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SKIN'S SOFT TISSUE AND FASCIA LAYERS

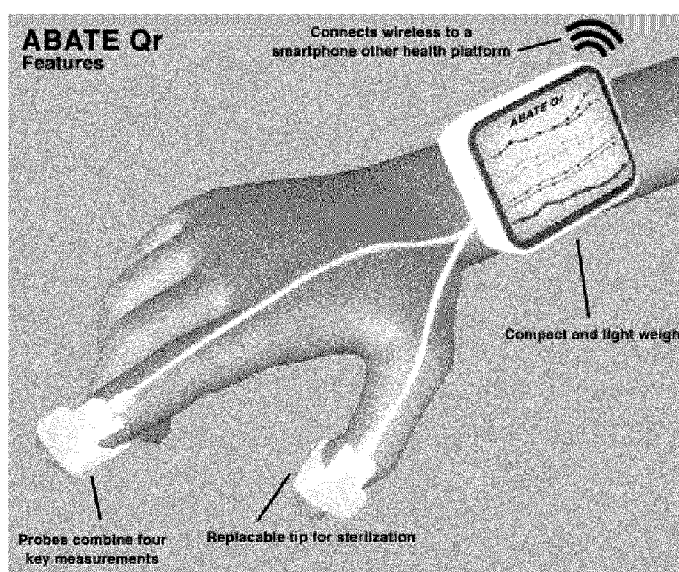


Figure 1

(57) Abstract: The present invention relates to an apparatus for diagnosing a skin condition of the patient. The apparatus comprises a lens having radial lines of conductivity dividing the surface into quadrants, each quadrant having spaced apart lines of conductivity, with a center of the lines having a temperature sensitive element and a temperature sensitive element positioned at an outer extreme of each of the radial lines of conductivity.



An Apparatus and Method to Locate, Measure, Monitor, and Treat Inflammation of the Skin's Soft Tissue and Fascia Layers

FIELD OF THE INVENTION

The present method relates to a method and apparatus for locating, assessing, treating and evaluating treatment outcomes for soft tissue inflammations as manifested by pain and disease in the tissue of human beings and animals.

BACKGROUND

It is known that the electrical resistance of skin is controlled largely through the nervous system. Canadian Patent No. 1,254,269 issued May 16, 1989 to Woodley et al. discloses a diagnostic device based upon resistance measurements of the skin which is used to detect abnormal areas of the body where there is pain or sympathetic dysfunction. U.S. Patent No. 4,966,158 issued to Honma et al. discloses a device having two probes which measures the moisture content retained in the skin both in the keratinous layer and also in the deeper layer so as to provide information as to the condition of the skin. Patent Cooperation Treaty Application No. PCT/GB90/01991 discloses a device having a common probe and a reference probe. The measurement of resistance is switched between a common probe applied to an area of skin under test and a reference probe located on the identical area on the other side of the body. A difference in the readings indicates a damaged area of the skin. Thus, known devices measure only one parameter of the skin.

Cellular damage can occur due to prolonged stress, which increases build-up of metabolites and tissue ischemia. The latter build-up directly excites pain receptors and causes cellular degeneration or necrosis. Lack of use, poor posture, over use, a blow or hyperextension will cause inflammation. Inflammatory by products include histamine, bradykinin, acids, etc. are released into the capillary bed. The five cardinal signs and symptoms of inflammation-rubor, tumor, calor, and dolor, functio laesa (redness, swelling, heat, pain and loss of function) date back to Celus.

Pain causes a reflex response of muscle hoarding and/or spasms. Such a response leads to immobility and eventual wasting away or atrophy due to loss of the alternating relaxing and contracting of muscles. The muscles provide a circulatory pumping action during normal relaxation and contracting which will be ineffective on areas affected by atrophy. Ordinarily, painful areas in the skin are associated with abnormalities such as changes in temperature, and moisture, tenderness, swelling or edema, inflammation, stringiness due to fibrous tissue changes, nodules or small knotted areas, fatigue or lack of tone in the tissues, and metabolite retention characterized by crystal-like formations in the tissue. Such areas of abnormality are conventionally located by palpation.

Manual compressions, such as applied by acupressure or massage, remove the stimuli causing pain and stop the stimulation of the sweat glands and arterial vessel constriction, the primary cause of pain and degenerative tissue disorders. Such compression and massage are

accompanied by the sound of the breaking up processes of metabolite and tissue by-products. Thus, factors such as moisture, sound, temperature, electrical conductivity, edema are all a function of the condition of the skin and can be used to measure the presence of areas of pain of inflammation.

In order to be able to cross correlate different types of measurements of a given area and thus obtain confirmation of the condition and a more accurate diagnosis, it would be useful to be able to measure several different parameters simultaneously.

Ultimately without controls for discrepancies data would be corrupted, for example more or less force applied when achieving a reading would change the reading of each and or any given sensor in our application.

Technically, one could first apply a device to measure resistance to a particular area and then one designed to measure moisture. However, such an approach would be impractical because not only could the condition of the area under test change from one measurement to the other, but positioning the probe on precisely the same area for both measurements would be difficult if not impractical. Secondly, many such measuring devices require measurements to be made using two separate probes applied to two separate but corresponding sides of the body.

A number of problems must be overcome in order to achieve a probe which is capable of providing measurements of a workable accuracy. For example, if one were to use infrared sensors to measure temperature, an area of the size of a quarter would be the minimum size achievable with current sensors. Thermistors would also have a limit to the area of detectability that is greater than the focal point of conductivity, which is approximately 1 millimeter (mm).

The time required to measure body temperature depends on the mass of the probe. Consequently, it is important to limit the mass of the probe in order to minimize this time. (Figure 7)

Improved sensing of sound is also important and the shape of the sensor and how it is used is vital in detecting tissue sounds associated with crepitus and taut tendinous bands. (Figure 8)

- 1) Historically massage is an empirical, tried, tested, and true practice. The applicant spent 30 years of her career relieving pain and suffering. She researched and authored numerous scientific papers. In her practice, she uses the art of massage and gets extraordinary results in the treatment of pain, disease, and trigger and acupressure point.
- 2) Traditionally medical practitioners are trained in palpation; they use their fingers and thumbs to detect soft tissue damage. Massage therapists palpate and massage simultaneously.
- 3) Devices like ultrasound, x-ray, MRIs, and CAT scans are not able to measure or localize pain causing soft tissue inflammations at its origin.
- 1) "Pain is the most common reason Americans turn to complementary and integrative health practices," said Josephine P. Briggs, M.D., Director of NCCAM.
- 2) The International Association for the Study of Pain (IASP) defines pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage, described in terms of such damage.
- 3) IASP supports the study of pain and translates that knowledge into improved pain relief worldwide; according to the IASP, biologists recognize that those stimuli, which cause pain, are liable to damage tissue. Since pain perception is influenced by psychosocial factors, pain that is experienced is also associated with actual or potential tissue damage.

Pain is generally assessed by subjective reports, using visual analogy scales (Price et al. 1983), questionnaires, which can be converted to numeric scores (McGill, 1975) or discrete numeric scales (Price et al. 1994).

- 4) Early disease detection relied on the use of one's hands to evaluate the soft tissues; skilled hands can detect indications of inflammation/pain causalgia.
- 5) Current measurement devices do not provide sufficient evidence for measuring soft tissue inflammations that cause pain. Subjective reports of pain perception alone are considered unreliable.
- 6) Because there are no tools to measure pain independently, we have relied on a patient's verbal confirmation of pain, which has proven to be under evaluated. There are many obstacles to diagnose soft tissue inflammatory parameters associated with pain accurately.
- 7) The unifying law of pain states that the biochemical origin of all pain is inflammation and the inflammatory responses. When there is significant damage to tissue, several chemicals are released resulting in an inflammatory soup, an acidic mixture that stimulates and sensitizes the nociceptors. This is called hyperalgesia, which is Greek for super pain. Irrespective of the type of pain whether it is acute or chronic pain, peripheral or central pain, nociceptive or neuropathic pain, the underlying origin is inflammation and the inflammatory response.
- 8) Active signs of inflammation include the following:
 - Calor-heat is created from inflammation or lack of heat as in fibrosis
 - Dolor-pain is created when pressure is applied.
 - Functio laesa-loss of function or muscle withdrawal reflexes
 - Maturation and remodeling phase fibrosis
 - Rubor-redness is due to histamine and inflammatory chemicals
 - Sweat is how the body dissipates heat from inflammation and creates sympathetic skin response causing sweat used by the body to dissipate heat GSR measurements are used in Biofeedback and lie detectors test sympathetic skin response
 - Tissue sounds crepitus and taut muscle bands
 - Tumor-swelling oedema/tropho-edema creates a visual denting.
- 9) It is well known that pain is felt when pressure is applied manually or by tissue algometry. For a fibromyalgia diagnosis, a force of 4 kg or 10 lbs for a tender point to be considered "positive" the subject must state that palpation was painful. Tender is not considered painful. Studies suggest that a trigger point for myofascial pain has a reliable and reproducible pain-pressure threshold. This measure of pain still requires a subjective input patient response to indicate whether pressure stimulus is painful and is still not an objective means of determining severity of soft tissue injury.
- 10) Another approach to locating sites of injury is skin thermography. Skin temperature, assessed by thermography, has been found to be a sensitive test for myofascial pain syndrome. At myofascial trigger points, temperature is higher than that of surrounding locations on the skin. It has also been suggested that electrical conductivity of the skin can be used as a diagnostic measure to locate tender areas in soft tissue. Acupuncture points, known to be tender areas, appear to have higher conductivity than that of surrounding tissue. Thus, it might be possible to combine these two measures to detect the presence or

absence of soft tissue injury in a more objective fashion than pain threshold or pain scores.

- 11) Objective measurements are difficult to obtain because skin temperature and electrical resistance of healthy tissue vary moment by moment and are not the same between individuals and both environmental and psychological factors play a role. There is no known stable norm parameter from which to obtain a base comparative measure in using existing equipment.
- 12) The Galvanic Skin Response (GSR) equipment measures electrical conductance in the skin, associated with the activity of the sweat glands. A very slight electrical current runs through the skin and the GSR machine measures changes in moisture produced from sweat gland ducts. The more emotionally aroused the persons the more active sweat glands and greater electrical conductivity of skin.
- 13) A German Professor named Tarchanoff first discovered skin conductivity around 1888. In the early 1900s, Dr. Carl Jung established that GSR measurements could track physiological arousal or stress in the body. In the 1930's Dr. Hans Selye began sharing information that could tell us about the body. These discoveries have led to the creation of many common devices, such as the polygraph. Later in the 20th century, Dr. Reinholt Voll and others identified further uses for GSR, including the monitoring of acupuncture points to determine the condition of the body's energy meridians.
- 14) Biofeedback and lie detection tests use GSR as emotions affect the skin's conductivity.
- 15) Psycho-galvanometer, biofeedback, Electro Dermal Testing (EDT), Electro Dermal Analysis (EDA), and/or GSR devices have a known potential for artifacts and spikes in the sweat and or temperature. Stable room temperature should be obtained with the bias being slightly on the warmer side 22-24-degrees Celsius. Physiological body actions like coughing, deep respiratory movements (deep sighs), sneezes, and excessive talking can all generate sweat production and thus a rest period and patient calming should happen before testing.
- 16) Sweat is how the body dissipates heat from inflammation creates sweat caused by sympathetic skin responses. Electro dermal activity is the property of the human body that causes continuous variation in the electrical characteristics of the skin. Since the body is in a continual state of adapting to stress and external elements there is no normal or base on which to compare either people or points of soft tissue.
- 17) Historically, EDA has also been known as skin conductance, GSR, Electro Dermal Response (EDR), Psychogalvanic Reflex (PGR), Skin Conductance Response (SCR), and Skin Conductance Level (SCL). The long history of research into the active and passive electrical properties of the skin by a variety of disciplines has resulted in an excess of names, now standardized to electro dermal activity.
- 18) The traditional theory of EDA holds that skin resistance varies with the state of sweat glands in the skin. Sweating is controlled by the sympathetic nervous system, sympathetic skin response and skin conductance is an indication of psychological or physiological arousal.
- 19) Electrical resistance of skin was studied with the aid of a specially designed meter that compared the resistance per surface area of small skin points with that of the surrounding skin. In a systematic study of the hands, face and ears in five subjects' low-resistance skin points were repeatedly found in characteristic loci, comparable in different individuals and symmetric about the body midline. The low-resistance skin points had diameters of 1.5 +/-

0.5 mm and their borders were abrupt. On dry skin, resistance values were around 10 kilo-ohms at the center of the points but around 3 mega-ohms in the surrounding skin.

Voltages could also be recorded at these points, but they proved to be result of electrode polarization reflected at these points because of their low electrical resistance. The distribution of the low points in the hands, face, and ears resembled that of classical acupuncture points.

- 20) If the sympathetic branch of the autonomic nervous system is highly aroused, then sweat gland activity also increases, which in turn increases skin conductance. In this way, skin conductance can be a measure of emotional and sympathetic responses.
- 21) More recent research and additional phenomena (resistance, potential, impedance, and admittance, sometimes responsive and sometimes apparently spontaneous) suggest this is not a complete answer, and research continues into the source and significance of EDA. The study of EDA has led to such important and vital tools the electrocardiograph (ECG) and the electroencephalograph (EEG).
- 22) The sympathetic branch of the autonomic nervous system is easily aroused, increasing sweat gland activity, which increases skin conductance.
- 23) Physiological and psychological influences on the sympathetic nervous system affect blood flow.
- 24) The traditional theory of Galvanic Skin Responses holds that skin resistance varies with the state of sweat glands in the skin. Sweating is controlled by the sympathetic nervous system, and skin conductance is an indication of psychological or physiological arousal.
- 25) More recent research and additional phenomena are sometimes apparently spontaneous. To account for changes that occur during the taking of measurements the soft tissue (including the examination process itself), we purpose a multimodal biosensors uses the concept of differential comparatives to normative tissues so that these measurement changes can be interpreted accurately.

Accordingly, it is an object of the invention to provide an improved method and apparatus for simultaneous and accurate measuring of at least two different points of the skin and at least two parameters in those points.

Summary of the Invention

According to the invention there is provided apparatus for diagnosing the skin condition of a human being or animal, which includes two probes for contacting the desired area of skin. The probe has means for measuring the conductivity of the skin at the area and means for measuring the sound produced by probes running over the skin at that area, the force applied by the probes to the skin and the temperature of the skin. The moisture content is related to the electrical resistance of the skin.

Means for measuring the conductivity or resistance of the skin may be an electrical resistance measuring device with an electrode configuration interconnecting a plurality of thermistors. For measuring the sound, a pick-up microphone is located in the probe tip (Figure 11) skin as the probe passes over a protrusion inflammation area.

The temperature sensor for measuring the temperature of the skin may be a plurality of thermistors spaced apart over a number of probes, thermocouple located at a tip of the probe. (Figure 6)

A pressure sensor may include a strain beam coupled to the probe operative to measure applied force applied to the probe as it passes over the skin. (Figure 4)

Figure 1	▪ Overall ABATE Qr System ▪ Colored line represent data in the display ▪ Galvanic Skin Response GSR-blue ▪ Sound-Yellow ▪ Force-Green ▪ Heat-Red-heat ▪ Purple-Patient Response Module PRM ▪ Blue Tooth/wireless communicates to software
Figure 2	▪ Miniaturized design meant to mimic fingers and/or thumbs in clinical palpation. Probes are portable and can be placed in any receptacle. ▪ Probe tips are portable be integrated into a number of various receptacle and as wearable monitor and small enough to be worn under compression garments. ▪ Pen receptacle probe with sensor tip. ▪ Option for multiple bio-sensor probes design pen probe design and or into other ergonomic design, Probe#1 and Probes #2 options for Probes #3,#4,#5 etc.... Finger and or Pen Probe sample design sensor tip is movable
Figure 3	▪ Probe assembly illustrates ceiling floor for pressure transducer ▪ Force sensor sits between floor ceiling and tip of probe pushes the sensor floor up to ceiling, pressure transducer is activated. ▪
Figure 4	▪ Pressure transducer for detection of force applications
Figure 5	▪ Interdigitated grid pattern for GSR covers a larger area of skin making GSR easier to locate ▪ Position traces so few as possible are cut/isolated by the centre hold for thermistor

Figure 6	▪ Thermistor protrudes slightly from head, which allows for indenting of the skin creating pitting edema
Figure 7	▪ Flower pot shape to house the heat sensor decreasing thermal mass. Note infrared sensor sits in from of the sensor probe set. ▪ A- thermistor slightly protruds for pitting edematous tissues.
Figure 8	▪ Size and of the heat sensor tip creates visual pitting. Fig 8-
Figure 9	▪ Conically shaped sensor head for eliciting a pain response, mobilizing crepitus, and showing visual dents from edematous tissue.
Figure 10	▪ Foam padding enables the GSR sensor to lay flat on the skin surface while foam pads mimic the padding of
Figure 11	Conical shaped housing for the Microphone to act as an eco-chamber for sounds from soft tissue
Figure 12	▪ LCD display
Figure 13	▪ Patient Response Module (PRM) numerical scale 1-10 ▪
Figure 14	▪ Facial expression muscle withdraw reflex ▪ Patient Response Facial Haptic sensors move when facial expressions scaled 1-10
Figure 15	Infrared sensor sits ahead of the probe as to shoot the sensor beam in front of the sensor tip head to lead the way to the hot spots
Figure 16	▪ Patient plates with two reference points ▪ Base compared to data collected from two reference points

Fig 17	Data is displayed simultaneously as a differential comparison between a minimum of two points and then is stored as a pressure point in a referential data base.
Figure	Schematic of basic functions
Figure 20	- Air cell is inflated either manually or automatically - Patient Response Module can control the force being applied, the air cell will automatically release air every 30 to 90 seconds to avoid ischemia (lack of oxygen to cells)

- 1) This device includes an apparatus and system to locate, measure, and treat soft tissue inflammations.
- 2) This device provides an objective means of determining the severity of soft tissue injury.
- 3) This device involves a wearable monitor and a treatment-outcome software system.

Further features include:

- 1) In an attempt to minimize the influence of bias or prejudice on the part of the examiner, it would be effectual to provide several multi-modal parameters simultaneously between test sites to control for autonomic fluctuations. The use of two or more probes to test differences sites stabilizes for fluctuations of the soft tissues and accounts for the ever changing the base measurement by which to compare.
- 2) The origin of all pain is inflammation and the inflammatory response.
- 3) Nociceptive neurons translate certain stimuli into action potentials that are then transmitted to more central parts of the nervous system, such as the brain. Biochemical mediators of inflammation include cytokines, neuropeptides, growth factors, and neurotransmitters. Inflammatory chemical soup consists of prostaglandins, potassium, serotonin, bradykinin, and histamine.
- 4) By-products of inflammatory response create measurable factors such as: temperature changes, metabolic waste and scar tissue build up, sympathetic nervous functions all a function of the condition of the soft tissue be used to measure the presence of inflammation.
- 5) Inflammation is caused by an opening of thousands of tiny local blood vessels in response to the interaction between cellular and chemical components and the irritation of free nerve endings.
- 6) The inflammatory fluid contains a high concentration of protein. This fibrinogen-containing protein is a necessary part of the body's defence mechanism against infection.
- 7) Excessive formation of fibrin from fibrinogen will lead to excessive scar formation. Felt as thickening, palpation elicits tissue sounds mobilizing tissue waste, the sensor probe can hear amplify and record digitized data.

- 8) In addition, the presence of protein increases the osmotic pressure of the tissue fluid in the damaged area, thus drawing more fluid out of the local capillaries into the tissues, causing local oedema. Inflammatory swelling starts to develop approximately two hours after the injury and may last for days and or weeks. The immediate management to control the acute inflammatory response is important to minimize the undesirable effect of the natural healing process.
- 9) Circulatory by-products accumulate in capillaries creating crepitus and fluid retention. Crepitus is a medical term to describe the grating, crackling, or popping sounds and sensations experienced under the skin and joints or a crackling sensation due to the presence of air in the subcutaneous tissue. Tissue sounds can also be attributed to taut muscle bands and fibrous density changes.
- 10) A soft tissue injury is an acute connective tissue injury that may involve muscle, ligament, tendon, capsular, and cartilaginous structures. In a sprain, strain, bruise or crush, the local network of blood vessels is damaged, and the oxygenated blood can no longer reach the tissues, resulting in cellular damage.
- 11) A soft tissue injury can involve muscle withdrawal reflexes a built in mechanism that allows the body's own muscles to pull away when pain is experienced by the nervous system, often with no awareness or control consciously.
- 12) Pain requires a conscious subject that is able to experience pain. The molecular, cellular, and systemic mechanisms that deal with the processing of pain-related information its amplification, or depression are called nociceptive, pro-nociceptive, and anti-nociceptive, respectively.
- 13) Pain is just one of many possible end-points of nociception. Others include but are not limited to withdrawal reflexes, vegetative and hormonal responses, and vocalization, all of which normally accompany pain experience but may under experimental and some pathological conditions be observed in the absence of pain experience, e.g., in the intact but deeply anesthetized subject or in inflammationed animals.
- 14) A patient can verbally express pain on a numerical scale however; studies have shown this is unreliable. Intensive care patients are people suffering from serious injuries or diseases. These people receive highly specialized care and medical attention, and are under continuous observation and monitoring.
- 15) It is important to note that ICU patients may not be able to respond to a voice or tactile stimulation. Many patients in the ICU are in breathing tubes, which prevents them from communicating the pain that they are experiencing as well.
- 16) Health care providers need to provide cost effective pain therapies that will enable the therapist to gain the information needed to deploy treatments and objectively monitor results. It quickly locates inflammation and any soft tissue damage. R.I.C.E. is the acronym for Rest, Ice, Compression, and Elevation; commonly prescribed for patient with acute soft tissue injury.
- 17) The purposed apparatus uses the complete thesis understanding bio physiological functions of the soft tissue to obtain a multiple sensors electronic measures to locate differential comparative areas that indicate inflammations.
- 18) A centralized database would enable analysis of outcomes from therapies. Data can also be exported in anonymous nationwide comparison outcomes analytics of pain therapies.

- 19) In order to overcome the physiologically adaptations to psychological and environment stress and factors including the applying pressure to pain points cause continual physiological adaptations and adjustment in the systemic and local measurements, so there is no such thing as normative data to compare to in the collection of the skins environmental adaptive attributes.
- 20) Physiological and psychological influences on the sympathetic nervous system controls the blood flow to the inflamed tissues as does systemic sympathetic nervous function creating the sympathetic branch of the autonomic nervous system is easily aroused increasing sweat gland activity increases, this in turn increases skin conductance and blood flow.
- 21) The traditional theory of Galvanic Skin Responses holds that skin resistance varies with the state of sweat glands in the skin. Sweating is controlled by the sympathetic nervous system, and skin conductance is an indication of psychological or physiological arousal.
- 22) More recent research and additional phenomena are sometimes apparently spontaneous. To account for changes that occur during the taking of measurements the soft tissue, including the examination process itself, we propose multimodal biosensors that use the concept of differential comparatives to normative tissues so that these measurement changes can be interpreted accurately.
- 23) In order to overcome the physiologically adaptations to psychological and environment stress and factors including applying pressure to pain points which causes continual adaptation and adjusting, so there is no such thing as normative data to compare to in the collection of the skins environmental elements.

Brief Description of the Drawings

Further features and advantages will be apparent from the following detailed description, given by way of example, of a preferred embodiment taken in conjunction with the accompanying drawings, wherein:

Figure 1 is an elevation of a massage therapist wrist with an LCD display and the fingers of a hand holding the instrument, which carries a probe set for differential measurements of temperature, sound, moisture, and applied force

Figures 2a and 2b is a first perspective view of the probe miniaturized design that can be portable into other receptacles.

Figure 3 is an exploded view of the sensor unit

Figures 4a and 4b is a first perspective view of the pressure transducer sensor unit

Figure 5 is a perspective view of the GSR sensor and sensor unit with the concentric, interdigitated electrode array and temperature sensors

Figure 6 is a perspective view of a thermistor that is mounted into the probe tips, it lies in a slight recess within the flower pot shape See Figure 7;

Figures 7a and 7b a function of probe for a non-thermal flower pot shape to eliminate the conductive temperature measurements being absorbed by a mass, this shows the protrusion shaped sensor tip that houses thermistors in the very central position, this also permits and or allows for pitting the tissue See Figure 8;

Figures 8a and 8b as it passes through a inflammation both before and after massage; as a function of the probe, when pressure and or friction massage is applied on the skin, the

protruded shape tip elicits or helps create sounds from inflamed soft tissues, pitting is also a visible sign (camera can take an image and store it in patient file record) of inflamed soft tissue created by the protruded shape

Figure 9 exact dimensions for conical shaped head of sensor for eliciting pain with pressure and crepitus sounds with massaging action

Figure 10 is a foam padding that cushions the sensor tip to feel more like a finger, it also stops external sounds from entering the conical shaped housing for the microphone as a function of probe position as it passes over an inflammation both before and after massage

Figure 11 is a conical shaped housing hosts a flower pot base where the microphone sits and is isolated from external sounds by a ceiling see figure 3 and by foam pad see figure 10.

Figure 12 is a LCD display

Figure 13 is a Patient Response Module a handheld device in the patient's hand used blind to the sensor data that allows the patient to rate their pain as pressure is being applied without need for verbal communication

Figure 14 is a facial expression showing how muscles react to pain whereby haptic sensors can be placed on said muscles to supplement the patient response module (see Figure 13) when a patient is unable to verbalize pain

Figure 15 is an infrared sensor that sits in front of the probe tip to lead therapist toward the inflammation.

Figure 16 is software that allows mapping of pain points on digitized images and stores data related those points.

Figure 17 is software that allows data to be displayed as a differential from two or more probes and simultaneously displays input from the patient response module.

Figure 18 is a schematic of the basic function of the probes and Bluetooth wireless communication

Figure 19 is an air cell that sits on top of the miniaturized sensor tip and can be inflated manually or automatically and is controlled by the patient including using the patient response module wirelessly see Figure 15.

Figure 20 is a sectional view of a sensor with an inflatable air cell.

Detailed Description With Reference to the Drawings

Referring to Figures 1 and 2 there is shown a sensor instrument on the finger receptacle. The probe can be installed in the bottom any receptacle Figure 2. Figure 1 shows an LCD display screen. A separate infrared sensor Figure 17 detects infrared Z(IR) radiation from the skin boundary forwardly of the sensor instrument. Such an arrangement has the advantage of increased IR sensitivity, a constant elevation reference, and no influence from lens warming or lens absorption of IR body energy.

The probe tips house a circuit board and other components including a strain beam Figure 4 that has downward force applied. This will exert a bending movement on beam Figure 4 and result in a strain that is recorded by load cells. Thus, the strain beam provides a measure of the force applied user or air cell Figure 20.

The exploded view of Figure 3 shows the various components of the probe including thermistors on its tip Figure 7 located in the center. When the central thermistor is over an

inflammation, it records the temperature of the point of inflammation while the other thermistors record a base temperature a short distance away from the inflammation.

A printed GSR sensor Figure 5 of interconnected silver conductive electrodes formed into a ring, fits over the rest of the sensor tip on top of foam pads (see figure 10) the centre is left open to accommodate the thermistor sensor tip. When a voltage is applied across the silver the differences between probes is established. Typically the focal point of conduction on the skin is approximately 1 mm. Thus, using only a thermistor to find the focal point would be inaccurate due to the much larger dimensions of the thermistor. When the probe presses against the skin, any inflammation will usually be between a set of concentric electrodes. Thus the resistance between the inflammation electrodes will be the body resistance $xR1$ of the skin on one side of the inflammation, the inflammation resistance $R2$ of the inflammation and the body resistance $yR1$ of the skin on the other side of the inflammation, where $x + y = 1$. As the inflammation gets closer to the center of the concentric electrodes, and the body resistance of the skin therefore becomes less in inflamed areas. Thus, by monitoring the resistance as the probe moves over the skin, a user can tell if the inflammation is moving towards the center. When the point of inflammation is over the center of pain the display screen shows the difference.

An IR sensor receives filtered IR light passing through the lens Figure 15.

A high sensitivity microphone (Figure 11) is mounted in the center of the probe tip under the top base printed circuit board (PCB). The microphone (Figure 11) detects the sound of the display screen moving over the skin.

The temperature component of the probe figure 6 is formed by thermistors, which contact the skin and sense the temperature between probe tips. The precise center of the inflammation can be determined using the measurements mentioned above.

Prior to using the instrument (Figure 1), a massage therapist or other professional locates the point of inflammation manually and then measures the conductivity of the skin a few inches away from the point of inflammation. This measurement of the body resistance provides a base measurement for moisture content of the skin. Further measurements near the inflamed area are then compared to the base measurement to give a relative measure of moisture content.

The simultaneous development of signals which correspond to moisture content, temperature, and sound allow all three of these factors to be cross correlated to confirm an indicated condition by any one of them and to more accurately define the nature and extent of the condition. The strain beam measurement allows a user to monitor and control the amount of pressure being applied. Pressure must be equally applied between probes to maintain consistency for stabilizing other measures. This is extremely important otherwise pressure will alter the viability of other readings.

One may determine the pressure required to cause pitting edema, another sign of inflammations. As protrusion inflammations develop and become fibrous, they create a "speed bump" to the probe Figure 8 as it passes over the area of the protrusion inflammation. Applied pressure rises as the pressure sensor on the probe presses over inflammation pitting of soft tissue can be a result Figure 8. Digital images can be imported into patient record.

Figures 16 and 17 show graphs of the readings of temperature, resistance, and sound as one progresses towards, over and then away from an inflammation. The same figures show readings of inflammation after applying massage. Thus, the probe allows the massage therapist to both apply massage and determine the effect of the massage on an inflammation to a quantifiable extent. A therapist can use the sound output to rapidly locate suspected

damaged areas of the skin and then to confirm the damage using the other readings of temperature, moisture content and resistance. Any extraneous readings in any one or more of the factors of temperature, moisture, and sound can be checked as to their origin by comparing them to the readings for the other factors.

Figure 20 shows an inflatable air cell that can be placed under a tensile bandage or other means of securing it on top of the sensor probe. The probe is used to locate the precise point of inflammation and then the air cell is secured in place to apply pressure to the probe and air cell by pumping compressed air through the valve. Expansion of the air cell against the tensile force of a bandage causes the tip of the probe to press against the point of inflammation. This function can be done automatically or manually and the patient can control the amount of force being applied by the air cell either manually or wirelessly via the patient response module.

Accordingly, while this invention has been described with reference to illustrative embodiments, this description is not intended to be construed in a limiting sense. Various modifications of the illustrative embodiments, as well as other embodiments of the invention, will be apparent to persons skilled in the art upon reference to this description. It is therefore contemplated that the appended claims will cover any such modifications or embodiments as fall within the true scope of the invention.

I CLAIM:

1. Apparatus for diagnosing the skin condition of a human being or animal, comprising a probe (10) for contacting a desired area of skin, said probe having

a lens having radial lines of conductivity dividing said surface into quadrants, each quadrant having concentric spaced apart lines of conductivity with a center of said concentric lines having a temperature sensitive element, said concentric spaced apart lines forming two groups, each group of concentric lines connected together, and a temperature sensitive element positioned at an outer extreme of each of said radial lines of conductivity, and

wherein concentric lines in a quadrant are connected alternately to one and then to another of two radial lines defining each of said quadrants.
2. Apparatus according to claim 1, means for applying a potential difference across said groups of concentric lines and measuring fluctuations of voltage necessary to maintain a constant current or measuring fluctuations in current resulting from a constant applied voltage.
3. Apparatus according to claim 1, wherein said temperature sensitive elements are thermistors.
4. Apparatus according to claim 1, wherein said probe includes a crepitus pickup microphone for emitting sound as said probe travels over skin.
5. Apparatus according to claim 3, wherein said probe has a lens with a planar outer surface onto which conductance lines are deposited.
6. Apparatus according to claim 1, including means for measuring force applied to the probe (10) as the probe is passed over the skin.

7. Apparatus according to claim 6, wherein said means for measuring force is a cantilevered strain beam attached at a distal end to said probe and having a strain gauge element mounted on said cantilevered strain beam proximate an opposite end.
8. Apparatus according to claim 1, including means for measuring a moisture content of skin, comprising said concentric lines and radial lines of conductance, a power supply applied across said 2 groups of concentric lines of conductance, a voltage detector for detecting a voltage applied across said 2 groups of concentric lines of conductance and a current meter for detecting and measuring current flowing from one group of concentric conductors to another.
9. Apparatus according to claim 1, including means for measuring a moisture content of skin, comprising said concentric lines and radial lines of conductance, a power supply operative to apply voltage across said 2 groups of concentric lines of conductance, a current meter for detecting variations in current across said 2 groups of concentric lines of conductance and calculating resistance based upon measurements of the current and voltage.
10. Apparatus according to claim 1, wherein said probe has a central contact operative to measure the resistance and, hence, moisture content of the skin at said area and said means for measuring the sound is a microphone operative for measuring the sound generated by the skin tissue as said probe passes over a inflammation or protuberance on the skin.
11. Apparatus according to claim 3, wherein each of said thermistors measures a temperature of skin contacted by said each thermistor.
12. A method of locating and treating pain, comprising:
- (a) passing over an area of skin of a patient a probe having 2 groups of interdigitated concentric conductors on an outer surface thereof and applying a voltage between said 2 groups of conductors and measuring resistance and sound emanating from the skin so as to rapidly position a center of said probe over soft tissue inflammations of the skin,
 - (d) applying manual massage to said inflammations; and

(e) re-measuring the electrical resistance and sound of the skin at the location of said inflammations to determine the amount of decrease thereof;

wherein locating and massaging inflammations verifies the presence of inflammations and re-measuring provides an indication of the effectiveness of treating the inflammations.

13. A method according to claim 7, including measuring the temperature at the point of contact of the skin with the thermistors mounted on the center of the outer surface of the probe.

Claim 1

Claim 1 is an apparatus with two or more multimodal biosensor probes, which simultaneously compare and establish a differential between a healthy base site and a painful site. (Figure 1)

Claim 1 uses proprietary coding built on a Delphi software platform, data is transmitted via Bluetooth or other wireless device enabling users to view the results on a device such as a PC, a LCD, a LED, OLE, or other mobile devices. (Figure 16 and 17)

An apparatus in Claim 1 that enables therapist with two probes to circumscribe the inflamed area to delineate the dimensions or size inflamed tissues as a pressure point that has been found and then size of inflamed area can be mapped into a digitized image

An apparatus in Claim 1 includes a GSR sensor on a foam pad with a flat surface to cover a larger circumference of soft tissue enabling faster locations for GSR sensor readings.

A means in Claim 1 to control consistency of pressure from the probe tips between two or more probes because pressure effects and controls recordable readouts and their fluctuations from pressure and stimuli

An apparatus in Claim 1 that includes a low thermal mass environment to enable the thermistors to warm up and cool down faster Figure 7

An apparatus in Claim 1 includes a probe tip (Figure 8) designed specifically with a thumb shaped small protruding tip. The tip is small enough so that when pressure is applied, with an equal amount of force and over an equal amount of time, the inflamed tissues will show pitting or visual dents and turn painful tissues red (Figure 16 and 17) whereby healthy tissue rebound to normal. These images can be recorded.

An apparatus in Claim 1 includes a replaceable cushioned foam pad that covers the conical-shaped tips so when force being is applied to the soft tissue it replicates the experience of thumbs or fingers while preventing tissue damage.

An apparatus in Claim 1 that enables miniaturized sensors to be worn as a wearable monitor and treatment device that digitally measures treatment of inflammatory pain and treatment outcomes

An apparatus in Claim 1 is a miniaturized biosensor probe set to find painful soft tissue and then apply automatic intermittent compression massage.

An apparatus in Claim 1 includes conically shaped probe tips (Figure 9) to apply a force that mimics the denting of fingers and thumbs.

An apparatus in Claim 1 includes digital thermistors contained in a nipple-shaped protuberance in the center of the probe tips (Figure 7).

An apparatus in Claim 1 whereby each probe includes sensors can measure galvanic skin response, give biofeedback, create soft tissue pain, create muscle reflex, show temperature, crepitus, taunt tendons bands, sound/vibration, and an amount of force applied.

An apparatus in Claim 1 includes two probes or a series of probes that are interchangeable and can be used in a variety of ergonomic housings and receptacles such as a penholder, fingers like holders, gloves, and or placed into a compass-or slide rule type holder and/or placed on the skin as a wearable.

An apparatus in Claim 1 includes two probes, which simultaneously compare and establish a differential between a healthy base site and a painful site. Probe #1 always provides the baseline pain-free data, higher or lower indicates soft tissue inflammation that causes pain.

An apparatus in Claim 1 used to palpate soft tissue, apply compression massage, and monitor the results of treatment (medications, exercise, medications, and mental stress).

A method in Claim 1 ensures that after the same amount of pressure over the same amount of time with the conically shaped tips the healthy tissue rebounds and painful tissue retains a dent and is red in colour (Figure 17).

A method in Claim 1 that captures and stores digital images in software

A method in Claim 1 that charts points of inflamed tissues and references those points during subsequent treatments

A method in Claim 1 that ensures equal pressure is applied to all probes to verify data validity.

A method in Claim 1 that ensures pressure is applied equally (with the conically shaped tips) to a painful soft tissue point and a healthy soft tissue point.

A method in Claim 1 that ensures the shape of the probe elicits a crepitus sound during palpation

A method in Claim 1 that ensures the shape of the probe produces a pitting (Figure 18) and histamine creating a visual affect.

A method in Claim 1 that uses a timer to prevent tissue ischemia (tissue damage caused by prolonged compression of more than 90 seconds)

A means in Claim 1 that enables users to examine a larger area at the same time it locates the thermo graphic spot (a discoid region 5 to 10cm) when there is localized damage and/or areas of pain with pressure of soft tissue

A means in Claim 1 that ensures that the Galvanic Skin Responses (GSR) sensor has a larger circumference to enable users to cover a larger area in search of small diameter sweat to be examined

A means in Claim 1 that ensures that the Galvanic Skin Responses (GSR) sensor uses flexible and durable silver silk-screened interdigitated grid pattern onto hypoallergenic cloth

A means in Claim 1 that ensures that the Galvanic Skin Responses (GSR) sensor uses a replaceable single-use sensor to prevent cross contamination

A means in Claim 1 that uses a conically shaped probe tip (Figure 2) with a slightly protruded thermistor so when pressure is applied it creates a visual dent in the soft tissue (called oedema).

A means in Claim 1 that uses a conically shaped probe tip (Figure 2) with a slightly protruded thermistor so that when pressure is applied it creates skin redness (caused by histamines, an inflammatory chemical in vulnerable tissues)

A means in Claim 1 that uses a Galvanic Skin Responses (GSR) sensor to measures and record systemic sympathetic sweat glands activity.

A means in Claim 1 that uses the Patient Response Model (PRM) to verify a patient's input against probe results

A means in Claim 1 to capture and save digital images of visual denting (a sign of inflammation)

A means in Claim 1 to collect data used to illustrate a positive or negative outcome of the therapies.

A means in Claim 1 where software can be used to gamify data and trains users to use probes and their inputs without medical training

A means in Claim 1 to use captured data to gamify the program creating a fun experience for children

A means in Claim 1 whereby infrared thermography sensors, located in head of the probe tip (Figure 2), can identify larger thermal mass areas directing the user to move the probe to the correct area faster

A means in Claim 1 whereby the data collected can be used to monitor changes that occur from treatments time for treatment outcomes and evidence based medicine and practices.

A means in Claim 1 whereby two probes can simultaneously compare and establish a differential between a healthy tissue site and painful tissue site and record the data for future reference.

Claim 2

Claim 2 is a handheld apparatus that uses electronic input called the Patient Response Module (PRM) (Figure 15) to control the amount of force being applied

A method in Claim 2 generates data for comparison

A method in Claim 2 provides a means to express pain dynamically without oral prompting

A method in Claim 2 provides data in reference to other digitized data being displayed and stored in a database.

A method in Claim 2 provides confirmation that pain has been experienced and to what degree

A method in Claim 2 provides training patients to control pressure according to their Pain Pressure Tolerance (PPT)

An apparatus in Claim 2 that contains a strip plot mounted ergonomically onto a hand held device, enabling subjects to rate their pain level on a scale of 1-10, by sliding their finger across the strip plot

An apparatus in Claim 2 that provides a third GSR sensor, which monitors systemic sympathetic responses

An apparatus in Claim 2 that houses a GSR sensor placed on the PRM to measure conductivity (biofeedback) to provide a baseline to compare the systemic inconsistent fluctuation for systemic GSR in contrast to the probe tips and their fluctuations from pressure and stimuli (Figure 13)

An apparatus in Claim 2 that provides a continual comparison of the systemic nervous system
Claim 3

Claim 3 is an inflatable air cell (Figure 20) device that is placed on top of the biosensor probes. The air cell sits directly on top of the wearable pain biosensor probe. Since prolonged pressure from the air could cause tissue damage, an automated control releases every 90 seconds and then reapplies pressure.

A means in Claim 3 to apply probe tips (Figure 2) to the skin to keep the air cells (Figure 22) held in place with a tensor or medical grade adhesive to the soft tissue surface.

A means in Claim 3 whereby pressure is controlled either manually or automatically by using the Patient Response Module

An apparatus in Claim 3 that includes a compression device designed to inflate at a slow enough speed (max 1 lb per second up to 10 pounds).

An apparatus in Claim 3 that includes a release overflow valve for safety

An apparatus in Claim 3 that includes a small portable mechanical motor to inflate the air cell while the patient controls the amount of inflation using the Patient Response Module (PRM) (Figure 13)

An apparatus in Claim 3 that includes an air cell(s) (Figure 20) that is controlled by the Patient Response Module (Figure 13) to the level of the user's tolerance to force.

An apparatus in Claim 3 that includes an air cell(s) (Figure 20) that provides intermittent compression massage to treat inflammatory pain as required.

An apparatus in Claim 3 that includes the ability of air cells (Figure 20) to inflate and deflate intermittently to prevent ischemia and or pressure ulcers that constant pressure would create.

Claim 4

Claim 4 involves an apparatus with strategically located electronic hair-like haptic sensors. Haptic stretch as the muscle withdraws or face expressions twitches (Figure 14) and supplements the Patient Response Module (Figure 13) for non-verbal communication of PPT such as intubated patients, a child, a dementia patient, and language barriers

An apparatus in Claim 4 is a wearable pain monitor that when treatment is successful biosensor display shows area(s) being treated return to normal as haptic sensors are no longer stretched

A means in Claim 4 to address nonverbal children having control the over communicating their tolerance to pressure, and to limit excessive force from being applied by the sensor tip.

A means in Claim 4 to provide corroborative evidence to other measures

A means in Claim 4 to show facial expression changes and or muscle withdrawal reflex (Figure 16) to monitor pain and control pressure or excessive force for persons whom cannot use the Patient Response Module.

Claim 5

Claim 5 is a software program that records, displays, and compares data from the Patient Response Module (Figure 13) and the probe sensors.

A means in Claim 5 to include the ability to collect data and use it to compare to the gold pain questionnaire providing a means to identify effectiveness treatment outcomes in software

A means in Claim 5 to include the ability to save and reference data on a subject image or body template along with visual effects of redness from histamine release.

A means in Claim 5 to include the ability to include images taken from the same distance session to session

A means in Claim 5 to include the ability to measure and record the amount of time it took for a reduction of pain because of pressure being applied

A means in Claim 5 to include software that enables a differential measurement to be collected, mapped, and stored.

A means in Claim 5 to include the ability to chart pain points on a picture chart i.e. a digital patient image and or anatomical chart for mapping points so that data is collected and stored against the said points and can be used for future reference and if further treatment is required.

A means in Claim 5 to include a software system to track patient's therapy progress and treatment outcomes

A means in Claim 5 to include protocols to meet Evidence Based Medicine

A means in Claim 5 to include a centralized database depository that demonstrates the modality type and treatment outcomes for evidence based medicine and practices

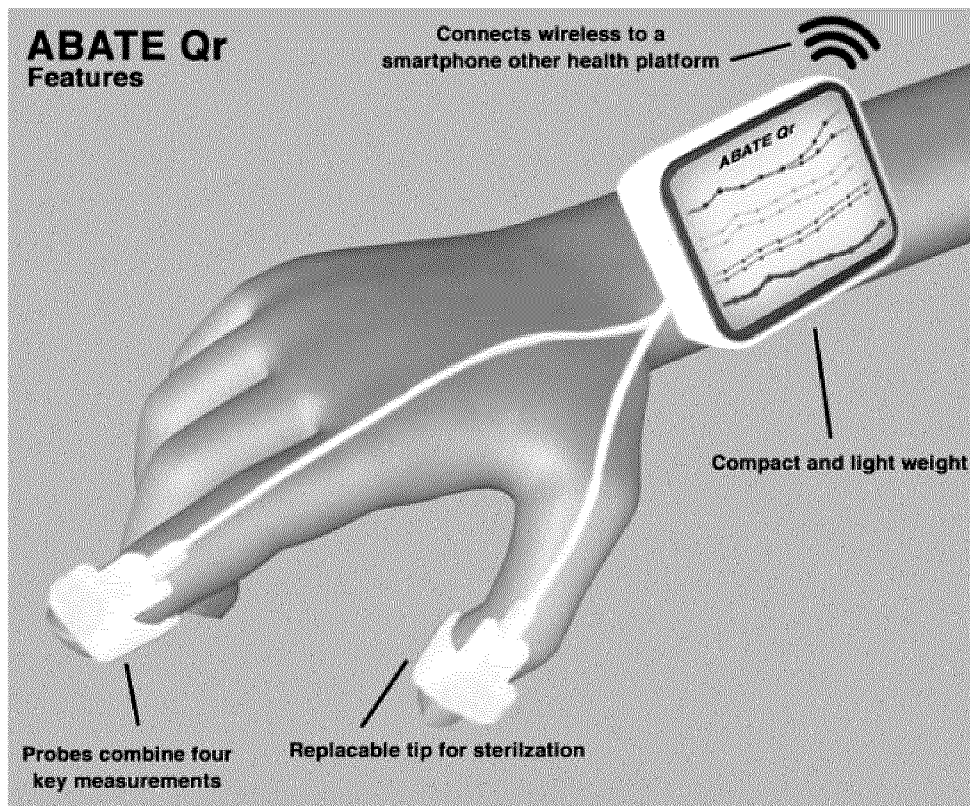


Figure 1

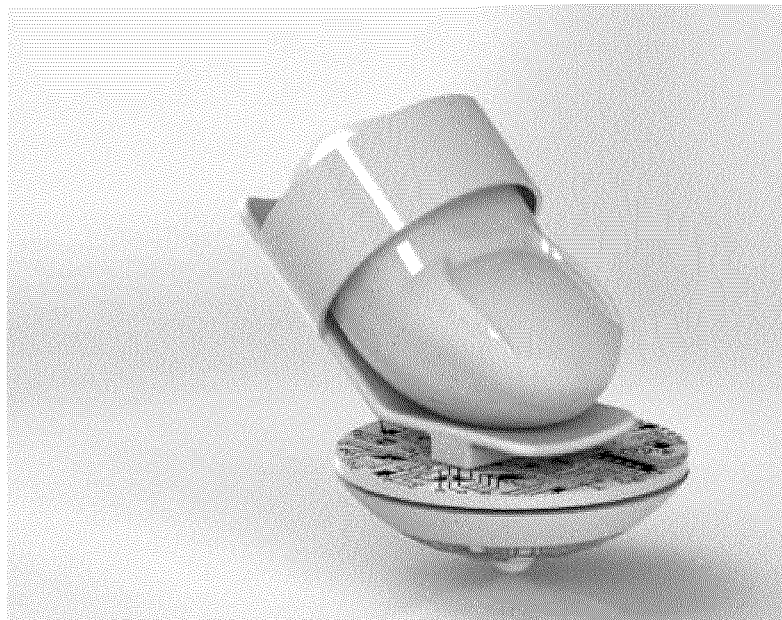


Figure 2a

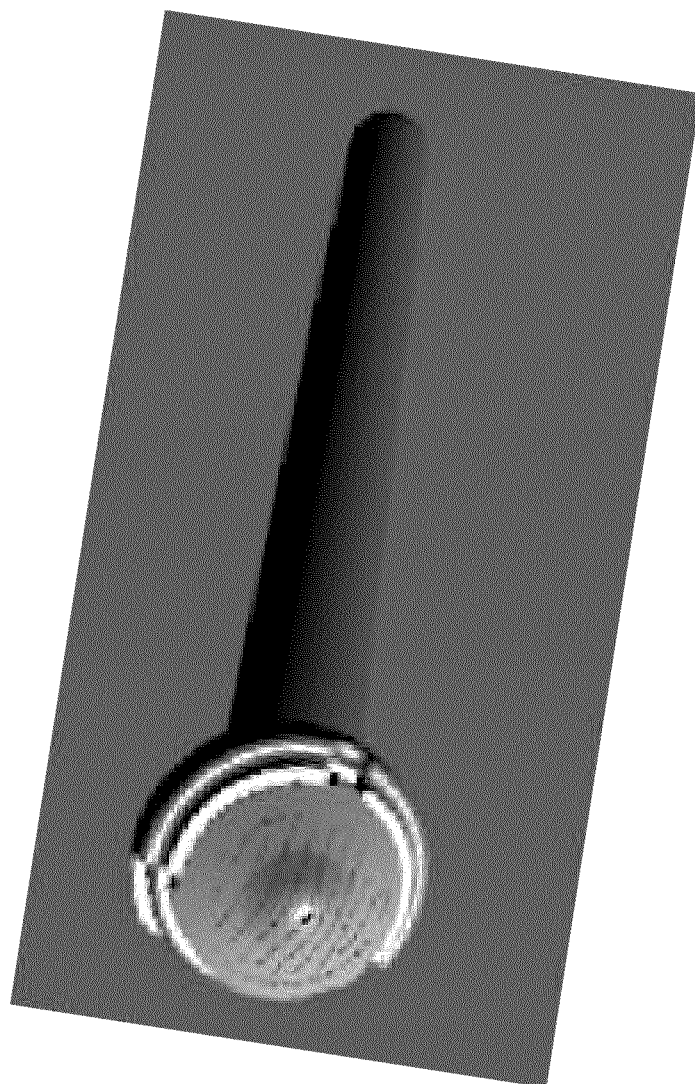


Figure 2b

3 of 13

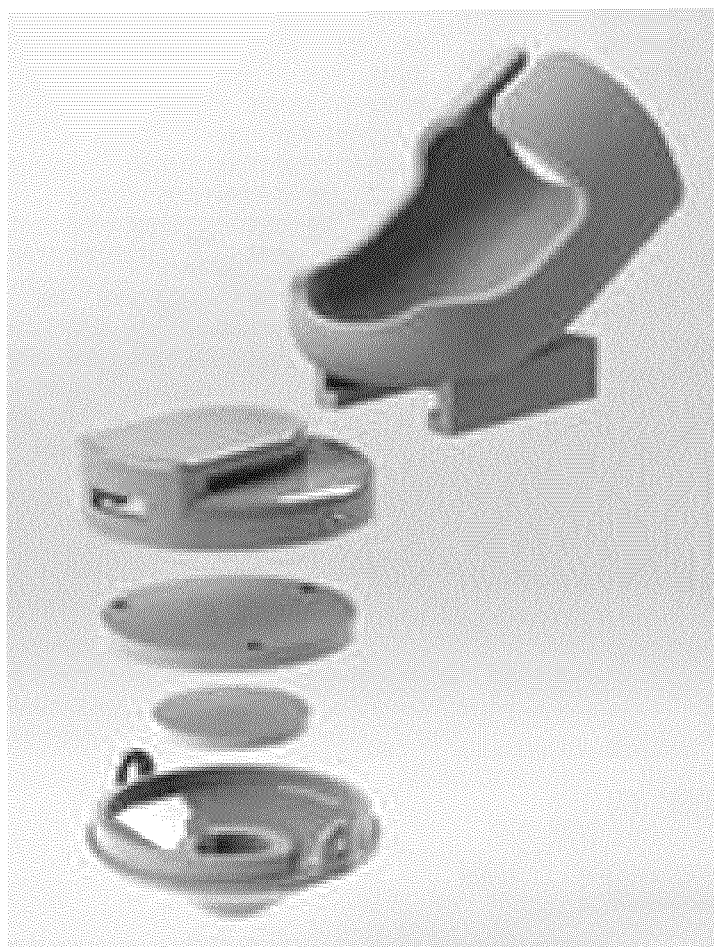


Figure 3

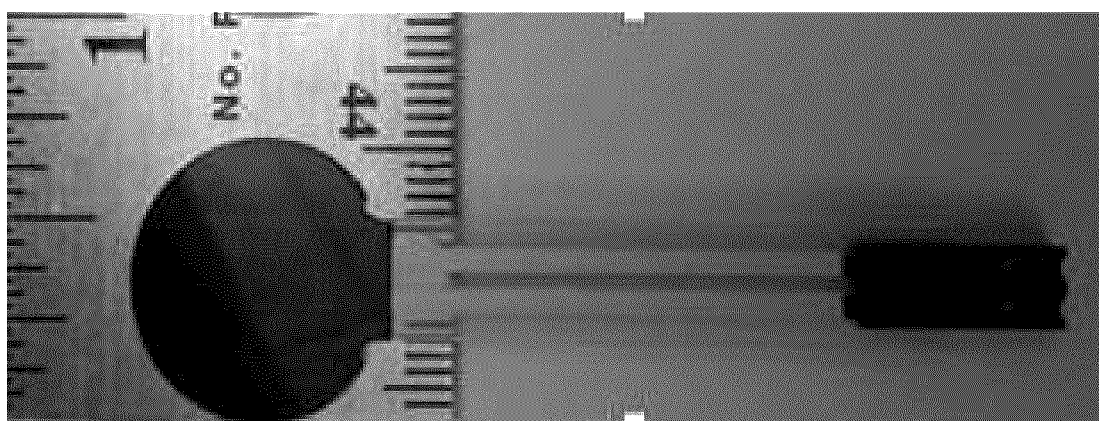


Figure 4a

4 of 13

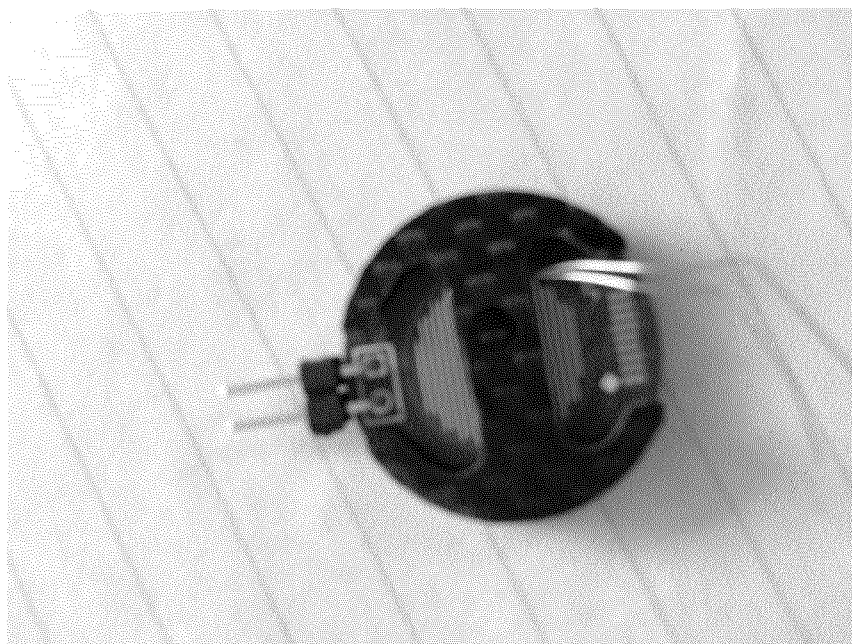


Figure 4b

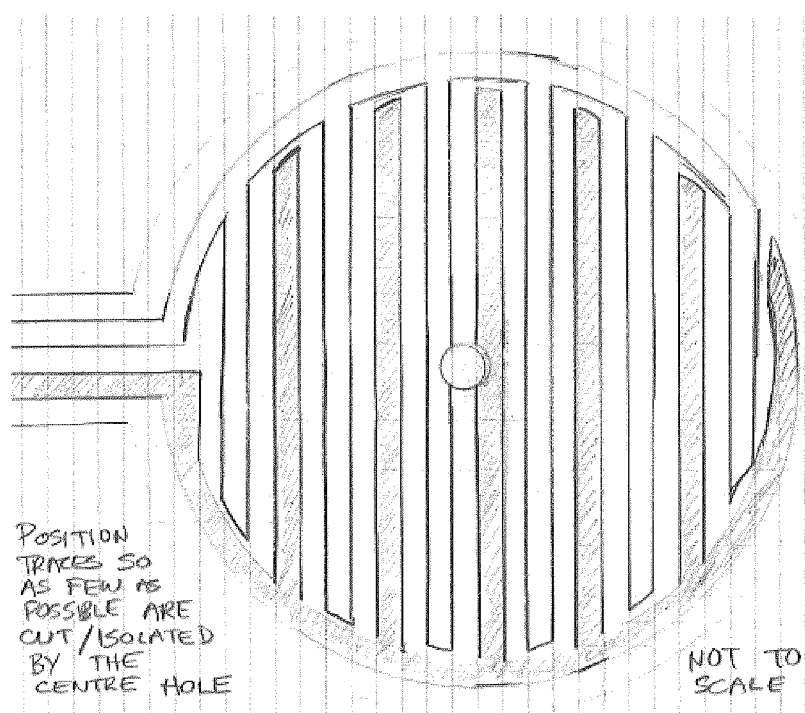


Figure 5

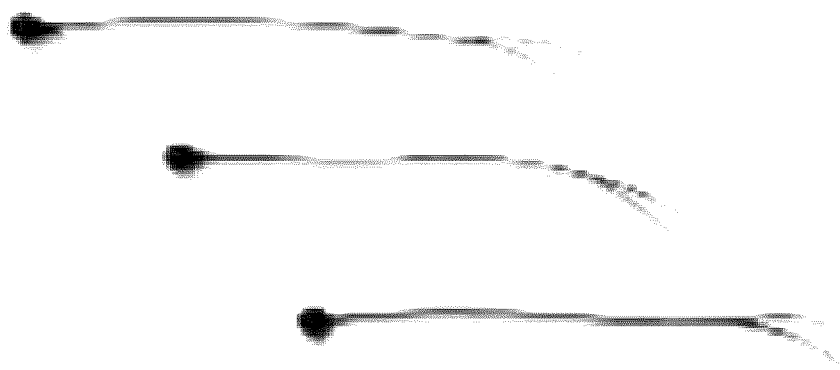


Figure 6

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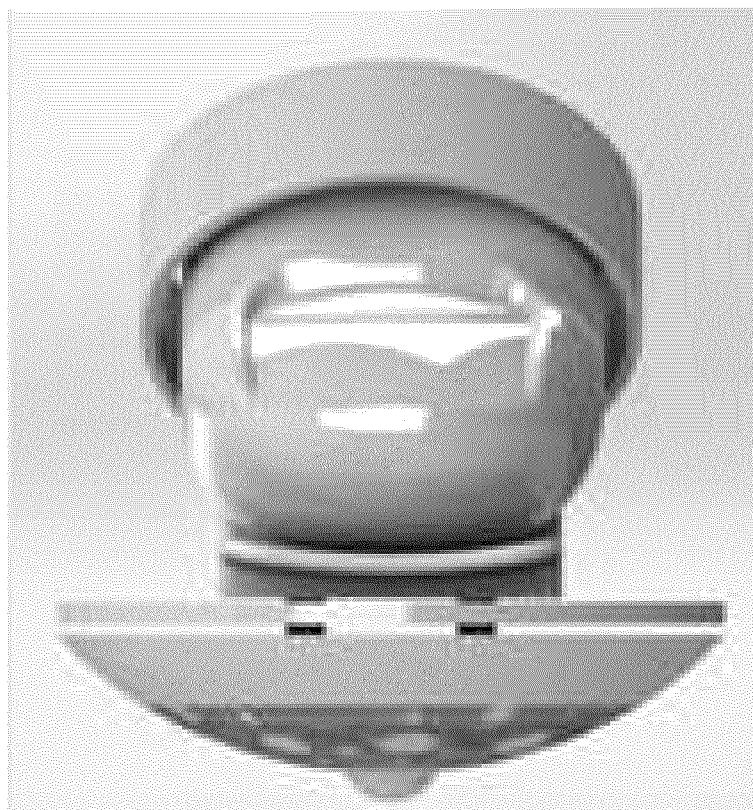


Figure 7a

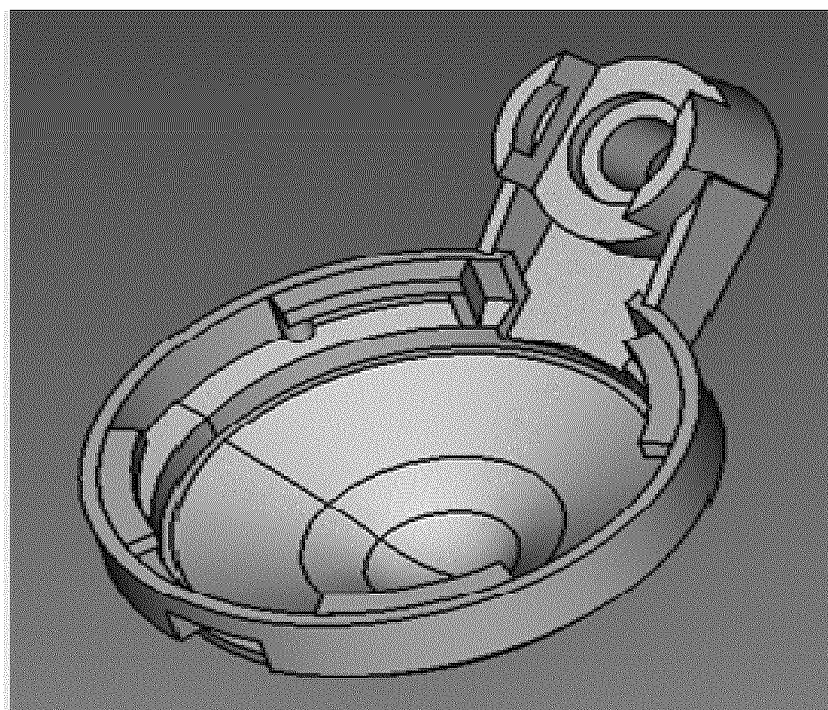


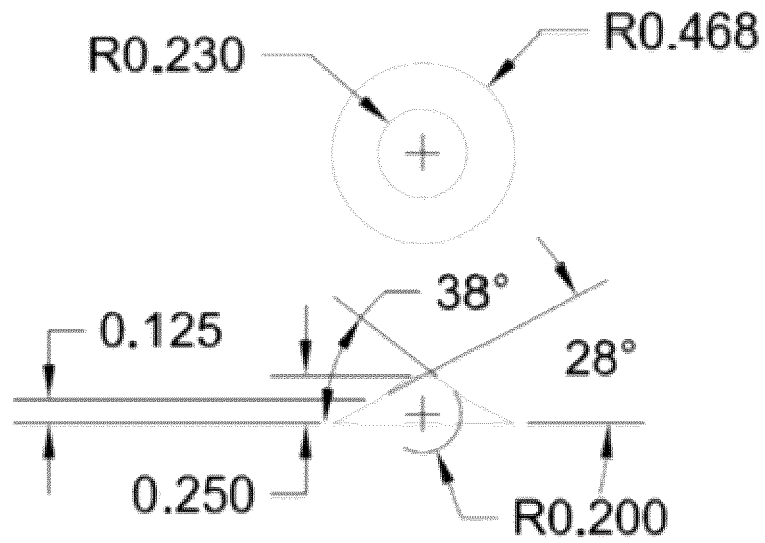
Figure 7b



Figure 8a



Figure 8b



PROBE TIP SHAPE

Figure 9

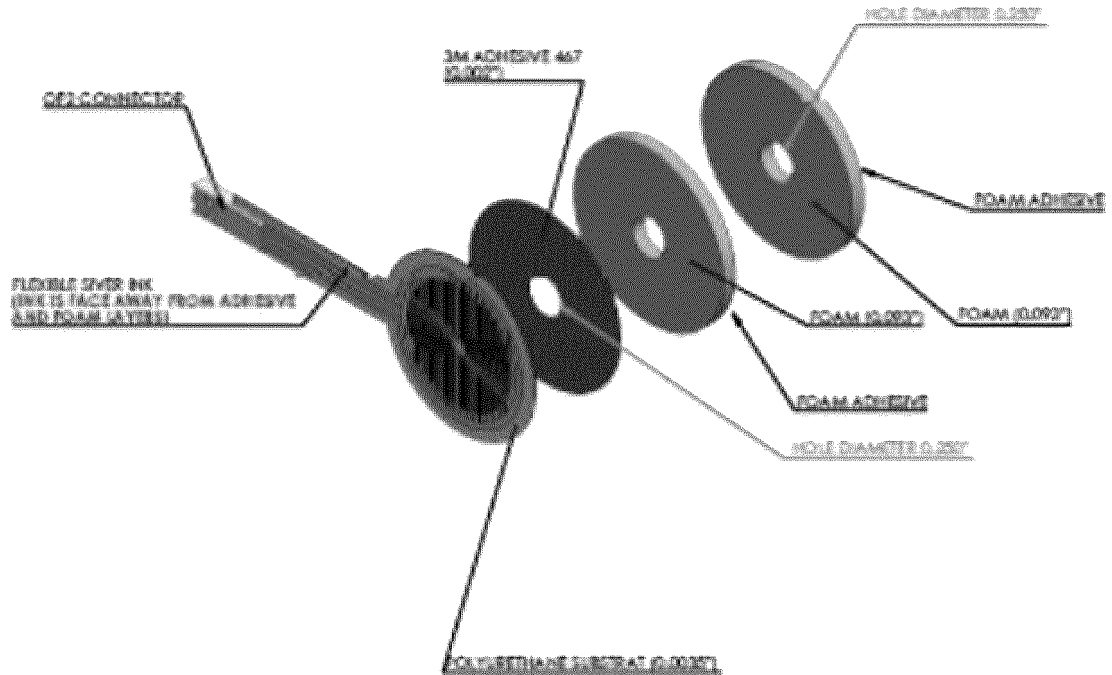


Figure 10

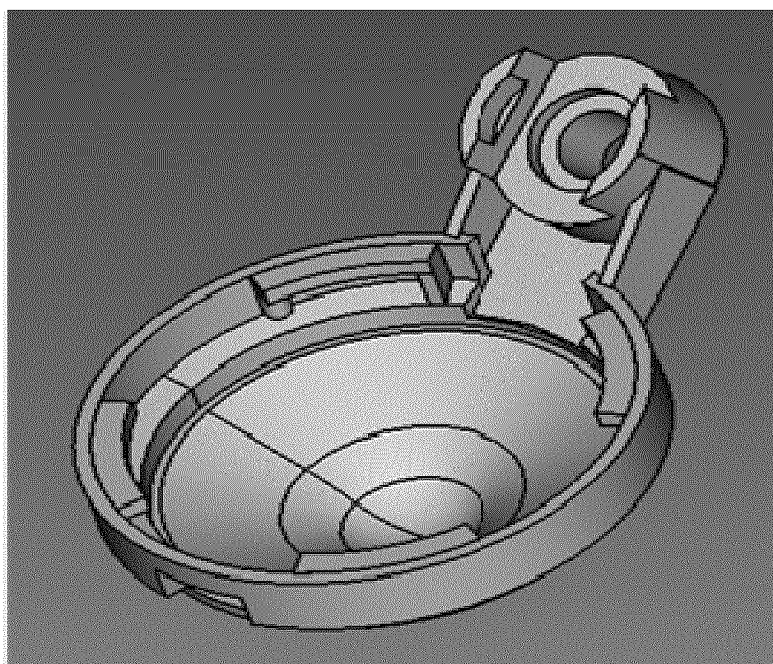


Figure 11



Figure 12



Figure 13



Figure 14

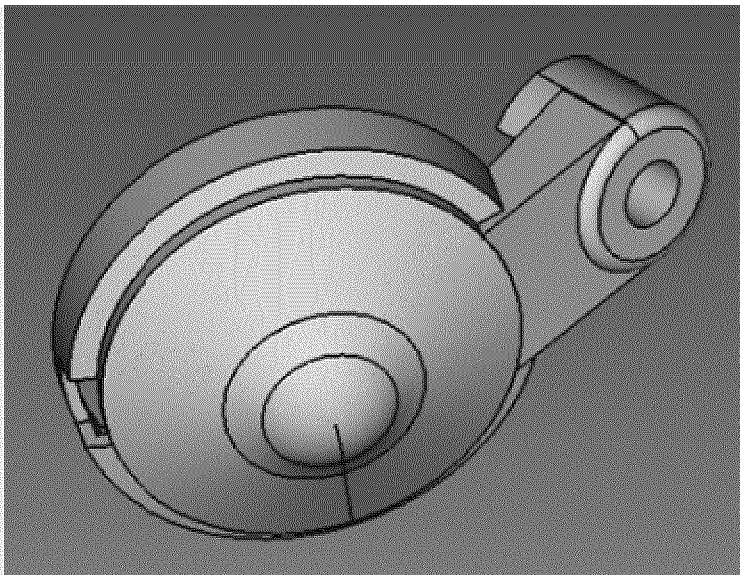


Figure 15

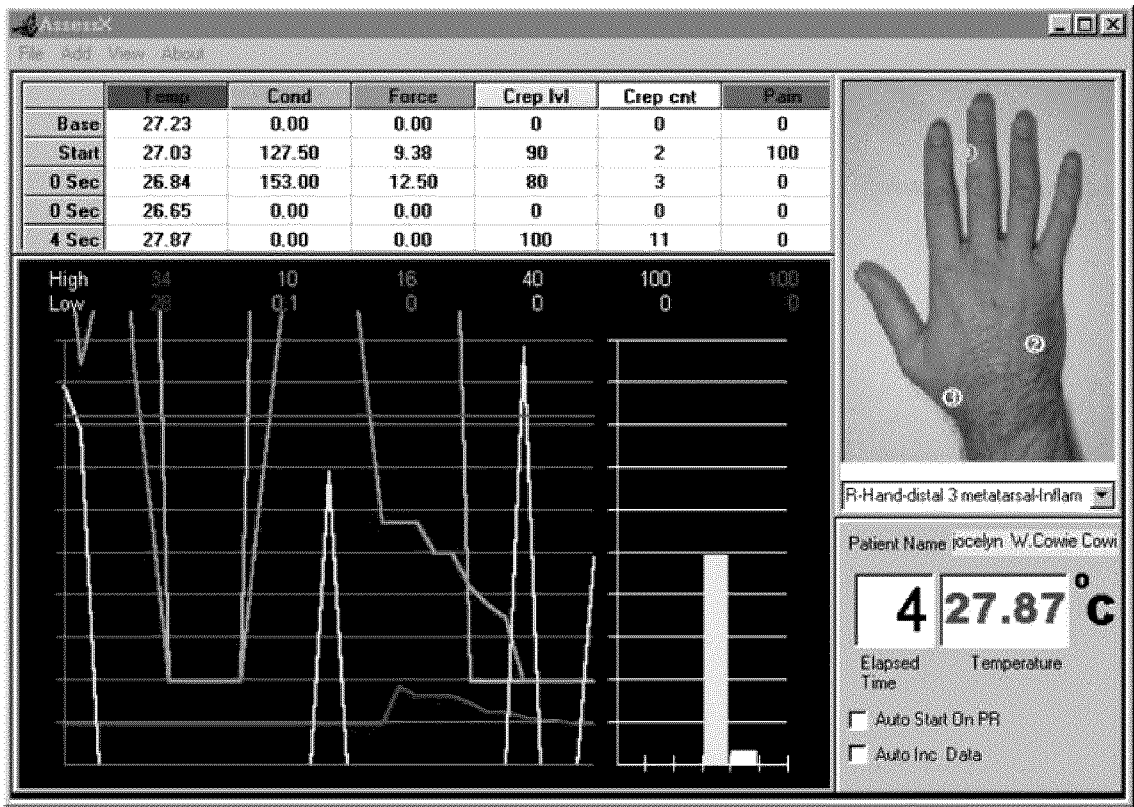


Figure 16

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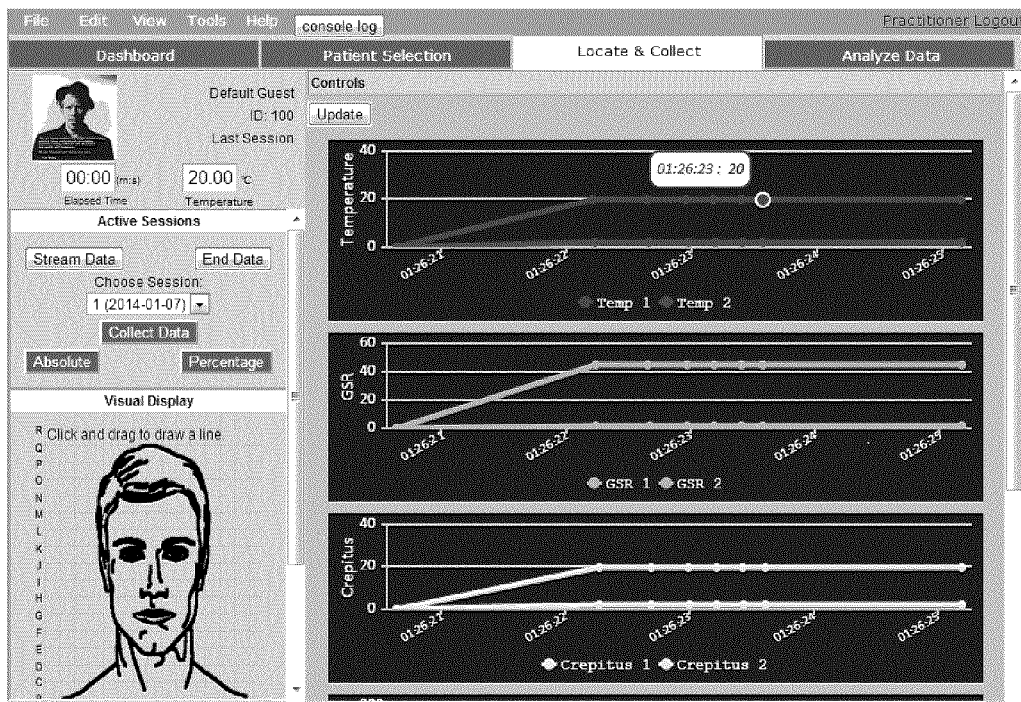


Figure 17

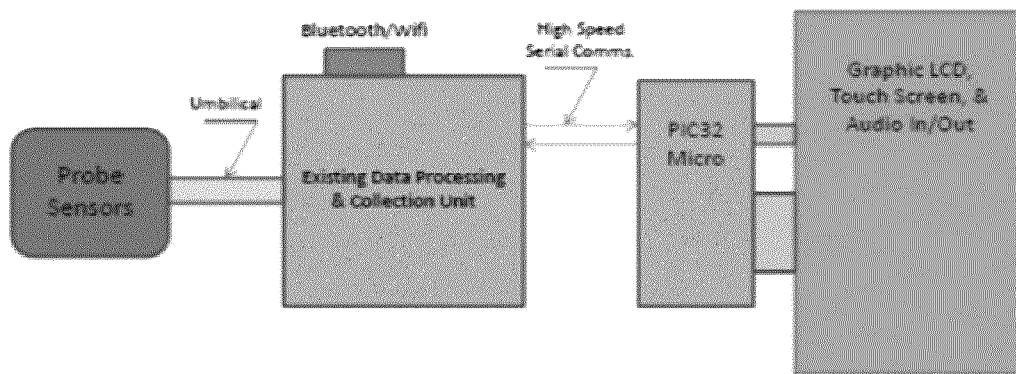


Figure 18

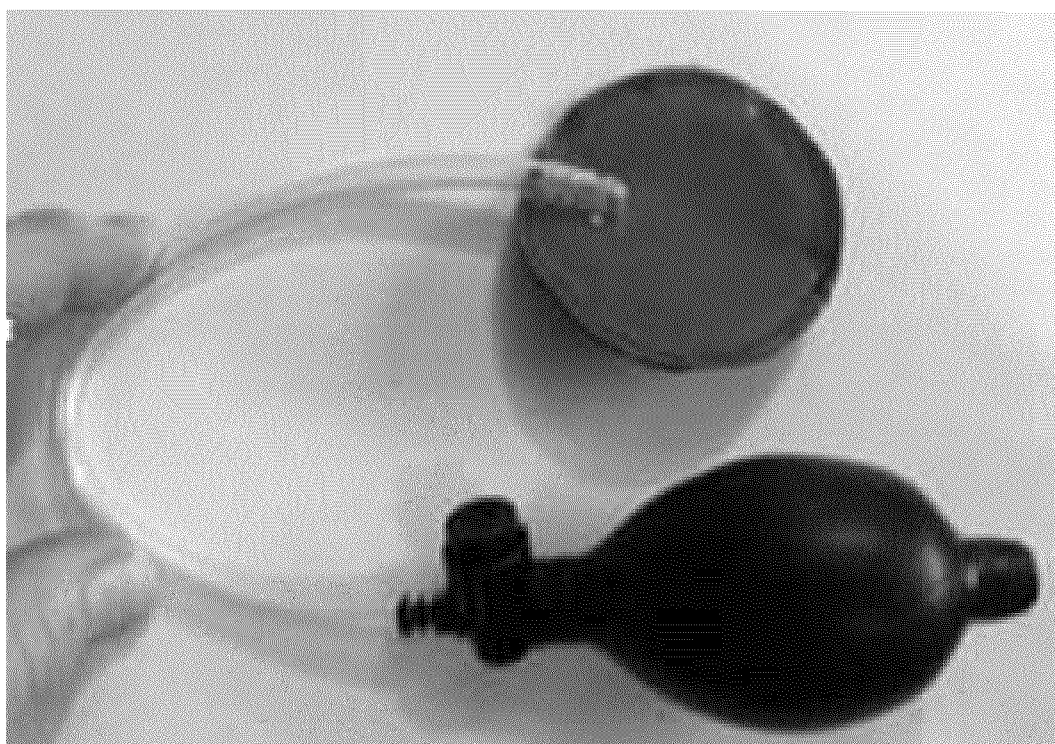


Figure 19

INTERNATIONAL SEARCH REPORT

International application No.

PCT/CA2017/050360

A. CLASSIFICATION OF SUBJECT MATTER

IPC: *A61B 5/00* (2006.01), *A61B 5/01* (2006.01), *A61B 5/053* (2006.01), *A61H 39/02* (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC: A61B* (2006.01)(in combination with keywords)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)

Questel Orbit, Google, Canadian Patent Database (keywords: probe, skin, condition, diagnosis, temperature, lens, thermistor, quadrant)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,588,440 (Cowie) 31 December 1996 (31-12-1996) • See entire document	1-11
A	US 2015/0005691 A1 (Harris et al.) 1 January 2015 (01-01-2015) • See entire document	1-11
A	US 2009/0043293 A1 (Pankratov et al.) 12 February 2009 (12-02-2009) • See entire document	1-11
A	US 2014/0200487 A1 (Ramdas et al.) 17 July 2014 (17-07-2014) • See entire document	1-11

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier application or patent but published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search
09 August 2017 (09-08-2017)Date of mailing of the international search report
11 August 2017 (11-08-2017)Name and mailing address of the ISA/CA
Canadian Intellectual Property Office
Place du Portage I, C114 - 1st Floor, Box PCT
50 Victoria Street
Gatineau, Quebec K1A 0C9
Facsimile No.: 819-953-2476

Authorized officer

Saadia Khan (819) 561-2161

INTERNATIONAL SEARCH REPORT

International application No.

PCT/CA2017/050360**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of the first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claim Nos.: 12, 13
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 12, 13 are directed to a method for treatment of the human or animal body by surgery or therapy, which the International Searching Authority is not required to search under PCT Rule 39.1(iv). However, this Authority has carried out a search based on the alleged effect or purpose/use of the product defined in claims 12, 13.
2. ☐ Claim Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claim Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claim Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.

PCT/CA2017/050360

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
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专利名称(译)	用于定位，测量，监测和治疗皮肤软组织和面层的炎症的装置和方法		
公开(公告)号	EP3432778A4	公开(公告)日	2019-11-06
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优先权	62/390094 2016-03-21 US		
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摘要(译)

用于诊断患者皮肤状况的设备技术领域本发明涉及一种用于诊断患者皮肤状况的设备。该设备包括透镜，该透镜具有将表面划分成多个象限的径向电导率线，每个象限具有间隔开的电导率线，并且这些线的中心具有位于每个电极的外端的温度敏感元件和温度敏感元件。径向电导率线。