The American Academy of Thermology Guidelines for Breast Thermology 2021

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ABSTRACT

The guidelines contained herein will focus upon passive infrared imaging of the breast for the detection of physiologic changes that have been found to be useful in the promotion of breast thermology as a breast thermal findings assessment tool. 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 at any time. Suggestions for improvement of this guideline are welcome and should be addressed to the president of the American Academy of Thermology. Breast infrared imaging (thermology) is a physiologic study that can assess changes in breast tissue by providing accurate and reproducible high-resolution images of skin temperature. This image can be analyzed both qualitatively for thermovascular mapping and quantitatively for minute changes in skin heat emission. Thermal findings can then be utilized as an assessment tool of breast health.
Key Words: Thermography, Infrared, breast.

RESUMO

As diretrizes contidas neste documento se concentrarão na imagem infravermelha passiva da mama para a detecção de alterações fisiológicas que foram consideradas úteis na promoção da termologia como um instrumento de avaliação dos achados térmicos da mama. Esta diretriz foi preparada por membros da *American Academy of Thermology* (AAT) como um guia para auxiliar o termologista da mama, e outras partes interessadas, na aplicação clínica da imagem infravermelha da mama. Implica um consenso de especialistas no campo da termologia mamária e daqueles substancialmente interessados em seu escopo e disposições. Sugestões para aprimoramento desta diretriz são bem-vindas e devem ser dirigidas ao presidente da Academia Americana de Termologia. A imagem infravermelha da mama (termologia) é um estudo fisiológico que pode avaliar as alterações no tecido mamário, fornecendo imagens precisas e reproduzíveis de alta resolução da temperatura da pele. Esta imagem pode ser analisada qualitativamente para mapeamento termovascular e quantitativamente para mudanças mínimas na emissão de calor pela pele. As descobertas térmicas podem então ser utilizadas como um instrumento de avaliação da saúde da mama.
Palavras-Chave: Termografia, Infravermelho, mama.

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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 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.

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STATEMENT OF NEED

Medical Thermology is a non-invasive technology available to image and map micro-circulatory shunting associated with circulatory changes in breast 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 thermology can also play a useful role in monitoring treatment effects.

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

Other structural imaging technologies such as Mammography, Breast Ultrasound, MRI, and Breast CT do not provide skin vascular, or metabolic information offered by Medical Thermology. The clinical application of Thermology can help physicians both understand breast pathophysiology 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.

BREAST THERMOLOGY

PURPOSE

Breast infrared imaging (thermology) is a physiologic study that can assess changes in breast tissue by providing accurate and reproducible high-resolution images of skin temperature. This image can be analyzed both qualitatively for thermovascular mapping and quantitatively for minute changes in skin heat emission. Thermal findings can then be utilized as an assessment tool of breast health. As with many physiologic studies, anatomic findings may not correlate exactly and may not even be detected by other noninvasive technologies.

The guidelines contained herein will focus upon passive infrared imaging of the breast for the detection of physiologic changes that have been found to be useful in the promotion of breast thermology as a breast thermal findings assessment tool.

INDICATIONS

a) Vasomotor mapping of breast temperature and skin vascular patterning
b) Serial evaluation for change in baseline physiology
c) Documentation of breast temperature and Thermobiological (TH) classification
d) Monitoring of the physiologic state and physiologic responses of breast tissue
e) Adjunctive monitoring of breast temperature and vascular patterning in the presence of:
f) Exclusion criteria for structural imaging
g) Small breasts
h) Dense breasts
i) Fibrocystic disease
j) Post mastectomy
k) Post breast reconstruction
l) Post Implant for cosmetic augmentation
m) Radiation exposure concerns
n) Adjunctive information for other structural breast imaging studies such as Mammography, Ultrasound, CT or MRI
o) 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)
p) Adjunctive monitoring of breast temperature and vascular patterning in the perioperative and post-operative patient.
q) To provide physiologic information as part of a breast thermal findings assessment.

CONTRAINDICATIONS AND LIMITATIONS

a) Contraindications include the uncooperative patient or those patients with medical morbidity that precludes obtaining a proper exam with full consent.
b) Since breast thermology 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.
c) While generally considered to be rare, it is possible that symmetric, bilateral pathologies can co-exist and a false negative study would result.

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

1.4 Avoid physical stimulation or treatment of the breasts, chest, neck, or back for 24 hours prior to the examination. Avoid massage, skeletal manipulation, acupuncture, chiropractic, physical therapy, ice or heat use, ultrasound, dry needling, moxibustion, occupational therapy, saunas, the use of TENS or electric muscle stimulation units, laser therapy, or ozone therapy 24 hours prior to imaging.

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

1.6 No lotions, creams, powders, or makeup on the breasts and avoid the application of underarm deodorants or antiperspirants the day of the exam.

1.7 Avoid underarm shaving on the day of the examination.

1.8 No smoking and alcoholic beverages for four hours before the exam.

1.9 No yoga massage, or strenuous exercise (physical therapy) for at least 3 hours before the examination.

1.10 No bathing or use of a hair dryer 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, niacin, or female hormones are being taken as a medication.

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 any 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, including non-prescription agents.
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 the results of the most recent mammograms.
n) Date and result of the most recent breast ultrasonography and the location of the area studied (when applicable).

o) Date and result of the most recent breast MRI (when applicable).
p) Presence of odontalgia (persistent toothache, especially mandibular) if clinically suspicious to be pertinent.

3. EXAMINATION GUIDELINES

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

3.1 Emissivity is a fractional representation of the amount of energy radiated from a material versus the energy that would come from a black body at the same temperature. Passive IR imaging (thermology) measures and maps the pattern of skin thermal radiance (the degree and distribution of skin temperature changes). Medical grade imagers should be calibrated against the emissivity of a black body at 1.0 spanning the physiologic temperature range.

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 is 25 degrees, patient to imager distance 3-8 feet (as needed to allow the region of interest to fill approximately 75% of the image) and lens quality is satisfactory to the vast majority of observers.

3.2 The following specifications should be incorporated into the design of clinical IR hardware and software systems. These specifications are considered to be minimum requirements for an IR system and are intended to speak to the design of modern infrared imaging equipment that is considered commonplace today. They are not intended in any way reflect on systems used in the past, or what may become available in the future.

a) Emissivity correction set to 0.98 (human skin).
b) Imager detector spectral bandwidth: typically, 8 to 14 microns (micrometers).
c) Preferred Absolute detector resolution of > 640 X 480 coupled with a suitable microbolometer and 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 a high-quality microbolometer, lens and compensatory software or firmware innovations they can approach the image quality, spatial resolution and spot measurement requirements found in 640 X 480 systems.
d) measurable spot size is 2.1×2.0 mm (3×3 or 9 pixels) at 40 cm distance.
e) Spot resolution quality at 8 feet (2.4 meters) equivalent to ≤ 1 sq. mm at 40 cm from the detector(s).
f) Spatial resolution quality at 8 feet (2.4 meters) equivalent to ≤ 2.6 mRad IFOV (Instantaneous Field of View) at 40 cm minimum focus.
g) Thermal sensitivity of <50 mK NETD (Noise Equivalent Temperature Difference) @ 30 0C.
h) Ability to perform accurate quantitative differential temperature analysis with a precision of ≤± 0.05 0C (50mK).
i) Repeatability and precision of ≤ ±05 0C (50mK) 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).
j) Thermal drift (caused by internal heating of equipment during normal operation or by changes in external ambient temperature) to be strictly controlled by calibration to a known temperature standard if necessary for the study under consideration.
k) Maintenance of detector uniformity and correction via calibration to a known temperature standard.
l) Ability to render images in hi-resolution color and grayscale.

m) High-resolution image visual display for interpretation.
n) If video mode is used, it may incorporate real-time image focus and capture capability. While 10Hz, 20Hz, and 30Hz frame rates are capable of real-time imaging, having faster capability is preferred (i.e.: 50Hz). For temperature analysis, radiometric video files are preferred.
o) Imager temperature range set to cover temperatures within the range of human emissions (20-45 °C).
p) Precision autofocus of the infrared image is recommended.
q) Ability to archive images for future reference and image comparison at same patient positioning and distance from the imager.
r) Software manipulation of the images should be maintained within strict parameters to ensure that the original qualities of the images are not compromised.
s) Imaging software capable of identifying areas of temperature calculations and locations for reporting.
t) Contact thermology devices that utilize single or multiple probes or sheets of thermally-sensitive liquid crystals for breast thermographic analysis are considered obsolete considering the current advances in non-contact digital infrared imaging. Thermographic scanning systems that cannot acquire and display thermal differences of 0.05°C are also to be considered obsolete for medical purposes.

3.3 Environmental Controls: All studies should be performed in a room where ambient temperature is strictly controlled, free from drafts, and without exposure to significant external or internal infrared sources (ex. sunlight, incandescent lighting). Ventilation systems should be designed to avoid airflow onto the patient and imager, and natural convection kept at or below 0.2 m/s. Walls and ceiling should be of a matte finish non-reflective to infrared radiation. Mirrors, glass framed pictures, glass cabinets, or any reflective surface should not be placed in the imager field of view. Carpeted flooring is preferred.

3.4 The thermal imaging room should ideally be kept between 20-21 degrees Centigrade (68-70 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 moisture build up on the skin, perspiration, or vapor levels that can interact with radiant infrared energy. Relative Humidity below 70% is generally acceptable.

3.5 Equilibration: The patient will be asked to disrobe their upper body completely and not to stand any areas of draft. The patient most commonly undergoes equilibration in a standing, sitting, or supine position; however other positioning as determined by the interpreting thermologist for the study being performed may be utilized as well. 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 and to hold their arms in such a fashion so that their arms do not interfere with axillary equilibration during this time. During the last 5 minutes of the acclimation time the patient will be asked to raise their hands above their head (e.g.: hands clasped on head) and to maintain this posture throughout image acquisition. If the patient is unable to raise their arms other appropriate measures may be taken to ensure proper imaging.

3.6 Passive Infrared Imaging:

a) After the equilibration time images taken should include bilateral frontal breast view, right and left oblique breast views (30-45 degrees), and right and left lateral views. If the shape of the breast does not allow for an adequate assessment of the inferior quadrants of the breasts, then additional inferior views with the breasts elevated to expose the inferior quadrants should be taken as well. If inadequate imaging of the axillary and supraclavicular lymphatic regions of interest occurs, then additional views should be taken. Further images may also include single right and left breast close-up views. The reader is referred to the AAT Atlas of Normals for exemplary images.
b) Additional images beyond those described in 3.6a) may be requested and are up to the discretion of the interpreting thermologist. The interpreting thermologist is also encouraged to look beyond pathophysiologic findings related solely to the breast. For example, side to side skin temperature asymmetries due to imbalance in sympathetic tone are more readily detected with images taken after a cold pressor test.
c) With modern microbolometer-based imagers capable of detecting and displaying thermal differences of 0.05°C, displays capable of at least 8-bit resolution (256 different shades or colors, minimum) are required to visualize the fine details necessary for modern breast thermography. Breast thermology studies have typically employed gradient color, grey scale or reverse grey scale palettes that employ at least eight colors during study acquisition. Each palette type is typically formatted across a range of 8-10°C, however there is not a universally accepted explanation for why these temperature and color parameters are utilized. Different temperature spans may be desirable as necessitated by radiometric findings. For example, a common thermographic practice is to narrow the temperature span to one that is more specific to the region of interest after acquisition has been obtained. When post-acquisition manipulation of the temperature span is performed, the body of the report should document the same. The intent of using a broader temperature span is to ensure that no relevant radiometric image information is lost at the extremes of temperature throughout the range of all regions of interest. Care should be taken with this approach as too broad a temperature display range can “wash out” finer details of the qualitative image. One should keep in mind that as span changes the scope of findings may be impacted. If a specific office does employ post-acquisition manipulation of data to reduce temperature span, then care should be taken not to sacrifice qualitative or quantitative information as otherwise referenced in this Guideline.
d) Post-image processing with varying palettes and addition of isothermal overlays may be performed as necessary by the interpreting thermologist.

4. REVIEW OF THE INFRARED THERMOLOGY EXAMINATION

(EXAMPLE TEMPLATES ARE AVAILABLE FOR MEMBERS IN THE KNOWLEDGE CENTER WITHIN THE AAT MEMBER PORTAL)

4.1 The data acquired during the breast thermology study 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.

5. PREPARATION AND STORAGE OF EXAM FINDINGS

5.1 Images should be taken and saved in radiometric file format at the highest resolution possible to help assure the best possible focus and adequate vascular pattern analysis. All radiometric images should have the capability to be converted to standard digital image formats to assist in record keeping and interpretative report preparation. JPEG, TIF, or PNG image formats may be utilized however "Lossless" image formats such as TIF or PNG may be less likely to distort image findings. Images should be time and date stamped and include demographics within the image in a location that does not interfere with image analysis.

While DICOM (Digital Imaging and Communications in Medicine) imaging formats are commonly employed with standard universal medical imaging and storage procedures, they are still being developed to include all the metadata required to identify thermal images, patient demographics, and imaging protocols.

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. If the interpreting thermologist determines that abnormalities with urgent findings are present then the patient and referring practitioner should be notified as soon as possible.

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.

6. EXAM TIME CONSIDERATIONS

When scheduling patients for breast thermology, 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) Initial report preparation 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 one-on-one interaction.

7. CONTINUING PROFESSIONAL EDUCATION

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

Technologist certification is considered the standard of practice for breast thermal imaging. It indicates an individual's competence to perform breast infrared studies at the entry level.

Supervising physicians should keep current on advances in diagnosis and treatment of breast disease, especially thermal imaging equipment, imaging techniques, new interpretation and reporting software, and published studies on thermal imaging. They should at a minimum be a member in good standing of a nationally recognized medical thermographic organization that offers literature, training including, but not necessarily limited to, Medical Breast Thermology.

All Breast Thermologists are expected to understand the common anatomy and biology of the breast and keep current with:

a) Advances in diagnosis and treatment of breast disease
b) Changes in infrared and examination protocols or published laboratory criteria.
c) Advances in infrared technology used for breast examinations.
d) Advances in other technology used for breast infrared examination.

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 complementary 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 or structural studies such as mammography, ultrasound, MRI, CT, X-ray, or others."

"Thermology 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 disease 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.

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 imager model used and the set of images obtained for study should be documented. If a standard protocol for obtaining and reading images is used then this should be stated as well.

Thermographic Findings should be documented and any abnormalities or pertinent normal findings noted.

Neither Clinical nor Thermographic Impressions are to be included in the Thermographic Findings section.

Thermographic Impressions include classification according to an accepted naming system (i.e.: "TH" classification) or summarization of the Thermographic Findings.

Clinical Impressions are medical opinions. Statements in this section of the report include differential diagnosis and recommendations for further diagnostic assessment or treatment. Clinical Impressions should not be provided by the interpreting thermologist unless he/she has performed a history and physical examination of that patient.

Treatment recommendations should not be formulated based on imaging alone. Imaging may clarify clinical presentation, and recommendations may include further studies to more accurately assess the diagnosis, but any treatment recommendations must be based on patient contact. This does not preclude treatment recommendations from imaging done in conjunction with a patient consultation.

Generally accepted generic statements of risk factor reduction should not be included in either the Thermographic or Clinical impression sections of the report. Including such statements is optional. If they are included, they should be placed in a separate section of the report titled: Generic Statements of Risk Factor Reduction.

9.2 Determination of abnormality: The following recommendations outline minimal observations (Table 1):

Table 1. Determination of abnormality

Measurement Site	Threshold for Abnormal Temperature
Nipple	1.0 degree Centigrade
Other Contralateral Regions of Interest	1.5 degree Centigrade

Contralateral nipple measurement should not exceed 1.0 degree centigrade. Contralateral areas of temperature measurement in other regions of the breast 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 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 temperature 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 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 as adapted from the Villa Marie Breast Thermology Grading Scale is as follows (Table 2):

Table 2. The TH system as adapted from the Villa Marie Breast Thermology Grading Scale.

Grade	Patterns
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)

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 was normal (TH-1 and TH-2). Recall of patients who fall within the TH-3 classification should occur at three-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.

11. EMERGING TECHNOLOGIES

11.1 Technology is constantly being introduced that can challenge existing guidelines or that do not necessarily conform to currently accepted practices. These technologies can span the entire spectrum of sophistication and hence require different adaptive responses. On one end of the spectrum there are innovations based upon accepted medical scientific methodology that has 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 General industrial or personal thermal imagers that do not meet the specification guidelines contained herein are not intended for use in Medical Thermology. "Add-on" thermal imagers that plug into a cellular phone are, at present, not adequate for medical thermology imaging.

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 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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