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A review of thermography as promising non-invasive detection modality for breast tumor

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Abstract

From the last 1.5 decades of complying with the strict standardized thermogram interpretation protocols by proper infrared trained personnel as documented in literature, breast thermography has achieved an average sensitivity and specificity of 90%. An abnormal thermogram is reported as the significant biological risk marker for the existence of or continues development of breast tumor. This review paper further discusses the performance and environmental requirements in characterizing thermography as being used for breast tumor screening under strict indoor controlled environmental conditions. The essential elements on performance requirements include display temperature color scale, display temperature resolution, emissivity setting, screening temperature range, workable target plane, response time and selection of critical parameters such as uniformity, minimum detectable temperature difference, detector pixels and drift between auto-adjustment. The paper however does not preclude users from potential errors and misinterpretations of the data derived from thermal imagers.

Keywords: Thermogram; Breast tumor; Angiogenesis risk marker; Infrared; Noninvasive; Protocols

1. Introduction

Thermography is a non-invasive, non-contact skin surface temperature screening method that is economic, quick and does not inflict any pain on the patient. It is a relatively straightforward imaging approach that detects the variation of temperature on the human skin surface. Thermography is widely used in the medical arena [5,7,9,12,14,16,17,21,32,35,47–52,55–59,63,68,70,71,73,76,80,85]. These include the detection of breast cancer, which is the refocus of many biomedical researches in recent years [1]. The earliest breast thermogram was reported by Lawson [37–40]. He observed that the venous blood draining the cancer site is often warmer than its arterial supply. However, these measurements have never been confirmed by others and the findings might thus have been questionable. Thermograms alone however will not be sufficient for the medical practitioner to make a diagnosis. Analytical tools such as bio-statistical methods and artificial neural network are recommended to be incorporated to analyze the thermogram objectively [30,48,52,55–57,60,87]. Notice that these approaches may improve the interpretation of thermal images which may lead to a higher diagnostic accuracy of infrared thermography, but these methods for analysis are not more objective than any other highly accurate and precise measurement. With the rising use of thermal imaging, there is a need to have regulations and standards to provide accurate and consistent results. The standards are mainly based on the physics of radiation and thermoregulation of the body.

Like in many other developed countries, breast cancer is the main cancer afflicting women in Singapore today. Every day, 3 women are diagnosed with breast cancer here and every week 5 women die in this part of the world from malign breast disease. But breast cancer is a highly treatable disease, with 97% chance of survival if discovered early. Application of thermography in suspected malign breast disease holds great promise in detecting early cancer [35]. Gros and Gautherie [22] reported a large scale study comprising 85,000 patients screened. Cul-

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mination of the data resulted in a 90% sensitivity and 88% specificity for thermography [22,41,74] when compared with clinical mammogram examination. In brief, a quick review of 15 large scale studies from 1967 to 1998, breast thermography revealed an average sensitivity and specificity of 90% [31,61, 64,82,83]. The researchers summarized the study by stating that "the findings clearly support that early identification of women at high risk of breast cancer based on the objective thermal assessment of breast health results in a dramatic survival benefit" [6,18,29].

Keyserlingk et al. [35] observed that the tumor diameter missed in thermogram was 12.8 mm and that in a mammogram was 16.6 mm. They conducted a study using a retrospective case-control design to investigate the potential adjuvant benefit that could be gained from infrared imaging in a multi-modality diagnostic setting. This study was classified as a level-four evidence because interpretation of both the index test and the comparators were not blinded, and it is unclear what information was available to those interpreting the reference standard. However, the authors themselves have been aware of the restrictions of their study and have expressed the need for further investigations in a controlled, prospective manner. Keyserlingk et al. [35] reported that the sensitivity for the detection of ductal carcinoma by clinical examination alone was 61%, by mammography alone was 66%, and by infrared (IR) imaging alone was 83%. When suspicious and equivocal mammograms were combined the sensitivity increased to 85%. A sensitivity of 95% was obtained when suspicious and equivocal mammograms were combined with abnormal IR images. However, when clinical examination, mammography, and IR images were combined, a sensitivity of 98% was achieved [35]. Both IR imaging and mammography technologies are of the complimentary nature. Neither used alone is sufficient, but when combined, each may counteract the deficiencies of the other. It also seems evident that a multimodal approach would serve the screening best for other diseases such as orthostatic disease in children [75] or imaging of Raynaud's phenomenon [46], respectively. A combination of clinical examination, mammography and IR imaging may provide the greatest potential for breast conservation and survival. Thermography may have the potential to detect breast cancer 10 years earlier [19,35] than the traditionally golden method—mammography. However, due to inconsistencies in diagnosis from breast thermograms, it has not been commonly used and is not regarded as a reliable adjunct tool to mammography in Singapore currently. This review paper aims to achieve a high level of consistency in the use of breast thermography by providing some pointers to its performance evaluation.

The main components recommended to characterize thermal imaging as a potential complimentary tool for breast cancer detection include:

- Thermal radiation theory.
- Preparation of patient.
- Examination environment.
- Standardization of thermal imager system.
- Image capture protocol.
- Image analysis protocol.
- Reporting, archiving and storing.

2. Thermal radiation theory

2.1. Planck radiation law

Any object whose temperature is above absolute zero Kelvin emits radiation at a rate and with a distribution of wavelengths. This wavelength distribution is dependent on the temperature of the object and its spectral emissivity, $\varepsilon(\lambda)$. The spectral emissivity, which may also be considered as the radiation efficiency at a given wavelength, is in turn characterized by the radiation emission efficiency based on whether the body is a blackbody, grey body or selective radiators. The blackbody is an ideal body. It is a perfect absorber that absorbs all incident radiation and is conversely a perfect radiator. This implies that a blackbody absorbs and emits energy of the maximum theoretically possible at a given temperature. Within a given wavelength:

- $\varepsilon = 1$ for blackbody.
- $\varepsilon = \text{constant} < 1$ for grey body.
- $0 \leqslant \varepsilon \leqslant 1$ for selective radiator.

The radiative power (or energy) and its wavelength distribution is given by Planck radiation law [10]:

$$W(\lambda, T) = \frac{2\pi hc^2}{\lambda^4}\left[\exp\left(\frac{hc}{\lambda kT}\right) - 1\right]^{-1} \text{W cm}^{-2}\,\mu\text{m}^{-1} \quad (1)$$

or in number of photons emitted:

$$P(\lambda, T) = \frac{2\pi hc}{\lambda^4}\left[\exp\left(\frac{hc}{\lambda kT}\right) - 1\right]^{-1} \text{photons s}^{-1}\,\text{cm}^{-2}\,\mu\text{m}^{-1} \quad (2)$$

where:

h (Planck's constant) $= 6.6256 \times 10^{-34}$ J s.
c (velocity of light in vacuum) $= 2.9979 \times 10^{8}$ ms^{-1}.
k (Boltzmann's constant) $= 1.38054 \times 10^{-23}$ W s K^{-1}.
λ = wavelength μm.
T = temperature K.

Human skin emits IR radiation mainly in the range of 2–20 μm wavelength and with an average peak at 9–10 μm [6]. With the application of Plank's equation and Wien's law, it is found that approximately 90% of the emitted IR radiation in humans is in the longer wavelengths (6–14 μm).

2.2. Heat transport mechanism of skin and physiology of thermal signatures

The skin is the largest organ in the human body and helps to maintain the core body temperature within a narrow range by modifying heat transfer processes from the body and to the environment and vice versa (thermoregulation). Heat transport to, within and from the skin utilize all three mechanisms of heat transfer which are conduction (through tissue layers) convection (through the vascular system) and radiation (mainly to and from the environment). Heat transfer is coupled with complicated physiological processes, including blood circulation, sweating, metabolic heat generation, and, sometimes, heat dissipation via hair or fur above the skin surface. The thermal properties of skin vary between different layers; even within the same layer, there exists large non-homogeneity and anisotropy due to the presence of blood vessels. Both the physiological processes and thermal properties of skin are influenced by a variety of factors such as temperature, damage, pressure, and age etc. The study on the heat exchange processes of the body from the deep tissues to the skin and subsequently to the environment may provide information on pathology [49,54–57].

For modeling of a heat transfer mechanism in skin, it is treated as a layered—"laminated"—material, whose overall properties are assembled in a composite manner. Its thermomechanical behavior is simplified to be a 'sequentially-coupled' problem so that the mechanical and thermal properties are independent of each other. Initially, for the simplest case, the skin is regarded as a single-layer material, whose thermal response using bioheat equation can be solved in closed form without computational assistance: although much simplified, this provides an essential calibration tool for more complex numerical analysis [56,88]. One can additionally modeled the heat transfer by hair above skin, which incorporates sweating effects. For more complicated cases, where the skin tissue is regarded as a multilayered material, computation with finite difference scheme and finite element analysis is needed. This allows investigation of the influence of different parameters on the thermomechanical response, assessing their relative contributions, with some interesting results. For example, the stratum corneum layer (the surface layer of skin) is incredibly thin compared to the rest of the skin thickness, but it dominates the thermomechanical response; if it is neglected (because of its thickness), as often performed by many researchers, the heated response has quite a different character [88].

2.3. *Infrared thermography*

Infrared thermography was originally developed for military purposes. In recent times, its applications have been extended to engineering applications. Thermography is used as a technique for medical imaging for more than 50 years. IR thermography makes use of a thermal imager to detect the IR radiation and measure the heat pattern of the object surface or human skin with emissivity of nearly 1.0 [50,58,69]. It is passive in nature as it will not emit any harmful radiation or subject the patient to any risk. Hence, many consider thermography as a physiological test (i.e. normal and abnormal physiologic functions of the nervous, vascular and muscular systems and local inflammatory processes are imaged) compared to anatomical tests such as Computed Tomography (CT) imaging, X-rays or mammography. In addition, it is a non-contact screening process, making it a hygienic procedure. Other advantages of thermography include high portability and real time imaging, which made it possible for the data to be recorded in computer for processing. Clinical thermogram resembles the anatomic area under study which represents the patient's skin surface temperatures creating thermal patterns.

When measured with an infrared radiometer, the temperature of objects with a curved surface such as female breast is however also dependent on the angle of view since the emissivity values of an object will change when infrared measurements are taken at various angles. The porcine eye was used by Hatcher and D'Andrea [23] as it was readily available. Two methods for determining the emissivity of the porcine eye were used including the black tape method (Scotch 33–0.95 emissivity) and a Cole-Parmer Thermistor Thermometer. Both methods yielded the same results for measurements at zero and at 90 angles, respectively. An error factor of about 15% was produced for measurements at 0° while 20% error exists for measurements at 90° and these errors are enough to give an inaccuracy of the collected data. The effect of physical shape of an object thus affects the accuracy of thermography by giving different values of emissivity at different measuring locations. The errors produced by the curvature factor are significant and therefore it should always be considered during breast screening.

The imager converts the invisible thermal energy to electrical signals in order to display the temperature profile of the subject. The temperature is an illustration of many colors each of which indicate a particular temperature. It is worthy to note that however false colors do not represent a particular temperature. They just indicate a threshold of temperature, meaning a false color band is representing all temperature values above the threshold and below the threshold of the adjacent color band. Fig. 1 shows a basic set-up of a typical thermal imager (by courtesy of www.spiritsolutions.us). The selected target distance between the imager and the target should optimize the resolution of the color display of heat patterns. While IR radiation is invisible to human eye, it can be detected and displayed by special IR cameras. The thermal imager is coupled with computer software for the interpretation of the IR images (thermal maps). As a diagnostic tool, thermography has several advantages in clinical use [53]. The test is ideal for detecting hot and cold spots, or areas of different emissivities on the skin surface since humans radiate IR energy very efficiently.

Although IR systems have many advantages for temperature screening, other than its cost, there are however many variables that can affect its accuracy [28,50]. Ideally, the thermal imager should be operated in a stable indoor environment with stability of the operating ambient temperature within ±1 °C, and facilities to control all ambient conditions such as temperature, humidity and additional infrared sources.

The accuracy of the thermal imager is highly dependent on the skill and knowledge of the operator [53,78]. Mishandling of the equipment will result in erroneous data. It is also important to understand that each model of IR equipment has different specifications and accuracies that can affect observed temperatures. Various scanners have different drift between self-corrections (Fig. 2), uniformity within the field of view, minimum detectable temperature difference, error, stability of temperature reading (Fig. 3), distance effect and mini-

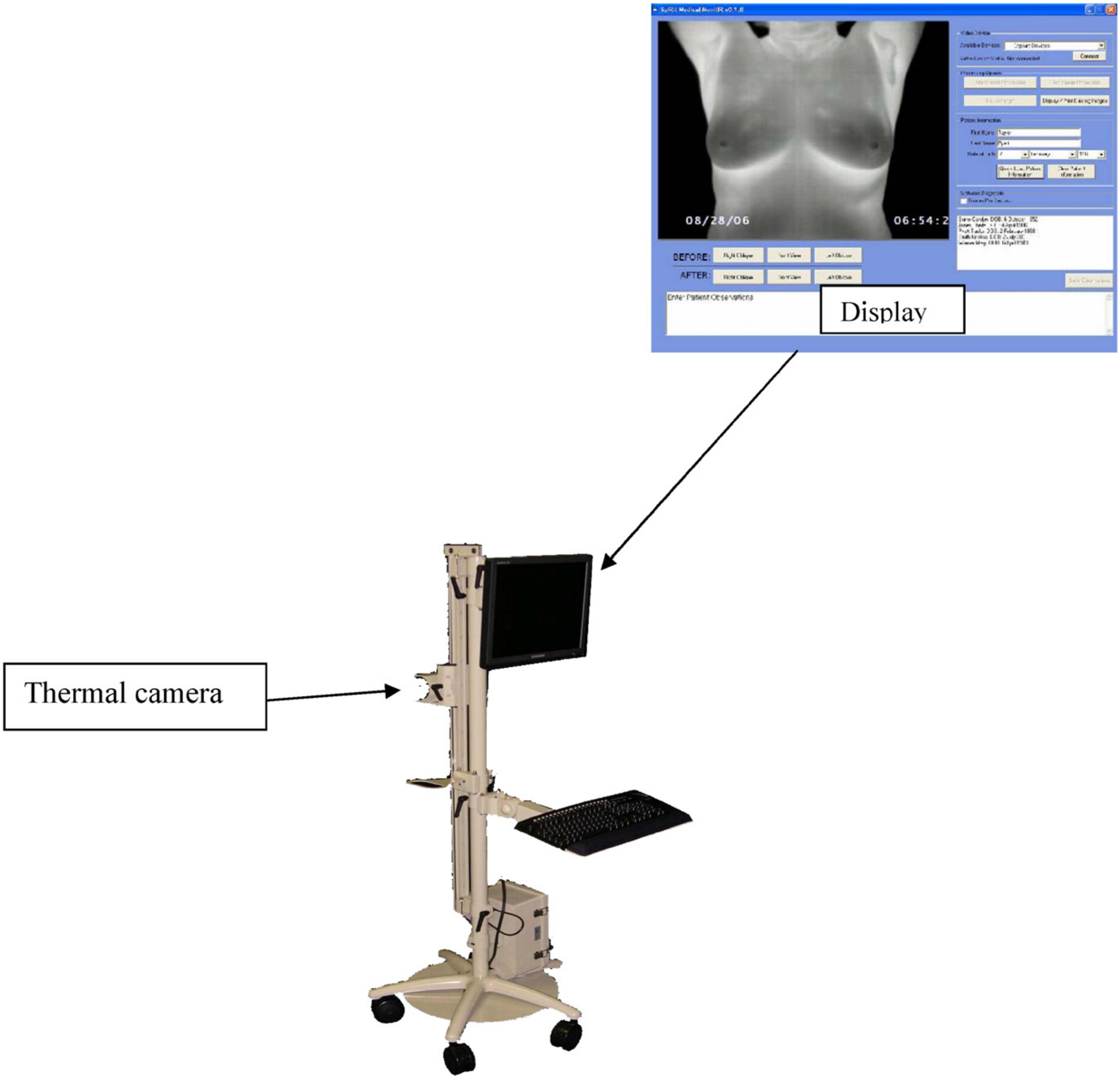

Fig. 1. Thermal Imager setup (courtesy of www.spiritsolutions.us).

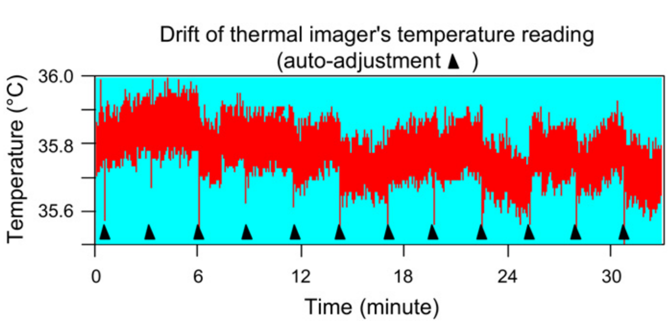

Fig. 2. An example of the drift of a typical thermal imager's temperature reading between auto-adjustments (Reproduced with permission of SPRING Singapore. Copyright remains with STR 15-1: 2003).

mum number of detector pixels in addition to different environmental requirements and subject conditions. For rapid and effective screening of subjects, it is essential that the thermal imager be capable of operating in a real time dynamic processing mode.

Disease processes can produce significant and unpredictable changes in body temperatures. Circulatory problems, previous injuries and alcohol consumption can reduce body surface temperature such as reduced perfusion caused by arterial occlusion [11,62], muscular inactivity due to disuse or loss of motor nerve fiber supply [2,27,44], regular cigarette smoking [24,86] can decrease body surface temperature. Studies on changes of skin temperature after caffeine intake are contradictory (*temperature decrease*: [66]; *temperature increase*: [26]; *no tem-*

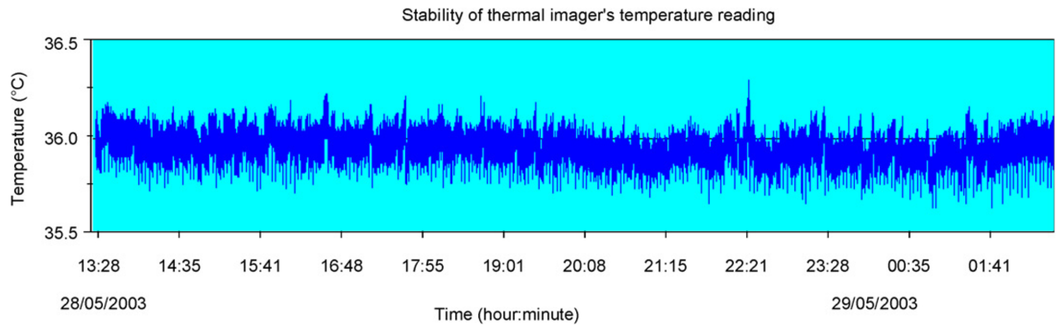

Fig. 3. An example of the stability of a typical thermal imager's temperature reading (Reproduced with permission of SPRING Singapore. Copyright remains with STR 15-1: 2003).

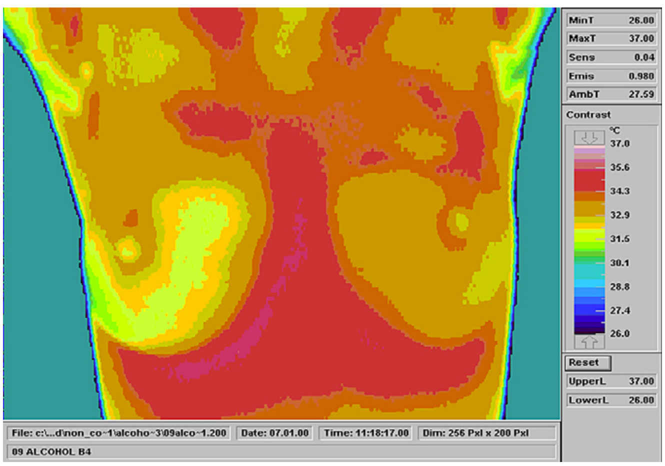

Fig. 4. Typical thermogram of an asymptomatic volunteer age 35.

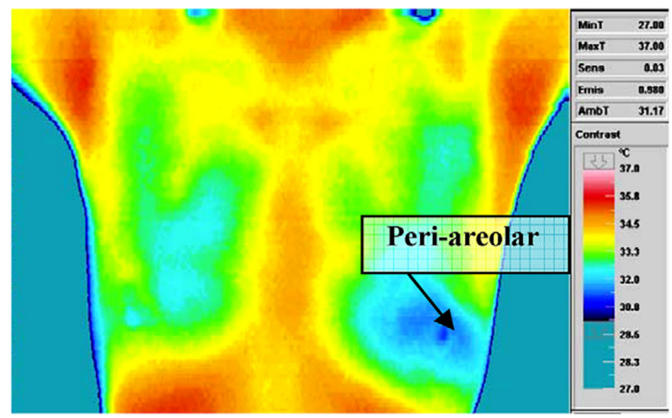

Fig. 5. Asymmetric thermogram of a 52 year old woman with left breast abnormality.

perature change: [15]). Conversely, skin surface temperature can be increased by physical exertion, the use of stimulants such as alcohol [3,45,77], topically applied nicotinate [13] and inflammation secondary to trauma [43,72] or even sunburn [25]. Heavy powdering on chest, hormone replacement therapy (HRT), pregnancy and menstruation, can also affect breast surface temperature.

Figs. 4 and 5 illustrate examples of a typical thermogram of an asymptomatic volunteer (aged 24) and a typical asymmetric thermogram of a 52 year old woman with left breast abnormality. Based on mammographic examinations in 1000 Singapore women on the eve of the breast cancer awareness month (Oct. 1998, [8,84]), the average size of a cancerous lump [54] was 1.415 cm in spheroid shape when detected in the clinic for the first time.

From the breast thermograms, temperature data are extracted from them. The thermograms consist of many colored pixels, each representing a temperature. From the thermograms, it is possible for an experienced medical practitioner to diagnose abnormalities such as a cyst. After every pixel's temperature is compiled, bio-statistical technique can be used to treat them, such as determining the mean, median and modal temperature of the breast region [52].

In summary, thermal imagers offer an excellent means of making a qualitative determination of surface temperature, but there are many difficulties in obtaining an absolute measurement. Some researchers concluded that the thermogram provides a reflection of functional tumor induced angiogenesis and metabolic activity rather than structurally based parameters (i.e. tumor size, architectural distortion, microcalcifications, [36]). With a direct reflection of the biological activity in the breast, IR imaging has been recommended as a significant biological risk marker for cancer [1,33].

3. Performance evaluation

A recent Health Technology Assessment from New Zealand could not find sufficient evidence for infrared thermal imaging as a screening test for breast cancer [34]. Whether thermal imaging carries the potential of a risk marker for breast disease, must be answered with adequate methodology and inclusion of all studies performed in the field.

3.1. *Preparation of patient*

Skin surface temperature is greatly affected by the numerous conditions such as perspiration. In order to reduce errors such as thermal artifacts brought upon by these controllable conditions, thermographer must employ the correct management of patients before and during the imaging process [65]. Such an action ensures the usefulness and consistency of thermal images.

3.1.1. *Instructions prior to examinations*

The following is a recommended set of instructions to be given to patient prior to examination [69].

(i) No sun bathing on area to be imaged 5 days prior to examination,
(ii) Avoid using of lotion, cream, powder or makeup, deodorant or antiperspirants on the body area to be imaged the day of the examination [42],
(iii) If the body area includes in the image are to be shaved, this should be done the evening before or at least 4 hour prior to the examination,
(iv) No physical therapy should be done 24 hours before examination, avoid stimulation or treatment of the breasts,
(v) No exercise 4 hours prior to the examination,
(vi) If bathing, it must be no closer than 1 hour before examination,
(vii) If not contraindicated by the doctor, avoid using pain medication on the day of examination,
(viii) No smoking and alcohol intake before the examination [20,81],
(ix) Large meals and above average intake of tea or coffee should also be avoided,
(x) Avoid tight fitted clothing.

3.1.2. Patient data form [69]

The practitioner should use a proper designed patient data form to cover the areas of complaints with specific pain image, previous tests and examinations. Any past histories of diagnoses, surgeries and HRT are to be documented for better understanding of the patient background.

3.1.3. Patients acclimation

Patients upon arrival should be briefed on the examination procedures, given proper instruction to remove appropriate clothing, and be informed to sit in the cubicle with loose pyjamas for a fixed time of about 15 minutes to achieve adequate thermal stability with the surrounding ambient temperature. During the period of equilibrium, areas to be imaged must remain completely uncovered (no bra). Avoid folding or crossing of arms and legs during this period.

3.2. Examination environment

The environmental conditions in the room are essential in obtaining quality image control.

(a) Room size
The size should be sufficient to maintain a homogenous temperature in the room and for working. Minimum room size of 2×3 meters is sufficient but 3×4 meters are more preferable to cater working space for both the patients and trained thermographer. If it is possible, the room should be carpeted [67], else a well-insulated area rug is sufficient to avoid increased physiologic stress.
(b) Environmental control system
The heat generated by the electronic equipment and human body will affect the surrounding air and therefore the air-conditioning unit must be designed for the maximum number of patients and operators in the room. Allowable ambient temperature should be maintained between 18 to 25 °C. Patients will most likely shiver under low temperature, or perspire due to temperature over 25 °C. Relative humidity is to be kept from 40 to 75%. Clear indication of the room air temperature is important and to be visible in anywhere of the room [67]. Air-conditioning vents should be kept away (or be baffled to diffuse the airflow) from patients to experience direct draught or turn off during examination.
(c) Computer equipment
Processing equipment must be located sufficiently away from patients to avoid disturbance in temperature reading. A sink with cold and hot water supply would be required for a temperature (cold) stress test.
(d) Patient cubicle
This is to allow privacy for the patients and a resting area for the acclimatization period.
(e) Minimizes infrared source interferences
All windows must be shielded to prevent any IR radiation from coming into the room, else shades or binds (suitable curtains) may be adequate for this purposing, depending the amount of direct radiation. Avoid lightings such as incandescent, quartz tungsten halogen, sunlight or any heat produce light. Florescent light are being recommend here. Openings such as window and door should be adequately sealed to prevent any airflow to the patients' area. A plain, non reflective background should be used including the furnishers and other objects in the vicinity of the instrument. i.e. to cover reflective surfaces and other surrounding objects with some heavy velvet drapes.

3.3. Standardization of thermal imager system

With the latest generation of camera available in the market, cooling is no longer an issue and it almost provides maintenance free technology. Common practice on the setting up of the camera before use is however normally inadequate. Variation in the measurement from a black/grey body radiant source at a known temperature reference must be established for the imaging system, and the minimum camera warm-up time must be noted.

(a) Temperature reference
An external black body source is recommended to check for any drift in the temperature sensitivity setting unless routine servicing is done. Thermographer or trained operator has to check on the IR system with the camera and the source left on the whole day. These checks may be the only satisfactory way of proving the repeatability of the temperature measurement.
The threshold temperature (if any) shall also be calibrated, as it is a reference point that the thermal imagers used to differentiate an evaluated temperature from normal temperature. Consistency of the threshold temperature setting throughout the imaging operation is usually achieved by monitoring the threshold temperature setting.

(b) Mounting [67]
Studio camera stands are ideal as oppose to photographic tripod stand, as there is provision for vertical height adjustment with counterbalance weight compensation. As it is stable with a weighted base on wheels, it allows the operator to rapidly set up the camera in any reproducible position [67]. Ceiling mounted stands are likely to require position motors if camera is beyond operator's reach.

(c) Camera initialization
Start up time stated by the manufacturer are claimed to be very short, however the image stability is not related to speed with which the image become visible. It is thus a good practice to set up the system at least 15 minutes before screening. Allow the scanner to stabilize within the first 3 scans (about 30 sec), but it is usually better to allow the scanner to run for a few minutes on continual scan before screening.

(d) Electromagnetic Compatibility (EC)
An appropriate EC standard for IR camera should be complied according to its intended operating condition and location.

3.4. Image Capture Protocol (ICP)

Image capture protocol is considered to be the major source of variation due to the camera focus distance and its viewing angles. Thermograms must include area of interest relevant to patient's symptom, along with any anatomically and physiologically related area. A complete set of standard views (capture masks) should be devised based on the cameras being maintained at 90° to the target, and parallel to the ground when mounted on a parallax free stand. The thermograms through the standard view will be approximately the same size for all normal adult subjects regardless of their body size. By maintaining the same temperature limits throughout, it allows the collective analysis of groups of subjects within specified age bands placed in decades of life. Supplementary images can be added if essential to record the full dynamic range of the subject. The following are some guidance related to the ICP [4]:

(a) Capture mask or image size
Size of the image is dependent on 3 parameters which is the distance of the patient, the camera and the focal length of camera. As most IR equipment manufacturers do not provide data regarding spot size for their instruments, the introduction of capture masks (workable target plane) for each standard view of the human body is necessary.
In the imaging software, an electronic outline will automatically appear when each standard view is selected from the menu [4]. The outline ensures that the image will have a meaningful viewing area by making sure the target fills the frame as much as possible, and the limits are defined by anatomical description. This is also to provide adequate spatial resolution and interpretation accuracy. These capture mask are 1/3 the size of the width and 2/3 the height of the thermal imager's target working plane.

(b) Patient's positioning
Standing, sitting or even lying down will affect the surface temperature of the area exposed. With the help of the capture masks, basic standardized patient and equipment position must be incorporated to give a good comparison between results with the help of the capture masks [4].
For breast imaging, multiple views from different angles to process the necessary information of the different surface aspect of breast [65]. If the view that are obscured due to the patient's anatomy, additional imaging may be necessary to image specific area.
Patient has to remain stationary during the imaging process, as movement will cause changes to the ambient IR radiation being reflected from the subject's skin surface that will be detected. Dynamic changing on the angles of the skin surface will affect reliability, and hence causing inaccurate data due to the effect between the air and body movements.

(c) Software program
It is important to note that software manipulation of the images should be maintained under strict parameters to ensure that diagnostic qualities are not comprised [67]. The software used in the imaging process should have the following features to produce accurate and reliable thermograms.
   (i) Sequential image analysis program.
   It is to perform trend analyses and provide subtraction of thermograms.
   (ii) Thermal asymmetry detection program.
   This program is for detection of asymmetries in the thermograms. This is done by comparing the mean values and standard deviation of the temperature pixels following the line scans in the region of interest for both the involved and contra lateral sides.
   (iii) Thermographic index.
   This is to perform calculation of a thermogram which indicated the thermographic index of a region of interest.
   (iv) Temperature distribution analysis in a region of interest.
   This is to permit the measurement of mean, maximum and minimum temperature (with standard deviations), and provide a histogram of the temperature gradient along specific axes or in other directions.

(d) Detector(s) response greater than 5 microns and less than 15 micron with the spectral bandwidth encompassing the 8–10 micro regions [69].

(e) Repeatability and precision of 0.1 °C detection of temperature difference (i.e. the ability to perform accurate quantitative differential temperature analysis or display temperature resolution).

(f) Accuracy of ±2% of reading temperature or less with temperature calibration (5–150 °C) or accuracy of ±1 °C (<100 °C).

(g) Spatial resolution of 1 sq. mm at the skin surface at 40 cm from the detector (2.5 mrad).

(h) Thermal resolution at 30 °C better than 100 mK.

(i) Limiting temperature window/range of 30 to 40 °C (unadjusted mode).

(j) Significantly variable contrast (level) setting.
(k) A maximum scanning time of 4 seconds (response time) or less with real-time capture.
(l) Ability to capture image in high-resolution grayscale.
(m) High-resolution image display color scale for visual interpretation and identification of temperature.
(n) Ability to archive image for future reference and image comparison for medical thermography.
(o) Detector pixel at least 120 (H) × 120 (V) to display a target with sufficient details during screening (e.g., pixel resolution: 10 μm, horizontal field of view: 2.6 mm, vertical field of view: 2.6 mm).
(p) Maximum permissible drift is to be 0.3 °C between self-correction (applicable to thermal imager that does self-correction, Fig. 3).
(q) Uniformity: the maximum permissible difference in temperature measured at various location distributed across a work plane is to be 0.3 °C (Fig. 4).
(r) Appropriate skin emissivity setting is in the range from 0.94 to 0.99. This is to allow verification of the temperature reading under different emissivity settings and facilitate the performance requirement tests.
(s) Information supplied by the manufacturer to include instruction manual with specifications and adequate instructions for proper operation and maintenance of the thermal imager, and application of the thermal imager for its intended temperature screening operation.
(t) The maximum permissible minimum detectable temperature difference (MDTD) shall be 0.4 °C.

3.5. Image analysis protocol

Early methods for interpretation of breast thermogram were based solely on qualitative (subjective) criteria. The images were read for variations in vascular patterning with no regard to temperature variations between the breasts (Tricore method, [18]). This leads to wide variations in the outcomes of studies performed with inexperienced interpreters. With the aid of software masks, a set of thermal images has to be recorded for each standard view [4], and thus images obtained are then comparable. Minor adjustments can be made if the fit is less satisfactory. Images for a selected age band can be merged to derive a mean range of temperature and thermal pattern for each area of the body. This can be achieved by creating a mean normal image for each anatomical area with defined standard deviations. With this policy being implemented, thermal images obtained in area of interest result in good reproducibility by any operator. Many subjective variables in analysis can be removed or minimized with the use of capture mask.

3.6. Reporting, Archiving and Storing [81]

The following activities are suggested:

(a) Color and temperature scale
Every image that is produced must indicate the temperature range with the display of an appropriate color/temperature scale. The color scale should be standardized with temperature scale of 30 to 40 °C (unadjusted). Minimum requirement stipulated in the standards should adopt isotherm color display mode. The scale should also extend for identification above the threshold setting. Display temperature resolution should be at least 0.1 °C.
(b) Processing reported image
Background temperature must be avoided, and cleaning the image by processing the temperature range or overwriting the lower temperature with a background of white, grey or black to improve visual presentation. During the process where images are recorded, great care must be taken. Image clarity can be improved by the use of hardboard or cold towel arrange just prior to imaging. Region of interest must be indicated.
(c) Archiving image and data
Computers are now a common place for storing information and a place of reference for repeated investigation. Multiple windows can be open to recall a set of earlier pictures for comparison, and to ensure that the same position and temperature setting have been used. All data relating to each image must be clearly identified and its relation with the original image. For future and archiving purposes, the image captured should indicate which anatomic view and information of the patients with the Digital Imaging and Communications in Medicine (DICOM) standard.

4. Recent advancements of thermography

Modern IR real-time high-resolution uncooled focal plane array detectors coupled with high speed computers, running sophisticated image analysis software capturing 200 frames per second with a sensitivity of 0.009 °C. It is proposed to monitor alterations in a normal vasomotor oscillation frequency band in the arterial structures of the human body as there may be disturbances in this normal oscillatory rate when a malignancy is forming. Hardware advancement from military application in narrow band filtering hold promise in providing multispectral and hyperspectral images such as the real-time intraoperative cytology. Post-image processing of the raw data from the IR sensor array using ANN/AI, fuzzy logic, threshold algorithm and automated target recognition (ATR) are also in active research which is useful in analyzing the complex thermovascular patterns seen in breast thermogram. This would allow less operator dependence and thus a substantial increase in both accuracy and objectivity.

5. Conclusion

Thermal imaging is not a new concept in the medical field. The potential of this technique is well accepted and acknowledge in 1959, but the earlier technology of the IR camera were inadequate that led to some early work being discredited. With the improvement in the quality of camera over the years, this has led to the increasing use of thermal imaging as a tool for diagnostic imaging procedure that records and produce images of skin surface temperatures. The skin surface temperature is however greatly depends on both the skin blood perfusion and environmental conditions. There is also a need for thermal imagers to be used in a stable environment with minimum environmental interference to produce reliable results. This review paper provides cautionary statement of clinical performance evaluation (with regards to its intended function for breast screening) and its intended operating conditions such as minimize environmental IR sources interference, free from draft and direct airflow.

From the last 1.5 decades of complying with the strict standardized thermogram interpretation protocols by proper infrared trained personnel as documented in literature, breast thermography has achieved an average sensitivity and specificity of 90%. An abnormal thermogram is reported as the significant biological risk marker for the existence of or continues development of breast tumor.

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