<u>Apparatus and method for real-time full field</u> <u>thermal imaging of the sole of the foot</u>

Background

Temperature monitoring is a common technique used to study a large number of medical conditions which have a negative impact on human health. For example, thermal changes at the plantar surface of the human foot can be predictive of ulceration in foot related complications of diabetes mellitus.

The present invention relates to a liquid crystal thermography (LCT) system for assessment of the lower extremities, preferably the sole of the feet. The invention is particularly relevant for use in the healthcare sector, such as, within GP clinics and specialised podiatric medicine centres. It would also find application in research labs to further understanding of foot dysfunction and in particular the diabetic foot with neuropathy. The important advantage of the present system over the prior art is the capability to obtain real time full field images during dynamic changes in skin temperature. Furthermore the system is compatible with existing sensory testing modalities used to assess foot function preferably for diabetic patients with loss of sensation (diabetic neuropathy).

Assessment of circulation, neuropathy, and foot pressure are employed routinely to determine the risk of foot ulceration in the patient with diabetes mellitus. However thermological measurements of the foot to assess responses to thermal stimuli and cutaneous thermal discrimination threshold are relatively uncommon. Quantitative clinical evaluation of thermal response is not routinely assessed in the diabetic foot clinic. This may be due to unavailability of a low cost thermal measurement technique and lack of research focus on thermal patterns under the plantar foot. A simple thermometer is obviously such a technique; however it is the potential for relating temperature variations to the underlying neuropathic condition that distinguishes the current invention.

Recent improvements in liquid crystal technology (LCT) including, insensitivity to pressure, faster response times, lower cost and fast image acquisition have offered the possibility to realise a clinical imaging platform for static and dynamic thermographic assessment of the diabetic foot. Previously proposed liquid crystal based systems are shown in EPO00189381, JP8154904, WO0003634, US006090050A, US005642096A, US676730B2 and KR20040001568. The former four can be classified as general thermometric diagnostic devices whereas; US005642096A & KR2004001568 are independent devices specifically for diagnosing ischemic and neuropathic foot disease in the diabetic and US676730B2 is a foot temperature and health monitoring system. However these systems do not support full-field and real time imaging.

There has been a growing interest in home monitoring and ambulatory measurements of foot temperatures in the diabetic neuropathic foot to prevent foot ulceration. Typically,

simple digital thermometers, LCT technology and smart insoles¹ have been employed. The most recent invention relevant to the present invention is Spectrasole Pro 1000² indicator sheets for quick assessment of the diabetic feet. Another commercial contact thermography system Contflex System³ based on liquid crystals is currently available but suffers from certain disadvantages including cost, limited colour versus temperature calibration, inability to measure temperature under load and poor conformance with underlying anatomy.

However, a clinical thermometry system with a standardised assessment protocol can further current knowledge about the diabetic foot and provide clinically useful information to aid prevention of infection and subsequent ulceration. Advocating increased use of a home based monitoring approach is further justified by clinical evidence that neuropathic thermal patterns are not constant from day to day, described as autosympathectomy. Therefore, using LCT to assess the diabetic neuropathic foot will yield useful clinical information at a lesser cost and allow an improved monitoring rate in comparison to existing Infrared thermometry.

Thermochromic liquid crystals (TLC) respond to temperature by selectively reflecting incident light. This is the basis for the technique of LCT which provides a colour response proportional to the temperature of a heated surface in contact with the crystals. A sequence of thermographic images provides quantitative spatial and temporal data in relation to plantar thermal variations.

From a clinical standpoint, LCT is an economical, non-invasive and nonionising diagnostic tool used to produce temperature distribution and identify local hot spots (e.g. inflammation and/or infection). It can be used as an adjunct to other diagnostic modalities such as radiography, ultrasound, nuclear medicine and neurophysiological tests; or in some cases as a primary diagnostic tool where other modalities are unfavourable. A typical LCT thermography system provides a RGB colour image that reflects the temperature distribution at the superficial body surface in contact with the TLC sensor. For an objective assessment, as in the proposed system the image is processed to extract detailed information at the most common sites of foot ulceration. The proposed system preferably gathers both steady state and dynamic full-field data in real-time that aids in carrying assessment of the neurological function of the foot.

Statement of invention

The present invention facilitates the real-time monitoring of skin temperature and provides a full field image of the sole of the human foot. This is achieved using a measurement platform, high resolution video camera, instrumentation together with a dedicated measurement procedure and analytical process.

¹ Zephyr Technology Ltd., Auckland, Newzealand

² By SpectraSole Foot Indicators, Sweden

³By I.P.S. s.r.l. - International Products & Services, Milan (Italy)

Advantages

In the preferred embodiment of the invention, an appropriate support mechanism preferably constructed from a metal chassis with wood cladding is used to safely support a subject standing normally on the platform. The upper surface of the platform includes a rectangular transparent optical window preferably constructed of optical grade polycarbonate which is used to visualise the sole of the feet via a video camera mounted within the platform. The inside of the platform including the inspection window is preferably illuminated using an array of light emitting diodes with well defined optical properties. On the upper side of the platform above the polycarbonate viewing window is a sheet of polyester backed thermochromic liquid crystal sheet. The advantage of this setup is the capability of obtaining full-field real-time images of the variation in the thermal patterns under the human feet subject to normal loading (i.e. standing).

In the preferred embodiment of the system the video camera within the measurement platform is connected to preferably a Laptop computer that can be used to acquire, store and process image data in real-time. This has the advantage of significantly increasing the amount of image data that can be obtained and in providing real-time visualisation of the physiological function of the foot to clinicians.

The liquid crystal based temperature sensing technique that is employed in the system has the advantage of lower cost and higher spatial resolution over competing techniques, such as, (US676730B2) which employs costly infra-red sensors arranged as a discontinuous sensing array.

Introduction to drawings

Figure 1 illustrates the preferred embodiment of the system.

Detailed description

The preferred embodiment of the invention allows simultaneous thermal imaging of the unclad human feet 1. The subject places both feet 1 upon a sealed sheet of thermochromic liquid crystal (TLC) with the soles of the feet in contact with the black polyester backing of the TLC sheet 2. The TLC sheet is located upon a rectangular viewing window 3 which is preferable constructed from a single sheet of polycarbonate or acrylic preferably of a minimal thickness of 15mm thick and of optical grade thus avoiding any image distortion due to flexure and improving image clarity. Items 1 to 3 are supported preferably by a metal reinforced metal platform 4. Within the platform a preferably high reflectance optical mirror 5 which can be aligned via a simple adjustment mechanism 6 is used to redirect light from the underside of the viewing window towards a video camera 7. The internal area of the platform is illuminated by suitably placed lighting 8 which is preferable white LED strip lighting. Each LED preferably produces cool white light with

colour temperature 8000K and has an emission angle of 85°. Continuous image data from the video camera is captured preferably by a laptop computer 9 and displayed as a sequence of real-time thermal images 10.

In the preferred embodiment of the invention, different foot sizes for both men and women can be imaged and assessed due to the large surface area for the TLC sensing sheet. The method of measurement relies upon thermal provocation of the feet external to the system in the simplest method the feet are warmed or cooled in a water bath preferably for a period of 3 minutes. The feet are then dried by standing on tissue paper and located upon the TLC sheet where the system captures continuous real-time full-field spatial thermal images of the soles of the feet as they recover from the thermal provocation. Preferably image data continues to be captured until the system detects a no change condition or a return to a predetermined thermal image i.e. consistent with that obtained at normal skin temperatures.

During or following image capture post processing of the data using custom algorithms is applied to extract quantitative data relating to foot function. This information can be displayed using standardised thermograms.

The preferred clinical application of the system is in assessing neurological function, infection and inflammation in the diabetic foot. The system is not suitable for diagnosis and is intended as an aid to visualising the status of the at risk foot.

Drawings

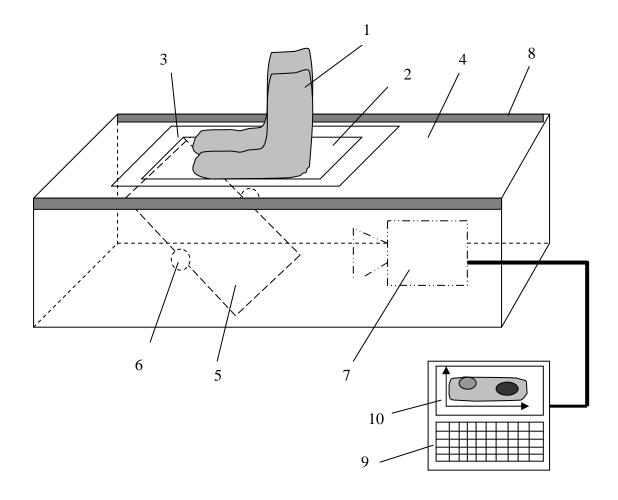


Figure 1 Preferred embodiment of the system