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Guidelines for Breast Thermography

American Academy of Thermology - AAT

Committee Chair: Philip Getson, DO

Committee Members: Robert G. Schwartz MD,, Marcos Brioschi, MD, John Pittman, MD, Bruce Rind, MD, Jan Crawford, BSN, Hisashi Usuki, MD, William Amalu, DC, Jonathan Head, PhD

General Statement — This guideline was prepared by members of the American Academy of Thermology (AAT) as a guide to aid the breast thermologist, and other interested parties, in the clinical application of infrared breast imaging. It implies a consensus from experts in the field of breast thermology and those substantially concerned with its scope and provisions. The AAT guideline may be revised or withdrawn at any time. The procedures of the AAT require that action be taken to reaffirm, revise, or withdraw this guideline no later than three years from the date of publication. Suggestions for improvement of this guideline are welcome and should be addressed to the president of the American Academy of Thermology. No part of this guideline may be reproduced in any form, in an electronic retrieval system or otherwise, without the prior written permission of the publisher.

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The American Academy of Thermology (AAT)
500 Duvall Drive
Greenville, SC 29607
Telephone: (864) 236-1073
Email: contact@aathermology.org

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STATEMENT OF NEED

Thermography is a non-invasive technology available to image and map microcirculatory shunting associated with breast circulatory changes in the skin. It can play an important adjunctive role in the assessment of allostasis in breast health, clinical diagnosis, and in distinguishing between benign, early, advanced, and progressive disease. Breast thermography can also play a useful role in monitoring treatment effects.

In addition, measuring both elevated and other skin temperature aberrations provides important insight into physiologic manifestations of illness. Further since vascularity plays an important role in cancer growth thermal imaging has particular application for breast health.

Other structural imaging technologies such as Mammography, Breast Ultrasound, MRI, and Breast CT do not provide skin vascular and metabolic information offered by Medical Thermal imaging. The clinical application of Thermography can help physicians both understand breast patho-physiology and improve patient outcomes.

The American Academy of Thermology supports the incorporation of infrared thermal imaging into clinical medicine and its specific application in monitoring breast health. The AAT recognizes a current and ongoing need to promulgate continuing medical education in the science and methods of thermal imaging and in the practical clinical application of variant heat patterns obtained from thermal imaging.

PURPOSE

Infrared imaging (thermography) is a physiologic study that can assess the earliest possible changes in breast tissue by providing an accurate and reproducible high resolution image of skin temperature. This image can be analyzed both qualitatively for thermovascular mapping and quantitatively for minute changes in skin heat emission. As with most physiologic studies, anatomic findings may not correlate and may not even be present.

The guidelines contained herein will focus solely upon infrared imaging of the breast for the earliest possible detection of changes consistent with breast disease.

INDICATIONS

Vasomotor mapping of breast temperature and skin vascular patterning

Serial evaluation for change in baseline physiology

Documentation of breast temperature and Thermobiological (TH) classification

Monitoring of physiologic responses of breast tissue

Adjunctive monitoring of breast temperature and vascular patterning in the presence of:

Small breasts
Dense breasts
Fibrocystic disease
Post mastectomy
Post breast reconstruction
Placement of prosthesis
Radiation exposure concerns

Adjunctive information for other structural breast imaging studies such as Mammography, Ultrasound or MRI

Adjunctive monitoring of breast temperature and vascular patterning in conjunction with or in the absence of other interventions (including, but not limited to radiation and chemotherapy)

Adjunctive monitoring of breast temperature and vascular patterning in the perioperative and post-operative patient.

CONTRAINDICATIONS AND LIMITATIONS

Contraindications include the uncooperative patient or those patients with medical morbidity that precludes obtaining a proper exam with full consent.

-Since breast thermography operates under the premise that the body is fundamentally a symmetrical entity (with allowances for innate variation from side to side) the post-mastectomy patient represents a unique situation. Specific protocols have been established for this situation.

- While generally considered to be rare, it is possible that symmetric, bilateral pathologies can co-exist and a false negative study would result.

GUIDELINE 1:
PATIENT COMMUNICATION AND PRE EXAMINATION PREPARATION

1.1 The examiner should address any questions and concerns about any aspect of the examination.

1.2 The examiner should refer specific treatment or prognostic questions to the patient's attending physician.

1.3 No yoga massage, or strenuous exercise (physical therapy) for at least three hours before the examination.

1.4 Avoid smoking for four hours before the exam.

1.5 No lotions, creams, powders, or makeup on the breasts the day of the exam.

1.6 Avoid the application of underarm deodorants or antiperspirants.

1.7 Avoid underarm shaving on the day of the examination.

1.8 Avoid extended sun exposure or sun burn the day before and the day of the exam.

1.9 No physical stimulation or treatment of the breasts, chest, neck, or back for 24 hours prior to the examination (no chiropractic, acupuncture, TENS, physical therapy, electrical muscle stimulation, ultrasound, massage, or ice or heat use).

1.10 No bathing closer than 1 hour before the examination.

1.11 Continue to take all prescribed medications but provide a list of such medications and supplements to the technician at the time of the exam. Specifically notify the technician if beta blockers are being taken as a medication.

1.12 Do not wear external breast prosthesis for at least 12 hours prior to the examination.

GUIDELINE 2:
PATIENT ASSESSMENT

Patient assessment should be performed before infrared imaging. This includes assessment of the patient's ability to tolerate the procedure and evaluation of any contraindications to the procedure.

2.1 The patient should complete a pertinent breast history prior to the performance of the examination. This history should include:

a. Any history of breast cancer and its location.

b. The presence of any palpable mass.

c. The presence of nipple discharge, inversion, or changes in the nipples.

d. Skin changes.

e. Areas of pain, burning, stinging, tenderness, achiness.

f. History of breast surgery to include implants, lifts or reductions.

g. History of breast biopsies, diagnoses and the applicable sites.

h. History of surgical interventions, including biopsy or lumpectomy with specific information as to the site of the lumpectomy and the year it was performed and diagnosis (benign or malignant).

i. History of breast radiation specific as to the site and the time frame (beginning and end) when it was performed.

j. The administration of pharmacologic agents for breast cancer.

k. The history of mastectomy and surgical breast revision with dates of both.

l. Date and result of most recent mammogram (when applicable).

m. Approximate dates of prior mammograms and to the extent possible the interval in which they have been performed.

n. Date and result of the most recent breast ultrasonography and the location of the breast studied.

o. Date and result of the most recent breast MRI .

GUIDELINE 3:
EXAMINATION GUIDELINES

In order to produce quality infrared images certain requirements should be followed. Both the patient's physiology and the technical aspects of infrared imaging equipment need to be taken into account.

3.1 Infrared imaging (thermography) measures and maps radiosity (the degree and distribution of skin temperature changes for medical thermal imaging purposes). In order to discuss minimum specifications certain some assumptions have to be made. While recognizing that individual circumstances will vary for the purposes of this document lens FOV will be set at 25 degrees, patient to camera distance at 6-8 feet (as needed to allow the region of interest to fill approximately 75% of the image) and that lens quality is satisfactory to the vast majority of observers. Cameras should be calibrated against

the emissivity of a black body at 1.0. The emissivity is a fractional representation of the amount of energy for material versus the energy that would come from a black body at the same temperature.

3.2 The following minimum specifications should be incorporated in the design of infrared hardware and software systems. These specifications are intended to speak to the design of modern infrared imaging equipment that are considered commonplace today. They are not intended in any way reflect on systems used in the past.

• Emissivity set to 0.98 (human skin).

• Camera detector(s) response above 5 and below 14 microns.

• Preferred Absolute detector resolution of > 640 X 480 coupled with a suitable lens. Most modern medical imaging systems today utilize uncooled focal plane array detectors found in the 320 X 240 sensor range or higher. When systems with 320 X 240 sensors are coupled with lens and software or firmware innovations they can approach the image quality, spatial resolution and spot measurement requirements found in 640 X 480 systems.

• Min. measurable spot size is 2.1x2.0 mm at 40 cm distance (3x3 or 9 pixels).

• Spot resolution quality at 8 feet equivalent to ≤ 1 sq. mm at 40 cm from the detector(s).

• Spatial resolution quality at 8 feet equivalent to ≤ 2.6 mRad at 40 cm from the detector(s).

• Thermal sensitivity of < 50 mK NETD @ 30 ºC.

• Ability to perform accurate quantitative differential temperature analysis with a precision of ≤ ± 0.05 ºC.

• Repeatability and precision of ≤ ±0.05 ºC detection of temperature difference. The repeatability of a differential measurement must be in the presence of +/- 3 NETD (6 sigma - 99.9% defect free mfg. standard).

• Changes in external ambient temperature to be strictly controlled at natural convection at or below 0.2 m/s.

• Thermal drift (caused by internal heating of equipment during normal operation or by changes in external ambient temperature) to be strictly controlled at natural convection at or below 0.2 m/s.

• Maintenance of detector uniformity and correction via calibration.

• Ability to capture images in hi-resolution color and grayscale.

• High-resolution image visual display for interpretation.

• Real time image focus and capture capability. While 10Hz, 20Hz, and 30Hz are capable of real time imaging faster capability is preferred (50Hz).

• Temperature range set to cover temperatures within the range of human emissions (20-45 ºC).

• Ability to archive images for future reference and image comparison at same patient positioning and distance from the camera.

• Software manipulation of the images should be maintained within strict parameters to insure that the original qualities of the images are not compromised.

• Imaging software capable of identifying areas of calculations and locations for reporting

Contact thermography devices that utilize single or multiple probes for breast thermographic analysis are considered obsolete considering the current advances in digital infrared imaging.

3.3 Environmental Controls: All studies should be performed in a room where ambient temperature is controlled, free from drafts, and no exposure to significant external or internal heat sources (ex. sunlight, incandescent lighting). Ventilation systems should be designed to avoid airflow onto the patient. Carpeted flooring is also preferred.

3.4 The thermal imaging room should ideally be kept between 20-23 degrees Centigrade (68-72 degrees Fahrenheit). The temperature of the room should be such that the patient's physiology is not altered to the point of shivering or perspiring. Room temperature changes during the course of an examination must be gradual so that steady state physiology is maintained and all parts of the body can adjust uniformly. The temperature of the room should not vary more than one degree Celsius during the course of a study. The humidity of the room must also be controlled such that there is no air moisture builds up on the skin, perspiration, or vapor levels that can interact with radiant infrared energy.

3.5 Equilibration: The patient will be asked to disrobe their upper body completely and not to stand in a corner of the room. An equilibration time of fifteen minutes is deemed appropriate prior to obtaining the images. The patient will be

asked not to have any contact with their breasts during this time. During the last 5 minutes of the acclimation (15 minutes) time the patient will be asked to raise their hands above their head (hands clasped on head) and to maintain this posture throughout the examination. If the patient is unable to raise their arms, appropriate measures may be taken to insure proper imaging.

3.6 Infrared Imaging:

a) After the equilibration time images taken should include bilateral frontal breast view, and right and left oblique breast views and preferably right and left lateral views. If lateral views are omitted then the interpreting thermologist should address how the protocol used accounts for the inherent limitations when only oblique views are obtained. If the shape of the breast does not allow for an adequate assessment of the inferior quadrants of the breasts then additional inferior views should be taken as well. If inadequate imaging of the axillary and supraclavicular lymphatic regions of interest results, then additional views should be taken.

b) Further images may also include single right and left breast close-up views. Images should be taken and saved in both color and black and white at the highest resolution possible to help assure the best possible focus and adequate vascular pattern analysis.

c) Additional images beyond those described in 3.6a may be requested and are up to the discretion of the interpreting thermologist. The interpreting thermologist however is encouraged to look beyond pathophysiologic findings related solely to the breast (therefore minimal baseline views alone may be insufficient). For example in the absence of thermoregulatory challenge testing and at least a single posterior view interpretive considerations for physiological findings related to the same are lost. With regard to thermoregulatory challenge the most common methods are hand immersion in ice water or holding a cold pack for one minute. Additional images may also include extra views or modification of previous views,

d) Breast themography studies typically employ color, grey scale or reverse grey scale palettes that employ eight colors during study acquisition. Each palette type is typically formatted across a range of 10°C.

e) Post-image processing may then be performed in varying palettes as deemed necessary by the interpreting thermologist.

GUIDELINE 4:
REVIEW OF THE INFRARED THERMOGRAPHY EXAMINATION

4.1 The data acquired during breast thermography should be reviewed to ensure that the evaluation has been performed and documented. Any exceptions to the routine examination protocol (i.e., study omissions or revisions) should be noted and reasons given.

4.2 Record the technical findings utilized to complete the final interpretation.

4.3 Complete required laboratory documentation of the study.

4.4 It is the interpreting thermologist's responsibility to assure that all pre-imaging preparation and office protocols are followed. Any deviation should be charted by the technician. If a technician obtains images independent of medical direction then the patient should be notified of the same.

GUIDELINE 5:
PREPARATION AND STORAGE OF EXAM FINDINGS

5.1 Images should be presented to the interpreting physician for use in analysis and archival purposes. Radiometric images in either radiometric image format or radiometric image convertible format such as JPEG or DICOM are acceptable.

5.2 Images are preferably read within 48 hours of the examination. As part of their protocol imaging facilities should consider sending each patient a summary report within 30 days of the thermographic examination.

5.3 The imaging clinic should adhere to all established federal and state regulations. Archiving of image data and the analysis/report are to be maintained for no less than seven years.

GUIDELINE 6:
EXAM TIME CONSIDERATIONS

When scheduling patients for breast thermography, certain factors need to be considered for adequate time management. A combination of direct and indirect exam components may be time consuming, but these elements create the foundation for producing quality infrared imaging

6.1 Indirect exam components include pre-exam procedures:

a. Obtaining previous exam data and completing pre-exam paperwork.

b. Exam room and equipment preparation.

c. Patient assessment and history.

6.2 Post-exam procedures include:

a. Cleanup consisting of compiling, processing, and reviewing data for formal interpretation.

b. Patient communication.

c. Examination charge and billing activities where appropriate.

6.3 Direct exam components include equipment optimization, patient positioning throughout the exam, and the actual one-on-one interaction.

GUIDELINE 7: CONTINUING PROFESSIONAL EDUCATION

Certification is considered the standard of practice for clinical infrared imaging. It indicates an individual's competence to perform Breast infrared imaging at the entry level. After achieving certification, all infrared technologists are expected to keep current with changes in infrared examination protocols.

The person performing the analysis/reporting of breast thermology should be a member in good standing of a nationally recognized medical thermographic organization that offers literature, training and support specific to breast thermology and should maintain appropriate certification from that organization.

Interpreting physicians should keep current on advances in diagnosis and treatment of breast disease.

GUIDELINE 8: INFORMED CONSENT

8.1 Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a patient. Each patient should sign a form acknowledging that they have been provided with information applicable to informed consent that reflects expert consensus of the strengths and weaknesses of infrared breast imaging.

A sample of such information would be as follows: "Thermal imaging is an examination of physiology that is complimentary to anatomical imaging techniques. Though proven to be highly accurate, thermal imaging is an adjunctive procedure; and as such, it is not intended to replace anatomic studies such as mammography, ultrasound, MRI, CT, X-ray, or others."

"Thermography utilizes infrared technology which does not see into the body. It does not image any structure deeper than the skin or superficial mucosa. The technology detects heat and measures temperature. A normal thermographic study does NOT necessarily indicate that there is no abnormality and an abnormal study should only be considered as a risk marker. Infrared imaging can only be considered as one part of the evaluative process."

Since it is possible for similar heat patterns to exist in both breasts in the presence of an abnormality in each breast, it is possible to have a cancerous condition in both breasts at the same time without an abnormal thermogram. Patients should also be advised that the first study will provide a baseline against future determinations. Subsequent examinations can be compared to the baseline examination due to the markings of areas of interest noted above.

GUIDELINE 9: REPORTING

9.1 Report layout: The body of the Infrared Breast Thermographic report should clearly state that Infrared Breast Thermal Imaging is not a standalone study and should be considered adjunctive in monitoring breast health. Laboratory procedures that follow a peer reviewed, internationally accepted guideline should be noted. The set of images obtained for study should be documented. If a standard protocol for reading images is used then this should be stated as well.

Thermographic Findings should be documented and any abnormalities noted.

Thermographic Impressions include classification according to an accepted naming system or summarization of the Thermographic Findings.

Impressions are not to be included in the Thermographic Findings paragraph.

9.2 Determination of abnormality: The following recommendations outline minimal observations:

Contralateral nipple measurement should not exceed 1.0 degrees centigrade. Contralateral areas of measurement in other regions of the breast including, but not limited to, areolar/ periareolar heat extending outward to the entirety of the superior quadrants of the breast and the axillary areas should not exceed 1.5 degrees centigrade. It is noteworthy that many malignant tumors may be present below these temperatures and these values serve only as a reference and not as a diagnostic criterion of malignancy.

It is helpful to clearly mark with regions of interest within an image. These demarcations can take the form of points, circles, rectangles, lines, etc. The purpose of such markings of regions of interest is to get an accurate computer generated determination of the quantitative measurement of an individual breast for comparison against the contralateral breast. Further, such measurements permit serial evaluations to determine whether any contralateral changes are progressive, regressive, or static.

In the presence of post-mastectomy patients, the breast is considered against itself. Specific areas of excessive heat or abnormal vascular patterning should be noted. Concentric measurements from the nipple outward can also provide gradient temperature measurements allowing for the determination of suspected abnormalities.

9.3 Additional rating factors may also be listed and include, but are not be limited to, the following: hot spot, global heat, heat in an area of anatomic finding, increased nipple temperature, areolar/periareolar heat, breast bulges or retractions, vascular changes such as inverted V, fragments, closed patterns, other iterations, and findings inferior to the nipple.

9.4 Classification Systems

There are many variations in reporting. One widely utilized and established classification system is the TH (Thermobiological) grading system. It is noteworthy that the TH system is not a comparative rating to BIRADS. The TH system is as follows:

TH-1 Symmetrical, bilateral, nonvascular (non-suspicious, normal study)

TH-2 Symmetrical, bilateral, vascular (non-suspicious, normal study)

TH-3 Equivocal (low index of suspicion)

TH-4 Abnormal (moderate index of suspicion)

TH-5 Highly abnormal (high index of suspicion)

9.5 Clinical Impression: It is often preferable to further elaborate on study findings. This can be a minimal comment that might take the form of minimally, moderately, or significantly suspicious (ie: suspect for abnormality, not necessarily malignancy) followed by the thermal rationale for the comment (ie: increased nipple temperature, hot spots, vascular changes, etc.).

All patients with "atypical" and "abnormal" breast thermology findings should be referred for other clinically appropriate diagnostic evaluation. This may include clinical examination, blood markers, targeted ultrasound, mammogram or magnetic resonance imaging (MRI).

9.6 Breast Thermal Risk Index Determination

Many interpreting Breast Thermographers find it helpful to provide a clinical impression that takes into account the patient's Breast Thermal Risk Index. This index is based upon both thermal and convention factors associated with breast disease. A breast history should be provided to the interpreting clinician to determine the thermal risk of breast disease. The Breast Thermal Risk Index should not be construed as altering thermographic impressions. It utility is only applicable regarding interpreting thermologist suspicion relating to thermal findings. The method for determining the Breast Thermal Risk Index is as follows:

- The patient's age should be doubled and rounded to the nearest decade. The zero is then dropped.

-A history of breast cancer in the family is given 15 points if the family member is the patient, mother, sister, or daughter.

-Any other family member to include, but not limited to, maternal grandmother, maternal aunt, maternal cousin, paternal grandmother, paternal aunt, paternal cousin should be assessed at ten-point value. Only one such value is given among the above, the highest number being added to the risk index.

-Parity is assessed. One point is added if the first pregnancy occurred in teenage years, two points if it occurred in the 20's, five points in the 30's, seven points in the 40's. If the woman is nulliparous the final number in age calculation is doubled. One point is subtracted for each child nursed for more than one month.

-Medication. The number of years that birth control pills have been taken is divided in half

and added to the running total. If the patient has been on hormones, one point is added for every five years of hormone intake.

-If the patient is menopausal one point is added for every eight years since the onset of menopause. One point is subtracted for every five years the woman is post-oophorectomy if that oophorectomy occurred under the age of 45.

-Other: If the patient is overweight, one point is added for every 20 pounds overweight. Two points are added for each biopsy

The patient's Breast Thermal Risk Index Scale is then categorized into one of the following three categories:

<20	Low risk
20-30	Moderate risk
>30	High risk

By way of reiteration Thermal risk factor indexes do not necessarily correspond to breast cancer risk. Some readers have however found this index to provide additional useful information.

GUIDELINE 10: FOLLOW UP STUDIES

Unless other examination procedures or imaging studies have obviated the need for serial infrared imaging, follow up evaluations are generally done on an annual basis if the previous examination as normal (TH-1 and TH-2). Recall of patients who fall within the TH-3 classification should occur at six months but the exact timing is subject to the interpreting thermologist's clinical impressions and the thermal risk factor(s) present. It is recommended that TH-4 and TH-5 follow up examinations should occur at approximately three months. All recalls should be accompanied by the recommendation that patients should maintain their regularly scheduled breast health examinations with their primary care physician. Recommendations for additional treatment should be made by the patient's healthcare practitioner of choice.

GUIDELINE 11: EMERGING TECHNOLOGIES

11.1 Technology is constantly being introduced that at times can challenge existing guidelines or that do not necessarily conform to currently accepted practices. These technologies can span the entire spectrum of sophistication and therefor require different adaptive responses. On one end of the spectrum there are innovations based upon generally accepted medical scientific methodology that have gained regulatory acceptance and on the other end there are technologies that are intended for personal use only or that have applications in non-medical fields but have not been accepted as suitable for medical practice.

11.2 Unless otherwise stated general industrial or personal thermal imaging cameras are not intended for use in medical thermology.

11.3 Technologies not otherwise covered in these Guidelines that employ methodologies, hardware, or protocols that have gained Federal Regulatory approval for Medical Thermology may become available however over time. In cases where these technologies are employed the body of the report should document which deviations occurred and why, and other components of the Guideline should still be followed.

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