International Association of Certified Thermographers Quality Assurance Guidelines

Standards and Protocols for Medical Infrared Imaging

January 2007

Introduction –

The following document is issued as a quality assurance guideline for the use of thermal imaging in health care. The information is based 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. 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 provide the highest standards in clinical thermal imaging and patient safety.

The guidelines have been divided into the following sections:

DEFINITION OF CLINICAL THERMOGRAPHY –

Thermography, when used in a clinical setting, is an 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. Clinical thermography is appropriate and germane to health care practice whenever a clinician feels that a physiologic imaging test is needed to aid in the differential diagnosis process and/or the monitoring of physiologic responses to treatment. Clinical thermography is a physiologic imaging technology that provides 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 physiologic information with regard to dermatologic, endocrine, and breast conditions.

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 and in determining the most effective treatment.

Clinical thermography is an acceptable analytical procedure that may be performed by a doctor or technician who has been adequately trained and certified. However, it is strongly recommended that the interpretation of the thermal images be made only by health care providers who are licensed to diagnose and hold credentials as board certified clinical thermographers. 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.

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, and computerized infrared imaging among others.

LABORATORY REQUIREMENTS

Room Design: As part of image quality control, the design and environmental conditions of the 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 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.

A complete infrared survey of the room should be performed to inspect for any infrared sources and leakage (e.g. windows, heating 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.

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.

EQUIPMENT GUIDELINES -

In order to provide 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).

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 visual 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.

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 images that may be analyzed for pathology, the following minimum specifications should be incorporated in the design of clinical IRT hardware and software systems:

- Detector(s) response greater than 5 microns and less than 15 microns with the spectral bandwidth encompassing the 8-10 micron region.
- Repeatability and precision of 0.1 degree C detection of temperature difference.

- Accuracy of +/- 2% or less.
- Spatial resolution of 1 sq. mm (2.5 mRad) at 40 cm from the detector(s).
- Limiting temperature windows (span) of 5 and 10 degrees C.
- Significantly variable contrast (level) settings.
- A maximum scanning time of 4 seconds or less with real-time capture preferred.
- Ability to perform accurate quantitative differential temperature analysis with a precision of 0.1 degree C.
- Ability to capture images in hi-resolution grayscale.
- High-resolution image display for interpretation.
- Ability to archive images for future reference and image comparison.
- Software manipulation of the images should be maintained within strict parameters to insure that the diagnostic qualities of the images are not compromised.

OTHER THERMAL DETECTION DEVICES –

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

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 temperatures) 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 current 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 clinical value.

A current 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.
- 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 beam 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 camera systems.
- Repeatability and precision of 0.1 degree C detection of temperature difference.
- Accuracy of +/- 2% or less.
- Ability to perform accurate quantitative differential temperature analysis.
- High-resolution image display for interpretation.
- Ability to archive images for future reference and image comparison.
- Software manipulation of the images should be maintained within strict parameters to insure that the diagnostic qualities of the images are not compromised.

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 at this time infrared telethermography or liquid crystal thermography is better suited for clinical use. More research is needed in this area.

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 or temporal 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 (e.g. thermocouple or thermistor), 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. There is no available research in the body of literature to support the use of this type of equipment for full body or breast analysis. It is not considered suitable as it suffers from many data acquisition problems, notably of which is an extreme lack of absolute and spatial resolution.

Multiple Sensor Devices: Thermal detection devices that fall into this category are usually composed of 3 or more spot radiometers (infrared sensors) 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 temperatures), the system may be defined as thermography. These devices may be mounted on a movable stand or hand-held by the operator and passed over the surface of the skin. If the device incorporates the need for surface contact (e.g. thermocouple or thermistor sensors), certain inherent problems can cause significant errors when a thermal analysis is performed.

There is no available research to support the use of this type of equipment for breast analysis. It is not considered suitable as it suffers from many data acquisition problems, notably of which are a lack of absolute and spatial resolution. Depending on its design, many other inherent problems may also prevent its use for anything other than simple surface temperature analysis. 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 have clinical value.

Equipment of this type usually incorporates the same type of spot radiometers (infrared sensors) as those used in similar surface scanning devices. As such, the same minimum design specifications are recommended in order to produce accurate, reproducible, and clinically relevant thermal data.

- An infrared detector response greater than 5 microns and less than 15 microns with the spectral bandwidth encompassing the 8-10 micron region.
- 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 beam 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 or image can be produced.
- A sufficient number of infrared samples must be taken in order to maintain an adequately detailed graph or image resolution. The number of samples taken should be equivalent to the minimum standards of acceptable camera systems.
- Repeatability and precision of 0.1 degree C detection of temperature difference.
- Accuracy of +/- 2% or less.
- Ability to perform accurate quantitative differential temperature analysis.
- High-resolution image display for interpretation.
- Ability to archive images for future reference and image comparison.
- Software manipulation of the images should be maintained within strict parameters to insure that the diagnostic qualities of the images are not compromised.

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.

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 sun bathing of the area to be imaged 5 days prior to the exam.
- No use of lotions, creams, powders, or makeup on the body area to be imaged the day of the exam.
- For upper body 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 evening before the exam or at least 4 hours prior to examination.
- No physical therapy, EMS, TENS, ultrasound treatment, acupuncture, chiropractic, physical stimulation, hot or cold pack use for 24 hours before the exam.
- No exercise 4 hours prior to the exam.
- If bathing, it must be no closer than 1 hour before 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.

Intake Forms: Intake forms should be used and formatted to cover the areas of complaint with specific pain diagrams, 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.

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. 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. During breast imaging equilibration, the last 5-10 minutes of the 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.

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 interpreting clinician.

IMAGING PROTOCOLS -

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

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. A single thermographic series is considered adequate for analysis if performed under the conditions previously outlined.

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

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 (with the exception of breast imaging) or lower body is imaged in order to analyze the physiology related to these areas. Specialized or limited views may be added, or taken as an individual study, as needed.

With 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 views necessary include the bilateral frontal breast along with the right and left oblique views. Optional close-up single views of each breast may also be included. The close-up views maximize the use of the detector allowing for the highest thermal and spatial resolution of the breasts. With certain patients, additional views may be necessary to image specific surface areas that are obscured due to the individual's anatomy.

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 maintained 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) should not be altered for the two views unless allowed for in post-image computer processing. 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.

Additional Studies: Stress studies involving symptom exacerbation, thermoregulatory challenge, or alcohol spray (e.g. thyroid studies) 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 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 thermoregulatory challenge may be added to an examination to clarify the extent of the nervous system's involvement in a suspected pathologic process. The addition of this test is up to the discretion of the interpreting doctor and not the technician.

With regard to thermal 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 since the early 1970's. Studies have shown that the use of fans directed at the breast(s) generally produces a superficial effect while ice water (hand, feet, or thoracic spine area stimulus) causes a central nervous system mediated sympathetic reflex resulting in vasoconstriction. The use of fans may also introduce many variables that cannot be controlled for which could adversely affect the quality of the images. The use of the thermoregulatory challenge in thermal breast imaging was intended to enhance the detection of the neoangiogenic process. However, a review of the literature does not support an increase in sensitivity or specificity with the use of this test. Consequently, the addition of the thermoregulatory challenge is not mandatory with thermal breast imaging.

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 other archived documents:

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

2.) The imaging facility name and address

IMAGE INTERPRETATION AND REPORTING -

Note: It is strongly recommended that the interpretation of thermal images for health care purposes be made only by health care providers who are licensed to diagnose and hold credentials as board certified clinical thermographers from a recognized organization.

Thermogram Interpretation: Interpretation of thermal images is based on 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.

Breast Thermogram Interpretation: Standardized interpretation guidelines in thermal breast imaging have been utilized since the adoption of the 20 point TH interpretation and classification system in the early 1980's. This system has been continually updated as ongoing research has dictated. Many large-scale studies performed over the last three decades, 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 qualitative and quantitative analysis of thermal breast images. The 20 point TH interpretation and classification system is the accepted standard in thermal breast imaging analysis.

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

- Imaging facility address and phone number
- Patient name and age
- Date of examination
- Clinical data
- Symptomatology

- Relevant thermographic findings
- Impression
- Recommendations (if appropriate)
- Signature of qualified interpreter (either hand written or electronically processed)

CLINICAL THERMOGRAPHY EDUCATION GUIDELINES –

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

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.

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.

Breast Thermologist: Extended training in breast thermography is strongly recommended for doctors who are intending on interpreting thermal breast images. This level of education commonly exceeds the information covered on thermal breast imaging that is found 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.

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.

SUMMARY –

The guidelines in this document are designed to assist practitioners in the use of 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.

We encourage professional discourse regarding any area(s) in this document that come into question. Since the authors based their recommendations primarily from the available literature base, it becomes the responsibility of dissenting individuals to take the initiative to establish a research base from which changes could be made. Justification for such changes must be made available in the form of research papers published in the peer-reviewed literature. It is only through published research that significant advances in clinical thermal imaging can occur.