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(54) Disposable protective overlay covering for biomedical sensors

Wegwerfbare Kontaktschutzauflagenabdeckung für biomedizinische Sensoren

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Description

FIELD OF INVENTION

[0001] The system described herein relates to the field of sensing bio-potentials generated within a living body and more particularly, relates to the securement of sensors placed on the surface of the skin for detecting the electrical activity from muscles using the surface Electromyographic (sEMG) signal.

BACKGROUND

[0002] A contracting muscle generates an electrical field that can be sensed with electrodes placed on the skins surface. The resulting voltage is defined as a surface electromyographic (sEMG) signal. Applications for using sEMG signal measurement are diverse and can range from sports and ergonomic activities to clinical evaluation of patients, as well as neuromuscular research applications which investigate motor control. Analysis of the sEMG signal can provide valuable information about muscle performance not obtainable by other means. The sEMG signal amplitude may be representative of force generated by the muscle, which unlike externally applied force measuring devices, can be used to assess the individual force contributions from a group of muscles acting together on a joint. Multiple sEMG sensors placed on the limbs can monitor muscle activity levels and coordination during gait studies, or in neurological disorders such as Parkinson's disease. Changes in a frequency spectra of the sEMG signal resulting from localized muscle fatigue can be used to more objectively assess appropriate activity levels and durations of tasks in the workplace. Using sEMG signal detection and analysis may be a valuable asset when investigating human muscular performance in these types of applications.

[0003] Conventionally, the configuration of a sensor designed to detect sEMG signals includes two electrode contacts placed on the skin over the muscle and oriented in a direction parallel to the muscle fibers. A third "reference" contact may be located at an electrically inactive location on the body. Disposable sEMG sensors designed for clinical use may include two electrodes filled with skin impedance reducing electrolytic gel or formed from hydrophilic gel; one for each signal input placed singularly, or in pairs, mounted on a flexible non-conductive pad adhered to the skin over the muscle. In some sensors, the two signal and reference contacts are placed on the same insulating pad in the form of an equilateral triangle. The electrodes are attached by snaps or spring loaded clips and connected to remote electronic preamplifier circuitry via individual lead wires. The preferred recording configuration is the single differential configuration where the voltage at each signal input contact is measured with respect the third reference contact and subtracted using a differential preamplifier circuit.

[0004] In addition, encased sEMG sensor designs incorporating integrated preamplifier circuitry with signal and reference electrode contacts secured to the bottom eliminate the need for individual lead wires and associated snaps or spring loaded clips. The sEMG signal output of these designs may be tethered to data acquisition hardware using a thin cable or can be completely wireless.

[0005] Despite recent advancements in sensor designs, sensors may still retain limited functionality in demanding applications, such as when recording data in uncontrolled movement disorders, in many sports activities, or in the work place environment. The widespread utilization of sEMG technology outside the laboratory environment has been limited by several factors related to the nature of the sEMG signal: The voltage amplitude of sEMG component of the signal detected by a sensor is inherently small, ranging from 10 microvolts to several millivolts. In addition to the sEMG signal component, the voltage at the sensor output includes the contribution from other noise sources generated by the inherent noise of the sensor's electronics, the electrolytic interface established between the metallic contacts of the sensor and intervening tissue, and artifact voltages induced from the movement of the sensor contacts with respect to the intervening tissue. Externally induced voltages from power lines and electrostatic (triboelectric) sources can also contaminate the detected sEMG signal. The magnitude of the contaminating electrostatic and movement artifact noise sources can be equal to or exceed the magnitude of the sEMG component of the sensors signal output when used in vigorous clinical, sports, and ergonomic activities, such as when monitoring neurologically impaired patients with flailing limbs, athletes performing jumping and throwing movements, or workers exposed to sudden accelerations and impacts. The problems of movement artifact and sensitivity to electrostatic fields are especially severe when the sensor is placed under clothing garments. Even normal activities such as walking can induce electrostatic voltage artifacts as a result of walking on carpet or contact with certain fabrics under low humidity conditions. These artifacts could easily be misinterpreted as muscle activity. Current sensor technologies restrict the user to conventional laboratory assessments; e.g. during sustained or repeated isometric contractions or during non-demanding dynamic tasks that are encountered in daily life, such as reaching for an object, walking/climbing stairs, lifting an object, or doing other non-vigorous, low-velocity activities. There may be additional burden to the subject and researcher on occasions when the subject is asked to change into a t-shirt and/or shorts prior to being instrumented so that no obstructions to the sensor from clothing are encountered.

[0006] All of the aforementioned tethered and wireless sensor configurations offer only a limited set of solutions for detecting high fidelity sEMG signals in applications involving dynamic contractions. The susceptibility of the described sensors to induced movement artifacts precludes use in vigorous applications and during conditions where electrostatic fields may be generated such as sensor placement under an individual's clothing. The common practice of using adhesive tapes and bandages to secure the sensor to the skin can exacerbate the generation of electrostatic charge when in contact with garments.

[0007] US 2008/0259577 A1 describes a flexible substrate for covering a sensor. The flexible substrate includes a circuit layer that serves to ground parasitic noise to reduce electromagnetic interference.

[0008] WO 2013/164827 A2 describes an adhesive patch for attaching at least one EM probe to a subject's body. The adhesive patch comprises a planar member having at least one layer of radiation absorbing material and at least one layer of an adhesive attached over at least part of a bottom surface of the planar member.

[0009] US-2005/096513-A1, US-2013/060098-A1, WO-2006/094513-A2, US-2009/150113-A1 and WO-2010/100649-A1 show other known sensor overlays.

[0010] It would be an improvement to provide a disposable sensor overlay covering configuration that secures and shields the sensor from mechanical and electrostatic disturbances when used under clothing.

SUMMARY OF THE INVENTION

[0011] The invention is defined by the claims. The system described herein includes a disposable, low profile sensor overlay covering for use with biomedical sensors including a framework of flexible component layers supporting an arrangement of electrically shielding, insulating, cushioning, and electrically conductive adhesive substrate components configured to form a protective covering encasing the sensor. The combination of component layers provides a means to stabilize the relative position of the sensor with respect to the skin and reduce the potential for sensor dislodgment. The mechanical and electrical configurations act in synergy to shield the sensor from external electrical fields and suppress movement artifact.

[0012] The system described herein relates to an improved type of biomedical sensor overlay covering that secures and shields the sensor from mechanical and external electrical interference disturbances when used under clothing. Unlike existing sensor coverings using double sided tapes or tape strips applied over the sensor, the system described herein incorporates features that can mold to the contours of the underlying musculature and flex with skin movement and cushion the sensor from the effects of direct mechanical contact disturbances. Furthermore, the integral shielding membrane is designed to dissipate the accumulation of electrostatic charges to the skin, and to allow for the transmission and reception of radio frequency signals from encased wireless biomedical sensors.

[0013] According to one feature of the system described herein, the biomedical sensor overlay covering is configured as a framework of flexible component layers supporting an arrangement of electrically conductive shielding, electrically insulating, cushioning, and electrically conductive adhesive substrate component layers, configured to form a flexible protective contoured covering that envelops and mechanically stabilizes the sensor, securing it to the skin.

[0014] According to another feature of the system described herein, the biomedical sensor overlay covering is in the form of a flexible, elongated strip, with a receptacle region shaped and contoured to retain a biomedical sEMG sensor and conductive adhesive regions securing the sensor to the skin, thereby dissipating electrostatic charges to the body through contact with the skin's surface.

[0015] According to another feature of the system described herein, the biomedical sensor overlay covering is in the alternative form of a continuous band, with a receptacle region shaped and contoured to retain a biomedical sEMG sensor and encircle a limb with conductive adhesive regions securing the sensor to the skin, thereby dissipating electrostatic charges to the body through contact with the skin's surface.

[0016] According to another feature of the system described herein, the biomedical sensor overlay covering contains segments of stretchable elastic providing compliance with the underlying skin tissue.

[0017] According to another feature of the system described herein, the biomedical sensor overlay covering is in the alternative form of a patch, with a receptacle region shaped and contoured to retain a biomedical sEMG sensor, and perimeter electrically conductive adhesive regions securing the sensor to the skin, thereby dissipating electrostatic charges to the body through contact with the skin's surface.

[0018] According to another feature of the system described herein, the biomedical sensor overlay covering can be used with tethered and wireless sensor technologies.

[0019] According to yet another feature of the system described herein, the biomedical sensor overlay covering contains an electrostatic shield substrate layer formed from an electrically conductive material.

[0020] According to another feature of the system described herein, the electrostatic shield substrate layer is alternatively formed from electrically resistive material.

[0021] According to another feature of the system described herein, the conductive and resistive materials of the electrostatic shield substrate layers are formed with a plurality of apertures.

[0022] According to another feature of the system described herein, the electrostatic shield substrate layer is alternatively formed from electrically non-conductive material with a plurality of electrically conductive traces.

[0023] According to another feature of the system described herein, the electrically conductive traces of the non-conductive electrostatic shield substrate layer are in the form of a printed circuit.

[0024] According to another feature of the system described herein, the electrical conductivity, and geometrical configuration of the apertures and traces of the electrostatic shield substrate layer provide a means of ingress and egress for radio frequency signal reception and transmission.

[0025] According to another feature of the system described herein, the biomedical sensor overlay covering contains a body-directed electrostatic shield contact pad substrate layer formed from electrically conductive, adhesive, cross-linked hydrophilic polymer gel establishing a mechanical and electrical contact between the electrostatic shield substrate layer and the surface of the skin, thereby dissipating electrostatic charges to the body.

[0026] According to another feature of the system described herein, an electrically insulating substrate layer, contoured to match the profile of the electrostatic shield substrate layer, forms an insulating barrier between the electrostatic shield and the sensor.

[0027] According to another feature of the system described herein, the insulating substrate layer is shaped so as to selectively expose, electrically conductive regions of the electrostatic shield substrate layer to the electrostatic shield contact pad substrate layer.

[0028] According to yet another feature of the system described herein, a cushioning substrate layer, contoured and shaped to match the upper surfaces of the sensor is adhered to the lower surface of the insulating substrate layer so that it makes mechanical contact.

[0029] According to another feature of the system described herein, the cushioning substrate layer is formed from absorbent open cell foam or interwoven fibers arranged so that they wick away and retain excessive skin moisture.

[0030] According to another feature of the system described herein the component materials are hypoallergenic, breathable, and designed for use without slippage or skin breakdown.

[0031] According to another feature of the system described herein, the sensor overlay covering is cosmetically textured and colored so that it more closely matches the color and texture of the underlying skin.

[0032] According to another feature of the system described herein, the body-directed adhesive surfaces of the sensor overlay covering are mounted on a release liner.

[0033] According to another feature of the system described herein, the sensor overlay covering is single use and disposable. The sensor overlay cushions the sensor suppressing movement artifacts, molds to the contours of the skin, and flexes with skin movement. An integral electrically conducting shield mitigates the effects of electrostatic and externally generated electrical fields. The disposable sensor overlay may be used in conjunction with both existing tethered and wireless sensor technologies. The combination of these features represents innovations not found in comparable sensor systems and significantly expands the ability of researchers and clinicians to investigate human movement and muscle function during clinical, sports, and ergonomic applications.

DESCRIPTION OF THE DRAWINGS

[0034] These and other objects and features of the system described herein will become more apparent upon perusal of the following description taken in conjunction with the accompanying drawings wherein:

FIG. 1a is an exploded view of a biomedical sensor overlay covering according to the system described herein;

FIG. 1b is a top and a cross-sectional view of the sensor overlay covering shown in **FIG. 1a**;

FIG. 2a is a side pictorial view of the sensor overlay covering shown in **FIG. 1** secured to the leg;

FIG. 2b is a close up view of the sensor overlay covering shown in **FIG. 2a** shown secured to the upper leg;

FIG. 2c is a bottom view of the sensor overlay covering shown in **FIG. 2b** showing the body-directed substrate layers;

FIG. 2d is a close up view of an alternative sensor overlay covering shown in **FIG. 2a** with a continuous band encircling the lower leg;

FIG. 3a is an exploded view of another embodiment of the biomedical sensor overlay covering according to the system described herein;

FIG. 3b is a top and a cross-sectional view of the sensor overlay covering shown in **FIG. 3a**;

FIG. 4a is an expanded detail view of the electrostatic shield substrate layer of the sensor overlay covering shown in **FIG. 3a**, showing a conductive substrate with an arrangement of apertures;

FIG. 4b is an expanded detail view of the electrostatic shield substrate layer of the sensor overlay covering shown in **FIG. 3a**, showing an non-conductive substrate with an arrangement of conductive traces;

FIG. 4c is an expanded detail view of the electrostatic shield substrate layer of the sensor overlay covering shown in **FIG. 3a**, showing an electrically resistive substrate;

FIG. 5a is a side pictorial view of the sensor overlay covering shown in **FIG. 3** secured to the leg;

FIG. 5b is a close up view of the sensor overlay covering shown in **FIG. 5a**, shown secured to the upper leg;

FIG. 5c is a bottom view of the sensor overlay covering shown in **FIG. 5b** showing the body-directed substrate layers;

FIG. 5d is a close up view of an alternative sensor overlay covering shown in **FIG. 5a** with a continuous band encircling the lower leg;

FIG. 6a is a time domain plot of an sEMG sensor signal output when used under clothing during walking, without the presence of an electrostatic shield, showing regions of electrostatic artifact;

FIG. 6b is a time domain plot of an sEMG sensor signal output when used under clothing during walking, with the incorporation of an electrostatic shield, showing regions where the electrostatic artifact has been suppressed;

FIG. 7a is an exploded view of a third embodiment of the biomedical sensor overlay covering according to the system described herein;

FIG. 7b is a top and a cross-sectional view of the sensor overlay covering shown in **FIG. 7a**;

FIG. 8a is an expanded detail view of the electrostatic shield substrate layer of the sensor overlay covering shown in **FIG. 7a**, showing a conductive substrate with an arrangement of apertures;

FIG. 8b is an expanded detail view of the electrostatic shield substrate layer of the sensor overlay covering shown in **FIG. 7a**, showing an non-conductive substrate with an arrangement of conductive traces;

FIG. 8c is an expanded detail view of the electrostatic shield substrate layer of the sensor overlay covering shown in **FIG. 7a**, showing an electrically resistive substrate;

FIG. 9a is a side pictorial view of the sensor overlay covering shown in **FIG. 7** secured to the leg;

FIG. 9b is a close up view of the sensor overlay covering shown in **FIG. 9a**;

FIG. 9c is a bottom view of the sensor overlay covering shown in **FIG. 9b** showing the body-directed substrate layers;

DESCRIPTION OF VARIOUS EMBODIMENTS

[0035] A biomedical sensor overlay covering **11** includes an electrostatic shield contact pad substrate layer **20**, a cushioning substrate layer **30**, an insulating substrate layer **40**, and an electrostatic shield substrate layer **50**, disposed on a release liner **12** as illustrated in the exploded view of **FIG. 1a**. The assembled components of the sensor overlay covering **11** are in the form of a flexible, elongated strip **70**, with a receptacle region shaped and contoured to retain a biomedical sEMG sensor and conductive adhesive regions **20** securing the sensor to the skin. The assembled components of the sensor overlay covering **11** are configured so as to dissipate the accumulation of electrostatic charges on the covering's outer surface **78** into the body and shield the underlying sensor from externally generated low frequency electrical fields such as power line interference. The open-sided geometry of the sensor overlay covering **11** provides compatibility with passive sensor configurations comprised of surface electrode contacts terminated with lead wires, or tethered sensor configurations with active electronics terminated by cable. The constructional architecture of the sensor overlay covering **11** is detailed in **FIG. 1b** which shows a top view **80**, cross-sectional views **25**, **35**, **45**, **55** of each subsequently added substrate layer, and a cross-sectional view **75** of the assembled components, each of which are individually described.

[0036] The electrostatic shield contact pad substrate layer **20** of the sensor overlay covering **11** includes two, electrically conductive, adhesive, cross-linked hydrophilic polymer gel sheets whose top surface **24** is disposed on regions **72** of the bottom surface **52** of the electrostatic shield substrate layer **50** establishing a mechanical and electrical contact with the electrostatic shield substrate layer **50.** Each electrostatic shield contact pad substrate layer **20** is shaped and contoured to match the profile of the regions **72** of the electrostatic shield substrate layer **50.** The body-directed surface **22** of the electrostatic shield contact pad substrate layer **20** establishes a mechanical and electrical contact between the electrostatic shield substrate layer **50** and the surface of the skin, thereby dissipating electrostatic charges to the body and securing the sensor overlay covering **11.**

[0037] The cushioning substrate layer **30** of the sensor overlay covering **11** includes a flexible, compliant, mat whose upper surface **34** is disposed on and adhered to the lower surface **42** of the insulating substrate layer **40** so that it makes mechanical contact in retaining region **74.** The thickness, compliance and contour of the cushioning substrate layer **30** is selected so that when the sensor overlay covering **11** is applied over a sensor, its lower surface **32** conforms to the upper surfaces of a sensor, thereby retaining and cushioning the sensor from externally applied mechanical disturbances. The cushioning substrate layer **30** component of the sensor overlay covering **11** is formed from a sheet of non-triboelectric, absorbent material with permeability and thickness selected so that it wicks away and retains excessive skin moisture.

[0038] The insulating substrate layer **40** of the sensor overlay covering **11** includes a flexible, compliant sheet of electrically insulating material whose upper surface **44** is disposed on and adhered to the lower surface **52** of the electrostatic shield substrate layer **50** so that it makes mechanical contact and forms an electrically insulating barrier between the electrostatic shield **50** and a sensor. The profile of insulating substrate layer **40** is shaped so as to selectively expose, electrically conductive regions **72** of the bottom surface **52** of the electrostatic shield substrate layer **50** to the upper surface **24** of the electrostatic shield contact pad substrate layer **20**, so as to form an electrical inter-connection between the electrostatic shield layer **50** and contact pad substrate layer **20.** The insulating substrate layer **40** is formed from a double-sided adhesive coated sheet of non-triboelectric, material with thickness selected so that the material resists electrical breakdown from static electrical discharges (ESD) to the skin.

[0039] The electrostatic shield substrate layer **50** of the sensor overlay covering **11** includes a flexible, compliant layer with electrically conductive properties configured so as to dissipate the accumulation of electrostatic charges on the covering's outer surface **78** into the body, and shield the underlying sensor from externally generated electrical fields. The contoured region **74** of the electrostatic shield substrate layer **50** is shaped to retain a biomedical sensor. The upper surface **54** of the electrostatic shield substrate layer **50** forms the outer covering **78** of the sensor overlay **11** which is cosmetically textured and colored so that it more closely matches the color and texture of the underlying skin. The exposed regions **72** of the body directed surface **52** of the electrostatic shield substrate layer **50** form a mechanical and electrical inter-connection with the upper surfaces **24** of the electrostatic shield contact pad substrate layer **20.**

[0040] Pictorial views of the assembled components of the elongated strip configuration **70** of the sensor overlay covering embodiment **11** and an alternative configuration where the elongated strip **70** is formed into a continuous band **90** are shown in **FIGs. 2a**, **2b**, **2c**, and **2d.** As illustrated in the example use-cases in **FIG. 2a**, the elongated strip configuration **70** is placed on the muscles of the upper leg **82. FIG. 2b** details a close up view of the elongated strip configuration **70** positioned on the skin **84.** A tethered sensor **85** is retained in a receptacle region **74** of overlay configuration **70** so that the sensor's cable **86** is unencumbered. **FIG. 2c** shows a bottom view of the sensor retained in the overlay configuration **70** and arranged so that the sensor's bottom surface **88** containing the sensor contacts **87** and the surfaces **22** of the electrostatic shield contact pad substrate layer **20** are directed towards the skin. The elongated strip configuration **70** of the sensor overlay covering embodiment **11** is suitable for securing the sensor at locations which are not amenable to an encircling band, such as the torso and large limb muscles, or in locations where an encircling band would encumber movement such as sensor placements on the hand, neck and face. As further illustrated in example use-case in **FIG. 2a**, an alternative continuous band overlay configuration **90** may be suitable for a secure sensor placement on smaller limb muscles such as the lower leg **83**, especially for applications monitoring sEMG activity during vigorous, dynamic limb movements such as walking and running. **FIG. 2d** shows a close up view of the continuous band overlay configuration **90.** The geometrical configuration and structural architecture is similar to the elongated strip configuration **70**, including a receptacle region **74** shaped and contoured to retain a biomedical sEMG sensor **85**, with the addition of segments of stretchable elastic **92** which form the overlay covering into a continuous band **90** for encircling the limb, while providing compliance with the underlying skin tissue.

[0041] The skin **84** application of the configurations **70**, **90** of sensor overlay covering **11** used the examples illustrated in **FIG 2a**, is detailed as follows: Initially, the body-directed surface **88** of the sensor **85** containing the electrode contacts **87** is applied to the surface of the skin **84.** Prior to use, the release liner **12** of overlay configuration **70** is removed and the retaining region **74** of overlay covering **70** is positioned and pressed into place over the sensor **85.** Next, the exposed body-directed surfaces **22** of each of the electrostatic shield contact pads **20** are applied to the surface of the skin **84**, and the outer surface **78** of the overlay **70** is pressed to the skin **84**, securing the sensor **85** and overlay covering configuration **70.** Application of the continuous band overlay configuration **90** follows a similar procedure as described for the application of the elongated strip overlay configuration **70** with the exception that the release liner **12** covering the body-directed surfaces **22** of each of the electrostatic shield contact pads **20** is not removed prior to the application of the sensor overlay band. The sensor **85** is applied to the surface of the skin **84** at position **83** and the elasticized region **92** of band overlay configuration **90** is stretched so that the band can be placed into position **83** over the limb so that the retaining region **74** of overlay covering configuration **90** is positioned over the sensor **85** as show in the close up view of **FIG. 2d.** After the retaining region **74** of overlay covering configuration **90** is positioned over the sensor **85**, the release liner **12** is removed from the inner surface **94** by pulling on the tab **13**, exposing the body-directed surfaces **22** of each of the electrostatic shield contact pads **20.** Next, the outer surface **96** of the overlay covering configuration **90** is pressed to the surface of the skin **84**, securing the sensor **85** and overlay covering configuration **90.**

[0042] Another biomedical sensor embodiment **111** includes an electrostatic shield contact pad substrate layer **120**, a cushioning substrate layer **130**, an insulating substrate layer **140**, and an electrostatic shield substrate layer **150**, disposed on a release liner **112** as illustrated in the exploded view of **FIG. 3a.** The assembled components of the sensor overlay covering **111** are in the form of a flexible, elongated strip **170**, with a receptacle region shaped and contoured to retain a wireless biomedical sEMG sensor and conductive adhesive regions securing the sensor to the skin. The enclosed geometry of the sensor retaining region **174** of the sensor overlay covering **111** is in the form of a contoured pocket **177** designed to be compatible with wireless sensor technologies, and provide a means to dissipate the accumulation of electrostatic charges on the covering's outer surface **178** into the body, and shield the underlying sensor from externally generated low frequency electrical fields such as power line interference while maintaining a means of ingress and egress for radio frequency signal reception and transmission for the wireless sensor. The constructional architecture of the sensor overlay covering **111** is detailed in **FIG. 3b** which shows a top view **180**, cross-sectional views **125**, **135**, **145**, **155** of each subsequently added substrate layer, and a cross-sectional view **175** of the assembled components, each of which are individually described.

[0043] The electrostatic shield contact pad substrate layer **120** of the sensor overlay covering **111** includes an electrically conductive, adhesive, cross-linked hydrophilic polymer gel sheet with an central opening **126**, and whose top surface **124** is disposed on region **172** of the bottom surface **152** of the electrostatic shield substrate layer **150** establishing a mechanical and electrical contact with the electrostatic shield substrate layer **150.** The electrostatic shield contact pad substrate layer **120** is shaped and contoured to match the profile of the region **172** of the electrostatic shield substrate layer **150.** The body-directed surface **122** of the electrostatic shield contact pad substrate layer **120** establishes a mechanical and electrical contact between the electrostatic shield substrate layer **150** and the surface of the skin, thereby dissipating electrostatic charges to the body and securing the sensor overlay covering **111.**

[0044] The cushioning substrate layer **130** of the sensor overlay covering **111** includes a flexible, compliant, mat whose upper surface **134** is disposed on and adhered to the lower surface **142** of the insulating substrate layer **140** so that it makes mechanical contact in retaining region **174.** The thickness, compliance and contour of the cushioning substrate layer **130** is selected so that when the sensor overlay covering **111** is applied over a sensor, its lower surface **132** conforms to the upper surfaces of a sensor, thereby retaining and cushioning the sensor from externally applied mechanical disturbances. The cushioning substrate layer **130** component of the sensor overlay covering **111** is formed from a sheet of non-triboelectric, absorbent material with permeability and thickness selected so that it wicks away and retains excessive skin moisture.

[0045] The insulating substrate layer **140** of the sensor overlay covering **111** includes a flexible, compliant sheet of electrically insulating material whose upper surface **144** is disposed on and adhered to the lower surface **152** of the electrostatic shield substrate layer **150** so that it makes mechanical contact and forms an electrically insulating barrier between the electrostatic shield **150** and a sensor. The profile of insulating substrate layer **140** is shaped so as to selectively expose, the electrically conductive region **172** of the bottom surface **152** of the electrostatic shield substrate layer **150** to the upper surface **124** of the electrostatic shield contact pad substrate layer **120**, so as to form an electrical inter-connection between the electrostatic shield layer **150** and contact pad substrate layer **120.** The insulating substrate layer **140** is formed from a double-sided adhesive coated sheet of non-triboelectric, material with a thickness selected so that it resists electrical breakdown from static electrical discharges (ESD) to the skin.

[0046] The electrostatic shield substrate layer **150** of the sensor overlay covering **111** includes a flexible, compliant layer with electrically conductive properties configured so as to dissipate the accumulation of electrostatic charges on the covering's outer surface **178** into the body and shield the underlying sensor from externally generated low frequency electrical fields such as power line interference, while maintaining a means of ingress and egress for radio frequency signal reception and transmission for the wireless sensor. The contoured region **174** of the electrostatic shield substrate layer **150** is shaped to retain and encase a biomedical sensor. The upper surface **154** of the electrostatic shield substrate layer **150** forms the outer covering **178** of the sensor overlay **111** which is cosmetically textured and colored so that it more closely matches the color and texture of the underlying skin. The exposed region **172** of the body directed surface **152** of the electrostatic shield substrate layer **150** forms a mechanical and electrical inter-connection with the upper surface **124** of the electrostatic shield contact pad substrate layer **120.** The contoured pocket region **177** of electrostatic shield substrate layer **150** contains an aperture region **160** formed from a plurality of apertures **161. FIG. 4a.** is pictorial view of an electrically conductive **151** electrostatic shield substrate layer **150**, accompanied by an encircled magnified view **152** showing the plurality of apertures **161** forming the aperture region **160.** The height **162**, width **163**, separation **167**, and number of apertures within the aperture region **160** of the electrically conductive **151** electrostatic shield substrate layer **150** are selected to maximize the level of ingress and egress of radio frequency signal reception and transmission for a given radio frequency bandwidth of a wireless sensor while maintaining dissipation of electrostatic fields. **FIGs. 4b** and **4c** show two alternative constructional configurations of the of electrostatic shield substrate layer **150. FIG. 4b** is pictorial view of an electrically non-conductive **153** electrostatic shield substrate layer **150**, accompanied by an encircled magnified view **154** showing a plurality of electrically conductive traces **164** retained in a non-conductive substrate **153.** The pattern of traces **164** can be formed using printed circuit board technology, can be formed from a plurality of electrically conductive wires embedded within the electrically non-conductive substrate **153**, or formed using other selective electrically conductive trace **164** deposition techniques.

[0047] The width **165**, spacing **166**, and number electrically conductive traces **164** are selected to maximize the level of ingress and egress of radio frequency signal reception and transmission for a given radio frequency bandwidth of a wireless sensor while maintaining dissipation of electrostatic fields. **FIG. 4c** is pictorial view of an electrically resistive **155** electrostatic shield substrate layer **150**, accompanied by an encircled magnified view **156** showing the distribution of resistive composition throughout the electrostatic shield substrate layer **150.** The bulk resistivity of the substrate **155** is selected to maximize the level of ingress and egress of radio frequency signal reception and transmission for a given radio frequency bandwidth of a wireless sensor while maintaining dissipation of electrostatic fields.

[0048] Pictorial views of the assembled components of the elongated strip configuration **170** of the sensor overlay covering embodiment **111** and an alternative configuration where the elongated strip **170** is formed into a continuous band **190** are shown in **FIGs. 5a**, **5b**, **5c**, and **5d.** As illustrated in the example use-cases in **FIG. 5a**, the elongated strip configuration **170** is placed on the muscles of the upper leg **182. FIG. 5b** details a close up view of the elongated strip configuration **170** positioned on the skin **184.** A wireless sensor **185** is retained in a receptacle region **174** of overlay configuration **170.** The arrangement of apertures **161** in the sensor overlay covering embodiment **111** proves for the ingress and egress for a radio frequency signal **189.** The **FIG. 5c** shows a bottom view of the sensor retained in the overlay configuration **170** and arranged so that the sensor's bottom surface **188** containing the sensor contacts **187** and the surfaces **122** of the electrostatic shield contact pad substrate layer **120** are directed towards the skin. The elongated strip configuration **170** of the sensor overlay covering embodiment **111** is suitable for securing the sensor at locations which are not amenable to an encircling band, such as the torso and large limb muscles, or in locations where an encircling band would encumber movement such as sensor placements on the hand, neck and face. As further illustrated in example use-case in **FIG. 5a**, an alternative continuous band overlay configuration **190** may be suitable for a secure sensor placement on smaller limb muscles such as the lower leg **183**, especially for applications monitoring sEMG activity during vigorous, dynamic limb movements such as walking and running. **FIG. 5d** shows a close up view of the continuous band overlay configuration **190.** The geometrical configuration and structural architecture is similar to the elongated strip configuration **170**, including a receptacle region **174** shaped and contoured to retain a biomedical sEMG sensor **185**, with the addition of segments of stretchable elastic **192** which form the overlay covering into a continuous band **190** for encircling the limb, while providing compliance with the underlying skin tissue.

[0049] The skin **184** application of the configurations **170**, **190** of sensor overlay covering **111** used the examples illustrated in **FIG 5a**, is detailed as follows: Initially, the body-directed surface **188** of the sensor **185** containing the electrode contacts **187** is applied to the surface of the skin **184.** Prior to use, the release liner **112** of overlay configuration **170** is removed and the retaining region **174** of overlay covering **170** is positioned and pressed into place over the sensor **185.** Next, the exposed body-directed surfaces **122** of the electrostatic shield contact pad **120** is applied to the surface of the skin **184**, and the outer surface **178** of the overlay **170** is pressed to the skin **184**, securing the sensor **185** and overlay covering configuration **170.** Application of the continuous band overlay configuration **190** follows a similar procedure as described for the application of the elongated strip overlay configuration **170** with the exception that the release liner **112** covering the body-directed surfaces **122** of the electrostatic shield contact pad **120** is not removed prior to the application of the sensor overlay band. The sensor **185** is applied to the surface of the skin **184** at position **183** and the elasticized region **192** of band overlay configuration **190** is stretched so that the band can be placed into position **183** over the limb so that the retaining region **174** of overlay covering configuration **190** is positioned over the sensor **185** as show in the close up view of **FIG. 5d.** After the retaining region **174** of overlay covering configuration **190** is positioned over the sensor **185**, the release liner **112** is removed from the inner surface **194** by pulling on the tab **113**, exposing the body-directed surfaces **122** of the electrostatic shield contact pad **120.** Next, the outer surface **196** of the overlay covering configuration **190** is pressed to the surface of the skin **184**, securing the sensor **185** and overlay covering configuration **190.**

[0050] **FIGs. 6a** and **6b** are time domain plots of wireless sEMG sensor **185** signal outputs recorded when the sensor was placed under clothing and positioned at location **182** on the upper leg. The signal outputs were recorded during an initial time period of continuous manual rubbing **202** of the clothing against the surface of the sensor while the subject was not contracting their leg muscle, followed by a time period of 5 walking steps **205. FIG. 6a** is a signal plot **198** recorded without the presence of an electrostatic shield overlay covering. During the time period of continuous manual rubbing **202**, the signal plot **198** exhibits the presence of electrostatically generated artifact signal (encircled shaded region) **203**, generated as the result of the triboelectric voltage effect of the clothing rubbing across the sensor's surface. During the time period of walking steps **205**, the signal plot **198** exhibits individual bursts of sEMG activity **206** corresponding to a muscle contraction during each step, accompanied by bursts of electrostatically generated signal artifacts (encircled shaded regions) **207** associated with the corresponding periodic clothing contact with the sensor. **FIG. 6b** is a signal plot **201** recorded with an electrostatic shield overlay covering embodiment **111** placed over the sensor **185.** During the time period of continuous manual rubbing **202**, the signal plot **201** exhibits the dissipation of the electrostatically generated voltage as show by the absence of artifact signal in the encircled region **204.** During the time period of walking steps **205**, the signal plot **201** exhibits individual bursts of sEMG activity **208** corresponding to a muscle contraction occurring with each step, accompanied quiescent periods containing no signal artifact (encircled regions) **209**, indicating the dissipation of the electrostatically generated voltage corresponding to the periodic clothing contact with the sensor overlay covering **170.**

[0051] Another biomedical sensor embodiment **211** includes an electrostatic shield contact pad substrate layer **220**, a cushioning substrate layer **230**, an insulating substrate layer **240**, and an electrostatic shield substrate layer **250**, disposed on a release liner **212** as illustrated in the exploded view of **FIG. 7a.** The assembled components of the sensor overlay covering **211** are in the form of a flexible, patch **270**, with a receptacle region shaped and contoured to retain a wireless biomedical sEMG sensor and a conductive adhesive region **272** securing the sensor to the skin. The enclosed geometry of the sensor retaining region **274** of the sensor overlay covering embodiment **211** is in the form of a contoured pocket **277** designed to be compatible with wireless sensor technologies, and provide a means to dissipate the accumulation of electrostatic charges on the covering's outer surface **278** into the body and shield the underlying sensor from externally generated low frequency electrical fields such as power line interference, while maintaining a means of ingress and egress for radio frequency signal reception and transmission for the wireless sensor. The rounded contour of the sensor embodiment **211** enables close placement of adjacent multiple sensors, and provides unencumbered use on smaller muscle groups. The constructional architecture of the sensor overlay covering **211** is similar to sensor embodiment **111** and is detailed in **FIG.7b** which shows a top view **280**, cross-sectional views **225**, **235**, **245**, **255** of each subsequently added substrate layer, and a cross-sectional view **275** of the assembled components, each of which are individually described.

[0052] The electrostatic shield contact pad substrate layer **220** of the sensor overlay covering **211** includes a ring shaped sheet of electrically conductive, adhesive, cross-linked hydrophilic polymer gel with a central opening **226**, and whose top surface **224** is disposed on region **272** of the bottom surface **252** of the electrostatic shield substrate layer **250** establishing a mechanical and electrical contact with the electrostatic shield substrate layer **250.** The electrostatic shield contact pad substrate layer **220** is shaped to match the profile of the region **272** of the electrostatic shield substrate layer **250.** The body-directed surface **222** of the electrostatic shield contact pad substrate layer **220** establishes a mechanical and electrical contact between the electrostatic shield substrate layer **250** and the surface of the skin, thereby dissipating electrostatic charges to the body and securing the sensor overlay covering **211.**

[0053] The cushioning substrate layer **230** of the sensor overlay covering **211** includes a flexible, compliant, mat whose upper surface **234** is disposed on and adhered to the lower surface **242** of the insulating substrate layer **240** so that it makes mechanical contact in retaining region **274.** The thickness, compliance and contour of the cushioning substrate layer **230** is selected so that when the sensor overlay covering **211** is applied over a sensor, its lower surface **232** conforms to the upper surfaces of a sensor, thereby retaining and cushioning the sensor from externally applied mechanical disturbances. The cushioning substrate layer **230** component of the sensor overlay covering **211** is formed from a sheet of non-triboelectric, absorbent material with permeability and thickness selected so that it wicks away and retains excessive skin moisture.

[0054] The insulating substrate layer **240** of the sensor overlay covering **211** includes a flexible, compliant sheet of electrically insulating material whose upper surface **244** is disposed on and adhered to the lower surface **252** of the electrostatic shield substrate layer **250** so that it makes mechanical contact and forms an electrically insulating barrier between the electrostatic shield **250** and a sensor. The profile of insulating substrate layer **240** is shaped so as to selectively expose, the electrically conductive region **272** of the bottom surface **252** of the electrostatic shield substrate layer **250** to the upper surface **224** of the electrostatic shield contact pad substrate layer **220**, so as to form an electrical inter-connection between the electrostatic shield layer **250** and contact pad substrate layer **220.** The insulating substrate layer **240** is formed from a double-sided adhesive coated sheet of non-triboelectric, material with thickness selected so that it resists electrical breakdown from static electrical discharges (ESD) to the skin.

[0055] The electrostatic shield substrate layer **250** of the sensor overlay covering **211** includes a flexible, compliant layer with electrically conductive properties configured so as to dissipate the accumulation of electrostatic charges on the covering's outer surface **278** into the body and shield the underlying sensor from externally generated low frequency electrical fields such as power line interference, while maintaining a means of ingress and egress for radio frequency signal reception and transmission for the wireless sensor. The contoured region **274** of the electrostatic shield substrate layer **250** is shaped to retain and encase a biomedical sensor. The upper surface **254** of the electrostatic shield substrate layer **250** forms the outer covering **278** of the sensor overlay **211** which is cosmetically textured and colored so that it more closely matches the color and texture of the underlying skin. The exposed region **272** of the body directed surface **252** of the electrostatic shield substrate layer **250** forms a mechanical and electrical inter-connection with the upper surface **224** of the electrostatic shield contact pad substrate layer **220.** The contoured pocket region **277** of electrostatic shield substrate layer **250** contains an aperture region **260** formed from a plurality of apertures **261. FIG. 8a** is pictorial view of an electrically conductive **251** electrostatic shield substrate layer **250**, accompanied by an encircled magnified view **252** showing the plurality of apertures **261** forming the aperture region **260.** The height **262**, width **263**, separation **267**, and number of apertures within the aperture region **260** of the electrically conductive **251** electrostatic shield substrate layer **250** are selected to maximize the level of ingress and egress of radio frequency signal reception and transmission for a given radio frequency bandwidth of a wireless sensor while maintaining dissipation of electrostatic fields.

[0056] **FIGs. 8b** and **8c** show two alternative constructional configurations of the of electrostatic shield substrate layer **250. FIG. 8b** is pictorial view of an electrically non-conductive **253** electrostatic shield substrate layer **250**, accompanied by an encircled magnified view **254** showing the plurality of electrically conductive traces **264** retained in a non-conductive substrate **253.** The pattern of traces **264** can be formed using printed circuit board technology, can be formed from a plurality of wires embedded within the electrically non-conductive substrate **253**, or formed using other selective conductive trace **164** deposition techniques. The width **265**, spacing **266**, and number electrically conductive traces **264** are selected to maximize the level of ingress and egress of radio frequency signal reception and transmission for a given radio frequency bandwidth of a wireless sensor while maintaining dissipation of electrostatic fields. **FIG. 8c** is pictorial view of an electrically resistive **255** electrostatic shield substrate layer **250**, accompanied by an encircled magnified view **256** showing the distribution of resistive composition throughout the electrostatic shield substrate layer **250.** The bulk resistivity of the substrate **255** is selected to maximize the level of ingress and egress of radio frequency signal reception and transmission for a given radio frequency bandwidth of a wireless sensor while maintaining dissipation of electrostatic fields.

[0057] Pictorial views of the assembled components of the patch configuration **270** of the sensor overlay covering embodiment **211** are shown in **FIGs. 9a**, **5b**, and **5c.** As illustrated in the example use-case in **FIG. 9a**, the patch overlay configuration **270** is placed on the muscles of the upper leg **282.** The example shows a closely spaced array of the patch configuration **270**, each retaining a wireless sensor **285** configured for monitoring adjacent muscle groups. **FIG. 9b** details a close up view of an individual patch overlay configuration **270** positioned on the skin **284.** A wireless sensor **285** is retained in a contoured pocket region **277** of overlay configuration **270. FIG. 9c** shows a bottom view of the sensor retained in the overlay configuration **270** and arranged so that the sensor's bottom surface **288** containing the sensor contacts **287** and the surface **222** of the electrostatic shield contact pad substrate layer **220** are directed towards the skin. The arrangement of apertures **261** in the sensor overlay covering embodiment **211** provides for the ingress and egress for a radio frequency signal **289.**

[0058] The patch configuration **270** of the sensor overlay covering embodiment **211** is suitable for securing the sensor at locations which are not amenable to an encircling band, such as the torso and large limb muscles, or for applications where multiple, closely spaced, adjacent sensors are required. The skin **284** application of the patch configuration **270**, of sensor overlay covering **211** used the example illustrated in **FIG. 5a**, is detailed as follows: Initially, the body-directed surface **288** of the sensor **285** containing the electrode contacts **287** is applied to the surface of the skin **284.** Prior to use, the release liner **212** of overlay configuration **270** is removed and the retaining region **274** of overlay covering **270** is positioned and pressed into place over the sensor **285.** Next, the outer surface **278** of the overlay **270** is pressed to the skin **284**, securing the sensor **285** and overlay covering configuration **270.**

[0059] Obviously, many modifications and variations of the present invention are possible in light of the above teachings. It is to be understood, therefore, that the invention can be practiced otherwise than as specifically described.

[0060] The invention is defined by the claims. Other specific aspects of the technology described herein are leasted in the following structured clauses:

Clause 1. A biomedical sensor overlay covering, comprising:

a framework of flexible component layers;

a plurality of adhesive substrate components supported by the flexible component layers and forming a flexible protective contoured covering, enveloping, mechanically stabilizing, and securing the sensor to the skin, wherein each of the substrate components is at least one of: electrically shielding, insulating, cushioning, and electrically conductive and wherein electrically shielding and electrically conductive substrate components cooperate with a cushioning substrate to shield the sensor from external electrical fields, dissipate accumulation of electrostatic charge, and suppress movement artifact.

Clause 2. A biomedical sensor overlay covering as in clause 1, wherein the framework of flexible component layers is an elongated strip, with a receptacle region shaped and contoured to retain a biomedical sEMG sensor, and with conductive adhesive regions securing the sensor to the skin. Clause 3. A biomedical sensor overlay covering as in clause 1, wherein the framework of flexible component layers is a continuous band to encircle a limb, with a receptacle region shaped and contoured to retain a biomedical sEMG sensor, and with conductive adhesive regions securing the sensor to the skin.

Clause 4. A biomedical sensor overlay covering as in clause 3, wherein the framework of flexible component layers contains segments of stretchable elastic providing compliance with the underlying skin tissue.

Clause 5. A biomedical sensor overlay covering as in clause 1, wherein the framework of flexible component layers is a patch, with a receptacle region shaped and contoured to retain a biomedical sEMG sensor, and with conductive adhesive regions securing the sensor to the skin. Clause 6. A biomedical sensor overlay covering as in clause 1, wherein the framework of flexible component layers contains an electrostatic shield substrate layer formed from an electrically conductive metallic sheet.

Clause 7. A biomedical sensor overlay covering as in clause 6, wherein the electrostatic shield substrate layer is formed with a plurality of apertures.

Clause 8. A biomedical sensor overlay covering as in clause 1, wherein the framework of flexible component layers contains an electrostatic shield substrate layer formed from an electrically conductive plastic sheet.

Clause 9. A biomedical sensor overlay covering as in clause 8, wherein the electrostatic shield substrate layer is formed with a plurality of apertures.

Clause 10. A biomedical sensor overlay covering as in clause 1, wherein the framework of flexible component layers contains an electrostatic shield substrate layer formed from electrically resistive material.

Clause 11. A biomedical sensor overlay covering as in clause 10, wherein the electrostatic shield substrate layer is formed with a plurality of apertures.

Clause 12. A biomedical sensor overlay covering as in clause 10, wherein the electrical and geometrical configuration of the electrostatic shield substrate layer provides a means of ingress and egress for radio frequency signal reception and transmission.

Clause 13. A biomedical sensor overlay covering as in clause 1, wherein the framework of flexible component layers contains an electrostatic shield substrate layer formed from electrically non-conductive material with a plurality of electrically conductive traces.

Clause 14. A biomedical sensor overlay covering as in clause 12, wherein the electrically conductive traces for the electrostatic shield substrate layer are formed from electrically conductive printed circuit traces.

Clause 15. A biomedical sensor overlay covering as in clause 13, wherein the electrical and geometrical configuration of the electrostatic shield substrate layer provides a means of ingress and egress for radio frequency signal reception and transmission.

Clause 16. A biomedical sensor overlay covering as in clause 1, wherein the framework of flexible component layers contains an electrostatic shield substrate layer formed from electrically resistive material with a plurality of electrically conductive traces.

Clause 17. A biomedical sensor overlay covering as in clause 16, wherein the electrically conductive traces for the electrostatic shield substrate layer are formed from electrically conductive printed circuit traces.

Clause 18. A biomedical sensor overlay covering as in clause 1, wherein the framework of flexible component layers contains a body-directed electrostatic shield contact pad substrate layer formed from electrically conductive, adhesive, cross-linked hydrophilic polymer gel establishing a mechanical and electrical contact with the surface of the skin.

Clause 19. A biomedical sensor overlay covering as in clause 18, wherein the body-directed electrostatic shield contact pad substrate layer is contoured to match a profile of an electrostatic shield substrate layer, and which is adhered to a lower surface of an electrostatic shield substrate layer to make mechanical and electrical contact with selectively exposed electrically conductive regions of the electrostatic shield substrate layer, thereby dissipating electrostatic charges to the body through contact with body skin surface.

Clause 20. A biomedical sensor overlay covering as in clause 1, wherein the framework of flexible component layers contains an electrically insulating substrate layer, contoured to match a profile of an electrostatic shield substrate layer and shaped so as to selectively expose electrically conductive regions of an electrostatic shield substrate layer, and which is adhered to a lower surface of electrostatic shield substrate layer to make mechanical contact.

Clause 21. A biomedical sensor overlay covering as in clause 20, wherein the electrically insulating substrate layer is formed from an insulating membrane with a double-sided adhesive coating.

Clause 22. A biomedical sensor overlay covering as in clause 1, wherein the framework of flexible component layers contains a compliant, cushioning substrate layer, contoured and shaped to match upper surfaces of the sensor and which is adhered to a lower surface of an insulating substrate layer to make mechanical contact.

Clause 23. A biomedical sensor overlay covering as in clause 22, wherein a cushioning substrate layer is formed from an absorbent material arranged to wick away and retain excessive skin moisture.

Clause 24. A biomedical sensor overlay covering as in clause 1, wherein the overlay covering is formed from materials that are hypoallergenic, breathable, and designed for use without slippage or skin breakdown.

Clause 25. A biomedical sensor overlay covering as in clause 1, wherein the overlay covering is cosmetically textured and colored to more closely match color and texture of underlying skin.

Clause 26. A biomedical sensor overlay covering as in clause 1, wherein body-directed adhesive surfaces of the overlay covering are mounted on a release liner.

Clause 27. A biomedical sensor as in clause 1, wherein the sensor is single use and disposable.

Claims

1. A biomedical sensor overlay covering (11) for a biomedical sensor (85), comprising:

flexible component layers (20,30,40,50,70);
a plurality of adhesive substrate components (20,40);
and forming a flexible protective contoured covering (11), wherein the flexible protective contoured covering (11) envelops, mechanically stabilizes, and secures the sensor (85) to the skin, wherein each of the substrate components (20,30,40,50) is at least one of:
electrically shielding, insulating, cushioning, and electrically conductive, **characterized in that** it includes an electrostatic shield substrate layer (50) with electrically conductive properties and an electrostatic shield contact pad substrate layer (20) establishing a mechanical and electrical contact between the electrostatic shield substrate layer (50) and the surface of the skin, wherein the electrically shielding and electrically conductive substrate components (50, 20) cooperate with a cushioning substrate (30) to shield the sensor from external electrical fields, dissipate accumulation of electrostatic charge, and suppress movement artifact.

2. A biomedical sensor overlay covering (11) as in claim 1, wherein the flexible component layers form an elongated strip (70), with a receptacle region (74) shaped and contoured to retain the biomedical sensor (85), and with conductive adhesive regions (72) securing the biomedical sensor (85) to the skin (84).

3. A biomedical sensor overlay covering (11) as in claim 1, wherein the flexible component layers (20,30,40,50,70) form a continuous band (90) to encircle a limb, with a receptacle region (74) shaped and contoured to retain the biomedical sensor (85), with conductive adhesive regions (72) securing the biomedical sensor (85) to the skin (84) and optionally contain segments of stretchable elastic (92) providing compliance with the underlying skin tissue.

4. A biomedical sensor overlay covering (211) as in claim 1, wherein the flexible component layers form a patch (270), with a receptacle region (274) shaped and contoured to retain a biomedical sensor (285), and with conductive adhesive regions (272) securing the biomedical sensor (285) to the skin (284).

5. A biomedical sensor overlay covering (111) as in any one of the preceding claims, wherein the electrostatic shield substrate layer (150) is formed from an electrically conductive sheet that is metallic, plastic or an electrically resistive material and wherein the electrostatic shield substrate layer (150) is optionally formed with a plurality of apertures (161).

6. A biomedical sensor overlay covering (111) as in claim 5, wherein the electrical and geometrical configuration of the electrostatic shield substrate layer (150) provides a means of ingress and egress for radio frequency signal reception and transmission.

7. A biomedical sensor overlay covering (111) as in any one of claims 1 to 4, wherein the flexible component layers (170) contain an electrostatic shield substrate layer (150) formed from electrically non-conductive material with a plurality of electrically conductive traces (164) and wherein the electrically conductive traces (164) for the electrostatic shield substrate layer (150) are optionally formed from electrically conductive printed circuit traces and wherein the electrical and geometrical configuration of the electrostatic shield substrate layer (150) optionally provide a means of ingress and egress for radio frequency signal reception and transmission.

8. A biomedical sensor overlay covering (111) as in any one of claims 1 to 4, wherein the flexible component layers (170) contain an electrostatic shield substrate layer (150) formed from electrically resistive material with a plurality of electrically conductive traces (164) and wherein the electrically conductive traces (164) for the electrostatic shield substrate layer (150) are optionally formed from electrically conductive printed circuit traces.

9. A biomedical sensor overlay covering (11) as in any one of the preceding claims, wherein the body-directed electrostatic shield contact pad substrate layer (20) is formed from electrically conductive, adhesive, cross-linked hydrophilic polymer gel establishing a mechanical and electrical contact with the surface of the skin (84) and wherein the body-directed electrostatic shield contact pad substrate layer (20) is optionally contoured to match a profile of an electrostatic shield substrate layer (50), and which is adhered to a lower surface of an electrostatic shield substrate layer (50) to make mechanical and electrical contact with selectively exposed electrically conductive regions (72) of the electrostatic shield substrate layer (50), thereby dissipating electrostatic charges to the body through contact with body skin surface.

10. A biomedical sensor overlay covering (11) as in any one of the preceding claims, wherein the component layers (20,30,40,50,70) contain an electrically insulating substrate layer (40), contoured to match a profile of an electrostatic shield substrate layer (50) and shaped so as to selectively expose electrically conductive regions (72) of an electrostatic shield substrate layer (50), and which is adhered to a lower surface (52) of electrostatic shield substrate layer (50) to make mechanical contact and wherein the electrically insulating substrate layer (40) is optionally formed from an insulating membrane with a double-sided adhesive coating.

11. A biomedical sensor overlay covering (11) as in any one of the preceding claims, wherein the flexible component layers (70) contain a compliant, cushioning substrate layer (30), contoured and shaped to match upper surfaces of the sensor and which is adhered to a lower surface (42) of an insulating substrate layer (40) to make mechanical contact and wherein a cushioning substrate layer (30) is optionally formed from an absorbent material arranged to wick away and retain excessive skin moisture.

12. A biomedical sensor overlay covering (11) as in any one of the preceding claims, wherein the overlay covering (11) is formed from materials that are hypoallergenic, breathable, and designed for use without slippage or skin breakdown.

13. A biomedical sensor overlay covering (11) as in any one of the preceding claims, wherein the overlay covering (11) is cosmetically textured and colored to more closely match color and texture of underlying skin.

14. A biomedical sensor overlay covering (11) as in any one of the preceding claims, wherein body-directed adhesive surfaces (22) of the overlay covering (11) are mounted on a release liner (12).

15. A single use and disposable biomedical sensor comprising a sensor overlay covering (11) as in any one of the preceding claims.

Patentansprüche

1. Deckauflage (11) für einen biomedizinischen Sensor (85), umfassend:

   flexible Komponentenschichten (20, 30, 40, 50, 70);
   eine Mehrzahl adhäsiver Substratkomponenten (20, 40);
   welche eine flexible schützende konturierte Abdeckung (11) bildet, wobei die flexible schützende konturierte Abdeckung (11) den Sensor (85) umhüllt, mechanisch stabilisiert und an der Haut befestigt, wobei jede der Substratkomponenten (20, 30, 40, 50) mindestens eine der folgenden Eigenschaften aufweist: elektrisch abschirmend, isolierend, dämpfend und elektrisch leitend, **dadurch gekennzeichnet, dass** sie eine Substratschicht (50) zur elektrostatischen Abschirmung mit elektrisch leitenden Eigenschaften und eine Kontaktpad-Substratschicht (20) für die elektrostatische Abschirmung aufweist, welche einen mechanischen und elektrischen Kontakt zwischen der Substratschicht (50) zur elektrostatischen Abschirmung und der Hautoberfläche herstellt, wobei die elektrisch abschirmenden und elektrisch leitenden Substratkomponenten (50, 20) mit einem dämpfenden Substrat (30) zusammenwirken, um den Sensor gegen externe elektrische Felder abzuschirmen, Ansammlungen elektrostatischer Ladung abzuführen und Bewegungsartefakte zu unterdrücken.

2. Deckauflage (11) für einen biomedizinischen Sensor nach Anspruch 1, wobei die flexiblen Komponentenschichten einen länglichen Streifen (70) bilden, mit einem Aufnahmebereich (74), welcher geformt und konturiert ist, um den biomedizinischen Sensor (85) zu halten, und mit leitenden adhäsiven Bereichen (72), welche den biomedizinischen Sensor (85) an der Haut (84) befestigen.

3. Deckauflage (11) für einen biomedizinischen Sensor nach Anspruch 1, wobei die flexiblen Komponentenschichten (20, 30, 40, 50, 70) ein kontinuierliches Band (90) bilden, um eine Extremität zu umschließen, mit einem Aufnahmebereich (74), welcher ge-

formt und konturiert ist, um den biomedizinischen Sensor (85) zu halten, mit leitenden adhäsiven Bereichen (72), welche den biomedizinischen Sensor (85) an der Haut (84) befestigen, und wahlweise Segmente aus dehnbarem elastischem Material (92) enthalten, welche die Anpassung an das darunter liegende Hautgewebe gewährleisten.

4. Deckauflage (211) für einen biomedizinischen Sensor nach Anspruch 1, wobei die flexiblen Komponentenschichten ein Pflaster (270) bilden, mit einem Aufnahmebereich (274), welcher geformt und konturiert ist, um einen biomedizinischen Sensor (285) zu halten, und mit leitenden adhäsiven Bereichen (272), welche den biomedizinischen Sensor (285) an der Haut (284) befestigen.

5. Deckauflage (111) für einen biomedizinischen Sensor nach einem beliebigen der vorangehenden Ansprüche, wobei die Substratschicht (150) zur elektrostatischen Abschirmung aus einer elektrisch leitenden Folie gebildet ist, welche aus Metall, Kunststoff oder einem elektrisch resistiven Material besteht, und wobei die Substratschicht (150) zur elektrostatischen Abschirmung wahlweise mit einer Mehrzahl von Öffnungen (161) gebildet ist.

6. Deckauflage (111) für einen biomedizinischen Sensor nach Anspruch 5, wobei die elektrische und geometrische Konfiguration der Substratschicht (150) zur elektrostatischen Abschirmung ein Eingangs- und Ausgangsmittel für den Empfang und die Übertragung von Radiofrequenzsignalen bereitstellt.

7. Deckauflage (111) für einen biomedizinischen Sensor nach einem beliebigen der Ansprüche 1 bis 4, wobei die flexiblen Komponentenschichten (170) eine Substratschicht (150) zur elektrostatischen Abschirmung enthalten, welche aus einem elektrisch nicht leitendem Material mit einer Mehrzahl elektrisch leitender Leiterbahnen (164) gebildet ist, und wobei die elektrisch leitenden Leiterbahnen (164) für die Substratschicht (150) zur elektrostatischen Abschirmung wahlweise aus elektrisch leitenden Leiterplattenbahnen gebildet sind und wobei die elektrische und geometrische Konfiguration der Substratschicht (150) zur elektrostatischen Abschirmung wahlweise ein Eingangs- und Ausgangsmittel für den Empfang und die Übertragung von Radiofrequenzsignalen bereitstellt.

8. Deckauflage (111) für einen biomedizinischen Sensor nach einem beliebigen der Ansprüche 1 bis 4, wobei die flexiblen Komponentenschichten (170) eine Substratschicht (150) zur elektrostatischen Abschirmung enthalten, welche aus einem elektrisch resistiven Material mit einer Mehrzahl elektrisch leitender Leiterbahnen (164) gebildet ist, und wobei die elektrisch leitenden Leiterbahnen (164) für die Substratschicht (150) zur elektrostatischen Abschirmung wahlweise aus elektrisch leitenden Leiterplattenbahnen gebildet sind

9. Deckauflage (11) für einen biomedizinischen Sensor nach einem beliebigen der vorangehenden Ansprüche, wobei die zum Körper gewandte Kontaktpad-Substratschicht (20) für die elektrostatische Abschirmung aus einem elektrisch leitenden, adhäsiven, vernetzten hydrophilen Polymergel gebildet ist, welches einen mechanischen und elektrischen Kontakt mit der Oberfläche der Haut (84) herstellt, und wobei die zum Körper gewandte Kontaktpad-Substratschicht (20) für die elektrostatische Abschirmung wahlweise so konturiert ist, dass sie einem Profil einer Substratschicht (50) zur elektrostatischen Abschirmung entspricht, und welche an einer unteren Oberfläche einer Substratschicht (50) zur elektrostatischen Abschirmung haftet, um mechanischen und elektrischen Kontakt mit selektiv freiliegenden elektrisch leitenden Bereichen (72) der Substratschicht (50) zur elektrostatischen Abschirmung herzustellen, wodurch durch Kontakt mit der Körperhautoberfläche elektrostatische Ladungen an den Körper abgeführt werden.

10. Deckauflage (11) für einen biomedizinischen Sensor nach einem beliebigen der vorangehenden Ansprüche, wobei die Komponentenschichten (20, 30, 40, 50, 70) eine elektrisch isolierende Substratschicht (40) enthalten, die so konturiert ist, dass sie einem Profil einer Substratschicht (50) zur elektrostatischen Abschirmung entspricht, und so geformt ist, dass sie selektiv elektrisch leitende Bereiche (72) einer Substratschicht (50) zur elektrostatischen Abschirmung freilegt, und welche an einer unteren Oberfläche (52) der Substratschicht (50) zur elektrostatischen Abschirmung haftet, um einen mechanischen Kontakt herzustellen, und wobei die elektrisch isolierende Substratschicht (40) wahlweise aus einer Isoliermembran mit einer doppelseitigen adhäsiven Beschichtung gebildet ist.

11. Deckauflage (11) für einen biomedizinischen Sensor nach einem beliebigen der vorangehenden Ansprüche, wobei die flexiblen Komponentenschichten (70) eine nachgiebige, dämpfende Substratschicht (30) enthalten, welche so konturiert und geformt ist, dass sie den oberen Oberflächen des Sensors entspricht, und welche an einer unteren Oberfläche (42) einer isolierenden Substratschicht (40) haftet, um einen mechanischen Kontakt herzustellen, und wobei eine dämpfende Substratschicht (30) wahlweise aus einem absorbierenden Material gebildet ist, welches angeordnet ist, um übermäßige Hautfeuchtigkeit abzuleiten und zu speichern.

12. Deckauflage (11) für einen biomedizinischen Sensor nach einem beliebigen der vorangehenden Ansprüche, wobei die Deckauflage (11) aus Materialien gebildet ist, welche hypoallergen, atmungsaktiv und zur Verwendung ohne Gleiten oder Hautschäden ausgelegt sind.

13. Deckauflage (11) für einen biomedizinischen Sensor nach einem beliebigen der vorangehenden Ansprüche, wobei die Deckauflage (11) so kosmetisch texturiert und gefärbt ist, dass sie besser zu Farbe und Textur der darunterliegenden Haut passt.

14. Deckauflage (11) für einen biomedizinischen Sensor nach einem beliebigen der vorangehenden Ansprüche, wobei zum Körper gewandte Haftflächen (22) der Deckauflage (11) auf einer Trennschicht angebracht sind.

15. Biomedizinischer Einweg-Sensor zum einmaligen Gebrauch, umfassend eine Sensor-Deckauflage (11) nach einem beliebigen der vorangehenden Ansprüche.

Revendications

1. Revêtement d'habillage de capteur biomédical (11) pour un capteur biomédical (85), comprenant :

des couches constituantes flexibles (20, 30, 40, 50, 70) ;
une pluralité de composants de substrat adhésifs (20, 40) ;
et formant un revêtement de protection flexible profilé (11), dans lequel le revêtement de protection flexible profilé (11) enveloppe, stabilise mécaniquement, et fixe le capteur (85) sur la peau, chacun des composants de substrat (20, 30, 40, 50) ayant au moins l'une des caractéristiques suivantes :
électriquement blindant, isolant, capitonnant et électriquement conducteur, **caractérisé en ce qu'**il comprend une couche de substrat de blindage électrostatique (50) ayant des propriétés électriquement conductrices et une couche de substrat de tampon de contact de blindage électrostatique (20) établissant un contact mécanique et électrique entre la couche de substrat de blindage électrostatique (50) et la surface de la peau, les composants de substrat de blindage électrique et électriquement conducteurs (50, 20) coopérant avec un substrat de capitonnage (30) pour protéger le capteur vis-à-vis de champs électriques externes, dissiper une accumulation de charge électrostatique, et supprimer un artefact de mouvement.

2. Revêtement d'habillage de capteur biomédical (11) selon la revendication 1, dans lequel les couches constituantes flexibles forment un ruban allongé (70), ayant une zone de réceptacle (74) formée et profilée pour retenir le capteur biomédical (85), et ayant des zones adhésives conductrices (72) fixant le capteur biomédical (85) sur la peau (84).

3. Revêtement d'habillage de capteur biomédical (11) selon la revendication 1, dans lequel les couches constituantes flexibles (20, 30, 40, 50, 70) forment une bande continue (90) pour entourer un membre, ayant une zone de réceptacle (74) formée et profilée pour retenir le capteur biomédical (85), ayant des zones adhésives conductrices (72) fixant le capteur biomédical (85) sur la peau (84) et contiennent de manière facultative des segments de matière élastique extensible (92) permettant une compatibilité avec le tissu cutané sous-jacent.

4. Revêtement d'habillage de capteur biomédical (211) selon la revendication 1, dans lequel les couches constituantes flexibles forment un patch (270), ayant une zone de réceptacle (274) formée et profilée pour retenir un capteur biomédical (285), et ayant des zones adhésives conductrices (272) fixant le capteur biomédical (285) sur la peau (284).

5. Revêtement d'habillage de capteur biomédical (111) selon l'une quelconque des revendications précédentes, dans lequel la couche de substrat de blindage électrostatique (150) est formée d'une feuille électriquement conductrice qui est métallique, plastique ou un matériau électriquement résistant, et dans lequel la couche de substrat de blindage électrostatique (150) est formée de manière facultative d'une pluralité d'ouvertures (161).

6. Revêtement d'habillage de capteur biomédical (111) selon la revendication 5, dans lequel la configuration électrique et géométrique de la couche de substrat de blindage électrostatique (150) fournit des moyens d'entrée et de sortie pour une réception et une transmission de signaux radiofréquence.

7. Revêtement d'habillage de capteur biomédical (111) selon l'une quelconque des revendications 1 à 4, dans lequel les couches constituantes flexibles (170) contiennent une couche de substrat de blindage électrostatique (150) formée d'un matériau électriquement non conducteur ayant une pluralité de composés traces électriquement conducteurs (164) et dans lequel les composés traces électriquement conducteurs (164) pour la couche de substrat de blindage électrostatique (150) sont formés de manière facultative de composés traces de circuit imprimé électriquement conducteurs et dans lequel la configuration électrique et géométrique de la couche de substrat de blindage électrostatique (150) fournit de manière facultative des moyens d'entrée et de sortie pour une réception et une transmission de signaux radiofréquence.

8. Revêtement d'habillage de capteur biomédical (111) selon l'une quelconque des revendications 1 à 4, dans lequel les couches constituantes flexibles (170) contiennent une couche de substrat de blindage électrostatique (150) formée d'un matériau électriquement résistant ayant une pluralité de composés traces électriquement conducteurs (164) et dans lequel les composés traces électriquement conducteurs (164) pour la couche de substrat de blindage électrostatique (150) sont formés de manière facultative de composés traces de circuit imprimé électriquement conducteurs.

9. Revêtement d'habillage de capteur biomédical (11) selon l'une quelconque des revendications précédentes, dans lequel la couche de substrat de tampon de contact de blindage électrostatique dirigée vers le corps (20) est formée d'un gel polymère hydrophile réticulé, adhésif, électriquement conducteur, établissant un contact mécanique et électrique avec la surface de la peau (84) et dans lequel la couche de substrat de tampon de contact de blindage électrostatique dirigée vers le corps (20) est profilée de manière facultative pour correspondre à un profil d'une couche de substrat de blindage électrostatique (50), et qui est collée à une surface inférieure d'une couche de substrat de blindage électrostatique (50) pour établir un contact mécanique et électrique avec des zones électriquement conductrices exposées de manière sélective (72) de la couche de substrat de blindage électrostatique (50), en dissipant ainsi des charges électrostatiques vers le corps par contact avec une surface cutanée corporelle.

10. Revêtement d'habillage de capteur biomédical (11) selon l'une quelconque des revendications précédentes, dans lequel les couches constituantes (20, 30, 40, 50, 70) contiennent une couche de substrat électriquement isolante (40), profilée pour correspondre à un profil d'une couche de substrat de blindage électrostatique (50) et formée de manière à exposer sélectivement des zones électriquement conductrices (72) d'une couche de substrat de blindage électrostatique (50), et qui est collée à une surface inférieure (52) de la couche de substrat de blindage électrostatique (50) pour établir un contact mécanique et dans lequel la couche de substrat électriquement isolante (40) est formée de manière facultative d'une membrane isolante ayant un enduit adhésif double-face.

11. Revêtement d'habillage de capteur biomédical (11) selon l'une quelconque des revendications précédentes, dans lequel les couches constituantes flexibles (70) contiennent une couche de substrat de capitonnage compatible (30), profilée et formée pour correspondre à des surfaces supérieures du capteur et qui est collée à une surface inférieure (42) d'une couche de substrat isolante (40) pour établir un contact mécanique et dans lequel une couche de substrat de capitonnage (30) est formée de manière facultative d'un matériau absorbant conçu pour évacuer et retenir une humidité excessive de peau.

12. Revêtement d'habillage de capteur biomédical (11) selon l'une quelconque des revendications précédentes, dans lequel le revêtement d'habillage (11) est formé de matériaux qui sont hypoallergéniques, respirants, et conçus pour être utilisés sans glissement ni dégradation de peau.

13. Revêtement d'habillage de capteur biomédical (11) selon l'une quelconque des revendications précédentes, dans lequel le revêtement d'habillage (11) est texturé et coloré de manière cosmétique pour correspondre plus étroitement à la couleur et à la texture d'une peau sous-jacente.

14. Revêtement d'habillage de capteur biomédical (11) selon l'une quelconque des revendications précédentes, dans lequel des surfaces adhésives dirigées vers le corps (22) du revêtement d'habillage (11) sont montées sur une doublure antiadhésive (12).

15. Capteur biomédical à usage unique et jetable comprenant un revêtement d'habillage de capteur (11) selon l'une quelconque des revendications précédentes.

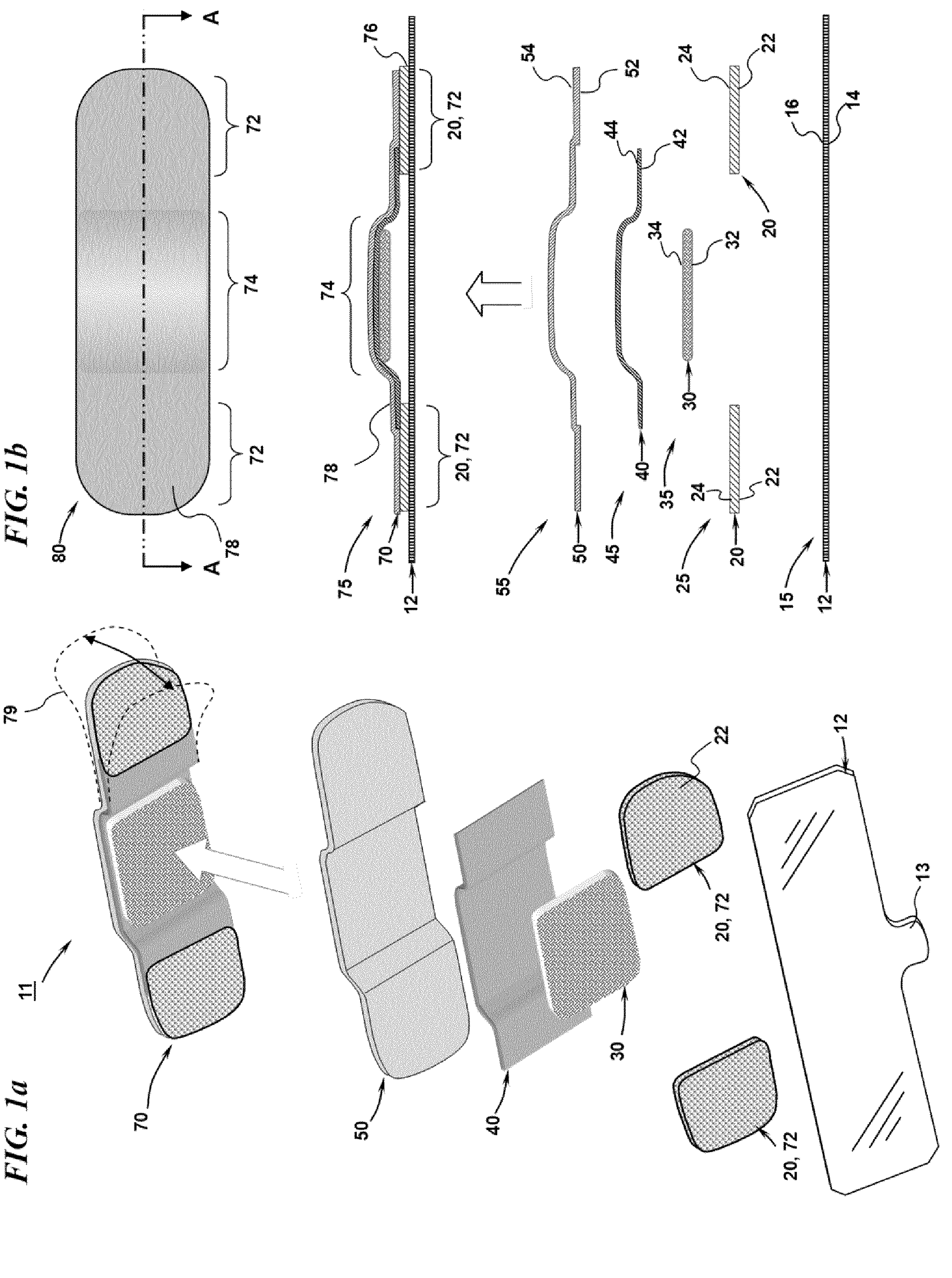
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FIG. 1a

FIG. 1b

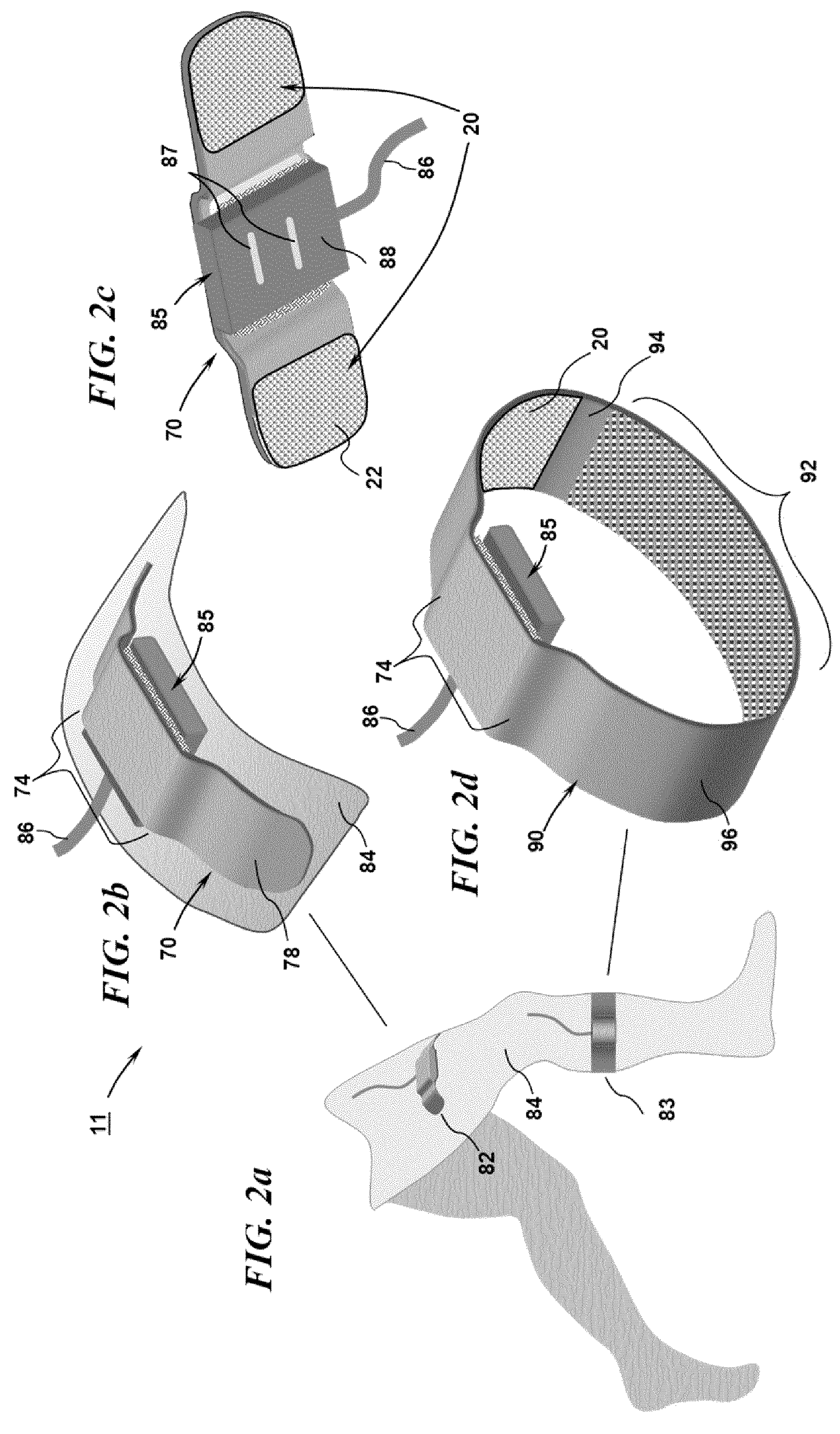
FIG. 2a
FIG. 2b
FIG. 2c
FIG. 2d
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FIG. 3b

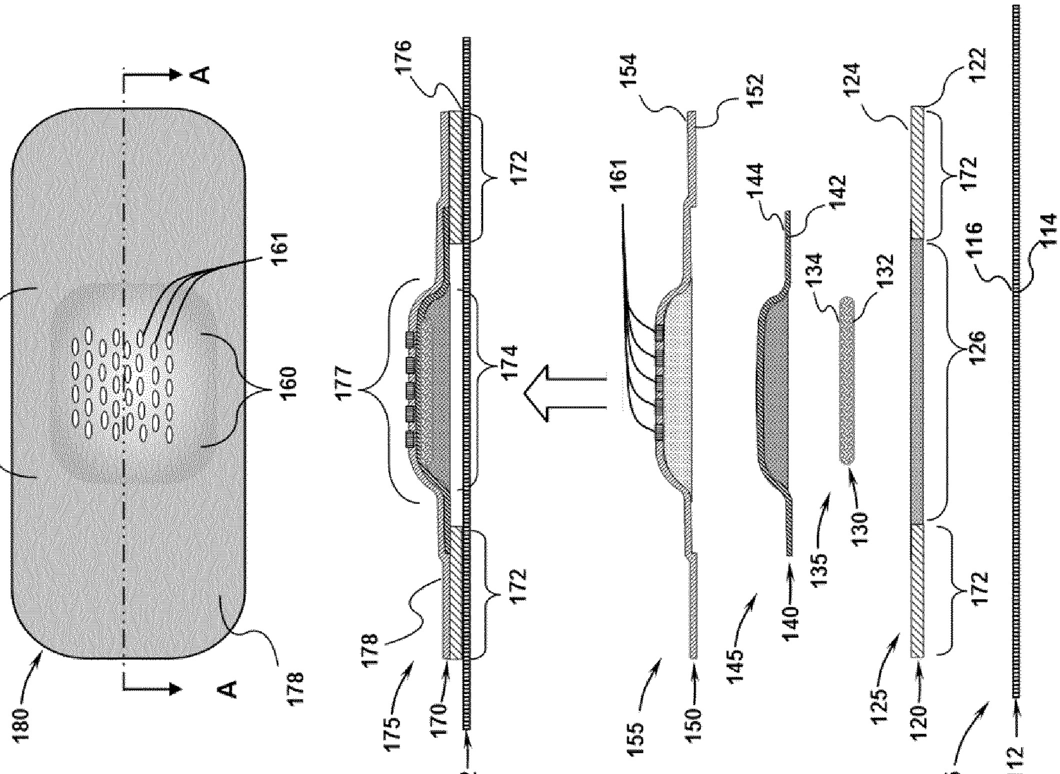
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FIG. 3a

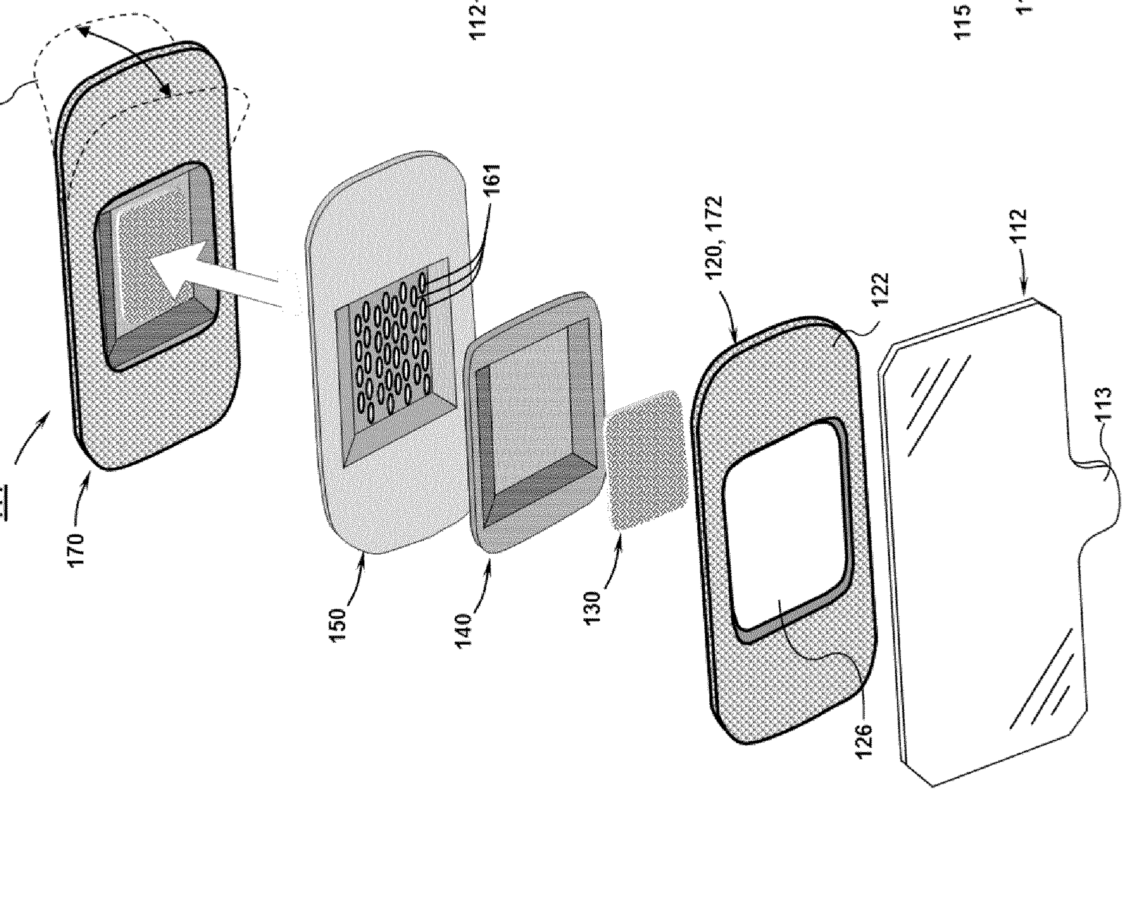
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FIG. 4a

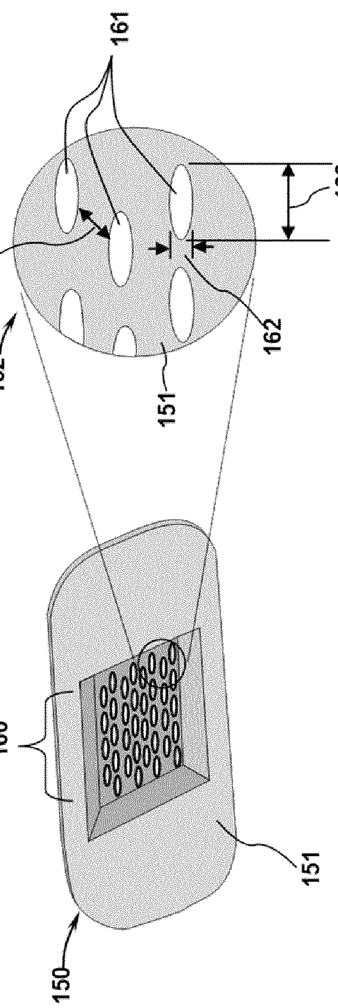


FIG. 4b

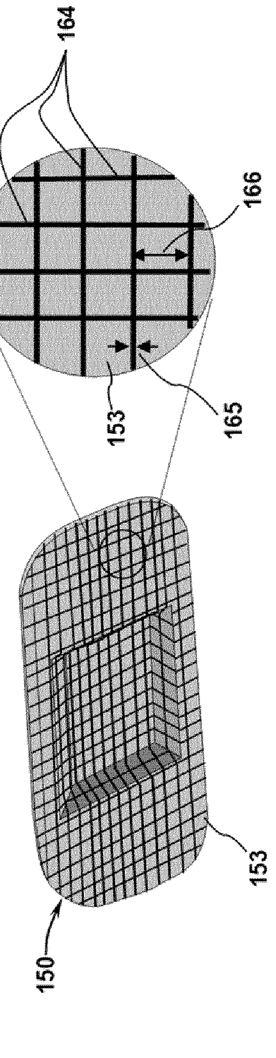
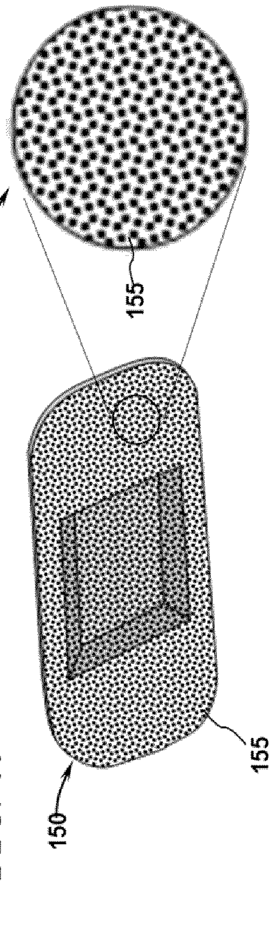


FIG. 4c



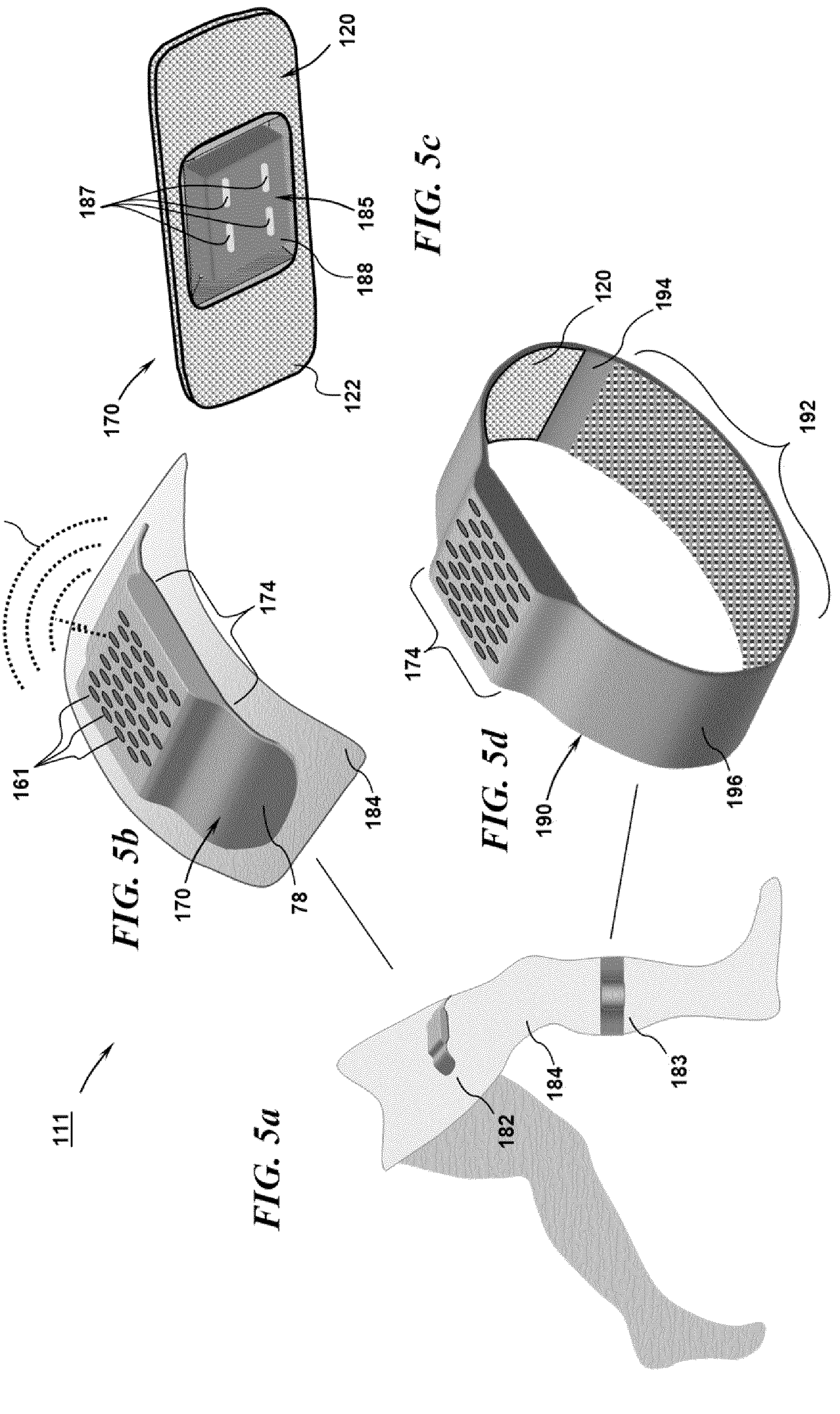


FIG. 5a

FIG. 5b

FIG. 5c

FIG. 5d

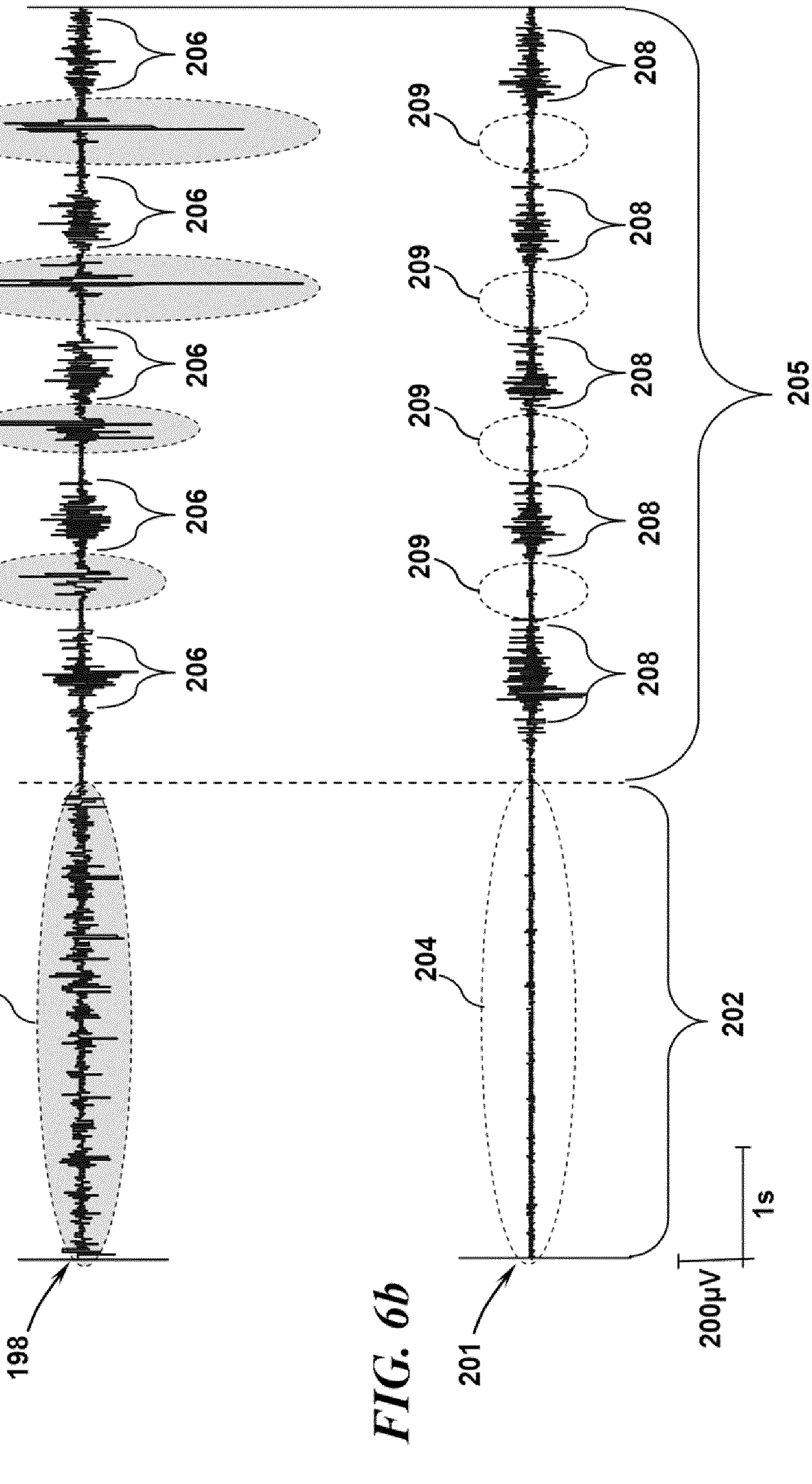


FIG. 6a

FIG. 6b

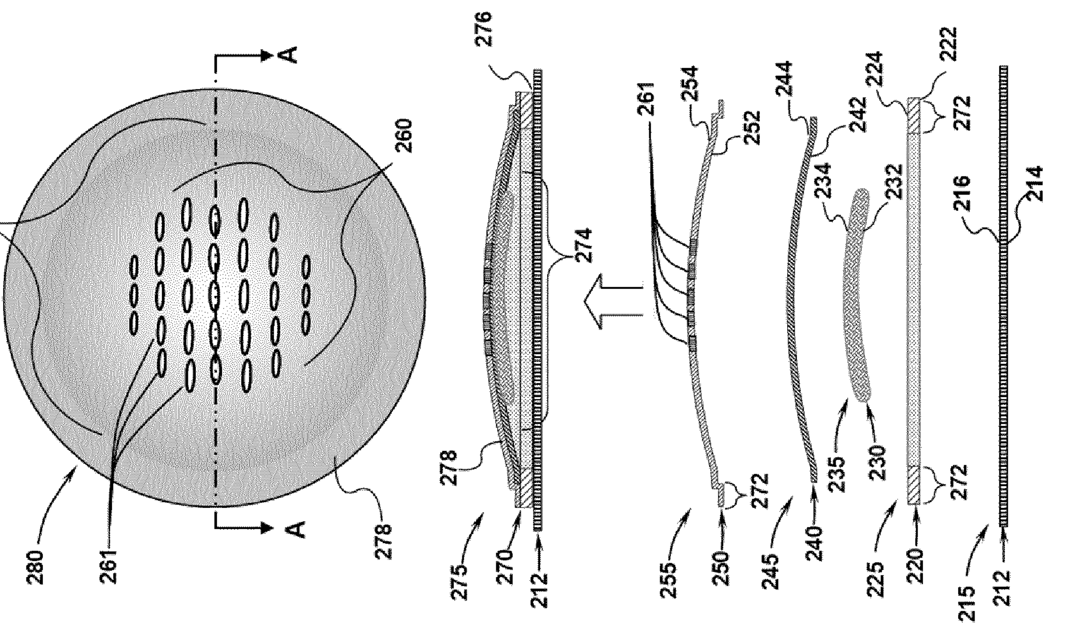

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FIG. 7b

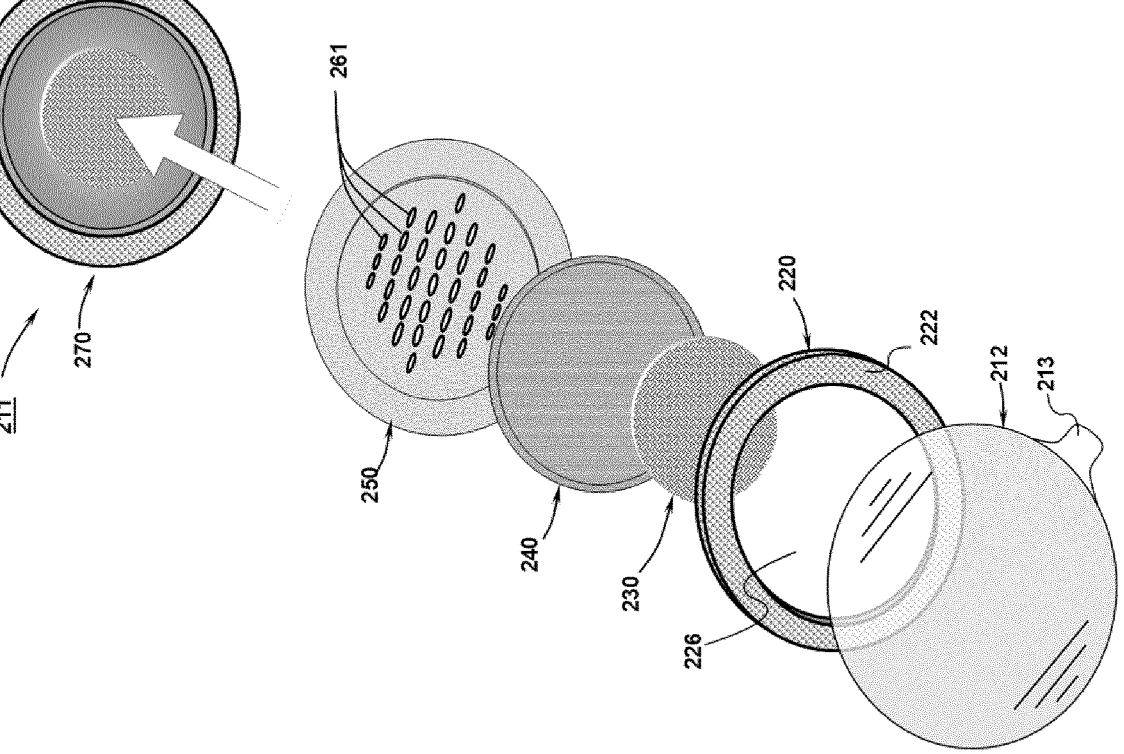
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FIG. 7a

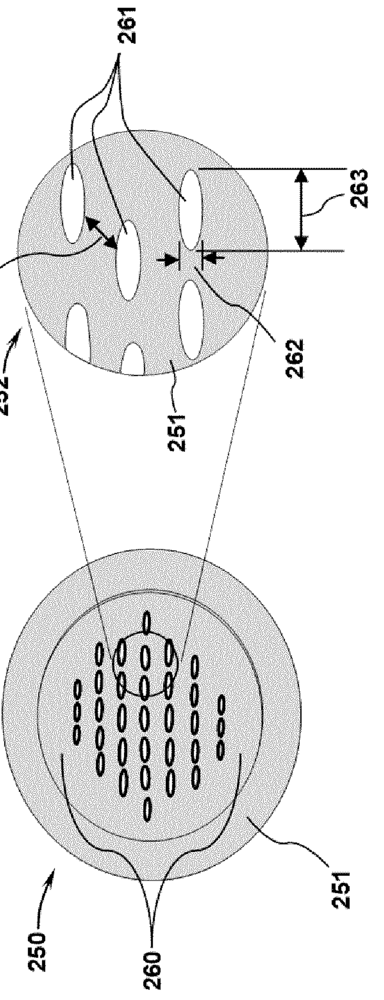

FIG. 8a

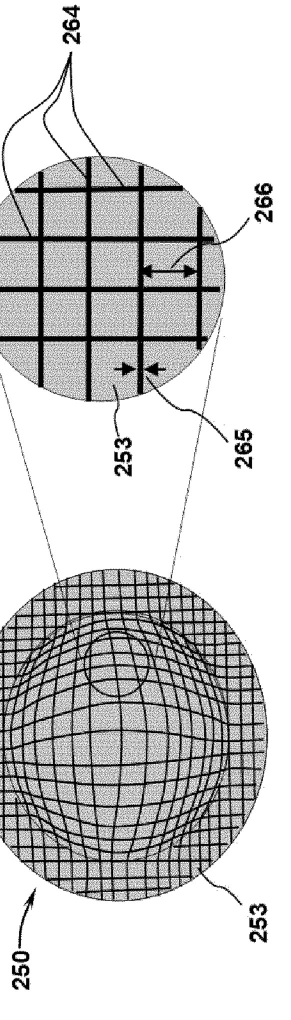

FIG. 8b

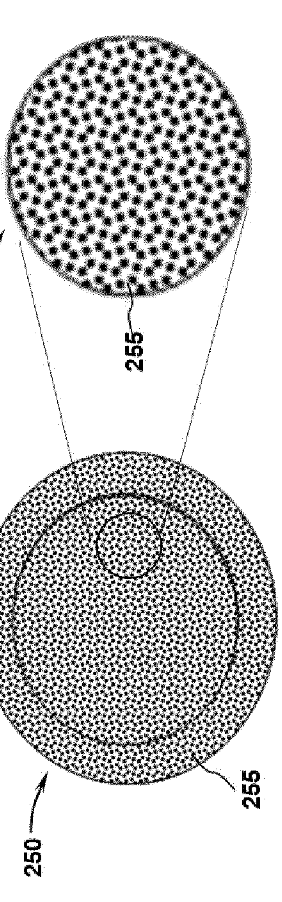

FIG. 8c

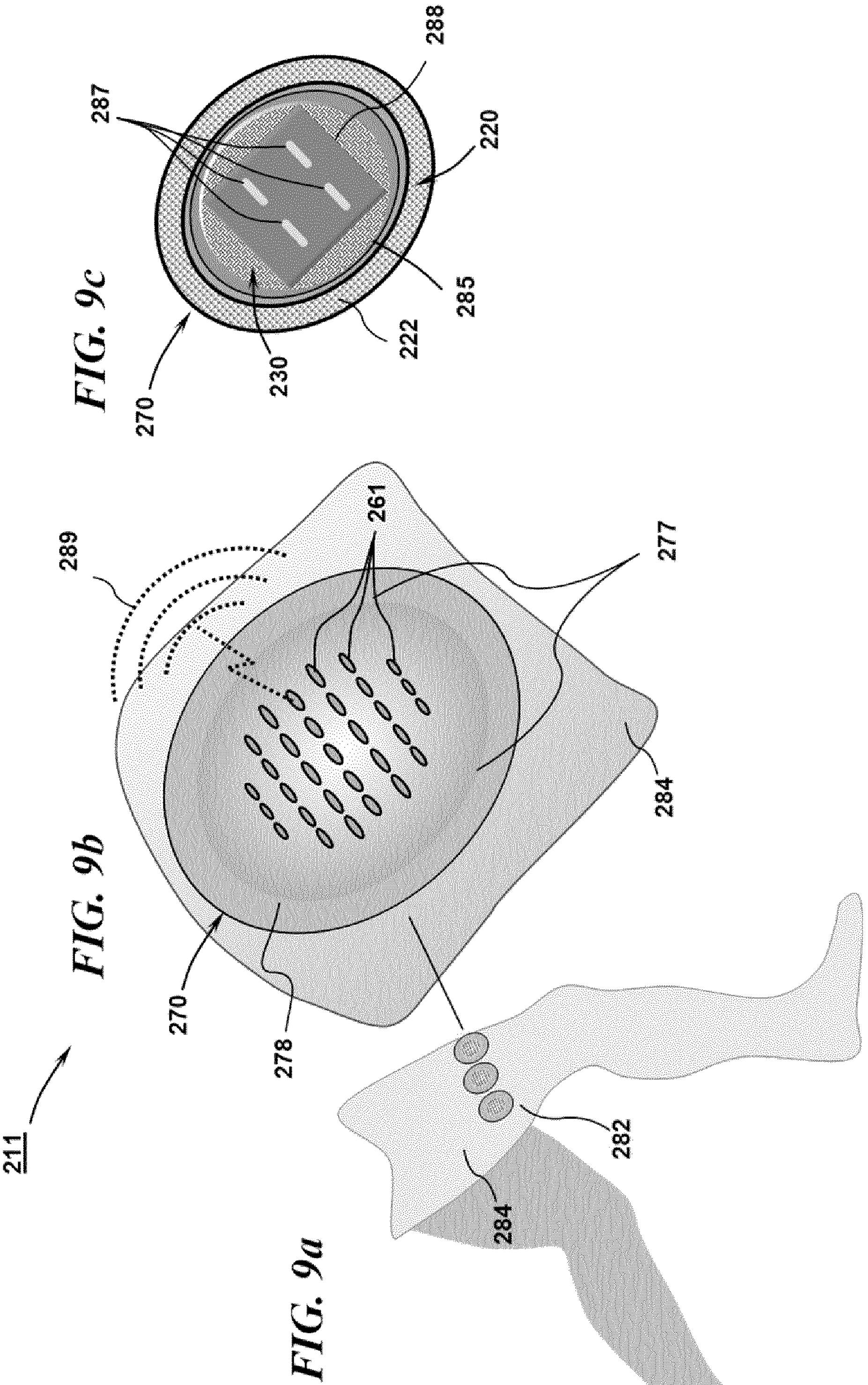

FIG. 9a

FIG. 9b

FIG. 9c

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	用于生物医学传感器的一次性保护罩		
公开(公告)号	EP2848195B1	公开(公告)日	2019-04-10
申请号	EP2014183957	申请日	2014-09-08
[标]申请(专利权)人(译)	ALTECH INDS		
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当前申请(专利权)人(译)	ALTEC，INC.		
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发明人	GILMORE, L. DONALD DE LUCA, CARLO J.		
IPC分类号	A61B5/0492 A61B5/00		
CPC分类号	A61B5/0492 A61B5/6833 A61B2560/0412 A61B2562/182 H05F3/00		
优先权	14/026521 2013-09-13 US		
其他公开文献	EP2848195A1		
外部链接	Espacenet		

摘要(译)

一种用于生物医学传感器的一次性薄型传感器覆盖物，其包括支撑静电屏蔽，绝缘，缓冲和导电粘合剂基底部件的柔性部件层的框架，所述柔性部件层被配置成形成包围传感器的保护性覆盖物。组件层的组合提供了稳定传感器相对于皮肤的相对位置的手段，并降低了传感器移位的可能性。机械和电气配置协同作用以屏蔽传感器免受外部电场影响并抑制运动伪影。