more particularly to skin ulcer monitoring via measurement of Sub-epidermal Moisture (SEM).

[0007] 2. Description of Related Art

[0008] 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.

[0009] 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.

BRIEF SUMMARY OF THE INVENTION

[0010] An aspect of the present invention 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.

[0011] An aspect of this invention 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.

[0012] 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.

[0013] 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 post-operative 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.

[0014] One aspect 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.

[0015] Another aspect 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.

[0016] Further aspects of the invention 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)

[0017] The invention will be more fully understood by reference to the following drawings which are for illustrative purposes only:

[0018] FIG. 1 illustrates an assembled perspective component view of the SEM Scanner of the present invention.

[0019] FIG. 2 illustrates a perspective view of a Kapton-based conforming sensing substrate assembly of the present invention.

[0020] FIG. 3 shows a top view of an exemplary concentric sensing electrode

in accordance with the present invention.

[0021] FIG. 4 illustrates a side view of a flex stack-up for the Kapton-based conforming sensing substrate shown in FIG. 2.

[0022] FIG. 5 illustrates a side view of an alternative flex stack-up for a Kapton-based conforming sensing substrate.

[0023] FIG. 6 shows a top view of two-electrode sensing Kapton-based flex sensor substrates for three alternative types of capacitive sensing concentric electrodes.

[0024] FIG. 7 illustrates an exploded perspective component view of the SEM scanner of FIG. 1.

[0025] FIG. 8 illustrates a schematic side view of the SEM scanner of FIG. 1.

[0026] FIG. 9 illustrates a schematic side view of the SEM scanner of FIG. 8 in contact with subject skin.

[0027] FIG. 10 illustrates a perspective view of an assembled SEM scanner with an alternative array of sensors in accordance with the present invention.

[0028] FIG. 11 is a plot of normalized responses of the tested electrodes of the present invention.

[0029] FIG. 12 is a graph of measured equivalent capacitance for dry volar arm for three different concentric sensor electrodes.

[0030] 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).

[0031] 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).

[0032] FIG. 15 is a plot of fractional change vs. time.

[0033] FIG. 16 shows a SEM scanner electrode system and electrode layering providing proper shielding from interference.

[0034] FIG. 17 shows an SEM scanner mechanical compliance for electrodes developed to enable probing of bony prominence.

DETAILED DESCRIPTION OF THE INVENTION

[0035] 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.

[0036] FIG. 1 illustrates an SEM scanning/sensing apparatus 10 according to the present invention. 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.

[0037] 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.

[0038] 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.

[0039] 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.

[0040] FIG. 3 illustrates a close-up top view of a concentric sensing pad 26 in accordance with the present invention. Pad 26 comprises a bipolar

large pad. The outer ring electrode inner diameter D_i 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.

[0057] 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.

[0058] FIG. 11 is a plot of normalized responses of the tested electrodes of the present invention. The four sensors' (XXS, XS, S, M) normalized responses are compared in FIG. 11 and Table 2.

[0059] 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.

[0060] The SEM scanner 10 was also tested on the inner arm. A resistive pressure sensor (e.g. sensor 11 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.

[0061] 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.

[0062] 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).

[0063] FIG. 14 is a plot of time dependent fractional change in capacitance

[0068] 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.

[0069] 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.

[0070] 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).

[0071] The SEM scanner device 10 is preferably ergonomically shaped to encourage correct placement of the device on desired body location.

[0072] The SEM Scanner device 10 of the present invention is capable of generating physical, absolute measurement values, and can produce measurements at multiple depths.

[0073] From the foregoing it will be appreciated that the present invention can be embodied in various ways, which include but are not limited to the following:

[0074] 1. An apparatus for sensing sub-epidermal moisture from a location external to a patient's skin, comprising: a bipolar RF sensor embedded on a flexible substrate; 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; and interface electronics coupled to the sensor; wherein said interface electronics is configured to control emission and reception of RF energy to interrogate the patient's skin.

[0075] 2. The apparatus of embodiment 1, further comprising: an annular spacer adjacent and underneath the conformal pressure pad; wherein the

CLAIMS

What is claimed is:

1. An apparatus for sensing sub-epidermal moisture from a location external to a patient's skin, comprising:

a bipolar RF sensor embedded on a flexible substrate;

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; and

interface electronics coupled to the sensor;

wherein said interface electronics are configured to control emission and reception of RF energy to interrogate the patient's skin.

2. An apparatus as recited in claim 1, further comprising:

an annular spacer adjacent and underneath the conformal pressure pad;

wherein the annular spacer comprises a central opening configured to allow the conformal pressure pad to deflect freely into the central opening.

3. An apparatus as recited in claim 1, further comprising:

an array of bipolar RF sensors spaced across the flexible substrate;

wherein each of the sensors is independently coupled to the interface electronics to independently interrogate the patient's skin.

4. An apparatus as recited in claim 3:

wherein each of the sensors is configured to measure an equivalent sub-epidermal capacitance of a target region of skin;

said sub-epidermal capacitance corresponding to the moisture content of the target region of skin.

5. An apparatus as recited in claim 4:

wherein the array of sensors comprises a first sensor having a first contact area and a second sensor having a second contact area larger than the first sensor; and

wherein the first and second sensors interrogate the skin at different depths.

6. An apparatus as recited in claim 4:

wherein the substrate comprises a substrate assembly comprising a substrate layer; and

wherein the sensor comprises a sensing pad having a first electrode embedded on a first side of the substrate and a second electrode embedded on a second side of the substrate.

7. An apparatus as recited in claim 6, further comprising a biocompatible cover layer disposed over said first side of said substrate layer.

8. An apparatus as recited in claim 6, further comprising a cover layer disposed under said second side of said substrate layer.

9. An apparatus as recited in claim 6, further comprising:

a stiffener layer disposed under said second side of said substrate layer;

wherein the stiffener layer comprises a footprint substantially similar to that of the sensor array.

10. An apparatus as recited in claim 6:

wherein said first electrode comprises an annular ring having an inner radius and an outer radius;

wherein said second electrode comprises an outer radius having a smaller diameter than the inner radius of the first electrode; and

wherein said second electrode is concentric with said first radius.

11. An apparatus as recited in claim 1, wherein the interface electronics are configured to transmit data retrieved from said sensors.

12. An apparatus as recited in claim 4, further comprising:

a pressure sensor positioned in line with said RF sensor;

said pressure sensor configured to measure an applied pressure of the substrate at a location on the patient's skin.

13. An apparatus as recited in claim 1, wherein the flexible substrate comprises Kapton or Polyimide.

14. A scanner for sensing sub-epidermal moisture from a location external to a patient's skin, comprising:

an array of bipolar RF sensors 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;

wherein said sensor array is configured to emit and receive RF energy to interrogate the patient's skin, and

wherein each of the sensors are independently are individually wired to independently interrogate the patient's skin.

15. A scanner as recited in claim 14, further comprising:

interface electronics coupled to the sensor;

wherein said interface electronics is configured to control the emission and reception of RF energy.

16. A scanner as recited in claim 14, further comprising:

an annular spacer adjacent and underneath the conformal pressure pad;

wherein the annular spacer comprises a central opening configured to allow the conformal pressure pad to deflect freely into the central opening.

17. A scanner as recited in claim 14:

wherein each of the sensors is configured to measure an equivalent sub-epidermal capacitance of a target region of skin;

said sub-epidermal capacitance corresponding to the moisture content of the target region of skin.

18. A scanner as recited in claim 14:

wherein the array of sensors comprises a first sensor having a first contact area and a second sensor having a second contact area larger than the first sensor; and

wherein the first and second sensors interrogate the skin at different depths.

19. A scanner as recited in claim 14:

wherein each sensor comprises a first electrode in the form of an annular ring having an inner radius and an outer radius and a second electrode comprising an outer radius having a smaller diameter than the first electrode; and

wherein said second electrode is concentric with said first radius.

20. A scanner as recited in claim 19:

wherein the substrate comprises a substrate assembly comprising a substrate layer; and

wherein the first electrode is embedded on a first side of the substrate and the second electrode embedded on a second side of the substrate.

21. A scanner as recited in claim 20, further comprising:

an upper biocompatible cover layer disposed over said first side of said substrate layer and a lower cover layer disposed under said second side of said substrate layer.

22. A scanner as recited in claim 20, further comprising:

a stiffener layer disposed under said second side of said substrate layer;

wherein the stiffener layer comprises a footprint substantially similar to that of the sensor array.

23. A scanner as recited in claim 14, further comprising:

an array of pressure sensors positioned in line with said RF sensor;

said pressure sensors are configured to measure an applied pressure of the substrate at corresponding locations on the patient's skin.

24. A method for monitoring the formation of pressure ulcers at a target location of a patient's skin, comprising:

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 sensors 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.

25. A method as recited in claim 24:

wherein the one or more sensors comprise an array of sensors disposed across said substrate; and

wherein the one or more sensors are individually controlled to independently excite the one or more sensors.

26. A method as recited in claim 24, further comprising:

measuring an applied pressure of the substrate at the target location on the patient's skin.

27. A method as recited in claim 25, further comprising:

measuring an applied pressure of the substrate on the patient's skin at each of the sensors in the array.

more particularly to skin ulcer monitoring via measurement of Sub-epidermal Moisture (SEM).

[0007] 2. Description of Related Art

[0008] 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.

[0009] 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.

BRIEF SUMMARY OF THE INVENTION

[0009a] The invention is defined in the independent claims. Some optional features of the invention are defined in the dependent claims.

[0010] In one exemplary technique, there is provided 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.

[0011] In another exemplary technique, there is provided 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.

[0012] 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.

[0013] One major implication of this sensor-enhanced paradigm may be 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.

[0014] One aspect 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 eception of RF energy to interrogate the patient's skin.

[0015] Another aspect 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.

[0016] Further aspects of the invention 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)

[0017] The invention will be more fully understood by reference to the following drawings which are for illustrative purposes only:

[0018] FIG. 1 illustrates an assembled perspective component view of the SEM Scanner.

[0019] FIG. 2 illustrates a perspective view of a Kapton-based conforming sensing substrate assembly.

[0020] FIG. 3 shows a top view of an exemplary concentric sensing electrode.

[0021] FIG. 4 illustrates a side view of a flex stack-up for the Kapton-based conforming sensing substrate shown in FIG. 2.

[0022] FIG. 5 illustrates a side view of an alternative flex stack-up for a Kapton-based conforming sensing substrate.

[0023] FIG. 6 shows a top view of two-electrode sensing Kapton-based flex sensor substrates for three alternative types of capacitive sensing concentric electrodes.

[0024] FIG. 7 illustrates an exploded perspective component view of the SEM scanner of FIG. 1.

[0025] FIG. 8 illustrates a schematic side view of the SEM scanner of FIG. 1 .

[0026] FIG. 9 illustrates a schematic side view of the SEM scanner of FIG. 8 in contact with subject skin.

[0027] FIG. 10 illustrates a perspective view of an assembled SEM scanner with an alternative array of sensors.

[0028] FIG. 11 is a plot of normalized responses of the tested electrodes.

[0029] FIG. 12 is a graph of measured equivalent capacitance for dry volar arm for three different concentric sensor electrodes.

[0030] 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).

[0031] 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).

[0032] FIG. 15 is a plot of fractional change vs. time.

[0033] FIG. 16 shows a SEM scanner electrode system and electrode layering providing proper shielding from interference.

[0034] FIG. 17 shows an SEM scanner mechanical compliance for electrodes developed to enable probing of bony prominence.

DETAILED DESCRIPTION OF THE INVENTION

[0035] In one exemplary embodiment, a smart handheld capacitive sensing device employs a programmable sensing electrode array. This is based on methods that use an interrogator to excite the embedded electrodes.

[0036] FIG. 1 illustrates an SEM scanning/sensing apparatus 10 as disclosed herein. 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.

[0037] 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.

[0038] 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.

[0039] 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.

[0040] FIG. 3 illustrates a close-up top view of a concentric sensing pad 26 as disclosed herein. Pad 26 comprises a bipolar

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 Dc 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.

[0057] 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.

[0058] FIG. 11 is a plot of normalized responses of the tested electrodes as disclosed herein. The four sensors' (XXS, XS, S, M) normalized responses are compared in FIG. 11 and Table 2.

[0059] 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.

[0060] The SEM scanner 10 was also tested on the inner arm. A resistive pressure sensor (e.g. sensor 11 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.

[0061] 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.

[0062] 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).

[0063] FIG. 14 is a plot of time dependent fractional change in capacitance

[0068] 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.

[0069] 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.

[0070] 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).

[0071] The SEM scanner device 10 is preferably ergonomically shaped to encourage correct placement of the device on desired body location.

[0072] The SEM Scanner device 10 as disclosed here may be capable of generating physical, absolute measurement values, and can produce measurements at multiple depths.

[0073] From the foregoing it will be appreciated that the present invention can be embodied in various ways, which include but are not limited to the following:

[0074] 1. An apparatus for sensing sub-epidermal moisture from a location external to a patient's skin, comprising: a bipolar RF sensor embedded on a flexible substrate; 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; and interface electronics coupled to the sensor; wherein said interface electronics is configured to control emission and reception of RF energy to interrogate the patient's skin.

[0075] 2. The apparatus of embodiment 1, further comprising: an annular spacer adjacent and underneath the conformal pressure pad; wherein the

CLAIMS

What is claimed is:

1. An apparatus for sensing sub-epidermal moisture from a location external to a patient's skin, comprising:

a bipolar RF sensor embedded on a flexible substrate;

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; and

interface electronics coupled to the sensor;

wherein said interface electronics are configured to control emission and reception of RF energy to interrogate the patient's skin.

2. An apparatus as recited in claim 1, further comprising:

an annular spacer adjacent and underneath the conformal pressure pad;

wherein the annular spacer comprises a central opening configured to allow the conformal pressure pad to deflect freely into the central opening.

3. An apparatus as recited in claim 1, further comprising:

an array of bipolar RF sensors spaced across the flexible substrate;

wherein each of the sensors is independently coupled to the interface electronics to independently interrogate the patient's skin.

4. An apparatus as recited in claim 3:

wherein each of the sensors is configured to measure an equivalent subepidermal capacitance of a target region of skin;

said sub-epidermal capacitance corresponding to the moisture content of the target region of skin.

5. An apparatus as recited in claim 4:

wherein the array of sensors comprises a first sensor having a first contact area and a second sensor having a second contact area larger than the first sensor; and

wherein the first and second sensors are configured to interrogate the skin at different depths.

6. An apparatus as recited in claim 4:

wherein the substrate comprises a substrate assembly comprising a substrate layer; and

wherein the sensor comprises a sensing pad having a first electrode embedded on a first side of the substrate and a second electrode embedded on a second side of the substrate.

7. An apparatus as recited in claim 6, further comprising a biocompatible cover layer disposed over said first side of said substrate layer.

8. An apparatus as recited in claim 6, further comprising a cover layer disposed under said second side of said substrate layer.

9. An apparatus as recited in claim 6, further comprising:

a stiffener layer disposed under said second side of said substrate layer;

wherein the stiffener layer comprises a footprint substantially similar to that of the sensor array.

10. An apparatus as recited in claim 6:

wherein said first electrode comprises an annular ring having an inner radius and an outer radius;

wherein said second electrode comprises an outer radius having a smaller diameter than the inner radius of the first electrode; and

wherein said second electrode is concentric with said first radius.

11. An apparatus as recited in claim 1, wherein the interface electronics are configured to transmit data retrieved from said sensors.

12. An apparatus as recited in claim 4, further comprising:

a pressure sensor positioned in line with said RF sensor;

said pressure sensor configured to measure an applied pressure of the substrate at a location on the patient's skin.

13. An apparatus as recited in claim 1, wherein the flexible substrate comprises Kapton or Polyimide.

14. A scanner for sensing sub-epidermal moisture from a location external to a patient's skin, comprising:

an array of bipolar RF sensors 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;

wherein said sensor array is configured to emit and receive RF energy to interrogate the patient's skin; and

wherein each of the sensors are independently are individually wired to independently interrogate the patient's skin.

15. A scanner as recited in claim 14, further comprising:

interface electronics coupled to the sensor;

wherein said interface electronics is configured to control the emission and reception of RF energy.

16. A scanner as recited in claim 14, further comprising:

an annular spacer adjacent and underneath the conformal pressure pad;

wherein the annular spacer comprises a central opening configured to allow the conformal pressure pad to deflect freely into the central opening.

17. A scanner as recited in claim 14:

wherein each of the sensors is configured to measure an equivalent subepidermal capacitance of a target region of skin;

said sub-epidermal capacitance corresponding to the moisture content of the target region of skin.

18. A scanner as recited in claim 14:

wherein the array of sensors comprises a first sensor having a first contact area and a second sensor having a second contact area larger than the first sensor; and

wherein the first and second sensors are configured to interrogate the skin at different depths.

19. A scanner as recited in claim 14:

wherein each sensor comprises a first electrode in the form of an annular ring having an inner radius and an outer radius and a second electrode comprising an outer radius having a smaller diameter than the first electrode; and

wherein said second electrode is concentric with said first radius.

20. A scanner as recited in claim 19:

wherein the substrate comprises a substrate assembly comprising a substrate layer; and

wherein the first electrode is embedded on a first side of the substrate and the second electrode embedded on a second side of the substrate.

21. A scanner as recited in claim 20, further comprising:

an upper biocompatible cover layer disposed over said first side of said substrate layer and a lower cover layer disposed under said second side of said substrate layer.

22. A scanner as recited in claim 20, further comprising:

a stiffener layer disposed under said second side of said substrate layer; wherein the stiffener layer comprises a footprint substantially similar to that of the sensor array.

23. A scanner as recited in claim 14, further comprising:

an array of pressure sensors positioned in line with said RF sensor;

said pressure sensors are configured to measure an applied pressure of the substrate at corresponding locations on the patient's skin.

24. A method for monitoring the formation of pressure ulcers at a target location of a patient's skin, comprising:

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 sensors 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.

25. A method as recited in claim 24:

wherein the one or more sensors comprise an array of sensors disposed across said substrate; and

wherein the one or more sensors are individually controlled to independently excite the one or more sensors.

26. A method as recited in claim 24, further comprising:

measuring an applied pressure of the substrate at the target location on the patient's skin.

27. A method as recited in claim 25, further comprising:

measuring an applied pressure of the substrate on the patient's skin at each of the sensors in the array.