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Guidelines for Neuromusculoskeletal Infrared Thermography Sympathetic Skin Response (SSR) Studies

American Academy of Thermology - AAT

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General Statement — This guideline was prepared by members of the American Academy Of Thermology (AAT) as a guide to aid the performance of medical infrared imaging in evaluating patients with neuromusculoskeletal complaints. It implies a consensus of those substantially concerned with its scope and provisions. The AAT guideline may be revised or withdrawn at any time.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.

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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 infrared imaging may also be valuable to document drug induced symptoms and paradoxical responses to sympathetic and peripheral nerve blockade.

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 neuromusculoskeletal 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 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.

INDICATIONS

Some of the common indications for performance of extremity and spine infrared SSR 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 planning of interventional therapeutics.
- Follow-up to determine technical adequacy of surgical intervention, i.e., sympathetic block, sympathectomy, peripheral nerve implantation and/or spinal cord stimulator placement.
- Follow-up to detect improvement, progression or spread of disease, which may reflect 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 viscero-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

1.1 The examining physician explains the medical necessity for performing neuromusculoskeletal Infrared SSR imaging

1.2 Responds to questions and concerns about any aspect of the examination.

1.3 Advises the patient about risk factors and symptoms of sympathetic nervous system dysfunction (vasomotor instability) and associated pain. Obtains informed consent either written or orally from the patient to proceed with infrared SSR imaging..

1.4 Refers specific diagnostic, treatment or prognosis questions to the patient's physician.

1.5 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 Shower or bathe the morning of the test to ensure that the skin is as clean as possible. Avoid hot water exposure to the skin for at least two hours prior to the test.

1.7 Avoid placing any material of any kind on the skin, such as any skin lotions, deodorants, preparations, moisturizers, liniments, makeup, hair spray, hair cream, topical analgesics, etc. for 8 hours prior to the examination.

1.8 Nicotine and caffeine products should be discontinued 4 hours prior to imaging.

1.9 Wear loose clothing to the test; avoid anything binding against the skin; avoid support undergarments or pantyhose. Do 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, occupational therapy, saunas, extended sun exposure, the use of TENS or electric muscle stimulation units. 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 always be recorded 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 contra-indications 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, rheumatic illness, 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. Erythemia, trophic changes, vasomotor or sudomotor changes, neurological symptoms, and possible pain generators should be documented.

GUIDELINE 3:
EXAMINATION GUIDELINES

3.1 Medical Infrared Thermography 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.

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 still need to be performed.

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 response to treatment and additional testing may still be required to complete this task.

3.2. The following minimum specifications should be incorporated in the design of infrared hardware and software systems. These specifications are intended to speak to the design of modern infrared imaging equipment that are considered commonplace today. They are not intended in any way reflect on systems used in the past.

• Emissivity set to 0.98 (human skin).

• Camera detector(s) response above 5 and below 14 microns

• Preferred Absolute detector resolution of > 640 X 480 coupled with a suitable 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 lens and software or firmware innovations they can approach the image quality, spatial resolution and spot measurement requirements found in 640 X 480 systems.

• Minimum measurable spot size is 2.1x2.0 mm at 40 cm distance (3x3 or 9 pixels).

• Spot resolution quality at 8 feet equivalent to ≤ 1 sq. mm at 40 cm from the detector(s).

• Spatial resolution quality at 8 feet equivalent to ≤ 2.6 mRad at 40 cm from the detector(s).

• Thermal sensitivity of ≤ ± 50 mK NETD @ 30 ºC.

• Ability to perform accurate quantitative differential temperature analysis with a precision of ≤ ± 0.05 ºC.

• Repeatability and precision of ≤ ±0.05 ºC 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).

• Changes in external ambient temperature to be strictly controlled at natural convection at or below 0.2 m/s.

• Thermal drift (caused by internal heating of equipment during normal operation or by changes in external ambient temperature) to be strictly controlled at natural convection at or below 0.2 m/s.

• Maintenance of detector uniformity and correction via calibration.

• Ability to capture images in hi-resolution color and grayscale.

• High-resolution image visual display for interpretation.

• Real time image focus and capture capability. While 10Hz, 20Hz, and 30Hz are capable of real time imaging faster capability is preferred (50Hz).

• Temperature range set to cover temperatures within the range of human emissions (20-45 ºC).

• Ability to archive images for future reference and image comparison at same patient positioning and distance from the camera.

• Software manipulation of the images should be maintained within strict parameters to insure that the original qualities of the images are not compromised

• Imaging software capable of identifying areas of 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.

3.3 All studies should be performed in a laboratory where ambient temperature is controlled, free from drafts and where there is no exposure to ultraviolet rays 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. used). The IR imaging suite should maintain a steady state 20° 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) is preferred. Unless a stress exam is intentionally being done no extraneous thermal stresses should exist.

3.4 Ventilation systems should be designed to avoid direct airflow onto the patient. The patient should be standing on a carpeted floor. Exposing the patient's feet may assist with equilibration, even with upper extremity examinations. Standard fluorescent lights are appropriate.

3.5 Infrared studies performed in a steady state 20° C (± 1°C) environment can be accomplished with one set of images, providing the patient equilibrated for 15-20 minutes prior to imaging. If studies are intended to be used for medical or medical legal purposes then more than one set of images however 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 either SSR or reproducibility and progressive change with increased exposure to the ambient temperature, then repeating the study one to two times at fifteen minute intervals should be performed. In post sympatholytic blockade studies or in patients who are undergoing solely cold water autonomic functional stress testing, equilibration is not required nor is the imaging suite temperature critical.

3.7 A standard exam protocol for each segment evaluated should be used. This will frequently require multiple infrared SSR 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 Neuromusculoskeletal studies typically employ color palettes of no less than ten colors and are typically formatted at 1°C per color. Many laboratories have found it beneficial to use palettes with greater than ten colors however the 1°C per color format should be retained.

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 recommendation to schedule follow up appointment with the attending physician, and to resume all medication treatment that may have been discontinued prior to the infrared SSR study.

GUIDELINE 4: REVIEW OF THE INFRARED THERMOGRAPHY EXAMINATION

4.1 The data acquired during the extremity and spinal infrared 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 thermography 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 required laboratory documentation of the study.

4.4 Alert medical director or other 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. Radiometric images in either radiometric image format or radiometric image convertible format such as JPEG or DICOM are acceptable.

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) clean up 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 Thermographic report should clearly state that laboratory procedures that follow a peer reviewed, internationally accepted guideline was utilized. The set of images obtained for study should be documented. If a standard protocol for reading images is used then this should be stated as well.

Thermographic Findings should be documented and any abnormalities 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 > 25% of the surface area of any individual region of interest and localized hot spots. Other findings include call outs such as venous tortuosities.

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 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 in this section of the report.

Clinical Impressions are not to be included in the Thermographic Findings paragraph but rather in a separately identifiable paragraph that speaks to the generator or etiology of those findings. Any discussion that is clinically relevant should be reserved for this paragraph.

GUIDELINE 9: CONTINUING PROFESSIONAL EDUCATION

Certification is considered the standard of practice for infrared and SSR technology. It indicates an individual's competence to perform neuromusculoskeltal infrared studies at the entry level. After achieving certification, all infrared technologists 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 neuromusculoskeletal infrared and SSR examination.

GUIDELINE 10: EMERGING TECHNOLOGIES

10.1 Technology is constantly being introduced that at times can challenge existing guidelines or that do not necessarily conform to currently accepted practices. These technologies can span the entire spectrum of sophistication and therefor require different adaptive responses. On one end of the spectrum there are innovations based upon generally accepted medical scientific methodology that have 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 Unless otherwise stated general industrial or personal thermal imaging cameras are not intended for use in medical thermology.

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 however 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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