INTRODUCTION

When the patient's presentation or the examination and its environment are not controlled, the diagnostic value of thermography suffers. Several internal and external factors have a significant effect on the examination's integrity and credibility. To enhance and assure the accuracy of thermographic studies, particularly serial examinations, it is essential to minimize the effects of these variables.

TAS's CBT (Computerized Breast Thermography) examination protocol consists of breast thermograms recorded according to strict examination criteria, using appropriate image capturing techniques, and interpreted by an objective procedure utilizing TAS's proprietary CBT software program. It incorporates the widely accepted interpretation system for breast thermograms, the Gautherie Interpretation Technique.

When the CBT examination protocol was first introduced in 1982 by TAS's founder, it was the first codified procedure that imposed various controls to breast thermography to maximize the integrity of the examination and provide comprehensive, meaningful breast cancer risk assessments. The principals underlying the CBT Protocol were embraced by the thermography community when the protocol was introduced, and those underlying principals continue in widespread use today.

The CBT examination was designed with several purposes in mind. First, and most important, to identify patients at high-risk for developing breast cancer. Second, to aid in the early detection of biological changes in the breast. Finally, to assist in the functional evaluation of breast pathology, and then to be used as an adjunct to other methods of breast examination, particularly MRI, Ultrasound, and physical examination.

To maximize thermography's benefits, women should receive a baseline CBT examination soon after achieving physiological equilibration (typically by age 27). If the thermogram is abnormal (positive), follow-up should proceed as recommended in the TAS Breast Thermography Evaluation Report. If the thermogram is negative, the second CBT is performed at age 30. Subsequent CBT examinations are routinely performed at least annually when the patient undergoes gynecological examination, which should include physical examination of the breasts.

If the first thermogram is abnormal (Th2 - Th5), a second examination should be performed three to six months after the first, to assure stability of the thermal patterns. A baseline MRI should be considered at age 30, especially if the first thermogram is abnormal.

TAS's CBT software program represents a major breakthrough in breast pathology detection, but the interpretive program by itself cannot obscure the errors inherent in improper testing procedures. The following examination protocol assures maximum accuracy of the recording of the thermogram and its interpretation, and should be adhered to as closely as possible. The reliability, accuracy and integrity of the thermographic examination can only be maintained if shortcuts are avoided. Proper patient scheduling, simple patient preparation requirements, attention to examination room conditions and camera positioning, and correct image capturing are all required to meet the rigid criteria for an accurate CBT examination.

Note that all other breast examinations or diagnostic modalities, including physical examination, must be performed only after the CBT examination has been completed, to eliminate spurious alterations of the thermal patterns of the breasts.

CLINICAL LAYOUT

Relatively small areas are required for patient cooling and evaluation; a typical examination room has proven to be generally acceptable. Sources of heat or cold which significantly affect the ambient environment of the cooling and examination rooms should be eliminated. High energy lights or office equipment, warm window areas, or drafts caused by heating or cooling equipment should be particularly avoided. If more than one room is used for cooling and/or examination, the rooms must be maintained at the same temperature, and transition from the cooling area to the examination room should be performed as quickly as possible.

The temperature of the cooling/examination room should be 68°F - 72°F. Note that temperature stability, not just the absolute temperature, is important. Thermograms performed in environments below 66°F or above 74°F are unsuitable for interpretation under the CBT requirements.

PATIENT PHYSICAL PROFILE

Proper patient scheduling and preparation prior to the test are necessary to assure adherence to the CBT requirements.

The phase of the patient's menstrual cycle at the time of the thermography examination is of particular importance. Hormonal changes during the menstrual cycle produce changes in the thermal characteristics of the breasts, which can result in serious errors. Examinations performed during pregnancy or these times should be rejected as unsuitable for interpretation.

Estrogen dilates blood vessels, so the patient’s estrogen level can have a profound affect on the thermal visualization of the breast’s underlying vascularity, resulting in misleading examination data. Estrogen level is significantly elevated during the week following menstruation; consequently, the CBT examination should not be performed during days seven through 14 of the patient’s menstrual cycle. The ideal time period is from ovulation to the onset of menstruation.

To reduce inaccuracies which might result from alterations in thermal signs due to the effects of Circadian Rhythm, the CBT examination should be performed in the morning hours.

Illnesses, with or without temperature elevation, may alter the normal thermal characteristics of the breasts; thus, patients suffering from colds, influenza, etc. should not be scheduled for a CBT examination.

PATIENT PRE-EXAMINATION PREPARATION

Patients must be instructed to follow the required CBT protocol prior to the test. These requirements have been established to maximize the accuracy of the test by eliminating various factors which could alter the thermal characteristics of the breasts.

Alcoholic beverages, coffee, tea or colas containing caffeine should not be consumed for twelve hours prior to the test. Hot or cold beverages should be avoided for at least one full hour before a CBT examination is performed.

If possible, aspirin, pain medications, vasodilators/constrictors and/or other similar medications should be avoided for 24 hours prior to the test.

Cigarettes should not be smoked for two hours prior to the CBT examination.

The CBT examination should not be scheduled within two weeks after the patient has been subjected to sunburn. Lotions or ointments should not be applied to the breasts for 24 hours prior to the test.

Physical exercises that might affect breast circulation should be avoided for 24 hours prior to the CBT examination.

CBT PATIENT COOLING (EQUILIBRATION)

Thermal equilibration is the process under which the patient's skin achieves thermal stability in a temperature-stabilized environment. Although sometimes required to increase the skin temperature, it is generally a cooling procedure. A ten to fifteen minute period of thermal equilibration is absolutely essential to the accuracy of the thermographic examination. Please, no shortcuts here - proper equilibration cannot be overlooked or avoided!

Static and Fan cooling are two methods used in the cooling of patients. Fan cooling should be avoided in favor of the more acceptable static cooling, as fan cooling has increased potential for both asymmetrical cooling and over-cooling.

1. Static Cooling: The patient disrobes from the waist up with her hands placed slightly above her hips and with the arms held away from the body. This position is maintained for ten minutes minimum with the patient either standing, or seated on a stool. Cooling for less than ten minutes invalidates the CBT examination.

2. Fan Cooling: The patient disrobes from the waist up, stands five to six feet from a slowly rotating 20" area fan, and is then positioned such that the air-flow from the fan is directed at the sternum. The air flow direction is important to avoid asymmetric cooling. Cooling time using this method should be approximately two minutes; at, or before this time, the nipples usually become erect. Note that asymmetrical cooling yields thermal asymmetry, while over-cooling causes unstable thermal patterns on the breasts.

It is extremely important that the breasts are not touched during the cooling period by either the patient or examiner.

PEFORMING THE EXAMINATION

Patients are scheduled so as to conform to the requirements of the test (i.e., proper phase of menstrual cycle, etc.) and are informed, prior to the scheduled examination, of the preparations required for the examination.

When the patient arrives for her examination, she is asked to disrobe from the waist up, assume the position appropriate to the cooling method being utilized, and undergo equilibration. Following the cooling procedure, the thermogram should be recorded in accordance with instructions and training.

INTERPRETING THE THERMOGRAMS

Analyzed properly, breast thermography can make a significant contribution to the overall evaluation of possible breast pathology. The information provided by the CBT regarding the thermovascular patterns and gross thermal abnormalities will inform the clinician which patients require more careful and continued evaluation. Proper interpretation of breast thermograms is difficult.

Thermograms are by their very nature difficult to analyze and interpret and generally require a highly trained individual to perform the task. A brief glance at the thermogram provides instant information regarding the thermal symmetry of the breasts only...nothing else!!! To accurately interpret thermograms requires careful evaluation of twenty individual signs. Do not attempt analysis of the thermogram without prior training as misinterpreted results can be misleading and inaccurate. Most of the criticism regarding breast thermography is a direct result of interpretative inaccuracies caused by untrained individuals rendering subjective analyses of thermograms.

Thermograms are objectively interpreted using TAS's proprietary breast thermography evaluation software. The program is interactive and forces objective responses to several questions designed to evaluate the thermal characteristics of the breasts. More than twenty different signs are evaluated during the process of CBT analysis.

The generated report summarizes information regarding the observed thermal signs and then provides detailed explanations of the interpreted findings with recommended follow-up instructions. When the CBT result is received by the physician, it should be correlated with physical and other diagnostic findings, as well as with the results of previous CBT's.

SUMMARY

When performed in conformance with the above protocol, the CBT examination is an extremely valuable adjunct for the earliest detection of possible breast pathology. The examination is safe, easy to perform, and has patient acceptance; however, certain minimum requirements must be observed in order to enhance its integrity. For certification as a CBT examination, the following must be adhered to:

1. Cooling/Examination Room Conditions. Maintain a constant ambient temperature between 68°F - 72°F.

2. Patient Thermal Equilibration. If static cooling is used, the minimum cooling time must be ten minutes. For fan cooling, two minutes minimum.

3. The patient must not be menstruating, ovulating or pregnant. Ideally, perform the test during the first week following menstruation.

4. No drugs or other substances that might alter the thermal characteristics of the breast should be used immediately prior to testing.

All other breast examinations or diagnostic modalities must be performed only after the CBT examination has been completed. The breasts should not be touched by the patient or physician from the beginning of the cooling period until after the CBT examination has been performed.

Follow these criteria avoiding the temptation to use shortcuts, take care to acquire the most suitable thermogram for evaluation, and your patients will enjoy the benefits inherent in early detection of breast pathology.