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(54) Benævnelse: **SEM-SCANNER TIL TIDLIG OPDAGELSE AF SÅR**

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DESCRIPTION

Description

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0001] This invention pertains generally to monitoring skin pressure ulcers and more particularly to skin ulcer monitoring via measurement of Sub-epidermal Moisture (SEM).

2. Description of Related Art

[0002] Patients' skin integrity has long been an issue of concern for nurses and in nursing homes. Maintenance of skin integrity has been identified by the American Nurses Association as an important indicator of quality nursing care. Meanwhile, pressure ulcers remain a major health problem particularly for hospitalized older adults. When age is considered along with other risk factors, the incidence of pressure ulcers is significantly increased. Overall incidence of pressure ulcers for hospitalized patients ranges from 2.7% to 29.5%, and rates of greater than 50% have been reported for patients in intensive care settings. In a multicenter cohort retrospective study of 1,803 older adults discharged from acute care hospitals with selected diagnoses, 13.2% (i.e., 164 patients) demonstrated an incidence of stage I ulcers. Of those 164 patients, 38 (16%) had ulcers that progressed to a more advanced stage. Pressure ulcers additionally have been associated with an increased risk of death one year after hospital discharge. The estimated cost of treating pressure ulcers ranges from $5,000 to $40,000 for each ulcer, depending on severity.

[0003] Therefore, there is an urgent need to develop a preventive solution to measure moisture content of the skin as a mean to detect early symptoms of ulcer development. Prior art document US 2009/312615 discloses an apparatus for the non-invasive glucose detection comprising an electrical detection device for measuring the response of the tissue or blood to an electric field at low frequencies below 1 MHz and at high frequencies above 10 MHz. The apparatus further comprises a force or acceleration sensor to detect the pressure of the apparatus against the skin and/or quick movements.
Prior art document US 2003/036674 discloses tissue sensors that house one or more sensor elements. Each element has a housing mounted substrate and a superstrate with a planar antenna between. A transitional periphery (TP) of a superstrate outer surface interconnects a

base to a plateau. Some of the TP has a generally smooth transition. Plural elements are spaced by the housing. In an alternative embodiment, the superstrate TP is flat, the housing extends to the outer superstrate surface and a shield surrounds the element. The housing is flush with or recessed below the superstrate and defines a TP between the housing and superstrate.
Prior art document US 2005/177061 discloses a method for measuring tissue edema. An electromagnetic probe is placed on the skin, and the capacitance of the probe is proportional to the dielectric constant of the skin and subcutaneous fat, which is proportional to the water content of the skin.
Prior art document US 2004/0254457 A1 describes an apparatus and method for near-field imaging of tissue. Pulsed or continuous-wave sources, broadband electromagnetic energy generally in the 10 MHz to 300 GHz range is applied through one or a plurality of near-field antennas such as coaxial probe tips in the form of a bundle of antennas. The bundle of antennas is scanned over a surface of the object on a pixel-by-pixel basis to determine the spectra of the sample on a pixel-by-pixel basis, allowing a two dimensional display of the absorption spectra to be provided.

[0004] Huang et al. Sensors and Actuators B vol. 134, no. 1, pp. 206-212 describes an apparatus for measuring skin moisture using an interdigital electrode structure.

BRIEF SUMMARY OF THE INVENTION

[0005] The above needs are met by an apparatus for in situ Sub-Epidermal Moisture (SEM) sensing of tissue as defined in claim 1. Preferred embodiments of the invention are set out in the dependent claims.

OUTLINE OF THE DISCLOSURE

[0006] An aspect of the present disclosure is a smart compact capacitive sensing conforming handheld apparatus configured to measure Sub-epidermal Moisture (SEM) as a mean to detect and monitor the development of pressure ulcers. The device incorporates an array of electrodes which are excited to measure and scan SEM in a programmable and multiplexed manner by a battery-less RF-powered chip. The scanning operation is initiated by an interrogator which excites a coil embedded in the apparatus and provides the needed energy burst to support the scanning/reading operation. Each embedded electrode measures the equivalent sub-epidermal capacitance corresponding and representing the moisture content of the target surface.

[0007] An aspect of this disclosure is the in situ sensing and monitoring of skin or wound or ulcer development status using a wireless, biocompatible RF powered capacitive sensing system referred to as smart SEM imager. The present invention enables the realization of smart preventive measures by enabling early detection of ulcer formation or inflammatory pressure which would otherwise have not been detected for an extended period with increased risk of infection and higher stage ulcer development.

[0008] In one beneficial embodiment, the handheld capacitive sensing imager apparatus incorporates pressure sensing components in conjunction with the sensing electrodes to monitor the level of applied pressure on each electrode in order to guarantee precise wound or skin electrical capacitance measurements to characterize moisture content. In summary, such embodiment would enable new capabilities including but not limited to: 1) measurement capabilities such as SEM imaging and SEM depth imaging determined by electrode geometry and dielectrics, and 2) signal processing and pattern recognition having automatic and assured registration exploiting pressure imaging and automatic assurance of usage exploiting software systems providing usage tracking.

[0009] One major implication of this sensor-enhanced paradigm is the ability to better manage each individual patient resulting in a timelier and more efficient practice in hospitals and even nursing homes. This is applicable to patients with a history of chronic wounds, diabetic foot ulcers, pressure ulcers or postoperative wounds. In addition, alterations in signal content may be integrated with the activity level of the patient, the position of patient's body and standardized assessments of symptoms. By maintaining the data collected in these patients in a signal database, pattern classification, search, and pattern matching algorithms can be developed to better map symptoms with alterations in skin characteristics and ulcer development. This approach is not limited to the specific condition of ulcer or wound, but may have broad application in all forms of wound management and even skin diseases or treatments.

[0010] One aspect of the present disclosure is apparatus for sensing sub-epidermal moisture (SEM) from a location external to a patient's skin. The apparatus includes a bipolar RF sensor embedded on a flexible substrate, and a conformal pressure pad disposed adjacent and underneath the substrate, wherein the conformal pressure pad is configured to support the flexible substrate while allowing the flexible substrate to conform to a non-planar sensing surface of the patient's skin. The apparatus further includes interface electronics coupled to the sensor; wherein the interface electronics are configured to control emission and reception of RF energy to interrogate the patient's skin.

[0011] Another aspect, which is not claimed, is a method for monitoring the formation of pressure ulcers at a target location of a patient's skin. The method includes the steps of positioning a flexible substrate adjacent the target location of the patient's skin; the flexible substrate comprising one or more bipolar RF sensors; conforming the flexible substrate to the patient's skin at the target location; exciting the one or more bipolar RF sensor to emit RF energy into the patient's skin; and measuring the capacitance of the skin at the target location as an indicator of the Sub-Epidermal Moisture (SEM) at the target location.

[0012] Further aspects of the disclosure will be brought out in the following portions of the specification, wherein the detailed description is for the purpose of fully disclosing preferred embodiments of the invention without placing limitations thereon.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)

[0013] The invention will be more fully understood by reference to the following drawings which are for illustrative purposes only:

FIG. 1 illustrates an assembled perspective component view of the SEM Scanner of the present invention.

FIG. 2 illustrates a perspective view of a Kapton-based conforming sensing substrate assembly of the present invention.

FIG. 3 shows a top view of an exemplary concentric sensing electrode in accordance with the present invention.

FIG. 4 illustrates a side view of a flex stack-up for the Kapton-based conforming sensing substrate shown in FIG. 2.

FIG. 5 illustrates a side view of an alternative flex stack-up for a Kapton-based conforming sensing substrate.

FIG. 6 shows a top view of two-electrode sensing Kapton-based flex sensor substrates for three alternative types of capacitive sensing concentric electrodes.

FIG. 7 illustrates an exploded perspective component view of the SEM scanner of FIG. 1.

FIG. 8 illustrates a schematic side view of the SEM scanner of FIG. 1.

FIG. 9 illustrates a schematic side view of the SEM scanner of FIG. 8 in contact with subject skin.

FIG. 10 illustrates a perspective view of an assembled SEM scanner with an alternative array of sensors in accordance with the present invention.

FIG. 11 is a plot of normalized responses of the tested electrodes of the present invention.

FIG. 12 is a graph of measured equivalent capacitance for dry volar arm for three different concentric sensor electrodes.

FIG. 13 is a plot of time dependent fractional change in capacitance relative to dry skin for three different concentric sensor electrodes (after 30 minutes of applying lotion).

FIG. 14 is a plot of time dependent fractional change in capacitance relative to dry skin for three different concentric sensor electrodes (after 15 minutes of applying lotion).

FIG. 15 is a plot of fractional change vs. time.

FIG. 16 shows a SEM scanner electrode system and electrode layering providing proper shielding from interference.

FIG. 17 shows an SEM scanner mechanical compliance for electrodes developed to enable probing of bony prominence.

DETAILED DESCRIPTION

[0014] In one exemplary embodiment, a smart handheld capacitive sensing device according to the present invention employs a programmable sensing electrode array. This is based on methods that use an interrogator to excite the embedded electrodes.

[0015] FIG. 1 illustrates an SEM scanning/sensing apparatus 10 according to the present disclosure. The scanner 10 comprises five main components, including a top silicone edge sealing gasket 18 encircling a Kapton-based sensing substrate 16, which rests on a conformal silicone pressure pad 12. A thick annular silicone spacer 20 is disposed under pressure pad to provide free space for the pressure pad to deform. The bottom layer comprises an interface electronics package enclosure 22 that houses interface circuitry for interrogating and transmitting data for evaluation. These five main components are described in further detail below.

[0016] In the embodiment shown in FIG. 1, an array 14 of individual RF electrode sensors 24 and 26 is embedded on a flexible biocompatible substrate 16. Substrate 16 may comprise a laminated Kapton (Polyimide) chip-on-flex.

[0017] FIG. 2 illustrates one embodiment of a Kapton sensor substrate 16a that comprises an array 14 of differing sized concentric sensing electrodes. A flexible biocompatible Polyimide or Kapton substrate 32 comprises a layer of sensing pads 14 and 15 coated on one side with an ultra thin cover layer 30 of Polyimide (e.g. CA335) to isolate pads electrodes 14,15 from direct moisture contact and also to provide a uniform contact surface.

[0018] In FIG. 2, sample capacitive sensing electrodes 14 are shown in different sizes (e.g. 24, 26, and 29), which are manipulated to achieve and sense different depths of skin. Sensing electrodes 14 may comprise any number of different shape and configurations, such as the concentric circles of array 14, or the interdigitating fingers of sensor 15.

[0019] FIG. 3 illustrates a close-up top view of a concentric sensing pad 26 in accordance with an embodiment of the present invention. Pad 26 comprises a bipolar configuration having a first electrode 36 comprising an outer annular ring disposed around a second inner circular electrode 38. Outer ring electrode 36 has an outer diameter D_0 and an inner diameter D, that is larger than the diameter D_C of the circular inner electrode 38 to form annular gap 40. Inner circular electrode 38 and outer ring electrode 36 are coupled electrically to interface electronics in the interface electronics package 22. As shown in greater detail in FIGS. 4 and 5, electrodes 36 and 38 are disposed on separate layers within the substrate assembly 16.

[0020] The dimensions of the sensor pads 24, 26 generally correspond to the depth of interrogation into the derma of the patient. Accordingly, a larger diameter pad (e.g. pad 26 or 29) will penetrate deeper into the skin than a smaller pad. The desired depth may vary depending on the region of the body being scanned, or the age, skin anatomy or other characteristic of the patient. Thus, SEM scanner 10 may comprise an array of different sized pads (e.g. small pads 24 and medium sized pads 26 shown in FIG. 1) each individually coupled to the interface electronics package 22.

[0021] FIG. 4 illustrates side view of a flex stack-up for a Kapton based substrate assembly 16, where thin adhesive layers 42 are used to attach a Kapton layer 32 in between copper layers 44 and 46, all of which are disposed between upper coverlay 30 and lower coverlay 48. A stiffener 50 is disposed under lower coverlay 48, being positioned directly under copper layer 46 of the sensing pads. The stiffener 50 forms a rigid portion of the substrate where sensing pad array 14, connectors (e.g. connectors 66, 76, or 86 shown in FIG. 6) and interfacing (e.g. lead wires 34) are located, so that these areas do not deform, whereas the rest of the substrate is free to deform. The top copper layer 44 is used to etch out electrode array 14 and corresponding copper routing 34 to the connectors. The bottom copper layer 46 preferably comprises a crisscross ground plane to shield electrode array 14 from unwanted electromagnetic interference.

[0022] In one embodiment, the flex substrate 16 assembly comprises Pyralux FR material from Dupont. In an exemplary configuration, approximately 127μm (5mil) thick FR9150R double-sided Pyralux FR copper clad laminate is used as the Kapton substrate. Top coverlay 30 comprises Pyralux 127μm (5mil) FR0150 and the bottom coverlay 48 comprises 25.4um (1 mil) FR01 10 Pyralux. The thickness of the top FR0150 coverlay 30 is an important parameter as it affects the sensitivity of sensing electrodes in measuring skin moisture content. Copper layers 44, 46 are generally 35.6μm (1 .4mil) thick, while adhesive layers 42 are generally 25.4μm (1 mil thick). The stiffener 50 shown in FIG. 4 is approximately 787.4μm (31 mil) thick.

[0023] FIG. 5 shows a side view of a preferred alternative flex stack-up for a Kapton based substrate 120, where thin adhesive layers 42 (25.4μm or 1 mil) are used to attach an 457.2μm (18 mil) Kapton layer 122 in between 35.6μm (1 .4 mil) copper layers 44 and 46, all of which are disposed between 50.8μm (2 mil) upper coverlay 30 and 25.4um (1 mil) lower coverlay 48. A stiffener 50 is disposed under lower coverlay 48, being positioned directly under copper layer 46 of the sensing pad. The 787.4μm (31 mil) FR4 stiffener 126 forms a rigid portion of the substrate under the array 14 of sensing pads, connectors 66 and interfacing 34. A 50.8μm (2 mil) layer of PSA adhesive 124 is used between the bottom coverlay 48 and stiffener 126. The layering of assembly 120 is configured to provide proper shielding from interference.

[0024] FIG. 6 shows a top view of three separate and adjacently arranged concentric bipolar electrode sensing Kapton-based flex pads 60, 70 and 80 having different sized capacitive sensing concentric electrodes. Pad 60 comprises a substrate having two large concentric electrodes 62 wired through substrate 64 via connectors 34 to lead line inputs 66. Pad 70 comprises a substrate having two medium concentric electrodes 72 wired through substrate 74 to lead line inputs 76. Pad 80 comprises a substrate having two small concentric electrodes 82 wired through substrate 84 to lead line inputs 86. The configuration shown in FIG. 6 is optimized for cutting/manufacturing and also to avoid interference between data lines and sensors. Each of the bipolar electrode pads is individually wired to the electronics package 22 to allow for independent interrogation, excitation, and data retrieval.

[0025] FIG. 7 illustrates an exploded perspective component view of the SEM scanner 10. The silicone edge sealing gasket 18 is applied over the Kapton sensor substrate assembly 16 to seal and shield the edge interface connectors through which interface electronics package 22 excite and controls the sensing electrode array 14. The Kapton sensor substrate assembly 16 rests on a conformal silicone pressure pad 12 that provides both support and conformity to enable measurements over body curvature and bony prominences.

[0026] In one beneficial embodiment, pressure sensor 1 1 may be embedded under each sensing electrode 24, 26 (e.g. in an identical array not shown), sandwiched between Kapton sensor substrate 26 and the conformal silicone pressure pad 28 to measure applied pressure at each electrode, thus ensuring a uniform pressure and precise capacitance sensing.

[0027] Lead access apertures 28 provide passage for routing the connector wires (not shown) from the substrate connectors (e.g. 66, 76, 86) through the pressure pad 12, annular spacer 20 to the interface electronics 22.

[0028] The annular silicone spacer 20 comprises a central opening 27 that provides needed spacing between the conformal silicone pressure pad 12 and the interface electronics package 22 to allow the pressure pad 12 and flexible substrate to conform in a non-planar fashion to conduct measurements over body curvatures or bony prominences.

[0029] In one embodiment, the interface electronics package 22 is connected to a logging unit or other electronics (not shown) through wire-line USB connector 56.

[0030] The interface electronics package 22 preferably comprises an enclosure that contains all the electronics (not shown) needed to excite, program and control the sensing operation and manage the logged data. The electronics package 22 may also comprise Bluetooth or other wireless communication capabilities to allow for transfer of sensing data to a computer or other remote device. Docked data transfer is also contemplated, in addition to real-time Bluetooth transfer. A gateway device (not shown) may be used for communicating with the SEM device 10 and data formatting prior to upload to a computer or backend server.

[0031] FIG. 8 is a schematic side view of the SEM scanner 10 in the nominal configuration, showing the edge gasket 18 over Kapton substrate 16, and lead access apertures 28, which provide access through annular spacer 20 and conformal pad 12 to electronics 22.

[0032] FIG. 9 illustrates a schematic side view of the SEM scanner 10 in contact with the target subject 25. The annular silicone spacer 20 provides enough spacing for conforming silicone pad 12 to conform to the target surface 25. The conforming silicone pad 12 enables continuous contact between the substrate 16 and patient's skin 25, thus minimizing gaps between the substrate 16 and patient's skin 25 that could otherwise result in improper readings of the patient anatomy. Electrode array 14, which is embedded in substrate16, is shown interrogating into the derma of tissue 25 by directing emission of an RF signal or energy into the skin and receiving the signal and correspondingly reading the reflected signal. The interrogator or electronics package 22 excites electrode coil 14 by providing the needed energy burst to support the scanning/reading of the tissue. Each embedded electrode 14 measures the equivalent sub-epidermal capacitance corresponding to the moisture content of the target skin 25.

[0033] While other energy modalities are contemplated (e.g. ultrasound, microwave, etc.), RF is generally preferred for its resolution in SEM scanning.

[0034] FIG. 10 illustrates a perspective view of an assembled SEM scanner 10 with an alternative substrate 16b having an array 14 of ten sensors dispersed within the substrate 16b. This larger array 14 provides for a larger scanning area of the subject anatomy, thus providing a complete picture of the target anatomy in one image without having to generate a scanning motion. It is appreciated that array 14 may comprise any number of individual sensors, in be disposed in a variety of patterns.

[0035] The SEM scanner 10 was evaluated using a number of different sized and types of sensors 26. Table 1 illustrates electrode geometries are used throughout the following measurements. As shown in FIG. 1 the outer ring electrode diameter D_0 varied from 5 mm for the XXS pad, to 55 mm for the large pad. The outer ring electrode inner diameter D, varied from 4 mm for the XXS pad, to 40 mm for the large pad. The inner electrode diameter D_c varied from 2 mm for the XXS pad, to 7 mm for the large pad. It is appreciated that the actual dimensions of the electrodes may vary from ranges shown in these experiments. For example, the contact diameter may range from 5 mm to 30 mm, and preferably ranges from 10 mm to 20 mm.

[0036] To measure the properties of each sensor size listed in Table 1 , the sensors were fabricated using both Kapton and rigid board. In testing with the rigid sensor pads, lotion was applied to the thumb continuously for 15 minutes.

[0037] FIG. 1 1 is a plot of normalized responses of the tested electrodes of the present disclosure. The four sensors' (XXS, XS, S, M) normalized responses are compared in FIG. 11 and Table 2.

[0038] As can be seen in FIG. 11 and Table 2, the S electrode appears to be most responsive overall to the presence of moisture. Both the M and S electrodes seem to exhibit a peak. This suggests a depth dependency of the moisture being absorbed into the skin, as the roll-off from the M electrode occurs about 5 minutes after the peak for S electrode.

[0039] The SEM scanner 10 was also tested on the inner arm. A resistive pressure sensor (e.g. sensor 1 1 shown in FIG. 7) was also used to measure pressure applied on sensor to the arm. This way, constant pressure is applied across measurements. First, the dry inner arm was measured using the XS, S and M electrodes. Then, the same area was masked off with tape, and moisturizer lotion was applied for 30 minutes. Subsequent measurements were made on the same location after cleaning the surface.

[0040] FIG. 12 is a graph of measured equivalent capacitance for dry Volar arm for three different sized (M, S, XS) concentric sensor electrodes before applying the commercial lotion moisturizer.

[0041] FIG. 13 is a plot of time dependent fractional change in capacitance relative to dry skin for three different concentric sensor electrodes (after 30 minutes of applying lotion).

[0042] FIG. 14 is a plot of time dependent fractional change in capacitance relative to dry skin for three different concentric sensor electrodes (after 15 minutes of applying lotion) on two subjects. This experiment was performed with faster sampling intervals and with lotion applied for 15 minutes only on forearms of two test subjects. Again, a resistive pressure sensor was used to measure pressure applied on sensor to the arm. This way, constant pressure is applied across measurements. First the dry inner arm was measured using the XS, S and M electrodes. Then the same area was masked off with tape, and lotion was applied for 15 minutes. Subsequent measurements were made on the same location every 5 minutes. Pressure was maintained at 50k Ohms, and the forearm was tested again. We noticed an interesting observation for the case "F" in comparison to case "A" and also compared to previous measurements. Case "F" took a shower right before running the measurements and hence as a result his skin was relatively saturated with moisture. As a result, we observed less degree of sensitivity to the applied deep moisturizer for case "F".

[0043] The experiment was performed again for case "F", with a time resolution of 3 minutes, knowing that the subject did not shower in the morning before the test. The lotion was applied to the inner forearm for 15 minutes. Pressure was maintained at 50k Ohms. The results confirm the sensitivity of the measurement to the residual skin moisture.

[0044] FIG. 15 is a plot of results for fractional change vs. time for M, S and XS electrodes.

[0045] FIG. 16 shows a preferred embodiment of a layered SEM scanner electrode system 100 having a first electrode pad 102 and second electrode pad 104. Pad 104 is connected to lead line inputs 1 16 via wiring 34 along curved path 1 12. Pad 102 is connected to lead line inputs 1 10 via wiring 34 along curved path 106. A stiffener layer (e.g. layer 126 in FIG. 5) is provided directly under lead inputs 1 10 and 1 16 (see footprint 108 and 1 14 respectively) and under pads 102 and 104 (see footprint 122 and 120 respectively).

[0046] In this embodiment, the electrode size is approximately 58.42mm (2300 mil) in width by 99.314mm (3910 mil) in height.

[0047] FIG. 17 illustrates the SEM Scanner mechanical compliance (force-displacement relationship) for electrodes of system 100, developed to enable probing of bony prominence. The diamond symbols show the upper electrode 104 response, square symbols show the lower electrode 102 response.

[0048] The SEM scanner device 10 may also include other instruments, such as a camera (not shown), which can be used to take pictures of the wound, or develop a scanning system to scan barcodes as a login mechanism or an interrogator.

[0049] Patients using the SEM scanner device 10 may wear a bracelet (not shown) that contains data relating to their patient ID. This ID can be scanned by the camera embedded in the SEM scanner 10 to confirm correct patient ID correspondence. Alternatively, a separate RF scanner (not shown) may be used for interrogating the bracelet (in addition to the camera).

[0050] The SEM scanner device 10 is preferably ergonomically shaped to encourage correct placement of the device on desired body location.

[0051] The SEM Scanner device 10 of the present invention is capable of generating physical, absolute measurement values, and can produce measurements at multiple depths.

[0052] Although the description above contains many details, these should not be construed as limiting the scope of the invention but as merely providing illustrations of some of the presently preferred embodiments of this invention. Therefore, it will be appreciated that the scope of the present invention is accordingly to be limited by nothing other than the appended claims, in which reference to an element in the singular is not intended to mean "one and only one" unless explicitly so stated, but rather "one or more."

Table 1

Symbol	XXS	XS	S	M	L
Contact Diameter (mm)	5	10	20	23	55
Approx Outer D_o (mm)	5	10	20	23	55
Approx Middle D_i (mm)	4	6	10	15	40
Approx Inner D_c (mm)	2	2	4	5	7

Table 2

Tabulated Normalized Responses of M, S, XS and XXS Electrodes								
Time	**M**	**M Baseline**	**S**	**S Baseline**	**XS**	**XS Baseline**	**XXS**	**XXS Baseline**
0	2.32	2.04	1.89	1.5	0.261	0.24	1.12	1.04
5	2.32	2.04	1.9	1.5	0.256	0.24	1.1	1.04
10	2.38	2.04	1.92	1.5	0.259	0.24	1.07	1.04
15	2.4	2.04	1.99	1.5	0.255	0.24	1.06	1.04
20	2.39	2.04	1.93	1.5	0.248	0.24	1.05	1.04
25	2.25	2.04	1.92	1.5	0.25	0.24	1.04	1.04
30	2.21	2.04	1.88	1.5	0.248	0.24	1.04	1.04
35	2.18	2.04	1.86	1.5	0.245	0.24	1.04	1.04

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Patentkrav

1. Apparat til in situ sub-epidermal fugtighedsmåling (SEM) af væv, omfattende:
et fleksibelt substrat (16, 32),
en række bipolære sensorer, hvor hver bipolær sensor består af en første elektrode (38) og en anden elektrode (36), der begge er indlejret på en fælles side af det fleksible substrat (16, 32);
et isolerende dæklag (30), der er koblet til det fleksible substrat (16, 32) og konfigureret til at fungere som en barriere mellem det væv, der måles, og den første og anden elektrode (38, 36);
en tryksensor (11), der er konfigureret til at registrere påført tryk, koblet til det fleksible substrat (16, 32) og anbragt på linje med den første og anden elektrode (38, 36); og
en elektronikpakke (22), der er individuelt forbundet til enhver af den første og anden elektrode (38, 36) og konfigureret til at:
at excitere og styre den første og anden elektrode (38, 36) for at måle en ækvivalent subepidermal kapacitans,
hvor den ækvivalente subepidermal kapacitans er en indikator for SEM.

2. Apparat ifølge krav 1, hvor det fleksible substrat (16, 32) omfatter en anden side, og hvor tryksensoren (11) er koblet til den anden side af det fleksible substrat (16, 32).

3. Apparat ifølge krav 1, yderligere omfattende en konform trykpude (12), der er anbragt på linje med den første og anden elektrode (38, 36), hvor den konforme trykpude (12) er konfigureret til at understøtte det fleksible substrat (16, 32) samtidig gøre det muligt for det fleksible substrat (16, 32) at tilpasse sig en ikke-plan føleoverflade.

4. Apparat ifølge krav 1, hvor den anden elektrode (36) er en ringformet elektrode, der er anbragt omkring den første elektrode (38).

5. Apparat ifølge krav 4, hvor den anden elektrode (36) er koncentrisk anbragt omkring den første elektrode (38).

6. Apparat ifølge krav 4, hvor den første elektrode (38) og den anden elektrode (36) er konfigureret således, at der er et ringformet mellemrum (40) mellem den første og anden elektrode (38, 36).

7. Apparat ifølge krav 6, hvor det ringformede mellemrum (40) er ensartet.

8. Apparat ifølge krav 1, hvor den første og anden elektrode (38, 36) er elektrisk isoleret fra hinanden.

9. Apparat ifølge krav 1, hvor elektronikpakken (22) er konfigureret til at excitere og styre den første og anden elektrode (38, 36) til at udsende og modtage radiofrekvensenergi (RF).

10. Apparat ifølge krav 9, hvor den første og den anden elektrode (38, 36) er koblet til elektronikpakken (22) for at danne en række af bipolære RF-sensorer (24).

11. Apparat ifølge krav 1, hvor elektronikpakken (22) yderligere er konfigureret til at overføre målte data til en fjernenhed, eventuelt hvor fjernenheden er en computer.

12. Apparat ifølge krav 11, hvor de målte data overføres via Bluetooth.

DRAWINGS

Drawing

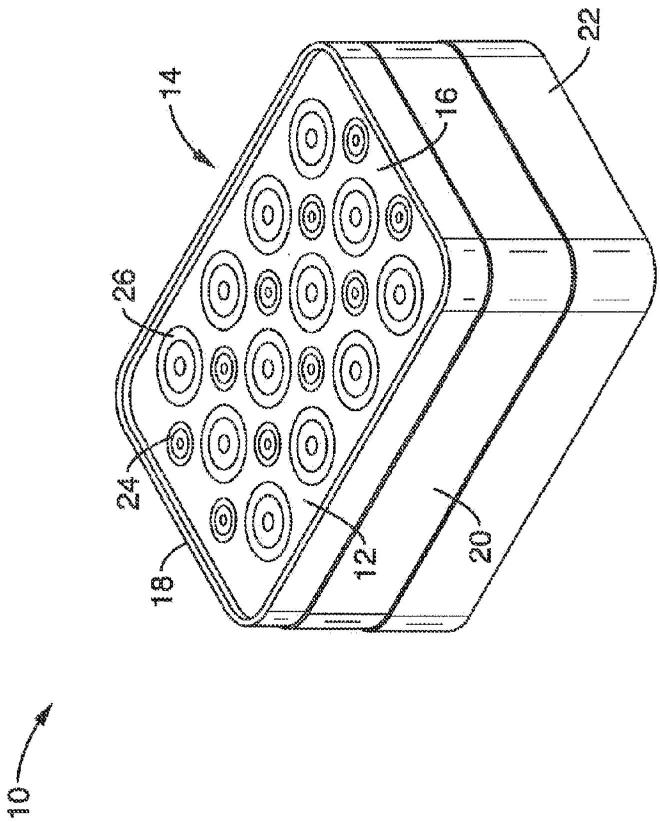

FIG. 1

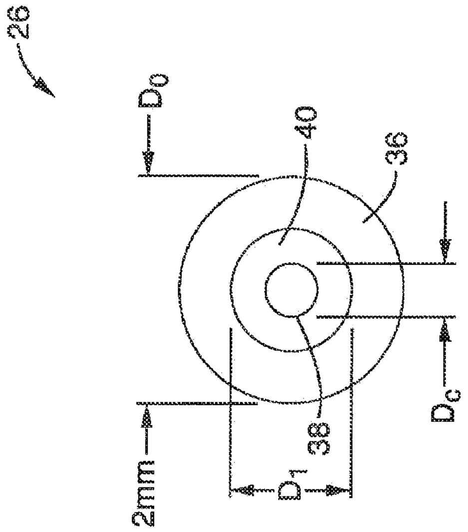

FIG. 3

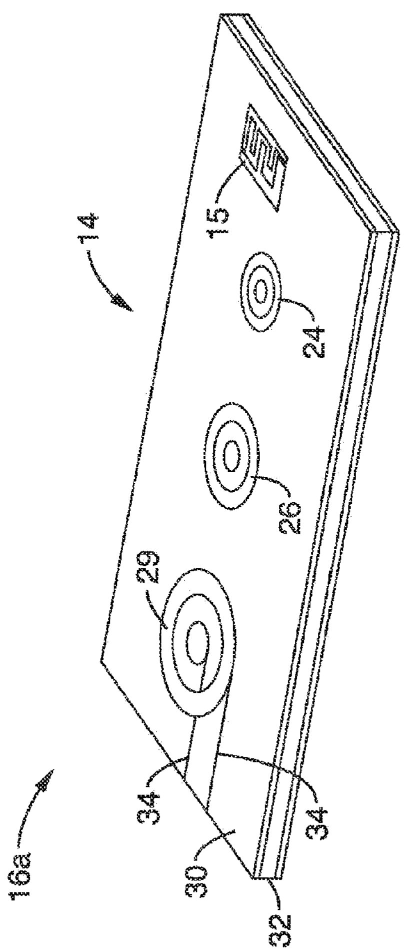

FIG. 2

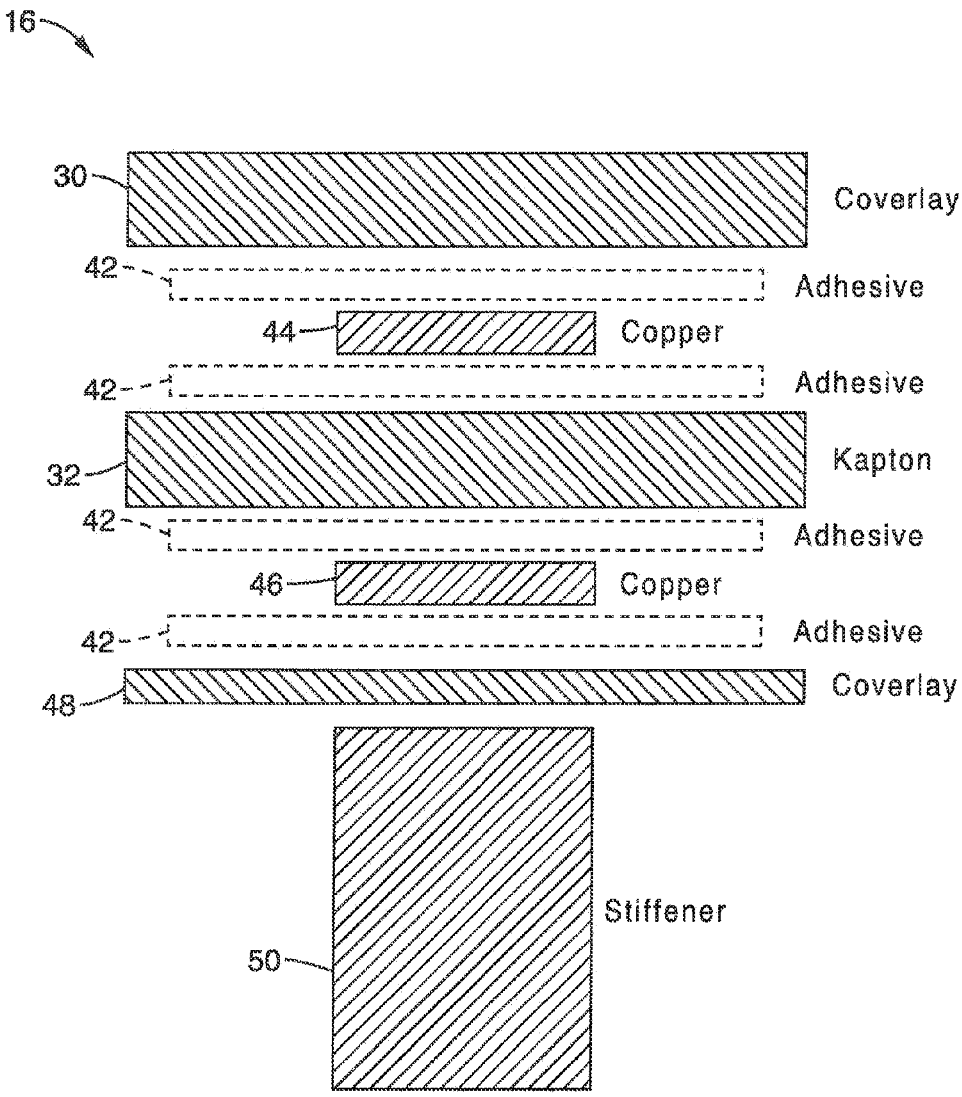
16
30
Coverlay
42
Adhesive
44
Copper
42
Adhesive
32
Kapton
42
Adhesive
46
Copper
42
Adhesive
48
Coverlay
Stiffener
50

FIG. 4

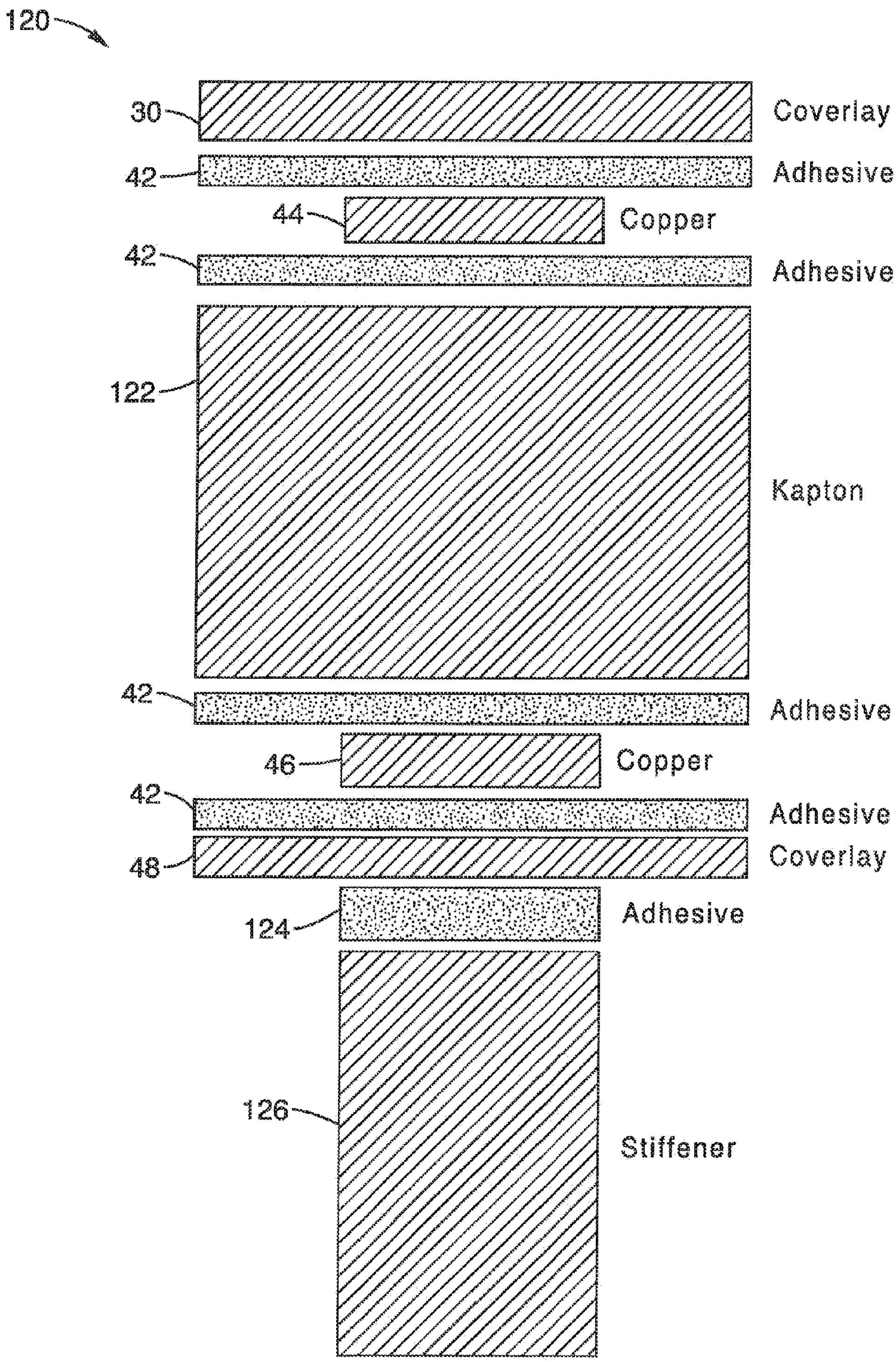
120
30
Coverlay
42
Adhesive
44
Copper
42
Adhesive
122
Kapton
42
Adhesive
46
Copper
42
Adhesive
48
Coverlay
124
Adhesive
126
Stiffener

FIG. 5

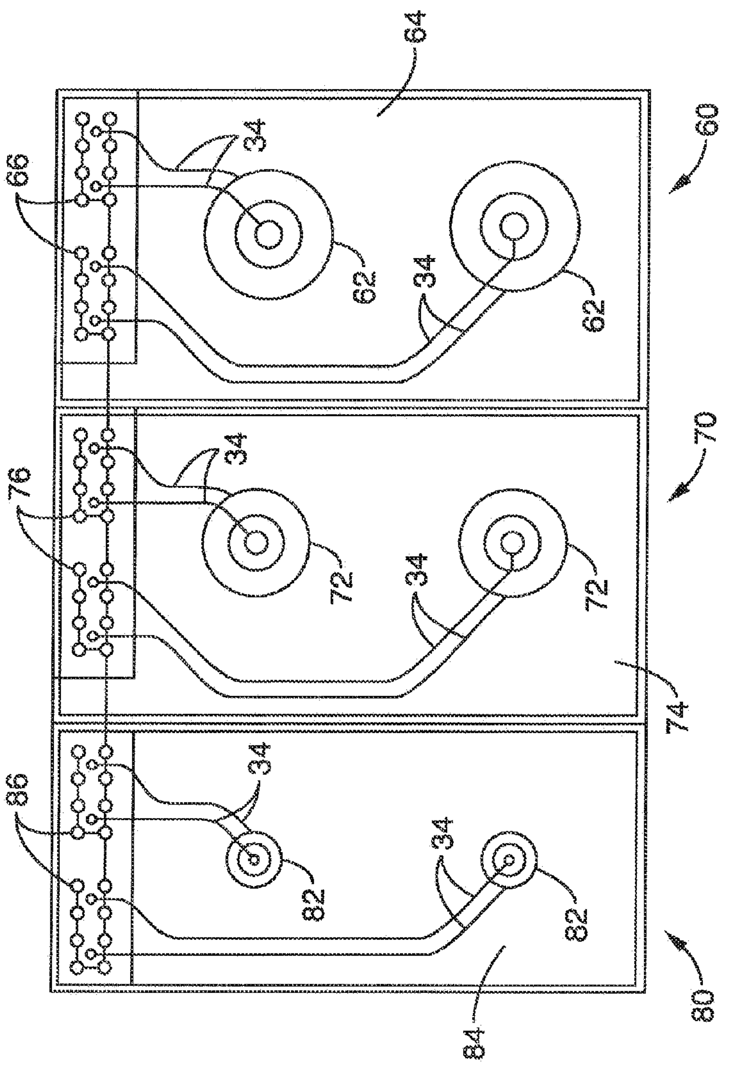

FIG. 6

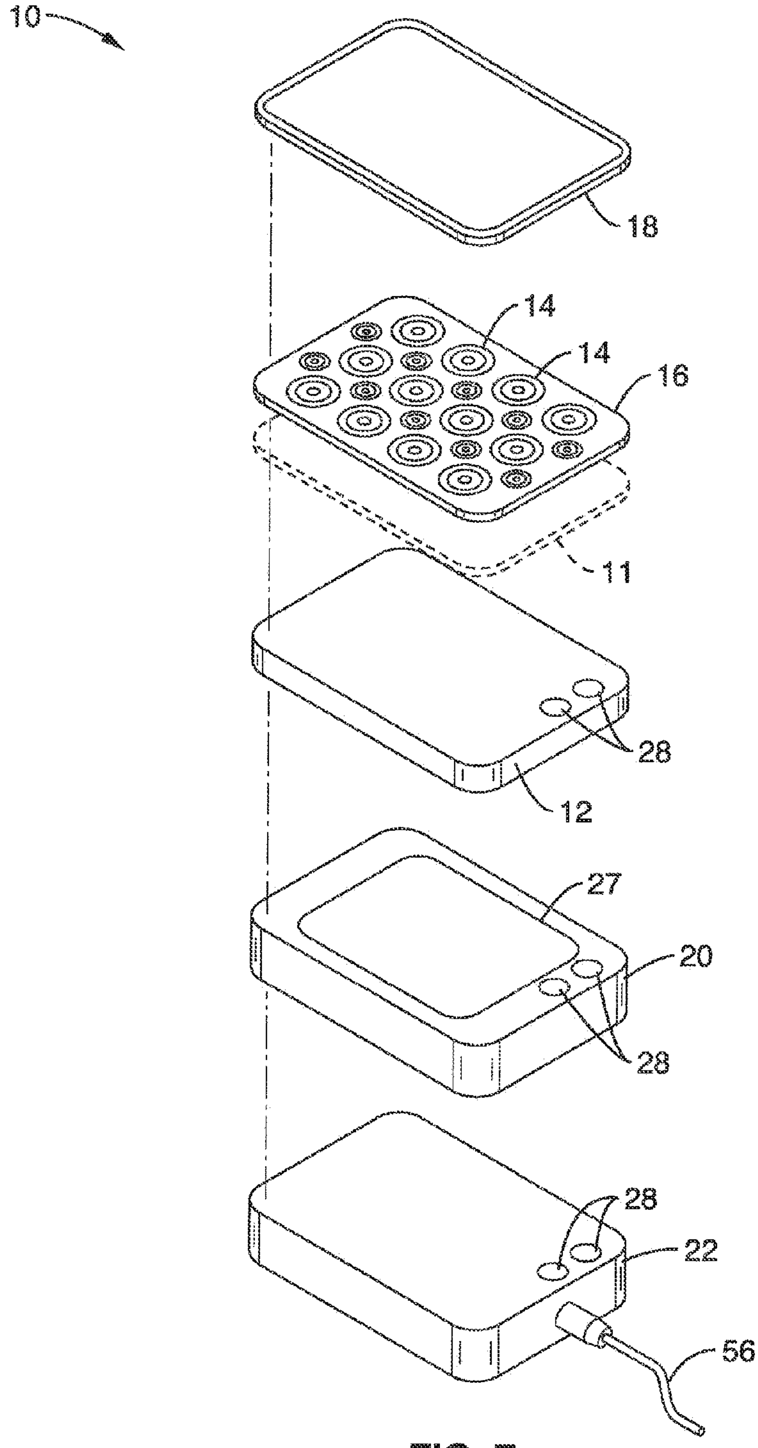

FIG. 7

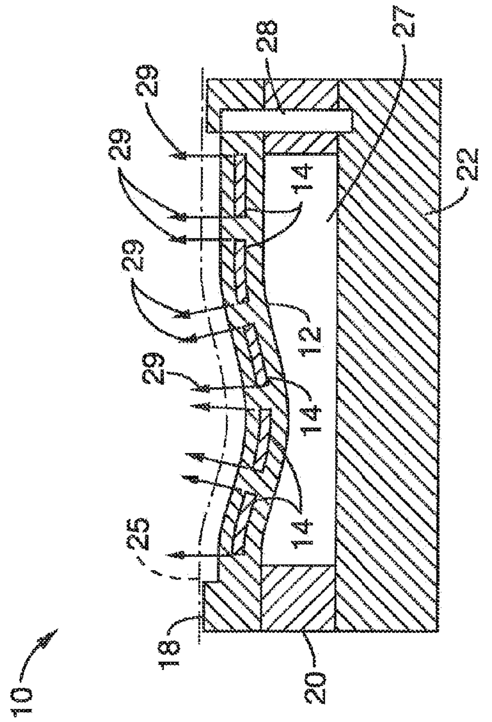

FIG. 9

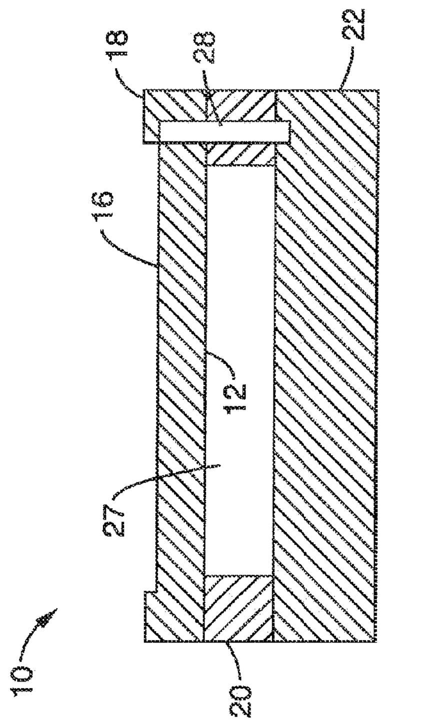

FIG. 8

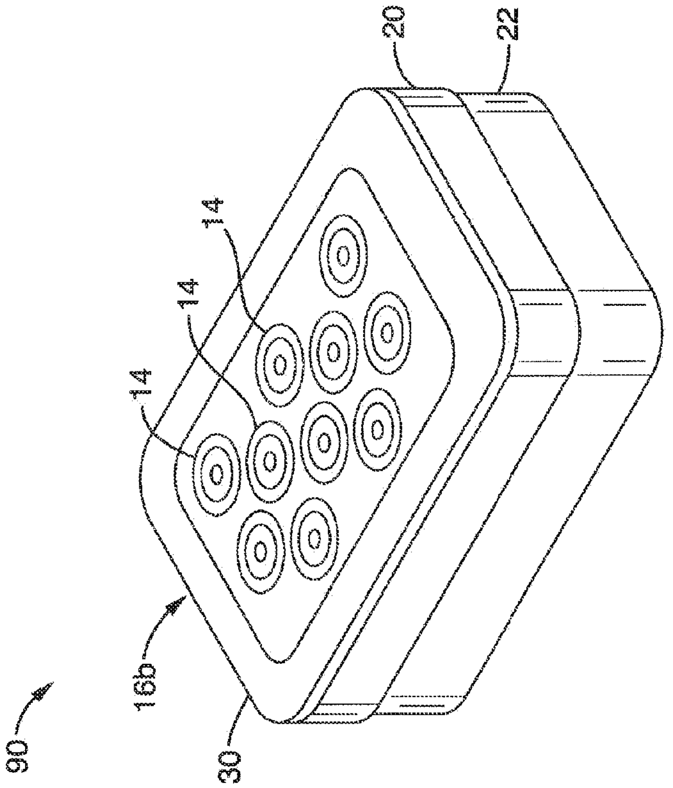

FIG. 10

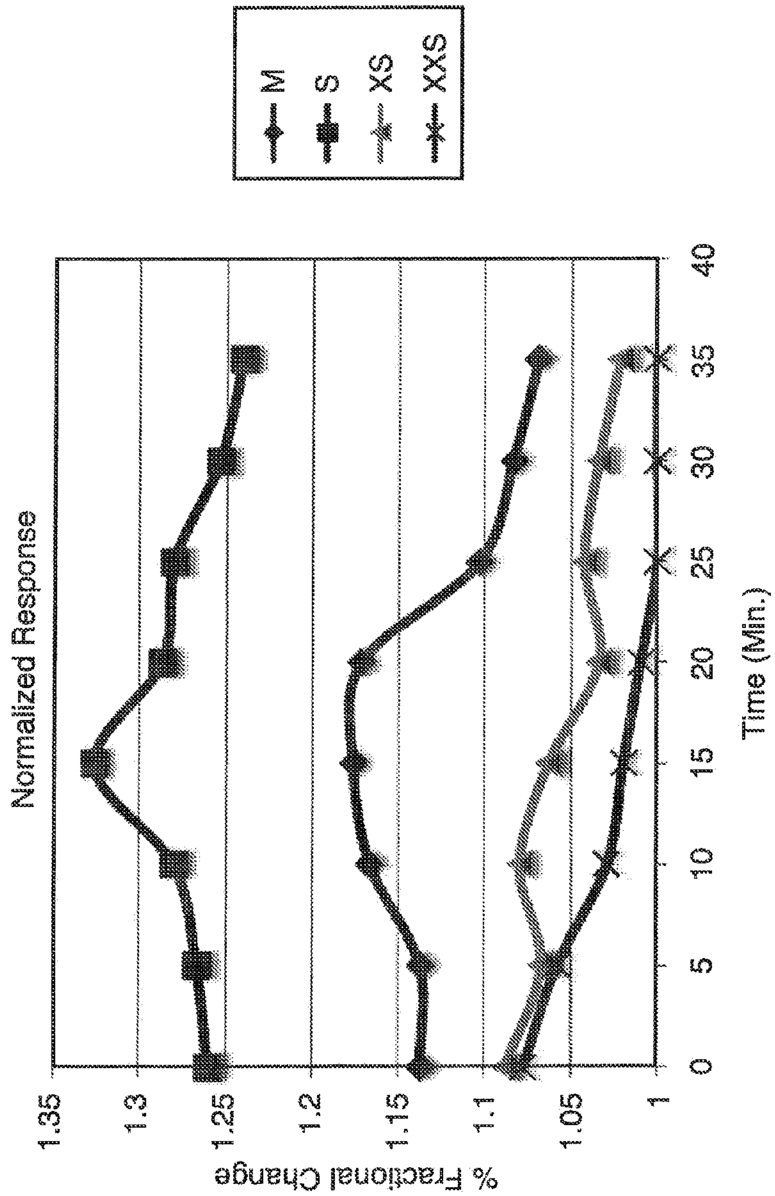
Normalized Response
% Fractional Change
1.35
1.3
1.25
1.2
1.15
1.1
1.05
1
0
5
10
15
20
25
30
35
40
Time (Min.)
M
S
XS
XXS

FIG. 11

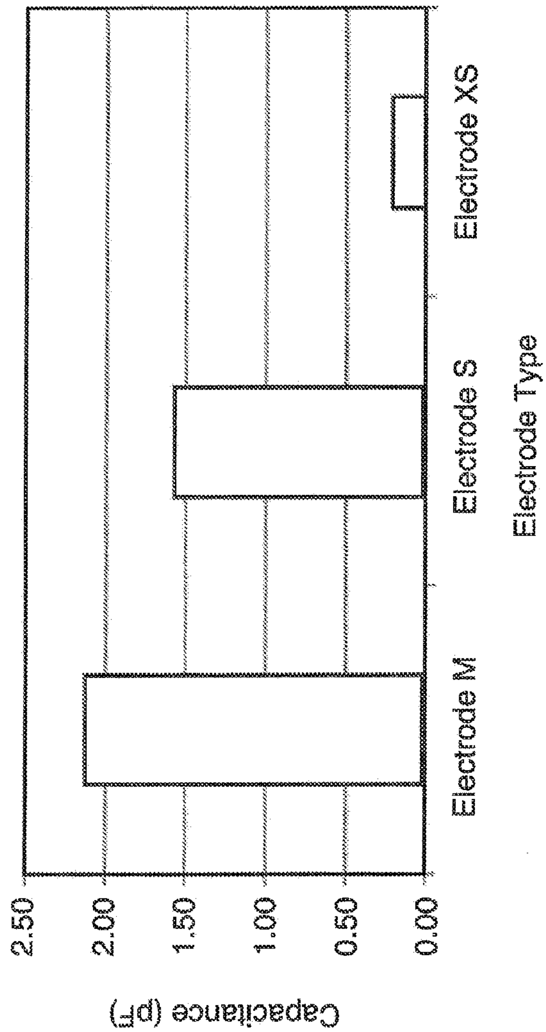
Capacitance (pF)
2.50
2.00
1.50
1.00
0.50
0.00
Electrode M
Electrode S
Electrode XS
Electrode Type

FIG. 12

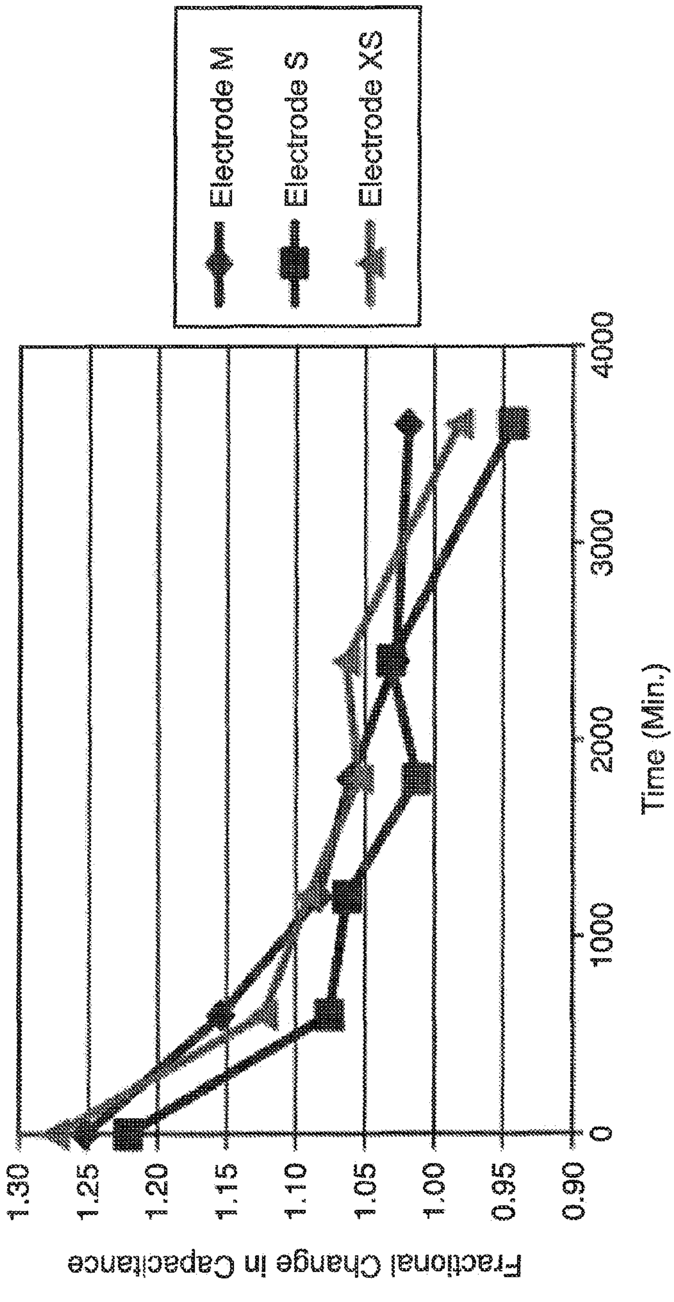
Fractional Change in Capacitance
1.30
1.25
1.20
1.15
1.10
1.05
1.00
0.95
0.90
0
1000
2000
3000
4000
Time (Min.)
Electrode M
Electrode S
Electrode XS

FIG. 13

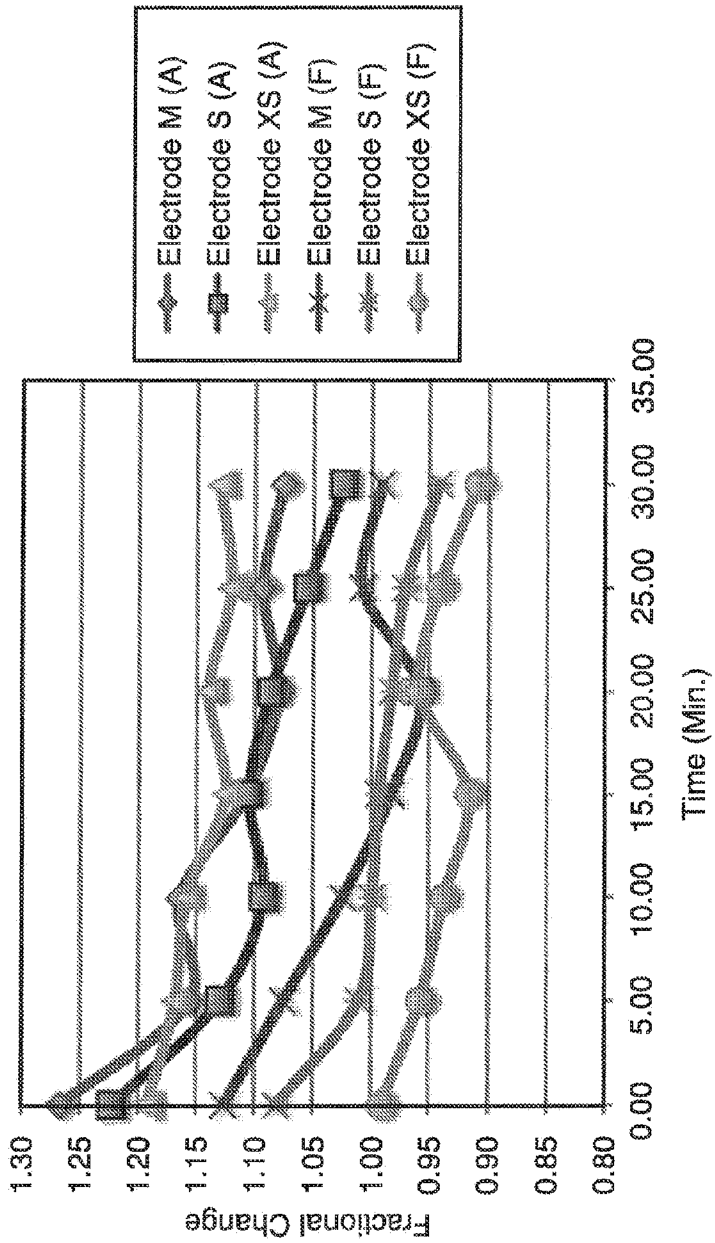
Electrode M (A)
Electrode S (A)
Electrode XS (A)
Electrode M (F)
Electrode S (F)
Electrode XS (F)
Fractional Change
1.30
1.25
1.20
1.15
1.10
1.05
1.00
0.95
0.90
0.85
0.80
0.00
5.00
10.00
15.00
20.00
25.00
30.00
35.00
Time (Min.)

FIG. 14

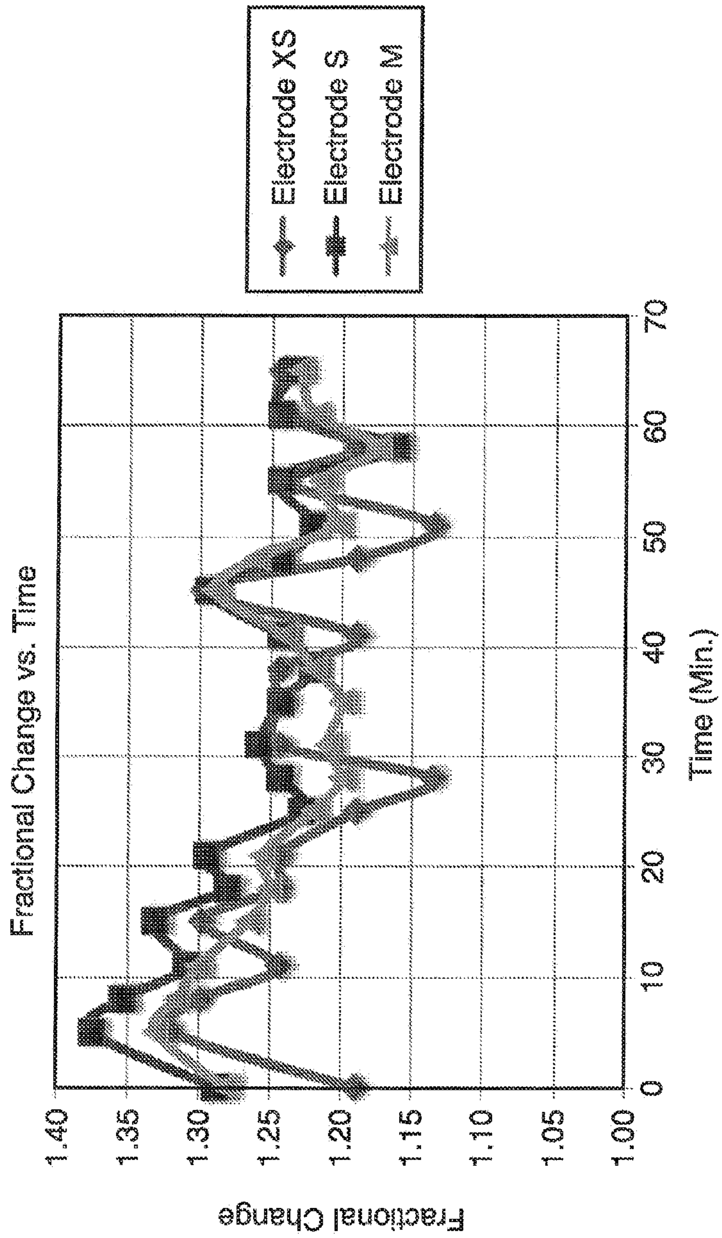
Fractional Change vs. Time
Electrode XS
Electrode S
Electrode M
Fractional Change
1.40
1.35
1.30
1.25
1.20
1.15
1.10
1.05
1.00
0
10
20
30
40
50
60
70
Time (Min.)

FIG. 15

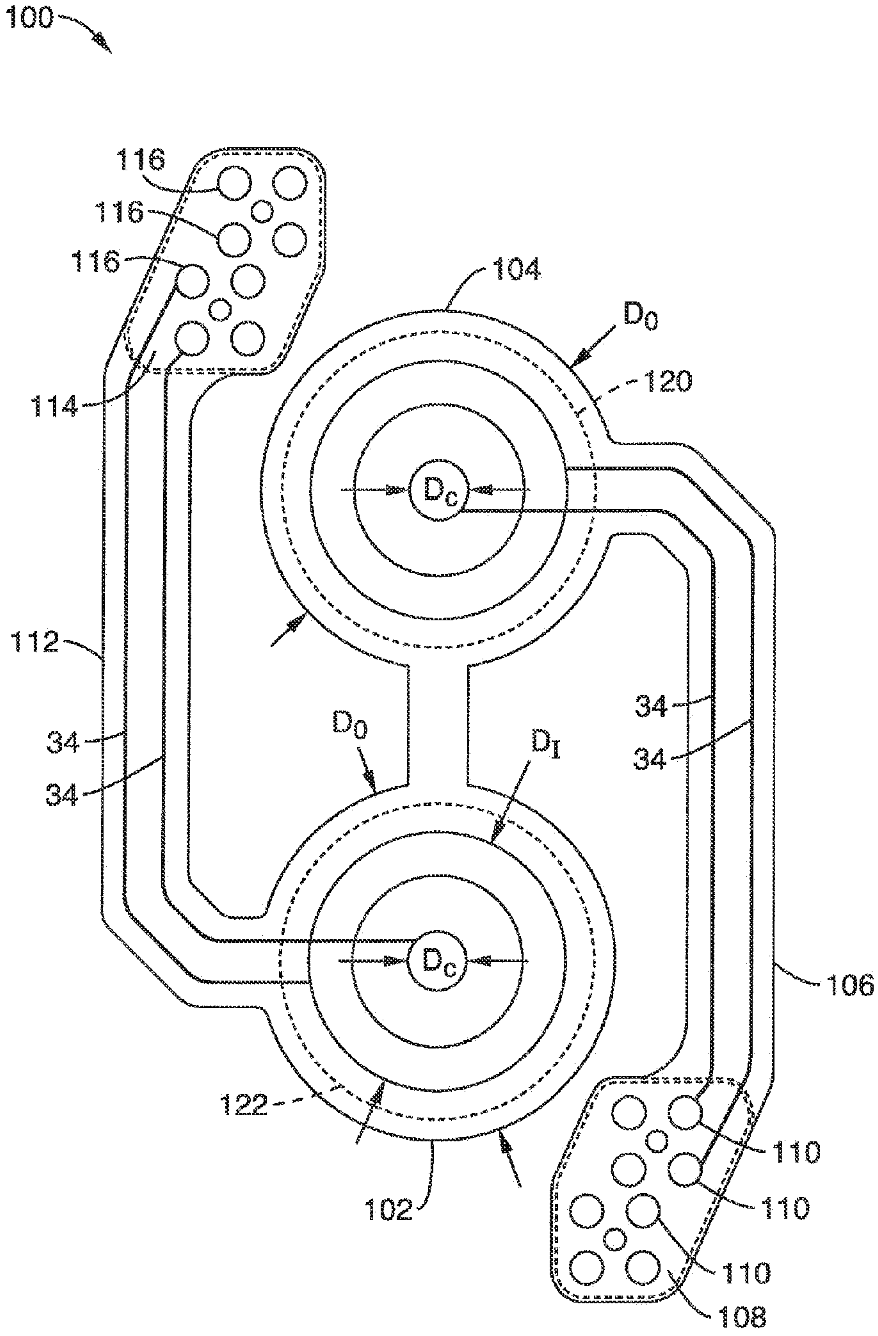
100
116
116
116
104
D_0
120
114
D_c
112
34
34
34
34
D_0
D_I
D_c
106
122
110
110
102
110
108

FIG. 16

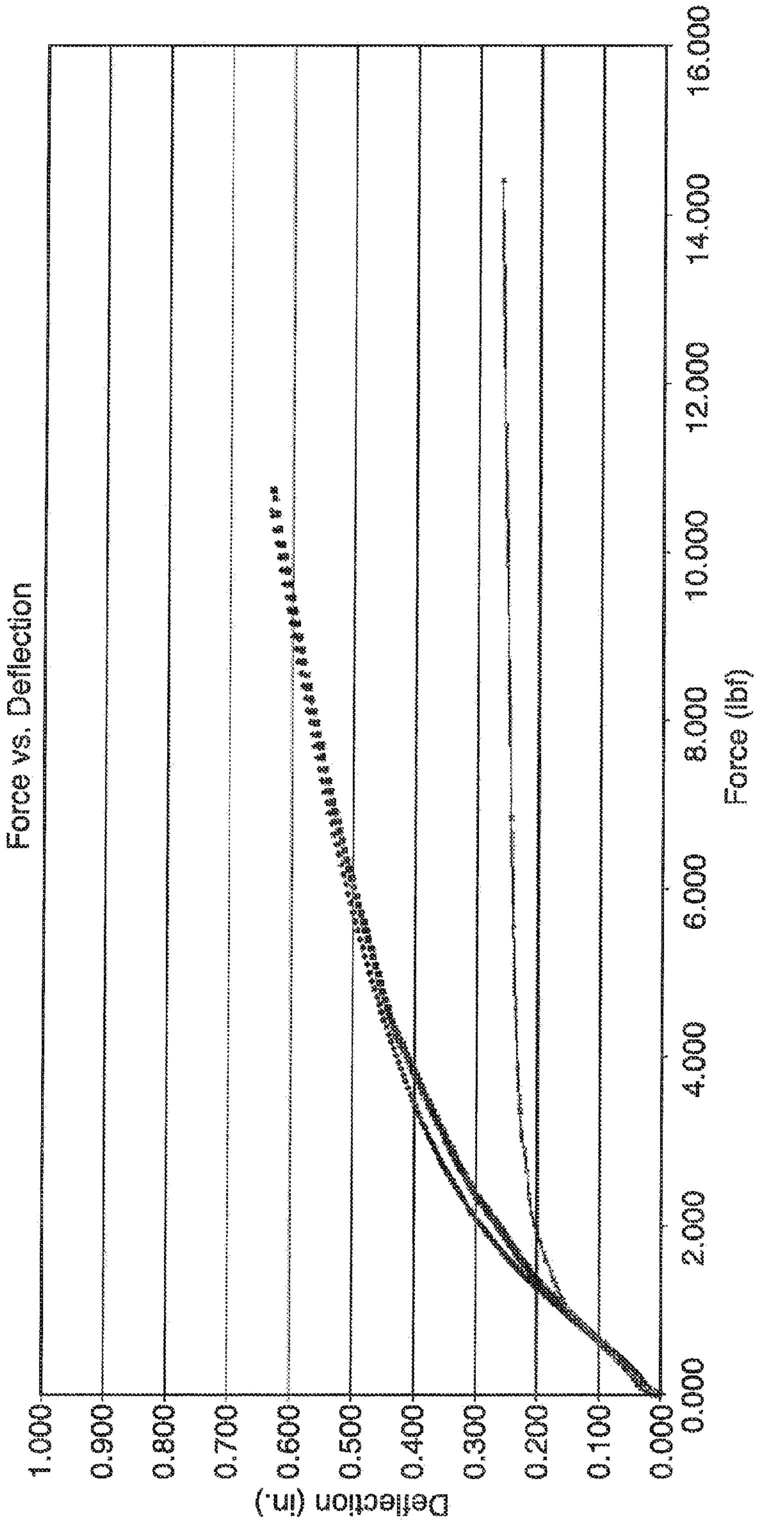
Force vs. Deflection
Deflection (in.)
1.000
0.900
0.800
0.700
0.600
0.500
0.400
0.300
0.200
0.100
0.000
0.000
2.000
4.000
6.000
8.000
10.000
12.000
14.000
16.000
Force (lbf)

FIG. 17