

**Guidelines for Neuro-Musculoskeletal
Infrared Medical Thermology & Sympathetic Skin Response (SSR) Studies**

General Statement:

This guideline was prepared by members of the American Academy Of Thermology (AAT) as a guide to aid the performance of medical infrared imaging in evaluating patients with neuro-musculoskeletal (NMSK) complaints. It implies a consensus of those substantially concerned with its scope and provisions. This AAT guideline may be revised or withdrawn at any time. The procedures of the AAT require that action be taken to reaffirm, revise or withdraw this guideline no later than three years from the date of publication. Suggestions for improvement of this guideline are welcome and should be sent to the executive director of the American Academy of Thermology. No part of this guideline may be reproduced in any form, in an electronic retrieval system or otherwise, without the prior written permission of the publisher.

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Statement Of Need

Pre-existing vasomotor tone and vasomotor capacitance plays a significant role in thermoregulation, clinical symptomatology and manifestations of systemic illness. Infrared Thermal Imaging is the only non-invasive technology available to image and map microcirculatory shunting (vasomotor instability) associated with these disorders. It can play an important role in clinical diagnosis and may be helpful distinguishing between central and peripheral changes affecting the sympathetic nervous system. Infrared SSR imaging may also be valuable to document drug induced symptoms and paradoxical responses to sympathetic and peripheral nerve blockade.

There are numerous musculoskeletal conditions whose diagnosis and treatment would be aided and abetted by infrared SSR that are not necessarily of autonomic origin as well. Ranging from thoracic outlet syndrome, fibromyalgia, and small fiber peripheral neuropathy to sports injuries, inflammatory arthritis, and over use syndromes, these conditions often are lacking in objective diagnostic gold standards. Neuro-musculoskeletal medical thermology can play an important role in helping to delineate each of these conditions like no other testing modality can.

Other technologies like PET scan, MRI, Spectroscopy, Electrodiagnostics or EEG do not provide the same information offered by Medical Thermal imaging. The clinical application of Infrared Thermal and SSR imaging may be instrumental in understanding the pathophysiology associated with these changes and improve patient outcomes.

The mission and bylaws of the American Academy of Thermology support the incorporation of thermal imaging into clinical medicine. The AAT recognizes a current and ongoing need to promulgate CME in the science and methods of thermal imaging and the clinical application of heat asymmetry patterns obtained from thermal imaging among both physicians and thermal technologists.

Purpose:

Infrared NMSK and SSR evaluations are performed to provide an overview of the location, extent and severity of sympathetic skin response abnormalities. When abnormalities due to vasomotor/sudomotor dysfunction occur there are associated changes in skin galvanic impedance and skin temperature. Skin galvanic impedance changes map closely with skin temperature. In physics, this is explained by the fractal nature of infrared waves and their relationship to resistance and conductivity. The NMSK and SSR evaluation can be performed from the cranium to the base of the spine (inclusive of all segments) and torso to the extremities, extended to the fingers and toes.

Common Indications:

Some of the common indications for performance of infrared SSR and NMSK head, neck, spine and extremity imaging include:

- Evaluation or follow-up of patients with known or suspected vasomotor instability.
- Assessment of patients with presumptive Complex Regional Pain Syndrome (CRPS) Type I or II - formally known as Reflex Sympathetic Dystrophy (RSD), Thoracic Outlet Syndrome, Vaso-motor Headache and Barre'-Leiou Syndrome.
- Pre-procedure assessment for the planning of interventional therapeutics.
- Follow-up to determine the technical adequacy of surgical intervention, i.e., sympathetic block, sympathectomy, peripheral nerve stimulator implantation and/or spinal cord stimulator placement.
- Follow-up to detect improvement, progression or spread of disease, which may reflect the change in condition.
- Evaluation of vasospastic disorders, rheumatic inflammation, and unexpected post-operative or post-fracture pain.
- Evaluation of sports injuries, tendinopathies, ligamentous strain, and persistent or aberrant soft-tissue pain.
- Evaluation of somato-autonomic and visceral-autonomic responses which may be present secondary to acute trauma or disease.
- Evaluation of other disorders associated with autonomic dysfunction such as shoulder-hand syndrome.
- Evaluation of non-myelinated neuropathies (small fiber neuropathies).
- Mapping of the extent of vasomotor instability to guide sympathetic response generator identification.

- Mapping of the location of vasomotor instability for impairment rating purposes.
- Confirmation of diagnostic inclusion criteria for clinical diagnostic purposes.
- Confirmation of diagnostic inclusion criteria for research purposes.
- Documentation for medical and medicolegal expert purposes.

Contraindications and Limitations:

Contraindications for extremity and spinal infrared SSR imaging include the following:

- Presence of casts, bandages or other technical factors that preclude the ability to expose skin to a temperature equilibration environment.
- An uncooperative patient

Guideline 1: Patient Communication and Preparation:

Communication:

- 1.1 The laboratory's medical director should ensure that the patient understands the medical necessity for performing Infrared NMSK and SSR imaging.
- 1.2 The laboratory's medical director should ensure that any patient questions and concerns about any aspect of the examination are responded to.
- 1.3 The laboratory's medical director should ensure that the patient is advised about risk factors and symptoms of vasomotor instability and associated pathophysiology and obtain informed consent either written or orally from the patient to proceed with infrared SSR imaging.
- 1.4 The laboratory's medical director should ensure that specific diagnostic, treatment or prognosis questions are referred to the patient's physician.

Preparation (exceptions should be noted in the record):

- 1.5 The patient should not have contact with any object if that body part is being imaged. Cotton garments may be worn to cover breast or genital areas when they are not under study with the understanding that the genital area and buttock should be exposed as much as possible for imaging.
- 1.6 The patient should shower or bathe the morning of the test to ensure that the skin is as clean as possible. The patient should avoid hot water exposure to the skin for at least two hours prior to the test.

- 1.7 The patient should avoid placing any material of any kind on the skin, such as any skin lotions, sun screens, deodorants, preparations, moisturizers, liniments, makeup, hair spray, hair cream, topical analgesics, etc. the day of the exam.
- 1.8 Nicotine and caffeine products should be discontinued by the patient 4 hours prior to imaging.
- 1.9 The patient should wear loose clothing to the test; avoid anything binding against the skin; avoid support undergarments or pantyhose. The patient should not wear jewelry, preferably including rings if the hands are to be examined (exceptions are made for rings which cannot be removed or jewelry which the patient chooses not to remove for personal reasons).
- 1.10 To the extent possible discontinue the use of medical appliances such as braces, neoprene wraps, Ace bandages etc. on the day of testing.
- 1.11 Avoid massage, skeletal manipulation, acupuncture, physical therapy, dry needling, moxibustion, occupational therapy, saunas, extended sun exposure, the use of TENS or electric muscle stimulation units, laser therapy, or ozone therapy 24 hours prior to imaging. Electrodiagnostic testing should be avoided for 24 hours prior to imaging. Exceptions should be noted in the record.
- 1.12 Whenever possible steroids, sympathetic blockers, vasoactive medications, opiates and transdermal patches should be avoided for 24 hours prior to testing (15-19 hours minimum). Exceptions should be noted in the record.
- 1.13 When Cold Stress examinations are being performed, medications that are not medically necessary and that alter sympathetic function should be avoided for at least 24 hours prior to testing.
- 1.14 In the absence of extenuating circumstances, for original diagnostic studies, sympathetic and neurolytic blocks should be avoided for 3 days prior to testing.
- 1.15 Peripheral nerve implants and spinal cord/dorsal column stimulators should be turned off 4 hours prior to testing.

Guideline 2: Patient Assessment

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

- 2.1 Obtain a complete, pertinent history by interview and/or review of the patient's medical record. A pertinent history includes:

- a. Current medical status, especially regarding pain and vasomotor instability.
 - b. Presence of any signs or symptoms of allodynia or hyperalgesia in association with sudomotor, vasomotor, or other autonomic dysfunction. A symptom diagram should be completed (ie: pain, numbness, tingling, etc).
 - c. Relevant risk factors for inflammation or vasomotor instability: prior history of RSD or CRPS, trauma, fracture, repetitive use, vibration syndrome, peripheral neuropathy, spinal pathology, radiculopathy, vasomotor headache, odontalgia, rheumatic illness, recent surgery, cardiovascular disease, hypertension, diabetes, peripheral vascular disease, coagulopathy, birth control pill use, hypothyroidism or infection.
 - d. Pathology/Laboratory investigation values.
 - e. Current medication or therapies.
 - f. Results of other SSR, thermographic or vascular studies.
 - g. Results of prior autonomic, sympathetic or vascular interventions.
 - h. Results of other relevant anatomic or physiologic studies (such as CT, MRI, Diagnostic Ultrasound, and electromyography).

2.2 Complete a limited, focused, detailed or extensive physical examination, which includes assessment of all structures under study. Inflammation, tender points, erythema, trophic changes, vasomotor or sudomotor changes, neurological symptoms, and possible pain generators should be documented.

Guideline 3: Examination Guidelines

3.1 Passive Medical Thermology measures and maps the degree and distribution of IR thermal emission. Skin temperature is largely under the control of the autonomic nervous system and bilateral symmetry is expected through-out the body. Asymmetric IR emission of 1°C or greater can be indicative of SNS dysfunction or pathology in a properly cooled subject.

Infrared evaluations do not test structure, but rather correlate to sympathetic nervous system physiology. Therefore, when structural injury is suspected additional radiographic imaging or diagnostic studies may be indicated to better define the diagnosis.

Due to the complex nature and etiology of painful conditions associated with skin temperature asymmetry patterns, only those doctors trained in the proper techniques required to perform and interpret medical infrared studies should do so. When present, the pattern of asymmetry discovered by the examination should guide the treating physician in determining the source or generator of the abnormality. Both responses to treatment and additional testing may still be required to complete this task.

3.2. The following minimum specifications should be incorporated into the design of infrared hardware and software systems. These specifications are considered to be

minimum requirements for an IR system and are intended to speak to the design of modern infrared imaging equipment that is considered commonplace today.

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

In order to discuss minimum specifications certain some assumptions have to be made. While recognizing that individual circumstances will vary for the purposes of this document, lens FOV is 25 degrees, patient to imager distance 3-8 feet (as needed to allow the region of interest to fill approximately 75% of the image) and lens quality is satisfactory to the vast majority of observers.

- Emissivity set to 0.98 (human skin).
- Image detector spectral bandwidth: typically, 8 to 14 microns (micrometers).
- Preferred Absolute detector resolution of \geq 640 X 480 coupled with a suitable microbolometer and lens. Most modern medical imaging systems today utilize uncooled focal plane array detectors found in the 320 X 240 sensor range or higher. When systems with 320 X 240 sensors are coupled with a high-quality microbolometer, lens and compensatory software or firmware innovations they can approach the image quality, spatial resolution and spot measurement requirements found in 640 X 480 systems.
- Min. measurable spot size is 2.1x2.0 mm (3x3 or 9 pixels) at 40 cm distance.
- Spot resolution quality at 8 feet (2.4 meters) equivalent to \leq 1 sq. mm at 40 cm from the detector(s).
- Spatial resolution quality at 8 feet (2.4 meters) equivalent to \leq 2.6 mRad IFOV (Instantaneous Field of View) at 40 cm minimum focus.
- Thermal sensitivity of \leq 50 mK NETD (Noise Equivalent Temperature Difference) @ 30°C.
- Ability to perform accurate quantitative differential temperature analysis with a precision of $\leq \pm 0.05$ °C (50mK).
- Repeatability and precision of $\leq \pm 0.05$ °C (50mK) detection of temperature difference. The repeatability of a differential measurement must be in the presence of +/- 3 NETD (6 sigma - 99.9% defect free mfg. standard).
- Thermal drift (caused by internal heating of equipment during normal operation or by changes in external ambient temperature) to be strictly controlled by calibration to a known temperature standard if necessary for the study under consideration.

- Maintenance of detector uniformity and correction via calibration to a known temperature standard.
- Ability to render images in hi-resolution color and grayscale.
- High-resolution image visual display for interpretation.
- If video mode is used, it may incorporate real-time image focus and capture capability. While 10Hz, 20Hz, and 30Hz frame rates are capable of real-time imaging, having faster capability is preferred (i.e.: 50Hz). For temperature analysis, radiometric video files are preferred.
- Precision Autofocus is recommended.
- Imager temperature range set to cover temperatures within the range of human emissions (20-45 °C).
- Ability to archive images for future reference and image comparison at same patient positioning and distance from the imager.
- Software manipulation of the images should be maintained within strict parameters to ensure that the original qualities of the images are not compromised.
- Imaging software capable of identifying areas of temperature calculations and locations for reporting

Appropriate infrared SSR instrumentation, which includes real-time display, electronic static image capture, storage, post-capture annotation or hard copy documentation capabilities, should be utilized. Contact thermology devices that utilize single or multiple probes or sheets of thermally-sensitive liquid crystals for breast thermographic analysis are considered obsolete considering the current advances in non-contact digital infrared imaging. Thermographic scanning systems that cannot acquire and display thermal differences of 0.05°C are also to be considered obsolete for medical purposes.

3.3 Environmental Controls:

All studies should be performed in a laboratory where ambient temperature is controlled, free from drafts and where there is no exposure to infrared sources that may result in heating. The imaging room should be comfortably cool to allow for pull-off of superficial heat which may produce artifact from the skin. Mirrors, glass and other reflective surfaces should not be placed in the imager field of view.

The IR imaging suite should maintain a steady state 19° to 25° (± 1°C) throughout testing. In cases where patients are being evaluated for sympathetic dysfunction (RSD/CRPS I or II) 20°C (± 1°C) or lower is preferred. Unless a cold stress exam that does not rely on cold ambient temperature is intentionally being done and recovery time is monitored then no extraneous thermal stresses should exist. Irrespective of what method is employed to perform the cold stress study each laboratory should validate that its protocol is indeed a cold pressor test.

3.4 Ventilation systems should be designed to avoid airflow onto the patient imager, and natural convection kept at or below 0.2 m/s. The patient should be standing on a carpeted floor. Exposing the patient's feet may assist with equilibration, even with upper extremity examinations. The patient most commonly undergoes equilibration in a standing, sitting, or supine position however different positioning as determined by the interpreting thermologist for the study being performed may be utilized as well. Standard fluorescent lights are appropriate. The humidity of the room must also be controlled such that there is no moisture build up on the skin, perspiration, or vapor levels that can interact with radiant infrared energy. Relative Humidity below 70% is generally acceptable.

3.5 Infrared studies performed in a steady state can be accomplished with one set of images, providing the patient equilibrated for 15-20 minutes prior to imaging in a cool environment 19°C-25°C (\pm 1°C). If studies are intended to be used for medical or medical-legal purposes however then more than one set of images taken at 15 minute or pre-defined recovery time monitoring intervals is advised.

3.6 If Infrared studies are performed in an environment where the ambient image suite temperature is greater than 21° C, or if the thermologist desires to assess SSR, recovery time, reproducibility, or progressive change with prolonged exposure to cold ambient temperature, then repeating the study one to two times at fifteen minute or pre-defined recovery time monitoring intervals should be performed. In post sympatholytic blockade studies or in patients who are undergoing monitoring solely for cold water autonomic functional stress testing, post blockade equilibration is not required and imaging suite temperature is not as critical.

3.7 A standard exam protocol for each segment evaluated should be used. This will frequently require multiple infrared windows with different points of focus (arm, forearm, wrist, hand, thigh, leg, foot, cervical, thoracic and lumbosacral spine). Each point of focus should include anterior, posterior, medial, lateral oblique views. Contralateral and AP views should be equidistant and fill the image screen. When possible, it is recommended that the contralateral extremity images should be captured in the same image. Additional images obtainment may be required for patients with specific, unique circumstances.

3.8 NMSK and SSR studies that wish to highlight vasomotor mapping and that are prepared for interpretation without post-acquisition radiometric image manipulation typically employ palettes of no less than ten colors and are formatted at 1°C per color. Many laboratories have found it beneficial to use a temperature span of more than 10°C (the 1°C per color format, however, is retained). The intent of using a broader temperature span is to ensure that no relevant radiometric image information is lost at the extremes of temperature maxima or minima across a wide range of regions of interest.

While vasomotor mapping for SSR studies and neuropathic pain may be more readily visible with a 1°C per color palette, gradient palettes that span less than 10°C are also commonly employed in NMSK studies that have a limited focus or region of interest and where visualization of vasomotor maps may not be necessary for that study's intended

use. None the less it is the clinician's the interpreting thermologist's responsibility to make sure that the absence of a vasomotor map is not clinically relevant for each study performed where the same is omitted.

The interpreting thermologist must also ensure that the range of temperature maxima and minima utilized does not mask (or effectively filter out) any radiometric data.

Laboratories must establish individual protocols for acquisition that do not exclude relevant findings. Even when only one region of interest is studied as the temperature span becomes more restricted more explanation by the interpreting physician as to why a limited temperature span was utilized may be required.

Images should be taken and saved in radiometric file format at the highest resolution possible to help assure the best possible focus and analysis. All images should be available in both color and black and white JPEG (or similar) format to further assist in record keeping and interpretative report preparation.

3.9 The patient's physical and mental status is assessed and monitored during the examination, with modifications made to the procedure plan according to changes in the patient's clinical status during the procedure. Also, findings are analyzed throughout the course of the examination to assure that sufficient data is provided to the physician to direct patient management and render a diagnostic impression.

3.10 Evaluate the patient's physical and mental status prior to discharge. Additional discharge instructions may include a recommendation to schedule follow up appointment with their attending physician, and to resume all medication that may have been discontinued prior to the infrared SSR study.

Guideline 4: Review of the Infrared Thermology Examination (example templates are available for Members in the Knowledge Center within the AAT Member Portal)

4.1 The data acquired during the NMSK or SSR 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.

4.2 Record all technical findings required to complete the final interpretation so that the measurements can be classified according to the laboratory diagnostic criteria (these criteria may be based on either published or internally generated data, but must be internally validated regardless of the source). It is recommended that published or internally generated diagnostic criteria should be validated for each thermology system used. When validating medical infrared diagnostic criteria it is important to realize that equipment, operator, and interpretation variability is inherent to this process.

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

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

Guideline 5: Presentation of Exam Findings

5.1 Provide preliminary results as provided for by internal policy based on examination findings.

5.2 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.

5.3 Alert laboratory medical director or appropriate health care provider when immediate medical attention is indicated.

Guideline 6: Preparation and Storage of Exam Findings

6.1 Images should be presented to the interpreting physician for use in analysis and archival purposes. Images should be available radiometric image format and may also be exported in a convertible format such as JPEG or DICOM. A color-to-temperature Thermal Scale must accompany each image. All studies should be time and date stamped and include demographics within the image in a location that does not interfere with image analysis.

6.2 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 7: Exam Time Recommendations

High quality and accurate results are fundamental elements of the infrared SSR study. A combination of direct and indirect exam components is the foundation for maximizing exam quality and accuracy. Recommended time: 60 minutes.

7.1 Indirect exam components include pre-exam procedures:

- a) obtaining previous exam data, completing pre-exam paperwork,
- b) exam room and equipment preparation and
- c) patient assessment, history, and positioning (Guideline 1 & 2).

- 7.2 Post exam procedures include:
- a) initial report preparation consisting of compiling, processing, and reviewing data for preliminary and/or formal interpretation (Guidelines 3 and 4),
 - b) patient communication (Guideline 2),
 - c) examination charge and billing activities where appropriate.
- 7.3 Direct exam components include equipment optimization, patient positioning throughout the exam, and the actual hands-on examination process (Guideline 3).

Guideline 8: Reporting

8.1 A Medical Director's report should be prepared within 24 hours of the study. As part of their protocol imaging facilities should consider sending each patient a summary report within 30 days of the thermographic examination.

8.2 Report layout: The body of the Infrared NMSK or SSR Thermographic report should clearly state that laboratory procedures that follow a peer-reviewed, internationally accepted guideline was utilized. 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, along with any pertinent normal findings, noted. Findings should be reported as asymmetric skin response when done as a cold stress sympathetic skin response study. Findings include asymmetry of ≥ 1 degree Centigrade in $\geq 25\%$ of the surface area of any individual region of interest or localized hot spots. Other findings include call-outs such as venous tortuositites.

Thermographic Impressions include classification according to an accepted naming system or summarization of the Thermographic Findings. When recognized patterns (thermal signatures) are seen due to the clustering of findings, they should be noted.

Thermographic Impressions may include the description of that pattern (for example, a sympathetic skin response asymmetry pattern is seen in an L5 distribution) however care should be taken not to make any statements about clinical diagnosis or generator of that signature in this section of the report.

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 the diagnosis, 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.

Neither Clinical nor Thermographic Impressions are not to be included in the Thermographic Findings section.

Guideline 9: Continuing Professional Education

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

Technologist certification is considered the standard of practice for infrared and SSR technology. It indicates an individual's competence to perform neuro-musculoskeletal infrared studies at the entry level.

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

All Thermologists are expected to keep current with:

9.1 Advances in diagnosis and treatment of pain syndromes with and without sympathetic nervous system dysfunction (vasomotor instability).

9.2 Changes in infrared and SSR examination protocols or published laboratory diagnostic criteria.

9.3 Advances in infrared and SSR technology used for the extremity and spine examinations.

9.4 Advances in other technology used for neuro-musculoskeletal infrared and SSR examination.

Guideline 10: Emerging Technologies

10.1 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.

10.2 General industrial or personal thermal imagers that do not meet the specification guidelines contained herein are not intended for use in Medical Thermology. “Add-on” thermal imagers that plug into a cellular phone are, at present, not adequate for medical thermology imaging.

10.3 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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