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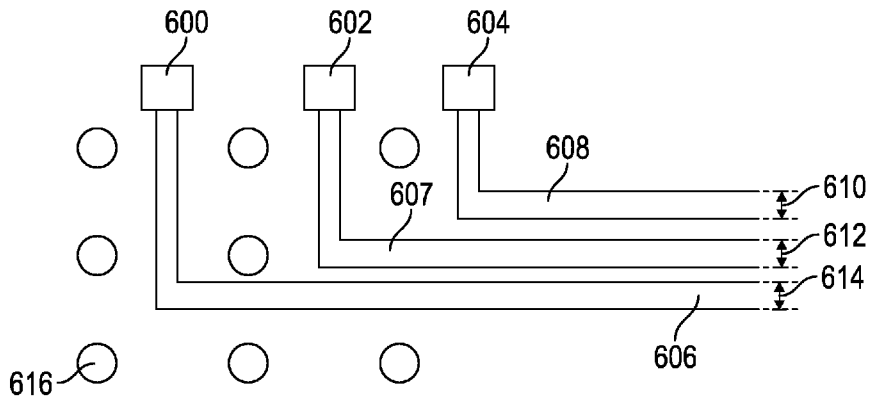


FIG. 4

(57) Abstract: Methods of manufacturing a wound monitoring and/or therapy apparatus and/or wound dressing include positioning electronic components and connections in regions of a substrate that are not configured to be perforated. The methods can also include following a set of rules for positioning the components as well as positioning and shaping the connections based on the constraints stemming from, among other things, the positioning of the perforations on the substrate and with the goal of maintaining acceptable levels of signal integrity. The methods further include manufacturing a multi-layered substrate. Wound monitoring and/or therapy apparatus manufactured using such methods are also disclosed.

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DESIGN RULES FOR SENSOR INTEGRATED SUBSTRATES

Technical Field

Embodiments of the present disclosure relate to sensor integrated substrates, which can be incorporated into wound dressings and systems, and in particular to design rules for such substrates.

Description of the Related Art

Nearly all areas of medicine may benefit from improved information regarding the state of the tissue, organ, or system to be treated, particularly if such information is gathered in real-time during treatment. Many types of treatments are still routinely performed without the use of sensor data collection; instead, such treatments rely upon visual inspection by a caregiver or other limited means rather than quantitative sensor data. For example, in the case of wound treatment via dressings and/or negative pressure wound therapy, data collection is generally limited to visual inspection by a caregiver and often the underlying wounded tissue may be obscured by bandages or other visual impediments. Even intact, unwounded skin may have underlying damage that is not visible to the naked eye, such as a compromised vascular or deeper tissue damage that may lead to an ulcer. Similar to wound treatment, during orthopedic treatments requiring the immobilization of a limb with a cast or other encasement, only limited information is gathered on the underlying tissue. In instances of internal tissue repair, such as a bone plate, continued direct sensor-driven data collection is not performed. Further, braces and/or sleeves used to support musculoskeletal function do not monitor the functions of the underlying muscles or the movement of the limbs. Outside of direct treatments, common hospital room items such as beds and blankets could be improved by adding capability to monitor patient parameters.

Such wound monitoring and/or treatment systems present unique problems due to being in contact with tissue. In addition, a wound should be allowed to heal without impediment. At the same time, care must be taken to ensure that such systems are reliable and safe for use on human or animal tissue.

Therefore, there is a need for improved wound monitoring and/or treatment systems.

SUMMARY

In some cases, a method of manufacturing a wound monitoring and/or therapy apparatus (such as, a wound dressing) can include positioning on a substantially flexible substrate a first conductive track configured to be connected to a first sensor, the first track having a first minimum width to maintain integrity of an electrical signal conducted by the first conductive track, positioning on the substrate a second conductive track configured to be connected to a second sensor, the second track having a second minimum width to maintain integrity of an electrical signal conducted by the second conductive track, and positioning on the substrate a third track configured to be connected to a third sensor, the third track having a third minimum width to maintain integrity of an electrical signal conducted by the first conductive track. The first, second, and third conductive tracks can be positioned on portions of the substrate that are not configured to be perforated with a plurality of openings, the plurality of openings configured to allow fluid to pass through the substrate. At least one of locations or sizes of the plurality of openings configured to allow fluid to pass through the substrate can constrain a maximum dimension at least one of the first, second, or third minimum widths. The first, second, and third sensors can be sensors of different types.

The method of the preceding paragraph and/or any of the methods described herein can include one or more of the following features. The method can include perforating the substrate to form the plurality of openings. Perforating the substrate to form the plurality of openings can include not perforating the portions of the substrate on which the first, second, and third conductive tracks are positioned. Positioning at least one of the first, second, or third conductive tracks can include printing the at least one of the first, second, or third conductive tracks using conductive ink. Conductive ink can include silver ink. The method can include positioning on the substrate a fourth track configured to provide power to at least one of the first, second, or third sensors, the fourth track having a fourth minimum width, wherein at least one of the locations or sizes of the plurality of openings can further constrain a maximum dimension of the fourth minimum width. The first, second, and third conductive tracks, first sensor, second sensor, and third sensor can be positioned at least a minimum distance away from the plurality of openings.

The method of any of the preceding paragraphs and/or any of the methods described herein can include one or more of the following features. At least two of the first, second, or third minimum widths can be different from one another. The first conductive track can be configured to conduct an analog signal, the second conductive track can be configured to conduct a digital signal, and the first minimum width can be smaller than the second minimum width. The first sensor can be a temperature sensor, the second sensor can be a light sensor, and the third sensor can be an impedance sensor.

In some cases, a method of manufacturing a wound monitoring and/or therapy apparatus (such as, a wound dressing) can include positioning on a substantially flexible substrate a first conductive track oriented in a first direction and configured to transmit electrical signals and positioning on the substrate adjacent to the first conductive track at a first minimum distance from the first conductive track a second conductive track, the second conductive track oriented in the first direction and configured to transmit electrical signals. The first minimum distance can be defined by at least one of a location or size of at least one opening configured to allow exudate to pass through the substrate.

The method of any of preceding paragraphs and/or any of the methods described herein can include one or more of the following features. The method can include perforating the substrate to form the at least one opening in a portion of the substrate separating the first conductive track from the second conductive track. The method can include positioning on the substrate a third conductive track oriented in a second direction and configured to transmit electrical signals, the second direction different from the first direction and positioning on the substrate adjacent to the conductive third track at a second minimum distance from the third conductive track a fourth conductive track, the fourth conductive track oriented in the second direction and configured transmit electrical signals, the second minimum distance being different than the first minimum distance. Positioning on the substrate third and fourth conductive tracks oriented in the second direction can include positioning third and fourth conductive tracks at a third minimum distance from each of the first and second conductive tracks oriented in the first direction. The second direction can be perpendicular to the first direction. Positioning at least one of the first, second, third, or fourth conductive tracks can

include printing the at least one of the first, second, third, or fourth conductive tracks using conductive ink. Conductive ink can include silver ink.

In some cases, a method of manufacturing a wound monitoring and/or therapy apparatus (such as, a wound dressing) can include positioning on a substantially flexible substrate a first conductive track oriented in a first direction and configured to transmit electrical signals, positioning on the substrate a second conductive track oriented in a second direction different from the first direction, the second conductive track configured to transmit electrical signals, the second conductive track having same width as the first conductive track, and forming an electrical connection between the first and second conductive tracks by forming a substantially circular conductive area overlapping the first and second conductive tracks, a radius of the conductive area being about one half of the width of the first and conductive second tracks.

The method of any of preceding paragraphs and/or any of the methods described herein can include one or more of the following features. Positioning at least one of the first or second conductive tracks can include printing the at least one of the first or second conductive tracks using conductive ink. Conductive ink can include silver ink. Forming the electrical connection can include removing at least a portion of dry ink to form the substantially circular conductive area with the radius of about one half of the width of the first and second conductive tracks.

In some cases, a method of manufacturing a wound monitoring and/or therapy apparatus (such as, a wound dressing) can include positioning on a substantially flexible substrate a first conductive track configured to transmit electrical signals, the first conductive track having a first width, positioning on the substrate a second conductive track configured to transmit electrical signals, the second conductive track having a second width different than the first width, and electrically connecting first and second tracks with a curved connector.

The method of any of preceding paragraphs and/or any of the methods described herein can include one or more of the following features. Portions of the first conductive track proximal to the connector and of the second conductive track proximal to the connector can be shaped to not include any transitions of approximately 90 degrees. At least one of positioning at least one of the first or second conductive tracks or electrically connecting first

and second tracks with the curved connector can include printing the at least one of the first conductive track, second conductive track, or the curved connector using conductive ink. Conductive ink can include silver ink.

In some cases, a method of manufacturing a wound monitoring and/or therapy apparatus (such as, a wound dressing) can include positioning on a flexible substrate a first conductive track oriented in a first direction and configured to transmit electrical signals; positioning on the flexible substrate a second conductive track oriented in a second direction different from the first direction, the second conductive track configured to transmit electrical signals, at least a portion of the second conductive track overlapping at least a portion of the first conductive track and forming a mask region between the portion of the first conductive track overlapping the portion of the second conductive track, the mask region electrically isolating the overlapping portions of the first and second conductive tracks. Positioning at least one of the first or second conductive tracks can include printing the at least one of the first or second conductive tracks using conductive ink. The mask region can be formed from non-conducive paint.

A wound dressing can include a flexible or substantially flexible substrate with a first side and a second side opposite the first side. A first electrically conductive track can be positioned on the first side of the substrate. A second electrically conductive track can be positioned on the second side of the substrate. The second electrically conductive track can be electrically connected to the first electrically conductive track via an electrically conductive material that passes through the substrate.

The wound dressing of any preceding paragraphs and/or any of the wound dressings disclosed herein can include one or more of the following features. The electrically conductive material is positioned in a perforation through the substrate. The wound dressing can include a first electronic component positioned on the first side of the substrate and electrically connected to the first electrically conductive track. The wound dressing can include a second electronic component positioned on the second side of the substrate and electrically connected to the second electrically conductive track. The first electronic component can include a plurality of sensors configured to measure a plurality of parameters of a wound. The second electronic component can include an antenna configured to transmit

at least some of the plurality of parameters measured by the plurality of sensors to a remote computing device.

The wound dressing of any preceding paragraphs and/or any of the wound dressings disclosed herein can include one or more of the following features. The wound dressing can include a substantially non-stretchable coating applied to at least one of the first electronic component, second electronic component, first electrically conductive track, or second electrically conductive track. The wound dressing can include a substantially stretchable coating applied over the substantially non-stretchable coating. The substrate can include or be made of thermoplastic polyurethane (TPU). A portion of the first electrically conductive track can overlap a portion of the second electrically conductive track. At least one of the first or second electrically conductive tracks can cover at least part of the perforation. First and second electrically conductive tracks can include conductive ink or conductive glue. The electrically conductive material can include conductive ink or conductive glue. Conductive ink can include silver ink. First electrically conductive track may not directly contact the second electrically conductive track.

The wound dressing of any preceding paragraphs and/or any of the wound dressings disclosed herein can include one or more of the following features. The wound dressing can include a third electrically conductive track positioned on the first side of the substrate. The wound dressing can include a first non-conductive mask separating the first and third electrically conductive tracks. The wound dressing can include a fourth electrically conductive track positioned on the second side of the substrate. The wound dressing can include a second non-conductive mask separating the second and fourth electrically conductive tracks.

A method of manufacturing a wound dressing can include passing an electrically conductive material through a flexible or substantially flexible substrate of the wound dressing. The method can include positioning a first electrically conductive track on a first side of the substrate. The method can include forming an electrical connection with the electrically conductive material. The method can include positioning a second electrically conductive track on a second side of the substrate located opposite the first side. The method can include

forming an electrical connection with the electrically conductive material. The first and second electrically conductive tracks can be electrically connected via the conductive material.

The method of any preceding paragraphs and/or any of the methods disclosed herein can include one or more of the following features. The method can include forming a perforation through the substrate and at least partially filling the perforation with the electrically conductive material. The method can include positioning a first electronic component on the first side of the substrate and electrically connecting the first electronic component to the first electrically conductive track. The method can include positioning a second electronic on the second side of the substrate and electrically connecting the second electronic component to the second electrically conductive track.

The method of any preceding paragraphs and/or any of the methods disclosed herein can include one or more of the following features. The method can include applying a substantially non-stretchable coating to at least one of the first electronic component, second electronic component, first electrically conductive track, or second electrically conductive track. The method can include applying a substantially stretchable coating over the substantially non-stretchable coating. The substrate can include or be made of thermoplastic polyurethane (TPU). Positioning the second electrically conductive track on the second side of the substrate can include overlapping a portion of the first electrically conductive track. Positioning at least one of the first or second electrically conductive tracks can include covering at least part of the perforation. Positioning at least one of the first or second electrically conductive tracks can include printing the at least one of the first or second electrically conductive tracks using conductive ink or conductive glue. Electrically conductive material can include conductive ink or conductive glue. Conductive ink can include silver ink.

The method of any preceding paragraphs and/or any of the methods disclosed herein can include one or more of the following features. The method can include positioning a third electrically conductive track on the first side of the substrate. The method can include positioning a first non-conductive mask between the first and third electrically conductive tracks. The method can include positioning a fourth electrically conductive track on the second side of the substrate. The method can include positioning a second non-conductive mask between the second and fourth electrically conductive tracks.

A method of manufacturing a wound monitoring and/or therapy apparatus (such as, a wound dressing) can include positioning on a substantially flexible substrate a first conductive track oriented in a first direction and configured to transmit electrical signals. The method can include positioning on the substrate a first non-conductive mask by covering the first conductive track with the first mask except for a portion of the first conductive track configured to be electrically connected to another conductive track or an electrical component. Covering the first conductive track with the first mask can prevent or reduce migration or dispersal of conductive material of the first conductive track.

The method of any of preceding paragraphs and/or any of the methods described herein can include one or more of the following features. Positioning the first conductive track can include printing the first conductive track on the substrate using conductive ink or conductive glue. The portion of the first conductive track can be a pad or a via. Positioning on the substrate the first mask can include covering substantially entire surface of the substrate with the first mask.

The method of any of preceding paragraphs and/or any of the methods described herein can include one or more of the following features. The method can include positioning on the substrate a second conductive track oriented in a second direction different from the first direction, the second conductive track configured to transmit electrical signals. The method can include positioning on the substrate a second non-conductive mask by covering the second conductive track with the second mask except for a portion of the second conductive track configured to be electrically connected to another conductive track or an electrical component. Covering the second conductive track with the second mask can prevent or reduce migration or dispersal of conductive material of the second conductive track. Positioning the second conductive track can include printing the second conductive track on the substrate using conductive ink or conductive glue. The portion of the second conductive track can be a pad or a via. Positioning on the substrate the second mask can include covering substantially entire surface of the substrate with the second mask.

Any of the features of any of the methods described herein can be used with any of the features of any of the other methods described herein.

In some cases, a wound monitoring and/or therapy apparatus (such as a wound dressing) manufactured using the methods of any one or more of preceding paragraphs and/or any of the methods described herein is disclosed. In some cases, a substrate supporting one or more electronic components and/or connections manufactured using the methods of any one or more of preceding paragraphs and/or any of the methods described herein is disclosed.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the present disclosure will now be described hereinafter, by way of example only, with reference to the accompanying drawings in which:

FIG. 1A illustrates a wound monitoring and therapy system;

FIGS. 1B-1D illustrate substrates supporting electronic components, in which FIG. 1B illustrates a perspective view of a substrate supporting electronic components and FIGS. 1C-1D illustrate perspective and top views of a perforated substrate supporting electronic components;

FIGS. 2A-2B illustrates cross-sections of wound dressings;

FIGS. 3A-3B illustrate perspective and top views of a perforated substrate supporting electronic components;

FIG. 4 illustrates components and traces positioned on a perforated substrate;

FIG. 5 illustrates a trace positioned on a perforated substrate;

FIG. 6 illustrates a plurality of traces positioned on a perforated substrate;

FIG. 7 illustrates adjacent traces separated by a minimum distance;

FIG. 8 illustrates two pairs of traces separated by minimum distances;

FIG. 9 illustrates two traces positioned in different layers;

FIG. 10 illustrates two traces joined at a joint;

FIG. 11 illustrates one trace meeting another trace at a joint;

FIG. 12 illustrates a plurality of traces connecting to components;

FIG. 13 illustrates traces positioned on a perforated substrate;

FIGS. 14A-14C illustrate perspective and cross-sectional views of a substrate supporting one or more electronic connections or electronic components.

DETAILED DESCRIPTION

Embodiments disclosed herein relate to apparatuses and methods of at least one of monitoring or treating biological tissue with sensor-enabled substrates. The embodiments disclosed herein are not limited to treatment or monitoring of a particular type of tissue or injury, instead the sensor-enabled technologies disclosed herein are broadly applicable to any type of therapy that may benefit from sensor-enabled substrates. Some implementations utilize sensors and data collection relied upon by health care providers to make both diagnostic and patient management decisions.

Some embodiments disclosed herein relate to the use of sensors mounted on or embedded within substrates configured to be used in the treatment of both intact and damaged human or animal tissue. Such sensors may collect information about the surrounding tissue and transmit such information to a computing device or a caregiver to be utilized in further treatment. In certain embodiments, such sensors may be attached to the skin anywhere on the body, including areas for monitoring arthritis, temperature, or other areas that may be prone to problems and require monitoring. Sensors disclosed herein may also incorporate markers, such as radiopaque markers, to indicate the presence of the device, for example prior to performing an MRI or other technique.

The sensor embodiments disclosed herein may be used in combination with clothing. Non-limiting examples of clothing for use with embodiments of the sensors disclosed herein include shirts, pants, trousers, dresses, undergarments, outer-garments, gloves, shoes, hats, and other suitable garments. In certain embodiments, the sensor embodiments disclosed herein may be welded into or laminated into/onto the particular garments. The sensor embodiments may be printed directly onto the garment and/or embedded into the fabric. Breathable and printable materials such as microporous membranes may also be suitable.

Sensor embodiments disclosed herein may be incorporated into cushioning or bed padding, such as within a hospital bed, to monitor patient characteristics, such as any characteristic disclosed herein. In certain embodiments, a disposable film containing such sensors could be placed over the hospital bedding and removed/replaced as needed.

In some implementations, the sensor embodiments disclosed herein may incorporate energy harvesting, such that the sensor embodiments are self-sustaining. For example, energy

may be harvested from thermal energy sources, kinetic energy sources, chemical gradients, or any suitable energy source.

The sensor embodiments disclosed herein may be utilized in rehabilitation devices and treatments, including sports medicine. For example, the sensor embodiments disclosed herein may be used in braces, sleeves, wraps, supports, and other suitable items. Similarly, the sensor embodiments disclosed herein may be incorporated into sporting equipment, such as helmets, sleeves, and/or pads. For example, such sensor embodiments may be incorporated into a protective helmet to monitor characteristics such as acceleration, which may be useful in concussion diagnosis.

The sensor embodiments disclosed herein may be used in coordination with surgical devices, for example, the NAVIO surgical system by Smith & Nephew Inc. In some implementations, the sensor embodiments disclosed herein may be in communication with such surgical devices to guide placement of the surgical devices. In some implementations, the sensor embodiments disclosed herein may monitor blood flow to or away from the potential surgical site or ensure that there is no blood flow to a surgical site. Further surgical data may be collected to aid in the prevention of scarring and monitor areas away from the impacted area.

To further aid in surgical techniques, the sensors disclosed herein may be incorporated into a surgical drape to provide information regarding tissue under the drape that may not be immediately visible to the naked eye. For example, a sensor embedded flexible drape may have sensors positioned advantageously to provide improved area-focused data collection. In certain implementations, the sensor embodiments disclosed herein may be incorporated into the border or interior of a drape to create fencing to limit/ control the surgical theater.

Sensor embodiments as disclosed herein may also be utilized for pre-surgical assessment. For example, such sensor embodiments may be used to collect information about a potential surgical site, such as by monitoring skin and the underlying tissues for a possible incision site. For example, perfusion levels or other suitable characteristics may be monitored at the surface of the skin and deeper in the tissue to assess whether an individual patient may be at risk for surgical complications. Sensor embodiments such as those disclosed herein may be used to evaluate the presence of microbial infection and provide an indication for the use of

antimicrobials. Further, sensor embodiments disclosed herein may collect further information in deeper tissue, such as identifying pressure ulcer damage and/or the fatty tissue levels.

The sensor embodiments disclosed herein may be utilized in cardiovascular monitoring. For example, such sensor embodiments may be incorporated into a flexible cardiovascular monitor that may be placed against the skin to monitor characteristics of the cardiovascular system and communicate such information to another device and/or a caregiver. For example, such a device may monitor pulse rate, oxygenation of the blood, and/or electrical activity of the heart. Similarly, the sensor embodiments disclosed herein may be utilized for neurophysiological applications, such as monitoring electrical activity of neurons.

The sensor embodiments disclosed herein may be incorporated into implantable devices, such as implantable orthopedic implants, including flexible implants. Such sensor embodiments may be configured to collect information regarding the implant site and transmit this information to an external source. In some embodiments, an internal source may also provide power for such an implant.

The sensor embodiments disclosed herein may also be utilized for monitoring biochemical activity on the surface of the skin or below the surface of the skin, such as lactose buildup in muscle or sweat production on the surface of the skin. In some embodiments, other characteristics may be monitored, such as glucose concentration, urine concentration, tissue pressure, skin temperature, skin surface conductivity, skin surface resistivity, skin hydration, skin maceration, and/or skin ripping.

Sensor embodiments as disclosed herein may be incorporated into Ear, Nose, and Throat (ENT) applications. For example, such sensor embodiments may be utilized to monitor recovery from ENT-related surgery, such as wound monitoring within the sinus passage.

Sensor embodiments disclosed herein may encompass sensor printing technology with encapsulation, such as encapsulation with a polymer film. Such a film may be constructed using any polymer described herein, such as polyurethane. Encapsulation of the sensor embodiments may provide waterproofing of the electronics and protection from local tissue, local fluids, and other sources of potential damage.

In certain embodiments, the sensors disclosed herein may be incorporated into an organ protection layer. Such a sensor-embedded organ protection layer may both protect the organ of interest and confirm that the organ protection layer is in position and providing protection. Further, a sensor-embedded organ protection layer may be utilized to monitor the underlying organ, such as by monitoring blood flow, oxygenation, and other suitable markers of organ health. In some embodiments, a sensor-enabled organ protection layer may be used to monitor a transplanted organ, such as by monitoring the fat and muscle content of the organ. Further, sensor-enabled organ protection layers may be used to monitor an organ during and after transplant, such as during rehabilitation of the organ.

The sensor embodiments disclosed herein may be incorporated into treatments for wounds (disclosed in greater detail below) or in a variety of other applications. Non-limiting examples of additional applications for the sensor embodiments disclosed herein include: monitoring and treatment of intact skin, cardiovascular applications such as monitoring blood flow, orthopedic applications such as monitoring limb movement and bone repair, neurophysiological applications such as monitoring electrical impulses, and any other tissue, organ, system, or condition that may benefit from improved sensor-enabled monitoring.

Wound Therapy

Some embodiments disclosed herein relate to wound therapy for a human or animal body. Therefore, any reference to a wound herein can refer to a wound on a human or animal body, and any reference to a body herein can refer to a human or animal body. The disclosed technology embodiments may relate to preventing or minimizing damage to physiological tissue or living tissue, or to the treatment of damaged tissue (for example, a wound as described herein) wound with or without reduced pressure, including for example a source of negative pressure and wound dressing components and apparatuses. The apparatuses and components comprising the wound overlay and packing materials or internal layers, if any, are sometimes collectively referred to herein as dressings. In some embodiments, the wound dressing can be provided to be utilized without reduced pressure.

Some embodiments disclosed herein relate to wound therapy for a human or animal body. Therefore, any reference to a wound herein can refer to a wound on a human or animal

body, and any reference to a body herein can refer to a human or animal body. The disclosed technology embodiments may relate to preventing or minimizing damage to physiological tissue or living tissue, or to the treatment of damaged tissue (for example, a wound as described herein).

As used herein the expression "wound" may include an injury to living tissue may be caused by a cut, blow, or other impact, typically one in which the skin is cut or broken. A wound may be a chronic or acute injury. Acute wounds occur as a result of surgery or trauma. They move through the stages of healing within a predicted timeframe. Chronic wounds typically begin as acute wounds. The acute wound can become a chronic wound when it does not follow the healing stages resulting in a lengthened recovery. It is believed that the transition from acute to chronic wound can be due to a patient being immuno-compromised.

Chronic wounds may include for example: venous ulcers (such as those that occur in the legs), which account for the majority of chronic wounds and mostly affect the elderly, diabetic ulcers (for example, foot or ankle ulcers), peripheral arterial disease, pressure ulcers, or epidermolysis bullosa (EB).

Examples of other wounds include, but are not limited to, abdominal wounds or other large or incisional wounds, either as a result of surgery, trauma, sterniotomies, fasciotomies, or other conditions, dehisced wounds, acute wounds, chronic wounds, subacute and dehisced wounds, traumatic wounds, flaps and skin grafts, lacerations, abrasions, contusions, burns, diabetic ulcers, pressure ulcers, stoma, surgical wounds, trauma and venous ulcers or the like.

Wounds may also include a deep tissue injury. Deep tissue injury is a term proposed by the National Pressure Ulcer Advisory Panel (NPUAP) to describe a unique form of pressure ulcers. These ulcers have been described by clinicians for many years with terms such as purple pressure ulcers, ulcers that are likely to deteriorate and bruises on bony prominences.

Wound may also include tissue at risk of becoming a wound as discussed herein. For example, tissue at risk may include tissue over a bony protuberance (at risk of deep tissue injury/insult) or pre-surgical tissue (for example, knee tissue) that may has the potential to be cut (for example, for joint replacement/surgical alteration/reconstruction).

Some embodiments relate to methods of treating a wound with the technology disclosed herein in conjunction with one or more of the following: advanced footwear, turning a patient, offloading (such as, offloading diabetic foot ulcers), treatment of infection, systemix, antimicrobial, antibiotics, surgery, removal of tissue, affecting blood flow, physiotherapy, exercise, bathing, nutrition, hydration, nerve stimulation, ultrasound, electrostimulation, oxygen therapy, microwave therapy, active agents ozone, antibiotics, antimicrobials, or the like.

Alternatively or additionally, a wound may be treated using topical negative pressure (TNP) and/or traditional advanced wound care, which is not aided by the using of applied negative pressure (may also be referred to as non-negative pressure therapy).

Advanced wound care may include use of an absorbent dressing, an occlusive dressing, use of an antimicrobial and/or debriding agents in a wound dressing or adjunct, a pad (for example, a cushioning or compressive therapy, such as stockings or bandages), or the like.

In some embodiments, a wound dressing comprises one or more absorbent layer(s). The absorbent layer may be a foam or a superabsorbent.

In some embodiments, the disclosed technology may be used in conjunction with a non-negative pressure dressing. A non-negative pressure wound dressing suitable for providing protection at a wound site may comprise an absorbent layer for absorbing wound exudate and an obscuring element for at least partially obscuring a view of wound exudate absorbed by the absorbent layer in use. The obscuring element may be partially translucent. The obscuring element may be a masking layer.

In some embodiments, the non-negative pressure wound dressing as disclosed herein comprises the wound contact layer and the absorbent layer overlies the wound contact layer. The wound contact layer can carry an adhesive portion for forming a substantially fluid tight seal over the wound.

In some embodiments, the wound dressing as disclosed herein further comprises layer of a superabsorbent fiber, or a viscose fiber or a polyester fiber.

In some embodiments, the wound dressing as disclosed herein further comprises a backing layer. The backing layer may be a transparent or opaque film. Typically the backing layer comprises a polyurethane film (typically a transparent polyurethane film).

In some cases, the foam may be an open cell foam, or closed cell foam, typically an open cell foam. The foam can be hydrophilic.

The wound dressing may comprise a transmission layer and the layer can be foam. The transmission layer may be a polyurethane foam laminated to a polyurethane film.

The non-negative pressure wound dressing may be a compression bandage. Compression bandages are known for use in the treatment of oedema and other venous and lymphatic disorders, e.g., of the lower limbs. The compression bandage in some embodiments may comprise a bandage system comprising an inner skin facing layer and an elastic outer layer, the inner layer comprising a first ply of foam and a second ply of an absorbent nonwoven web, the inner layer and outer layer being sufficiently elongated so as to be capable of being wound about a patient's limb.

Negative Pressure Wound Therapy

In some embodiments, treatment of wounds can be performed using negative pressure wound therapy. It will be understood that embodiments of the present disclosure are generally applicable to use in TNP systems. Briefly, negative pressure wound therapy assists in the closure and healing of many forms of "hard to heal" wounds by reducing tissue oedema; encouraging blood flow and granular tissue formation; removing excess exudate and may reduce bacterial load (and thus infection risk). In addition, the therapy allows for less disturbance of a wound leading to more rapid healing. TNP therapy systems may also assist on the healing of surgically closed wounds by removing fluid and by helping to stabilize the tissue in the apposed position of closure. A further beneficial use of TNP therapy can be found in grafts and flaps where removal of excess fluid is important and close proximity of the graft to tissue is required in order to ensure tissue viability.

Negative pressure therapy can be used for the treatment of open or chronic wounds that are too large to spontaneously close or otherwise fail to heal by means of applying negative pressure to the site of the wound. Topical negative pressure (TNP) therapy or

negative pressure wound therapy (NPWT) involves placing a cover that is impermeable or semi-permeable to fluids over the wound, using various means to seal the cover to the tissue of the patient surrounding the wound, and connecting a source of negative pressure (such as a vacuum pump) to the cover in a manner so that negative pressure is created and maintained under the cover. It is believed that such negative pressures promote wound healing by facilitating the formation of granulation tissue at the wound site and assisting the body's normal inflammatory process while simultaneously removing excess fluid, which may contain adverse cytokines or bacteria.

Some of the dressings used in NPWT can include many different types of materials and layers, for example, gauze, pads, foam pads or multi-layer wound dressings. One example of a multi-layer wound dressing is the PICO dressing, available from Smith & Nephew, includes a wound contact layer and a superabsorbent layer beneath a backing layer to provide a canister-less system for treating a wound with NPWT. The wound dressing may be sealed to a suction port providing connection to a length of tubing, which may be used to pump fluid out of the dressing or to transmit negative pressure from a pump to the wound dressing. Additionally, RENASYS-F, RENASYS-G, RENASYS-AB, and RENASYS-F/AB, available from Smith & Nephew, are additional examples of NPWT wound dressings and systems. Another example of a multi-layer wound dressing is the ALLEVYN Life dressing, available from Smith & Nephew, which includes a moist wound environment dressing that is used to treat the wound without the use of negative pressure.

As is used herein, reduced or negative pressure levels, such as -X mmHg, represent pressure levels relative to normal ambient atmospheric pressure, which can correspond to 760 mmHg (or 1 atm, 29.93 inHg, 101.325 kPa, 14.696 psi, etc.). Accordingly, a negative pressure value of -X mmHg reflects absolute pressure that is X mmHg below 760 mmHg or, in other words, an absolute pressure of (760-X) mmHg. In addition, negative pressure that is "less" or "smaller" than X mmHg corresponds to pressure that is closer to atmospheric pressure (such as,-40 mmHg is less than -60 mmHg). Negative pressure that is "more" or "greater" than -X mmHg corresponds to pressure that is further from atmospheric pressure (such as, -80 mmHg is more than -60 mmHg). In some embodiments, local ambient

atmospheric pressure is used as a reference point, and such local atmospheric pressure may not necessarily be, for example, 760 mmHg.

In some embodiments of wound closure devices described herein, increased wound contraction can lead to increased tissue expansion in the surrounding wound tissue. This effect may be increased by varying the force applied to the tissue, for example by varying the negative pressure applied to the wound over time, possibly in conjunction with increased tensile forces applied to the wound via embodiments of the wound closure devices. In some embodiments, negative pressure may be varied over time for example using a sinusoidal wave, square wave, or in synchronization with one or more physiological indices (such as, heartbeat).

Any of the embodiments disclosed herein can be used in combination with any of the features disclosed in one or more of WO2010/061225, US2016/114074, US2006/0142560, and US5,703,225, which describe absorbent materials; WO2013/007973, which describes non-negative pressure wound dressings; GB1618298.2 (filed on 28 October 2016), GB1621057.7 (filed on 12 December 2016), and GB1709987.0 (filed on 22 June 2017), which describe multi-layered wound dressings; EP2498829 and EP1718257, which describe wound dressings; WO2006/110527, US 6,759,566, and US2002/0099318, which describe compression bandages; US8,235,955 and US7,753,894, which describe wound closure devices; WO2013/175306, WO2016/174048, US2015/0190286, US2011/0282309, and US2016/0339158, which describe negative pressure wound therapy dressings, wound dressing components, wound treatment apparatuses, and methods. The disclosure of each of these applications is hereby incorporated by reference in its entirety.

Sensor Enabled Wound Monitoring and Therapy System

FIG. 1A illustrates a wound monitoring and therapy system 10 according to some embodiments. The system includes a sensor enabled wound dressing 22 connected to a controller 24. As is described herein, the dressing 22 can be placed on or in a wound of a patient and can utilize various sensors embedded or otherwise placed in the dressing 22 to collect measurement data from one or more of the wound or areas surrounding the wound, such as the periwound (which can include intact skin). The controller 24 can receive, store,

and process data collected by the dressing 22. To facilitate communication, the dressing 22 can include one or more communication modules, such as one or more antennas as described herein. In some cases, the controller 24 can transmit one or more of commands and data to the dressing 22.

In some embodiments, wound dressing 22 can be disposable and controller 24 can be reusable. In some embodiments, wound dressing 22 can be reusable. In some embodiments, wound dressing 22 can be re-sterilized or otherwise sanitized or disinfected. In some embodiments, controller 24 can be disposable. In some embodiments, wound dressing 22 and controller 24 can be permanently connected and the combined wound dressing and control box be disposable, or reusable or re-sterilized or otherwise sanitized or disinfected. The controller 24 can be positioned on the wound dressing 22. The controller 24 can be spatially separated from the wound dressing 22, such as by a cable or another wired or wireless electrical connection. The controller 24 can include a power source (such as a battery), one or more processors, one or more data storage elements, and a communication device. In some embodiments, the controller 24 can include one or more sensors, such as a temperature sensor or light (or optical) sensor to gather information on patient or environmental conditions located away from the wound dressing 22. In some embodiments, the one or more sensors of the controller 24 can include an accelerometer, motion sensor or gyroscope.

In some embodiments, the wound dressing 22 can include one or more indicators to communicate information to a user. The indicators can be visual, audible, haptic, or tactile. Communicated information can include measurement data, wound status, or the like.

The controller 24 can communicate data to a communication device 30 as requested, periodically, or the like. Communication can be performed over a wired or wireless interface, such as via near field communication (NFC), RFID, or the like when the communication device is placed in communication range. For example, communication range can be close proximity, such as within approximately 3 cm or less or more, to the controller 24. Communication device 30 can be placed in communication range by a clinician, such as during initialization and at the end of treatment. The controller 24 can respond with data to a command from the communication device 30 requesting data. Communication can be performed via transfer of hardware or data storage, such as one or more memory storage

devices (for example, SD card). In some cases, communication can be performed non-electronically, such as visually, audibly, or tactilely, and one or more of the controller 24 or communication device 30 can provide an interface for such non-electronic communication of data.

The communication device 30 can be connected via a wired or wireless interface to a computing device 40, such as a personal computer, tablet, smartphone, or the like. For example, wired USB protocol can be used for communication of data between devices 30 and 40. As another example, communication of data can be performed via transfer of hardware or data storage, such as one or more memory storage devices (for example, SD card). In some cases, communication of data can be performed non-electronically, such as visually, audibly, or tactilely, and one or more of the communication device 30 or computing device 40 can provide an interface for such non-electronic communication of data.

Computing device 40 can further process data collected by the dressing 22. For example, the computing device 40 can aggregate data collected from the dressing 22 and perfusion determination device 70, which is configured to determine skin perfusion pressure and communicate data to the computing device 40 via a wired or wireless interface. For example, wired USB protocol can be used for communication between devices 70 and 40.

Computing device 40 can be configured to communicate via a wired or wireless interface with a remote computing device 50 that stores and processes medical data. In some embodiments, remote computing device 50 can be a cloud computing device, which includes one or more of remote storage, server, processing device, or any means of information storage. For example, remote computing device 50 can process and store medical data according with one or more applicable security and privacy standards, such as Health Insurance Portability & Accountability Act (HIPAA), European Union's Directive on Data Protection, or the like. Remote computing device 50 can make data provided by one or more of the computing device 40 or the mobile device 60 available for remote accessing and viewing, such as on a mobile device 60. In certain implementations, additional data can be added for storage on the remote computing device 50. For example, additional data can be added by the mobile device 60 via a dedicated app, web browser interface, or the like. The remote computing device 50 can process the data from one or more of the wound dressing 22,

perfusion determination device 70, or the mobile device and assess or determine treatment plan, such as suggest or adjust one or more treatment therapies.

As described herein, mobile device 60 can take one or more images of a patient's wound. Such data can be transmitted via wired or wireless interface to the remote computing device 50. Although a smartphone is illustrated, mobile device 60 can be any suitable computing device that includes imaging functionality, such as a camera. Mobile device 60 can also collect additional data, such as data input by a healthcare provider in response to a questionnaire.

Sensor Enabled Substrates and Wound Dressings

A wound dressing that incorporates a number of electronic components, including one or more sensors, can be utilized in order to monitor characteristics of a wound. Collecting and analyzing data from a wound can provide useful insights towards determining whether a wound is on a healing trajectory, selecting proper therapy, determining whether the wound has healed, or the like.

In some implementations, a number of sensor technologies can be used in wound dressings or one or more components forming part of an overall wound dressing apparatus. For example, as illustrated in FIGS. 1B-1D, one or more sensors can be incorporated onto or into a substrate (such substrate can be referred to as "sensor integrated substrate" or "sensor enable substrate"). The substrate is illustrated as having a square shape, but it will be appreciated that the substrate may have other shapes such as rectangular, circular, oval, etc. In some cases, a substrate supporting one or more sensors can be provided as an individual material layer that is placed directly or indirectly over or in a wound. The sensor integrated substrate can be part of a larger wound dressing apparatus. In some cases, the sensor integrated substrate is part of a single unit dressing. Additionally or alternatively, the sensor integrated substrate can be placed directly or indirectly over or in the wound and then covered by a secondary wound dressing, which can include one or more of gauze, foam or other wound packing material, a superabsorbent layer, a drape, a fully integrated dressing like the Pico or Allevyn Life dressing manufactured by Smith & Nephew, or the like.

The sensor integrated substrate can be placed in contact with a wound and can allow fluid to pass through the substrate while causing little to no damage to the tissue in the wound. The substrate can be flexible, elastic, extensible, or stretchable or substantially flexible, elastic, extensible, or stretchable in order to conform to or cover the wound. For example, the substrate can be made from a stretchable or substantially stretchable material, such as one or more of polyurethane, thermoplastic polyurethane (TPU), silicone, polycarbonate, polyethylene, polyimide, polyamide, polyester, polyethelene tetraphthalate (PET), polybutalene tetreaphthalate (PBT), polyethylene naphthalate (PEN), polyetherimide (PEI), along with various fluropolymers (FEP) and copolymers, or another suitable material.

Stretchable or substantially stretchable material can be stretched to 5% or less or more, 10% or less or more, 20% or less or more, or more than 20% of its starting dimensions, such as length or width. In some cases, the stretchable or substantially stretchable material can return to within 5% or less or more of the starting dimensions (such as length or width) after being stretched.

In some cases, the substrate can include one or more flexible circuit boards, which can be formed of flexible polymers, including polyamide, polyimide (PI), polyester, polyethylene naphthalate (PEN), polyetherimide (PEI), along with various fluropolymers (FEP) and copolymers, or the like. One or more sensors can be incorporated into a two-layer flexible circuit. In some scenarios, the one or more circuit boards can be a multi-layer flexible circuit board.

In some cases, the sensor integrated substrate can incorporate adhesive, such as a wound contact layer as described herein, that adheres to wet or dry tissue. In some cases, one or more sensors, which can be positioned one or more flexible circuits, can be incorporated into any layer of the wound dressing. For example, a wound contact layer can have cutouts or slits that allow for one or more sensors to protrude out of the lower surface of the wound contact layer and contact the wound directly. In some situations, one or more sensors can be incorporated into or encapsulated within other components of a wound dressing, such as an absorbent layer.

As shown in FIGS. 1B-1D, a sensor integrated substrate 100B can support a plurality of electronic components and a plurality of electronic connections interconnecting at least

some of the components. The electronic components can be one or more of any electronic components described herein, such as a sensor, amplifier, capacitor, resistor, inductor, controller, processor, diode, or the like. The electronic connections can electrically connect one or more of the electronic components. The electronic connections can be can be traces or tracks printed on the substrate, such as using copper, conductive ink (such as silver ink, graphite ink, carbon ink, etc.), or the like. At least some of the electronic connections can be flexible or stretchable or substantially flexible or stretchable.

The plurality of electronic components can include one or more impedance or conductivity sensors 110, which can be arranged in an outer 4x4 grid and an inner 4x4 grid as illustrated in FIGS. 1B-1D. Sensors 110 are illustrated as pads configured to measure impedance or conductivity of tissue across any pair of the pads. Two (or more) excitation pads 115 can be arranged as illustrated to provide the excitation signal across the pads, which is conducted by the tissue and responsive to which impedance or conductance of the tissue can be measured across the pads 110. Electrical components, such as one or more amplifiers 120, can be used to measure impedance or conductance of the tissue. Impedance or conductance measurements can be used to identify living and dead tissue, monitor progress of healing, or the like. The arrangement of the pads 110 in the inner and outer grids can be used to measure the impedance or conductance of the wound, perimeter of the wound, or tissue or areas surrounding the wound.

The plurality of electronic components can include one or more temperature sensors 130 configured to measure temperature of the wound or surrounding tissue. For example, nine temperature sensors arranged around the perimeter of the substrate 100B. One or more temperature sensors can include one or more thermocouples or thermistors. One or more temperature sensors can be calibrated and the data obtained from the one or more sensors can be processed to provide information about the wound environment. In some cases, an ambient sensor measuring ambient air temperature can also be used to assist in eliminating problems associated with environment temperature shifts.

The plurality of electronic components can include one or more optical sensors 150. One or more optical sensors 150 can be configured to measure wound appearance or image the wound. In some cases, a light source or illumination source that emits light and a light

sensor or detector that detects light reflected by the wound are used as one or more optical sensors. The light source can be a light emitting diode (LED), such as one or more of white LED, red, green, blue (RGB) LED, ultraviolet (UV) LED, or the like. The light sensor can be one or more of an RGB sensor configured to detect color, infrared (IR) color sensor, UV sensor, or the like. In some cases, both the light source and detector would be pressed up against the skin, such that light would penetrate into the tissue and take on the spectral features of the tissue itself. In some scenarios, one or more optical sensor can include an imaging device, such as a charge-coupled device (CCD), CMOS image sensor, or the like.

In some cases, ultra bright LEDs, an RGB sensor, and polyester optical filters can be used as components of the one or more optical sensors to measure through tissue color differentiation. For example, because surface color can be measured from reflected light, a color can be measured from light which has passed through the tissue first for a given geometry. This can include color sensing from diffuse scattered light, from an LED in contact with the skin, or the like. In some embodiments, an LED can be used with a proximal RGB sensor to detect the light which has diffused through the tissue. The optical sensors can image with diffuse internal light or surface reflected light.

One or more of the plurality of electronic components can be controlled by a control module. The control module can receive and process one or more measurements obtained by the one or more sensors. An external control module, such as 24 illustrated in FIG. 1A, can be connected to at least some of the plurality of electronic components via a connector 140. In some cases, the connector 140 can be positioned at the end of a conductive track portion as illustrated in FIG. 1C or attached to the conductive track portion at a position away from the end as illustrated in FIG. 1B (such as, attached to the top of the track portion with glue). The control module can include one or more controllers or microprocessors, memory, or the like. In some cases, one or more controllers can be positioned on the substrate, and the connector 140 is not used. In some cases, data and commands can be communicated wirelessly, such as by a transceiver positioned on the substrate, and the connector 140 is not used.

In some cases, additional or alternative sensors can be positioned on the substrate, such as one or more pH sensors, pressure sensors, perfusion sensors, or the like.

In some cases, a substrate can be perforated as illustrated in FIGS. 1C-1D. A plurality of perforations 160 can be formed in the substrate 100C, allowing fluid to pass through the substrate. It may be advantageous to use a perforated substrate in conjunction with application of negative pressure wound therapy, during which reduced pressure is applied to the wound covered by a dressing and which causes removal of fluid (such as wound exudate) from the wound. Perforations 160 can be formed around a plurality of electronic components and connections as illustrated in FIGS. 1B-1D. Perforations 160 can be formed as slits or holes. In some cases, perforations 160 can be small enough to help prevent tissue ingrowth while allowing fluid to pass through the substrate.

In some cases, any of the wound dressings or wound dressing components described herein can be part of a kit that also includes a negative pressure wound therapy device. One or more components of the kit, such as the sensor integrated substrate, secondary dressing, or the negative pressure wound therapy device can be sterile.

Any of the embodiments disclosed herein can be used with any of the embodiments described in International Patent Publication No. WO2017/195038, titled "SENSOR ENABLED WOUND MONITORING AND THERAPY APPARATUS," International Patent Publication No. WO2018/189265, titled "COMPONENT STRESS RELIEF FOR SENSOR ENABLED NEGATIVE PRESSURE WOUND THERAPY DRESSINGS," International Patent Application No. PCT/EP2018/069886, titled "SKEWING PADS FOR IMPEDANCE MEASUREMENT," and International Patent Application No. PCT/EP2018/075815, titled "SENSOR POSITIONING AND OPTICAL SENSING FOR SENSOR ENABLED WOUND THERAPY DRESSINGS AND SYSTEMS," each of which is incorporated by reference in its entirety.

Encapsulation and Stress Relief

In some cases, the substrate can be coated to encapsulate or coat one or more of the substrate or components supported by the substrate. Coating can provide biocompatibility, shield or protect the electronics from coming into contact with fluids, provide padding for the electronic components to increase patient comfort, or the like. Such coating cam be

sometimes referred to as "conformal coat" or "soft coat." Soft coat can be stretchable or substantially stretchable. Soft coat can be hydrophobic or substantially hydrophobic.

In some cases, while it may be desirable for a substrate to be stretchable or substantially stretchable to better conform to or cover the wound, at least some of the electronic components or connections may not be stretchable or flexible. In such instances, undesirable or excessive localized strain or stress may be exerted on the one or more electronic components, such as on the supporting area or mountings of an electronic component, when the substrate is positioned in or over the wound. For example, such stress can be due to patient movement, changes in the shape or size of the wound (such as, due to its healing), or the like. Such stress may cause movement, dislodgment, or malfunction of the one or more electronic components or connections (for example, creation of an open circuit from a pin or another connector becoming disconnected). Alternatively or additionally, it may be desirable to maintain the position of one or more electronic components, such as one or more sensors, in the same or substantially same location or region with respect to the wound (such as, in contact with the wound) so that measurements collected by the one or more electronic components accurately capture changes over time in the same or substantially same location or region of the wound. While the surface of the stretchable substrate may move when, for example, the patient moves, it may be desirable to maintain same or substantially same locations of one or more electronic components relative to the wound.

To address these problems, in some cases, non-stretchable or substantially non-stretchable coating (such coating can sometimes be referred to as "hard coat") can be applied to one or more electronic components, one or more electronic connections, or the like. Hard coat can provide one or more of reinforcement or stress relief for one or more electronic components, one or more electronic connections, or the like. Hard coating can be formed from acrylated or modified urethane material. For example, hard coat can be one or more of Dymax 1901-M, Dymax 9001-E, Dymax 20351, Dymax 20558, Henkel Loctite 3211, or another suitable material. Hard coat can have viscosity from about 13,500cP to 50,000cP before being cured or from about 3,600cP to about 6,600cP before being cured. In some cases, hard coat can have viscosity of no more than about 50,000cP. Hard coat can have hardness from about D40 to about D65 and/or linear shrinkage of about 1.5–2.5%.

In some cases, another coating (or coatings) can be applied to encapsulate or coat one or more of the substrate or components supported by the substrate, such as the electronic connections or the electronic components. Coating can provide biocompatibility, shield or protect the electronics from coming into contact with fluids, provide padding for the electronic components to increase patient comfort, or the like. As used herein, biocompatible can mean being in compliance with one or more applicable standards, such as ISO 10993 or USP Class VI. As described herein, such coating can be sometimes referred to as "conformal coat" or "soft coat."

Soft coat can be formed from one or more suitable polymers, adhesives, such as 1072-M adhesive (for example, Dymax 1072-M), 1165-M adhesive (such as, Dymax 1165-M), parylene (such as, Parylene C), silicones, epoxies, urethanes, acrylated urethanes, acrylated urethane alternatives (such as, Henkel Loctite 3381), or other suitable biocompatible and substantially stretchable materials. Soft coat can be thin coating, for example, from about 80 microns or less up to several millimeters or more. Soft coat can have hardness lower than about A100, A80, A50 or lower. Soft coat can have elongation at break higher than about 100%, 200%, 300% or more. Soft coat can have viscosity of about 8,000–14,500 centipoise (cP). In some cases, coating can have viscosity no less than about 3,000cP. In some cases, coating can have viscosity less than about 3,000cP.

Any of the hard or soft coats described herein can be applied by one or more of laminating, adhering, welding (for instance, ultrasonic welding), curing by one or more of light, UV, thermal (such as, heat), or the like. Any of the hard or soft coat described herein can be transparent or substantially transparent to facilitate optical sensing. Any of the coatings described herein can retain bond strength when subjected to sterilization, such as EtO sterilization. Any of the coatings described herein can be modified to fluoresce, such as under UV light.

FIGS. 2A-2B illustrate cross-sections of wound dressings that include sensor integrated substrates. Dressing 200A shown in FIG. 2A can include a sensor integrated substrate 205 supporting a plurality of electronic components (shown as protruding from the substrate) and a plurality of electronic connections, as described herein. The dressing 200A can include hard coat 214, applied to one or more electronic components or connections. In

some cases, hard coat can be applied to areas where electronic components are connected to electronic connections. This can reinforce these connections. In some cases, hard coat can be applied to each of the one or more of the electronic components or connections.

The dressing 200A can include soft coat 216, which can be applied to the entire wound facing side of the substrate. Soft coat 216 can be applied to an entire or substantially entire area of the wound facing side of the substrate to encapsulate the substrate, electronic components, and connections. In some cases, soft coat 216 can be applied to certain regions of the substrate, such as those regions supporting one or more of electronic components or connections.

The dressing 200A can include a wound contact layer 218. The wound contact layer 218 can include adhesive material configured to adhere the substrate to the wound, which can facilitate maintaining contact of one or more sensors with the wound. The wound contact layer 218 can be formed from silicone. The silicone material can be low tac (or tack) silicone. The wound contact layer 218 can include silicone adhesive mounted on a film. In some cases, the wound contact layer 218 can be similar to the material used in Allevyn Life Non-Bordered dressing manufactured by Smith & Nephew.

The wound contact layer 218 can be applied to entire or substantially entire area of the wound facing side of the substrate. In some cases, the wound contact layer 218 can be applied to certain regions of the substrate, such as those regions supporting one or more of electronic components or connections.

As illustrated in FIG. 2A, a plurality of perforations 230 can be formed through one or more of the substrate, hard coat, soft coat, and wound contact layer. As described herein, perforations can be made in regions or areas of the substrate that do not support electronic components or connections.

The dressing 200A can include a protective layer 220 applied to the wound contact layer 218. The protective layer 220 can be made of paper, such as laminated paper. The protective layer 220 can protect the wound contact layer 218 prior to use and facilitate easy application for a user. The protective layer 218 can include a plurality (such as two) handles. The handles can be applied in a folded configuration, in which a slit separating the handles is

covered by one of handles folded over the slit. In some cases, the protective layer 218 can be similar to the protective layer used in the Allevyn Life Non-Bordered dressing.

As illustrated, a wicking layer 212 can be positioned over an opposite, non-wound facing side of the substrate. The wicking layer 212 can facilitate passage of fluid through the layers below the wicking layer. For example, the wicking layer can transport (or "wick") fluid away from the lower layers, such as from the substrate, toward one or more upper layers positioned over the wicking layer 212. Such one or more upper layers can include one or more absorbent materials as described herein. In some cases, the wicking layer 212 is formed from foam, such as foam similar to that used in the Allevyn Life Non-Bordered dressing. The wicking layer can be extensible or substantially extensible.

As illustrated in the dressing 200B of FIG. 2B, additional layer of soft coat 210 can be positioned over the non-wound facing side of the substrate between the substrate and the wicking layer 212. For example, soft coat 210 can protect the non-wound facing side of the substrate from fluid if the substrate is formed from material that is not impermeable to fluid. In such case, soft coat 210 can be hydrophobic or substantially hydrophobic. Soft coat 210 can be made of same or different material than soft coat 218. Soft coat 210 can be perforated as illustrated and described. In some cases, soft coat can encapsulate the entire substrate, including both the wound facing and non-wound facing sides.

FIGS. 3A-3B illustrate coated sensor integrated substrates 300. The substrates 300 are illustrated with non-wound facing side 216 up. The substrates 300 can be similar to any of the substrates described herein.

Any of the embodiments disclosed herein can be used with any of the embodiments described in International Patent Application No. PCT/EP2018/069883, titled "BIOCOMPATIBLE ENCAPSULATION AND COMPONENT STRESS RELIEF FOR SENSOR ENABLED NEGATIVE PRESSURE WOUND THERAPY DRESSINGS," which is incorporated by reference in its entirety.

In some implementations, borders or edges of the substrate can be smoothed by cuts, have smooth contours, include fibers, or the like to improve patient comfort.

In some cases, the substrate can include one or more antennas for wireless communication. For example, one or more antennas can be printed as one or more

connections or traces on the substrate. The one or more antennas can be used to communicate measurement data collected by the one or more sensors without using a controller, such as the controller 24. The one or more antennas can additionally be used to receive power wirelessly from a power source. In certain cases, the one or more antenna traces can be positioned on a substantially non-stretchable material (as described herein) such that the resonant frequencies of the one or more antennas remain fixed when the substrate is placed under stress when in use on a patient. Fixing the one or more resonant frequencies can be advantageous for certain communication protocols, such as RFID.

Design Rules for Positioning Components on Perforated Substrate

In some cases, a plurality of perforations can be formed in a substrate as depicted in FIGS. 1C-1D. The positioning of perforations, such as one or more of the size, number, density, or distance between adjacent perforations, can be dictated by a particular application in which the substrate will be used, such as negative pressure wound therapy. For example, it may be desirable to form perforations of a particular minimum size and at a particular maximum distance from adjacent one or more perforations in order to ensure that fluid moves through the substrate without undesirable pooling at a region of the wound below the substrate (which can cause maceration of skin, infection, or the like). On the other hand, because it may be undesirable to form perforations through the electrical components and connections, positioning of the perforations can provide a set of limitations or constraints on the dimensions and positioning on the substrate of the electrical components and connections to ensure that the electronics positioned on the substrate functions correctly and efficiently. Such set of constraints can sometimes be referred to as "design rules." In some cases, additional or alternative set of limitations or constraints can be dictated by one or more requirements of maintaining electrical signal integrity along the traces. The following paragraphs describe at least some of the design rules.

FIG. 4 illustrates a plurality of electronic components and traces positioned on a substrate with a plurality of perforations 616. Any of the perforations 616 can be circular or triangle, square, cross-shaped, star-shape, or the like. In some cases, any of the perforations 616 can have an opening of about 0.400 mm to about 2.00 mm, such as an opening with a

diameter of 1.8 mm (or less or more). The components positioned on the substrate can include a temperature sensor 600, an optical sensor 602, and a conductivity sensor or pad 604. The components can be connected to other parts of the circuitry by traces 606, 607, and 608. The traces can be made out of conductive ink (as described herein) or another conductive material that is suitable for being positioned on the substantially flexible substrate as described herein. The traces can be positioned onto the substrate by screen printing. In some cases, the traces can have a thickness of less than about 10 μm, about 10 μm, or more than about 10 μm. The traces can be positioned onto the substrate by two screen printings. In such cases, the traces can have a thickness of less than about 20 μm, about 20 μm, or more than about 20 μm. In some instances, thicker traces can advantageously have smaller variability in impedance (and/or smaller overall impedance) than thinner traces, which can improve signal integrity of an electrical signals conducted by the traces.

As shown in FIG. 4, the traces 606, 607, and 608 can be positioned to maneuver around the perforations 616. Although three components 600, 602, and 604 and three traces 606, 607, and 608 are illustrated, in some cases, there can be more or less components and/or traces. In order to reduce variability in impedance, the traces can have minimum width requirements. Each of the traces 606, 607, and 608 can have its own minimum width requirement or one or more of the traces can share same minimum width requirement. Positioning of the perforations, such as the size of perforations and distance between adjacent perforations, can constrain the minimum width of the traces, as illustrated in FIG. 5. Because positioning of the perforations may not allow the minimum width of the traces to exceed certain dimension(s), one or more properties of the traces, such as type of material(s) used to make the traces, may need to be selected accordingly. In some cases, traces that are configured to conduct digital signals can have smaller minimum width requirements that traces that are configured to conduct analog signals (for example, because impedance variability for a trace conducting analog signals may need to be smaller since analog signals are more susceptible to signal degradation than digital signals). In some cases, the minimum width of a digital signal trace (such as, temperature or optical signal trace) can be about 0.3 mm (or less or more), and the minimum width of analog signal traces (such as, conductivity signal trace) can be about 0.5 mm (or less or more), about 1.0 mm (or less or more), or the like. Minimum

widths of the traces 606, 607, and 608 are illustrated as 614, 612, and 610 respectively. In some implementations, if conductive ink with lower impedance is used as the material for at least some of the traces, the width of such traces can be decreased. This may be due to smaller variability in impedance along a trace formed of conductive ink with lower impedance than that of trace formed of conductive ink with higher impedance.

In some cases, one or more of power or ground traces can also have minimum width requirements. For example, a power source trace (such as, 15V to power analog electronics) can have a minimum width of about 1.0 mm (or less or more). As another example, a power source trace for a lower voltage signal (such as, 3V to power digital electronics) can have a minimum width of about 0.5 mm (or less or more). In some cases, one or more of power or ground traces for digital circuitry, such as a control signal for a light sensor of an optical sensor, can have a wider minimum width requirement than those of digital signal traces. This can be due to the power and/or ground traces needing to accommodate the switching noise associated with operation of digital circuitry. For instance, a power trace for a light sensor can have a minimum width of about 0.75 mm (or less or more).

In some instances, analog and digital grounds can be formed as separate one or more traces with different minimum width. As described herein, the analog traces can have wider width requirements because analog traces have less tolerance for increased or higher variability impedance.

In some cases, one or more of the electronic components or traces are positioned a minimum distance away from the perforations, such as from the edge or center of one or more adjacent perforations. This can advantageously improve electrical immunity of the substrate and/or circuitry supported by the substrate by, for example, reducing the risk of electrical current or electrostatic discharge being conducted from an electronic component or electrical trace to the tissue through a perforation, particularly in operation when conductive fluid, such as exudate, fills the perforation.

FIG. 5 illustrates a trace 700 positioned on a substrate with perforations 702. As shown in FIG. 5, the width of the trace is constrained or limited by the positioning of the perforations 702, such as by the distance or spacing between adjacent perforations. Due to

such limitations, the minimum width of the trace 700 can be no more than the illustrated width 704.

In some cases, traces of same or different widths can be connected to one another (or a trace can have portions having different width connected to one another). In order to improve signal integrity, it can be advantageous to make such connections or transitions be one or more of gradual or smooth. Such transitions can sometimes be referred to as "teardrops." For example, the connections or transitions can be without sharp corners or edges (such as 90 degree corners). This can reduce variability in impedance and improve signal integrity. FIG. 6 illustrates a plurality of traces connecting to a connector 806 (which can be similar to the connector 140 illustrated in FIGS. 1B-1D. The plurality of traces are positioned on a substrate with perforations 808. As shown in FIG. 6, trace 822 can carry a light source (such as, LED) on/off signal. Such signal can be a digital signal. Trace 822 can taper into a narrower portion of the trace 824 as it approaches the connector 806. As illustrated, the transition between portions 822 and 824 can be gradual and smooth. For example, the transition can be elongated and round. Trace 816 can carry a voltage signal for the light source. Trace 816 can taper into narrower portions of the trace 818 and 820 as the trace approaches the connector 806. The transitions from portions 816 to 818 and 818 to 820 can be gradual and smooth, such as elongated and round, as illustrated in FIG. 6.

Trace 810 can carry a digital power source signal, such as a 3V signal. Trace 810 can taper into narrower portions of the trace (or other traces) 812 and 814 as the trace approaches the connector 806. The transitions from portions (or traces) 810 to 812 and 812 to 814 cam be gradual and smooth, such as elongated and round, as illustrated in FIG. 6. Trace 800 can carry a digital ground signal. Trace 800 can taper into narrower portions of the trace (or other traces) 802 and 804 as the trace approaches the controller 806. The transitions from portions (or traces) 800 to 802 and 802 to 804 cam be gradual and smooth, such as elongated and round, as illustrated in FIG. 6.

In some cases, the width of the traces narrows (or tapers) closer to the connector 806 because of space constraints caused by connecting numerous traces to the connector 806. In some instances, any of the traces can include more than two gradual and smooth portions.

In some cases, unlike with a printed circuit board (PCB) substrate, it may not be possible to provide multiple layers for increasing the area in which the traces can be routed on substantially flexible substrates described herein. With such substrates, traces may need to be printed on a single side of the substrate, such as on the wound facing side or the non-wound facing side. To increase the area for routing the traces on such substrates, two layers can be formed by routing the traces left/right or horizontally (referred to as the first layer, which can serve as a bottom layer using PCB terminology) and up/down or vertically (referred to as the second layer, which can serve as a top layer using PCB terminology). Additional layers can be formed in some cases by routing the traces, for example, diagonally. Different layers can be separated by a mask made out of non-conductive material, such as nonconductive paint. For example, as described herein, a mask region can be positioned where two traces from first and second layers crossover (unless it is desired for the two traces to be electrically connected).

In some implementations, there can be minimum distance (or gap) requirements between adjacent traces in order to avoid or minimize the risk of creating a short circuit between the adjacent traces (such as, when printing the conductive ink to form the traces). Such minimum distance requirements can be the same or different for traces in the first and second layers. Minimum distance requirements can be constrained by the positioning of the perforations, such as by the distance or spacing between adjacent perforations.

FIG. 7 illustrates a pair of adjacent traces positioned on a substrate with perforations 904. As shown in FIG. 7, trace 900 and trace 902 are separated by a minimum distance D. Also as shown in FIG. 7, the traces 900 and 902 are positioned in areas of the substrate where there are no perforations 904. In some cases, traces in the first layer (or second layer) can have a minimum distance requirement of at least about 0.2 mm (or more or less). In some cases, traces in the second layer (or first layer) can have a minimum distance requirement of at least about 0.4 mm (or more or less). These differences in the minimum distances may be due to the traces in the first layer (or second layer) being printed before the traces in the second layer (or first layer) are printed.

In some instances, some or all portions of the traces are not parallel. In such instances, the minimum distance D can be measured at the point where the two traces 900, 902 are nearest to each other.

FIG. 8 illustrates two pairs of traces. As shown in FIG. 8, traces 1000 and 1002, which are oriented in the same direction, are separated by a minimum distance D1. Traces 1004 and 1006 are separated by a minimum distance D2. As shown in FIG. 8, portions of the traces 1004 and 1006 are oriented in a different direction from the traces 1000 and 1002. The two pairs of traces 1000, 1002 and 1004, 1006 are positioned so that there is a minimum distance D3 between the two pairs of traces. Distance D3 can be measured between traces 1002, 1004, which are the two traces from the pairs closest to each other. The two traces from the pairs that are closest to each other can be oriented in different directions. Minimum distances D1, D2, and D3 can be different from one another. In some cases, any two or more minimum distances can be the same.

As shown in FIG. 9, trace 1100 can be positioned in a horizontal layer and trace 1102 can be positioned at least partially in a vertical layer. As described herein, portions of the traces 1100 and 1102 positioned in the same layer can be separated by a minimum distance D. In some cases, the minimum distance D can be at least about 0.3mm (or less or more). A mask 1104 can separate the traces 1100 and 1102 in a crossover region where a portion of the trace 1102 positioned in the vertical layer intersects the trace 1100, which is positioned in the horizontal layer. The mask 1104 can be positioned between the traces 1100 and 1102. The mask 1104 can be electrically isolating and can prevent traces 1100, 1102 from being electrically connected to one another. In some embodiments, the mask can be made of nonconductive paint. In some embodiments, the mask can have an area larger than the area of the intersection of the traces.

FIG. 10 illustrates portions of two traces 1200 and 1202 electrically connected at a connection or joint 1204. The joint 1204 can be designed to minimize or eliminate any changes or increases in the impedance, which can improve signal integrity. The joint 1204 can form an overlap between the two traces. In some cases, as shown in FIG. 10, the joint 1204 can have a circular or substantially circular shape with a radius equal to, for example, at least half of the width of the traces 1200 and 1202 (when the traces have the same or substantially same width W). In some cases, as illustrated in FIG. 11, the radius can be, for example, at least half of the width of a trace having the larger width (when the traces do not have the same

width). Sizing the joint 1204 this way can advantageously increase the overlap between the traces. In some instances, the radius of the joint can be more or less than half the width.

In some cases, a joint can be formed as an island on the substrate and the traces can be positioned to touch the island. The island can have round or substantially round shape because such shape can be more advantageous for maintaining signal integrity than, for example, a shape with sharp transitions (such as, rectangular shape with 90 degree transitions).

In some cases, the joint 1204 can have an elongated shape with substantially circular ends. In some embodiments, the elongation can be with respect to the direction of at least one of the traces. The joint 1204 can be made of conductive material. For example, the joint can be made of same or different conductive ink than that of the traces. In some embodiments, the joint can be positioned onto the substrate by first printing a non-circular area and then removing the material (such as, when it dries) to form a circular area.

From the perspective of signal integrity, it can be advantageous to form electrical connections between traces by shaping the traces to avoid formation of any sharp angles or corners (such as 90 degree corners) at or proximal to a joint connecting the traces. As described herein, teardrops can be used for forming at least some electrical connections. This can reduce variability in impedance, reduce parasitic capacitance, or the like, which can lead to improved signal integrity. For example, as shown in FIG. 10, the traces 1200 and 1200 are routed to connect at an angle that is smaller (or more acute) than 90 degrees.

As another example, as described herein, traces of different widths can be connected to one another (or portions of the same trace having different widths can be connected to one another). The traces (or trace portions) can be shaped to have gradual or smooth transitions, such as round transitions, at and/or proximal to a joint connecting the traces (or trace portions).

FIG. 11 illustrates portions of two traces electrically connected at a joint 1302. As shown in FIG. 11, the traces 1300 and 1304 have different widths. Transitioning portions 1306 and 1308 of the traces 1300 and 1304, respectively, proximal to the joint 1302 can be designed to have smooth shapes. The transitioning portions can have substantially round or circular shapes. As shown in FIG. 11, the transitioning portions 1306, 1308 approach the

joint 1302 at an angle and have rounded or circular shape (or are arc-shaped). In some instances, the transitioning portions 1306, 1308 can be straight when the respective traces are co-linear or substantially co-linear. In some implementations, a mask isolating a pair of traces in a crossover region can have a smooth shape, such as a substantially round shape.

FIG. 12 illustrates a perspective view of a substrate supporting an electronic component 1400 and traces 1404, 1406. Trace 1406 can be connected to the pins of an electronic component 1400. As described herein, one or more of the traces 1406 can be positioned in a vertical layer, and the trace 1404 can be positioned in a horizontal layer. In some embodiments, the manufacturing method of placing the electronics on the substrate can include of printing more than two layers of traces. The traces 1404 and 1406 can be separated by a mask region 1402 at a point where the traces crossover. The mask region 1402 can be made of a nonconductive material, such as non-conductive paint. In some embodiments, the mask can have an area larger than the area of the intersection of the traces.

Preventing Migration of Traces

As described herein, traces (or tracks) can be made from conductive ink or glue, such as silver ink. It may be possible for conductive material of the traces to migrate or disperse and, in some cases, cause short circuiting between adjacent traces. Migration may have negative impact on signal integrity (particularly for analog signals) and negatively impact patient safety. Migration may be due to coating the substrate, for example, with soft coat as described herein.

Migration can be prevented or reduced by applying one or more masks. FIG. 13 illustrates a substrate 1500, which can be similar to any of the substrates described herein. The substrate 1500 can be perforated with one or more perforations 1516, as described herein (for example, with reference to FIGS. 4-5). The substrate 1500 can include one or more traces 1504 in a vertical layer and one or more traces 1506 in a horizontal layer, as described herein (for example, in connection with FIG. 12). To prevent migration, the traces can be applied on the substrate (such as, printed on the substrate) as follows. Traces in one of the layers (such as, traces 1506 in the horizontal layer or traces 1504 in the vertical layer) can be applied first. After the traces in one of the layers have been applied on the substrate 1500, a

first mask can be applied to the substrate 1500. The first mask can protect and isolate the applied traces of one of the layers. For instance, with reference to FIG. 13, a portion of such mask is illustrated as 1502. The first mask can be applied to the entire substrate 1500 with the exception of regions where electrical connection with a trace should be formed, such as a pad (for example, to connect with a pin 1410 of the component 1400 in FIG. 12), region (sometimes referred to as via) connecting the trace to another trace (for example, 1510 in FIG. 13), or the like. After the first mask has been applied, traces in the other layer can be applied to the substrate 1500. Subsequently, a second mask can be applied to the substrate 1500. The second mask can protect and isolate the applied traces. As described herein, the second mask can be applied to the entire substrate 1500 with the exception of regions where electrical connection with a trace should be formed. Application of one or more masks can prevent or minimize migration of the conductive material of the traces.

Multilayer Flexible Substrate

FIG. 14A illustrates a perspective view of a substrate 400 supporting one or more electronic connections or electronic components. The substrate 400 can be similar to any of the flexible or substantially flexible substrates described herein, such as any of the substrates 100A, 100B, 200, or 300. The substrate 400 can include a first side 402 and second side 404 opposite the first side. The first side 402 can be the wound facing side and the second side 404 can be the non-wound facing side (or vice versa). As described herein, at least one conductive track 432 can be positioned on the first side 402 of the substrate 400. It may be advantageous to position at least another conductive track on the second side 404 of the substrate 400. This can increase the area in which tracks can be routed on the substrate 400, the area for positioning one or more electronic components, and positioning of one or more planes (such as, a ground plane, power plane, etc.). Using printed circuit board (PCB) terminology, the first and second sides 402 and 404 can serve as first and second layers (or top and bottom layers) on which tracks can be routed. This way, two layers can be formed on the substrate.

In some cases, one or more of tracks or components positioned on opposite sides of the substrate 400 may be electrically connected. For example, an antenna can be positioned

on a first side of the substrate 400, while at least some of radio frequency (RF) circuitry, which can be configured to transmit and/or receive signals (for example, function as a transceiver), can be positioned on the second side of the substrate 400 (or vice versa). The RF circuitry may be connected to the antenna. As another example, a ground or power plane can at least partially be positioned on a first side of the substrate 400, while one or more electronic components can be positioned on the second side of the substrate 400 (or vice versa). At least some of the one or more electronic components may be connected to the ground or power plane.

Multilayer PCBs may use a via for connecting tracks positioned in different layers of the PCB. A via can include a barrel (for example, a conductive tube filling a drilled hole in the PCB), a pad (for example, connection of each end of the barrel to a component or track), and antipad (for example, a clearance hole between the barrel and a component or track to which the barrel is not connected). Because, unlike a PCB, the substrate 400 can be flexible or substantially flexible, it may not support such vias. In some cases, a conductive connection can be made through the substrate in order to connect one or more tracks or components positioned on the opposite sides of the substrate 400. Connection can be made by passing conductive material through the substrate 400. For example, a perforation can be made the substrate 400 and conductive material can be positioned in the perforation, such as fill the perforation. In some cases, the conductive material can be conductive ink, conductive glue, solder paste, wire, or the like.

With reference to FIGS. 14A-14B, conductive track 432 positioned on the first side 402 of the substrate 400 can be electrically connected to another conductive track 434 positioned on the second side 404 of the substrate 400 via a connection 450. A portion of track 432 can overlap a portion of track 434. Connection 450 can be formed where the portions of the tracks 432 and 434 overlap. As illustrated in FIG. 14B, which shows cross-sectional view of the substrate 400, connection 450 can be a perforation through the substrate. Conductive material can be positioned in the perforation, such as fill the perforation. Tracks 432 and 434 can cover at least part of the perforation. For example, overlapping portions of the tracks 432 and 434 can cover at least part of the perforation.

As illustrated in FIGS. 14A-14B, track 432 may not be electrically connected to another track 436. With reference to FIG. 14B, track 436 can be positioned on the second side 404 of the substrate 400. Tracks 432 and 436 may not be electrically connected because no connection between the tracks 432 and 436 is formed through the substrate, as shown in FIG. 14B.

In some cases, track 436 can be positioned on the first side 402 of the substrate 404. As illustrated in FIGS. 14A and 14C, a mask region or mask 442 made of electrically isolating or nonconductive material can be positioned on the substrate 400. The mask 442 can prevent formation of an electrical connection between the tracks 432 and 436. Mask can be positioned in a region where two or more tracks positioned on the same side of the substrate 400 intersect or crossover, but should not be electrically connected. Mask can be positioned between the tracks. Mask can have an area larger than the area of the intersection of the tracks. Mask can be made of nonconductive paint or another nonconductive material.

Additionally or alternatively, to increase the area in which tracks can be routed on the substrate 400 and the area for positioning one or more electronic components, tracks can be routed along the y-axis (such as, left/right or horizontally) on the same size of the substrate (which can be referred to as a first layer) and along the x-axis (or up/down or vertically) on the same side of the substrate (which can be referred to as a second layer). This way, four layer can be formed on the substrate. For example, track 432 is illustrated as being routed along the y-axis (or being positioned in the first layer), and track 436 is illustrated as being routed along the x-axis (or being positioned in the second layer). As described herein, tracks in different layers on the same side of the substrate can be separated by a mask. For example, a mask can be positioned where tracks from first and second layers crossover (unless it is desired for the tracks to be electrically connected). With reference to FIG. 14A, the mask 442 can be positioned between the tracks 432 and 436.

Although track 432 is shown as running in the direction along the y-axis, track 432 can run in a direction along the x-axis. Although tracks 434 and 436 are shown as running in a direction along the x-axis, tracks 434 and 436 can run in a direction along the y-axis.

In some cases, multiple substrates can be stacked. For example, if two substrates are stacked, this can result in formation of four layers (each substrate having top and bottom layer), eight layers (each substrate having top, bottom, first, and second layer), or the like.

Other Variations

Although some of the disclosed embodiments illustrate arrangement of electronic components, such as sensors, in or on a wound dressing, disclosed component arrangements are not so limited. In some implementations, the components can be arranged on another dressing, structure, or substrate or could be provided separately for being positioned over any wound, as broadly defined herein. Component arrangements can be used for one or more of preventing or treating a wound. In addition, embodiments disclosed herein are broadly applicable to any substrate that supports one or more electronic components or connections, whether or not such substrate will be used for monitoring or treating a wound.

Any of the embodiments disclosed herein can be used with any of the embodiments described in International Patent Publication No. WO2017/195038, titled "SENSOR ENABLED WOUND MONITORING AND THERAPY APPARATUS," International Patent Publication No. WO2018/189265, titled "COMPONENT STRESS RELIEF FOR SENSOR ENABLED NEGATIVE PRESSURE WOUND THERAPY DRESSINGS," International Patent Application No. PCT/EP2018/069883, titled "BIOCOMPATIBLE ENCAPSULATION AND COMPONENT STRESS RELIEF FOR SENSOR ENABLED NEGATIVE PRESSURE WOUND THERAPY DRESSINGS," and International Patent Application No. PCT/EP2020/052111 , titled "SENSOR INTEGRATED DRESSINGS AND SYSTEMS," each of which is incorporated by reference in its entirety.

In some embodiments, one or more electronic components can be positioned on the side of a substrate the side that faces the wound. Systems and methods described herein are equally applicable to such arrangements of components. Any wound dressing embodiment described herein can include features of any of the other described wound dressing embodiments. Similarly, any controller described herein can include features of any of the other described wound dressing embodiments. Further, any device, component, or module

described in a certain embodiment can include features of any of the other described embodiments of the device, component, or module.

Any value of a threshold, limit, duration, etc. provided herein is not intended to be absolute and, thereby, can be approximate. In addition, any threshold, limit, duration, etc. provided herein can be fixed or varied either automatically or by a user. Furthermore, as is used herein relative terminology such as exceeds, greater than, less than, etc. in relation to a reference value is intended to also encompass being equal to the reference value. For example, exceeding a reference value that is positive can encompass being equal to or greater than the reference value. In addition, as is used herein relative terminology such as exceeds, greater than, less than, etc. in relation to a reference value is intended to also encompass an inverse of the disclosed relationship, such as below, less than, greater than, etc. in relations to the reference value. Moreover, although blocks of the various processes may be described in terms of determining whether a value meets or does not meet a particular threshold, the blocks can be similarly understood, for example, in terms of a value (i) being below or above a threshold or (ii) satisfying or not satisfying a threshold.

Features, materials, characteristics, or groups described in conjunction with a particular aspect, embodiment, or example are to be understood to be applicable to any other aspect, embodiment or example described herein unless incompatible therewith. All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of such features or steps are mutually exclusive. The protection is not restricted to the details of any foregoing embodiments. The protection extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

While certain embodiments have been described, these embodiments have been presented by way of example only, and are not intended to limit the scope of protection. Indeed, the novel methods and systems described herein may be embodied in a variety of other forms. Furthermore, various omissions, substitutions and changes in the form of the methods and systems described herein may be made. Those skilled in the art will appreciate that in

some embodiments, the actual steps taken in the processes illustrated or disclosed may differ from those shown in the figures. Depending on the embodiment, certain of the steps described above may be removed, others may be added. For example, the actual steps or order of steps taken in the disclosed processes may differ from those shown in the figure. Depending on the embodiment, certain of the steps described above may be removed, others may be added. For instance, the various components illustrated in the figures may be implemented as software or firmware on a processor, controller, ASIC, FPGA, or dedicated hardware. Hardware components, such as controllers, processors, ASICs, FPGAs, and the like, can include logic circuitry. Furthermore, the features and attributes of the specific embodiments disclosed above may be combined in different ways to form additional embodiments, all of which fall within the scope of the present disclosure.

Although the present disclosure includes certain embodiments, examples and applications, it will be understood by those skilled in the art that the present disclosure extends beyond the specifically disclosed embodiments to other alternative embodiments or uses and obvious modifications and equivalents thereof, including embodiments which do not provide all of the features and advantages set forth herein. Accordingly, the scope of the present disclosure is not intended to be limited by the specific disclosures of preferred embodiments herein, and may be defined by claims as presented herein or as presented in the future.

Conditional language, such as "can," "could," "might," or "may," unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements, or steps. Thus, such conditional language is not generally intended to imply that features, elements, or steps are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without user input or prompting, whether these features, elements, or steps are included or are to be performed in any particular embodiment. The terms "comprising," "including," "having," and the like are synonymous and are used inclusively, in an open-ended fashion, and do not exclude additional elements, features, acts, operations, and so forth. Also, the term "or" is used in its inclusive sense (and not in its exclusive sense) so that when used, for example, to connect a list of elements, the term "or" means one, some, or all of the elements in the list.

Further, the term "each," as used herein, in addition to having its ordinary meaning, can mean any subset of a set of elements to which the term "each" is applied.

Conjunctive language such as the phrase "at least one of X, Y, and Z," unless specifically stated otherwise, is otherwise understood with the context as used in general to convey that an item, term, etc. may be either X, Y, or Z. Thus, such conjunctive language is not generally intended to imply that certain embodiments require the presence of at least one of X, at least one of Y, and at least one of Z.

Language of degree used herein, such as the terms "approximately," "about," "generally," and "substantially" as used herein represent a value, amount, or characteristic close to the stated value, amount, or characteristic that still performs a desired function or achieves a desired result. For example, the terms "approximately", "about", "generally," and "substantially" may refer to an amount that is within less than 10% of, within less than 5% of, within less than 1% of, within less than 0.1% of, and within less than 0.01% of the stated amount. As another example, in certain embodiments, the terms "generally parallel" and "substantially parallel" refer to a value, amount, or characteristic that departs from exactly parallel by less than or equal to 15 degrees, 10 degrees, 5 degrees, 3 degrees, 1 degree, or 0.1 degree.

The scope of the present disclosure is not intended to be limited by the specific disclosures of preferred embodiments in this section or elsewhere in this specification, and may be defined by claims as presented in this section or elsewhere in this specification or as presented in the future. The language of the claims is to be interpreted broadly based on the language employed in the claims and not limited to the examples described in the present specification or during the prosecution of the application, which examples are to be construed as non-exclusive.

WHAT IS CLAIMED IS:

1. A method of manufacturing a wound monitoring and/or therapy apparatus, the method comprising:

positioning on a substantially flexible substrate a first conductive track configured to be connected to a first sensor, the first track having a first minimum width to maintain integrity of an electrical signal conducted by the first conductive track;

positioning on the substrate a second conductive track configured to be connected to a second sensor, the second track having a second minimum width to maintain integrity of an electrical signal conducted by the second conductive track; and

positioning on the substrate a third track configured to be connected to third sensor, the third track having a third minimum width to maintain integrity of an electrical signal conducted by the third conductive track,

wherein first, second, and third conductive tracks are positioned on portions of the substrate that are not configured to be perforated with a plurality of openings, the plurality of openings configured to allow fluid to pass through the substrate,

wherein at least one of locations or sizes of the plurality of openings configured to allow fluid to pass through the substrate constrain a maximum dimension of at least one of the first, second, or third minimum widths, and

wherein the first, second, and third sensors are sensors of different types.

2. The method of any of the preceding claims, further comprising perforating the substrate to form the plurality of openings.

3. The method of claim 2, wherein perforating the substrate to form the plurality of openings comprises not perforating the portions of the substrate on which the first, second, and third conductive tracks are positioned.

4. The method of any of the preceding claims, wherein positioning at least one of the first, second, or third conductive tracks comprises printing the at least one of the first, second, or third conductive tracks using conductive ink.

5. The method of claim 3, wherein the conductive ink comprises silver ink.

6. The method of any of the preceding claims, further comprising positioning on the substrate a fourth track configured to provide power to at least one of the first, second, or third sensors, the fourth track having a fourth minimum width, wherein at least one of the locations or sizes of the plurality of openings further constrains a maximum dimension of the fourth minimum width.

7. The method of any of the preceding claims, wherein the first, second, and third conductive tracks, first sensor, second sensor, and third sensor are positioned at least a minimum distance away from the plurality of openings.

8. The method of any of the preceding claims, wherein at least two of the first, second, or third minimum widths are different from one another.

9. The method of any of the preceding claims, wherein the first conductive track is configured to conduct an analog signal and the second conductive track is configured to conduct a digital signal, and wherein the first minimum width is smaller than the second minimum width.

10. The method of any of the preceding claims, wherein the first sensor comprises a temperature sensor, the second sensor comprises a light sensor, and the third sensor comprises an impedance sensor.

11. A wound monitoring and/or therapy apparatus and/or wound dressing manufactured using the method of any one or more preceding claims.

12. A method of manufacturing a wound monitoring and/or therapy apparatus, the method comprising:

positioning on a substantially flexible substrate a first conductive track oriented in a first direction and configured to transmit electrical signals; and

positioning a second conductive track on the substrate adjacent to the first conductive track and at a first minimum distance from the first conductive track, the second conductive track oriented in the first direction and configured to transmit electrical signals,

wherein the first minimum distance is defined by at least one of a location or size of at least one opening configured to allow exudate to pass through the substrate.

13. The method of claim 12, further comprising perforating the substrate to form the at least one opening in a portion of the substrate separating the first conductive track from the second conductive track.

14. The method of any of claims 12 to 13, further comprising:

positioning on the substrate a third conductive track oriented in a second direction and configured to transmit electrical signals, the second direction different from the first direction; and

positioning a fourth conductive track on the substrate adjacent to the conductive third track and at a second minimum distance from the third conductive track, the fourth conductive track oriented in the second direction and configured transmit electrical signals, the second minimum distance being different than the first minimum distance.

15. The method of claim 14, wherein:

positioning on the substrate third and fourth conductive tracks oriented in the second direction comprises positioning third and fourth conductive tracks at a third minimum distance from each of the first and second conductive tracks oriented in the first direction.

16. The method of any of claims 14 to 15, wherein the second direction is perpendicular to the first direction.

17. The method of any of claims 14 to 16, wherein positioning at least one of the first, second, third, or fourth conductive tracks comprises printing the at least one of the first, second, third, or fourth conductive tracks using conductive ink.

18. The method of claim 17, wherein the conductive ink comprises silver ink.

19. A wound monitoring and/or therapy apparatus and/or wound dressing manufactured using the method of any of claims 12 to 18.

20. A method of manufacturing a wound monitoring and/or therapy apparatus, the method comprising:

positioning on a substantially flexible substrate a first conductive track oriented in a first direction and configured to transmit electrical signals;

positioning on the substrate a second conductive track oriented in a second direction different from the first direction, the second conductive track configured to transmit electrical signals, the second conductive track having same width as the first conductive track; and

forming an electrical connection between the first and second conductive tracks by forming a substantially circular conductive area overlapping the first and second conductive tracks, a radius of the conductive area being about one half of the width of the first and conductive second tracks.

21. The method of claim 20, wherein positioning at least one of the first or second conductive tracks comprises printing the at least one of the first or second conductive tracks using conductive ink.

22. The method of any of claims 20 to 21, wherein forming the electrical connection comprises removing at least a portion of dry ink to form the substantially circular conductive area with the radius of about one half of the width of the first and second conductive tracks.

23. A wound monitoring and/or therapy apparatus and/or wound dressing manufactured using the method of any of claims 20 to 22.

24. A method of manufacturing a wound monitoring and/or therapy apparatus, the method comprising:

positioning on a substantially flexible substrate a first conductive track configured to transmit electrical signals, the first conductive track having a first width;

positioning on the substrate a second conductive track configured to transmit electrical signals, the second conductive track having a second width different than the first width; and

electrically connecting first and second tracks with a curved connector.

25. The method of claim 24, wherein portions of the first conductive track proximal to the connector and of the second conductive track proximal to the connector are shaped to not include any transitions of approximately 90 degrees.

26. The method of any of claims 24 to 25, wherein at least one of positioning at least one of the first or second conductive tracks or electrically connecting first and second tracks with the curved connector comprises printing the at least one of the first conductive track, second conductive track, or the curved connector using conductive ink.

27. A wound monitoring and/or therapy apparatus and/or wound dressing manufactured using the method of any of claims 24 to 26.

28. A wound dressing comprising:

a flexible or substantially flexible substrate with a first side and a second side opposite the first side;

a first electrically conductive track positioned on the first side of the substrate; and

a second electrically conductive track positioned on the second side of the substrate, the second electrically conductive track electrically connected to the first electrically conductive track via an electrically conductive material that passes through the substrate.

29. The wound dressing of any of the preceding claims, wherein the electrically conductive material is positioned in a perforation through the substrate.

30. The wound dressing of any of the preceding claims, further comprising:

a first electronic component positioned on the first side of the substrate and electrically connected to the first electrically conductive track; and

a second electronic component positioned on the second side of the substrate and electrically connected to the second electrically conductive track.

31. The wound dressing of any of the preceding claims, wherein the first electronic component comprises a plurality of sensors configured to measure a plurality of parameters of a wound and the second electronic component comprises an antenna configured to transmit at least some of the plurality of parameters measured by the plurality of sensors to a remote computing device.

32. The wound dressing of any of claims 30 to 31, further comprising a substantially non-stretchable coating applied to at least one of the first electronic component, second electronic component, first electrically conductive track, or second electrically conductive track.

33. The wound dressing of claim 32, further comprising a substantially stretchable coating applied over the substantially non-stretchable coating.

34. The wound dressing of any of the preceding claims, wherein the substrate comprises thermoplastic polyurethane (TPU).

35. The wound dressing of any of the preceding claims, wherein a portion of the first electrically conductive track overlaps a portion of the second electrically conductive track.

36. The wound dressing of any of the claims 29 to 35, wherein at least one of the first or second electrically conductive tracks covers at least part of the perforation.

37. The wound dressing of any of the preceding claims, wherein first and second electrically conductive tracks comprise conductive ink or conductive glue.

38. The wound dressing of any of the preceding claims, wherein the electrically conductive material comprises conductive ink or conductive glue.

39. The wound dressing of any of claims 37 to 38, wherein the conductive ink comprises silver ink.

40. The wound dressing of any of the preceding claims, wherein the first electrically conductive track does not directly contact the second electrically conductive track.

41. The wound dressing of any of the preceding claims, further comprising:

a third electrically conductive track positioned on the first side of the substrate; and

a first non-conductive mask separating the first and third electrically conductive tracks.

42. The wound dressing of any of the preceding claims, further comprising:

a fourth electrically conductive track positioned on the second side of the substrate; and

a second non-conductive mask separating the second and fourth electrically conductive tracks.

43. A method of manufacturing a wound dressing, the method comprising:

passing an electrically conductive material through a flexible or substantially flexible substrate of the wound dressing;

positioning a first electrically conductive track on a first side of the substrate and forming an electrical connection with the electrically conductive material; and

positioning a second electrically conductive track on a second side of the substrate located opposite the first side and forming an electrical connection with the electrically conductive material,

wherein the first and second electrically conductive tracks are electrically connected via the conductive material.

44. The method of claim 43 further comprising forming a perforation through the substrate and at least partially filling the perforation with the electrically conductive material.

45. The method of any of claims 43 to 44 further comprising:

positioning a first electronic component on the first side of the substrate and electrically connecting the first electronic component to the first electrically conductive track; and

positioning a second electronic on the second side of the substrate and electrically connecting the second electronic component to the second electrically conductive track.

46. The method of claim 45, further comprising applying a substantially non-stretchable coating to at least one of the first electronic component, second electronic component, first electrically conductive track, or second electrically conductive track.

47. The method of claim 46, further comprising applying a substantially stretchable coating over the substantially non-stretchable coating.

48. The method of any of claims 43 to 47, wherein positioning the second electrically conductive track on the second side of the substrate comprises overlapping a portion of the first electrically conductive track.

49. The method of any of claims 43 to 48, wherein positioning at least one of the first or second electrically conductive tracks comprises printing the at least one of the first or second electrically conductive tracks using conductive ink or conductive glue.

50. The method of claim 49, wherein the conductive ink comprises silver ink.

51. The method of any of claims 43 to 50, wherein the electrically conductive material comprises conductive ink or conductive glue.

52. The method of claim 51, wherein the conductive ink comprises silver ink.

53. A method of manufacturing a wound monitoring and/or therapy apparatus, the method comprising:

positioning on a substantially flexible substrate a first conductive track oriented in a first direction and configured to transmit electrical signals; and

positioning on the substrate a first non-conductive mask by covering the first conductive track with the first mask except for a portion of the first conductive track configured to be electrically connected to another conductive track or an electrical component.

54. The method of claim 53, wherein positioning the first conductive track comprises printing the first conductive track on the substrate using conductive ink or conductive glue.

55. The method of any of claims 53 to 54, wherein the portion of the first conductive track comprises a pad or a via.

56. The method of any of claims 53 to 55, wherein positioning on the substrate the first mask comprises covering substantially entire surface of the substrate with the first mask.

57. The method of any of claims 53 to 56, further comprising:

positioning on the substrate a second conductive track oriented in a second direction different from the first direction, the second conductive track configured to transmit electrical signals; and

positioning on the substrate a second non-conductive mask by covering the second conductive track with the second mask except for a portion of the second

conductive track configured to be electrically connected to another conductive track or an electrical component.

58. The method of claim 57, wherein positioning the second conductive track comprises printing the second conductive track on the substrate using conductive ink or conductive glue.

59. The method of any of claims 57 to 58, wherein the portion of the second conductive track comprises a pad or a via.

60. The method of any of claims 53 to 59, wherein positioning on the substrate the second mask comprises covering substantially entire surface of the substrate with the second mask.

61. A wound monitoring and/or therapy apparatus and/or wound dressing manufactured using the method of any of claims 53 to 60.

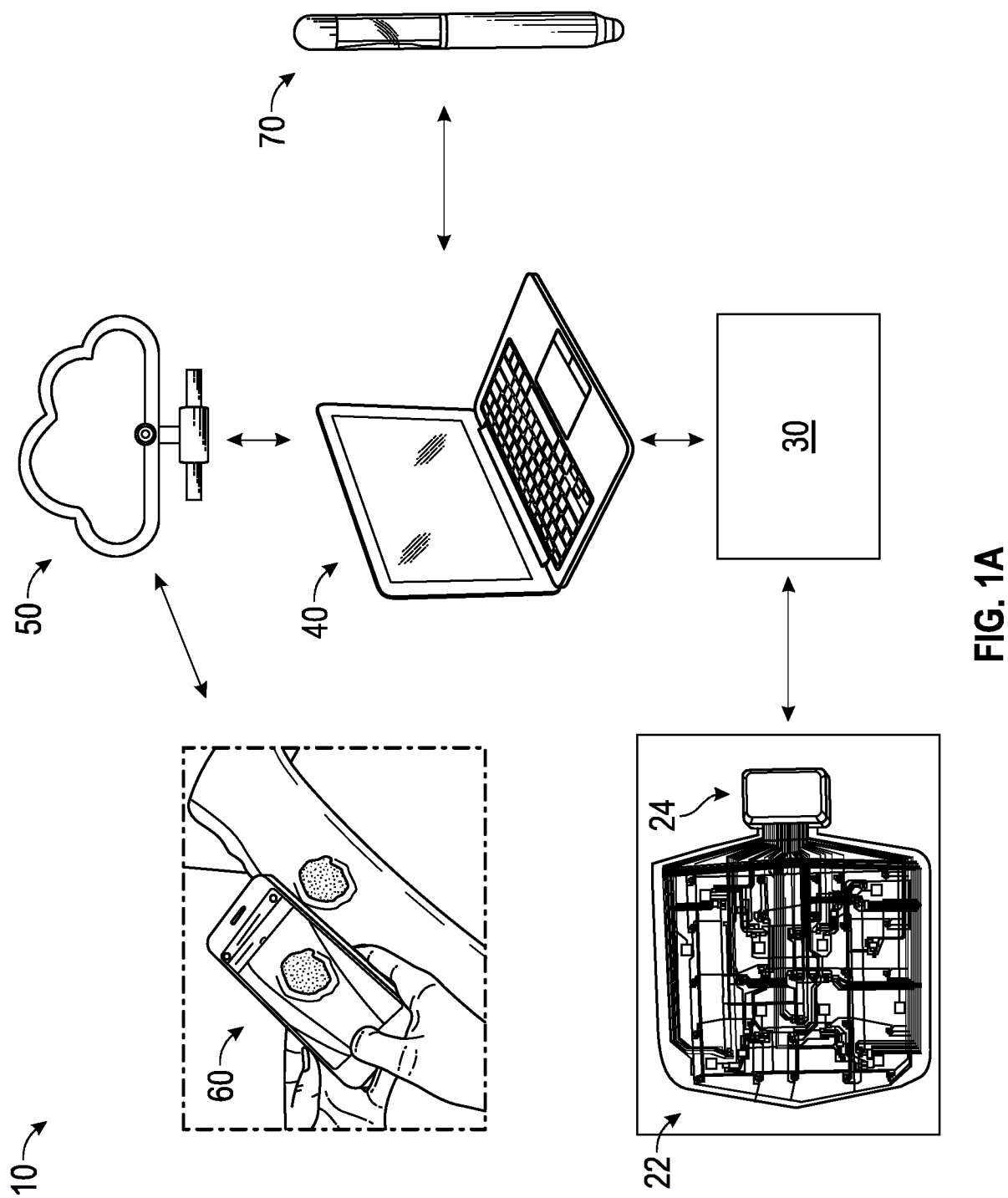


FIG. 1A

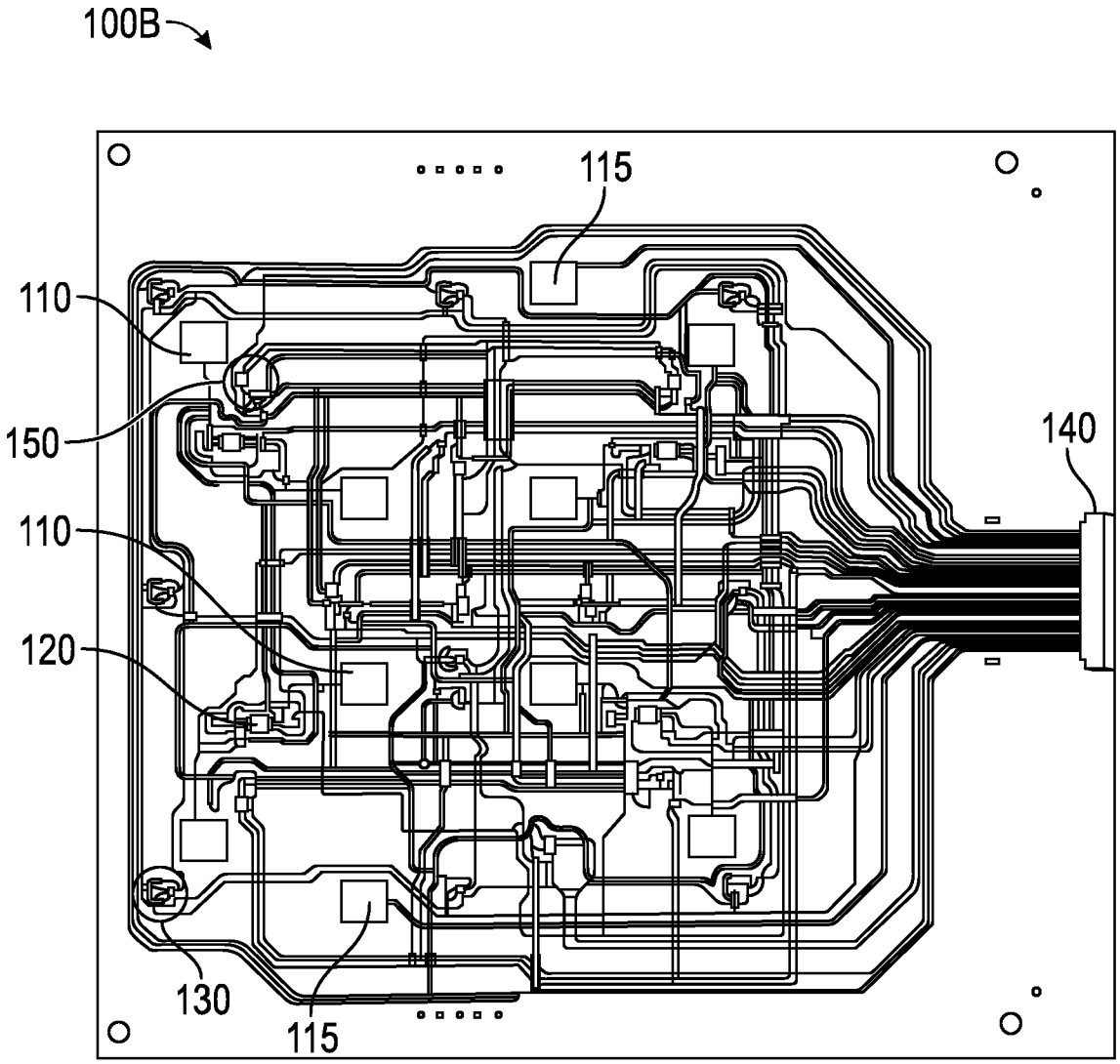


FIG. 1B

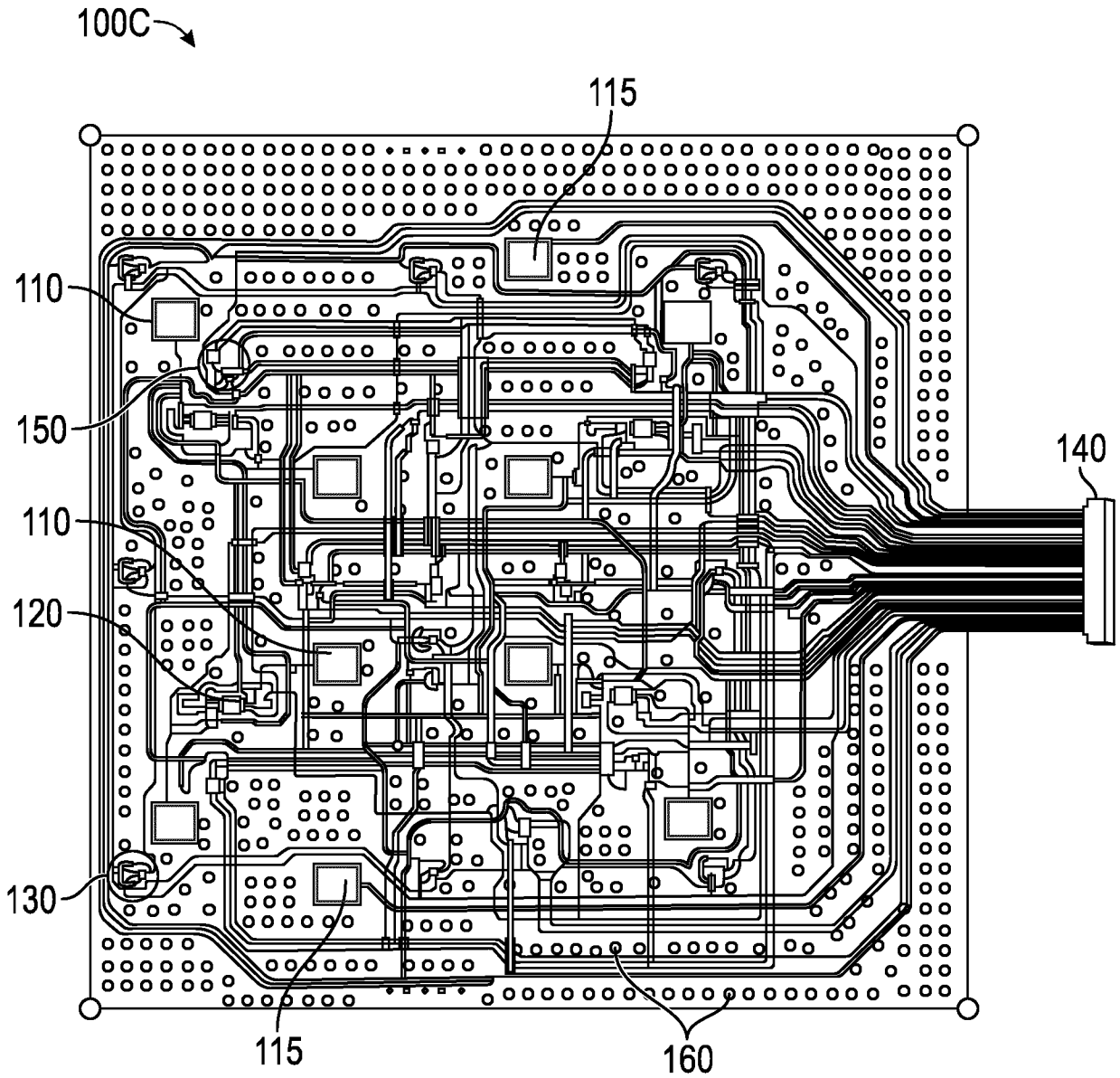


FIG. 1C

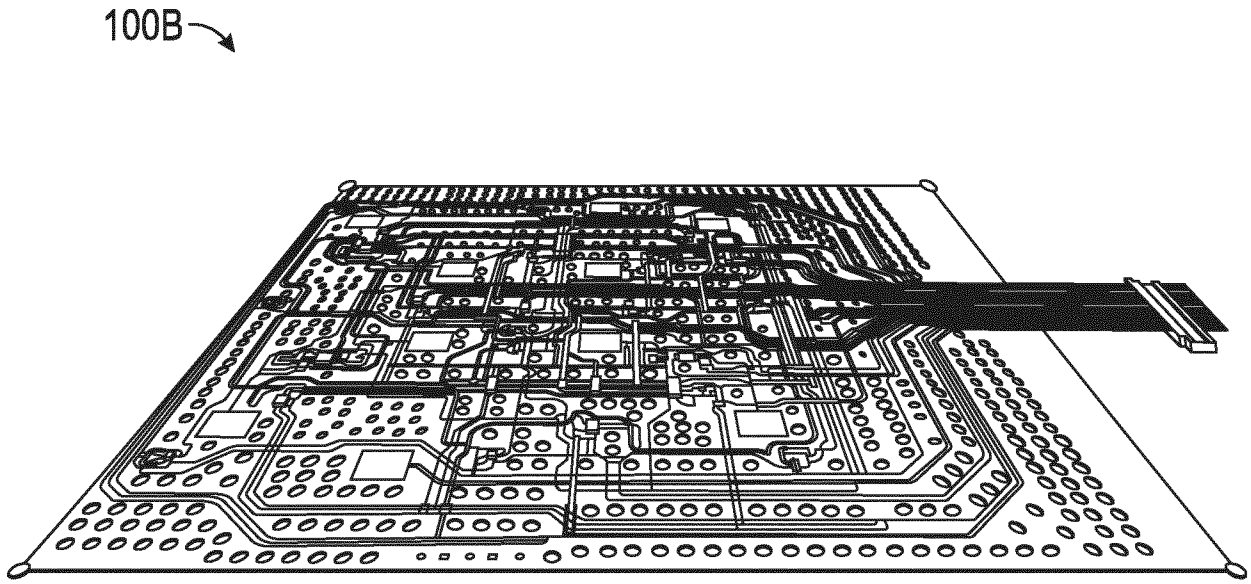


FIG. 1D

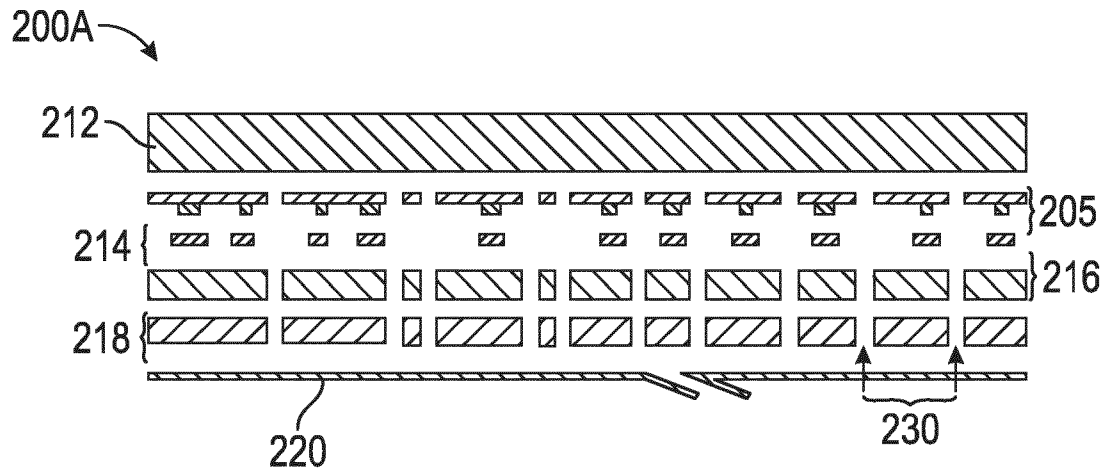

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FIG. 2A

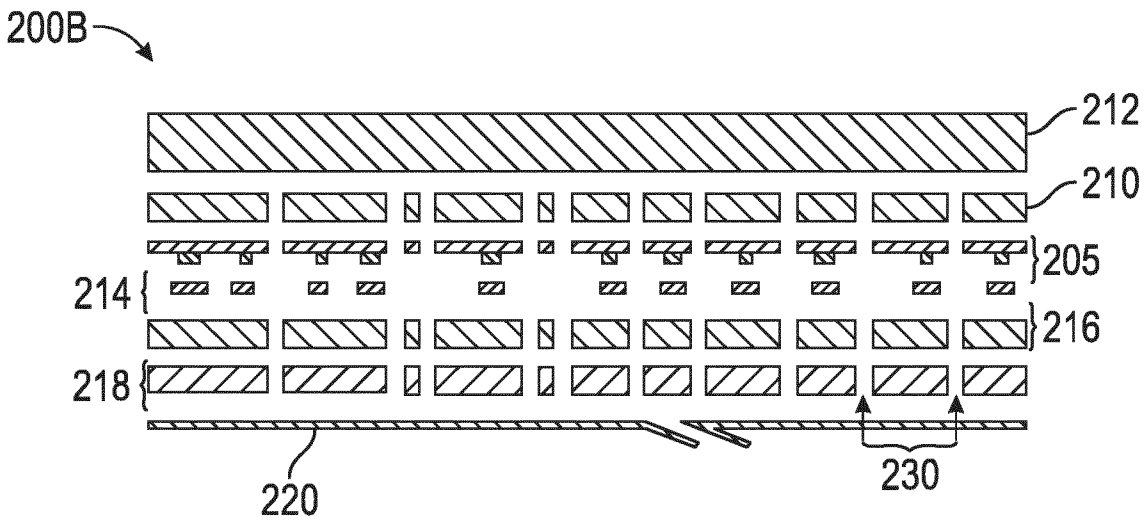

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FIG. 2B

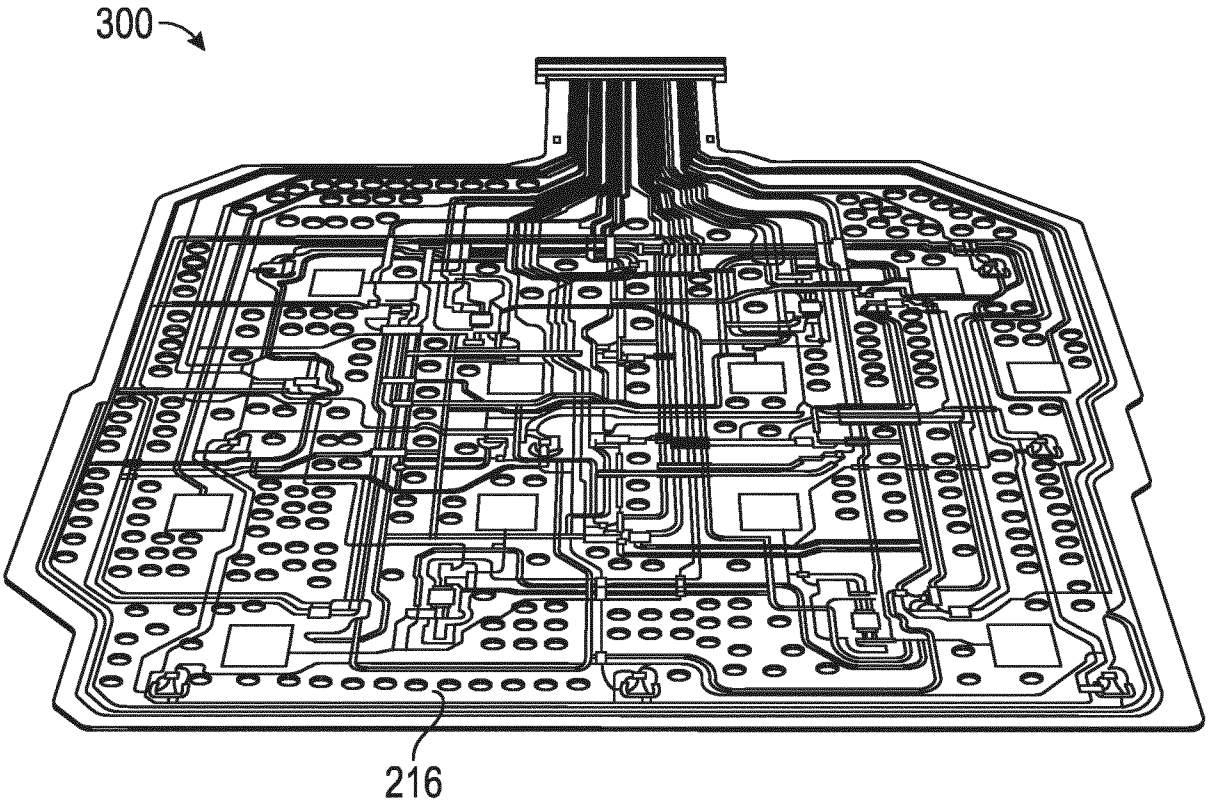


FIG. 3A

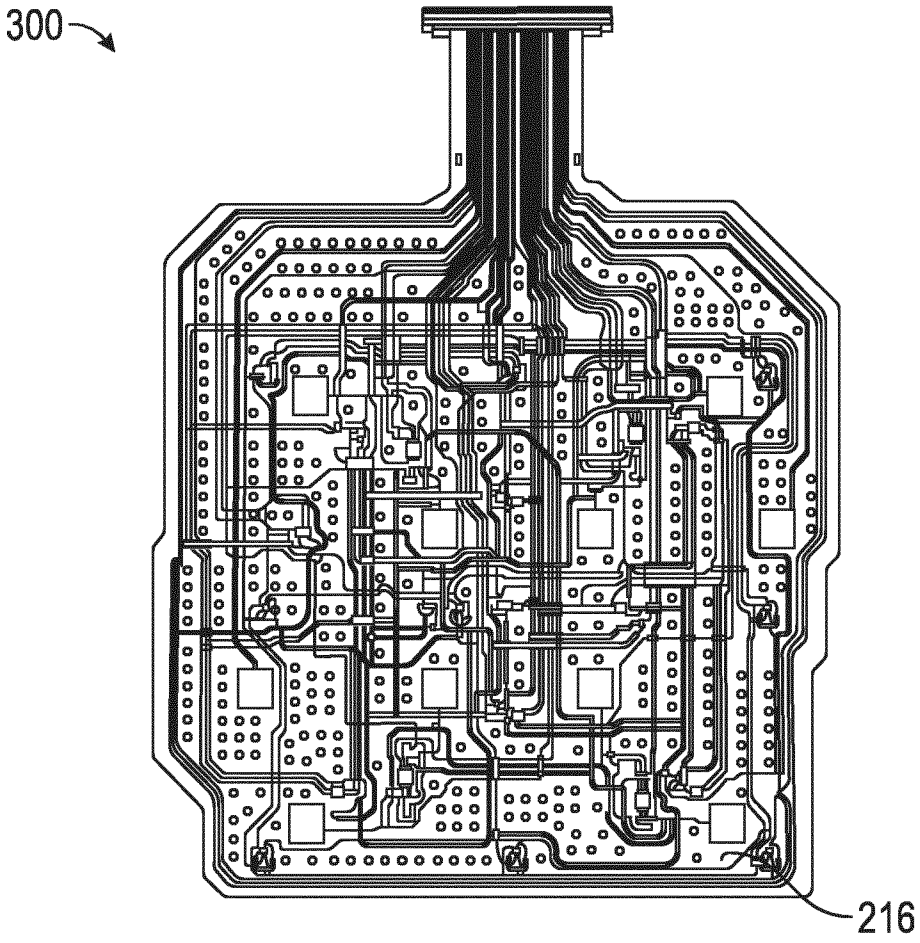


FIG. 3B

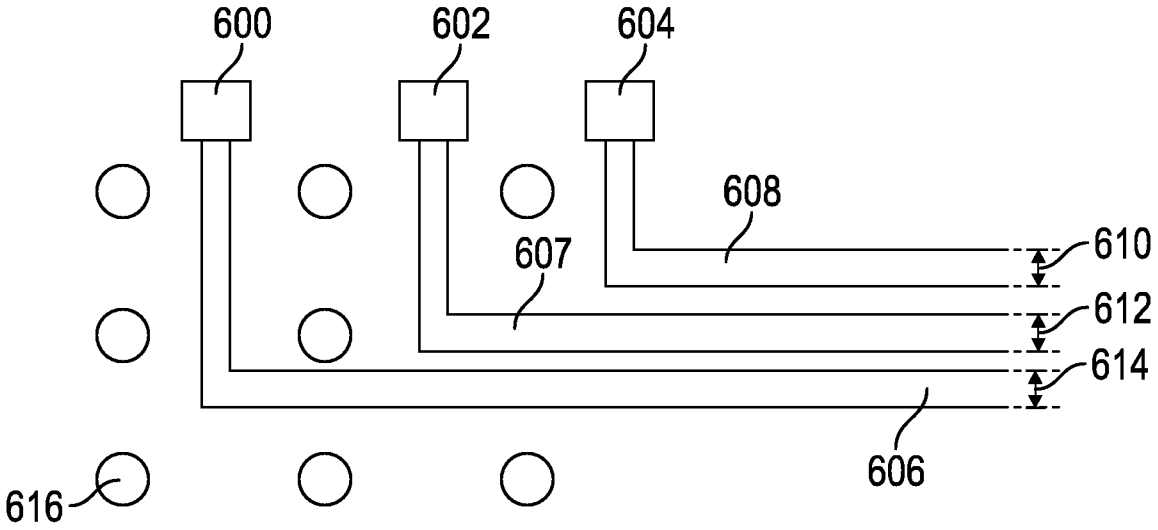


FIG. 4

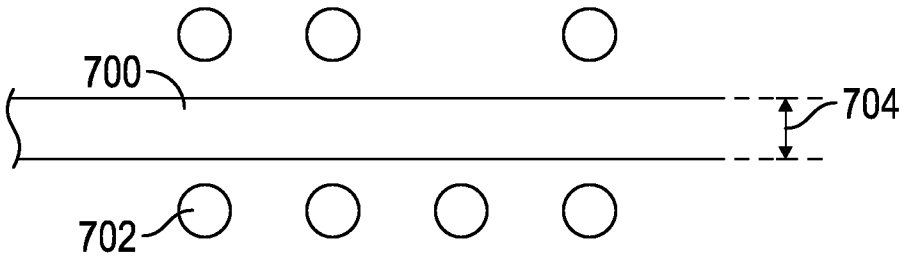


FIG. 5

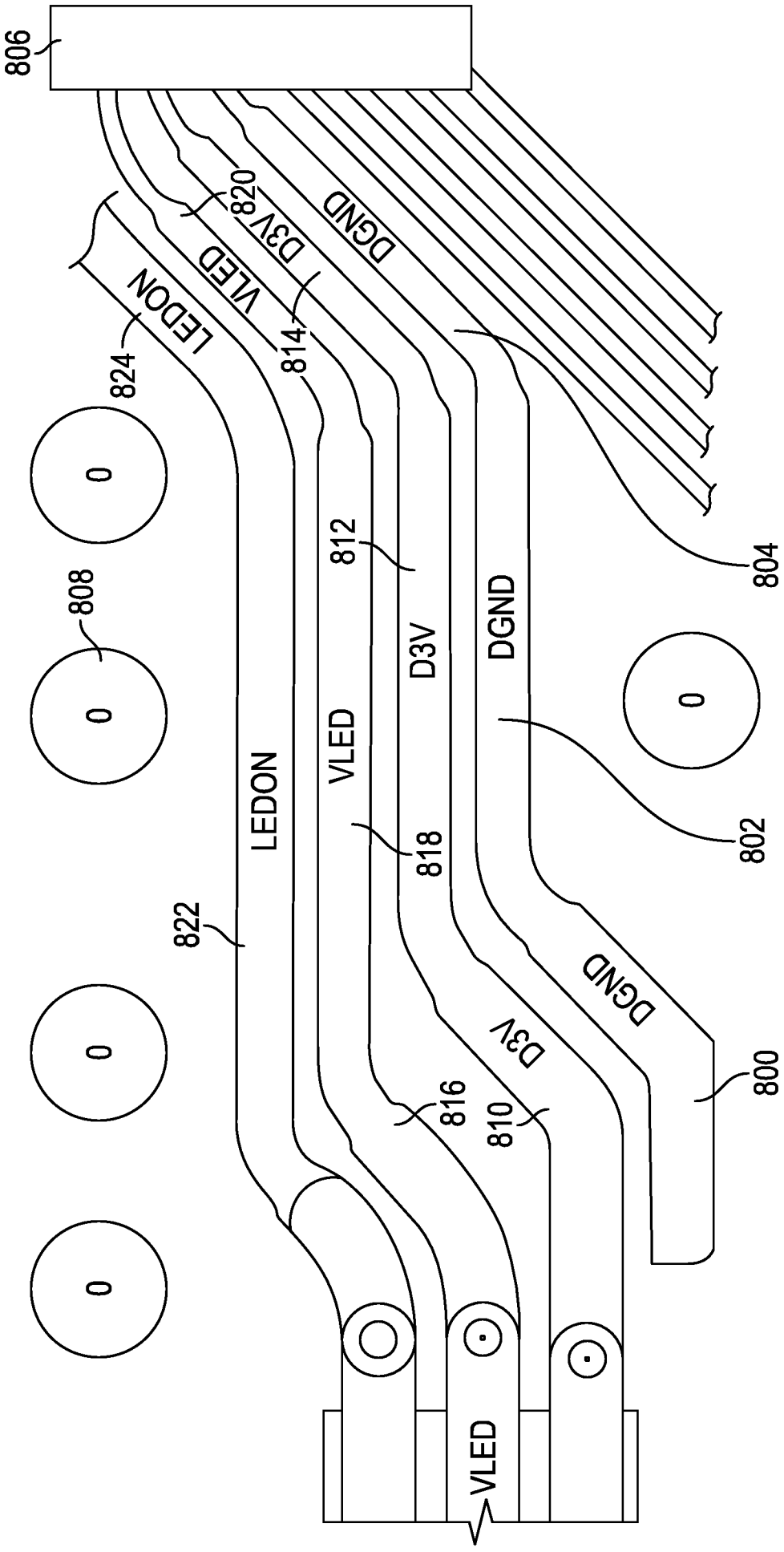

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FIG. 6

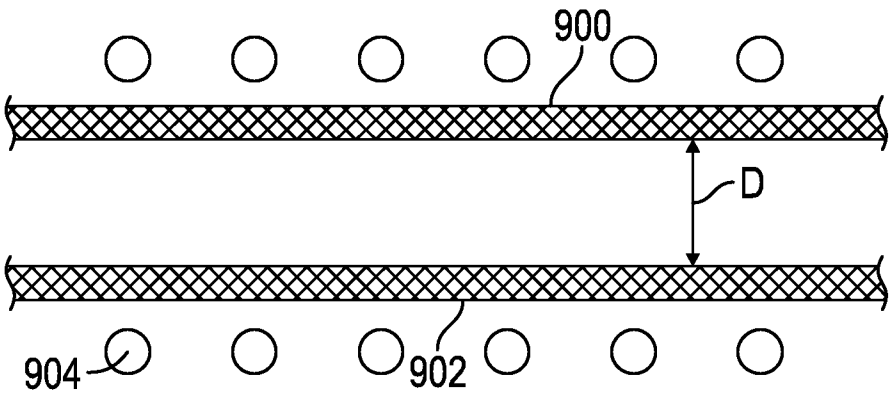


FIG. 7

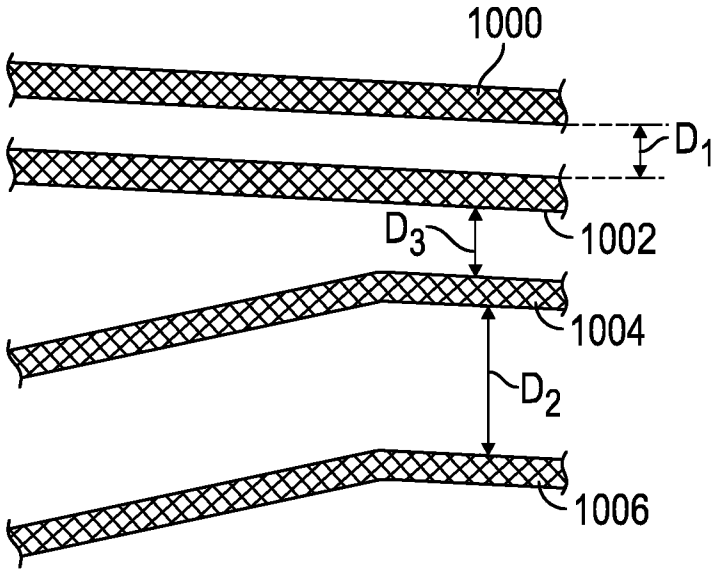


FIG. 8

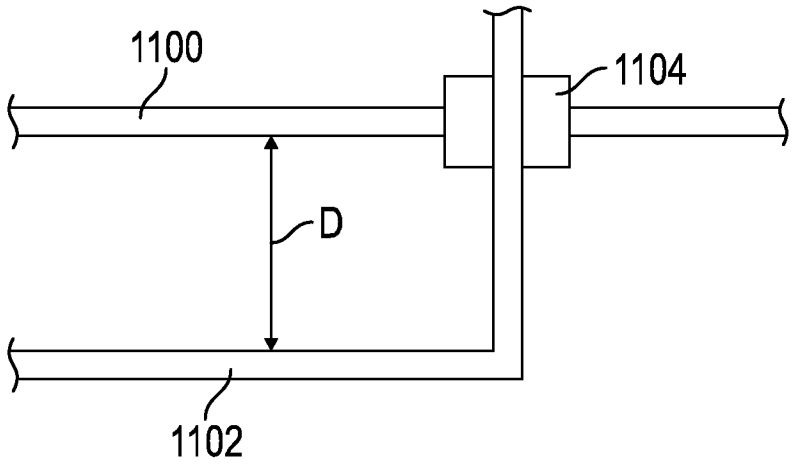


FIG. 9

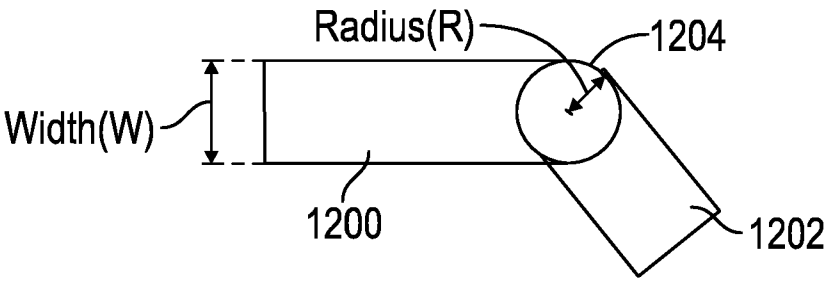


FIG. 10

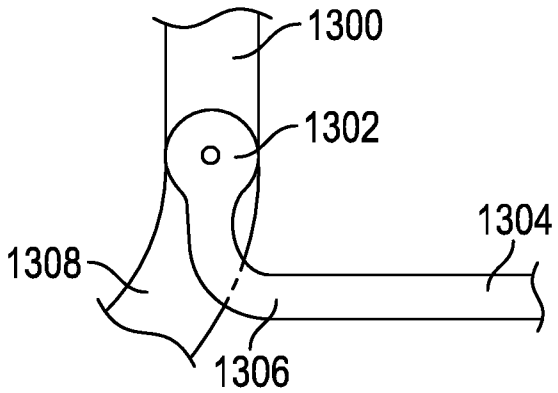


FIG. 11

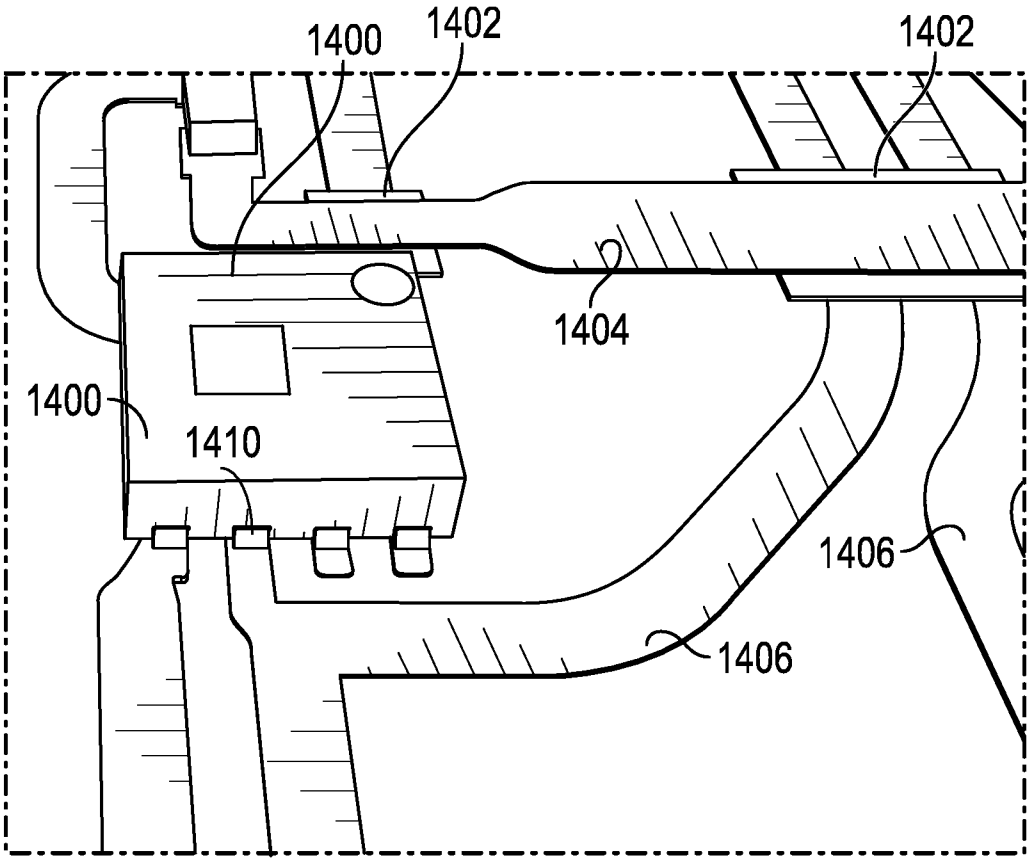


FIG. 12

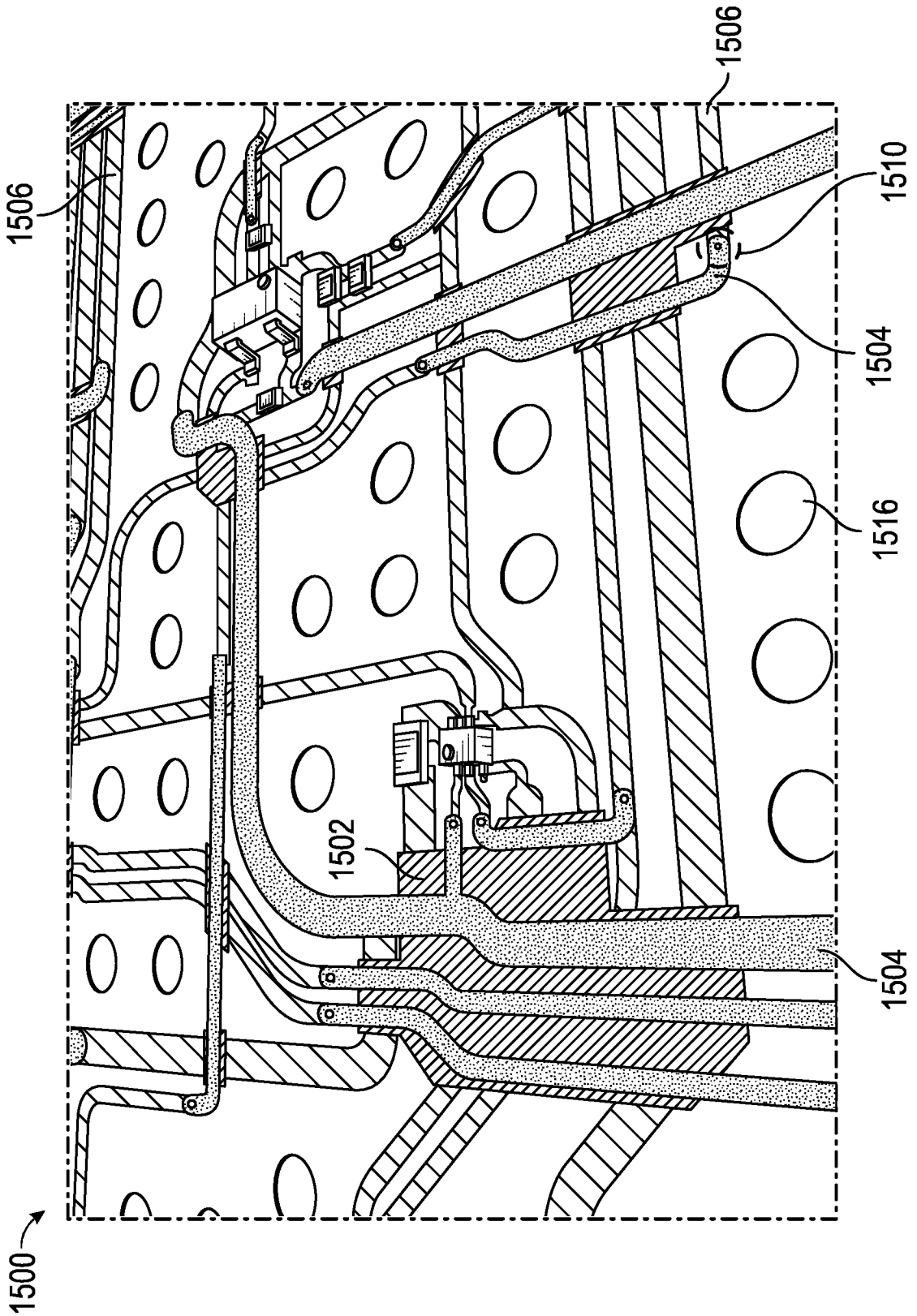


FIG. 13

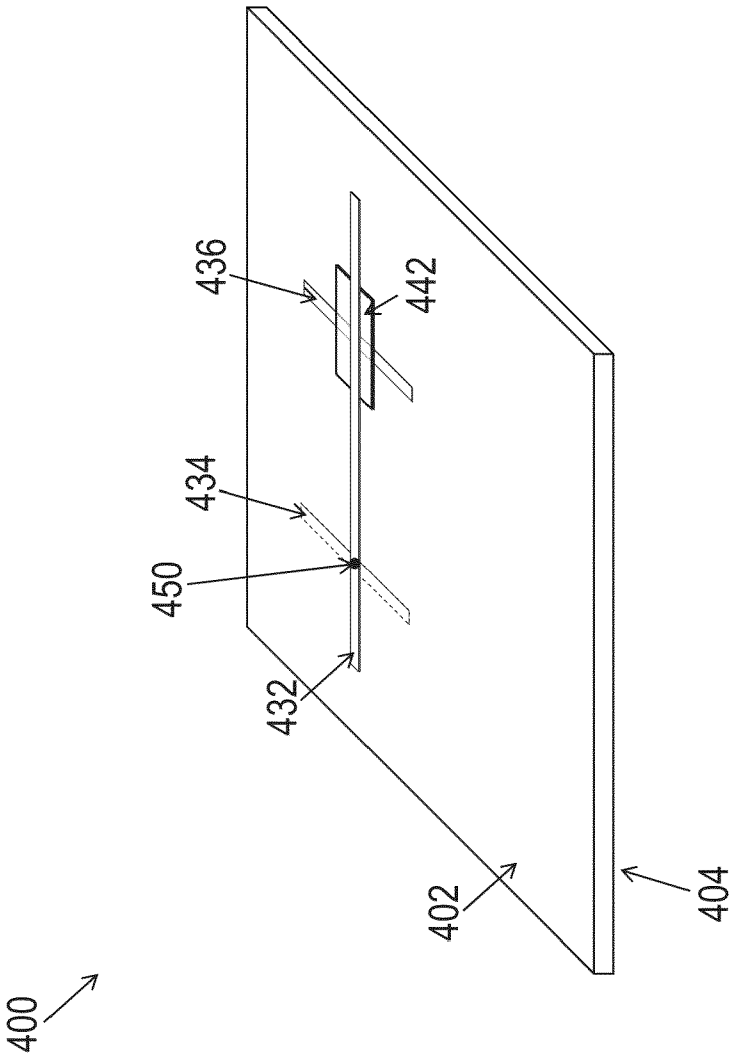


FIG. 14A

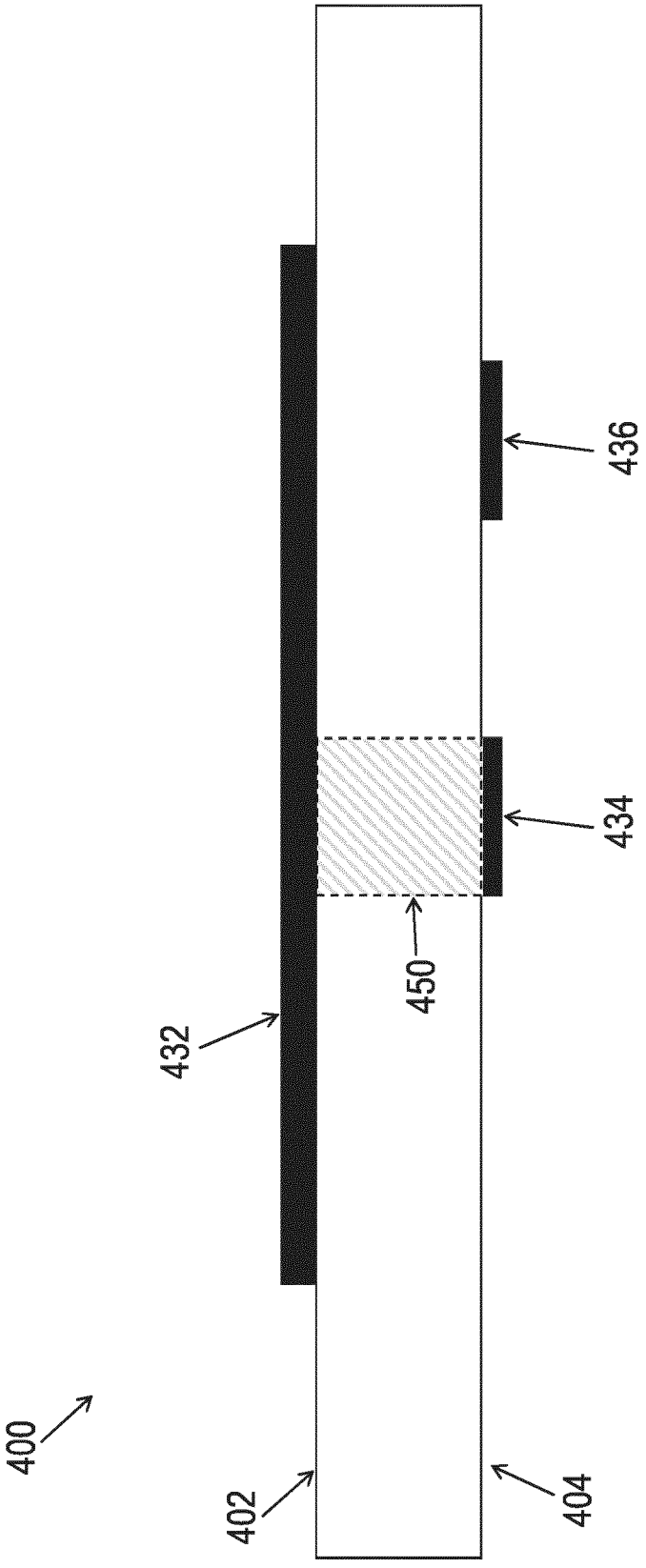


FIG. 14B

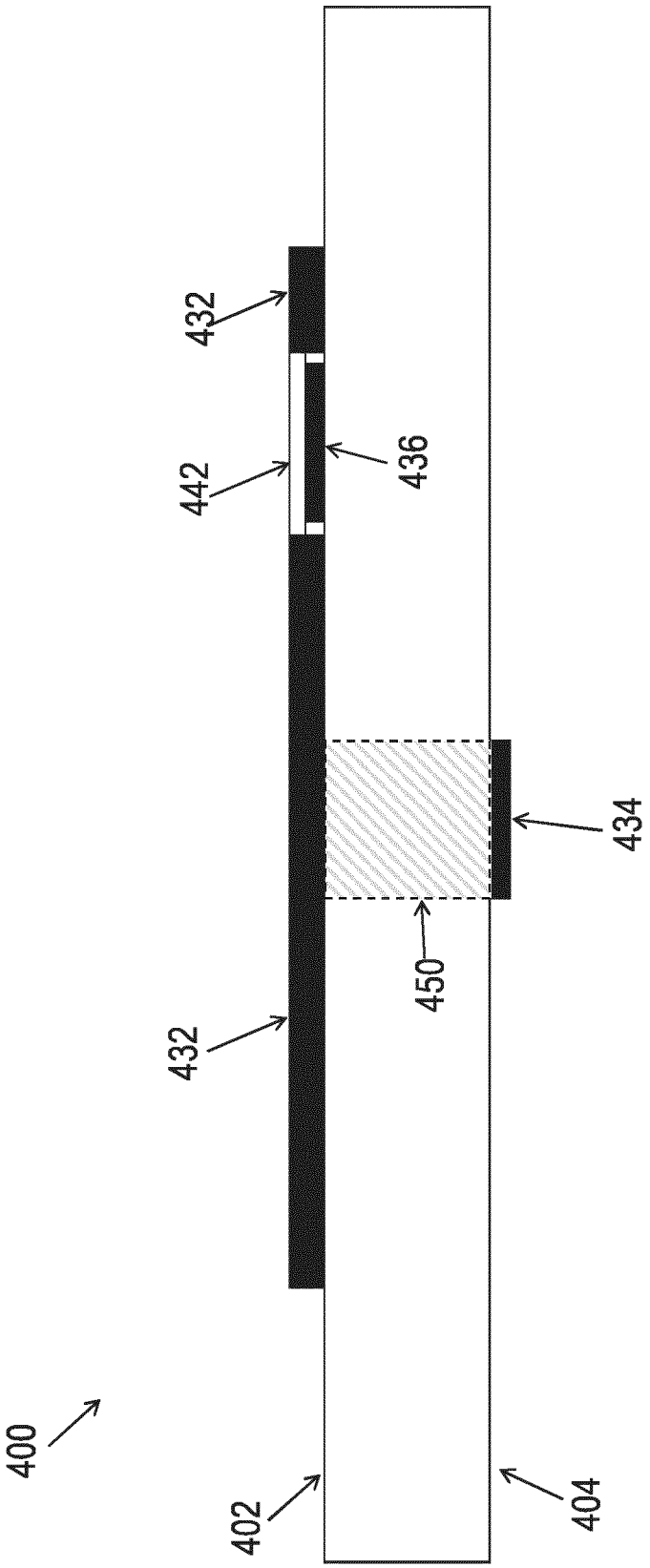


FIG. 14C

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2020/057145

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F13/00 G06F1/00 G06K9/00
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	WO 2019/048626 A1 (SMITH & NEPHEW [GB]) 14 March 2019 (2019-03-14) page 30, lines 3-9; figures 1-7 page 32, lines 9-18 paragraph [bridgingpages9/10] -----	1,2,4,5, 10,11 3,6-9
X Y	WO 2019/020550 A2 (SMITH & NEPHEW [GB]) 31 January 2019 (2019-01-31) paragraph [0255]; figures 1-18 -----	1,2,4,5, 10,11 3,6-9
A	US 2015/018792 A1 (MARSIQUET CYRIL [FR] ET AL) 15 January 2015 (2015-01-15) paragraphs [0071], [0079]; figures 1-12 -----	12-19

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
3 August 2020	24/08/2020

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Gennari, Silvia

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2020/057145

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☒ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

1-19

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-11

   method of manufacturing a sensing system for monitoring wound having a plurality of different sensors

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2. claims: 12-19

   method of manufacturing a sensing system for monitoring wound having an opening

   ---

3. claims: 20-27

   method of manufacturing a sensing system for monitoring wound having circular/curved conductive paths

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4. claims: 28-52

   method of manufacturing a sensing system for monitoring wound having a conductive material

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5. claims: 53-61

   method of manufacturing a sensing system for monitoring wound having a non-conductive mask

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2020/057145

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2019048626 A1	14-03-2019	AU 2018327682 A1	05-03-2020
		CN 111093725 A	01-05-2020
		EP 3681548 A1	22-07-2020
		US 2020222597 A1	16-07-2020
		WO 2019048626 A1	14-03-2019
WO 2019020550 A2	31-01-2019	CN 110870393 A	06-03-2020
		EP 3659409 A2	03-06-2020
		SG 11202000087Q A	27-02-2020
		US 2020163802 A1	28-05-2020
		WO 2019020550 A2	31-01-2019
US 2015018792 A1	15-01-2015	EP 2809282 A1	10-12-2014
		FR 2986151 A1	02-08-2013
		US 2015018792 A1	15-01-2015
		WO 2013114273 A1	08-08-2013