Guidelines for Breast Thermology

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. 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.

Sponsored and published by:
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Internationally Peer Reviewed

Statement of Need

Medical Thermology is the scientific study of the medical application of infrared thermal imaging thermography), a non-invasive technology available to image and map micro-circulatory flow (shunting) associated with circulatory changes in skin. Measuring skin temperature aberrations (deviations or abnormalities in the skin temperature from the expected or baseline levels) provides important insight into physiologic manifestations of potential injury or illness. This is particularly applicable to breast health, given that vascularity plays a significant role in cancer growth. Breast thermography, however, is not a replacement for traditional diagnostic methods, and its role is best defined within a comprehensive, multimodal approach to breast health assessment.

When thermal findings are considered beyond those used for adjunctive cancer detection, thermography proves beneficial in the evaluation of non-tumor-related breast pain, implant-related abnormalities, post-radiation changes, traumatic breast injuries, post-biopsy complications, postsurgical scar monitoring, mastitis pathophysiology, endocrine disorders, menstrual cycle and menopausal studies, breast immune response assessment, dermatological and infectious conditions, complementary therapy effectiveness, and prenatal monitoring.

While other structural imaging technologies such as Mammography, Breast Ultrasound, MRI, and Breast CT may offer some insights into vascular conditions through modalities like Doppler ultrasound or angiography, they may not provide the same dynamic information about skin vascular patterns and metabolic activities as offered by Medical Thermography. The clinical application of Thermology, capturing dynamic skin temperature patterns, not only assists physicians in comprehending breast pathophysiology but also yields distinctive insights into skin vascularization and metabolic activities specifically related to the breast glands. This comprehensive information contributes to improved patient outcomes, encompassing enhanced treatment efficacy, reduced side effects, better overall quality of life, faster recovery, and minimized complications.

The American Academy of Thermology ardently supports the integration of infrared thermal imaging into clinical medicine, particularly in the critical realm of monitoring breast health. The AAT is committed to advancing continuing medical education in both the science and methodology of thermal imaging. This commitment extends to the practical clinical application of diverse heat patterns derived from thermal imaging, underscoring their pivotal role in enhancing diagnostics, patient monitoring, and overall clinical care.

Purpose

Infrared imaging, or thermology, serves as a physiological study that evaluates alterations in breast tissue by offering precise and reproducible high-resolution images of skin temperature. This imaging technique allows for both qualitative analysis, providing thermovascular mapping, and quantitative assessment, detecting minute changes in skin heat emission. These thermal findings are invaluable for evaluating breast health, as they directly correlate with the metabolic activity of the mammary gland, intricately linked to tissue perfusion and blood flow. Notably, these thermal patterns may exhibit asymmetry and alterations between breasts, providing insights

into various pathological states and conditions affecting the breast and thoracic region. It's essential to highlight that, akin to many physiological studies, thermological findings may not precisely align with anatomical observations and may go undetected 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

Breast infrared imaging, or thermology, plays a vital role in assessing various aspects of breast physiology. One key application is the vasomotor mapping of breast temperature and skin vascular patterning, offering valuable insights into the dynamic physiological state of the breast tissue. This technique proves especially useful for serial evaluations, allowing for the detection of changes in baseline physiology over time.

Documentation of breast temperature and classification of findings with tools like the Thermobiological (TH) system enhances the diagnostic capabilities of thermology. This classification system aids in categorizing thermal findings, contributing to a comprehensive understanding of the breast's physiological responses. The monitoring function extends to the physiologic state and responses of breast tissue, providing a nuanced assessment of its health.

Thermology serves as an adjunctive tool for cases where structural imaging faces limitations, making it particularly relevant for individuals with small or dense breasts, fibrocystic disease, and those post mastectomy, breast reconstruction, or implant placement for cosmetic augmentation. Moreover, it addresses concerns related to radiation exposure, offering a noninvasive alternative.

The versatility of thermology is evident in its role as adjunctive information for other structural breast imaging studies, including Mammography, Ultrasound, CT, or MRI. It complements these modalities, contributing additional insights into breast temperature and vascular patterning. This adjunctive role extends to scenarios involving other interventions such as radiation and chemotherapy, where thermology provides valuable monitoring of breast temperature and vascular patterning.

In the perioperative and post-operative phases, breast thermology serves as an adjunctive monitoring tool, aiding in the assessment of breast temperature and vascular patterning during these critical periods. This comprehensive approach aligns with the overarching goal of providing physiologic information as part of a breast thermal findings assessment. In essence, breast thermology emerges as a multifaceted tool, contributing to a holistic understanding of breast health and complementing traditional imaging modalities.

Contraindications and Limitations:

Breast thermography, as a non-invasive imaging technique, exhibits both absolute contraindications and relative limitations in its application. **Absolute contraindications** encompass scenarios where obtaining accurate thermographic reading is fundamentally impeded. This includes uncooperative patients or individuals with medical morbidities that hinder a proper examination conducted with full consent. Additionally, patients with severe skin conditions affecting the breast area may present challenges to obtaining reliable thermographic data.

Furthermore, breast thermology operates under the premise that the body is fundamentally a symmetrical entity, allowing for innate variation from side to side. However, this premise encounters a unique situation with post-mastectomy patients. While specific protocols have been established to address this circumstance, extensive surgical scarring on the breast may still pose challenges, potentially impacting the interpretability of thermal patterns.

In addition to absolute contraindications, breast thermography presents **relative limitations** that warrant careful consideration. Instances where the technique may be less reliable include extremely small or extremely large breasts, where achieving consistent and representative thermal images can be challenging. Factors such as menstrual cycle variations, hormone replacement therapy, and breastfeeding introduce dynamic fluctuations in breast physiology, influencing baseline assessments and potentially complicating the interpretation of thermal patterns.

Moreover, the possibility of symmetric, bilateral pathologies co-existing, although generally rare, introduces a risk of false-negative studies. Patients with conditions leading to altered blood flow dynamics, such as severe vascular diseases or significant circulatory abnormalities, may present limitations in the accurate assessment of breast thermography. The efficacy of breast thermography in detecting deep-seated lesions or early-stage tumors is also acknowledged to be limited compared to other imaging modalities, emphasizing the importance of its role as an adjunctive rather than standalone tool.

Guideline Part 1: Patient Communication and Pre-Examination Preparation

Patient communication and pre-examination preparation for breast thermography involve a series of careful considerations aimed at ensuring the accuracy and reliability of the imaging results. Open communication with the patient is essential to alleviate any worries or uncertainties, fostering a cooperative and comfortable environment for the examination. The examiner plays a crucial role in this process, addressing any questions or concerns raised by the patient and referring specific treatment or prognostic inquiries to the patient's attending physician. Specific treatment or prognostic queries are directed to the attending physician to ensure that the thermographic examiner focuses solely on the imaging process and its interpretation.

For patients who have undergone recent breast surgeries or interventions, additional information about the procedures and dates should be communicated to the technician at the time of the exam. This allows the examiner to tailor the approach based on the patient's medical history and

recent interventions. Knowledge of recent surgeries allows the technician to tailor the examination approach, considering potential alterations in breast physiology post-intervention.

Several precautions are outlined to enhance the reliability of thermographic imaging. Patients are advised to avoid extended sun exposure or sunburn on the day before and the day of the exam. Extended sun exposure or sunburn can affect skin temperature, introducing variables that may interfere with accurate thermographic readings. Physical stimulation or treatment of the breasts, chest, neck, or back is to be refrained from for 24 hours prior to the examination. This includes a comprehensive list of activities such as massage, skeletal manipulation, acupuncture, chiropractic treatments, and various physical therapies. Physical treatments and activities, including massage, skeletal manipulation, and certain therapies, can influence blood flow and skin temperature, impacting the thermographic results.

Additional measures include abstaining from wearing external breast prosthesis for at least 12 hours before the examination, refraining from applying lotions, creams, powders, or makeup on the breasts, and avoiding the use of underarm deodorants or antiperspirants on the day of the exam. Underarm shaving on the examination day is also advised against. Removal of external breast prostheses minimizes interference, ensuring that the thermography captures accurate temperature patterns directly from the natural breast. Substances applied to the skin can alter thermal conductivity, potentially distorting temperature readings and compromising the reliability of the imaging. The application of deodorants or antiperspirants may contain substances that can affect skin temperature, influencing the thermographic assessment. Shaving can cause temporary skin irritation and alter blood flow, introducing potential confounding factors into the thermographic evaluation.

Patients are instructed to abstain from smoking and alcoholic beverages for four hours before the exam, and strenuous activities such as yoga, massage, or physical therapy for at least 3 hours prior to the examination. Bathing or using a hair dryer is to be avoided closer than 1 hour before the examination. Both smoking and alcohol consumption can influence blood circulation and skin perfusion, affecting thermal patterns in the breast. Engaging in strenuous exercises or activities can induce physiological changes, impacting skin temperature and blood flow during the examination. Recent exposure to water or heat from a hair dryer may temporarily affect skin temperature, potentially interfering with thermographic readings.

Crucially, patients are encouraged to continue taking all prescribed medications, and to provide a comprehensive list of such medications and supplements to the technician at the time of the examination. While a comprehensive list of vasodilating medications and supplements is impossible to include, specific notification is required for beta blockers, niacin, and female hormones or androgens. Other common categories or compounds that may have an impact on skin temperature include antidepressants, thyroid, insulin, nitrous oxide, and neurotransmitter containing supplements.

If changes have been introduced or discontinued during an interval prior to follow up examination then it is important to note that in the patient's record prior to the study, and to notify the interpreting physician when images are sent for review. Discussions with patients

regarding pre-existing conditions, medications, and supplements can lead to a more comprehensive understanding of pre-existing influences upon thermographic findings.

Adherence to this comprehensive set of guidelines is designed improve the likelihood of achieving controlled and standardized conditions for breast thermographic examination, promote accurate and reliable results in the diagnostic process, and enhance clinical utility of the obtained thermographic images for utilization as a breast health assessment.

Guideline Part 2: Patient Assessment

Patient assessment before infrared imaging is crucial for ensuring the procedure's safety and efficacy. This assessment involves evaluating the patient's ability to tolerate the examination and identifying any contraindications that may affect the results. Each aspect of the patient's breast history contributes valuable medical information, guiding the thermographic examination in a comprehensive manner.

Firstly, a detailed history of breast cancer, including its location, provides insights into the patient's previous experiences with the disease. The presence of palpable masses, nipple abnormalities, and changes in the nipples can indicate potential issues that need closer examination. Skin changes, areas of pain, burning, stinging, tenderness, and achiness offer additional clues about the breast's current physiological state.

The history of breast surgeries, such as implants, lifts, or reductions, helps in understanding the anatomical alterations that might affect thermographic imaging. Information on breast biopsies and diagnoses, including the specific sites, is crucial for assessing potential areas of concern. Surgical interventions, like biopsy or lumpectomy, provide details on previous treatments and their outcomes.

A history of breast radiation, including the site and timeframe, is essential for considering the impact of radiation exposure on the breast tissue. The administration of pharmacologic agents for breast cancer, including non-prescription agents, informs the examiner about ongoing treatments that may influence thermographic results.

Details about mastectomy and surgical breast revision, along with their respective dates, contribute to understanding the patient's surgical history. Information on recent mammograms, prior mammograms, breast ultrasonography, and breast MRI results aids in correlating thermographic findings with other imaging modalities. Additionally, the presence of odontalgia, especially mandibular persistent toothache, is considered pertinent for clinical suspicion.

In summary, each element of the patient assessment is medically justified as it provides a comprehensive overview of the patient's breast health history, ensuring a more informed and tailored approach to thermographic examination.

Guideline Part 3: Exam Time Considerations

When scheduling patients for breast thermology, careful consideration must be given to various factors to manage time effectively. The examination process involves a combination of direct and indirect components, and while it may be time-consuming, these elements collectively form the basis for generating high-quality infrared imaging.

Indirect components encompass pre-exam procedures, such as obtaining previous exam data and completing necessary paperwork, preparing the exam room and equipment, and conducting patient assessments and history reviews.

Post-exam procedures involve tasks like preparing the initial report, which includes compiling, processing, and reviewing data for formal interpretation. Additionally, communication with the patient and activities related to examination charges and billing, where applicable, are part of the post-exam process.

Direct components of the exam entail optimizing equipment, ensuring proper patient positioning throughout the procedure, and maintaining one-on-one interaction for a comprehensive evaluation.

Guideline Part 4: Examination Procedures

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.

4.1 To establish minimum specifications for breast thermography, certain assumptions are considered. The lens field of view (FOV) is assumed to ranging from 24 to 54 degrees, with the patient-to-imager distance set between 3 to 8 feet, adjusted as needed to ensure that the region of interest fills approximately 75% of the image. Larger FOV lenses are preferable as they allow for a more extensive capture of the breast area and occupy less space in the examination room. Additionally, satisfactory lens quality ensures clear and accurate imaging for most observers.

Most cameras come with 24-degree lenses as they are designed for capturing images from a distance and industrial application (open field, outdoor). Cameras with lenses ranging from 42 to 54 degrees are more suitable for medical clinic use as they don't require as much distance to obtain the same quality image as a 24-degree lens (indoor). All brands in the market offer these lens degree options.

4.2 Emissivity is a fractional representation of the amount of energy radiated from a material versus the energy from a black body at the same temperature. Medical-grade imagers should be calibrated against the emissivity of a black body at 1.0 spanning the physiologic temperature range, if required for the examination being performed. This calibration should be conducted using accepted protocols or by the manufacturer. Calibration should be performed at least every two years. The imager emissivity correction should be set to 0.98, specifically calibrated for

human skin. This adjustment accounts for variations in skin emissivity and enhances the accuracy of temperature readings.

4.3 Medical-grade infrared imagers should adhere to specific technical specifications to ensure accurate and reliable results.

The imager's detector spectral bandwidth is crucial, typically ranging from 8 to 14 microns (long wave). This specification ensures that the imager captures the relevant infrared wavelengths emitted by the human body, allowing for optimal thermal imaging.

A preferred absolute detector resolution of greater than 640 X 480, coupled with a suitable microbolometer and lens, is essential for achieving high-quality thermal images. While many medical imaging systems use uncooled focal plane array detectors in the 320 X 240 sensor range, advancements in microbolometer quality and software innovations can approach the image quality and spatial resolution of 640 X 480 systems.

Measurable spot size, spot resolution quality, and spatial resolution quality at specified distances contribute to the precision of thermal imaging. These factors ensure that the imager can accurately detect and differentiate temperature variations in the observed area.

The imager should have a thermal sensitivity of greater than 50 mK NETD to detect subtle temperature differences. NETD (Noise Equivalent Temperature Difference) represents the smallest temperature difference that a thermal imaging system can reliably detect. It should perform accurate quantitative differential temperature analysis with a precision of greater than or equal to approximately 0.05 ºC. Additionally, repeatability and precision in detecting temperature differences should be maintained at greater than or equal to approximately 0.5º C.

Strict control over thermal drift, calibration to a known temperature standard, and maintenance of detector uniformity are essential for reliable and consistent imaging results ($v<0.2m/s$). The imager should also provide high-resolution color and grayscale images, supporting detailed analysis and interpretation.

For video mode applications, real-time capabilities, including image focus and capture, are preferred, with higher frame rates (e.g., 50Hz) enhancing temperature analysis. The imager's temperature range should cover human emissions (18-45 ºC), ensuring applicability to physiological variations.

Precision autofocus is recommended to optimize infrared image clarity. The imager should incorporate appropriate instrumentation for real-time display, electronic static image capture, storage, annotation, and hard copy documentation. Archiving capabilities enable future reference and image comparison, maintaining consistency in patient positioning and distance.

Software manipulation should adhere to strict parameters to preserve the original image qualities, and the imaging software should identify areas for temperature calculations and reporting locations. These technical specifications collectively contribute to the reliability and accuracy of medical thermography, ensuring its effectiveness as a diagnostic tool.

Given the current advancements in non-contact digital infrared imaging, older contact thermology devices that involve single or multiple probes or sheets of thermally-sensitive liquid crystals are deemed outdated for thermographic analysis. While several new wearable innovations are being introduced, their application for medical purposes remains to be seen. Thermographic scanning systems incapable of capturing and displaying thermal differences of 0.05°C are not currently supported for medical purposes.

4.4 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.

4.5 The AAT recommends that thermologists collaboratively communicate with clinical thermography technicians to establish the ambient temperature range conducive to their interpretive practices, whether it be a fixed temperature (20-21°C; 68-70°F) or within a broader physiologically comfortable range. Fixed temperature laboratories provide for greater standardization among studies, however accommodating an acceptable, comfortable range caters to differing environmental needs. In any instance, 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 should be gradual so that steady state physiology is maintained and all parts of the body can adjust uniformly. Further, 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.

4.6 Thermal Equilibration:

In the context of this Guideline, it is noted that the body does not at any point reach thermal equilibrium with room temperature; it consistently remains warmer than the ambient temperature. Providing an adequate environment and time period for skin temperature thermal equilibration, however, is still necessary for the person under study. Physiologically, this procedure provides an opportunity for the body's skin to adjust to the room's lower temperature; it allows the skin to cool and provide a clear thermal signature.

The patient will be asked to disrobe their upper body completely and not to stand any areas of draft. The patient most commonly undergoes thermal 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. A physiologic cooling time of fifteen minutes is deemed appropriate prior to obtaining the images, less or equal than ten minutes is not recommended. 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 physiologic cooling 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, exposing the armpits. If the patient is unable to raise their arms other appropriate measures may be taken to ensure proper imaging.

4.7 Passive Infrared Imaging:

a) After the thermal equilibration period, images should include bilateral frontal breast views, right and left mediolateral oblique (MLO) 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. Example templates can be accessed by members in the Knowledge Center within the AAT Member Portal.

b) Additional images beyond those described in 3.7a 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. In some cases of cervicobrachialgia and central neurological diseases, breast asymmetry may occur due to a sympathetic vasomotor reaction in the skin.

Additional images, such as those of the back, posterior cervical region, and upper limbs, can help elucidate this clinical situation, especially in patients experiencing pain. Moreover, side-to-side skin temperature asymmetries resulting from an imbalance in sympathetic tone are more easily detected with images taken after a cold pressor test, a provocative test used to assess altered sympathetic vasomotor response in these cases.

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. In breast thermology studies, gradient color scale, grey scale, or reverse grey scale, utilizing a minimum of eight colors during study acquisition, are commonly employed. Each color scale type is usually formatted across a range of 8-10°C. However, the rationale for the specific choice of these temperature and color parameters varies, and it depends on the preferences, experience, and available software for the evaluator conducting the analysis.

Different temperature spans may also be desirable as necessitated by radiometric findings. In addition, 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 purpose of employing a wider temperature span is to guarantee the retention of all pertinent radiometric image information, avoiding loss at the temperature extremes within the range of all regions of interest. However, caution is advised when adopting this approach, as an excessively broad temperature display range has the potential to 'wash out' finer details

in the qualitative image. It is important to note that alterations in the span can have an impact on the scope of findings, emphasizing the need for thoughtful consideration and adjustment.

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. This cautionary approach is rooted in the technical consideration that excessively narrowing the temperature span (color compression effect) may result in the loss or distortion of critical image details, adversely affecting the accuracy and reliability of both qualitative and quantitative assessments.

d) Post-image processing with varying color scales and addition of monochromatic temperature range highlighting (MTRH) overlays may be performed as necessary by the interpreting thermologist.

Guideline Part 5: Review and Presentation of the Infrared Examination

5.1 The data acquired during the examination should be reviewed to ensure that a complete and comprehensive 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.

5.2 Record all technical findings required to complete the final interpretation so that the measurements can be classified according to the laboratory procedures & protocols (these may be internally generated or from published data, but in any event they must be internally validated). It is important to realize that equipment, operator, and interpretation variability is inherent to this process.

5.3 The quality of findings should be analyzed throughout the examination to assure that sufficient data is provided to the physician to direct patient management and render a thermographic impression.

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

5.5 Complete all required laboratory documentation of the study so that it may become part of the patient's medical record.

5.6 Present the record of diagnostic images and when applicable, explanations for sub-optimal examination findings to the interpreting physician for use in diagnosis and archival purposes.

5.7 Alert medical director, or the responsible physician, when immediate medical attention is indicated, based on examination findings.

5.8 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.

Example templates can be accessed by members in the Knowledge Center within the AAT Member Portal.

Guideline Part 6: Reporting

6.1 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. As is customary in medical practice, it is a good idea to have literature references to support any such statements. While the interpreting thermologist may choose to include references for risk factor reduction in their report, at a minimum he/she should be prepared to produce them upon request.

With the advancement of artificial intelligence (AI), the potential exists to create a computerized report of findings. Thermographic reporting of findings and interpretation however requires specialized training and expertise. A certain level of training remains essential to help ensure the quality of the images obtained and to evaluate automated reports.

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

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.

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

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.

6.3 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.

6.4 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:

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)

It is often desirable for the interpreting thermologist to elaborate on study findings. If a minimal comment such as minimally, moderately, or significantly suspicious (i.e.: suspect for abnormality, not necessarily malignancy) is employed and followed by the thermal rationale for the comment (i.e.: increased nipple temperature, hot spots, vascular changes, etc.) then such comments should be included in the Thermographic Impression.

Computer aided analysis, software tools and artificial intelligence based innovations are still relatively new to the field of breast thermology. They show promise of making interpretations and thermographic impressions more qualitative going forward. If the application of machine learning or Artificial Intelligence (AI) gains greater acceptance over time then this technological shift may lead to a tendency to move away from the TH system and, instead, report a predictive risk value for the patient, independent of TH, based on a comprehensive database of confirmed cases.

Researchers in thermal imaging AI programs should include information on the specific algorithms used, the purpose of their application, and its level of involvement in the interpretive process. It is also advised that they explicitly outline the temperature variation range considered in their data samples, such as a range of 18 to 25°C.

If AI tools are utilized during image acquisition, thermal reports of findings, or inclusion of thermographic impressions, then the report should explicitly state that AI was employed in the analysis. The specific tool employed and supporting references for it should be included in the body of the report as well.

All patients with “atypical” and “abnormal” breast thermology findings should be referred for other clinically appropriate diagnostic evaluation or to their primary breast health provider. If any recommendation is made by the thermologist then the thermologist should understand that doing so may mean that he/she has taken responsibility for the medical management of that patient.

Guideline Part 7: 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.

Guideline Part 8: Report Timeliness and Storage of Exam Findings

8.1 Images should ideally be reviewed within 48 hours of the examination, and it is recommended that imaging facilities consider sending a summary report to each patient within 7 days of the thermographic examination as part of their protocol. However, it is crucial to acknowledge the importance of timely medical communication, especially in telemedicine, where remote patient care is a priority. Considering the potential urgency of certain abnormalities, it might be advisable for interpreting thermologists to notify patients and referring practitioners as soon as possible if abnormalities with urgent findings are identified. This approach aligns with the goal of providing prompt and effective healthcare services, minimizing patient anxiety, and facilitating swift responses to urgent medical situations.

8.2 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.

DICOM (Digital Imaging and Communications in Medicine) imaging formats are preferred because they are commonly employed in standard universal medical imaging and storage procedures. This alignment with the technological infrastructure of modern healthcare systems is crucial. The integration of DICOM plays a pivotal role within Hospital Information Systems (HIS) and Radiology Information Systems (RIS), forming a standardized framework for the management and exchange of medical images.

DICOM offers a comprehensive solution by encapsulating not only the visual representation of thermal images but also essential metadata, ensuring the seamless identification of patients, imaging protocols, and pertinent clinical data. This standardized format facilitates interoperability, allowing for the integration of thermal images into the broader medical imaging landscape.

Furthermore, adherence to the principles of the Health Insurance Portability and Accountability Act (HIPAA) is of paramount importance in the healthcare ecosystem. The utilization of DICOM aligns with HIPAA's mandate to safeguard patient information, providing a secure and standardized method for transmitting, storing, and retrieving medical images while upholding strict privacy and security standards.

By leveraging DICOM, healthcare providers can ensure compliance with HIPAA regulations, as the format inherently supports encryption, access controls, and audit trails. This not only enhances the security and confidentiality of thermal images but also promotes the seamless flow of information across different healthcare systems.

While DICOM export is preferred, other formats such as JPEG, TIF, or PNG image formats may also be utilized. “Lossless” image formats such as TIF or PNG are generally preferred over JPEG because they better preserve image findings with less distortion (it is noted, however, that some manufacturers preserve radiometric data in their JPEG export format). Irrespective of the format

used, images should be time and date stamped and include demographics within the image in a location that does not interfere with image analysis.

8.3 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 Part 9: Continuing Professional Education

In the realm of medical thermology, a clear distinction exists between the roles of a thermographer, who is the technical professional responsible for conducting thermographic procedures, and a thermologist, the specialist tasked with interpreting and analyzing thermographic images.

For the thermographer and interpreting thermologist, certification is considered the benchmark for competence in performing breast infrared studies at the entry level or for providing medical thermograpahic interpretive reports. Individuals should be a member in good standing and hold appropriate certification of a nationally recognized medical thermographic organization such as the American Academy of Thermology (AAT), or its equivalent. The AAT is an internationally recognized medical thermographic organization that offers comprehensive resources, including literature, training, and support specific to medical thermology.

Supervising physicians overseeing the thermographic process are required to stay abreast of advancements in the diagnosis and treatment of breast diseases, with a specific focus on thermal imaging equipment, imaging techniques, new interpretation and reporting software, and published studies on thermal imaging. These physicians, at a minimum, should be members of the American Academy of Thermology (AAT), or its equivalent.

All Breast Thermologists are expected to possess a comprehensive understanding of the common anatomy and biology of the breast, including knowledge in disciplines such as breast pathology, plastic surgery, lactation, mammary chemotherapy, radiation therapy, breast reconstruction, breast and chest wall pain, and vascular diseases,. Additionally, it is recommended that they should be proficient in the physical assessment of the breasts through techniques like inspection and palpation, have expertise in preventive and predictive medicine, public health, and screening.

They should possess a basic understanding of other breast imaging modalities such as mammography, ultrasound, and MRI. Additionally, they should stay current with ongoing advancements, including changes in infrared and examination protocols or published laboratory criteria, developments in infrared technology used for breast examinations, and progress in other technologies employed for breast infrared examination. This commitment to continuous education ensures that professionals in both roles contribute effectively to the field of medical thermology.

Guideline Part 10: Informed Consent

10.1 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.

Guideline Part 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 use 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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