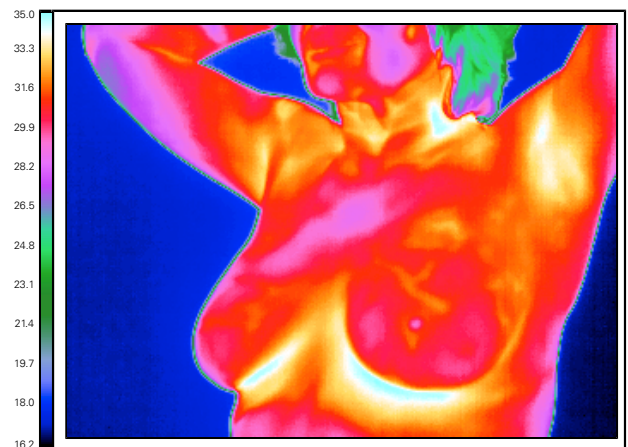
04 February 2011, Pre-Challenge, Frontal Thorax



04 February 2011, Post-Challenge, Frontal Thorax



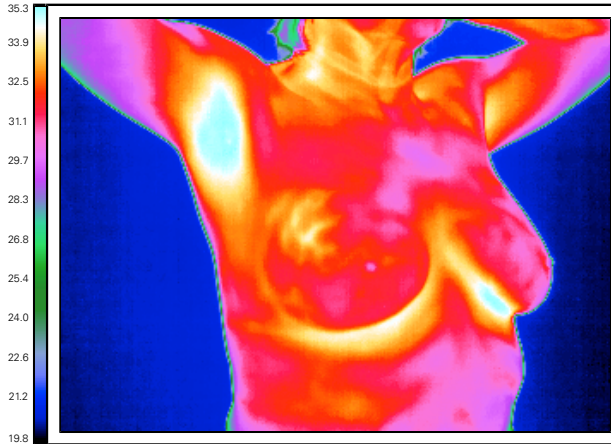
04 February 2011, Pre-Challenge, Left Aspect of Thorax



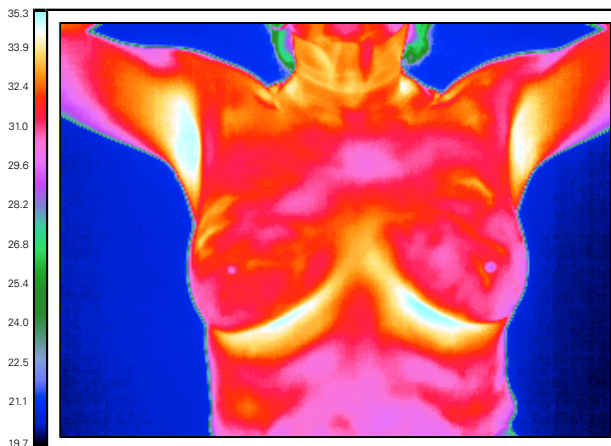
04 February 2011, Post Challenge, Left Aspect of Thorax

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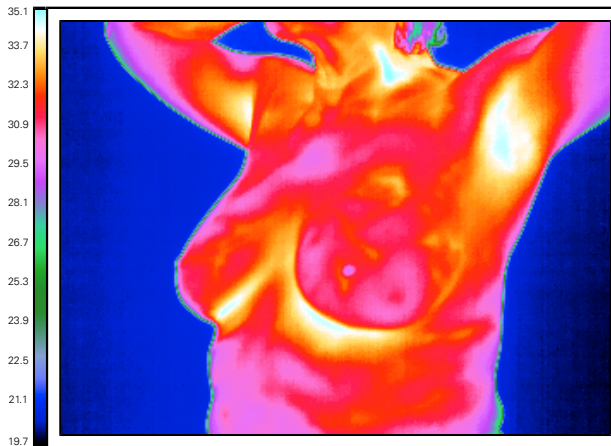
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10 September 2010, Pre-Challenge, Right Aspect of Thorax



10 September 2010, Pre-Challenge, Frontal Thorax



10 September 2010, Pre-Challenge, Left Aspect of Thorax



## Autonomic Challenge Discussion

We have had several questions as to whether or not the Autonomic or “Cold” Challenge IMS requires is necessary when performing an Infrared Mammography given today’s sensitive infrared cameras. Our answer is a resounding yes, and here’s why.

Let’s start by reviewing some basics of how Infrared Mammography works. Here’s what we know from the literature. We know that medical infrared imaging detects heat radiating from the skin and, we also know that increased localized heat in the breast is a strong indication of the existence of a tumor. This increased heat when analyzed with several other factors is distilled into a Marseilles scale ranking. A high Marseilles scale ranking is the single most effective predictor of breast cancer known, up to 22 times more effective than is any other predictor. The question then becomes, what is generating the heat that the infrared camera is recording.

In the 1950’s and 1960’s when the correlation between heat and a tumors existence was being observed and documented, many theorized that the fast growing tumor cells were radiating heat because of the increased metabolic activity. This theory was abandoned in the 1970’s and 1980’s with the recognition that neo-angiogenesis, or new blood vessel creation, was critical to the development of a malignant tumor. Further, in 1989, the coupling of the effects of neo-angiogenesis with the observed vaso dillitation, or unregulated blood vessel dilation, the effects of nitric oxide being generated by the tumor, validated the contention that the increased blood flow not the tumor was responsible for the increased heat signature.

The recognition that the blood flow necessary to nourish a tumor is the cause of the abnormal heat radiating is also to recognize that the increased heat is due to physiologic reasons rather than structural reasons. As a result, it is clear that both the tests and the analytical techniques to interpret the tests must be adapted to measure physiologic not structural phenomena.

An analytical technique used by virtually everyone trained to interpret infrared images is called Pattern Recognition. This technique is normally applied to a structurally based imaging system such as X-Ray Mammography. The same technique may also be used with an imaging system relying on physiologic differences such as Infrared Mammography, but with some modifications. The difference is that in physiologic measures vs structural measures, there can be many benign reasons for a physiologic anomaly. Only with an additional functional evaluation can the benign conditions be differentiated from the malignant ones.

An Autonomic or “Cold” Challenge is simply a functional evaluation of the body’ normal response to conserve critical core body temperature blood by constricting nonessential blood vessels such as those in the breast. If, during such challenge, the vessels do not constrict, benign physiological reasons for the increased blood flow to the area are ruled out such as pregnancy, lactation, or hormone imbalances. At IMS, we have developed a specific protocol for the Autonomic or “Cold” Challenge which has been in use since 1989 that incorporates a series of carefully controlled analytic criteria. With the proper application of the protocol, our diagnostic sensitivity is approximately 97% and more importantly, the specificity on a standalone basis is approximately 64%.

Given the above, it is our contention that any interpretive service of infrared images that does not incorporate the Autonomic or “Cold” Challenge is either unaware of the progress that has been made in understanding the formation and growth of malignant tumors or has chosen to sacrifice the progress of the science on the altar of expediency. It is certainly easier and faster to interpret an Infrared Mammogram if no analytics are performed on the pre and post Autonomic of “Cold” Challenge images, but the resulting analysis is, at best, incomplete and, at worst, misleading.