

International Academy of Clinical Thermology Quality Assurance Guidelines

Standards and Protocols in Clinical Thermographic Imaging Current Revision July 2015

Introduction -

The following document is issued as a quality assurance guideline for the clinical use of thermal imaging. The process of establishing standards and protocols was guided by the board of the International Academy of Clinical Thermology and represents a consensus from experts in the field of clinical thermology and consultants in relevant fields of expertise.

The foundation of the methodological approach to the development of any guideline must be grounded in scientific evidence. In the guideline and development process, all available scientific evidence must be considered. This requires an extensive literature search followed by a critical review of all the relevant publications. To the extent possible, recommendations made in the guidelines should be based on the results of well designed studies.

The information in these guidelines is based primarily on a review of the current and past peer-reviewed indexed literature. Consultation with authorities in relevant fields of expertise, standards and guidelines issued by other qualified organizations, and clinical experience concerning the application of thermal imaging was also considered.

It is not the purpose of this organization to regulate clinical thermography, but rather to promote scientific validity and quality imaging. The information that follows has been compiled to insure the highest standards in clinical thermal imaging and patient safety.

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GUIDELINE SECTIONS -

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DEFINITION OF CLINICAL THERMOGRAPHY –

Thermography, when used in a clinical setting, is an adjunctive imaging procedure that detects, records, and produces an image (thermogram) of a patient's skin surface temperatures and/or thermal patterns. The procedure uses equipment that can provide both qualitative and quantitative representations of these temperature patterns.

Thermography does not entail the use of ionizing radiation, venous access, or other invasive procedures; therefore, the examination poses no harm to the patient.

There are two currently recognized methods of clinical thermographic imaging: electronic infrared telethermography and liquid-crystal thermography. The following terminology is commonly used interchangeably for clinical thermographic analysis and computer interfaced infrared thermography systems: thermal imaging, thermography, infrared imaging, digital infrared imaging, digital infrared thermal imaging, computed thermal imaging, computerized infrared imaging, and medical infrared imaging among others.

Ref: 1, 2-4, 65, 12-19

STATEMENT OF NEED -

Clinical thermography is appropriate and germane to health care practice whenever a clinician feels a physiologic imaging test is needed for differential diagnostic purposes. Clinical thermography is a physiologic imaging technology that provides important information on the normal and abnormal functioning of the sensory and sympathetic nervous systems, vascular system, musculoskeletal system, and local inflammatory processes. The procedure also provides valuable diagnostic information with regard to dermatologic, endocrine, and breast conditions. Other imaging technologies such as radiography, mammography, ultrasonography, CT, and MRI do not provide the neurological, vascular, and metabolic information provided by thermography.

Clinical thermography may contribute to the diagnosis and management of the patient by assisting in determining the location and degree of irritation, the type of functional disorder, and treatment prognosis. The procedure may also aid the clinician in the evaluation of the case, in determining the most effective treatment, and improving patient outcomes.

Clinical thermography is an acceptable analytical procedure that may be performed by a doctor or technician who has been adequately trained and certified by a recognized organization. However, it is strongly recommended that the interpretation of the thermal images be made only by health care providers who are formally trained in clinical diagnosis and hold credentials as board certified clinical thermographers from a recognized organization. This is meant to insure that directed care and proper follow-up recommendations will be made available to the patient if warranted by the interpretation of the images.

Ref: 1, 12-19, 65

GUIDELINE 1: LABORATORY REQUIREMENTS

1.1 Imaging Room Design: As part of image quality control, the design and environmental conditions of the imaging room should conform to the thermodynamic attributes required in thermal image acquisition. The room itself should be of adequate size to maintain a homogenous temperature. There must be sufficient space for the placement of equipment and freedom of movement for both the technician and patient. It should also be large enough to allow for patients of all sizes to be positioned adequately for each anatomic image. A room approximately 8` x 10`, or dimensions similar in square footage, is adequate to meet these requirements. Larger rooms may also be used as long as a steady homogenous ambient temperature can be maintained (see Environmental Controls section below). During the examination, the patient should be able to be placed relatively equidistant and adequately spaced from each wall. The room should be carpeted. If this is not possible, a well-insulated area rug will suffice.

1.2 Environmental Controls: The temperature of the room should be such that the patient's physiology is not altered to the point of shivering or perspiring. The temperature range should be maintained between 18 and 23 degrees C. 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 build-up on the skin, perspiration, or vapor levels that can interact with radiant infrared energy. The examining room must have an ambient temperature thermometer to accurately monitor the temperature of the room.

A complete infrared survey of the room should be performed to inspect for any infrared sources and leakage (e.g. windows, heating/AC ducts, light fixtures, hot water pipes). Any significant findings need to be remedied. All windows must be covered or shielded to prevent outside infrared radiation from entering the room. Shades or blinds may be adequate for this purpose depending on the amount of direct infrared radiation. The room must be free from drafts. Windows and doors should be adequately sealed to prevent airflow in the area where the patient is positioned. Heat and air conditioning sources must be minimized in the room and kept well away from the patient. Vents should be directed away from the patient and thoroughly diffused or turned off during the examination. Incandescent lighting should not be used during the examination due to the amount of infrared radiation produced. Standard fluorescent lighting is adequate.

Ref: 1, 4, 7, 9, 10, 12-19, 20, 22-26, 27-38, 41-42, 50-51, 57, 65, 66, 68-73

GUIDELINE 2: IMAGING SYSTEM REQUIREMENTS

In order to provide for quality image production and accurate clinical interpretations, certain minimum equipment standards should be maintained. There are two currently recognized types of thermographic imaging equipment: electronic infrared telethermography (IRT) and liquid-crystal thermography (LCT).

2.1 Liquid Crystal Thermography: LCT utilizes a range of interchangeable "screens" or "pillows" impregnated with cholesteric methyl-ester derivatives that change color as a function of their temperature. The "screens" or "pillows" are touched to the anatomic surface for development. A standard picture of the image is taken for later analysis and archive. The thermal precision and resolution of the equipment is well within accepted limits for clinical interpretation.

2.2 Electronic Infrared Telethermography: IRT equipment incorporates single or multiple infrared detectors that sample the field-of-view in two directions simultaneously. The process does not involve contact with the surface of the skin. A current review of the literature suggests that in order to produce accurate and reproducible diagnostic images the following minimum specifications should be incorporated in the design of clinical IRT hardware and software systems for image-capture, display, and analysis:

- Detector(s) response greater than 5 microns and less than 15 microns with the spectral bandwidth encompassing the 8-10 micron region.
- System temperature range set to cover temperatures over the range of human emissions.
- Emissivity set to 0.98 (human skin).

- Absolute resolution of at least 19,200 temperature points per image frame with an appropriate lens. The largest lens applicable to the detector is desired.
- Spatial resolution of 1 sq. mm at 40 cm from the detector(s) (2.5 mRad IFOV).
- Thermal sensitivity of less than 80 mK NEDT.
- Repeatability and precision of 0.1 degree C detection of temperature difference.
- Thermal drift strictly controlled with corrective calibration to as close to 0.00 degrees C as possible at system equilibration to ambient temperature guidelines.
- Maintenance of detector uniformity to within 0.20 degree C Delta-T across 80% of the central field.
- Absolute temperature accuracy of +/- 2 degree C or +/- 2% of reading or less.
- Manual adjustment of temperature span.
- Manual adjustment of level settings.
- Manual adjustment of focus.
- Minimum focus distance capable of close-up views of selected sectional anatomy.
- Capture frame-rate set to allow for live image focusing and capture.
- Ability to capture images in high-resolution grayscale.
- High-resolution image display for interpretation.
- Imaging software capable of accurate quantitative analysis.
- Ability to perform accurate quantitative differential temperature analysis with a precision of 0.1 degree C.
- Ability to annotate areas of interest with accurate temperature values.
- Software manipulation of the images (both live and post-image processing) should be maintained within strict parameters to insure that the diagnostic qualities of the original images are not compromised.
- Ability to archive images for future reference and image comparison. Proprietary formatting with an image convertible format such as JPEG or DICOM is acceptable.

Due to the natural progression of technical advancements in the field of thermal imaging, infrared imaging systems for clinical use typically exceed these requirements. However, there is no evidence (Class 1 or Class 2) in the current research literature to support the need of using imaging systems that surpass the above minimum standards.

Ref: 1, 5, 7, 8, 11, 12-19, 38, 64, 65, 106, 351, 354, 377, 393, 422, 427, 430-433, 445-459

GUIDELINE 3: OTHER THERMAL DETECTION DEVICES

As previously mentioned, certain minimum equipment standards should be maintained in order to produce infrared images that are diagnostic. There are many different types of thermal detection devices available that may be used for specific purposes (e.g. temporal and tympanic thermometers), but may not be suitable for body or breast examinations. A brief summary is given below regarding some of these devices.

3.1 Dual Sensor Paraspinal Devices: Since the early 1920's, thermal detection devices have been used in the examination of the paraspinal region. These devices are designed to be hand-held and moved by the operator up or down the spine over the paraspinal surfaces. The equipment is composed of a linear array of two spot radiometers (infrared sensors) spaced adequately to straddle the spine and interfaced to a hard-copy readout device or computer. This creates a system best defined as surface thermometry or computerized surface thermometry if a computer interface is used. If enough plotted data is displayed for analysis (e.g. scan distance for anatomic location, direct and differential temperature displays) the system may be defined as paraspinal

thermography. Earlier contact devices using thermocouples or thermistors have been replaced with infrared sensors to avoid the inherent errors produced when instruments of this type are used.

These infrared devices are limited in their use to the evaluation of conditions arising from the area of the spine and paraspinal tissues. If the device is manufactured to the strict minimum standards imposed on all quality clinical infrared devices (e.g. accuracy, repeatability, and thermal stability), then the information yielded will be of diagnostic value.

A review of the literature concerning infrared sensor instruments of this type suggests that in order to produce accurate, reproducible, and clinically relevant thermal data the following minimum specifications should be incorporated in their design:

- An infrared detector response greater than 5 microns and less than 15 microns with the spectral bandwidth encompassing the 8-10 micron region.
- System temperature range set to cover temperatures over the range of human emissions.
- Emissivity set to 0.98 (human skin)
- Accurate data repeatability in temperature value and location.
- A direct linear correspondence between the distance traveled, anatomic location, and the displayed temperature values.
- Controlled infrared sensor collimation to prevent sensor cross-talk.
- Within a reasonable range of distance from the skin, the recorded temperature, and the spot size being measured, should not vary.
- The skin surface covered by the sensor must be controlled within a small enough area to yield data with which a sufficiently detailed graph can be produced.
- A sufficient number of infrared samples must be taken in order to maintain an adequately detailed graph resolution. The number of samples taken should be equivalent to the minimum standards of acceptable clinical infrared camera systems.
- Repeatability and precision of 0.1 degree C detection of temperature difference.
- Absolute temperature accuracy of +/- 2 degree C or +/- 2% of reading or less.
- Ability to perform accurate quantitative differential temperature analysis.
- High-resolution image display for interpretation.
- Ability to archive images and graphs for future reference and image comparison.
- Software manipulation of the images and graphs should be maintained within strict parameters to insure that the diagnostic qualities of the images and graphs are not compromised.

3.2 Microwave Thermography: Past research has determined that microwave thermography has some limited value in the evaluation of the breast. Studies have demonstrated that certain inherent problems exist with this technology. Concerns raised include: introduction of errors from surface contact, depth of analysis, area coverage, and low spatial and thermal resolution. Research on this technology suggests that infrared telethermography or liquid crystal thermography is better suited for clinical use.

3.3 Single Sensor Devices: The devices in this category are usually designed to be hand-held and moved by the operator over a particular area of the skin or to areas of the body where single spot temperature readings are taken (e.g. tympanic thermometers, skin surface thermometry). Thermal detection devices that fall into this category are best described as surface thermometry. Most of these devices are designed using a single spot radiometer (infrared sensor). If the device incorporates the need for surface contact, certain inherent problems can cause significant errors when a thermal analysis is performed. Incorporation of a computer interface to the sensor creates a system best defined as computerized surface thermometry. We are unaware of any acceptable level of peer-reviewed research in the body of literature to support the use of this type of equipment for body or breast analysis.

Single sensor devices are not considered suitable for clinical use as they suffer from many data acquisition problems, notably of which is an extreme lack of absolute and spatial resolution. Devices of this type are considered obsolete.

Ref: 1, 45, 62, 65, 421

GUIDELINE 4: PATIENT MANAGEMENT PROTOCOLS

Proper management of the patient, both before and during the examination, decreases the chance of thermal artifacts and increases the accuracy of the images. It is the technician's responsibility to ensure that all pre-imaging preparation and laboratory protocols are followed.

4.1 Pre-examination Preparation: Pre-examination preparation instructions are of great importance in decreasing thermal artifacts. The following is a minimal list of instructions that should be given to the patient prior to the examination:

- No sunbathing of the area to be imaged 5 days prior to the exam.
- No use of lotions, oils, creams, powders, or makeup on the body area to be imaged the day of the exam.
- For upper body and breast imaging, no use of deodorants or antiperspirants the day of the exam.
- If any body areas included in the images are to be shaved, this should be done the day before the exam.
- No physical therapy, EMS, TENS, ultrasound treatment, acupuncture, chiropractic, physical stimulation, sauna or steam room use, hot or cold pack use for 24 hours before the exam.
- No exercise the day of the exam.
- If showering, it must be no closer than 1 hour before the exam. No baths for 24 hours prior to the exam.
- If not contraindicated by the patient's doctor, avoid the use of pain medications and vasoactive drugs the day of the exam. The patient must consult with their doctor before changing the use of any medications.
- For breast imaging, if the patient is nursing they should try to nurse as far from 1 hour prior to the exam as possible. The last breast nursed should be identified (e.g. right or left).
- If the patient has had any surgical procedure (e.g. any type of biopsy) within the last 12 weeks, the imaging office should be notified and the surgical procedure cleared before an appointment is made.

4.2 Intake Forms: Intake forms should be used and formatted to cover the areas of complaint along with specific pain diagrams, precise location of scars, previous tests and examinations, and a current and past history of any diagnoses, surgeries, and traumas. Intake forms for breast imaging should include additional questions pertaining to anatomic and physiologic changes noted in the breast along with breast diagrams for determining the precise locations of clinical and imaging findings. All of these forms should be designed to be thorough and specific to the body area(s) being imaged.

4.3 Informed Consent: Informed consent is a process, not just a form. Information must be presented in such a manner that enables persons to voluntarily decide whether or not to participate in imaging. Each patient must sign the consent form in the presence of office personnel. The form needs to acknowledge that they have been provided with information applicable to informed consent that reflects expert consensus of the strengths and weaknesses of clinical infrared imaging. Informed consent forms must also contain clear wording that infrared imaging is an adjunctive procedure; and as such, is not a replacement for mammography, ultrasonography, CT, MRI, or any other form of imaging.

4.4 Patient Acclimation: Prior to imaging, the patient's body must be given sufficient time to equilibrate with the ambient conditions of the laboratory such that an approximate steady physiologic state of thermodynamic equilibrium can be reached. A minimum equilibration period of 15 minutes should be observed; further equilibration results in minimal surface temperature changes. During the equilibration period, and the subsequent examination,

the area to be imaged should remain completely uncovered of clothing or jewelry. To provide a level of modesty prior to certain examinations, a loose fitting gown may be worn during the equilibration period provided that it does not restrict airflow or constrict the skin surface in any way that would produce an artifactual result on the thermogram. Special gowning procedures, specific to the clinic or examination, may be required and are permitted as long as the above stipulations are observed.

The only exception to gowning is in breast imaging where the breasts should remain uncovered during the entire equilibration period, and subsequent examination, in order to avoid contact artifacts. Due to the individual anatomy of each patient, special positioning during the equilibration period and examination may be needed. If the patient is seated or standing, the last 5 minutes of the equilibration period should be spent with the patient placing their hands over their head in order to lift the breasts for adequate surface area exposure. Depending on the individual patient's anatomy, this posture may need further modification during the acclimation period. This posture is also to be maintained throughout the examination.

4.5 Clinical Examination: When appropriate to the individual case, a clinical examination may be performed after thermal imaging to correlate specific findings. The examination may include visual inspection, palpation, neurologic, orthopedic or other forms of analyses as deemed necessary by the patient's doctor or the interpreting clinician if attending. Visual observation for skin changes and irregularities (e.g. scars, redness) should also be part of the normal imaging process for the attending technician.

Ref: 1, 2-4, 8, 11, 22, 26, 30-32, 35, 37-51, 54-55, 57-65, 70-72, 74-404

GUIDELINE 5: IMAGING PROTOCOLS

The guidelines given for strict laboratory environmental controls and patient preparation provide for a subject that is physiologically ready for thermal imaging.

Note: It is absolutely essential that the capturing of thermal images for health care purposes be made only by personnel who hold credentials as certified clinical thermographic technicians or board certified clinical thermographers from a recognized organization.

5.1 Imaging Series: A thermographic series consists of one or more images, captured on archival media, which permit the evaluation of the body surface area relevant to the purpose of the examination. Each thermographic series should include all or as many body surfaces as possible that are relevant to the patient's complaint and symptomatology, along with any anatomically and physiologically related areas. Standardized views of each body part have been established in order to provide adequate viewing of the skin surface for qualitative and quantitative analysis. A single thermographic series is considered clinically valid if performed under the conditions previously outlined.

5.2 Patient Positioning: The use of both electronic infrared and liquid crystal thermographic systems incorporate basic standardized patient and equipment positioning for each area of the body imaged. Typically, the entire upper body or lower body is imaged in sections in order to adequately analyze the physiology related to these areas. Specialized or limited views may be added, or taken as an individual study, as needed.

When positioning for breast imaging, multiple views from different angles are necessary to provide adequate imaging of the differing surface aspects of the breast and relevant anatomic areas. The minimum set of images taken should include the bilateral frontal, right oblique, and left oblique. In order to provide for an adequate view of the lateral aspect of the breast, the angle of the oblique views will vary depending on the patient's presenting anatomy. It is highly recommended that the unilateral "bullseye" close-up view of each breast be included on every series taken. This view provides optimal use of the detector by dedicating the greatest number of infrared sensors to each individual breast; thus, providing for an image with the highest absolute and spatial resolution. With certain patients, additional views may be necessary to image specific surface areas that are obscured due to the individual's anatomy (e.g. inferior quadrant lift views).

5.3 Imaging: Combined positioning of the equipment and the patient is critical to accurate imaging. Electronic infrared telethermography studies should be performed with the detector(s) as perpendicular as possible to the surface to be viewed. If other than perpendicular views are required, the angle must be kept exactly the same for comparable bilateral views. To maintain adequate spatial resolution and interpretation accuracy, the body part(s) of interest should be brought close enough to the detector(s) to fill the viewable image area. When multiple views are

required for bilaterally equivalent areas of the body, the equipment settings (or temperature scale "screen" selection with LCT) must not be altered for the two views. Liquid crystal thermography studies should be performed using the proper temperature scale "screen" for the body area imaged along with an adequate number of images to cover the surface area(s) of interest. The screens must also be allowed to cool/equilibrate between views of the opposite sides of the body.

5.4 Additional Studies: Any additional studies and/or images may be requested and are up to the discretion of the interpreting thermologist. Stress studies involving symptom exacerbation or a thermoregulatory challenge may be performed following a baseline thermographic series.

The use of a thermoregulatory challenge (a.k.a. cold challenge) is defined as dynamic thermography. The thermoregulatory challenge may be added to an examination to clarify the extent of the nervous system's involvement in a suspected pathologic process (e.g. Raynaud's disease, CRPS). The procedure entails the use of a cold stimulus (ice water or equivalent temperature stimulus) applied to the hands, feet, or lower half of the central thoracic spine. The test is commonly performed via hand or feet immersion in an ice water bath for a minimum of 45 seconds (or until pain tolerance) followed by repeated imaging (a single duplicate study or a timed cooling/warming series may be used) of the body area(s) under study. Warmer water (e.g. tap water in temperate climate zones) may not provide a strong enough stimulus to the sympathetic nervous system and is considered questionable as to its reliability. The addition of a thermoregulatory challenge test is up to the discretion of the interpreting thermologist and not the technician.

With regard to breast imaging, both direct airflow to the breast (fans) and ice water (hand, feet, or thoracic spine area stimulus) have been used as a thermoregulatory challenge in many thermal imaging studies. Studies have shown that the use of fans directed at the breast(s) generally produces an unreliable superficial effect while ice water (hand, feet, or thoracic spine area stimulus) assures a central nervous system mediated sympathetic reflex. The use of fans may also introduce many variables that cannot be controlled for which could adversely affect the quality of the images. The addition of a thermoregulatory challenge test is up to the discretion of the interpreting thermologist and not the technician. Studies have shown that the addition of the thermoregulatory challenge to the standard set of infrared breast images is not necessary to provide for accurate and reliable imaging.

5.5 Documentation: Each thermographic image, captured on archival media, should contain an indication of the anatomic view along with the following minimum information; either included with the original image or immediately traceable to the patient's individual database:

1.) The patient's name or identification code and imaging date

2.) The imaging facility name and address

Ref: 1, 4, 6, 11, 20, 21, 25, 27, 51, 57, 65, 70, 95, 171, 184, 296, 354-356, 388, 414, 420, 422, 426-438, 440-446

GUIDELINE 6: IMAGE INTERPRETATION AND REPORTING

Note: It is absolutely essential that the interpretation of thermal images for health care purposes be made only by health care providers who are formally trained in clinical diagnosis (e.g. MD, DC, DO) and hold credentials as board certified clinical thermographers from a recognized organization. Health care providers with specific specialties may also be included (e.g. DDS), with the use of thermography limited to the specialty.

6.1 Thermogram Interpretation: Interpretation of thermal images is based on a knowledge of thermography and its relation to human physiologic systems and processes. Interpretation provides information on the normal and abnormal functioning of the sensory and sympathetic nervous systems, vascular system, musculoskeletal system, endocrine system, and local inflammatory processes. Combining the information gained from the thermal images with clinical data allows for the formation of a clinical impression.

6.2 Breast Thermogram Interpretation: Standardized interpretation guidelines in thermal breast imaging have been utilized since the adoption of the 20 point TH (Thermobiological) interpretation and classification system in the early 1980's. This system has been continually updated as ongoing research has dictated. Many large-scale studies, encompassing well over 300,000 women participants, confirm the objectivity and accuracy of this interpretation and classification system. This system of interpretation is the most up-to-date method for use in the

analysis of thermal breast images. The 20 point TH interpretation and classification system is the accepted standard in thermal breast imaging analysis.

The TH grading system was devised in order to provide a method for the universal interpretation of both qualitative and quantitative thermal data and to use this data to convey the level of risk and concern. The grading system allows for the objective monitoring of the progression of possible pathology and to provide an objective indicator of improvement of the health of the breasts under care. The TH classification system is as follows:

- TH 1 Normal Symmetrical Non-Vascular
- TH 2 Normal Symmetrical Vascular
- TH 3 Questionable
- TH 4 Abnormal
- TH 5 Very Abnormal

Depending on the patient's recent clinical examination and imaging status, images that fall into the TH3 range and higher classification should be referred for further evaluation. This may include clinical examination, mammography, ultrasonography, magnetic resonance imaging (MRI) and/or a combination of these tests depending on the TH grading.

6.3 Written Reporting: The format for reporting should include as a minimum the following information:

- Imaging facility
- Patient name and age
- Date of examination
- Clinical data
- Symptomatology
- Relevant thermographic findings
- Impression
- Recommendations (if appropriate)
- Signature of qualified thermologist

6.4 Follow-up Thermographic Studies: The clinical need for follow-up thermograms is ultimately up to the discretion of the interpreting thermologist and is based on the pathophysiology of the presenting images and the clinical presentation of the patient. The need for and/or timing of thermographic follow-up will also be predicated on the patient's recent examination procedures and/or imaging.

With regard to breast thermograms, follow-up evaluations are generally done on an annual basis if the images are normal (TH1 or TH2). The following recall recommendations are based on the average doubling time of malignant mammary neoplasms. Depending on the patient's conventional risk factors, and other pertinent clinical data, the following recall times may be varied by the interpreting thermologist.

Patients who fall into the TH3 classification upon initial evaluation should be recalled at 6 months. If at the 6 month re-evaluation the thermogram remains stable as a TH3, or improves to a TH2 or TH1, the patient should be recalled once more at 6 months. If after 1 year of observation the patient remains stable as a TH3, or improves to a TH2 or TH1, the patient should be TH2 or TH1, a return to annual thermograms would be recommended.

Patients with an initial thermogram in the TH4 or TH5 classification should be recalled at 3 months. If at the 3 month re-evaluation the thermogram remains stable as a TH4 or TH5 (no increase to a higher classification), or improves to a lower classification, the patient should be recalled once more at 6 months. If at the 6 month re-evaluation the thermogram remains at a stable TH4 or TH5, thermograms should be performed at 6 month intervals until improvement to a TH3 or lesser classification or a pathology is discovered.

All imaging and recalls should be accompanied by the recommendation that the patient should be seeing their doctor and maintaining their regularly scheduled health examinations. Recommendations for treatment must be made by the patient's doctor.

Ref: 1, 11, 37, 49, 57, 59, 62, 63, 65, 95, 139, 142, 144, 146, 156, 195, 265, 276, 387-388, 405-411, 413-420, 422-425

GUIDELINE 7: CLINICAL THERMOGRAPHY EDUCATION GUIDELINES

Adequate training in thermographic imaging is a necessity to insure quality image acquisition, accurate interpretation, and patient safety.

7.1 Certified Clinical Thermographic Technicians: Training courses leading to certification are comprised of both formal classroom hours and practical imaging experience. Courses typically cover basic thermal imaging principles, patient management, laboratory and imaging protocols, and a time period of supervised practical field experience. Technicians are not trained in the interpretation of thermographic images. Candidates that complete a recognized course of study, and successfully pass the required examination(s), hold credentials as certified clinical thermographic technicians.

7.2 Board Certified Clinical Thermologist: Educational courses at this level are comprised of both formal classroom hours and practical imaging experience. The course material typically covered includes: a review of relevant anatomy and physiology, pathophysiologic processes and their relation to thermographic presentations, laboratory and imaging protocols, patient management, thermal imaging principles, image analysis and interpretation, and a time period of closely supervised practical field experience. Candidates that complete a recognized course of study, and successfully pass the required examinations, hold credentials as board certified clinical thermologists.

7.3 Breast Thermologist: It is essential that extended training in breast thermography be completed by doctors who are intending on interpreting thermal breast images. This level of education exceeds the thermal breast imaging information covered in courses leading to general board certification. A typical course of study includes: a review of breast anatomy and physiology, pathophysiologic breast processes and their relation to thermographic presentations, laboratory and imaging protocols, patient management, thermal imaging principles, image analysis and interpretation, and a time period of closely supervised practical field experience.

7.4 Certifying Organizations: Educational courses in clinical thermography are provided through recognized organizations. Due to the many non-clinical uses of thermographic imaging, only organizations specifically founded to serve the educational needs in clinical thermography are recognized.

Quality educational courses have been offered by the International Academy of Clinical Thermology since its beginnings as the California Thermographic Society in the early 1980's. The Academy provides training courses for both technicians and health care providers. The courses have been continually updated to meet the ongoing changes and advancements in the field of clinical thermology.

SUMMARY -

The guidelines in this document are designed to assist practitioners in the use of clinical thermal imaging and to provide outside agencies with knowledge in the application of the procedure. The guidelines, however, should not be considered permanent. Research in this field is ongoing internationally within private practices, hospitals, and universities. This research can be expected to impact the utilization of thermal imaging on a continuous basis ensuring that there is progression and growth in knowledge and understanding of the benefits and role of thermal imaging in the health care delivery system. As the results of such research begin to have a practical impact, the utilization of thermal imaging will change and future guidelines will have to take such changes into account. The guidelines in this document are reviewed annually by the guidelines committee with revisions made as research dictates.

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