Breast Thermography Screening Systems

for

Earliest Assessment of Cancer Risk

Primer and Classroom Study Guide

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INTRODUCTION

Every organ beneath the skin radiates heat. A portion of the radiated heat reaches the surface of the skin forming a stable pattern, or map. The temperature of the skin at a specific point is directly related to the heat transferred from the subcutaneous organs. Breast thermography is a medical science that evaluates these thermal patterns to derive diagnostic indications related to risk of breast cancer.

Thermography is an indicator of physiological function, unlike mammography, MRI and ultrasound, which reveal anatomical characteristics. Evaluated properly, thermography enjoys a significant advantage as an early indicator of breast disorder owing to the very early emergence of thermal signs indicating errant functional behavior.

Functional changes occurring within the breast with the early onset of a tumor (< 0.5 mm) are visible to thermography years before a tumor is otherwise detectable by traditional image techniques. Angiogenesis and vascular migration are two examples of serious early changes that are revealed only with thermography. Anatomical imaging detects tumors after they've grown to detectable size (≥ 5 mm), years after functional changes issue.

Breast thermography is an accurate, safe and noninvasive imaging technique that involves no touching or compression of the breast and uses no potentially dangerous radiation. The technology is widely employed throughout the world. Breast thermography was approved by the USA FDA in 1982 for breast cancer risk assessment.

The thermographic breast cancer screening procedure is an easy three-phase process. The patient is prepared according to examination protocol, and then a precision infrared-sensitive camera records the thermal patterns on the breasts. The recorded images are interpreted using innovative computer software to objectively assess and report the risk for development of the disease. Examinations may be interpreted locally or submitted to a remote central reading center.

Maximum precision assures that recorded thermograms clearly display the information required to perform a detailed analysis, so a quality image acquisition system is essential to examination credibility. Thermography Image Acquisition Systems' Model 325XP Image Acquisition System is an ideal solution.

While perfectly suited as a permanent fixture in the clinical environment, the compact nature of the Model 325XP is easily employed in a portable setting. Key system elements are built to withstand rugged use, and automatically self-calibrate to preemptively resolve maintenance and calibration issues. Trouble-free, extended operation under battery power is standard.

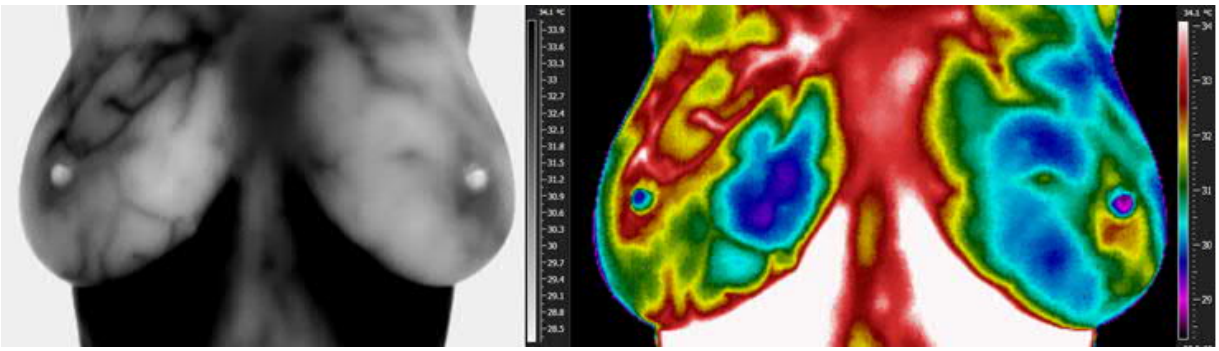
Scientific Basis for Breast Thermography

The science of breast thermography is relatively straightforward. Planck's Law of physics states that anything with a temperature above absolute zero radiates heat. Blood vessels, cysts, other benign sources, and metabolic processes such as growing breast tumors all radiate heat from within the breast. Thermodynamics teaches that heat flows from hot to cold, so a portion of the radiated heat flows to the cool surface of the breast, where it composes a stable thermal pattern. Analyzed properly, these patterns reveal the presence of breast disorders.

A breast thermography examination uses special infrared-sensitive cameras to digitally record the thermal patterns on the surface of the breast. The recorded images, called thermograms, are interpreted according to a strict and complicated analytical procedure. The analyzed images implicitly and explicitly disclose various pathological signs and abnormal processes.

Thermograms are viewed as anatomical images in grayscale or in temperature-related colors. Each shade of gray or color represents a range of temperatures. In the following figure, temperature scales are shown to the right of each image.

Example (abnormal) breast thermograms:



How Does Breast Thermography Detect Tumors?

Thermography does not directly diagnose breast cancer. Thermography is a unique indicator of the functional activity within the breast, unlike mammography, etc., which reveal anatomical structures such as tumors and their waste products.

The stable thermal patterns of the breasts aid in disclosing a variety of physiological processes, both normal and pathological. Breast thermography assesses the risk of developing breast cancer by analyzing the thermal patterns on the breasts to disclose the presence of certain thermal signs. The disorders are revealed by way of evidence-based reasoning derived from the factual presence of multiple known thermal characteristics statistically known to be symptoms of the disease.

Breast thermography is based on two solid principals. First, departure from the normal thermal symmetry of the two breasts indicates abnormality and the possible presence of serious

pathology. Second, and especially important in the earliest detection of breast disorders, pre-cancerous growths and cancerous tumors are characterized by thermographically visible changes in the breast's vascular system.

Thermal Symmetry: Humans are symmetrical, with a left side and a right side that in the perfect body, are mirror images of each other. The thermal patterns of two normal, healthy breasts are equally symmetrical uniform temperature distributions.

The normal functioning of the breast is altered with the presence of a breast disorder, and when the functional behavior of a breast changes, thermal symmetry is lost. The more serious the disorder, the more pronounced are the differences in thermal symmetry of the two breasts.

Vascular Changes: Developing cancers are characterized by abnormally elevated temperatures (hyperthermia) and hyper-vascularity. The developing tumor demands blood for both nourishment and cooling, and the body responds by increasing blood circulation to the region of the tumor. Dormant blood vessels are "awakened," blood vessels expand (vasodilation), existing veins migrate to the tumor site, and new blood vessels are created (angiogenesis). The faster the tumor metabolizes, the more additional blood flow is needed to support and cool it, and the more the body responds by amplifying the vascular capability of the breast. All of these changes are clearly visible and recordable with thermography, the only method available to observe these changes.

Interpreting Thermal Patterns: Breast thermograms are complex and difficult to manually analyze and interpret. The task is generally time-consuming, labor intensive and requires a highly trained individual to perform.

TAS overcomes these limitations with easy-to-use, internet-accessed, breast thermogram interpretation software that is the most accurate, credible, objective and comprehensive breast thermography assessment method available.

The interpretation software directs the analyst to identify up to twenty-two statistically significant thermal indicators of a breast at risk for developing breast cancer. If present, each of the twenty-two identified signs derives a weighted numerical score based on its statistical frequency of occurrence and statistically derived pathological significance from a population of more than 300,000 symptomatic patients. The sum of the scores is mapped to five classifications, TH1 – TH5, an ascending assessment of the patient's risk.

A proprietary algorithm computes an ascending risk classification (TH1 – TH5) by assessing the correlation between the reported thermal characteristics with the thermal characteristics known to be symptoms of the disease.

EXAMINATION PROTOCOL

When the patient's examination preparation or the examination and its environment are not controlled, the diagnostic value of thermography may be impacted. Several internal and external factors have a significant effect on the examination's integrity. To enhance and assure the accuracy of thermographic studies, particularly serial examinations, it is essential to minimize the effects of these variables.

TAS's breast thermography examination consists of breast thermograms recorded according to strict examination criteria, using appropriate image capturing techniques, and interpreted by an objective, credible procedure. The examination protocol assures maximum accuracy in capturing the thermogram and should be adhered to as closely as possible.

The reliability, accuracy and integrity of the thermographic examination can only be maintained if shortcuts are avoided. Proper patient scheduling, simple patient preparation requirements, attention to examination preparation, examination room conditions and image capturing are all required to meet the criteria for an accurate thermographic examination.

It is essential that all other breast examinations and diagnostic modalities, including physical examination must be performed after the thermography examination to eliminate spurious alterations of the thermal patterns of the breasts.

Clinical Layout

Relatively small areas are required for patient preparation and evaluation; a typical examination room has proven to be generally acceptable. Sources of heat or cold which significantly affect the ambient environment of the cooling and examination rooms should be eliminated. High energy lights or office equipment, warm window areas, or drafts caused by heating or cooling equipment should be particularly avoided. If more than one room is used for cooling and/or examination, the rooms must be maintained at the same temperature, and transition from the cooling area to the examination room should be performed as quickly as possible.

The temperature of the cooling/examination room should be 68°F - 72°F. Note that temperature stability, not just the absolute temperature, is important. Thermograms performed in environments below 66°F or above 74°F are unsuitable for accurate interpretation.

Patient Physical Profile

Proper patient scheduling and preparation prior to the test are necessary to assure adherence to the protocol requirements.

The phase of the patient's menstrual cycle at the time of the thermography examination is of particular importance. Estrogen level and consequential temporary vascular dilation are significantly elevated during the week following menstruation, resulting in ambiguous image interpretation. The ideal time period is from ovulation to the onset of menstruation.

To reduce inaccuracies which might result from alterations in thermal signs due to the effects of Circadian Rhythm, examinations should be performed in the morning hours.

Illnesses, with or without temperature elevation, may alter the normal thermal characteristics of the breasts; thus, patients suffering from colds, influenza, etc. should not be scheduled for an examination.

Patients must be instructed to follow the requirements established to maximize examination accuracy by eliminating various factors which could alter the thermal characteristics of the breasts. Strict adherence to the following is emphasized.

Alcoholic beverages, coffee, tea or colas containing caffeine should not be consumed for twelve hours prior to the test. Hot or cold beverages should be avoided for at least one full hour before an examination is performed.

If possible, aspirin, pain medications, vasodilators/constrictors and/or other similar medications should be avoided for 24 hours prior to the test.

Cigarettes should not be smoked for two hours prior to the thermographic examination.

Examination should not be scheduled within two weeks after the patient has been subjected to sunburn. Lotions or ointments should not be applied to the breasts for 24 hours prior to the test.

Physical exercises that might affect breast circulation should be avoided for 24 hours prior to the examination.

Pre-examination Equilibration (Cooling)

Thermal equilibration, generally a cooling procedure, is the process under which the patient's exposed breasts achieve thermal stability in a temperature-stabilized environment. A ten to fifteen minute period of thermal equilibration is absolutely essential to the integrity of the examination. Proper cooling cannot be overlooked or avoided!

Static and Fan cooling are two methods used in the cooling of patients. Fan cooling should be avoided in favor of the more acceptable static cooling, as fan cooling has increased potential for both asymmetrical cooling or over-cooling.

1. Static Cooling: The patient disrobes from the waist up with her hands placed slightly above her hips and with the arms held away from the body, exposing the full breast to the temperature of the examination room. This position is maintained for ten minutes minimum with the patient either standing, or seated on a stool. Cooling for less than ten minutes invalidates the examination.

2. Fan Cooling: The patient disrobes from the waist up, stands five to six feet from a slowly rotating 20" area fan, and is then positioned such that the air-flow from the fan is directed at the sternum. The air flow direction is important to avoid asymmetric cooling. Cooling time using this method should be approximately two minutes. Asymmetrical cooling yields thermal asymmetry, while over-cooling results in unstable thermal patterns on the breasts.

It is extremely important that the breasts are not touched during the cooling period by either the patient or the examiner.

When performed in conformance with the above protocol, the breast thermography examination is an extremely valuable adjunct for the earliest detection of possible breast pathology. The examination is safe, easy to perform, and has patient acceptance; however, certain minimum requirements must be observed in order to enhance its integrity.

It is of utmost importance to diligently adhere to the criteria, avoid the temptation to use shortcuts, and take care to acquire the most suitable thermograms for evaluation.

PEFORMING THE EXAMINATION

When presenting for the examination, the patient disrobes from the waist up, assumes the position appropriate to the cooling method being utilized, and undergoes equilibration.

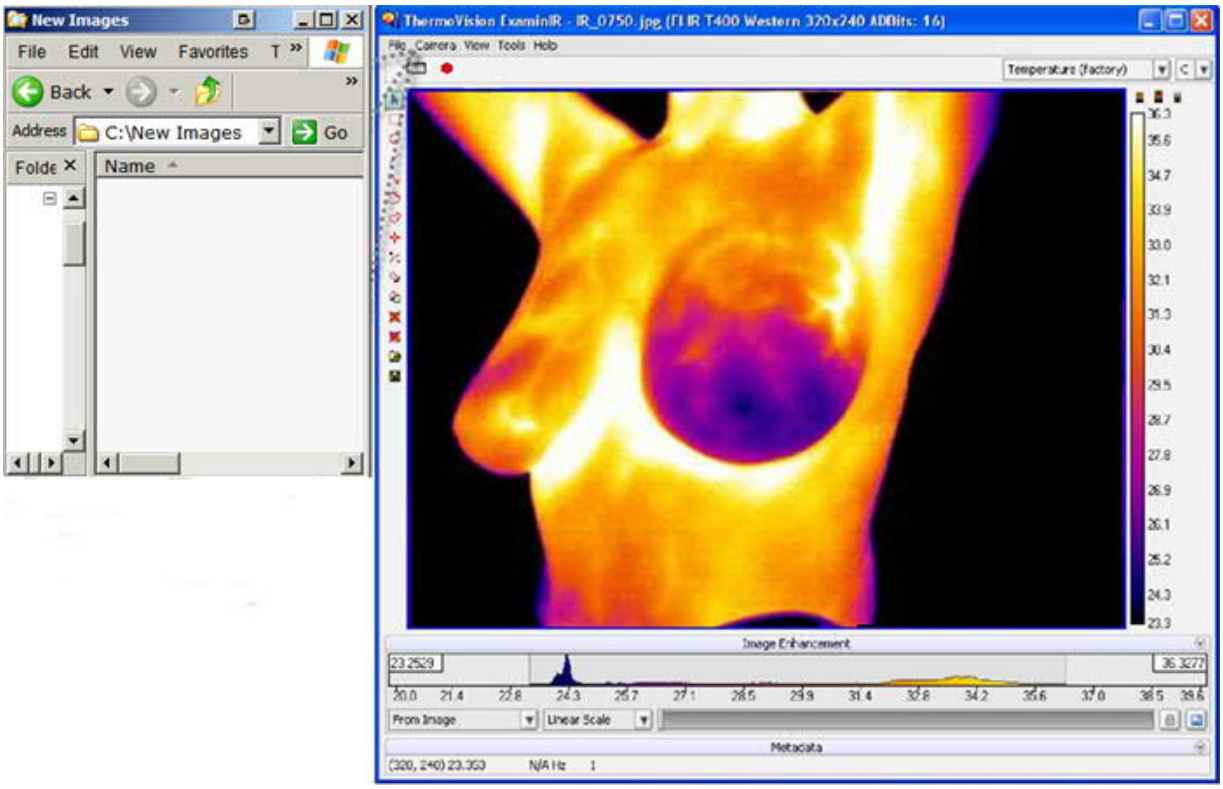
Following the cooling process, the thermogram should be recorded in accordance with the following procedure:

Recording the Images

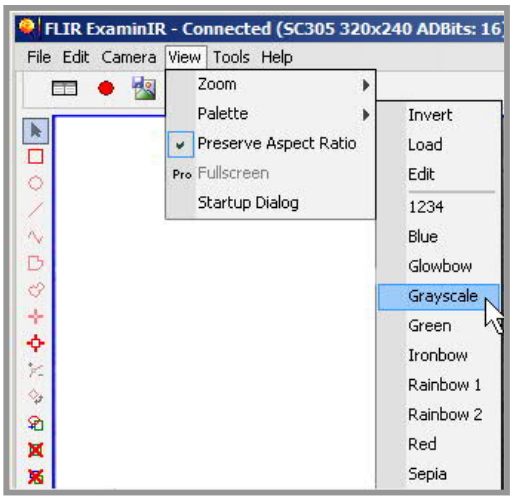
The image recording procedure is comprised of: A) Setup; B) patient positioning; C) focusing; D) capturing the image, and E) assuring the integrity of the image for interpretation.

Positioning Setup: Create a line on the floor where the patient is to stand. Align the patient's toes against the line. Position the camera between 3-1/2 – 4 feet from and perpendicular to the patient's sternum.

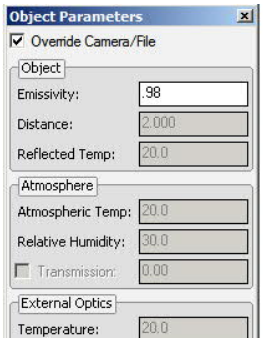
Computer Setup: In preparation for recording the captured images, the camera control software and an 'Explorer' window are opened on the desktop. The Explorer window is set to view the initially empty folder where captured images will be temporarily stored, providing a quick visual acknowledgement that captured images have been recorded. The Image Recording screen will initially appear similar to the following:

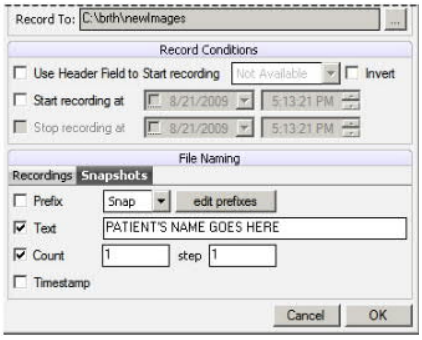


Camera Setup: Confirm that the camera is connected to the computer showing a live image, and prepared for recording image snapshots. The viewing palette should be set for viewing grayscale:



Follow the instructions for image recording and enter "Object Parameters" (emissivity = 0.98, distance, etc.) and "Recording Settings" (patient's name, etc.):





Position Patient for Recording Images: Typically, images of the patient in three positions are all that are required for accurate risk assessment of breast health. Larger-breasted patients require additional image recordings to assure that all areas of the breasts are examined. The minimum three views, right oblique, frontal, and left oblique are illustrated, below:

Patient positioning is a critical function, yet simple procedure. It is imperative that the patient is correctly positioned for image recording.

The first captured image is the frontal view. The patient is then rotated in a specific manner to achieve proper positioning for images of the oblique views.

Two positioning parameters must be carefully addressed. The patient must be properly positioned to capture oblique (45º) images of each breast and an image of both breasts. The distance between the closest point on the breast and the camera should be maintained for each view recorded.

Notice in the oblique views the nipples correctly point directly toward the camera. This is approximated when one foot is rotated 90º relative to the other, facing front foot. The objective is to capture as much of the breast as possible, so minor adjustments to achieve this are encouraged.

With the patient's toes aligned with a line (tape) on the floor, the correct foot positions are:

CORRECT

Important: The end position of the heels for the oblique views is with the heel of the rotated foot against the inside heel of the stationary foot. The patient's weight is supported on the stationary foot. The patient is standing relaxed in natural posture.

Maintaining camera calibration and focus for different patient views is an easily overlooked discipline. Specifically, the exact distance between the camera and the surface of the patient is a critical parameter for camera calibration, but small changes in camera-patient-distance are easily ignored, introducing the potential to comprise the ability to properly analyze the images.

This issue arises when the patient pivots on both feet to accommodate the oblique (and lateral) views. In the next diagram, the patient is initially positioned for a frontal view image, with toes aligned to a line marking the stored camera-patient distance. As the patient pivots for the oblique and lateral views, the camera-patient distance is lengthened.

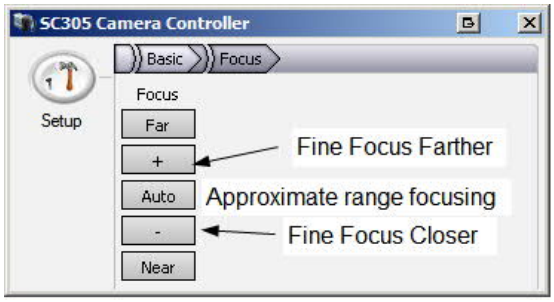
INCORRECT

Focusing Images: Impaired viewing and unreliable temperature measurements result when the areas of interest are not in focus.

The auto-focus feature of infrared cameras is generally unsuitable for breast thermography examinations. It should be used only for initial approximate range focusing.

It is important that the camera control software palette is set for Grayscale viewing, which aids the focusing process.

Focus by using auto-focus to initially coarse focus the image, and then manually fine tuning the focus controls.



The camera should be focused on the surface of the breast perpendicular to the camera. The camera's 'depth of field' maintains image focus for several inches behind the focal point, so the entire breast is in focus. If it is not possible to focus the complete breast, increase the camera-patient distance.

When the patient positioning procedure is adhered to, the distance between the camera and the breast's front surface breast remains constant. There is no need to refocus for each position.

Capturing the Images: Click the 'Capture Button' or press F7 to capture the first image.

Confirm in the Explorer folder window that the new file was created and named as expected, e.g. Jane Doe-000001.img.

Rotate the patient to achieve the left oblique view by keeping the left foot stationary with the toe aligned to the line on the floor and rotating patient's right foot 90º clockwise, with the heel of the right foot resting on the inside of the left heel. There should be no need to refocus. Execute the command to capture the second image. Confirm the image is named and numbered as the second image, e.g., Jane Doe-000002.img.

Return the patient to the frontal view position. Then, rotate the patient to achieve the right oblique view by keeping the right foot stationary with the toe aligned to the line on the floor and rotating patient's left foot 90º counterclockwise, with the heel of the left foot resting on the inside of the right heel. Execute the command to capture the third image. Confirm the image is named and numbered as the third image, e.g., Jane Doe-000003.img.

Should it be necessary to capture additional images, for example lateral views to reveal the sides of the breasts and accompanying axillary regions, repeat the above procedure for each additional view.

Confirm Image Suitability

Using the camera control software, individually drag the first recorded image to the program's window. Assure the image is properly focused, framed, and clearly displays the information required for interpretation. Repeat the suitability assurance check for each image. Should any image need replacing, delete the flawed image and re-record the view. When the integrity of the captured images is assured, the examination is ready for image interpretation.

IMAGE INTERPRETION METHODOLOGY

TAS proprietary interpretation software enables lay individuals to achieve expert results by objectively answering questions concerning the appearance of thermographic images. The program is proven effective. Tests employing analysts of varying levels of expertise, including trained physicians and individuals with no previous medical training have demonstrated examination sensitivity and specificity of 90%, with better than 90% repeatability.

The interpretation software is hosted on an internet server and shared among users. This allows practices the opportunity for local interpretation, the ability to submit images to a central interpretation center and to operate as an interpretation center to service the image evaluation needs of other practitioners. And, multiple sites using the same server software facilitates maintenance of the common patient data base.

History

The internationally accepted breast thermogram interpretation methodology employed today was first introduced in 1980. Dr. Michelle Gautherie of the Louis Pasteur Institute of Medicine, Strasbourg, France, and a recognized expert in evaluating breast thermograms statistically identified twenty significant thermal indicators identifying a breast at risk for developing breast cancer. He then codified a system expressing risk for the development of breast cancer based on the presence of a combination of these identified thermal indicators.

In 1982, TAS founder Ed Jay was tutored by Gautherie to learn his diagnostic technique, so that Jay could develop a commercially available artificial intelligence computer program embodying Gautherie's protocol and imparting his expertise to other, less experienced individuals.

The resulting computerized emulation of Gautherie’s technique consistently demonstrated outstanding integrity and objectivity with 95% repeatability among multiple interpreters. Use of the software was later credited with a 61% improvement in mortality of a 382 patient population followed over a twelve-year period.

Technological advances and further understanding of the anatomical function of the breast since 1982 combine to significantly improve the ability to thermographically assess risk with greater precision. More than 300,000 added case studies have been evaluated and integrated with the original interpretation algorithm. Two new statistically significant thermal indicators have been added to the original set of twenty, and these twenty-two signs have been refined to augment the original algorithm to account for advances in technology that elucidate previously obscured issues.

Overview of Interpretation Methodology

There are ten qualitative signs relating to specific thermovascular patterns found in physiological or pathological conditions, and twelve quantitative signs pertaining to the temperature characteristics of the ten qualitative signs.

The presence of each of these twenty-two signs carries a weighted numerical value (score) based on its statistical frequency of occurrence and statistically derived pathological significance in a large symptomatic population. The sum of the scores of which twenty-two signs are present is mapped to five risk classifications, with each classification indicating an assessment of the patient's risk. The five classes are TH1: Normal at very low risk, TH2: Borderline normal at low risk, TH3: Borderline abnormal at equivocal risk, TH4: Abnormal at high risk, and TH5: Severely abnormal at extremely high risk.

Qualitative Thermal Signs: The ten qualitative signs labeled P_1, P_2…P_{10} carry their respective statistically-derived scores, $Score_{P1}$, $Score_{P2...}Score_{P10}$, when identified by observation. If not identified, they carry no score:

$$P_i: (\text{if } P_i \text{ then } Score_{Pi} \text{ else } 0)$$

The ten qualitative thermal indicators and their general characteristics are:

P_1 – P_6 qualitatively categorize the venous pattern observed on each breast to one of the following six descriptions, each carrying its own score:

P1: Uniform Temperature Distribution with possible discrete vascular hyperthermia at the upper inner or upper outer edge of the breast:

P2: Regular Thermovascular Hyperthermia distributed over a limited region of the breast, often with an arborescent pattern and a general orientation corresponding to one or several of the physiological venous plexuses.

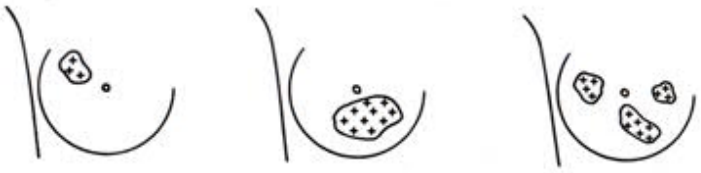
P3: Thermovascular Network consisting of multiple curvilinear vascular hyperthermia over the whole breast or over the upper quadrants only.

P4: Irregular Thermovascular Hyperthermia distributed over a particular area of the breast, generally with a common orientation not corresponding to any of the physiological venous plexuses.

P5: Distorted Thermovascular Hyperthermia with a distorted, sometimes hazy pattern, generally characterized by convolutions and ramifications distributed over a limited region of the breast.

P6: Anarchic Thermovascular Hyperthermia with an extremely disoriented (anarchic) pattern presenting clear discontinuities of the curvilinear thermovascular images and distributed over a limited region of the breast (angeogenesis).

P7: Focal Hyperthermic Area(s) comprised of one or more areas of localized hyperthermia with either a clear or a fuzzy outline located in any region of the breast and involving up to two quadrants.



P8: Hypothermic Area(s) consisting of one or multiple (several) areas of hypothermia with variable size and clear or fuzzy outline in any region of the breast, possibly a mottled pattern over the whole breast

P9: Asymmetrical Thermal Pattern observed with a clear difference between the thermal patterns of the two breasts, especially with regard to vascular hyperthermia.

P10: Distorted Thermal Outline evidencing a marked distortion in the thermographic outline of the breast with a locally flattened or hollow (concave) or embossed (convex) contour.

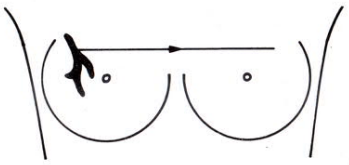
Quantitative Thermal Signs: The ten quantitative signs labeled H_1, H_2…H_{10} carry their respective statistically-derived scores, $Score_{H1}$, $Score_{H2}$… $Score_{H10}$, when a specific measured temperature difference, ΔT_{Hi} ("delta-T"), achieves its statistically-derived scoring threshold, T_{Hi}.

The scoring rule for quantitative thermal signs is:

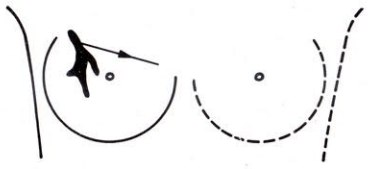
H_i: (if $\Delta T_{Hi} \geq T_{Hi}$ then $Score_{Hi}$ else 0)

The ten quantitative signs are:

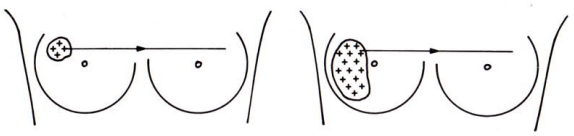
H_1: The temperature of the vascular hyperthermia (P1 – P6) of the breast is elevated 3ºC or more ($T_{H1} \geq 3.0$ºC) relative to the temperature of the same area on the contralateral breast.



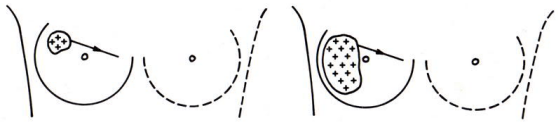
H_2: The temperature of the Vascular Hyperthermia (P1 – P6) of the breast is elevated 3.5ºC or more ($T_{H2} \geq 3.5$ºC) relative to the adjacent areas of the hyperthermic area and/or the mean temperature of the ipsilateral breast.



H_3: The temperature difference between any local, focal or regional hyperthermia seen anywhere on the breast, except the nipple and areola area, and the same area on the contralateral breast is 2.5ºC or more ($T_{H3} \geq$ 2.5ºC).



H_4: The temperature difference between any local, focal or regional hyperthermia seen anywhere on the breast, except the nipple and areola area, and the adjacent areas of the hyperthermic area and/or the mean temperature of the ipsilateral breast is 3.0ºC or more ($T_{H4} \geq$ 3ºC).



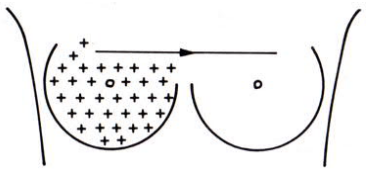
H_5: The temperature difference between the Nipple and Areola region and the nipple and areola region of the contralateral breast is 2.0ºC or more ($T_{H5} \geq 2.0$ºC).

H_{5a}: The temperature difference between the Periareola region and the Periareola region of the contralateral breast is 1.0ºC or more ($T_{H5a} \geq$ 1.0ºC).

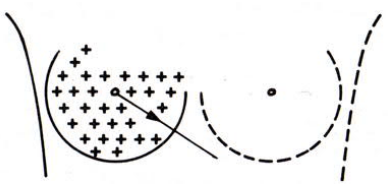
H_6: The temperature difference between the Nipple and Areola region and the mean temperature of the ipsilateral breast or the periareolar area is 2.0ºC or more ($\Delta_{H6} \geq 2.0$ºC).

H_{6a}: The temperature difference between the Periareola region and the mean temperature of the ipsilateral breast or the periareolar area is 2.5ºC or more ($\Delta_{H6a} \geq 2.5$ºC).

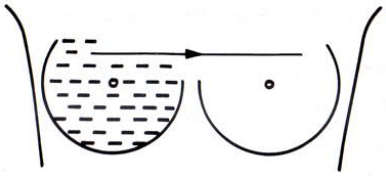
H_7: Global Hyperthermia is 2.0ºC or more ($T_{H7} \geq 2.0$ºC) relative to the average temperature of the contralateral breast.



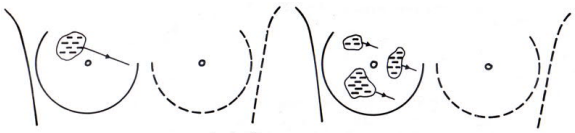
H_8: Global Hyperthermia exceeds 0ºC ($T_{H8} \geq$ 0ºC) relative to the temperature of the adjacent sternal area.



H_9: Global Hypothermia is 2.0ºC or more ($T_{H9} \geq$ 2.0ºC) relative to the average temperature of the contralateral breast.



H_{10}: The temperature difference between the Local or Regional Hypothermia anywhere in the breast, and the adjacent areas or mean temperature of the ipsilateral breast is 3.0ºC or more ($T_{H10} \geq 3.0$ºC).



Thermal Score: Each breast's Thermal Score, $S_{R/L}$, is calculated by adding the scores of the thermal signs identified on each breast:

$$S = \text{Thermal Score for subject breast} = \sum_{i=1}^{10} (P_i + \text{Score}_{Hi})$$

Quantitative Sign Examination Error Compensation: Violations of patient preparation protocol, image capture issues, and the exclusion of thermographic evidence slightly below scoring threshold levels are examples of common errors with potential to induce errant temperature measurements which may distort thermographic findings. To avoid erroneous thermographic findings due to possible examination errors, Draconian adherence to the yes/no quantitative sign scoring rule is substituted with an *error function* in the augmented interpretation algorithm.

Final Computation Model:

The Total Thermal Score is the sum of the scores of the qualitative and error- compensated quantitative signs. The software algorithm used to compute the augmented Total Thermal Score, $A_{rb/lb}$, for each breast is:

$$A_{br} = \sum_{1}^{10} (P_i + S_{Hi} / [1 + e^{-k_i(\delta T_i - m_i)}])$$

The range of computed Total Thermal Score is correlated to the Thermal Risk Classifications, TH1 – TH5.

Detailed Thermal Risk Classifications – The Internationally Accepted System

TH1 – Normal, Low Risk: The first classification category defines a normal thermal profile of the breasts that is devoid of any of the thermology signs or criteria associated with risk for malignant breast disease. Normal contours are discerned and no significantly hyperthermic focal or vascular features are presented. Some patients will demonstrate distinct and significantly hypothermic patterns that are frequently associated with established cysts and/or fibro-adenomas.

TH2 – Borderline Normal, Borderline Low Risk: The second category defines a thermal profile of the breasts that features symmetrical, non-complex and moderately hyperthermic vascular patterns. The TH2 score indicates no thermal signs or criteria for malignant breast disease. However, while very unlikely, it is possible that some small malignant tumors may be in a quiescent state and their vascular development could be minimal. In this event, the very minor thermal characteristics may evade discernment, especially in an initial study. This thermology category is frequently associated with benign changes, discernment, especially in an initial study. This thermology category is frequently associated with benign changes, such as glandular hyperplasia and the development of cysts and fibro-adenomas. This Annual comparative thermology restudy is recommended and more frequent restudy may be clinically indicated.

TH3 – Borderline Abnormal/Equivocal, Borderline High Risk: The third category indicates an atypical metabolic or vascular process. This may be based upon the discernment of an asymmetric and hyperthermic vascular or focal pattern, an asymmetric, diffuse and hyperthermic pattern involving a peri-areolar area or most of one breast, a discrete area in a vascular pattern that does not attenuate from the challenge procedure or an asymmetric physical distortion with local hyperthermia. This atypical category is associated with a minor or equivocal (<10-20%) risk of confirming malignant breast disease. It is likely that these atypical thermal features represent benign changes such as inflammation, acute cysts and/or fibro-adenoma development, infection or personal variant, especially in an initial study. A thermographic restudy in 60 to 90 days usually provides a differentiation. Clinical correlation is indicated for an association with a mass or abnormal skin changes that would have an additive effect on the overall risk for malignant disease. Strong familial or personal risk factors for breast cancer and are also additive. Other objective means of evaluating the breasts may be indicated. Experience demonstrates a targeted ultrasound as the most effective means of following-up on atypical or abnormal breast thermogram.

TH4 – Abnormal, High Risk: The fourth category must be considered a positive thermogram and represents a significant (65-85%) risk for malignant breast disease. Benign processes and personal variant are possible but unlikely as a basis for this abnormal classification, especially on an initial study. A clinical correlation is indicated for regional masses or abnormal skin changes and all available means of objective evaluation are indicated. However, it must be considered that a positive thermogram may precede positive results from other objective testing by 5-8 years. Thermography restudy in 60 - 90 days should be an important part of a comprehensive testing panel.

TH5 – Intensely Abnormal, Very High Risk: The fifth category indicates a very high (approx. 96%) probability of confirming malignant breast disease. Benign processes or personal variant are very unlikely. A clinical correlation is indicated for regional masses and abnormal skin changes. Clearly, a patient with such a score is indicated for a comprehensive panel of objective evaluation with all possible alacrity. A thermology restudy in 60 - 90 days should be a part of this evaluation if these other methods do not demonstrate malignant breast disease, as thermography may precede other abnormal features by 5-8 years.

TH Category	Finding	Risk	Br Ca Probability
TH1	Normal	Low Risk	≈ 0%
TH2	Borderline Normal	Borderline Low Risk	< 10%
TH3	Probable Abnormal	Borderline High Risk	10% - 25%
TH4	Abnormal	High Risk	65% - 85%
TH5	Intensely Abnormal	Very High Risk	≈ 96%

TAS SOFTWARE

Thermogram Assessment Services' proprietary breast thermography software system uniquely delivers quick, accurate and credible risk assessments derived from evaluating the complex thermal patterns of the human breast.

The breast thermography interpretation software was first introduced in 1980 and produced gratifying results. It quickly received acclaim from the medical community for objectivity, accuracy, and credibility. Technological advances since the 1980's have significantly improved image quality, resolution and thermal sensitivity. Combined with our increased knowledge of the breast's thermobiological function, the ability to assess risk with precision is now common.

Today's interpretation program is an evolutionary version of the author's original software developed in 1980. It refines, modernizes and augments the original computer model to account for technological and medical advances.

Some practitioners prefer to perform their own image evaluations, but because breast thermograms are often difficult to analyze and interpret, most practitioners outsource thermogram interpretation requirements to the expertise of specialized interpretation services called a reading service. Multiple practice sites, portable, and mobile practices are also well served by employing a common reading service, with practices submitting examination data and images over the internet for interpretation and reporting.

Using the TAS Software

To meet each application requirement, the program is configurable in three basic modes:

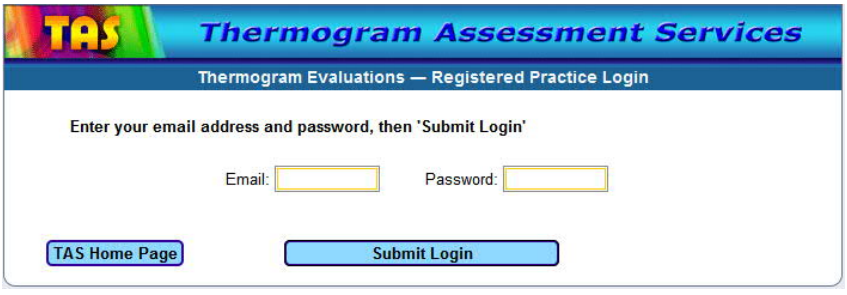
A) Image interpretation conducted at the local-practice;

B) Local practice outsources image interpretation to an interpretation center, and

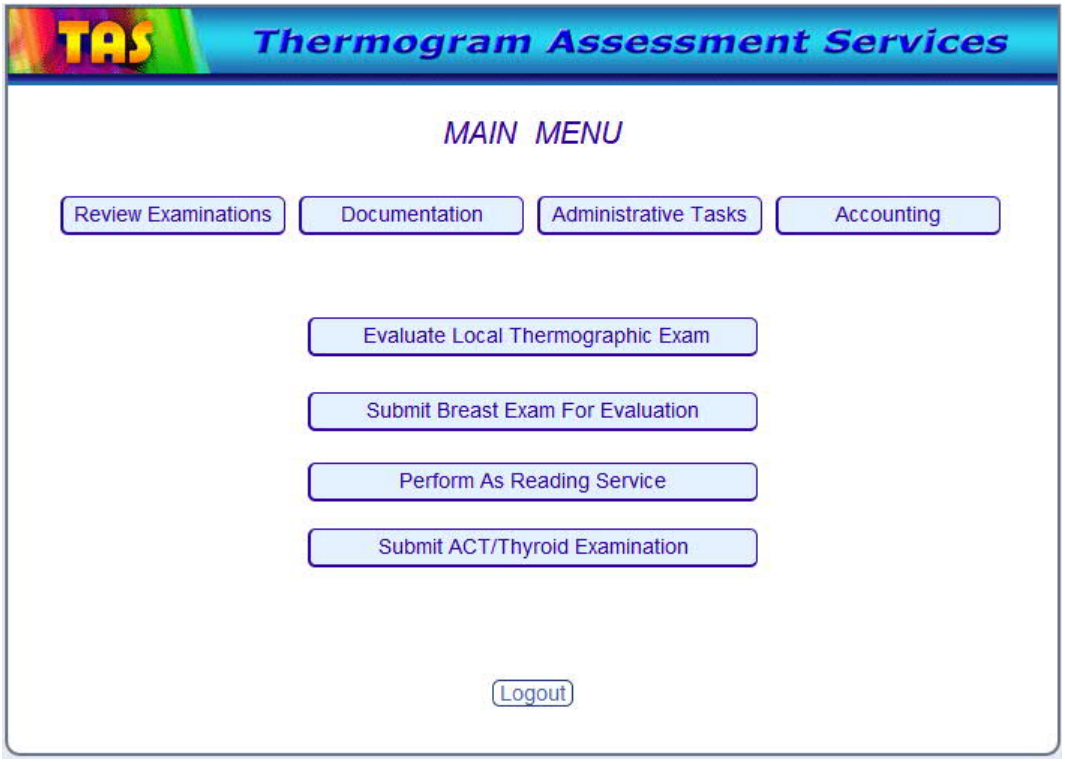
C) A thermogram evaluation and interpretation reading service.

The program operating mode is menu selected. With a mouse click, image interpretation and reporting may be performed for the local practice by the local practitioner (A), or the examination may be uploaded to a reading service (B). In the roll as a reading service (C), the local practitioner may evaluate examinations for others, or the program may be used as a dedicated reading service for multiple practices or remote examination centers.

Login: Using the software requires a login gateway:

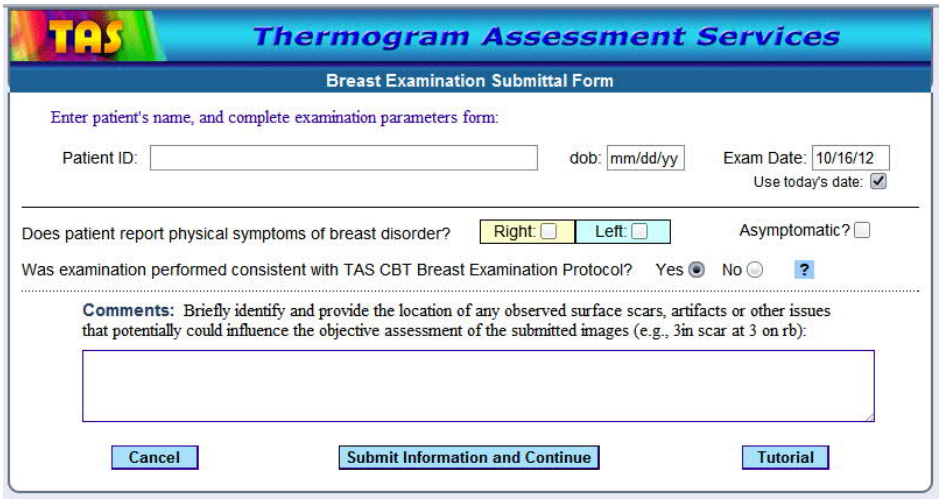


System Main Menu: The TAS Interpretation System Main Menu is launched following successful login:

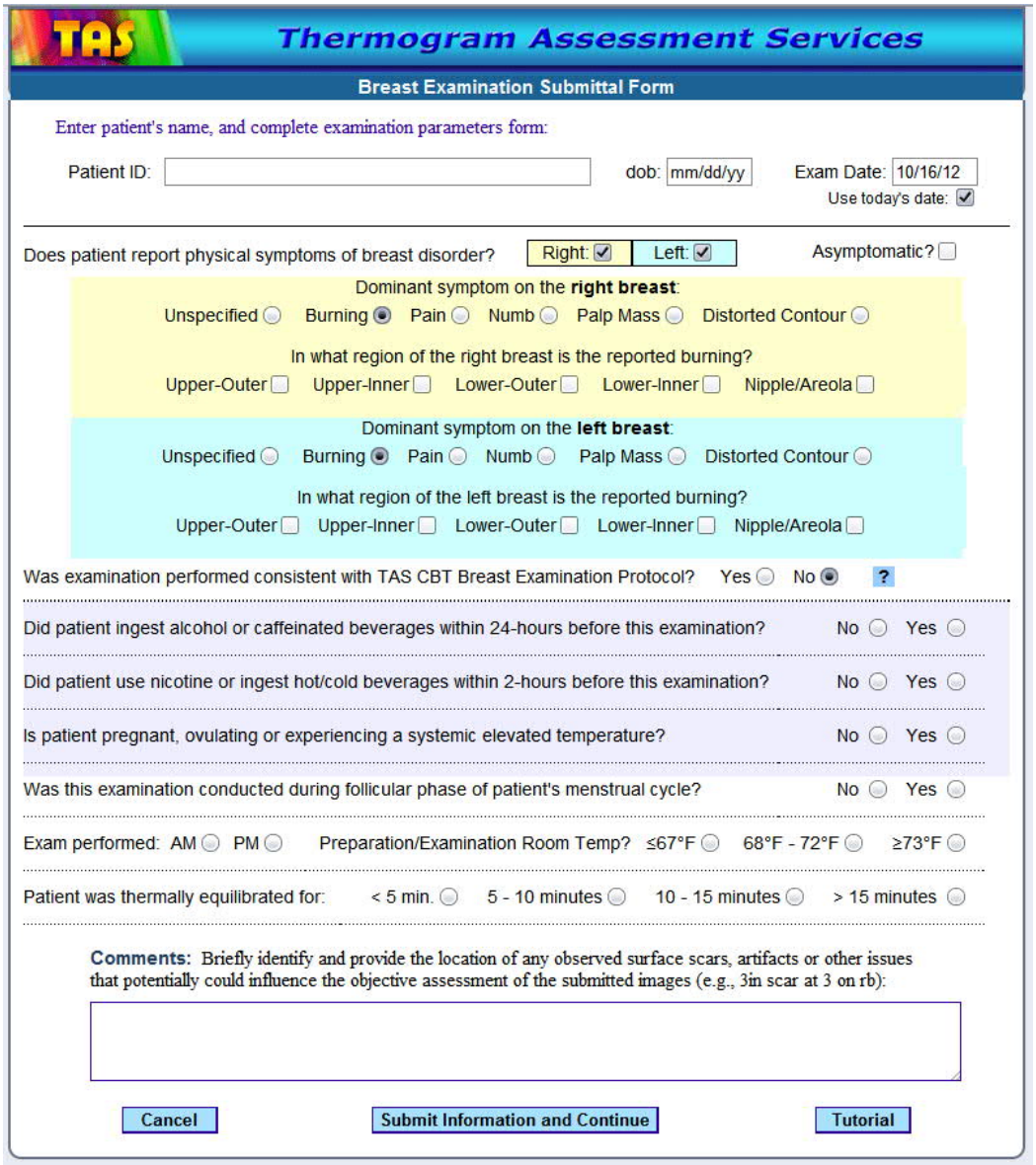


Software Mode Interfaces and Paths: Depending on the software operational mode, e.g., 'Practitioner,' 'Submitter,' or 'Service,' the software interface differs, as do the paths of program execution.

<u>Practitioner and Submitter</u>: Although each path and task is different, Main Menu selections of either 'Evaluate Local Thermographic Exam' or 'Submit Breast Exam for Evaluation' bring the practitioner to the



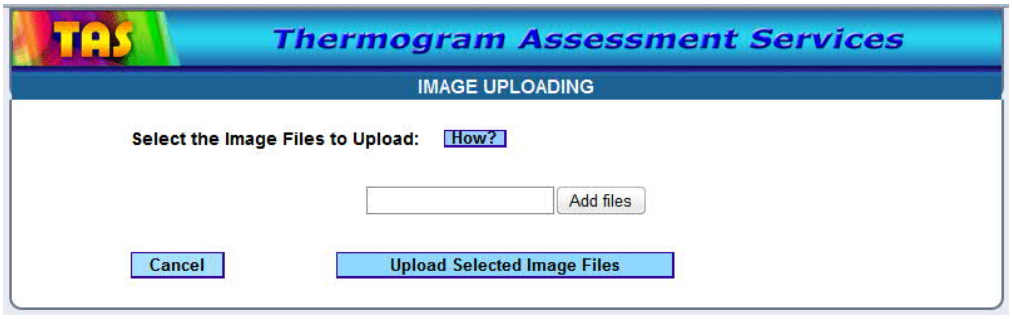
Depending on answers to questions posed in the Submittal Form, the form will expand in sections to ask follow-up questions. Fully expanded, the form appears as:



Practitioner Mode - Conducting a Local Evaluation: When in Practitioner Mode and conducting a local evaluation, clicking on the Examination Form's 'Submit Information and Continue' button launches the first page of the interpretation and evaluation program (see below).

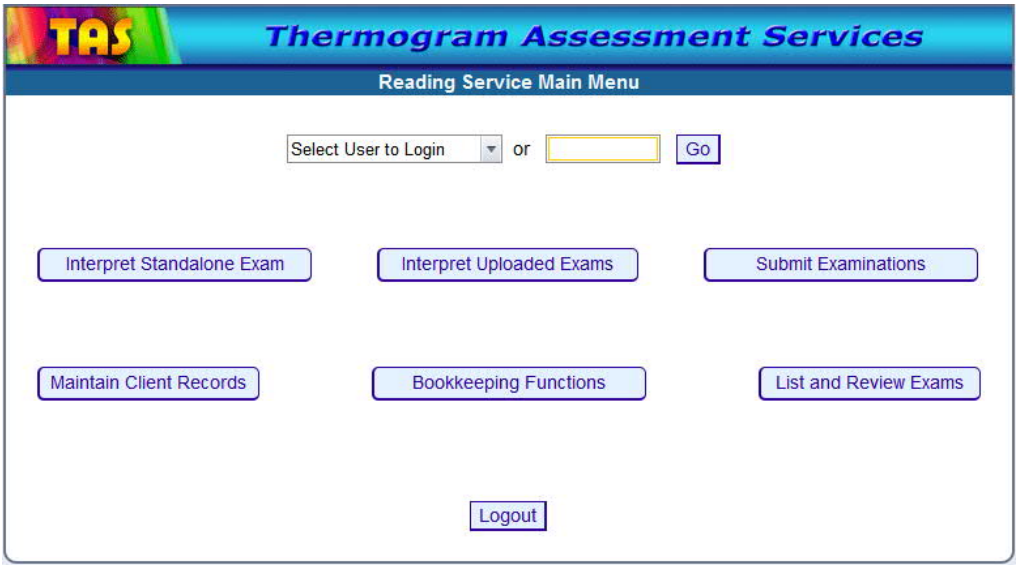
Submitter Mode - Submitting Examinations to Interpretation Service: When the form is completed and the examinations and images are ready for submission to an interpretation center,

the form's 'Submit Information and Continue' button is clicked and the File Selection page is launched:

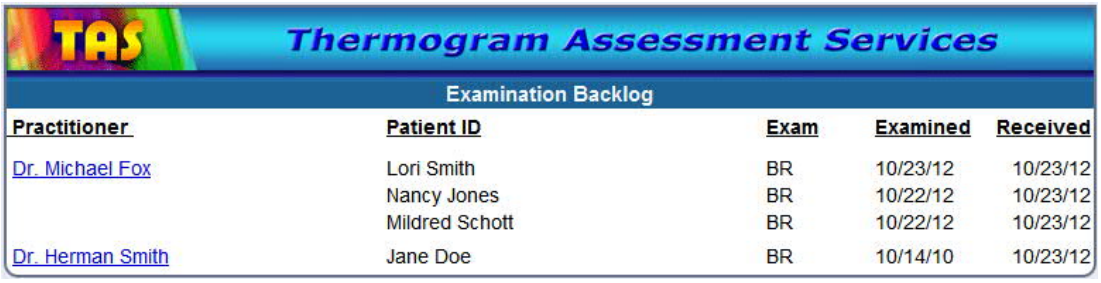


Clicking the 'Add Files' button launches the traditional Windows© File Explorer window set to the folder containing the new image files. Selecting the files and clicking 'Upload Selected Image Files,' causing the program to transfer the examination information and images to the reading center for interpretation and reporting findings via return email.

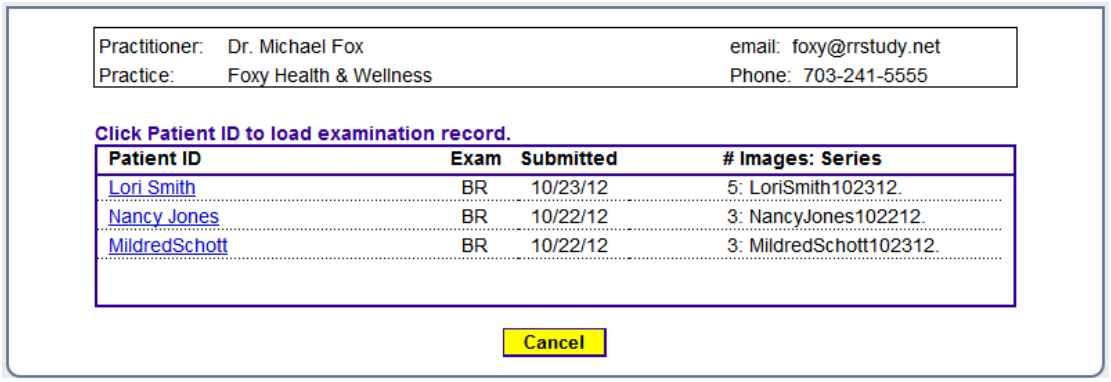
Interpretation Service Mode: On login as a service organization, the following Reading Service Main Menu page is launched:



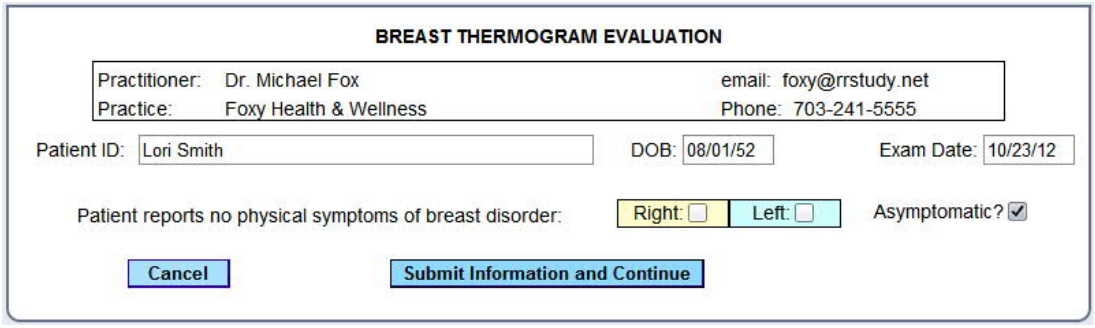
Examinations submitted by others are listed when 'Interpret Uploaded Exams' is selected:



Clicking on the submitting Practitioner's name launches the task page for that submitting practitioner, from which each submitted examination is selected for interpretation by clicking on the patient's ID:



When a Patient's ID is selected, the previously practitioner-/submitter-completed Examination Submittal Form and patient record are loaded for review and preparation for image interpretation:



As with a practitioner conducting a local evaluation, clicking on the Examination Form's 'Submit Information and Continue' button launches the first page of the interpretation and evaluation program.

Image Evaluation and Interpretation

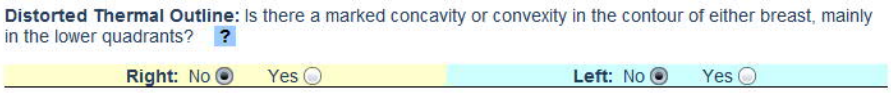
Using the software is easy. The image 'reader' answers queries seeking information pertaining to specific features of the images being evaluated.

As with the Examination Form, a decision-tree interrogation process is employed to eliminate superfluous questions.

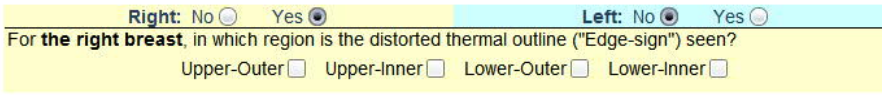
The following is a page-by-page tour of data inputted by the interpreter.

Page 1: Image evaluation begins with a question that solicits a simple yes/no qualitative response from the analyst. In addition to a broad statement regarding overall physiological symmetry, the question serves to initiate reader focus on the image details.

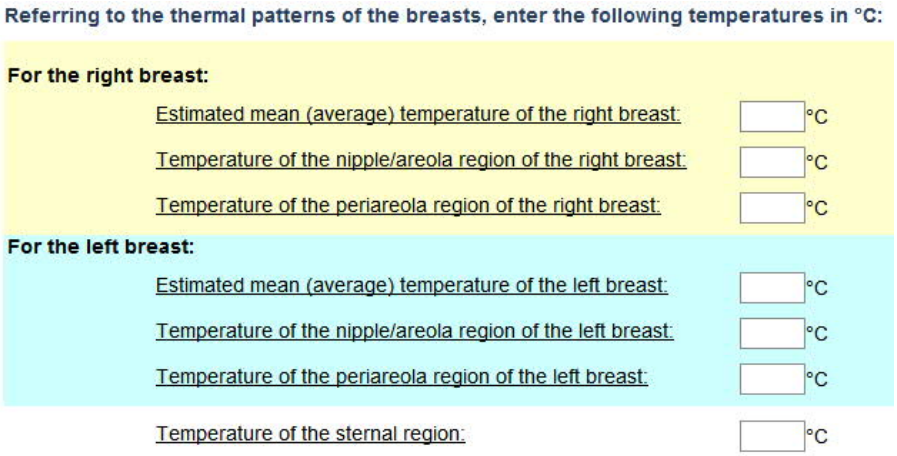
The second question on the first page serves to identify a thermographically-visible physical imparity, the 'edge-sign,' and again focuses the analyst's attention to the detail of the image.



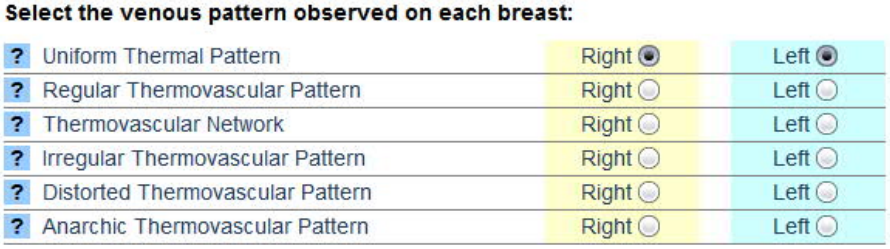
Should the analyst report a distorted thermal outline by clicking the No/Yes button for the identified breast, the form expands to ask the location of the sign:



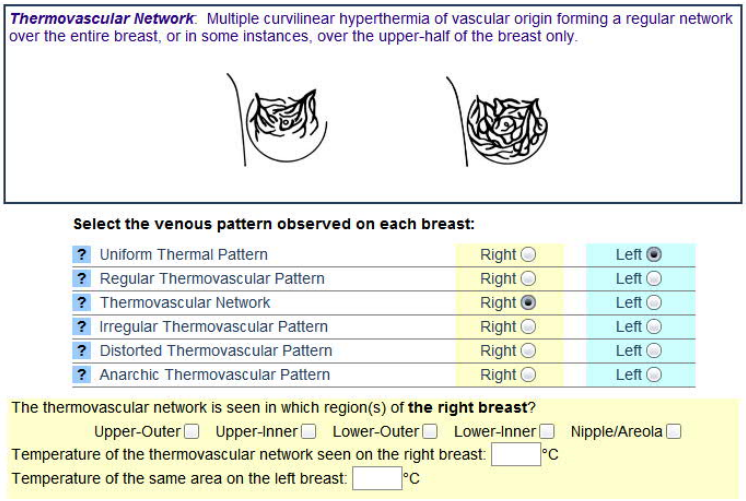
Page 2 – Enter Measured Temperatures: Enter temperatures for the larger, easy to define regions of the image:



Page 3 – Venous Characterization (P1 – P6): On this page, the analyst exercises qualitative judgment to categorize the venous pattern, P1 – P6, seen on each breast, and then enters quantitative information regarding the observed venous pattern.



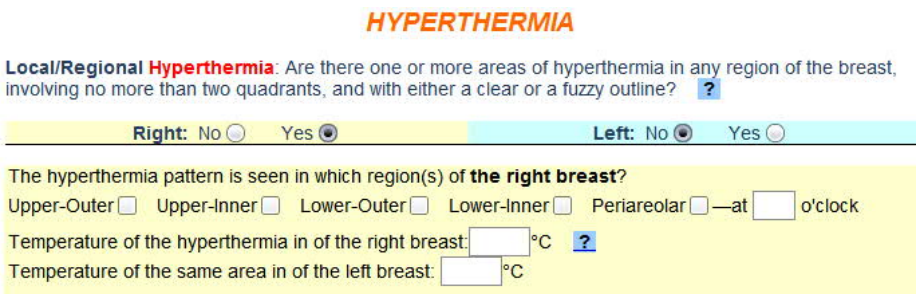
The ‘Help Aid’ avoids uncertainty by providing visual guidance in category selection. When a non-uniform (P1) category is selected, the form illustrates the selected venous pattern category and solicits the analyst for quantitative information:



The region or regions where the principal vascularity is observed is noted by clicking on all appropriate check boxes. Then, the highest temperature of the identified venous structure is measured and entered. The temperature of the mirror region of the opposite breast is then measured and entered. The process is performed for each breast.

Page 4 – Regional Hyperthermia: Local or regional hyperthermia is characterized as one or several areas of hyperthermia in any region of the breast, except the nipple/areola region, involving up to two quadrants, and with either a clear or a fuzzy outline:

The expanded form with necessary data requirements:



Page 5 – Hypothermia: Characterized as one, several or multiple areas of hypothermia in any region of the breast, with variable size and clear or a fuzzy outline, possibly extended over the entire breast (mottled pattern):

HYPOTHERMIA

Local/Regional Hypothermia: Are there one or more local hypothermic areas with either a clear or fuzzy outline involving up to two quadrants of either breast, or a mottled pattern extending globally over the total breast? ?

Right No ○ Yes ◉ **Left:** No ◉ Yes ○

In which region(s)of **the right breast** is the hypothermia seen?

Upper-Outer ☐ Upper-Inner ☐ Lower-Outer ☐ Lower-Inner ☐

Temperature of the hypothermia of the right breast: [ ] °C ?

Quantitative information regarding observed hypothermia is entered, as before.

Page 6 – Review Information Entered: The Review-to-Edit provides the opportunity to recheck all information entered, and return to edit an answer if needed:

Purpose of examination:
This is a screening examination. No symptoms of breast disorder.

Examination Parameters:
Examination performed consistent with TAS' recommended protocol. Edit

Thermal Symmetry and Contour:
Asymmetrical Thermal Patterns? No
Distorted Thermal Outline on right breast? No.
Distorted Thermal Outline on left breast? No. Edit

Temperature Measurements:
Mean temperature of the right breast: **33°C**
Temperature of the nipple/areola region of the right breast: **33°C**
Mean temperature of the periareolar region of the right breast: **33°C**
Mean temperature of the left breast: **33°C**
Temperature of the nipple/areola region of the left breast: **33°C**
Mean temperature of the periareolar region of the left breast: **33°C**
Temperature of the adjacent sternal region: **33°C** Edit

Venous Patterns:
Right venous pattern: Uniform thermal pattern
Left venous pattern: Uniform thermal pattern Edit

Local Hyperthermia:
Right breast local hyperthermia : None identified.
Left breast local hyperthermia : None identified. Edit

Local Hypothermia:
Right breast local hypothermia : None identified.
Left breast local hypothermia : None identified. Edit

Right Breast Signs:0 Score:0 TH1 **Left Breast** Signs:0 Score: 0 TH1

When the information has been verified, pressing the 'Generate Report for Review' launches a draft of the Findings Report followed with the opportunity to save the examination to the data base and print or email the report.

Thermographic Findings Report

The Findings Report is divided into four major sections: 1) Presentation; 2) Summary and Examination; 3) Impressions and Pathology, and 4) Suggested Follow-up. There are literally thousands of possible outcomes for each thermographic examination. It is not feasible to show each variation. The following is a sample Findings Report by major section.

Presentation: Describes the patient symptoms, if any, and the pre-examination conditions.

Presentation: Patient presents without physical symptoms of breast disorder. This is a screening examination.

Pre-Examination: The examination was performed in the morning outside the patient's menstrual follicular phase. The patient was partially disrobed and underwent thermal equilibration for 10 - 15 minutes with the temperature of the examination room 68°F - 72°F. Examination performed consistent with recommended protocol for thermal breast examinations.

The data for this examination were acquired using an infrared sensitive camera. Views of the breasts consisted of a frontal image, including the sternum, and lateral images that included the axillary regions.

Summary and Examination: Provides a summary of examination findings and detailed observations recorded by the analyst:

Summary: This thermographic examination of the breasts is positive. There are multiple significant thermal signs of abnormality (4R/2L) strongly indicating borderline high risk for the development of breast cancer. The right breast is seen at borderline high risk with Thermal Risk Category TH3 (Equivocal). The left breast is seen at low risk with Thermal Risk Category TH1 (Normal).

Examination and Observations:

Visualized Thermal Symmetry: There is a clear and significant difference between the thermal patterns of the right breast and the left breast.

Vascularity: A thermovascular network is seen on all quadrants of the right breast. It exhibits no remarkable vascular hyperthermia relative to the contralateral left breast, but evidences 1.0°C elevation relative to the mean temperature of the ipsilateral right breast.

A regular thermovascular pattern is seen on the upper-inner diagonal of the left breast. It exhibits 1.3°C vascular hyperthermia relative to the same area on the contralateral right breast, and 1.0°C elevation relative to the mean temperature of the ipsilateral left breast.

Hyperthermia: The right breast evidences localized hyperthermia in the periareolar region at six o'clock. It is elevated significantly [3.0°C] relative to the same area of the periareolar region of the left breast and 2.0°C higher than the mean temperature of the ipsilateral right breast.

Impressions and Pathology: The third section discusses conclusions reached based on the data entered and offers potential pathology outlooks:

Impressions: Atypical and Equivocal Breast Thermogram. TH3 Risk Category (Borderline High Risk).

This thermographic examination of the breasts is seen with classical evidence of thermal abnormality. There is a clear difference between the thermal patterns of the right breast and the left breast. The right breast is significantly more thermally symptomatic than the left breast.

Four significant thermal signs contributing to computed thermal risk are observed on the right breast. Two significant thermal signs are observed on the left breast.

The thermogram of the right breast is Equivocal with TH3 Thermal Risk (borderline high risk). This thermal finding may indicate the possible presence of significant pathology. The TH3 category carries between 10% - 20% risk of breast cancer. Diligent followup is appropriate as the right breast is borderline high risk for the development of breast cancer.

The thermogram of the left breast is Normal with TH1 Thermal Risk (low risk).

Note: A negative thermal finding does not preclude the possible presence of significant pathology.

Pathology: The right breast is seen with thermopathological evidence indicating possible significant abnormality. Notwithstanding other possible pathology, this abnormal TH3 Classification is generally characteristic of fast-growing fibroadenomas, multiple large cysts, fibrocystic dysplasia, in situ carcinomas, micro-invasive carcinomas (≤ 5mm), T1 carcinomas (< 2mm), young medullary cancers and colloid cancers.

The left breast is without thermopathological evidence.

Suggested Follow-up: The Suggested Follow-up section serves only as a guideline to appropriate follow-up procedures depending upon thermographic impressions. Note that other acceptable diagnostic modalities should never be ruled out for symptomatic patients, even when thermographic results are negative. A negative thermal finding does not preclude the possible presence of significant pathology.

The following are the suggested follow-ups for each TH classification:

TH1:

Suggested Followup: [TH1] A repeat thermal and physical examination should be performed in 12 months. If the repeat thermogram, as well as repeat physical examination is negative, routinely examine patient in 12-months. If the annual thermogram becomes abnormal or changes, especially if it worsens, further clinical evaluation is indicated. Normal annual follow-up is indicated as a precautionary measure, as the thermographic examination is normal in patients with this TH1 Thermographic classification.

TH2:

Suggested Followup: [TH2] A repeat thermal and physical examination should be performed in six months. If the repeat thermogram, as well as repeat physical examination is negative, routinely examine patient every 12-months. If the annual thermogram becomes abnormal or changes, especially if it worsens, further clinical evaluation is indicated. A baseline MRI should be considered if it has not been obtained previously. Normal annual follow-up is indicated since the thermographic examination is borderline normal in patients with this TH2 Thermographic classification.

TH3:

Suggested Followup: [TH3] If a clinical finding, e.g., palpable mass, is present, an MRI followed by a biopsy is indicated. If clinical finding is negative a baseline MRI should be considered if it has not been obtained previously. If MRI is positive, a biopsy is indicated. If negative, a repeat thermal and physical examination should be performed in 6-months. If the repeat thermogram, as well as repeat physical examination is negative, routinely examine patient every 12-months. If the repeat thermogram remains abnormal or changes, especially if it worsens, the MRI should be repeated. If it changes, a biopsy should be performed. Careful follow-up is indicated since the thermographic examination is abnormal in patients with this TH3 Thermographic classification.

TH4:

Suggested Followup: [TH4] If a clinical finding, e.g., palpable mass, is present, an MRI followed by a biopsy is indicated. If clinical finding is negative a baseline MRI should be considered if it has not been obtained previously. If MRI is positive, a biopsy is indicated. If negative, a repeat thermal and physical examination should be performed in 6-months. If the repeat thermogram, as well as repeat physical examination is negative, routinely examine patient every 6- to 12-months. If the repeat thermogram remains abnormal or changes, especially if it worsens, the MRI should be repeated. If it changes, a biopsy should be performed. **Mandatory follow-up is essential** since a high percentage of carcinomas are present in patients with this TH4 Thermographic classification.

TH5:

Suggested Followup: [TH5] If a clinical finding, e.g., palpable mass, is present, an MRI followed by a biopsy is indicated. If clinical finding is negative a baseline MRI should be considered if it has not been obtained previously. If MRI is positive, a biopsy is indicated. If negative, a repeat thermal and physical examination should be performed in 3- to 6-months. If the repeat thermogram, as well as repeat physical examination is negative, routinely examine patient every 6- to 12-months. If the repeat thermogram remains abnormal or changes, especially if it worsens, the MRI should be repeated. If it changes, a biopsy should be performed. **Mandatory follow-up is essential** since a significantly higher percentage of carcinomas are present in patients with this TH5 Thermographic classification.

EQUIPMENT CONSIDERATIONS - IMAGE ACQUISITION SYSTEMS

The credible thermography practice consists of a quality-constructed, precision infrared camera and its tripod, a laptop computer with a network connection and integrated system and camera control software. The complex system should masquerade as a simple, easy-to-use appliance, operable by paramedical office personnel.

In the following discussion, the Thermography Image Acquisition Systems Model 325XP Image Acquisition System serves as the example of an optimal system. Pertinent data sheets are attached to the electronic versions of this document.

Infrared Sensitive Cameras

The intrinsic value of a thermographic examination depends strongly on the quality of the acquired images. Maximizing precision and accuracy assures thermograms clearly display the information required to perform a detailed analysis. Deficiencies in the recording process can render the examination useless.

Thermographic imaging is accomplished by converting infrared radiation (IR) into a visual image that depicts the map of temperature variations across the breast. The main camera components are a lens, a detector in the form of a focal plane array (FPA), electronics, and software for capturing, displaying, and processing images.

A myriad of parameters define overall camera performance, with a few being of particular importance in defining the suitability of the camera used to record the thermographic images.

Image Resolution: The IR camera detector is an [focal plane] array (FPA) of micrometer-size pixels made of materials sensitive to IR wavelengths. The dimensions of the FPA measured in pixels is defined as image resolution. Today the entry-level image resolution standard for precision cameras is 320 px x 240 px. The next level brings 640 px x 400 px resolution, however, for breast thermography purposes, the entry-level resolution is adequate.

The standard camera included with the Model 325XP Image Acquisition System is 320 px x 240 px resolution.

Sensitivity: Camera sensitivity is the ability of an infrared camera to accurately discern small differences in temperature between two adjacent detectors, or pixels. This parameter is important to image quality. Camera sensitivity is specified in terms of noise-equivalent temperature-difference, NETD, the level of incident signal temperature that matches the internal noise of the detector. Most modern precision scientific IR cameras exhibit excellent sensitivity. Breast thermography requires NETD = 150 mk, or better.

The standard Model 325XP camera is specified NETD = 25 mk. This equates to approximately 0.05ºC adjacent-pixel resolution, about ten-times more than is adequate.

Accuracy: Basic temperature measurement accuracy concerns the quantitative analysis phase of the interpretation process. The industry standard specification for accuracy of science-class

precision cameras is ±2C° or ±2% of reading, as it is for the Model 325XP camera. This does not appear to be a precision measurement, and alone, it is not. The term camera accuracy as it applies to thermography is more complex and meaningful than temperature measurement accuracy.

The quantitative analysis of thermographic images deals with thermal asymmetry, measured by temperature difference, ΔT. When the temperature baseline remains constant, measurement errors are of no concern in measuring the pertinent ΔT. The measurement errors cancel each other in the subtraction of one temperature measurement from the other:

$$\Delta T = (T_2 + \delta t) - (T_1 + \delta t) = T_2 - T_1$$

T_1 and T_2 are temperature measurements and δt is the measurement error in degrees.

The key to precision accuracy lies in maintaining the stability of the camera's temperature baseline. The error component, δt, cannot drift over short periods of time otherwise ΔT becomes short-term time dependent. If the short-term drift is excessive, the measurement is suspect.

The Model 325XP camera has proven low temperature drift and measurement repeatability over hours and multiple days showing less than ±0.39ºC long-term drift. The camera's absolute accuracy is manufacturer specified at 0.30ºC at 27ºC over multiple days.

Self-Maintaining Accuracy: Continued, calibrated measurements are important factors that must be addressed by system designers. Each Model 325XP camera is factory calibrated using NIST traceable equipment to assure absolute accuracy to ±0.30ºC. Continued and uninterrupted accuracy and calibration, even under rugged remote conditions, is assured with automatic, self-calibrating electronic circuitry. Calibration occurs at frequent intervals and consists of closing the camera's shutter and temporarily substituting a black body FPA calibration source.

The Model 325XP camera features revolutionary temperature drift compensation technology to correct for ambient temperature changes in the environment over time. Using its on-camera temperature compensation techniques, the camera has demonstrated proven repeatability of measurements over hours and multiple days showing less than ±0.39ºC drift. Short-term drift is negligible.

Camera Control Software: The system should include software that makes previewing, capturing and recording live images from the camera quick and easy. For example, the Model 325XP System software automatically finds and connects to the camera on plug-in and begins displaying the real-time thermal image. Entering pertinent data, focusing, and capturing the image are then a simple push button process.

System Software: Basic system software owns the task of integrating all necessary camera control, interpretation software, etc., to render the Image Acquisition System fully functional as a medical appliance.