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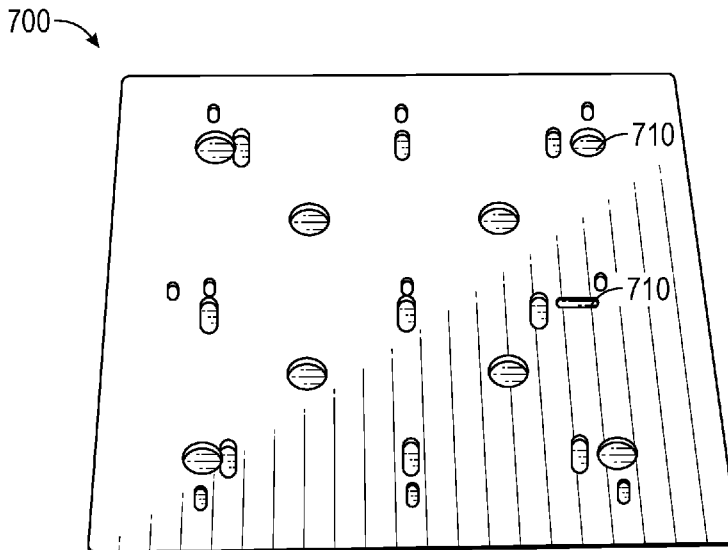


FIG. 10

(57) Abstract: Devices and methods for encapsulating a portion of a wound dressing with a coating are disclosed. In some embodiments, a method can comprise positioning a substantially flexible wound contact layer of the wound dressing on a perforated plate. The wound contact layer can include a first side supporting a plurality of electronic components protruding from a surface of the first side and a second side opposite the first side. The second side can be substantially smooth. The method can further comprise applying a vacuum to the wound contact layer through perforations in the perforated plate to hold the wound contact layer against the perforated plate and coating the wound contact layer with a coating.



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SYSTEMS AND METHOD FOR APPLYING BIOCOMPATIBLE ENCAPSULATION TO SENSOR ENABLED WOUND MONITORING AND THERAPY DRESSINGS

CROSS-REFERENCE TO RELATED APPLICATIONS

5 This application claims priority to U.K. Provisional Application No. 1816838.5, filed on October 16, 2018; the disclosure of which is hereby incorporated by reference in its entirety.

BACKGROUND

10 Field

Embodiments of the present disclosure relate to apparatuses, systems, and methods for the treatment of tissues via sensor-enabled monitoring in communication with various therapy regimes.

15 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.

Therefore, there is a need for improved sensor monitoring, particularly
5 through the use of sensor-enabled substrates which can be incorporated into existing treatment regimes.

SUMMARY

According to some embodiments, there is provided a method of coating a
10 wound dressing, the method can comprise applying a vacuum to a substantially flexible wound contact layer to hold the wound contact layer on the perforated plate, wherein the vacuum can be applied through one or more perforations in the perforated plate, the wound contact layer including a first side supporting a plurality of electronic components protruding from a surface of the first side and a second
15 side opposite the first side, the second side being substantially smooth, and coating the wound contact layer with a coating.

The method of coating a wound dressing described in the preceding paragraph may further comprise one or more of the following features. The method can further comprise supporting the first side of the wound contact layer in a
20 substantially flat position by a mold in the perforated plate, the mold including a plurality of recesses configured to support the plurality of electronic components, and substantially evenly applying the coating to the second side of the wound contact layer. The method can further comprise supporting the second side of the wound contact layer in a substantially flat position on the perforated plate, and
25 substantially evenly applying the coating to the first side of the wound contact layer. The perforated plate can be positioned within a frame. The frame can comprise an inner wall with a lip. The perforated plate can be supported within the frame on the lip. Coating can comprise encapsulating the wound contact layer with the coating. Coating can comprise covering the wound contact layer with a substantially non-
30 stretchable coating. Coating can comprise covering the wound contact layer with a substantially stretchable coating. The method can further comprise coating a first

portion of the wound contact layer positioned below an opening in a surface of a stencil with the coating, the stencil positioned on the wound contact layer and preventing the coating from being applied to a second portion of the wound contact layer not positioned below the opening. The stencil can be configured to be
5 removably coupled to a jig. The stencil can be configured to be attached to the jig or the perforated plate. The stencil can be positioned over a portion of the wound contact layer. The stencil can be positioned over the entire surface of the wound contact layer.

According to some embodiments, there is provided a device for coating a
10 wound dressing, the device can comprise a jig configured to support a substantially flexible wound contact layer of the wound dressing, the wound contact layer including a first side supporting a plurality of electronic components protruding from a surface of the first side and a second side opposite the first side, the second side being substantially smooth, a stencil configured to be positioned over the wound
15 contact layer, the stencil comprising an opening configured to permit a biocompatible coating to be applied to at least one of the first or second sides of the wound contact layer positioned below the opening in the stencil, the stencil further comprising an unbroken surface adjacent to the opening and configured to prevent the biocompatible coating from being applied to at least one of the first or second
20 sides of the wound contact layer positioned below the unbroken surface.

In some embodiments, the device for coating a wound dressing described in any of the preceding paragraphs can include one or more of the following features. The stencil can be configured to be removably coupled to the jig. The stencil can be configured to be attached to the jig. The jig can comprise at least one of a mold,
25 plate, perforated plate, or frame. The stencil can be configured to be positioned over a portion of the wound contact layer. The stencil can be configured to be positioned over the entire surface of the wound contact layer.

According to some embodiments, there is provided a method of coating a wound dressing, the method can comprise positioning a substantially flexible wound
30 contact layer of the wound dressing on a jig, a first side of the wound contact layer supporting a plurality of electronic components protruding from a surface of the first

side, a second side of the wound contact layer being positioned opposite the first side and being substantially smooth, the wound contact layer including a first registration mark, the positioning comprising aligning the first registration mark of the wound contact layer with a corresponding second registration mark on the jig, and causing coating to be applied to the wound contact layer.

The method of coating a wound dressing described in the preceding paragraph may further comprise one or more of the following features. The first and second registration marks can comprise at least one of a shape, a symbol, picture, dot pattern, or alpha-numerical character. The first registration mark can be positioned in a corner of the wound contact layer. The second registration mark on the jig can comprise a layout of the electronic components on the wound contact layer. The wound contact layer can be optically transparent around the first registration mark. The first registration mark of the wound contact layer can be optically aligned with the second registration mark on the jig.

According to some embodiments, there is provided a wound dressing. The wound dressing can comprise a substantially flexible wound contact layer comprising a first registration mark, a first side supporting a plurality of electronic components protruding from a surface of the first side, and a second side opposite the first side, the second side being substantially smooth, wherein the first registration mark is configured to provide alignment of the wound contact layer on a surface for coating the wound contact layer.

In some embodiments, the wound dressing described in any of the preceding paragraphs can include one or more of the following features. The first registration mark can comprise at least one of a shape, a symbol, picture, dot pattern, or alpha-numerical character. The first registration mark can be positioned in a corner of the wound contact layer. The surface can comprise a second registration mark, wherein the second registration mark is aligned with the first registration mark of the wound contact layer. The second registration mark on the surface can comprise at least one of a shape, a symbol, picture, dot pattern, or alpha-numerical character. The second registration mark on the surface can comprise a layout of the electronic components on the wound contact layer. The

wound contact layer can be optically transparent around the first registration mark. The first registration mark of the wound contact layer can be optically aligned with the second registration mark on the surface.

5 Other embodiments of a wound dressing, devices, kits and associated methods are described below.

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:

10 FIG. 1A illustrates a negative pressure wound treatment system according to some embodiments;

FIG. 1B illustrates a wound dressing according to some embodiments;

FIG. 2 illustrates a sensor array illustrating the sensor placement incorporated into a wound dressing according to some embodiments;

15 FIG. 3A illustrates a flexible sensor array including a sensor array portion, a tail portion and a connector pad end portion according to some embodiments;

FIG. 3B illustrates flexible circuit boards with different sensor array geometries according to some embodiments;

20 FIG. 3C illustrates the sensor array portion of a sensor array shown in FIG. 3B;

FIG. 3D illustrates a flexible sensor array incorporated into a perforated wound contact layer according to some embodiments;

FIG. 3E illustrates a control module according to some embodiments;

25 FIGS. 4A-4C illustrate a wound dressing with a plurality of electronic components according to some embodiments;

FIGS. 5A-5B illustrate coating(s) of a wound dressing according to some embodiments;

FIG. 6 illustrates coating a wound dressing with two biocompatible coatings according to some embodiments;

30 FIG. 7 illustrates coating a wound dressing with a biocompatible coating according to some embodiments;

FIG. 8 illustrates a device for coating a wound dressing according to some embodiments;

FIG. 9 illustrates spray coating a wound dressing according to some embodiments;

5 FIG. 10 illustrates a mold for coating a wound dressing according to some embodiments;

FIG. 11 illustrates another device for coating a wound dressing according to some embodiments;

10 FIGS. 12A-12B illustrate an assembled device for coating a wound dressing according to some embodiments;

FIG. 13 illustrates release liner for coating a wound dressing according to some embodiments;

FIGS. 14A-14B illustrate coating a wound dressing according to some embodiments;

15 FIG. 15 illustrates spray coating a wound dressing according to some embodiments;

FIG. 16 illustrates applying non-stretchable material to a wound dressing according to some embodiments;

20 FIGS. 17A-17B illustrate comparisons of performance without and with non-stretchable material according to some embodiments;

FIGS. 18A-18B illustrate embodiments of a device for coating a wound contact layer;

FIG. 18C illustrates a wound contact layer positioned on a perforated plate;

FIG. 19A illustrates an embodiment of a perforated plate with recesses;

25 FIG. 19B illustrates an embodiment of a wound contact layer positioned on a perforated plate illustrated in FIG. 19A;

FIG. 20 illustrates an embodiment of a stencil for use with a coating device; and

30 FIGS. 21A-21B illustrate embodiments of a wound contact layer with registration marks positioned on the wound contact layer; and

FIGS. 22A-22C illustrate an embodiment of a visual display for determining alignment of the substrate or wound contact layer within the manufacturing apparatus and/or jig.

5

DETAILED DESCRIPTION

Embodiments disclosed herein relate to apparatuses and methods of monitoring and 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.

15 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
20 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.

25 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
30 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
5 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-
10 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
15 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
20 surgical devices, for example, the NAVIO surgical system by Smith & Nephew Inc. In 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
25 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
30 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.

As described in greater detail below, the 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 as disclosed below. 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

5 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
10 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
15 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
20 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
25 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.

30 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).

5 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, sternotomies, 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.

10 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.

15 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 have the potential to be cut (for example, for joint replacement/surgical alteration/reconstruction).

20 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, systemics, antimicrobial, antibiotics, surgery, removal of tissue, affecting blood flow, physiotherapy, exercise, bathing, nutrition, hydration, nerve stimulation, ultrasound, electrostimulation, oxygen therapy, microwave
25 therapy, active agents ozone, antibiotics, antimicrobials, or the like.

Alternatively or additionally, a wound may be treated using topical negative pressure 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).

30 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, treatment of such wounds can be performed using traditional wound care, wherein a dressing can be applied to the wound to facilitate and promote healing of the wound.

Some embodiments relate to methods of manufacturing a wound dressing comprising providing a wound dressing as disclosed herein.

The wound dressings that may be utilized in conjunction with the disclosed technology include any known dressing in the art. The technology is applicable to negative pressure therapy treatment as well as non-negative pressure therapy treatment.

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, wound dressings may comprise a dressing layer including a polysaccharide or modified polysaccharide, a polyvinylpyrrolidone, a polyvinyl alcohol, a polyvinyl ether, a polyurethane, a polyacrylate, a polyacrylamide, collagen, or gelatin or mixtures thereof. Dressing layers comprising the polymers listed are known in the art as being useful for forming a wound dressing layer for either negative pressure therapy or non-negative pressure therapy.

In some embodiments, the polymer matrix may be a polysaccharide or modified polysaccharide.

In some embodiments, the polymer matrix may be a cellulose. Cellulose material may include hydrophilically modified cellulose such as methyl cellulose, carboxymethyl cellulose (CMC), carboxymethyl cellulose (CEC), ethyl cellulose, propyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, carboxyethyl sulphonate cellulose, cellulose alkyl sulphonate, or mixtures thereof.

In certain embodiments, cellulose material may be cellulose alkyl sulphonate. The alkyl moiety of the alkyl sulphonate substituent group may have an alkyl group having 1 to 6 carbon atoms, such as methyl, ethyl, propyl, or butyl. The alkyl moiety

may be branched or unbranched, and hence suitable propyl sulphonate substituents may be 1- or 2-methyl-ethylsulphonate. Butyl sulphonate substituents may be 2-ethyl-ethylsulphonate, 2,2-dimethyl-ethylsulphonate, or 1,2-dimethyl-ethylsulphonate. The alkyl sulphonate substituent group may be ethyl sulphonate.

5 The cellulose alkyl sulphonate is described in WO10061225, US2016/114074, US2006/0142560, or US 5,703,225, the disclosures of which are hereby incorporated by reference in their entirety.

10 Cellulose alkyl sulfonates may have varying degrees of substitution, the chain length of the cellulose backbone structure, and the structure of the alkyl sulfonate substituent. Solubility and absorbency are largely dependent on the degree of substitution: as the degree of substitution is increased, the cellulose alkyl sulfonate becomes increasingly soluble. It follows that, as solubility increases, absorbency increases.

In some embodiments, a wound dressing also comprises a top or cover layer.

15 The thickness of the wound dressing disclosed herein may be between 1 to 20, or 2 to 10, or 3 to 7 mm.

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:

20 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.

25 The non-negative pressure wound dressing may further comprise a region in or adjacent the obscuring element for allowing viewing of the absorbent layer. For example, the obscuring element layer may be provided over a central region of the absorbent layer and not over a border region of the absorbent layer. In some embodiments, the obscuring element is of hydrophilic material or is coated with a
30 hydrophilic material.

The obscuring element may comprise a three-dimensional knitted spacer fabric. The spacer fabric is known in the art and may include a knitted spacer fabric layer.

5 The obscuring element may further comprise an indicator for indicating the need to change the dressing.

In some embodiments, the obscuring element is provided as a layer at least partially over the absorbent layer, further from a wound site than the absorbent layer in use.

10 The non-negative pressure wound dressing may further comprise a plurality of openings in the obscuring element for allowing fluid to move therethrough. The obscuring element may comprise, or may be coated with, a material having size-exclusion properties for selectively permitting or preventing passage of molecules of a predetermined size or weight.

15 The obscuring element may be configured to at least partially mask light radiation having wavelength of 600 nm and less.

The obscuring element may be configured to reduce light absorption by 50% or more.

20 The obscuring element may be configured to yield a CIE L* value of 50 or more, and optionally 70 or more. In some embodiments, the obscuring element may be configured to yield a CIE L* value of 70 or more.

In some embodiments, the non-negative pressure wound dressing may further comprise at least one of a wound contact layer, a foam layer, an odor control element, a pressure-resistant layer and a cover layer.

25 In some embodiments, the cover layer is present, and the cover layer is a translucent film. Typically, the translucent film has a moisture vapour permeability of 500g/m²/24hours or more.

The translucent film may be a bacterial barrier.

30 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 carries an adhesive portion for forming a substantially fluid tight seal over the wound site.

The non-negative pressure wound dressing as disclosed herein may comprise the obscuring element and the absorbent layer being provided as a single layer.

5 In some embodiments, the non-negative pressure wound dressing disclosed herein comprises the foam layer, and the obscuring element is of a material comprising components that may be displaced or broken by movement of the obscuring element.

10 In some embodiments, the non-negative pressure wound dressing comprises an odor control element, and in another embodiment the dressing does not include an odor control element. When present, the odor control element may be dispersed within or adjacent the absorbent layer or the obscuring element. Alternatively, when present the odor control element may be provided as a layer sandwiched between the foam layer and the absorbent layer.

15 In some embodiments, the disclosed technology for a non-negative pressure wound dressing comprises a method of manufacturing a wound dressing, comprising: providing an absorbent layer for absorbing wound exudate; and providing an obscuring element for at least partially obscuring a view of wound exudate absorbed by the absorbent layer in use.

20 In some embodiments, the non-negative pressure wound dressing is may be suitable for providing protection at a wound site, comprising: an absorbent layer for absorbing wound exudate; and a shielding layer provided over the absorbent layer, and further from a wound-facing side of the wound dressing than the absorbent layer. The shielding layer may be provided directly over the absorbent layer. In some embodiments, the shielding layer comprises a three-dimensional spacer fabric
25 layer.

The shielding layer increases the area over which a pressure applied to the dressing is transferred by 25% or more or the initial area of application. For example, the shielding layer increases the area over which a pressure applied to the dressing is transferred by 50% or more, and optionally by 100% or more, and
30 optionally by 200% or more.

The shielding layer may comprise 2 or more sub-layers, wherein a first sub-layer comprises through holes and a further sub-layer comprises through holes and the through holes of the first sub-layer are offset from the through holes of the further sub-layer.

5 The non-negative pressure wound dressing as disclosed herein may further comprise a permeable cover layer for allowing the transmission of gas and vapour therethrough, the cover layer provided over the shielding layer, wherein through holes of the cover layer are offset from through holes of the shielding layer.

10 The non-negative pressure wound dressing may be suitable for treatment of pressure ulcers.

A more detailed description of the non-negative pressure dressing disclosed hereinabove is provided in WO2013007973, the entirety of which is hereby incorporated by reference.

15 In some embodiments, the non-negative pressure wound dressing may be a multi-layered wound dressing comprising: a fibrous absorbent layer for absorbing exudate from a wound site; and a support layer configured to reduce shrinkage of at least a portion of the wound dressing.

20 In some embodiments, the multi-layered wound dressing disclosed herein, further comprises a liquid impermeable film layer, wherein the support layer is located between the absorbent layer and the film layer.

25 The support layer disclosed herein may comprise a net. The net may comprise a geometric structure having a plurality of substantially geometric apertures extending therethrough. The geometric structure may for example comprise a plurality of bosses substantially evenly spaced and joined by polymer strands to form the substantially geometric apertures between the polymer strands.

The net may be formed from high density polyethylene.

The apertures may have an area from 0.005 to 0.32 mm².

The support layer may have a tensile strength from 0.05 to 0.06 Nm.

The support layer may have a thickness of from 50 to 150 μm.

30 In some embodiments, the support layer is located directly adjacent the absorbent layer. Typically, the support layer is bonded to fibers in a top surface of

the absorbent layer. The support layer may further comprise a bonding layer, wherein the support layer is heat laminated to the fibers in the absorbent layer via the bonding layer. The bonding layer may comprise a low melting point adhesive such as ethylene-vinyl acetate adhesive.

5 In some embodiments, the multi-layered wound dressing disclosed herein further comprises an adhesive layer attaching the film layer to the support layer.

In some embodiments, the multi-layered wound dressing disclosed herein further comprises a wound contact layer located adjacent the absorbent layer for positioning adjacent a wound. The multi-layered wound dressing may further
10 comprise a fluid transport layer between the wound contact layer and the absorbent layer for transporting exudate away from a wound into the absorbent layer.

A more detailed description of the multi-layered wound dressing disclosed hereinabove is provided in GB patent application filed on 28 October 2016 with application number GB1618298.2, the entirety of which is hereby incorporated by
15 reference.

In some embodiments, the disclosed technology may be incorporated in a wound dressing comprising a vertically lapped material comprising: a first layer of an absorbing layer of material, and a second layer of material, wherein the first layer being constructed from at least one layer of non-woven textile fibers, the non-
20 woven textile fibers being folded into a plurality of folds to form a pleated structure. In some embodiments, the wound dressing further comprises a second layer of material that is temporarily or permanently connected to the first layer of material.

Typically the vertically lapped material has been slitted.

In some embodiments, the first layer has a pleated structure having a depth
25 determined by the depth of pleats or by the slitting width. The first layer of material may be a moldable, lightweight, fiber-based material, blend of material or composition layer.

The first layer of material may comprise one or more of manufactured fibers from synthetic, natural or inorganic polymers, natural fibers of a cellulosic,
30 proteinaceous or mineral source.

The wound dressing may comprise two or more layers of the absorbing layer of material vertically lapped material stacked one on top of the other, wherein the two or more layers have the same or different densities or composition.

5 The wound dressing may in some embodiments comprise only one layer of the absorbing layer of material vertically lapped material.

The absorbing layer of material is a blend of natural or synthetic, organic or inorganic fibers, and binder fibers, or bicomponent fibers typically PET with a low melt temperature PET coating to soften at specified temperatures and to act as a bonding agent in the overall blend.

10 In some embodiments, the absorbing layer of material may be a blend of 5 to 95 % thermoplastic polymer, and 5 to 95 wt % of a cellulose or derivative thereof.

In some embodiments, the wound dressing disclosed herein has a second layer comprises a foam or a dressing fixative.

15 The foam may be a polyurethane foam. The polyurethane foam may have an open or closed pore structure.

The dressing fixative may include bandages, tape, gauze, or backing layer.

20 In some embodiments, the wound dressing as disclosed herein comprises the absorbing layer of material connected directly to a second layer by lamination or by an adhesive, and the second layer is connected to a dressing fixative layer. The adhesive may be an acrylic adhesive, or a silicone adhesive.

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

25 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).

30 A more detailed description of the multi-layered wound dressing disclosed hereinabove is provided in GB patent applications filed on 12 December 2016 with application number GB1621057.7; and 22 June 2017 with application number GB1709987.0, the entirety of each of which is hereby incorporated by reference.

In some embodiments, the non-negative pressure wound dressing may comprise an absorbent component for a wound dressing, the component comprising a wound contacting layer comprising gel forming fibers bound to a foam layer, wherein the foam layer is bound directly to the wound contact layer by an adhesive, polymer based melt layer, by flame lamination or by ultrasound.

The absorbent component may be in a sheet form.

The wound contacting layer may comprise a layer of woven or non-woven or knitted gel forming fibers.

The foam layer may be an open cell foam, or closed cell foam, typically an open cell foam. The foam layer is a hydrophilic foam.

The wound dressing may comprise the component that forms an island in direct contact with the wound surrounded by periphery of adhesive that adheres the dressing to the wound. The adhesive may be a silicone or acrylic adhesive, typically a silicone adhesive.

The wound dressing may be covered by a film layer on the surface of the dressing furthest from the wound.

A more detailed description of the wound dressing of this type hereinabove is provided in EP2498829, the entirety of which is hereby incorporated by reference.

In some embodiments, the non-negative pressure wound dressing may comprise a multi layered wound dressing for use on wounds producing high levels of exudate, characterized in that the dressing comprising: a transmission layer having an MVTR of at least 300 gm²/24 hours, an absorbent core comprising gel forming fibers capable of absorbing and retaining exudate, a wound contacting layer comprising gel forming fibers which transmits exudate to the absorbent core and a keying layer positioned on the absorbent core, the absorbent core and wound contacting layer limiting the lateral spread of exudate in the dressing to the region of the wound.

The wound dressing may be capable of handling at least 6g (or 8g and 15g) of fluid per 10cm² of dressing in 24 hours.

The wound dressing may comprise gel forming fibers that are chemically modified cellulosic fibers in the form of a fabric. The fibers may include carboxymethylated cellulose fibers, typically sodium carboxymethylcellulose fiber.

5 The wound dressing may comprise a wound contact layer with a lateral wicking rate from 5mm per minute to 40mm per minute. The wound contact layer may have a fiber density between 25gm² and 55gm², such as 35gm².

The absorbent core may have an absorbency of exudate of at least 10g/g, and typically a rate of lateral wicking of less the 20mm per minute.

10 The absorbent core may have a blend in the range of up to 25% cellulosic fibers by weight and 75% to 100% gel forming fibers by weight.

Alternatively, the absorbent core may have a blend in the range of up to 50% cellulosic fibers by weight and 50% to 100% gel forming fibers by weight. For example, the blend is in the range of 50% cellulosic fibers by weight and 50% gel forming fibers by weight.

15 The fiber density in the absorbent core may be between 150gm² and 250gm², or about 200 gm².

The wound dressing when wet may have shrinkage that is less than 25 % or less than 15 % of its original size/dimension.

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

The wound dressing may comprise one or more layers selected from the group comprising a soluble medicated film layer; an odor-absorbing layer; a spreading layer and an additional adhesive layer.

25 The wound dressing may be 2mm and 4mm thick.

The wound dressing may be characterized in that the keying layer bonds the absorbent core to a neighboring layer. In some embodiments, the keying layer may be positioned on either the wound facing side of the absorbent core or the non-wound facing side of the absorbent core. In some embodiments, the keying layer is positioned between the absorbent core and the wound contact layer. The keying
30 layer is a polyamide web.

A more detailed description of the wound dressing of this type hereinabove is provided in EP1718257, the entirety of which is hereby incorporated by reference.

In some embodiments, the non-negative pressure wound dressing may be a compression bandage. Compression bandages are known for use in the treatment
5 of oedema and other venous and lymphatic disorders, e.g., of the lower limbs.

A compression bandage systems typically employ multiple layers including a padding layer between the skin and the compression layer or layers. The compression bandage may be useful for wounds such as handling venous leg ulcers.

10 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. A compression bandage of this type is
15 disclosed in WO99/58090, the entirety of which is hereby incorporated by reference.

In some embodiments, the compression bandage system comprises: a) an inner skin facing, elongated, elastic bandage comprising: (i) an elongated, elastic substrate, and

20 (ii) an elongated layer of foam, said foam layer being affixed to a face of said substrate and extending 33% or more across said face of substrate in transverse direction and 67% or more across said face of substrate in longitudinal direction; and b) an outer, elongated, self-adhering elastic bandage; said bandage having a compressive force when extended; wherein, in use, said foam layer of the inner
25 bandage faces the skin and the outer bandage overlies the inner bandage. A compression bandage of this type is disclosed in WO2006/110527, the entirety of which is hereby incorporated by reference.

In some embodiments other compression bandage systems such as those disclosed in US 6,759,566 and US 2002/0099318, the entirety of each of which is
30 hereby incorporated by reference.

Negative Pressure Wound Dressing

In some embodiments, treatment of such wounds can be performed using negative pressure wound therapy, wherein a reduced or negative pressure can be applied to the wound to facilitate and promote healing of the wound. It will also be appreciated that the wound dressing and methods as disclosed herein may be applied to other parts of the body, and are not necessarily limited to treatment of wounds.

It will be understood that embodiments of the present disclosure are generally applicable to use in topical negative pressure ("TNP") therapy 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
5 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,
10 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)
20 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
25 atmospheric pressure is used as a reference point, and such local atmospheric pressure may not necessarily be, for example, 760 mmHg.

The negative pressure range for some embodiments of the present disclosure can be approximately -80 mmHg, or between about -20 mmHg and -200 mmHg. Note that these pressures are relative to normal ambient atmospheric
30 pressure, which can be 760 mmHg. Thus, -200 mmHg would be about 560 mmHg in practical terms. In some embodiments, the pressure range can be between about

-40 mmHg and -150 mmHg. Alternatively, a pressure range of up to -75 mmHg, up to -80 mmHg or over -80 mmHg can be used. Also in other embodiments a pressure range of below -75 mmHg can be used. Alternatively, a pressure range of over approximately -100 mmHg, or even -150 mmHg, can be supplied by the negative pressure apparatus.

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 patient physiological indices (such as, heartbeat). Examples of such applications where additional disclosure relating to the preceding may be found include U.S. Patent No. 8,235,955, titled "Wound treatment apparatus and method," issued on August 7, 2012; and U.S. Patent No. 7,753,894, titled "Wound cleansing apparatus with stress," issued July 13, 2010. The disclosures of both of these patents are hereby incorporated by reference in their entirety.

Embodiments of the wound dressings, wound dressing components, wound treatment apparatuses and methods described herein may also be used in combination or in addition to those described in International Application No. PCT/IB2013/001469, filed May 22, 2013, published as WO 2013/175306 A2 on November 28, 2013, titled "APPARATUSES AND METHODS FOR NEGATIVE PRESSURE WOUND THERAPY," U.S. Patent Application No. 14/418,908, filed January 30, 2015, published as US 2015/0190286 A1 on July 9, 2015, titled "WOUND DRESSING AND METHOD OF TREATMENT," the disclosures of which are hereby incorporated by reference in their entirety. Embodiments of the wound dressings, wound dressing components, wound treatment apparatuses and methods described herein may also be used in combination or in addition to those described in U.S. Patent Application No. 13/092,042, filed April 21, 2011, published as US2011/0282309, titled "WOUND DRESSING AND METHOD OF USE," and

U.S. Patent Application No. 14/715,527, filed May 18, 2015, published as US2016/0339158 A1 on November 24, 2016, titled "FLUIDIC CONNECTOR FOR NEGATIVE PRESSURE WOUND THERAPY," the disclosure of each of which is hereby incorporated by reference in its entirety, including further details relating to
5 embodiments of wound dressings, the wound dressing components and principles, and the materials used for the wound dressings.

Additionally, some embodiments related to TNP wound treatment comprising a wound dressing in combination with a pump or associated electronics described herein may also be used in combination or in addition to those described in
10 International Application PCT/EP2016/059329 filed April 26, 2016, published as WO 2016/174048 on November 3, 2016, entitled "REDUCED PRESSURE APPARATUS AND METHODS," the disclosure of which is hereby incorporated by reference in its entirety.

15 NPWT System Overview

FIG. 1A illustrates an embodiment of a negative or reduced pressure wound treatment (or TNP) system 100 comprising a wound filler 130 placed inside a wound cavity 110, the wound cavity sealed by a wound cover 120. The wound filler 130 in combination with the wound cover 120 can be referred to as wound dressing. A
20 single or multi lumen tube or conduit 140 is connected the wound cover 120 with a pump assembly 150 configured to supply reduced pressure. The wound cover 120 can be in fluidic communication with the wound cavity 110. In any of the system embodiments disclosed herein, as in the embodiment illustrated in FIG. 1, the pump assembly can be a canisterless pump assembly (meaning that exudate is collected
25 in the wound dressing or is transferred via tube 140 for collection to another location). However, any of the pump assembly embodiments disclosed herein can be configured to include or support a canister. Additionally, in any of the system embodiments disclosed herein, any of the pump assembly embodiments can be mounted to or supported by the dressing, or adjacent to the dressing.

30 The wound filler 130 can be any suitable type, such as hydrophilic or hydrophobic foam, gauze, inflatable bag, and so on. The wound filler 130 can be

conformable to the wound cavity 110 such that it substantially fills the cavity. The wound cover 120 can provide a substantially fluid impermeable seal over the wound cavity 110. The wound cover 120 can have a top side and a bottom side, and the bottom side adhesively (or in any other suitable manner) seals with wound cavity
5 110. The conduit 140 or lumen or any other conduit or lumen disclosed herein can be formed from polyurethane, PVC, nylon, polyethylene, silicone, or any other suitable material.

Some embodiments of the wound cover 120 can have a port (not shown) configured to receive an end of the conduit 140. For example, the port can be
10 Renasys Soft Port available from Smith & Nephew. In other embodiments, the conduit 140 can otherwise pass through or under the wound cover 120 to supply reduced pressure to the wound cavity 110 so as to maintain a desired level of reduced pressure in the wound cavity. The conduit 140 can be any suitable article configured to provide at least a substantially sealed fluid flow pathway between the
15 pump assembly 150 and the wound cover 120, so as to supply the reduced pressure provided by the pump assembly 150 to wound cavity 110.

The wound cover 120 and the wound filler 130 can be provided as a single article or an integrated single unit. In some embodiments, no wound filler is provided and the wound cover by itself may be considered the wound dressing.
20 The wound dressing may then be connected, via the conduit 140, to a source of negative pressure, such as the pump assembly 150. The pump assembly 150 can be miniaturized and portable, although larger conventional pumps such can also be used.

The wound cover 120 can be located over a wound site to be treated. The
25 wound cover 120 can form a substantially sealed cavity or enclosure over the wound site. In some embodiments, the wound cover 120 can be configured to have a film having a high water vapour permeability to enable the evaporation of surplus fluid, and can have a superabsorbing material contained therein to safely absorb wound exudate. It will be appreciated that throughout this specification reference is
30 made to a wound. In this sense it is to be understood that the term wound is to be broadly construed and encompasses open and closed wounds in which skin is torn,

cut or punctured or where trauma causes a contusion, or any other surficial or other conditions or imperfections on the skin of a patient or otherwise that benefit from reduced pressure treatment. A wound is thus broadly defined as any damaged region of tissue where fluid may or may not be produced. Examples of such wounds
5 include, but are not limited to, acute wounds, chronic wounds, surgical incisions and other incisions, 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. The components of the TNP system described herein can be particularly suited for incisional wounds
10 that exude a small amount of wound exudate.

Some embodiments of the system are designed to operate without the use of an exudate canister. Some embodiments can be configured to support an exudate canister. In some embodiments, configuring the pump assembly 150 and tubing 140 so that the tubing 140 can be quickly and easily removed from the pump
15 assembly 150 can facilitate or improve the process of dressing or pump changes, if necessary. Any of the pump embodiments disclosed herein can be configured to have any suitable connection between the tubing and the pump.

The pump assembly 150 can be configured to deliver negative pressure of approximately -80 mmHg, or between about -20 mmHg and 200 mmHg in some
20 implementations. Note that these pressures are relative to normal ambient atmospheric pressure thus, -200 mmHg would be about 560 mmHg in practical terms. The pressure range can be between about -40 mmHg and -150 mmHg. Alternatively, a pressure range of up to -75 mmHg, up to -80 mmHg or over -80 mmHg can be used. Also, a pressure range of below -75 mmHg can be used.
25 Alternatively, a pressure range of over approximately -100 mmHg, or even 150 mmHg, can be supplied by the pump assembly 150.

In operation, the wound filler 130 is inserted into the wound cavity 110 and wound cover 120 is placed so as to seal the wound cavity 110. The pump assembly 150 provides a source of a negative pressure to the wound cover 120, which is
30 transmitted to the wound cavity 110 via the wound filler 130. Fluid (such as, wound exudate) is drawn through the conduit 140, and can be stored in a canister. In

some embodiments, fluid is absorbed by the wound filler 130 or one or more absorbent layers (not shown).

Wound dressings that may be utilized with the pump assembly and other embodiments of the present application include Renasys-F, Renasys-G, Renasys
5 AB, and Pico Dressings available from Smith & Nephew. Further description of such wound dressings and other components of a negative pressure wound therapy system that may be used with the pump assembly and other embodiments of the present application are found in U.S. Patent Publication Nos. 2011/0213287, 2011/0282309, 2012/0116334, 2012/0136325, and 2013/0110058, which are
10 incorporated by reference in their entirety. In other embodiments, other suitable wound dressings can be utilized.

Wound Dressing Overview

FIG. 1B illustrates a cross-section through a wound dressing 155 according
15 to some embodiments. FIG. 1B also illustrates a fluidic connector 160 according to some embodiments. The wound dressing 155 can be similar to the wound dressing described in International Patent Publication WO2013175306 A2, which is incorporated by reference in its entirety. Alternatively, the wound dressing 155 can be any wound dressing embodiment disclosed herein or any combination of
20 features of any number of wound dressing embodiments disclosed herein, can be located over a wound site to be treated. The wound dressing 155 may be placed as to form a sealed cavity over the wound, such as the wound cavity 110. In some embodiments, the wound dressing 155 includes a top or cover layer, or backing layer 220 attached to an optional wound contact layer 222, both of which are
25 described in greater detail below. These two layers 220, 222 can be joined or sealed together so as to define an interior space or chamber. This interior space or chamber may comprise additional structures that may be adapted to distribute or transmit negative pressure, store wound exudate and other fluids removed from the wound, and other functions which will be explained in greater detail below.
30 Examples of such structures, described below, include a transmission layer 226 and an absorbent layer 221.

As used herein the upper layer, top layer, or layer above refers to a layer furthest from the surface of the skin or wound while the dressing is in use and positioned over the wound. Accordingly, the lower surface, lower layer, bottom layer, or layer below refers to the layer that is closest to the surface of the skin or wound while the dressing is in use and positioned over the wound.

The wound contact layer 222 can be a polyurethane layer or polyethylene layer or other flexible layer which is perforated, for example via a hot pin process, laser ablation process, ultrasound process or in some other way or otherwise made permeable to liquid and gas. The wound contact layer 222 has a lower surface 224 (for example, facing the wound) and an upper surface 223 (for example, facing away from the wound). The perforations 225 can comprise through holes in the wound contact layer 222 which enable fluid to flow through the layer 222. The wound contact layer 222 helps prevent tissue ingrowth into the other material of the wound dressing. In some embodiments, the perforations are small enough to meet this requirement while still allowing fluid to flow therethrough. For example, perforations formed as slits or holes having a size ranging from 0.025 mm to 1.2 mm are considered small enough to help prevent tissue ingrowth into the wound dressing while allowing wound exudate to flow into the dressing. In some configurations, the wound contact layer 222 may help maintain the integrity of the entire dressing 155 while also creating an air tight seal around the absorbent pad in order to maintain negative pressure at the wound. In some embodiments, the wound contact layer is configured to allow unidirectional or substantially one-way or unidirectional flow of fluid through the wound contact layer when negative pressure is applied to the wound. For example, the wound contact layer can permit fluid to flow away from the wound through the wound contact layer, but not allow fluid to flow back toward the wound. In certain case, the perforations in the wound contact layer are configured to permit such one-way or unidirectional flow of fluid through the wound contact layer.

Some embodiments of the wound contact layer 222 may also act as a carrier for an optional lower and upper adhesive layer (not shown). For example, a lower pressure sensitive adhesive may be provided on the lower surface 224 of the wound

dressing 155 whilst an upper pressure sensitive adhesive layer may be provided on the upper surface 223 of the wound contact layer. The pressure sensitive adhesive, which may be a silicone, hot melt, hydrocolloid or acrylic based adhesive or other such adhesives, may be formed on both sides or optionally on a selected one or none of the sides of the wound contact layer. When a lower pressure sensitive adhesive layer is utilized may be helpful to adhere the wound dressing 155 to the skin around a wound site. In some embodiments, the wound contact layer may comprise perforated polyurethane film. The lower surface of the film may be provided with a silicone pressure sensitive adhesive and the upper surface may be provided with an acrylic pressure sensitive adhesive, which may help the dressing maintain its integrity. In some embodiments, a polyurethane film layer may be provided with an adhesive layer on both its upper surface and lower surface, and all three layers may be perforated together.

A layer 226 of porous material can be located above the wound contact layer 222. This porous layer, or transmission layer, 226 allows transmission of fluid including liquid and gas away from a wound site into upper layers of the wound dressing. In particular, the transmission layer 226 can ensure that an open air channel can be maintained to communicate negative pressure over the wound area even when the absorbent layer has absorbed substantial amounts of exudates. The layer 226 can remain open under the typical pressures that will be applied during negative pressure wound therapy as described above, so that the whole wound site sees an equalized negative pressure. The layer 226 may be formed of a material having a three-dimensional structure. For example, a knitted or woven spacer fabric (for example Baltex 7970 weft knitted polyester) or a non-woven fabric could be used.

In some embodiments, the transmission layer 226 comprises a 3D polyester spacer fabric layer including a top layer (that is to say, a layer distal from the wound-bed in use) which is a 84/144 textured polyester, and a bottom layer (that is to say, a layer which lies proximate to the wound bed in use) which is a 10 denier flat polyester and a third layer formed sandwiched between these two layers which is a region defined by a knitted polyester viscose, cellulose or the like monofilament

fiber. Other materials and other linear mass densities of fiber could of course be used.

Whilst reference is made throughout this disclosure to a monofilament fiber it will be appreciated that a multistrand alternative could of course be utilized. The top spacer fabric thus has more filaments in a yarn used to form it than the number
5 of filaments making up the yarn used to form the bottom spacer fabric layer.

This differential between filament counts in the spaced apart layers helps control moisture flow across the transmission layer. Particularly, by having a filament count greater in the top layer, that is to say, the top layer is made from a
10 yarn having more filaments than the yarn used in the bottom layer, liquid tends to be wicked along the top layer more than the bottom layer. In use, this differential tends to draw liquid away from the wound bed and into a central region of the dressing where the absorbent layer 221 helps lock the liquid away or itself wicks the liquid onwards towards the cover layer where it can be transpired.

15 In some embodiments, to improve the liquid flow across the transmission layer 226 (that is to say perpendicular to the channel region formed between the top and bottom spacer layers, the 3D fabric may be treated with a dry cleaning agent (such as, but not limited to, Perchloro Ethylene) to help remove any manufacturing products such as mineral oils, fats or waxes used previously which might interfere
20 with the hydrophilic capabilities of the transmission layer. An additional manufacturing step can subsequently be carried in which the 3D spacer fabric is washed in a hydrophilic agent (such as, but not limited to, Feran Ice 30g/l available from the Rudolph Group). This process step helps ensure that the surface tension on the materials is so low that liquid such as water can enter the fabric as soon as it
25 contacts the 3D knit fabric. This also aids in controlling the flow of the liquid insult component of any exudates.

A layer 221 of absorbent material can be provided above the transmission layer 226. The absorbent material, which comprise a foam or non-woven natural or synthetic material, and which may optionally comprise a super-absorbent material,
30 forms a reservoir for fluid, particularly liquid, removed from the wound site. In some

embodiments, the layer 221 may also aid in drawing fluids towards the backing layer 220.

The material of the absorbent layer 221 may also prevent liquid collected in the wound dressing 155 from flowing freely within the dressing, and can act so as to contain any liquid collected within the dressing. The absorbent layer 221 also helps distribute fluid throughout the layer via a wicking action so that fluid is drawn from the wound site and stored throughout the absorbent layer. This helps prevent agglomeration in areas of the absorbent layer. The capacity of the absorbent material must be sufficient to manage the exudates flow rate of a wound when negative pressure is applied. Since in use the absorbent layer experiences negative pressures the material of the absorbent layer is chosen to absorb liquid under such circumstances. A number of materials exist that are able to absorb liquid when under negative pressure, for example superabsorber material. The absorbent layer 221 may typically be manufactured from ALLEVYN™ foam, Freudenberg 114-224-4 or Chem-Posite™11C-450. In some embodiments, the absorbent layer 221 may comprise a composite comprising superabsorbent powder, fibrous material such as cellulose, and bonding fibers. In some embodiments, the composite is an airlaid, thermally-bonded composite.

In some embodiments, the absorbent layer 221 is a layer of non-woven cellulose fibers having super-absorbent material in the form of dry particles dispersed throughout. Use of the cellulose fibers introduces fast wicking elements which help quickly and evenly distribute liquid taken up by the dressing. The juxtaposition of multiple strand-like fibers leads to strong capillary action in the fibrous pad which helps distribute liquid. In this way, the super-absorbent material is efficiently supplied with liquid. The wicking action also assists in bringing liquid into contact with the upper cover layer to aid increase transpiration rates of the dressing.

An aperture, hole, or orifice 227 can be provided in the backing layer 220 to allow a negative pressure to be applied to the dressing 155. In some embodiments, the fluidic connector 160 is attached or sealed to the top of the backing layer 220 over the orifice 227 made into the dressing 155, and communicates negative

pressure through the orifice 227. A length of tubing may be coupled at a first end to the fluidic connector 160 and at a second end to a pump unit (not shown) to allow fluids to be pumped out of the dressing. Where the fluidic connector is adhered to the top layer of the wound dressing, a length of tubing may be coupled at a first end
5 of the fluidic connector such that the tubing, or conduit, extends away from the fluidic connector parallel or substantially to the top surface of the dressing. The fluidic connector 160 may be adhered and sealed to the backing layer 220 using an adhesive such as an acrylic, cyanoacrylate, epoxy, UV curable or hot melt adhesive. The fluidic connector 160 may be formed from a soft polymer, for example a
10 polyethylene, a polyvinyl chloride, a silicone or polyurethane having a hardness of 30 to 90 on the Shore A scale. In some embodiments, the fluidic connector 160 may be made from a soft or conformable material.

In some embodiments, the absorbent layer 221 includes at least one through hole 228 located so as to underlie the fluidic connector 160. The through hole 228
15 may in some embodiments be the same size as the opening 227 in the backing layer, or may be bigger or smaller. As illustrated in FIG. 1B a single through hole can be used to produce an opening underlying the fluidic connector 160. It will be appreciated that multiple openings could alternatively be utilized. Additionally, should more than one port be utilized according to certain embodiments of the
20 present disclosure one or multiple openings may be made in the absorbent layer and the obscuring layer in registration with each respective fluidic connector. Although not essential to certain embodiments of the present disclosure the use of through holes in the super-absorbent layer may provide a fluid flow pathway which remains unblocked in particular when the absorbent layer is near saturation.

The aperture or through-hole 228 can be provided in the absorbent layer 221
25 beneath the orifice 227 such that the orifice is connected directly to the transmission layer 226 as illustrated in FIG. 1B. This allows the negative pressure applied to the fluidic connector 160 to be communicated to the transmission layer 226 without passing through the absorbent layer 221. This ensures that the negative pressure
30 applied to the wound site is not inhibited by the absorbent layer as it absorbs wound exudates. In other embodiments, no aperture may be provided in the absorbent

layer 221, or alternatively a plurality of apertures underlying the orifice 227 may be provided. In further alternative embodiments, additional layers such as another transmission layer or an obscuring layer such as described in International Patent Publication WO2014020440, the entirety of which is hereby incorporated by
5 reference, may be provided over the absorbent layer 221 and beneath the backing layer 220.

The backing layer 220 is can be gas impermeable, but moisture vapor permeable, and can extend across the width of the wound dressing 155. The backing layer 220, which may for example be a polyurethane film (for example,
10 Elastollan SP9109) having a pressure sensitive adhesive on one side, is impermeable to gas and this layer thus operates to cover the wound and to seal a wound cavity over which the wound dressing is placed. In this way an effective chamber is made between the backing layer 220 and a wound site where a negative pressure can be established. The backing layer 220 can be sealed to the wound
15 contact layer 222 in a border region around the circumference of the dressing, ensuring that no air is drawn in through the border area, for example via adhesive or welding techniques. The backing layer 220 protects the wound from external bacterial contamination (bacterial barrier) and allows liquid from wound exudates to be transferred through the layer and evaporated from the film outer surface. The
20 backing layer 220 can include two layers; a polyurethane film and an adhesive pattern spread onto the film. The polyurethane film can be moisture vapor permeable and may be manufactured from a material that has an increased water transmission rate when wet. In some embodiments the moisture vapor permeability of the backing layer increases when the backing layer becomes wet. The moisture
25 vapor permeability of the wet backing layer may be up to about ten times more than the moisture vapor permeability of the dry backing layer.

The absorbent layer 221 may be of a greater area than the transmission layer 226, such that the absorbent layer overlaps the edges of the transmission layer 226, thereby ensuring that the transmission layer does not contact the backing
30 layer 220. This provides an outer channel of the absorbent layer 221 that is in direct contact with the wound contact layer 222, which aids more rapid absorption of

exudates to the absorbent layer. Furthermore, this outer channel ensures that no liquid is able to pool around the circumference of the wound cavity, which may otherwise seep through the seal around the perimeter of the dressing leading to the formation of leaks. As illustrated in FIG. 1B, the absorbent layer 221 may define a smaller perimeter than that of the backing layer 220, such that a boundary or border region is defined between the edge of the absorbent layer 221 and the edge of the backing layer 220.

As shown in FIG. 1B, one embodiment of the wound dressing 155 comprises an aperture 228 in the absorbent layer 221 situated underneath the fluidic connector 160. In use, for example when negative pressure is applied to the dressing 155, a wound facing portion of the fluidic connector may thus come into contact with the transmission layer 226, which can thus aid in transmitting negative pressure to the wound site even when the absorbent layer 221 is filled with wound fluids. Some embodiments may have the backing layer 220 be at least partly adhered to the transmission layer 226. In some embodiments, the aperture 228 is at least 1-2 mm larger than the diameter of the wound facing portion of the fluidic connector 11, or the orifice 227.

For example, in embodiments with a single fluidic connector 160 and through hole, it may be preferable for the fluidic connector 160 and through hole to be located in an off-center position. Such a location may permit the dressing 155 to be positioned onto a patient such that the fluidic connector 160 is raised in relation to the remainder of the dressing 155. So positioned, the fluidic connector 160 and the filter 214 may be less likely to come into contact with wound fluids that could prematurely occlude the filter 214 so as to impair the transmission of negative pressure to the wound site.

Turning now to the fluidic connector 160, some embodiments include a sealing surface 216, a bridge 211 with a proximal end (closer to the negative pressure source) and a distal end 140, and a filter 214. The sealing surface 216 can form the applicator that is sealed to the top surface of the wound dressing. In some embodiments a bottom layer of the fluidic connector 160 may comprise the sealing surface 216. The fluidic connector 160 may further comprise an upper

surface vertically spaced from the sealing surface 216, which in some embodiments is defined by a separate upper layer of the fluidic connector. In other embodiments the upper surface and the lower surface may be formed from the same piece of material. In some embodiments the sealing surface 216 may comprise at least one aperture 229 therein to communicate with the wound dressing. In some
5 embodiments the filter 214 may be positioned across the opening 229 in the sealing surface, and may span the entire opening 229. The sealing surface 216 may be configured for sealing the fluidic connector to the cover layer of the wound dressing, and may comprise an adhesive or weld. In some embodiments, the sealing surface
10 216 may be placed over an orifice in the cover layer with optional spacer elements 215 configured to create a gap between the filter 214 and the transmission layer 226. In other embodiments, the sealing surface 216 may be positioned over an orifice in the cover layer and an aperture in the absorbent layer 220, permitting the fluidic connector 160 to provide air flow through the transmission layer 226. In
15 some embodiments, the bridge 211 may comprise a first fluid passage 212 in communication with a source of negative pressure, the first fluid passage 212 comprising a porous material, such as a 3D knitted material, which may be the same or different than the porous layer 226 described previously. The bridge 211 can be encapsulated by at least one flexible film layer 208, 210 having a proximal and
20 distal end and configured to surround the first fluid passage 212, the distal end of the flexible film being connected the sealing surface 216. The filter 214 is configured to substantially prevent wound exudate from entering the bridge, and spacer elements 215 are configured to prevent the fluidic connector from contacting the transmission layer 226. These elements will be described in greater detail
25 below.

Some embodiments may further comprise an optional second fluid passage positioned above the first fluid passage 212. For example, some embodiments may provide for an air leak may be disposed at the proximal end of the top layer that is configured to provide an air path into the first fluid passage 212 and dressing 155
30 similar to the suction adapter as described in U.S. Patent No 8,801,685, which is incorporated by reference herein in its entirety.

In some embodiment, the fluid passage 212 is constructed from a compliant material that is flexible and that also permits fluid to pass through it if the spacer is kinked or folded over. Suitable materials for the fluid passage 212 include without limitation foams, including open-cell foams such as polyethylene or polyurethane foam, meshes, 3D knitted fabrics, non-woven materials, and fluid channels. In some embodiments, the fluid passage 212 may be constructed from materials similar to those described above in relation to the transmission layer 226. Advantageously, such materials used in the fluid passage 212 not only permit greater patient comfort, but may also provide greater kink resistance, such that the fluid passage 212 is still able to transfer fluid from the wound toward the source of negative pressure while being kinked or bent.

In some embodiments, the fluid passage 212 may be comprised of a wicking fabric, for example a knitted or woven spacer fabric (such as a knitted polyester 3D fabric, Baltex 7970®, or Gehring 879®) or a nonwoven fabric. These materials selected can be suited to channeling wound exudate away from the wound and for transmitting negative pressure or vented air to the wound site, and may also confer a degree of kinking or occlusion resistance to the fluid passage 212. In some embodiments, the wicking fabric may have a three-dimensional structure, which in some cases may aid in wicking fluid or transmitting negative pressure. In certain embodiments, including wicking fabrics, these materials remain open and capable of communicating negative pressure to a wound area under the typical pressures used in negative pressure therapy, for example between -40 to -150 mmHg. In some embodiments, the wicking fabric may comprise several layers of material stacked or layered over each other, which may in some cases be useful in preventing the fluid passage 212 from collapsing under the application of negative pressure. In other embodiments, the wicking fabric used in the fluid passage 212 may be between 1.5 mm and 6 mm; more preferably, the wicking fabric may be between 3 mm and 6 mm thick, and may be comprised of either one or several individual layers of wicking fabric. In other embodiments, the fluid passage 212 may be between 1.2-3 mm thick, and preferably thicker than 1.5 mm. Some embodiments, for example a suction adapter used with a dressing which retains

liquid such as wound exudate, may employ hydrophobic layers in the fluid passage 212, and only gases may travel through the fluid passage 212. Additionally, and as described previously, the materials used in the system can be conformable and soft, which may help to avoid pressure ulcers and other complications which may result from a wound treatment system being pressed against the skin of a patient.

In some embodiments, the filter element 214 is impermeable to liquids, but permeable to gases, and is provided to act as a liquid barrier and to ensure that no liquids are able to escape from the wound dressing 155. The filter element 214 may also function as a bacterial barrier. Typically, the pore size is 0.2 μ m. Suitable materials for the filter material of the filter element 214 include 0.2 micron Gore™ expanded PTFE from the MMT range, PALL Versapore™ 200R, and Donaldson™ TX6628. Larger pore sizes can also be used but these may require a secondary filter layer to ensure full bioburden containment. As wound fluid contains lipids it is preferable, though not essential, to use an oleophobic filter membrane for example 1.0 micron MMT-332 prior to 0.2 micron MMT-323. This prevents the lipids from blocking the hydrophobic filter. The filter element can be attached or sealed to the port or the cover film over the orifice. For example, the filter element 214 may be molded into the fluidic connector 160, or may be adhered to one or both of the top of the cover layer and bottom of the suction adapter 160 using an adhesive such as, but not limited to, a UV cured adhesive.

It will be understood that other types of material could be used for the filter element 214. More generally a microporous membrane can be used which is a thin, flat sheet of polymeric material, this contains billions of microscopic pores. Depending upon the membrane chosen these pores can range in size from 0.01 to more than 10 micrometers. Microporous membranes are available in both hydrophilic (water filtering) and hydrophobic (water repellent) forms. In some embodiments, filter element 214 comprises a support layer and an acrylic copolymer membrane formed on the support layer. In some embodiments, the wound dressing 155 according to certain embodiments uses microporous hydrophobic membranes (MHMs). Numerous polymers may be employed to form MHMs. For example, the MHMs may be formed from one or more of PTFE, polypropylene,

PVDF and acrylic copolymer. All of these optional polymers can be treated in order to obtain specific surface characteristics that can be both hydrophobic and oleophobic. As such these will repel liquids with low surface tensions such as multi-vitamin infusions, lipids, surfactants, oils and organic solvents.

5 MHMs block liquids whilst allowing air to flow through the membranes. They are also highly efficient air filters eliminating potentially infectious aerosols and particles. A single piece of MHM is well known as an option to replace mechanical valves or vents. Incorporation of MHMs can thus reduce product assembly costs improving profits and costs/benefit ratio to a patient.

10 The filter element 214 may also include an odor absorbent material, for example activated charcoal, carbon fiber cloth or Vitec Carbotec-RT Q2003073 foam, or the like. For example, an odor absorbent material may form a layer of the filter element 214 or may be sandwiched between microporous hydrophobic membranes within the filter element. The filter element 214 thus enables gas to be
15 exhausted through the orifice. Liquid, particulates and pathogens however are contained in the dressing.

 The wound dressing 155 may comprise spacer elements 215 in conjunction with the fluidic connector 160 and the filter 214. With the addition of such spacer elements 215 the fluidic connector 160 and filter 214 may be supported out of direct
20 contact with the absorbent layer 220 or the transmission layer 226. The absorbent layer 220 may also act as an additional spacer element to keep the filter 214 from contacting the transmission layer 226. Accordingly, with such a configuration contact of the filter 214 with the transmission layer 226 and wound fluids during use may thus be minimized.

25 Similar to the embodiments of wound dressings described above, some wound dressings comprise a perforated wound contact layer with silicone adhesive on the skin-contact face and acrylic adhesive on the reverse. Above this bordered layer sits a transmission layer or a 3D spacer fabric pad. Above the transmission layer, sits an absorbent layer. The absorbent layer can include a superabsorbent
30 non-woven (NW) pad. The absorbent layer can over-border the transmission layer by approximately 5mm at the perimeter. The absorbent layer can have an aperture

or through-hole toward one end. The aperture can be about 10 mm in diameter. Over the transmission layer and absorbent layer lies a backing layer. The backing layer can be a high moisture vapor transmission rate (MVTR) film, pattern coated with acrylic adhesive. The high MVTR film and wound contact layer encapsulate the transmission layer and absorbent layer, creating a perimeter border of approximately 20 mm. The backing layer can have a 10 mm aperture that overlies the aperture in the absorbent layer. Above the hole can be bonded a fluidic connector that comprises a liquid-impermeable, gas-permeable semi-permeable membrane (SPM) or filter that overlies the aforementioned apertures.

10

Wound Dressing with Sensors

A wound dressing that incorporates a number of sensors can be utilized in order to monitor characteristics of a wound as it heals. Collecting data from the wounds that heal well, and from those that do not, can provide useful insights towards identifying measurands to indicate whether a wound is on a healing trajectory.

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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. 2 and 3D, which depict wound dressings 250 and 320 with sensor arrays according to some embodiments, one or more sensors can be incorporated onto or into a wound contact layer, which may be a perforated wound contact layer as shown in FIG. 3D. The wound contact layer in FIGS. 2 and 3D is illustrated as having a square shape, but it will be appreciated that the wound contact layer may have other shapes such as rectangular, circular, oval, etc. In some embodiments, the sensor integrated wound contact layer can be provided as an individual material layer that is placed over the wound area and then covered by a wound dressing apparatus or components of a wound dressing apparatus, such as gauze, foam or other wound packing material, a superabsorbent layer, a drape, a fully integrated dressing like the Pico or Allevyn Life dressing, etc. In other embodiments, the sensor integrated wound contact layer may be part of a single unit dressing such as described herein.

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The sensor-integrated wound contact layer can be placed in contact with the wound and will allow fluid to pass through the contact layer while causing little to no damage to the tissue in the wound. The sensor-integrated wound contact layer can be made of a flexible material such as silicone and can incorporate antimicrobials or other therapeutic agents known in the art. In some embodiments, the sensor-integrated wound contact layer can incorporate adhesives that adhere to wet or dry tissue. In some embodiments, the sensors or sensor array can be incorporated into or encapsulated within other components of the wound dressing such as the absorbent layer or spacer layer described above.

As shown in FIGS. 2 and 3D, five sensors can be used, including, for instance, sensors for temperature (such as, 25 thermistor sensors, in a 5 x 5 array, ~20mm pitch), oxygen saturation or SpO₂ (such as, 4 or 5 SpO₂ sensors, in a single line from the center of the wound contact layer to the edge thereof, 10mm pitch), tissue color (such as, 10 optical sensors, in 2 x 5 array, ~20mm pitch; not all 5 sensors in each row of the array need be aligned), pH (such as, by measuring colour of a pH sensitive pad, optionally using the same optical sensors as for tissue colour), and conductivity (such as, 9 conductivity contacts, in a 3 x 3 array, ~40mm pitch). As shown in FIG. 3A, the SpO₂ sensors can be arranged in a single line from the center of or near the center of the wound contact layer to the edge of the wound contact layer. The line of SpO₂ sensors can allow the sensor to take measurements in the middle of the wound, at the edge or the wound, or on intact skin to measure changes between the various regions. In some embodiments, the wound contact layer or sensor array can be larger than the size of the wound to cover the entire surface area of the wound as well as the surrounding intact skin. The larger size of the wound contact layer and/or sensor array and the multiple sensors can provide more information about the wound area than if the sensor was only placed in the center of the wound or in only one area at a time.

The sensors can be incorporated onto flexible circuit boards formed of flexible polymers including polyamide, polyimide (PI), polyester, polyethylene naphthalate (PEN), polyetherimide (PEI), along with various fluropolymers (FEP) and copolymers, or any material known in the art. The sensor array can be

incorporated into a two-layer flexible circuit. In some embodiments, the circuit board can be a multi-layer flexible circuit board. In some embodiments, these flexible circuits can be incorporated into any layer of the wound dressing. In some embodiments, a flexible circuit can be incorporated into a wound contact layer. For example, the flexible circuit can be incorporated into a wound contact layer similar to the wound contact layer described with reference to FIG. 1B. The 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 area directly.

In some embodiments, the sensor-integrated wound contact layer can include a first and second wound contact layer with the flexible circuit board sandwiched between the two layers of wound contact layer material. The first wound contact layer has a lower surface intended to be in contact with the wound and an upper surface intended to be in contact with flexible circuit board. The second wound contact layer has a lower surface intended to be in contact with the flexible circuit board and an upper surface intended to be in contact with a wound dressing or one or more components forming part of an overall wound dressing apparatus. The upper surface of the first wound contact layer and the lower surface of the second wound contact layer can be adhered together with the flexible circuit board sandwiched between the two layers.

In some embodiments, the one or more sensors of the flexible circuit board can be fully encapsulated or covered by the wound contact layers to prevent contact with moisture or fluid in the wound. In some embodiments, the first wound contact layer can have cutouts or slits that allow for one or more sensors to protrude out of the lower surface and contact the wound area directly. For example, the one or more SpO₂ sensors as shown in FIG. 3D are shown protruding out the bottom surface of the wound contact layer. In some embodiments, the SpO₂ sensors can be mounted directly on a lower surface of the first wound contact layer. Some or all of the sensors and electrical or electronic components may be potted or encapsulated (for example, rendered waterproof or liquid-proof) with a polymer, for example, silicon or epoxy based polymers. The encapsulation with a polymer can prevent ingress of fluid and leaching of chemicals from the components. In some

embodiments, the wound contact layer material can seal the components from water ingress and leaching of chemicals.

In some embodiments, gathering and processing information related to the wound can utilize three components, including a sensor array, a control or
5 processing module, and software. These components are described in more detail herein.

FIG. 3A illustrates a flexible sensor array circuit board 300 that includes a sensor array portion 301, a tail portion 302, and a connector pad end portion 303 according to some embodiments. The sensor array portion 301 can include the
10 sensors and associated circuitry. The sensor array circuit board 300 can include a long tail portion 302 extending from the sensor array portion 301. The connector pad end portion 303 can be enabled to connect to a control module or other processing unit to receive the data from the sensor array circuit. The long tail portion 302 can allow the control module to be placed distant from the wound, such
15 as for example in a more convenient location away from the wound.

FIG. 3B illustrates embodiments of the flexible circuit boards with four different sensor array geometries 301A, 301B, 301C, and 301D according to some embodiments. The illustrated embodiments include tail portions 302A, 302B, 302C,
20 and 302D. In some embodiments, four different sensor array geometries shown can be implemented in flexible circuits. While FIG. 3B show four different sensor array formats and configurations, the design 301B and 302B also includes the connector pads end portion 303 configured to provide electrical or electronic connection between the sensor array 301B and a control module. One or more of the designs
25 in 301A, 301C, or 301D can also include a connector pads end portion, such as the portion 303, to allow flexible circuit boards 301A, 301C, or 301D to communicate with a control module or other processing unit. In some embodiments, the sensor array communicates with the control module wirelessly and the tail portion may be omitted.

FIG. 3C shows the sensor array portion 301B of the sensor array design
30 shown of FIG. 3B in more detail. In any one or more of the embodiments of FIGS 2 or 3A-3D, the sensor array portion can include a plurality of portions that extend

either around a perimeter of a wound dressing component such as a wound contact layer, or inward from an outer edge of the wound dressing component. For example, the illustrated embodiments include a plurality of linearly extending portions that may be parallel to edges of a wound dressing component, and in some
5 embodiments, follow the entire perimeter of the wound dressing component. In some embodiments, the sensor array portion may comprise a first plurality of parallel linearly extending portions that are perpendicular to a second plurality of parallel linearly extending portions. These linearly extending portions may also have different lengths and may extend inward to different locations within an interior
10 of a wound dressing component. The sensor array portion preferably does not cover the entire wound dressing component, so that gaps are formed between portions of the sensor array. As shown in FIG. 2, this allows some, and possibly a majority of the wound dressing component to be uncovered by the sensor array. For example, for a perforated wound contact layer as shown in FIG. 2 and 3D, the
15 sensor array portion 301 may not block a majority of the perforations in the wound contact layer. In some embodiments, the sensor array may also be perforated or shaped to match the perforations in the wound contact layer to minimize the blocking of perforations to fluid flow.

FIG. 3D illustrates a flexible sensor array incorporated into a perforated
20 wound contact layer 320 according to some embodiments. As is illustrated, the sensor array can be sandwiched between two films or wound contact layers. The wound contact layers can have perforations formed as slits or holes as described herein that are small enough to help prevent tissue ingrowth into the wound dressing while allowing wound exudate to flow into the dressing. In some
25 embodiments, the wound contact layers can have one or more slits that increase flexibility of the wound contact layer with integrated sensor array. In some embodiments, one of the wound contact layers can have extra cut outs to accommodate the sensors so that they can contact the skin directly.

Connectivity for the sensor array can vary depending on the various sensors
30 and sensor array designs utilized. In some embodiments, for example as shown in FIG. 3B, a total of 79 connections can be used to connect the components of the

sensor array. The sensor arrays can be terminated in two parallel 40-way 0.5mm pitch Flat Flexible Cable (FFC) contact surfaces, with terminals on the top surface, designed to be connected to an FFC connector such as Molex 54104-4031.

5 In some embodiments, one or more of thermistors, conductivity sensors, SpO2 sensors, or color sensors can be used on the sensor array to provide information relating to conditions of the wound. The sensor array and individual sensors can assist a clinician in monitoring the healing of the wound. The one or more sensors can operate individually or in coordination with each other to provide data relating to the wound and wound healing characteristics.

10 Temperature sensors can use thermocouples or thermistors to measure temperature. The thermistors can be used to measure or track the temperature of the underlying wound or the thermal environment within the wound dressing. The thermometry sensors can be calibrated and the data obtained from the sensors can be processed to provide information about the wound environment. In some
15 embodiments, an ambient sensor measuring ambient air temperature can also be used to assist in eliminating problems associated with environment temperature shifts.

Optical sensors can be used to measure wound appearance using an RGB sensor with an illumination source. In some embodiments, both the RGB sensor
20 and the illumination source 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.

Light propagation in tissue can be dominated by two major phenomena, scattering and attenuation. For attenuation, as light passes through tissue, its intensity may be lost due to absorption by various components of the tissue. Blue
25 light tends to be attenuated heavily, whilst light at the red end of the spectrum tends to be attenuated least.

Scattering processes can be more complex, and can have various “regimes” which must be considered. The first aspect of scattering is based on the size of the scattering centre compared with the wavelength of incident light. If the scattering
30 center is much smaller than the wavelength of light, then Rayleigh scattering can be assumed. If the scattering center is on the order of the wavelength of light, then a

more detailed Mie scattering formulation must be considered. Another factor involved in scattering light is the distance between input and output of the scattering media. If the mean free path of the light (the distance between scattering events) is much larger than the distance travelled, then ballistic photon transport is assumed.

5 In the case of tissue, scattering events are approximately 100 microns apart – so a 1mm path distance would effectively randomise the photon direction and the system would enter a diffusive regime.

Ultra bright light emitting diodes (LEDs), an RGB sensor, and polyester optical filters can be used as components of the optical sensors to measure through
10 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. In some embodiments, an LED can be used with an RGB sensor nearby to detect the light which has diffused
15 through the tissue. The optical sensors can image with diffuse internal light or surface reflected light.

Additionally, the optical sensors can be used to measure autofluorescence. Autofluorescence is used because the tissue is absorbing light at one wavelength, and emitting at another. Additionally, dead tissue may not auto-fluoresce and so
20 this could be a very strong indication as to if the tissue is healthy or not. Due to blue light (or even UV light) having such a short penetration depth, it may be very useful for example to have a UV light with a red sensitive photodiode nearby (or some other wavelength shifted band) to act as a binary test for healthy tissue, which would auto-fluoresce at a very particular wavelength.

25 Conductivity sensors can be used to determine the difference between living and dead tissue or to show a change in impedance due to a wound being opened up in morbid tissue. Conductivity sensors can include Ag/AgCl electrodes and an impedance analyser. The conductivity sensors can be used to measure the change of impedance of a region of wound growth by measuring the impedance of the
30 surrounding tissue/area. In some embodiments, the sensor array can utilize conductivity sensors to measure the change in conductivity on perimeter electrodes

due to a wound size or wound shape change. In some embodiments, the conductivity sensors can be used in the wound bed or on the perimeter of the wound.

In some embodiments, pH changing pads can be used as a pH sensor. A spectrometer and a broadband white light source can be used to measure the spectral response of the pH dye. The illumination and imaging can be provided on the surface of the wound dressing that is in contact with the wound and at the same side as the fluid application, the bottom surface. Alternatively, in some embodiments, the illumination and imaging source can be provided on the surface of the wound dressing opposite the bottom surface and away from fluid application or the top surface of the dressing.

In some embodiments, pulse oximetry SpO₂ sensors can be used. To measure how oxygenated the blood is and the pulsatile blood flow can be observed. Pulse oximetry measurements work by taking a time resolved measurement of light absorption / transmission in tissue at two different optical wavelengths. When hemoglobin becomes oxygenated, its absorption spectrum changes with regards to non-oxygenated blood. By taking a measurement at two different wavelengths, one gains a ratio metric measure of how oxygenated the blood is.

The components in the sensor array can be connected through multiple connections. In some embodiments, the thermistors can be arranged in groups of five. Each thermistor is nominally 10k Ω , and each group of five has a common ground. There are five groups of thermistors, giving a total of 30 connections. In some embodiments, there can be nine conductivity terminals. Each conductivity terminal requires one connection, giving a total of 9 connections. In some embodiments, there can be five SpO₂ sensors. Each SpO₂ sensor requires three connections, plus power and ground (these are covered separately), giving a total of 15 connections. In some embodiments, there can be 10 color sensors. Each color sensor comprises an RGB LED and an RGB photodiode. Each color sensor requires six connections, however five of these are common to every sensor, giving a total of 15 connections. Power and ground are considered separately. In some embodiments, there can be 5 pH sensors. The pH sensors can be a color-change

discs, and can be sensed using the color sensors described above. Therefore, the pH sensors require no additional connections. There can be three power rails, and seven ground return signals, giving a total of 10 common connections. In some embodiments, the sensor array can include 25 thermistor (Murata
 5 NCP15WB473E03RC), 9 conductivity terminal, 5 SpO2 (ADPD144RI), 10 RGB LED (such as KPTF-1616RGBC-13), 10 RGB Color Sensor, 10 FET, a printed circuit board (PCB), and an assembly.

A control module can be used to interface with the sensor array. In some embodiments, the control module can contain a power source, such as batteries,
 10 and electronics to drive the sensors. The control module can also log data at appropriate intervals and allow data transfer to an external computing device, such as a personal computer (PC). The control module can be customized to have various features depending on the sensors used in the sensor array and the data collected by the sensors. In some embodiments, the control module can be
 15 comfortable enough and small enough to be worn continuously for several weeks. In some embodiments, the control module can be positioned near the wound dressing or on the wound dressing. In some embodiments, the control module can be positioned in a remote location from the wound dressing and accompanying sensor array. The control module can communicate with the sensor array and
 20 wound dressing through electrical wires or through wireless communication whether positioned on the dressing, near the dressing, or remote from the wound dressing. In some embodiments, the control module can be adapted to be utilized with different sensor arrays and can enable easy replacement of the sensor array.

In some embodiments, the control module can include various requirements
 25 and combination of features including but not limited to the features listed in Table 1 below.

TABLE 1. OPTIONAL FEATURES FOR CONTROL MODULE

7 day operation from a single set of batteries
28 day local, non-volatile, storage capacity
Easy to charge, or to replace battery

30

	Wireless link to PC / tablet (such as Bluetooth)
	Wired link to PC (optional, micro-USB)
	Drive electronics for thermistors
	Drive electronics for conductivity sensors
5	Drive electronics for optical sensors
	Drive electronics for SpO2 sensors
	Power management
	Real Time Clock (RTC) to allow accurate data logging, and correlation with other measurands
10	Ability to change sample rates and intervals (useful for SpO2) for each sensor
15	Indication of status via LED, such as (Green : Awake; Flashing green : Charging; Blue : Wireless link established; Flashing blue : Wireless data transfer; Yellow : Wired link established; Flashing yellow : Wired data transfer; Red : Battery low; Flashing red : Battery very low

FIG. 3E illustrates a block diagram 330 of a control module according to some embodiments. The block diagram of the control module includes a conductivity driver box 391 displaying features of the conductivity driver. Box 392 shows the features of the thermistor interface and box 393 shows the features of the optical interface. The control module can include a controller or microprocessor with features similar to those shown in box 394. Real time clock (RTC), Status LEDs, USB connector, Serial Flash, and Debug Connector can be included as features of the control module as shown in FIG. 3E.

In some embodiments, the microprocessor can have one or more of the following features: 2.4GHz or another suitable frequency radio (either integrated, or external); Supplied Bluetooth software stack; SPI interface; USB (or UART for external USB driver); I2C; 3 channel PWM; 32 GPIO; or 6-channel ADC. In some embodiments, the device can require at least 48 I/O pins or possibly more due to banking limitations. Bluetooth stack typically requires ~20kB on-board Flash, so a minimum of 32kB can be required. In some embodiment, 64kB can be required if complex data processing is considered. The processor core can be ARM Cortex

M4 or a similar processor core. In some embodiments, the parts can include ST's STM32L433LC or STM32F302R8, which would require an external radio, or NXP's Kinetis KW range including integrated radio.

In some embodiment, the control module can include a memory component
5 where the amount of local storage depends on the sample rate and resolution of the sensors. For example, an estimated data requirement of 256Mb (32MB) can be met by using a serial Flash device from a number of manufacturers (Micron, Spansion).

The control module can utilize one or more analogue switches. In some
10 embodiments, analogue switches with good on resistance and reasonable bandwidth can be used. For example, Analog Devices' ADG72 or NXP's NX3L4051HR can be used. Based on the initial system architecture, 8 of these will be required.

The control module can incorporate a power source, such as a battery. For
15 example, a 300mWh/day battery can be used. For 7 days this is 2100mWh. This could be provided by: a 10 days, non-rechargeable, ER14250 (14.5mm diameter x 25mm) LiSOCl₂ cell; or a 7 days, rechargeable, Li 14500 (14.5mm diameter x 500mm) Li-Ion.

The control module can incorporate a real time clock (RTC). The RTC can
20 be chosen from any RTC devices with crystal. The control module can also include miscellaneous resistors, capacitors, connectors, charge controllers, and other power supplies.

The PCB of the control module can be a 4-layer board, approximately 50mm
x 20mm, or 25mm x 40mm. The type of PCB used can be largely driven by connection requirements to sensor array.

25 The enclosure of the control module can be a two-part moulding, with clip features to allow easy access for changing sensor arrays or batteries.

The data collected through the sensor array can be passed through the
control module and processed by host software. The software may be executed on a processing device. The processing device can be a PC, tablet, smartphone, or
30 other computer capable of running host software. The processing device executing the software can be in communication with the control module through electrical

wires or through wireless communication. In some embodiments, the software may be configured to provide access to the data held on the control module, but not to perform big-data analysis. The host software can include an interface to the control module via Bluetooth or USB. In some embodiments, the host software can read
5 the status of control module, download logged data from control module, upload sample rate control to control module, convert data from control module into format suitable for processing by big-data analysis engine, or upload data to cloud for processing by analysis engine.

The software may be developed for PC (Windows / Linux), tablet or
10 smartphone (Android / iOS), or for multiple platforms.

In some embodiments, a source of negative pressure (such as a pump) and some or all other components of the topical negative pressure system, such as power source(s), sensor(s), connector(s), user interface component(s) (such as button(s), switch(es), speaker(s), screen(s), etc.) and the like, can be integral with
15 the wound dressing. In some embodiments, the components can be integrated below, within, on top of, or adjacent to the backing layer. In some embodiments, the wound dressing can include a second cover layer or a second filter layer for positioning over the layers of the wound dressing and any of the integrated components. The second cover layer can be the upper most layer of the dressing
20 or can be a separate envelope that enclosed the integrated components of the topical negative pressure system.

As used herein the upper layer, top layer, or layer above refers to a layer furthest from the surface of the skin or wound while the dressing is in use and positioned over the wound. Accordingly, the lower surface, lower layer, bottom
25 layer, or layer below refers to the layer that is closest to the surface of the skin or wound while the dressing is in use and positioned over the wound.

Component Positioning

In some embodiments, electrical or electronic components, such as sensors,
30 connections, or the like, can be placed or positioned on or embedded in one or more wound dressing components, which can be placed in or on the wound, skin, or

both the wound and the skin. For example, one or more electronic components can be positioned on a wound contact layer side that faces the wound, such as the lower surface 224 of the wound contact layer 222 in FIG. 1B. The wound contact layer can be flexible, elastic, or stretchable or substantially flexible, elastic, or stretchable in order to conform to or cover the wound. For example, the wound contact layer 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 fluoropolymers (FEP) and copolymers, or another suitable material. In some instances, one or more electronic components can be alternatively or additionally placed or positioned on or embedded in any one or more of a transmission layer, absorbent layer, backing layer, or any other suitable layer of the wound dressing.

15 In some implementations, while it may be desirable for the wound contact layer to be stretchable to better conform to or cover the wound, at least some of the electronic components 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 wound is dressed with the wound dressing and the wound contact layer 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 (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 on the wound contact layer 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 wound contact layer may move when, for example, the patient moves, it may be desirable to have the one or more electronic components be located in the same location or region with respect to the wound.

As described herein, in some embodiments, one or more stiff, rigid, or non-stretchable or substantially stiff, rigid, or non-stretchable regions, such as one or more regions of non-stretchable or substantially non-stretchable material, can be mounted, positioned, or placed on the wound contact layer (or another suitable wound dressing component) for supporting one or more electronic components. Mounting, positioning, or placing one or more electronic components in the one or more non-stretchable or substantially non-stretchable regions can prevent formation of localized stress or assist with maintenance of the position of the one or more electronic components with respect to the wound. In some instances, one or more electronic components can be alternatively or additionally flexible, such as mounted or printed on or supported by one or more flexible materials. For example, flexible plastic sheets or substrates, such as polyimide, polyether ether ketone (PEEK), polyester, silicone, or the like, can be used.

FIGS. 4A-4C illustrate a wound dressing 400 with a plurality of electronic components according to some embodiments. As is shown, a sheet or substrate 430 is configured to support one or more electronic components, including an electronic component or module 402 with a plurality of connectors 404 and a plurality of electronic connections 410, and non-stretchable or substantially non-stretchable regions 422 and 424. The substrate 430 can be a stretchable or substantially stretchable wound contact layer as described herein. The electronic module 402 can be any electronic component described herein, such as a sensor, light source (such as an LED, temperature sensor, optical sensor, etc.), controller or processor (such as a communication processor), or the like. Electronic connections 410 can be tracks printed on the substrate 430, such as using conductive copper, conductive ink (such as silver ink, graphite ink, etc.), or the like. At least some of the electronic connections 410 can be flexible or stretchable or substantially flexible or stretchable. Connectors 404 can be configured to electronically connect the electronic module 402 to the electronic connection 410 (as illustrated in FIG. 4B),

which in turn can be connected to other electronic modules (not shown) positioned on the substrate 430, on or in other components of the wound dressing, or external to the wound dressing. Connectors 404 can be pins, leads, bumps, or the like. Additionally or alternatively a socket can be used to support and electronically connect the electronic module 402. Regions 422 and 424 can include non-stretchable or substantially non-stretchable material, such as one or more of suitable adhesive, epoxy, polyester, polyimide, polyamide, PET, PBT, or another type of material with a high Young's modulus. One or more of the regions 422 and 424 can be printed on the substrate 430. As is used herein, printing material on a substrate can include one or more of laminating, adhering, or any other suitable technique.

FIG. 4B illustrates components positioned on the substrate 430. As shown, the electronic module 402 is mounted to or supported by the region 422. A portion or part of the electronic connections 410 is mounted to or supported by the region 424. Also illustrated are slits, holes, or perforations formed in the substrate 430 according to some embodiments. As described herein, the substrate 430 can be perforated using one or more of a cold pin perforation, hot pin perforation, laser ablation perforation, ultrasonic or ultrasound perforation, or the like to make the wound contact layer permeable to liquid and gas. In some implementations, one or more utilized perforation processes can generate a flat or substantially flat substrate around the hole rather than an uneven surface (such as donut-shaped surface). Having a flat or substantially flat substrate can assist in generating a homogenous layer when conformal coating is applied (such as, via spray, brush, or the like as described herein). Further, using a perforation process that leaves the surface of the substrate uneven or substantially uneven can introduce a greater risk of dislodging one or more components, such as the electronic connections 410 or the electronic module 402 when perforations are made around the components.

In certain implementations, perforations are made or patterned around one or more components placed on the substrate 430, such as the electronic connections 410, the electronic module 402, or the regions 422 or 424. As explained herein, component indexing can be used to automatically locate position of the one or more

components on the substrate 430 so that the one or more components are not damaged by perforations. In some embodiments, the substrate can be perforated before one or more components illustrated in FIG. 4A as placed on the substrate.

FIG. 4C illustrates optional application of one or more of coating 440 or one or more adhesive regions 452, 454, 456 according to some embodiments. Coating 440 can be conformal coating configured to encapsulate or coat one or more of the substrate 430 or components supported by the substrate, such as the electronic connections 410 or the electronic module 402. Coating 440 can provide biocompatibility, shield or protect the electronics from coming into contact with fluids, or the like. Coating 440 can be one or more of a suitable polymer, adhesive, such as 1072-M UV, light, or thermal curable or cured adhesive, Optimax adhesive (such as, NovaChem Optimax 8002-LV), parylene (such as, Parylene C), silicon, epoxy, urethane, acrylated urethane, or another suitable biocompatible and stretchable material. Coating 440 can be thin, such as about 100 microns thick, less than about 100 microns thick, or more than about 100 microns thick. Coating 440 can be applied and cured using one or more of UV, light, or thermal curing. In some implementations, coating 440 can be applied on the other side of the substrate 430 (or side facing away from the wound) particularly if the substrate is not impermeable to fluid. In some embodiments, coating is optional.

One or more adhesive pads, tracks, or regions 452, 454, 456 can be applied to the wound facing side of the substrate 430 as illustrated. In some embodiments, first adhesive region 452 can be shaped, sized, or positioned to affix the electronic module 402 in contact with or relative to a first specific or particular part of the wound, such as a first specific or particular area, region, or location in contact with or relative to the wound. Adhesive region 452 can be shaped and sized similarly to the region 422 or the electronic module 402 to affix the module to a particular location in the wound. Similarly, second adhesive region 454 can be shaped, sized, or positioned to affix the portion or part of the electronic connections 410 supported by the region 424 relative to a second specific or particular part of the wound, such as a second specific or particular area, region, or location in contact with or relative to the wound. Another (third) region of adhesive 456 is illustrated which can affix

another part of the wound contact layer to another (third) specific or particular part of the wound, such as another (third) specific or particular area, region, or location in contact with or relative to the wound. Adhesive material can be one or more of silicone, such as two-part silicone, one-part silicone, gel, epoxy, acrylic-based material, or another suitable material. Adhesive can be applied and cured using one or more of UV, light, or thermal curing. For example, adhesive can be printed, sprayed, coated, or the like and then cured by UV, light, thermal curing, catalytic, water vapor, or the like. In some embodiments, adhesive is optional.

In some embodiments, one or more adhesive regions can be patterned to position or affix specific components in particular areas, regions, or locations in contact with or relative to the wound even while the substrate 430 is under stress or strain. While the substrate may strain between the adhesive regions, the electronic module 402, such as a sensor, will remain in the same location in contact with or relative to the wound (due to the adhesive region 452), thus maintaining the most repeatable signal, and the portion or the part of the electronic connections 410 will remain in the same location in contact with or relative to the wound such that it will not be dragged across the wound (due to the adhesive region 454) when the substrate 430 undergoes strain. Additionally, the supporting area or mountings of the electronic module 402 will not be put under as much stress because the body (for instance, the skin, which may strain about 20%) will relieve some of the stress (for example, due to the attachment of the wound contact layer to the wound by the one or more adhesive regions) and the substrate will yield around the electronic module. Similar stress relief can be provided to the portion of the electronic connection 410 which is overlaid by the adhesive region 454. This can prevent malfunction of the one or more electronic components.

In certain embodiments, pattern of the adhesive regions can be based on the positioning of the one or more electronic components, which can be determined using indexing as described herein. As explained herein, it may be desirable to pattern the adhesive to equalize the stress or strain on the wound contact layer. Adhesive can be patterned to strengthen or support certain areas or regions, such as regions where one or more electronic components are placed, while weakening

(or making less rigid) other regions to distribute the stress or to avoid straining the one or more electrical components. For example, it may be desirable to cover at least 50% or more of the wound facing surface of the wound contact layer with the adhesive. In certain implementations, adhesive can be applied to cover or
5 substantially cover the entire wound facing side of the wound contact layer.

In some embodiments, adhesive material used to form the one or more adhesive regions can be non-stretchable or substantially non-stretchable. One or more regions of the non-stretchable or substantially non-stretchable material, such as regions 422 and 424, may not be used or may be sized or shaped differently
10 from one or more adhesive regions.

Although a single electronic module 402 is illustrated in FIGS. 4A-4C, in certain implementations, a plurality of electronic modules can be used. One or more of the additional electronic modules or one or more electronic connections 410 interconnecting the electronic module 402 and the additional electronic modules
15 can be placed on one or more additional non-stretchable or substantially non-stretchable regions. Additionally or alternatively, adhesive regions can be placed to further affix the one or more electronic modules or electronic connections in contact with or relative to the wound as described herein.

20 Component Encapsulation and Stress Relief

As described herein, biocompatible coating can be applied to the wound contact layer or electronic components positioned on the wound contact layer. In some embodiments, the wound contact layer includes a thin, flexible substrate that conforms to the wound. For example, the substrate can be made from stretchable
25 or substantially stretchable material or film, such as polyurethane, TPU, silicone, polycarbonate, polyethylene, polyimide, polyamide, polyester, PET, PBT, PEN, PEI, along with various FEP and copolymers, or another suitable material. The substrate may not be biocompatible. Coating can be flexible. Coating can include one or more suitable polymers, adhesives, such as 1072-M adhesive (for example Dymax
30 1072-M), 1165-M adhesive (such as, NovaChem Optimax 8002-LV, Dymax 1165-M, or the like), 10901-M adhesive (for instance, Dymax 1901-M or 9001-E Dymax),

5 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. Coating can be thin coating, for example, from about 80 microns or less up to several millimeters or more. As described herein, coating can be applied by laminating, adhering, welding (for instance, ultrasonic welding), curing by one or more of light, UV, heat, or the like. Coating can be transparent or substantially transparent to permit optical detection. Coating can retain bond strength when subjected to sterilization, such as EtO sterilization. Coating can have hardness lower than about A100, A80, A50 or lower. 10 Coating can have elongation at break higher than about 100%, 200%, 300% or more. Coating 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. Coating can be fluorescent.

15 It may be desirable for a substrate and electronic components supported by the substrate to be conformable as the substrate and the electronic components are intended to be positioned on or in the body. One property of conformability is the extensibility of the coating material as the electronic components may need to be isolated from the wound. Coating applied to the substrate may need to have the ability to stretch with the substrate (in case the substrate is stretchable or 20 substantially stretchable). Pairing the elongation characteristics of both the substrate and coating can maximize the desired properties of the device. In some examples, the substrate can be formed from TPU film. Coating can be formed from acrylated urethane, such as 1165-M Dymax, 1072-M Dymax, or another suitable material as described herein.

25 The substrate may need to be coated evenly and comprehensively (for example, the substrate may be encapsulated by the biocompatible coating). The substrate (for example, TPU) may be hydrophilic and, accordingly, may need to be encapsulated in hydrophobic coating to create a hydrophobic dressing to be placed on or in the wound.

30 FIGS. 5A-5B illustrate coating(s) of a wound dressing according to some embodiments. As described herein, one of the sides of a substrate 530 of the

wound dressing can include a plurality of electronic components 402 protruding from the surface. This is illustrated, for example, in FIGS. 4A-4C where the electronic module 402 protrudes from the wound facing surface of the substrate 430. As is shown in FIG. 5A, coating 440A can be applied to the side of the substrate supporting electronic components. As described herein, coating 440A can be biocompatible. Coating 440A can be hydrophobic. Coating 440A can be substantially stretchable or extensible.

As shown in FIG. 5B, coating 440B can be applied to the opposite side of the substrate. This can be advantageous when a substrate is not biocompatible or hydrophobic. Coating 440B can be biocompatible. Coating 440B can be hydrophobic. Coating 440B can be substantially stretchable or extensible. Coatings 440A and 440B can be the same or different. The substrate 530 can be encapsulated in the coating as shown in FIG. 5B. Although not illustrated, the left and right sides of the substrate 530 are also encapsulated in the coating.

FIG. 6 illustrates coating a wound dressing with two biocompatible coatings according to some embodiments. Electronic components 402 supported by the substrate 530 can be coated with coating 640A, particularly if the substrate 530 is stretchable or substantially stretchable. As described herein, coating 640A can be non-stretchable or substantially non-stretchable to provide stress relief for the electronic components (which may include electronic modules or electronic connections). Coating 640A can be applied on and around the electronic components. Coating 640A can be biocompatible. Coating 640A can be hydrophobic.

Non-stretchable or substantially non-stretchable coating described herein, such as the coating 640A, can be formed from acrylated or modified urethane material (such as, Henkel Loctite 3211). For example, coating can be one or more of Dymax 1901-M, Dymax 9001-E, Dymax 20351, Dymax 20558, Henkel Loctite 3211, or another suitable material. Coating 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, coating can have viscosity of no more than about 50,000cP. Coating can have hardness from about D40 to about D65 and/or linear

shrinkage of about 1.5–2.5%. Coating can be transparent or substantially transparent to permit optical detection. Coating may be colorless or substantially colorless. Coating 640A can be fluorescent. Coating can retain bond strength when subjected to sterilization, such as EtO sterilization.

5 As illustrated, coating 640B can be applied to the remaining surface of the side of the substrate supporting the electronic components. Coating 640B can also be applied to the opposite side of the substrate. Although not illustrated, the left and right sides of the substrate 530 are also encapsulated in the coating. Coating 640B can be biocompatible. Coating 640B can be hydrophobic. Coating 640B can
10 be substantially stretchable or extensible. Coating 640B may be similar to any of the one or more flexible or substantially flexible coatings described herein. For example, coating 640B may be formed from acrylated urethane or its alternative, such as 1165-M Dymax, 1072-M Dymax, Henkel Loctite 3381 or another suitable material.

15 In some embodiments, non-stretchable or substantially non-stretchable coating may not be biocompatible. As illustrated in FIG. 7, the electronic components 402 supported by the substrate 530 are coated with non-stretchable or substantially non-stretchable coating 740A, which is not biocompatible. A second coating 740B can be applied to the side of the substrate 530 supporting the
20 electronic components. Coating 740B can be applied over coating 740A. Coating 740B can also be applied to the opposite side of the substrate. Although not illustrated, the left and right sides of the substrate 530 are also encapsulated in coating 740B. Coating 740B can be biocompatible. Coating 740B can be hydrophobic. Coating 740B can be substantially stretchable or extensible.

25 Coating a thin, flexible substrate with biocompatible material is not trivial because the substrate may need to be coated on the side where electronic components are positioned and on the opposite side. In addition, the substrate may need to be coated evenly and comprehensively (for example, the substrate may be encapsulated by the biocompatible coating).

30 In some embodiments, a device 500 for coating a wound contact layer as shown in FIG. 8 can be used. The device 500 includes a bottom frame 514 and a

top frame 512 attached to the frame 514. Substrate 530 is held in tension or substantially in tension between the frames 514 and 512. In some implementations, the substrate 530 can be mounted on a backing, such as a substantially rigid backing made of material with high a Young's modulus (for instance, PET, PBT, or another suitable material). The backing can be shaped as a frame and can be attached to the periphery of the substrate 530. The substrate 530 is clamped or held in the device 500 so that the substrate does not sag. In some implementations, the frame 514 can be mounted on a base as described herein.

In some embodiments, coating can be applied thinly and evenly. For example, coating can be sprayed. In some embodiments, biocompatible coating can be applied to the wound contact layer by a device 600 of FIG. 9. As is illustrated, the substrate 530 is held by the device 500. Coating is applied by the device 610, which can spray the coating material on both sides of the substrate 530. For example, after a first side of the substrate 530 has been coated, the device 500 can be flipped to coat the opposite side of the substrate 530. The frames 514 and 512 can be made from material to which coating does not stick. Such material can include one or more of PTFE, nylon, or another suitable material. For example, PTFE frames are illustrated in the figures.

As described herein, one of the sides of the wound contact layer can include a plurality of electronic components protruding from the surface. This is illustrated, for example, in FIGS. 4A-4C where the electronic module 402 protrudes from the wound facing surface of the substrate 430. To efficiently and accurately coat the opposite side of such substrate, a plate or mold 700 of FIG. 10 can be used in some embodiments. As is illustrated, the mold 700 has recesses 710 into which one or more electronic components can be positioned. Such recesses can also be referred to as indentations, notches, engravings, wells, or contours. In some embodiments, the recesses 710 are shaped to allow the electronic components to be comfortably positioned. The opening area or depth of the recesses 710 can be larger than the combined area or depth of the electronic components and the coating to provide comfortable support. Positioning the one or more electronic components into one or more recesses permits the opposite side of the substrate to be held flat or

substantially flat or smooth so that coating can be evenly applied to that side. In addition, the mold 700 can prevent the substrate from sagging.

In certain implementations, the mold 700 can be made from material to which coating does not stick. Such material can include one or more of PTFE, nylon, or another suitable material. For example, a PTFE mold is illustrated in the figures.

In some embodiments, a mold can include recesses 710 shaped or arranged to permit coating of various substrates that may have different arrangements of electronic components. The mold 700 can include redundant or additional recesses 710 that are not in use when, for example, a first substrate is being coated. At least some of such additional recesses 710 can be used when a second substrate is being coated because they are arranged or shaped to permit positioning of the electronic components of the second substrate.

FIGS. 11 and 12A-12B illustrate a device 800 for coating a wound dressing according to some embodiments. In the device 800, the mold 700 is positioned on a base 518, which provides support. The base 518 can be made from material to which coating does not stick. Such material can include one or more of nylon, PTFE, or another suitable material. For example, a nylon base is illustrated in the figures.

The frame 514 is also positioned on the base as illustrated. In some embodiments, the frame 514 includes one or more pins that are configured to attach to one or more holes on the base. The pins can be dowel pins.

The frame 512 can also be attached to the frame 514 as illustrated. In certain implementations, the attachment is performed using one or more pins positioned on one of the frames and matching holes positioned on the other frame. The pins can be dowel pins.

In the illustrated arrangement, a substrate (not shown) can be positioned with the side supporting the electronic components placed on the mold 700 and be held in tension between the frames 514 and 512. This can permit applying the coating to the side opposite that which supports the electronic components. Subsequently, the mold 700 can be removed, the substrate can be flipped and positioned between the

frames 514 and 512 as described herein so that the side supporting the electronic components can be coated.

In some embodiments, a side of the substrate supporting the electronic components is coated first. The device 500 (without the mold) or 800 (with the mold) can be used hold the substrate between the frames 514 and 512. The mold 700 can have thickness that takes into account thickness of the coating. The mold 700 can have thickness of the frame 514 minus the thickness of the coating. For example, the frame 514 can be 10 mm thick and the mold 700 can be 9.85 mm thick when 150 micron (0.15 mm) coating is applied to a side of the substrate supporting the electronic components. When the substrate is flipped and the coated side supporting the electronic components is positioned on the mold 700, the substrate is precisely leveled on the mold 700 to be held in tension between the frames 514 and 512 to allow coating of the opposite (non-component) side of the substrate.

In some implementations, rigid or substantially rigid release layer or liner 1010 as illustrated in FIG. 13 can be additionally or alternatively used. Release liner 1010 can be applied to the substrate 530 to keep the substrate in tension or substantially in tension so that the substrate can be coated. Release liner 1010 can be applied to a first side of the substrate 530 (for example, the side not supporting the electronic components), permitting the opposite side to be coated. Afterwards, release liner 1010 can be removed and the other side (for example, the side supporting the electronics) can be coated. Release liner 1010 may be applied to the coated side to permit coating of the other side. Release liner can be shaped as a window frame as illustrated in FIG. 13. Release liner can be adhered to the substrate or attached by any other suitable method.

In certain implementations, release liner 1010 can serve as the backing described herein.

In some embodiments, as illustrated in FIGS. 14A-14B, a mold of the wound contact layer can be cast to enable the wound contact layer to be held flat or substantially flat during coating. As shown in FIG. 14A, casting material 1110 can be poured to cast a form or mold 1120. The mold includes recesses 1122 sized, shaped, and arranged to match the plurality of electronic components supported by

a wound contact layer. Such recesses can also be referred to as indentations, notches, engravings, wells, or contours.

FIG. 14B illustrates coating the substrate 530 using the mold 1120. The substrate 530 includes a plurality of electronic components 1102 protruding from the surface of the substrate. The electronic components 1102 are positioned in the recesses 1122 of the mold 1120 so that the opposite side of the substrate is substantially flat. Coating 1140 is evenly applied to encapsulate the opposite side of the substrate and its sides.

The side of the substrate 530 supporting the components can be coated before or after coating of the opposite side. For example, a release liner, such as the liner 1010, or another backing can be applied to the opposite, uncoated side to coat the side of the substrate 530 supporting the electronic components. Afterwards, the substrate 530 can be flipped and placed in the mold 1120 to coat the opposite side as illustrated in FIG. 14B. As described herein, the recesses 1122 of the mold 1120 can be shaped and sized to account for the coating on the electronic components.

As described herein, in some embodiments, acrylated urethanes can be used as coating material as these polymers have suitable adhesive properties and extensibility. Spray coating acrylated urethanes using the compressed air or inert gas can lead to oxygen inhibition of the polymerization reaction to cure the acrylated urethanes. Removal of oxygen from the system leads to removal of its negative effect on the polymerization reaction to cure the acrylated urethanes.

FIG. 15 illustrates spray coating a wound dressing according to some embodiments. The spray device 1200 includes a dispenser 1230 connected to a pressurized cylinder 1220 storing air or inert gas. Force of compressed air or gas causes coating 1240 to be sprayed from the dispenser 1230 onto the substrate 530. The substrate can be held in tension or substantially in tension by device 1210, which can include at least one of a plurality of frames or a mold as described herein. Coating 1240 can be biocompatible. Coating 1240 can be hydrophobic. Coating 1240 can be substantially stretchable or extensible.

In some embodiments, non-stretchable or substantially non-stretchable coating can be applied to at least some of the plurality of electronic components. FIG. 16 illustrates applying non-stretchable material to a wound dressing according to some embodiments. The spray device 1000 includes a dispenser 1030
5 connected to a pressurized cylinder 1020 storing air or inert gas. Force of compressed air or gas causes coating 1110 to be sprayed from the dispenser 1030 onto a connecting track 410. Coating 1110 can be stretchable or substantially non-stretchable. Alternatively or additionally to coating the track 410, an electronic module can also be coated.

10 In some embodiments, a single layer of stretchable or non-stretchable coating can be applied. In some embodiments, multiple layers of stretchable or non-stretchable coating can be applied. For example, multiple layers of non-stretchable coating can be applied to achieve desired stiffness or rigidity.

FIGS. 17A-17B illustrate comparisons of performance without and with non-stretchable material according to some embodiments. FIG. 17A illustrates how
15 much an electrical connection that has not been coated with non-stretchable or substantially non-stretchable coating stretches. Stretching may be caused, for example, by movement of the patient.

FIG. 17B illustrates how much an electronic connection that has been coated
20 with non-stretchable or substantially non-stretchable coating stretches. As is illustrated, both uncoated and coated electronic connections 410A and 410C are about the same length when not stretched. However, uncoated electronic connection 410B stretches to a much greater length than the coated electronic connection 410D.

25 In some embodiments, wound dressings described herein may need to comply with one or more safety standards, such as IEC 60601 standard for the safety and effectiveness of medical electrical equipment. Such one or more standards can require highly rigorous test method(s) to ensure the electrical safety of the wound dressing. Coatings described herein, such as coatings 440, 440A,
30 440B, 640A, 640B, 740A, 740B, 1240 can be applied to the substrate to ensure compliance with the applicable safety standard(s). For example, coatings can

protect the electrical components of the wound dressing against liquid ingress, ensure electrical safety, or the like. Coatings described herein can be formed from material(s) that comply with the one or more applicable safety standards.

5 In some embodiments, coating can include one or more pre-existing materials, such as film. Such pre-existing materials can be manufactured or tested to comply with the one or more applicable safety standards, such as IEC 60601 standard, before applying the one or more materials to the substrate as described herein. In certain implementations, pre-existing material can be TPU, acrylated urethane, or another material.

10 In some implementations, coating can be applied over the electronic components, which may cause the coating layer to experience localized thinning or stretching. This may be due to uneven surface of the substrate as a result of placement of the electronic components. In some cases, localized thinning or stretching may be present or be detectable when the coating is not sprayed. In 15 certain embodiments, electromagnetic/radiofrequency shielding can be applied to the coated surface to protect the electronic components from electromagnetic interference. For example, conductive ink can be used. The ink can be silicone, silver, or the like.

Additional examples of substrate embodiments and coating embodiments can 20 be found in International Application No. PCT/EP2018/059333 filed on April 11, 2018, entitled COMPONENT STRESS RELIEF FOR SENSOR ENABLED NEGATIVE PRESSURE WOUND THERAPY DRESSINGS, and International Application No. PCT/EP2018/069883 filed on July 23, 2018, entitled 25 BIOCOMPATIBLE ENCAPSULATION AND COMPONENT STRESS RELIEF FOR SENSOR ENABLED NEGATIVE PRESSURE WOUND THERAPY DRESSINGS, the disclosures of which are hereby incorporated by reference in their entireties.

Device for Coating a Substrate

30 As described herein, coating a thin, flexible substrate with biocompatible material is not trivial because the substrate may need to be coated on the side where electronic components are positioned and on the opposite side. In addition,

the substrate may need to be coated evenly and comprehensively (for example, the substrate may be encapsulated by the biocompatible coating). When using a coating device, including those described herein, the substrate can have a propensity to move or be knocked around by the force of the adhesive or coating being applied. Additionally, the compressed air during spraying can also have the propensity to move or alter the alignment or positioning of the substrate. It can be helpful to provide a way of mechanically holding the sample in place when it is being processed or coated. Clamps/bulldog clips can be awkward to apply and could leave imprints on the substrate. Double sided tape and adhesive could also be used to hold the substrate in place but can leave residue and contamination on the substrate. It can be helpful to secure the substrate to a platform or mold without having to attach the substrate to the platform or mold.

In some embodiments, a device 1800 for coating a wound contact layer as shown in FIGS. 18A-18B can be used. The device 1800 includes a frame 1812 and a perforated plate 1813 attached to or positioned in the frame 1812. The substrate 1830 can be held down on the perforated plate by using a vacuum. In some embodiments, the vacuum can be generated by a small venturi ejector attached to an on/off switch and/or a flow controller.

FIG. 18A illustrates the frame 1812 and perforated plate 1813 separated from each other. The frame 1812 can have an inner wall 1815 at the inner perimeter of the frame. The frame 1812 can have an outer wall 1816 at the outer perimeter of the frame. The perforated plate 1813 can be positioned within the inner perimeter of the frame 1812 as illustrated in 18B. The perforated plate 1813 can be attached to or coupled to the frame 1812. In some embodiments, the frame can be attached to the perforated plate as illustrated in FIGS 18A-18B by any attachment or coupling mechanisms known. In some embodiments, the perforated plate can be removably attached to or coupled to the frame.

In some embodiments, the perforated plate 1813 can be positioned on a lip 1814 (shown in FIG. 18A) on the inner wall 1815 of the frame 1812. In some embodiments, the perforated plate 1813 can be inset within the frame 1812. In some embodiments, the perforated plate 1813 can be inset within the frame 1812

without being attached to or coupled to the frame 1812. The perforated plate 1813 can be inset within the frame 1812 and can rest on the lip 1814 on the inner wall. The perforated plate 1813 can be removably supported by the lip 1814 on the inner wall 1815. In some embodiments, the perforated plate 1813 can be attached to or
5 coupled to the inner wall 1815 and/or lip 1814.

FIG. 18C illustrates the substrate 1830 positioned on the perforated plate 1813. As used herein, the substrate can be a wound contact layer as illustrated in FIG. 18C. The substrate 1830 can be held down on the perforated plate 1813 by applying a vacuum to the surface of the perforated plate opposite the surface of the
10 perforated plate supporting the substrate 1830. The surface of the perforated plate supporting the substrate 1830 is also referred to herein as the substrate contacting surface of the perforated plate. The substrate 1830 can be placed on the substrate contacting surface of the perforated plate. The vacuum can be generated by a pump or any other mechanisms or devices for generated a vacuum. The vacuum
15 generating device can be turned on and off as needed by using a switch or can be used in combination with a controller which can control the application of vacuum throughout the coating or manipulation of the substrate.

The vacuum can be applied to the substrate 1830 through the perforations in the perforated plate 1813. The application of vacuum to the perforated plate 1813
20 and substrate 1830 can hold the substrate 1830 in position as coating(s) and/or adhesive(s) are applied to the surface of the substrate 1830 opposite the surface that is in contact with the perforated plate 1813. The surface of the substrate 1830 in contact with the perforated plate 1813 can also be referred to herein as the perforated plate contacting surface of the substrate.

25 In some embodiments, the perforated plate 1813 can be replaceable and can allow for any perforation pattern and/or suction areas to be used. In some embodiments, the perforation pattern and/or suction area of the perforated plate 1813 can be selected based on the material coating requirements and/or the electronic components used on the substrate 1830. The perforated plate 1813 can
30 be switched out or replaced as the substrate 1830 is switched out or flipped.

By securing the substrate 1830 with the application of vacuum through the perforated plate 1813, the substrate 1830 does not need to be clamped or otherwise damaged by adhesives or mechanical pressure caused by clamping of the substrate 1830. Securing the substrate 1830 with a vacuum applied through the perforated plate 1813 can reduce damage to the substrate and/or does not leave adhesive residue.

In some embodiments, coating can be applied thinly and evenly. For example, coating can be sprayed. In some embodiments, biocompatible coating can be applied to the wound contact layer by the device 600 described with reference to FIG. 9 or any other application process known. The substrate 1830 can be held by the device 1800 with the application of a vacuum. Coating can be applied on both sides of the substrate 1830. For example, after a first side of the substrate 1830 has been coated, the substrate 1830 can be flipped to coat the opposite side of the substrate 1830. The perforated plate 1813 can be made to accommodate either side of the substrate 1830 or the perforated plate used for a first side of the substrate can be switched out for a perforated plate that can accommodate a second side of the substrate 1830.

In some embodiments, the substrate 1830 can be a wound contact layer or substrate that incorporates one or more electronic components. As described herein, one of the sides of the wound contact layer or substrate can include a plurality of electronic components protruding from the surface. This is illustrated, for example, in FIGS. 4A-4C where the electronic module 402 protrudes from the wound facing surface of the substrate 430.

It may be necessary to apply a coating or adhesive to the side of the substrate opposite the electronic components in order to achieve the appropriate level of insulation. In order to expose the TPU side of the substrate it can be necessary to lay the substrate component side down on the perforated plate. The side of the substrate with electronic components is a 3 dimensional surface and does not leave a flat surface to contact the perforated plate. These also makes it difficult to hold the substrate down with a vacuum as there is no seal forming between the substrate and the perforated plate as the components and coating

provide relief and hold the body of the substrate off the perforated plate. It can also be difficult to handle the material and remove the carrier material from the substrate. The substrate will try to fold back on itself and stick to itself.

To efficiently and accurately coat the opposite side of such substrate, a
5 perforated plate or mold with recesses 1913, as illustrated in FIG. 19A, can be used
in some embodiments. The perforated plate can be designed with appropriately
placed recessed areas into which the 3d componentry of the substrate can sit.
When nested correctly with all the components in the recess(es), the side of the
substrate opposite the electronic component side of the substrate is presented to
10 the spray head or other coating device as flat or substantially flat. The method of
coating the substrate with the electronic components in the recesses of the
perforated plate can also allow the substrate to form a seal over the perforations in
the perforated sheet allowing the sample to be held in place. By holding the
substrate in place with the vacuum, any carrier material or backing material applied
15 to the substrate can be removed exposing the surface of the substrate to be coated.

As is illustrated In FIG. 19A, the perforated plate 1913 can have recesses
1910 into which one or more electronic components can be positioned. Such
recesses can also be referred to as indentations, notches, engravings, wells, or
contours. In some embodiments, the recesses can be varying sizes and shapes. In
20 some embodiments, the recesses can have rounded edges. In some embodiments,
the recesses can be sized and shaped to prevent marks or damage to the substrate.
In some embodiments, the recesses 1910 are shaped to allow the electronic
components to be comfortably positioned. The opening area or depth of the
recesses 1910 can be larger than the combined area or depth of the electronic
25 components and the coating to provide comfortable support. Positioning the one or
more electronic components into one or more recesses permits the opposite side of
the substrate to be held flat or substantially flat or smooth so that coating or
adhesive can be evenly applied to that side. In addition, the perforated plate 1913
can prevent the substrate from sagging.

30 FIG. 19B illustrates areas on the substrate 1930 that align with recessed
areas 1910 of the perforated plate 1913. As illustrated in FIG. 19B, the recessed

areas 1910 of the perforated plate 1913 correspond with the location of the electronic components or modules on the perforated plate.

In some embodiments, a perforated plate 1913 can include recesses 1910 shaped or arranged to permit coating of various substrates that may have different arrangements of electronic components. The perforated plate 1913 can include
5 redundant or additional recesses 1910 that are not in use when, for example, a first substrate is being coated. At least some of such additional recesses 1910 can be used when a second substrate is being coated because they are arranged or shaped to permit positioning of the electronic components of the second substrate.

10 The substrate 1930 can be positioned with the side supporting the electronic components placed on the perforated plate 1913 with recesses 1910 and be held in position by a vacuum applied to the surface of the perforated plate 1913 opposite the substrate contacting surface of the perforated plate. This can permit applying the coating to the side of the substrate opposite that which supports the electronic
15 components. Subsequently, the substrate can be flipped and positioned on a perforated plate as described herein so that the side supporting the electronic components can be coated. In some embodiments, when the substrate is flipped, the same perforated plate can be used. In other embodiments, when the substrate is flipped, a first perforated plate with recesses can be replaced with a second
20 perforated plate with or without recesses.

In certain implementations, the perforated plate 1813, 1913 and/or frame 1812 can be made from material to which coating or adhesive does not stick. Such material can include one or more of PTFE, nylon, or another suitable material. For example, a PTFE perforated plate or frame can be used. In other examples, a nylon
25 perforated plate or frame can be used. In some embodiments, the perforated plate 1813, 1913 and/or frame 1812 can be made from aluminum. In some embodiments, the perforated plate 1813, 1913 and/or frame 1812 can be made from any smooth surface rigid material. In some embodiments, the adhesive never contacts the jig material and the adhesive only contacts the back side of the sample. In some
30 embodiments, the perforated plate can be formed from the same material as the

frame. In other embodiments, the perforated plate can be formed from a different material than the frame.

In some embodiments, the frame 1812 can include one or more pins that are configured to attach to one or more holes on the coating or material application device. In some embodiments, the pins can be dowel pins.

The substrate or wound contact layer can be coated according to various methods. In some embodiments, a method of coating a wound dressing or layer of a wound dressing can comprise positioning a substantially flexible wound contact layer of the wound dressing on a perforated plate. The wound contact layer can include a first side supporting a plurality of electronic components protruding from a surface of the first side and a second side opposite the first side. The second side can be substantially smooth. A vacuum can be applied to the wound contact layer through perforations in the perforated plate to hold the wound contact layer against the perforated plate. The wound contact layer can then be coated with a biocompatible coating. The method can also include supporting the first side of the wound contact layer in a substantially flat position by a mold or perforated plate, the mold or perforated plate can include a plurality of recesses configured to support the plurality of electronic components on the first side of the wound contact layer. The coating can be substantially evenly applied to the second side of the wound contact layer.

As described herein, a coating can be applied with a spray head similar to the device described with reference to FIGS. 9 and 15-16. In some embodiments, an adhesive coat spray head does not achieve a neat edge due to the nature of how the adhesive is sprayed from the nozzle with pressurized air. This can make it difficult to achieve precise coating around critical areas to avoid contamination.

As illustrated in FIG. 20, a stencil 2050 can be designed to fit onto or into a coating device. In some embodiments, the stencil 2050 can be designed to fit onto or into a jig. In some embodiments, the jig can comprise a mold, plate, perforated plate, frame, or any combination of the devices described herein with reference to FIGS. 8-19B used to secure or support a substrate. The stencil can be positioned over the substrate on a frame or on any device supporting the substrate. The stencil

can occlude critical areas of the substrate being coated. As illustrated in FIG. 20, the stencil 2050 can include masked areas 2051 and windows 2052. The windows 2052 can be openings in the stencil 2050 for positioning over an area of the substrate to be coated. In some embodiments, the masked areas 2051 can also be referred to herein as an unbroken surface of the stencil adjacent to the windows 2052.

In some embodiments, during the coating process, approximately 20mm of clearance between the spray head and the substrate can give suitable results in terms of surface finish. In some embodiments, a stencil can be approximately 10mm thick and can sit 5mm off the surface of the substrate (allowing clearance of all components). This can allow the stencil to be inserted between the substrate and the spray head. Other sizes of stencils can be used. In some embodiments, the stencil can be less than 1mm, about 1mm to about 100mm, or greater than 100mm thick. In some embodiments, the clearance between the spray head and substrate can be less than 10mm, about 10mm to about 100mm, greater than 100mm, or any other distance necessary for coating of the substrate. In some embodiments, the stencil can be manufactured and used to produce "bow tie" substrates, as illustrated in FIG. 20, on which the ends are exposed, allowing work to be performed on extensibility or other characteristics while allowing a crocodile clip to be connected to the exposed sections of the track. The bow tie stencil of FIG. 20 is just one possible embodiment. The stencil can take any shape to suit the application. For example, localized spots of adhesive can be placed on the components by using a stencil with small holes that align with areas about the components.

In some embodiments, the stencil can be deployed in any form, i.e. a stencil can be made to any shape to fit any area of application. For example, the stencil can be used to apply an extra thick layer of coating (e.g., stretchable and/or extensible coatings or non-stretchable coatings as described herein) over an electronic component (e.g., impedance pads) without spraying onto neighboring components. Positioning the stencil over a substrate to be coated can provide a method of avoiding contamination on nearby critical components.

A method of coating a wound dressing can be used. The method can comprise positioning a stencil on a substantially flexible wound contact layer of the wound dressing. The wound contact layer can include a first side supporting a plurality of electronic components protruding from a surface of the first side and a second side opposite the first side. In some embodiments, the second side can be substantially smooth. The stencil can comprise a surface with an opening. A first portion of the wound contact layer positioned below the opening of the stencil can then be coated with a biocompatible coating and the stencil can prevent the biocompatible coating from being applied to a second portion of the wound contact layer not positioned below the opening.

A device for coating a wound dressing can be used. The device can comprise a jig configured to support a substantially flexible wound contact layer of the wound dressing. The wound contact layer can include a first side supporting a plurality of electronic components protruding from a surface of the first side and a second side opposite the first side. The second side being substantially smooth. A stencil can be configured to be positioned over the wound contact layer. The stencil can comprise an opening configured to permit a biocompatible coating to be applied to at least one of the first or second sides of the wound contact layer positioned below the opening in the stencil. The stencil can further comprise an unbroken surface or masked area 2051 adjacent to the opening or window 2052 and configured to prevent the biocompatible coating from being applied to at least one of the first or second sides of the wound contact layer positioned below the unbroken surface or masked area 2051.

In some embodiments, it can be difficult to repeatedly place a substrate for coating on a jig or coating device. In some embodiments, the jig can comprise a mold, plate, perforated plate, frame, or any combination of the devices described herein with reference to FIGS. 8-19B used to secure or support a substrate. Registration marks can be used to repeatedly place a single substrate or place a series of substrates on a jig or coating device. In some embodiments, it can be helpful to provide a reliable way of accurately placing the substrate on the jig or

coating device to the level of precision required to complete the coating application on the substrate using an automatic spraying or coating device or robot device.

The location of the electronic components relative to the edge of the substrate can vary from substrate to substrate. Due to this variance, the coating or adhesive could be applied manually with a hand held dispenser, a new program
5 could be made every time a new substrate was laid down, or a larger volume of adhesive than required could be dispensed to cover a larger area to compensate for placement errors.

Registration marks can be used to mark a region of the substrate. The registration mark can be any shape or marking on the substrate. The registration
10 mark can be a shape, a symbol, picture, dot pattern, alpha-numerical character, or any other marking that can be placed on the substrate. Registration marks can be printed to a high degree of repeatability (something approximating +/- 10 microns) on the substrate. In some embodiments, the registration marks can be printed in the
15 corners of the substrate to the same level of repeatability. In some embodiments, the registration marks can be printed on any area of the substrate.

The registration marks can be used to optically align the sample on a jig or coating device. The surface of the jig or coating device that supports or secures the substrate can comprise a corresponding registration mark. In some embodiments,
20 the registration marks at the same pitch can be etched into a plate or frame that supports the substrate (for example, the plate or the frame described with reference to FIGS. 8-19B). In some embodiments, a software program run by the coating device or any other controller can be made to use the etched registration marks on a component of the jig or coating device as the datum points. In some embodiments,
25 the substrate can be optically transparent around the registration marks. The optical transparency of this portion of the substrate can allow for optical alignment of the registration mark on the substrate with the datum points on the jig or coating device. In some embodiments, the datum points can be referred to herein as registration marks on the jig or coating device. The datum point or registration mark can be any
30 shape or marking on the jig. The datum point or registration mark can be a shape, a symbol, picture, dot pattern, alpha-numerical character, or any other marking that

can be placed or etched on the jig. The optical alignment of the registration marks can allow for repeatable placement between substrates or when a substrate is flipped on the jig or coating device.

FIG. 21A illustrates a substrate on a coating device or jig such that the electronic components are on the side of the substrate opposite the side contacting a perforated plate of the coating device or jig. As illustrated in FIG. 21A, the substrate 2130 can have four registration marks 2161 positioned at the four corners of the substrate 2130. The four registration marks 2161 can align with datum points or registration marks on the perforated plate 2113. FIG. 21B illustrates the alignment of the registration marks 2161 on the substrate with datum points on the jig. As illustrated in the image with an "X" in FIG. 21B (image on left), the registration mark 2161 is not aligned with the datum point or registration mark 2162 on the perforated plate in FIG. 21B. As illustrated in the image with a check mark in FIG. 21B (image on right), the registration mark 2161 is aligned with the datum point or registration mark 2162 on the perforated plate in FIG. 21B.

In some embodiments, the jig used on the coating device can have two circles used as registration marks at the correct pitched in the top left and bottom right corners. The circles on the jig can correspond with the registration marks printed on the substrate. In some embodiments, the datum points can be etched on a plate (for example, the perforated plate described herein). In some embodiments, a portion of or the full circuit schematic can be etched onto the jig and the substrate with the circuit schematic printed on the substrate can be aligned accordingly. In some embodiments, the coating device can use a camera or other imaging device to detect the registration marks. In some embodiments, the coating device can make corrections for minor errors in the placement of the substrate on the jig or coating device. The coating device described herein can be similar to the coating devices described with reference to FIGS. 8-16 and 18A-19B. The coating device can comprise a controller, sensors, a processor and/or other computing device that can be used to align the substrate in the coating device and/or can be used to apply one or more coatings to the substrate.

In some embodiments, a method using registration marks can allow for a smaller volume of adhesive to be dispensed because the system does not have to be concerned with covering a larger than necessary area to achieve the desired coverage. In some embodiments, the registration marks can speed up the coating process as it can allow for the automation of the coating device (for example, a robotic coating device) without the need to program a coating pattern each time.

In some embodiments, a method of coating a wound dressing can be used. The method can comprise positioning a substantially flexible wound contact layer of the wound dressing on a jig. A first side of the wound contact layer can support a plurality of electronic components protruding from a surface of the first side. A second side of the wound contact layer can be positioned opposite the first side and can be substantially smooth. The wound contact layer can include a registration mark. In some embodiments, the positioning of the wound contact layer on the jig can comprise aligning the registration mark of the wound contact layer with a corresponding registration mark or datum point on the jig. The wound contact layer can then be coated with a coating. In some embodiments, the wound dressing can comprise a substantially flexible wound contact layer. The wound contact layer can comprise a registration mark, a first side supporting a plurality of electronic components protruding from a surface of the first side, and a second side opposite the first side. In some embodiments, the second side can be substantially smooth. In some embodiments, the registration mark can be configured to provide alignment of the wound contact layer on a surface for coating the wound contact layer.

The registration marks can be used to align the substrate or wound contact layer within one or more manufacturing apparatuses and/or a jig. As described herein the registration marks can be positioned on the substrate or wound contact layer to assist with alignment and orientation of the substrate on the manufacturing apparatus and/or jig. The registration marks can be observed by the user for proper alignment on the manufacturing apparatus and/or jig. In some cases, the registration marks can be viewed by the manufacturing apparatus through the use of an integrated camera or optical sensor. In such cases, the camera can be used to observe alignment and/or provide feedback to the control device to adjust the

manufacturing apparatuses and/or jig depending on the alignment of the registration marks with one or more datum points or registration marks on the manufacturing apparatus and/or jig. In some cases, the system can check for alignment of the wound contact layer within the manufacturing apparatus and/or jig and provide a visual representation of the alignment on a display.

FIGS. 22A-22C illustrate a visual display 2200 for determining alignment of the substrate or wound contact layer within the manufacturing apparatus and/or jig. As illustrated in FIG. 22A, at least a portion of the substrate or wound contact layer 2201 can be visible within the display. As shown in FIGS. 22A-22C, a portion of the substrate or wound contact layer 2201 that includes a registration mark 2202 can be visible on the display. The example shown in FIGS. 22A-22C can have a registration mark on each of the four corners of the substrate or wound contact layer 2201. In other cases, any number of registration marks on the substrate or wound contact layer can be used.

The display can provide visual, audio, and/or tactile feedback to the user signifying an alignment condition of the substrate or wound contact layer 2201. FIG. 22A illustrates a first alignment condition in which the substrate or wound contact layer 2201 are not properly aligned within the manufacturing apparatus and/or jig. The apparatus can use a camera or optical sensor to visualize or detect the registration marks 2202 on the substrate or wound contact layer. The apparatus can align the registration marks 2202 on the substrate or wound contact layer with the datum points or registration marks on the manufacturing apparatus and/or jig and/or with one or more predetermined locations stored in the control device or processor associated with the apparatus.

The proper alignment of the substrate or wound contact layer 2201 and registration marks 2202 with the manufacturing apparatus and/or jig can be visualized on the display using one or more indicators on the display. As shown in FIG. 22A-22C, indicators 2203, 2204, 2205, 2206, 2207, 2208, 2209, and 2210 can be used to correspond to registration marks 2202 on the substrate. As illustrated in FIG. 22A, the registration marks 2202 can be in a misaligned position which can be signified by a first color shown in the indicators 2203, 2204, 2205, 2206, 2207,

2208, 2209, and 2210. Other indicators can be used to indicate other alignment conditions of the substrate and/or wound contact layer 2201 similar to indicator 2211.

As the registration marks 2202 become aligned with the datum points or registration marks on the manufacturing apparatus and/or jig and/or with one or more predetermined locations stored in the control device or processor associated with the apparatus, one or more indicators can indicate a proper alignment condition by changing to a second color. FIG. 22B illustrates one or more indicators displaying a second color indicating a condition where some portions of the registration marks are properly aligned (shown with indicators 2204, 2206, and 2210) and one or more indicators displaying a first color indicating a condition where other portions of the registration marks are not properly aligned (shown with indicators 2203, 2205, 2207, 2208, and 2209). FIG. 22C illustrates the display when the substrate or wound contact layer is in an aligned position as indicated by all indicators in the second color. As the substrate or wound contact layer is moved or aligned, the indicators can move between the first and second color to assist the user in visualizing the proper alignment. While the examples described with reference to FIGS. 22A-22C use colors to indicate an alignment condition, other indicators can be used such as icons, text, images, and/or any other visual indicator.

In some cases, the display can also have a visual readout or indication when the substrate or wound contact layer is misaligned as shown in FIGS. 22A-22B with the "Fail" indication shown on the display. The display can have a visual readout or indication when the substrate or wound contact layer is properly aligned as shown in FIG. 22C with the "Pass" indication shown on the display.

25 Other Variations

In some embodiments, one or more electronic components can be positioned on the side of a wound contact layer opposite the side that faces the wound. Systems and methods described herein are equally applicable to such wound contact layers. Although spraying the coating is described above, other suitable methods for applying the coating can be used in certain embodiments. Such methods can include one or more of dip coating, spin coating, vapor deposition,

chemical deposition, electrochemical deposition, roll-to-roll coating, laminating, adhering, welding (for instance, ultrasonic welding), curing by one or more of light, UV, heat, or the like.

Although certain embodiments described herein relate to wound dressings, systems and methods disclosed herein are not limited to wound dressings or
5 medical applications. Systems and methods disclosed herein are generally applicable to electronic devices in general, such as electronic devices that can be worn by or applied to a user.

Any value of a threshold, limit, duration, etc. provided herein is not intended
10 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
15 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
20 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
25 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
30 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.

5 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
10 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.
15 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,
20 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
25 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
30 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.

5 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-
10 exclusive.

WHAT IS CLAIMED IS:

1. A method of coating a wound dressing, the method comprising:
applying a vacuum to a substantially flexible wound contact layer to hold the wound contact layer on a perforated plate, wherein the vacuum is applied through one or more perforations in the perforated plate, the wound contact layer including a first side supporting a plurality of electronic components protruding from a surface of the first side and a second side opposite the first side, the second side being substantially smooth; and coating the wound contact layer with a coating.
2. The method according to claim 1, further comprising:
supporting the first side of the wound contact layer in a substantially flat position by a mold in the perforated plate, the mold including a plurality of recesses configured to support the plurality of electronic components; and substantially evenly applying the coating to the second side of the wound contact layer.
3. The method according to any one of claim 1-2, further comprising:
supporting the second side of the wound contact layer in a substantially flat position on the perforated plate; and substantially evenly applying the coating to the first side of the wound contact layer.
4. The method according to any one of claims 1-3, wherein the perforated plate is positioned within a frame.
5. The method according to claim 4, wherein the frame comprises an inner wall with a lip.
6. The method according to claim 5, wherein the perforated plate is supported within the frame on the lip.
7. The method according to any one of claims 1-6, wherein coating comprises encapsulating the wound contact layer with the coating.
8. The method of according to any one of claims 1-7, wherein coating comprises covering the wound contact layer with a substantially non-stretchable coating.

9. The method according to any one of claims 1-8, wherein coating comprises covering the wound contact layer with a substantially stretchable coating.

10. A method of coating a wound dressing according to any of the preceding claims, the method further comprising:

5 coating a first portion of the wound contact layer positioned below an opening in a surface of a stencil with the coating, the stencil positioned on the wound contact layer; and

 preventing the coating from being applied to a second portion of the wound contact layer not positioned below the opening.

10 11. The method according to claim 10, wherein the stencil is configured to be removably coupled to a jig.

12. The method according to claim 10, wherein the stencil is configured to be attached to the jig or the perforated plate.

15 13. The method according to any one of claims 10-12, wherein the stencil is positioned over a portion of the wound contact layer.

14. The method according to any one of claims 10-12, wherein the stencil is positioned over the entire surface of the wound contact layer.

15. A device for coating a wound dressing, the device comprising:

20 a jig configured to support a substantially flexible wound contact layer of the wound dressing, the wound contact layer including a first side supporting a plurality of electronic components protruding from a surface of the first side and a second side opposite the first side, the second side being substantially smooth;

25 a stencil configured to be positioned over the wound contact layer, the stencil comprising an opening configured to permit a biocompatible coating to be applied to at least one of the first or second sides of the wound contact layer positioned below the opening in the stencil, the stencil further comprising an unbroken surface adjacent to the opening and configured to prevent the biocompatible coating from being applied to at least one of the
30 first or second sides of the wound contact layer positioned below the unbroken surface.

16. The device according to claim 15, wherein the stencil is configured to be removably coupled to the jig.

17. The device according to claim 15, wherein the stencil is configured to be attached to the jig.

5 18. The device according to any one of claims 15-17, wherein the jig comprises at least one of a mold, plate, perforated plate, or frame.

19. The device according to any one of claims 15-18, wherein the stencil is configured to be positioned over a portion of the wound contact layer.

10 20. The device according to any one of claims 15-18, wherein the stencil is configured to be positioned over the entire surface of the wound contact layer.

21. A method of coating a wound dressing, the method comprising:

15 positioning a substantially flexible wound contact layer of the wound dressing on a jig, a first side of the wound contact layer supporting a plurality of electronic components protruding from a surface of the first side, a second side of the wound contact layer being positioned opposite the first side and being substantially smooth, the wound contact layer including a first registration mark, the positioning comprising aligning the first registration mark of the wound contact layer with a corresponding second registration mark on the jig; and

20 causing coating to be applied to the wound contact layer.

22. The method according to claim 21, wherein the first and second registration marks comprise at least one of a shape, a symbol, picture, dot pattern, or alpha-numerical character.

25 23. The method according to any one of claims 21-22, wherein the first registration mark is positioned in a corner of the wound contact layer.

24. The method according to claim 21, wherein the second registration mark on the jig comprises a layout of the electronic components on the wound contact layer.

30 25. The method according to any one of claims 21-24, wherein the wound contact layer is optically transparent around the first registration mark.

26. The method according to claim 25, wherein the first registration mark of the wound contact layer is optically aligned with the second registration mark on the jig.

27. A wound dressing comprising:

5

a substantially flexible wound contact layer comprising:

a first registration mark;

a first side supporting a plurality of electronic components protruding from a surface of the first side; and

10

a second side opposite the first side, the second side being substantially smooth;

wherein the first registration mark is configured to provide alignment of the wound contact layer on a surface for coating the wound contact layer.

28. The dressing according to claim 27, wherein the first registration mark comprises at least one of a shape, a symbol, picture, dot pattern, or alpha-numerical character.

15

29. The dressing according to any one of claims 27-28, wherein the first registration mark is positioned in a corner of the wound contact layer.

30. The dressing according to any one of claims 27-29, wherein the surface comprises a second registration mark, wherein the second registration mark is aligned with the first registration mark of the wound contact layer.

20

31. The dressing according to claim 30, wherein the second registration mark on the surface comprises at least one of a shape, a symbol, picture, dot pattern, or alpha-numerical character.

32. The dressing according to claim 30, wherein the second registration mark on the surface comprises a layout of the electronic components on the wound contact layer.

25

33. The dressing according to any one of claims 27-32, wherein the wound contact layer is optically transparent around the first registration mark.

34. The dressing according to claim 33, wherein the first registration mark of the wound contact layer is optically aligned with the second registration mark on the surface.

30

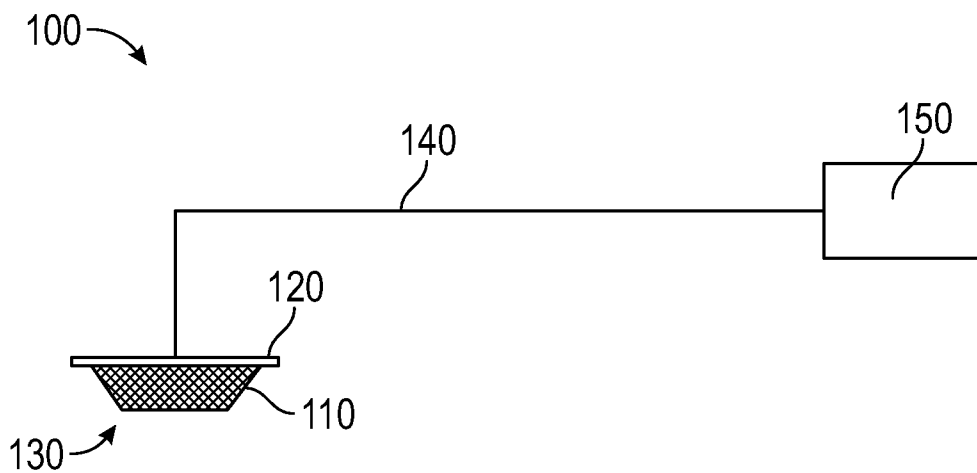


FIG. 1A

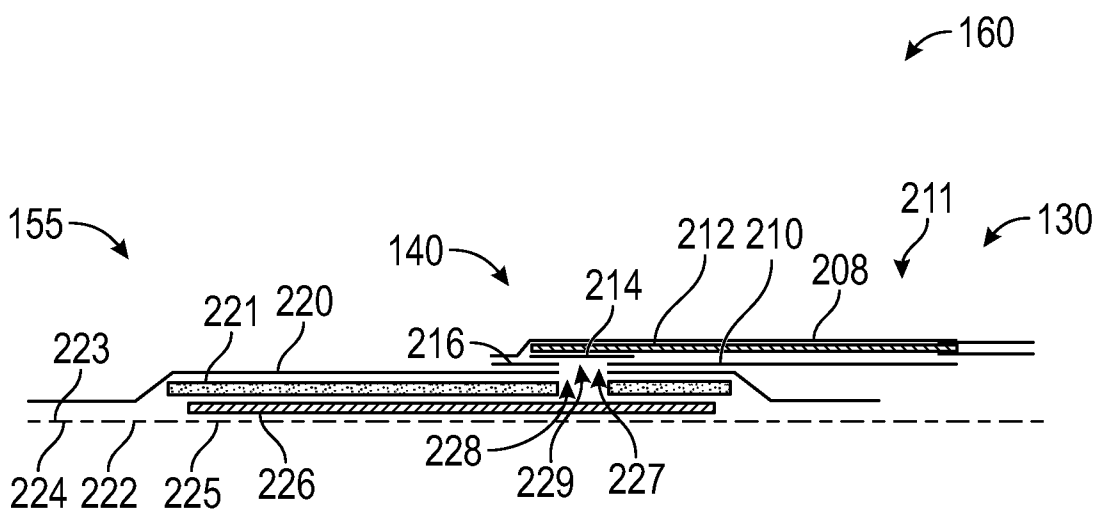


FIG. 1B

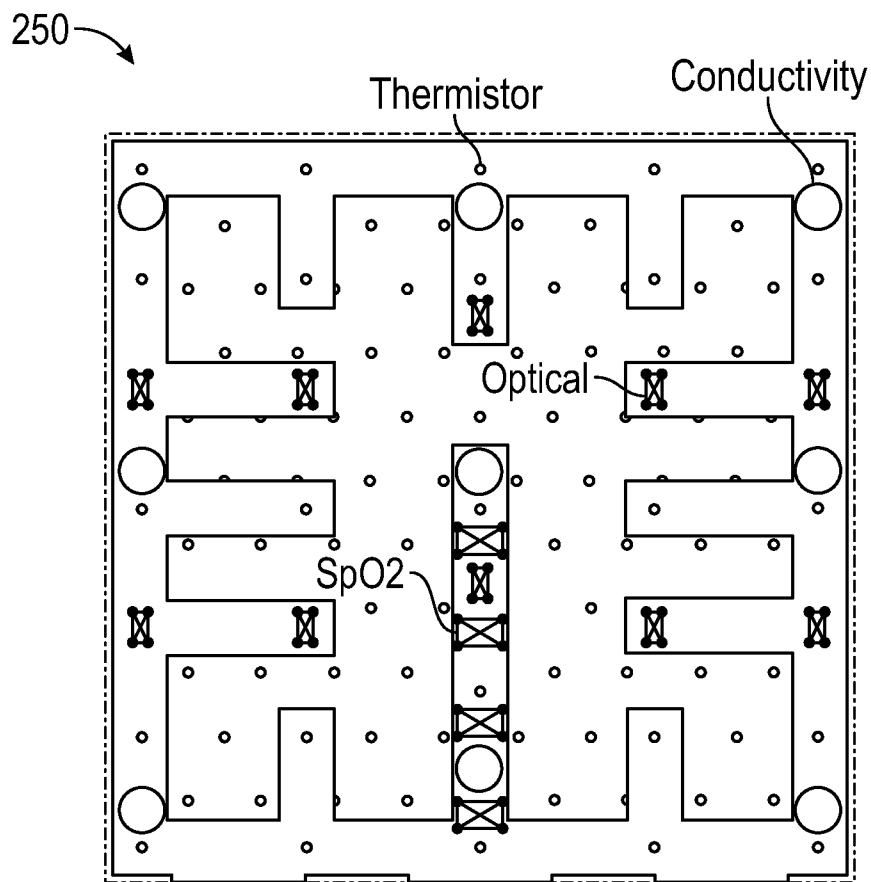


FIG. 2

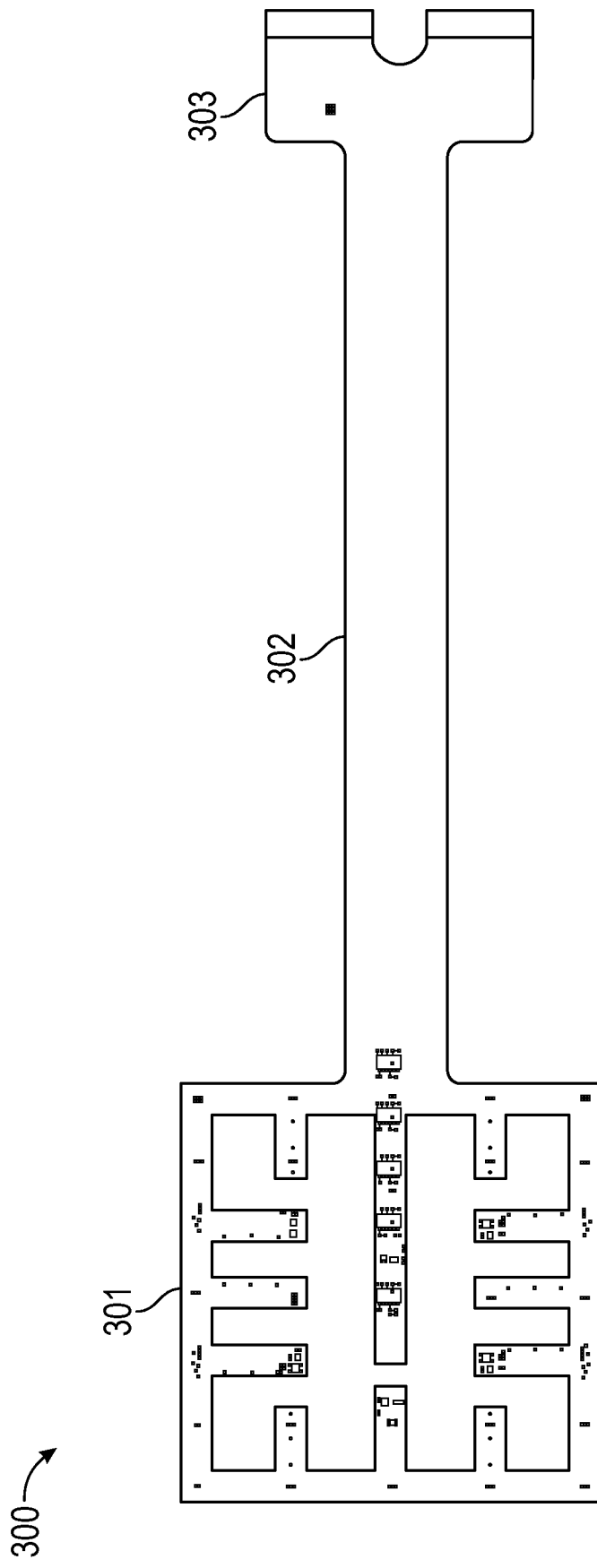


FIG. 3A

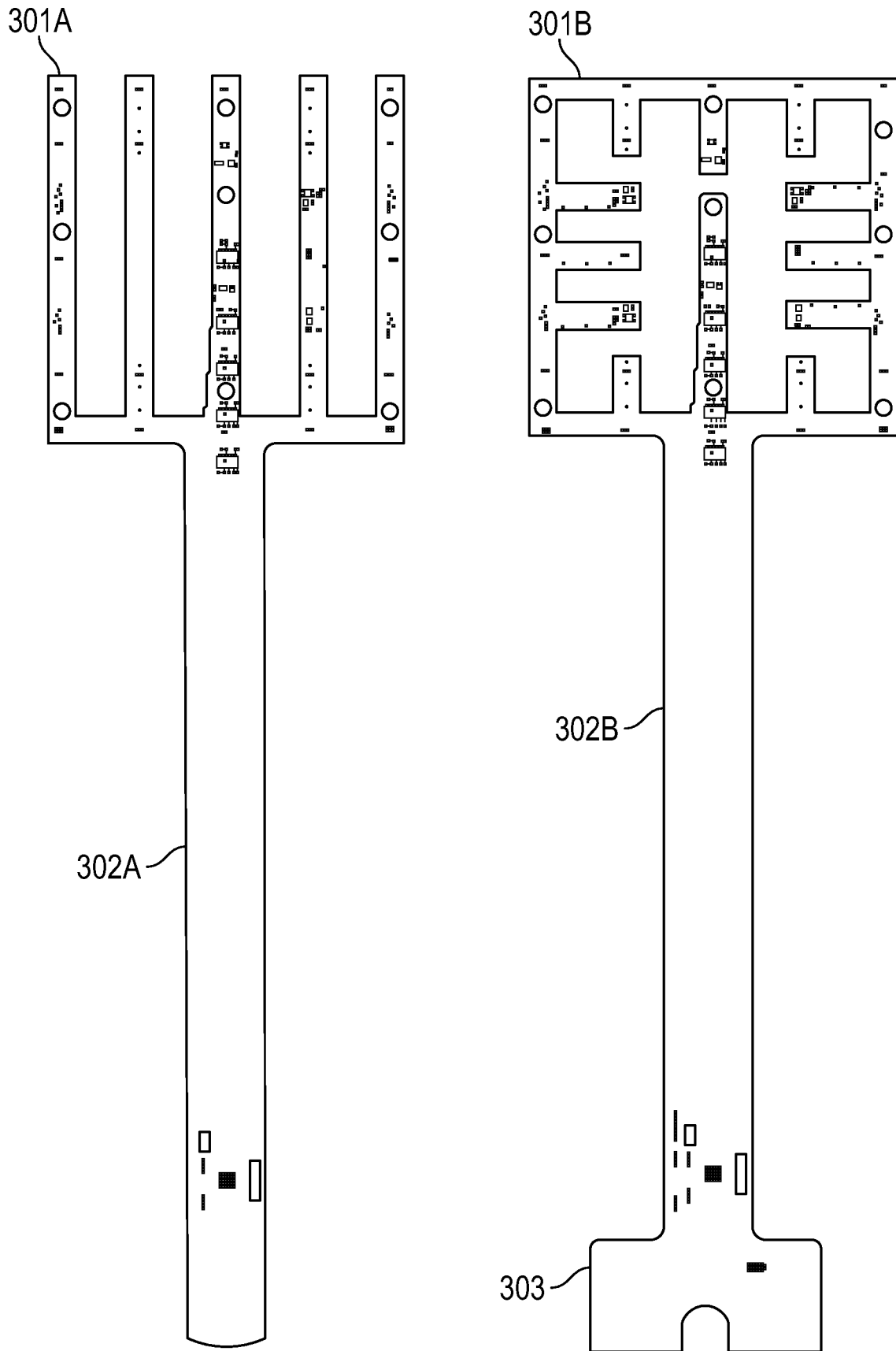


FIG. 3B

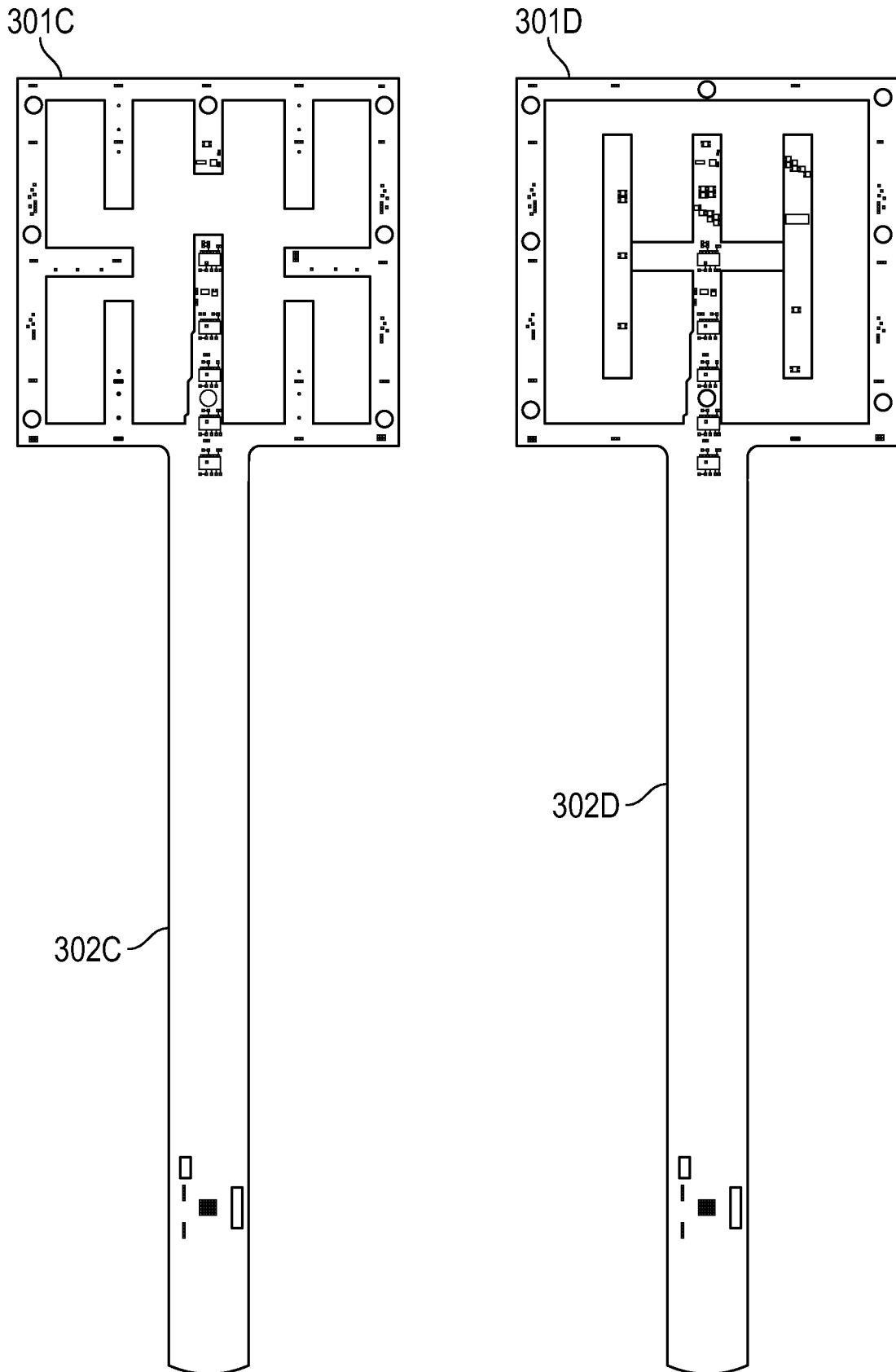


FIG. 3B
(Continued)

301B

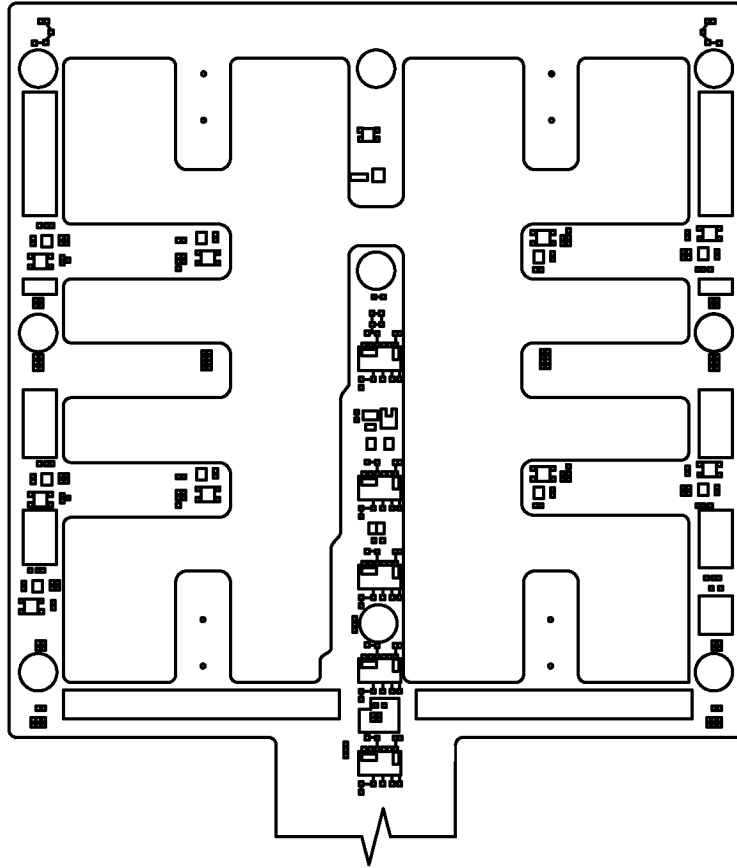


FIG. 3C

320

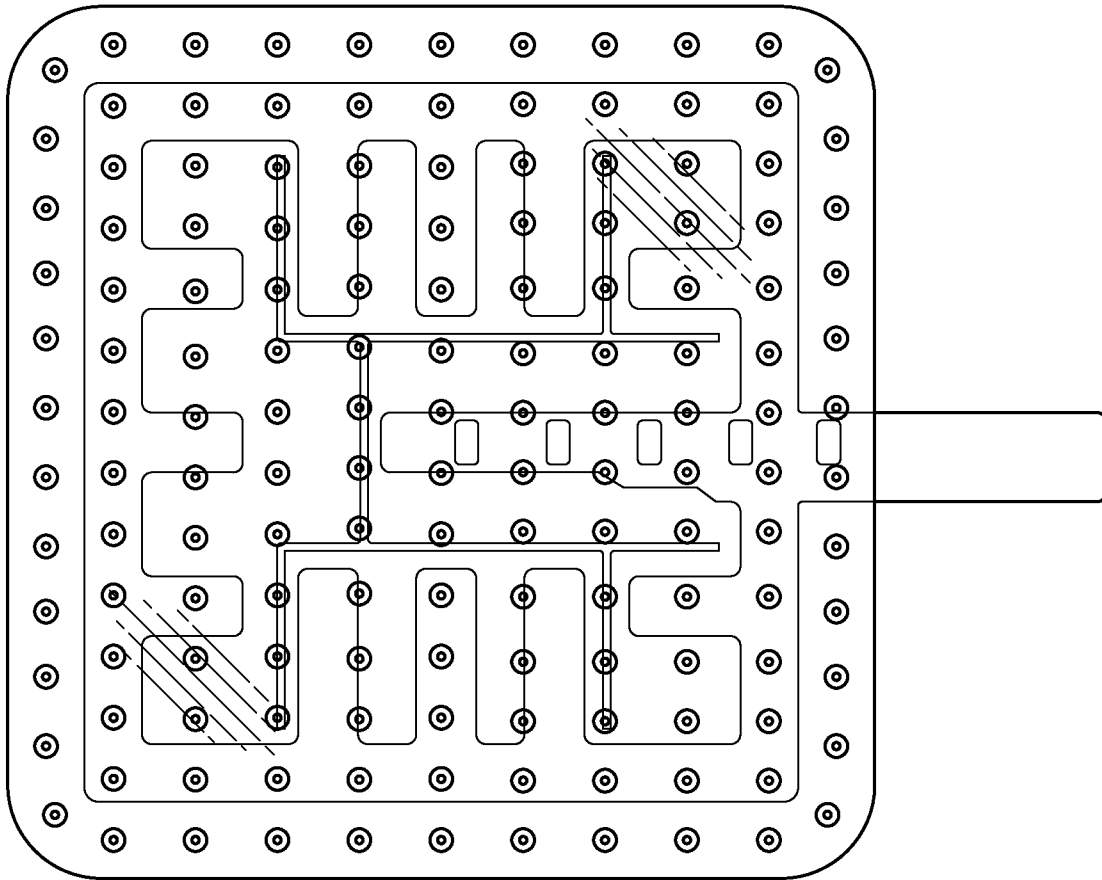


FIG. 3D

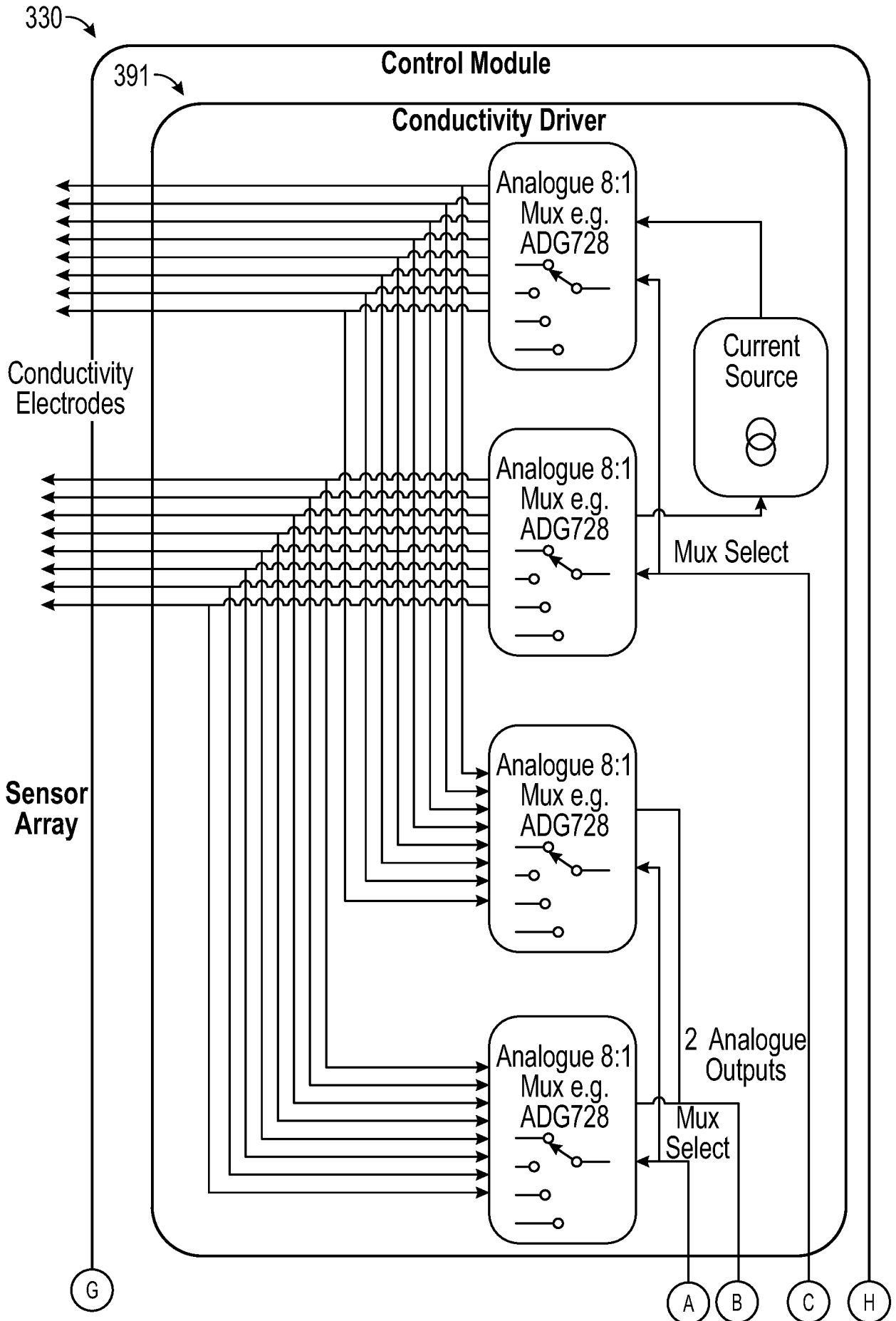


FIG. 3E

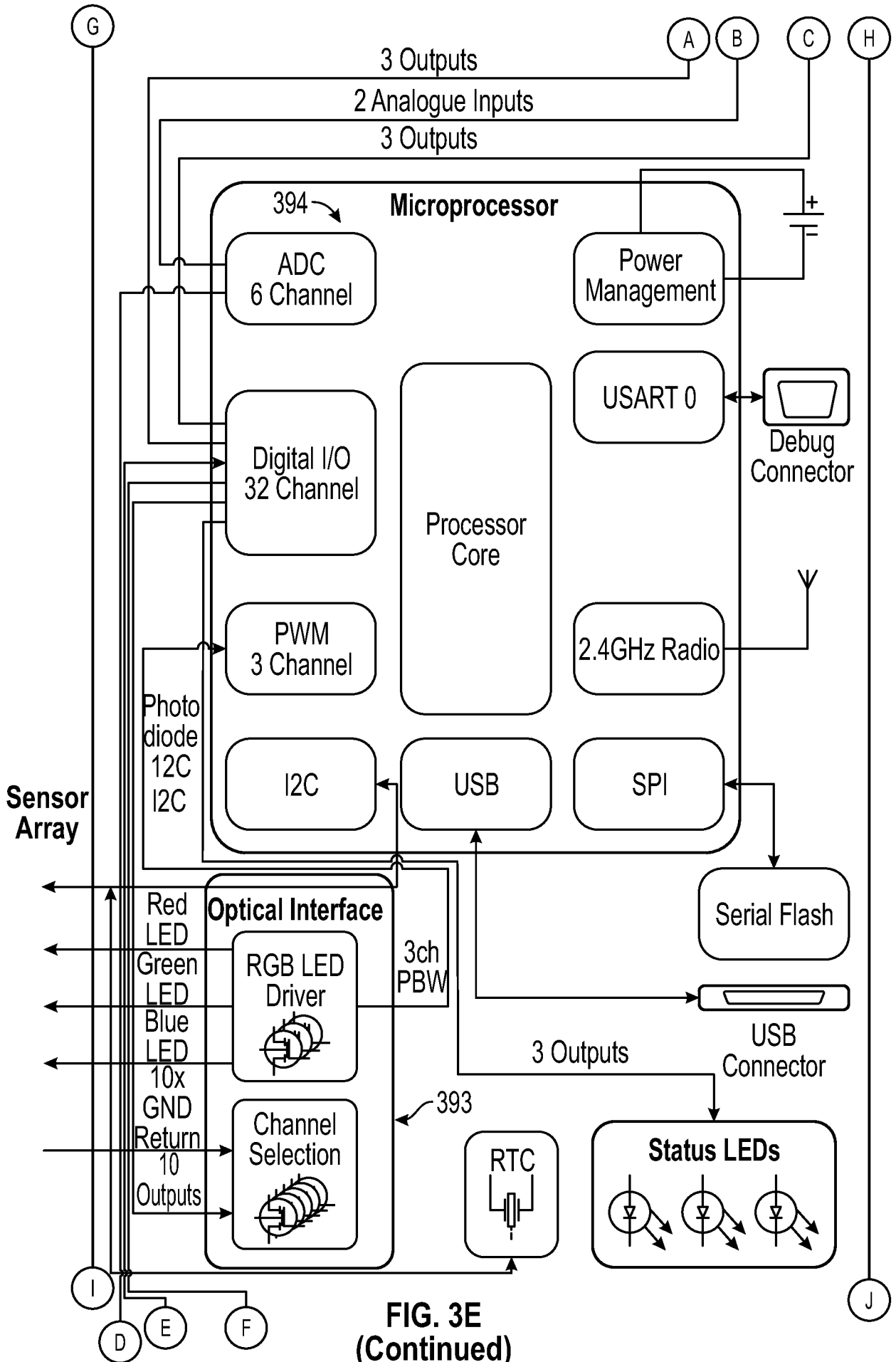


FIG. 3E
(Continued)

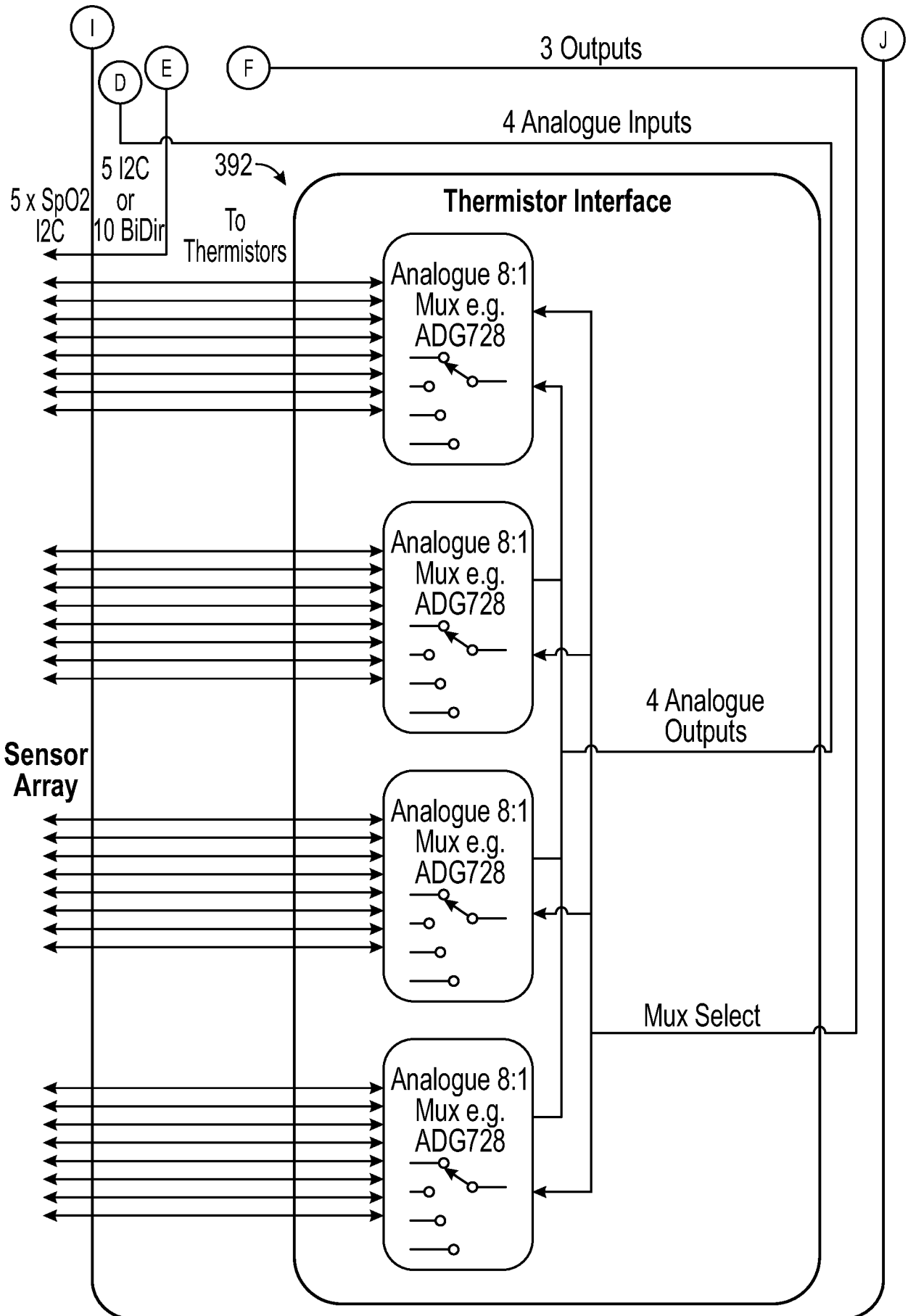


FIG. 3E
(Continued)

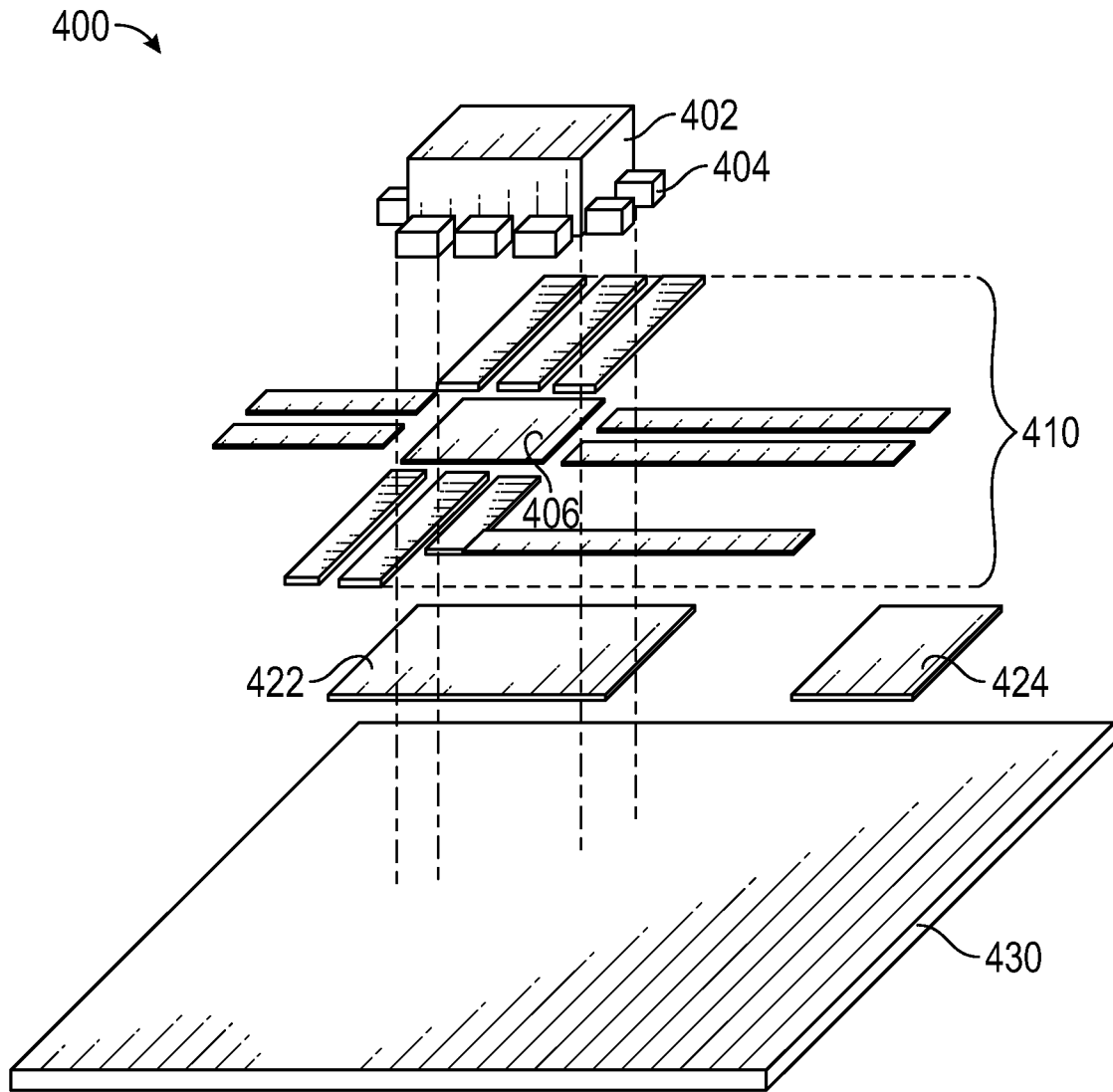


FIG. 4A

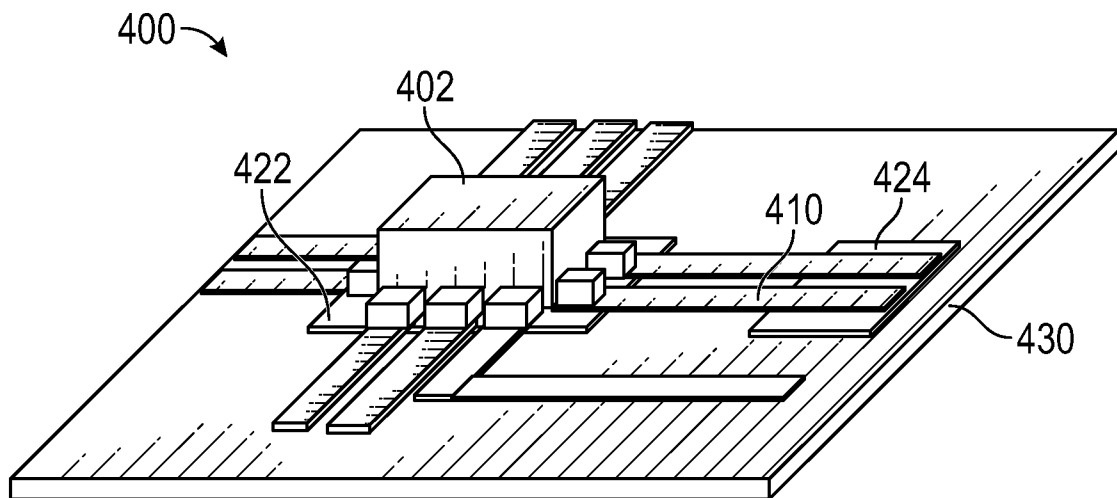


FIG. 4B

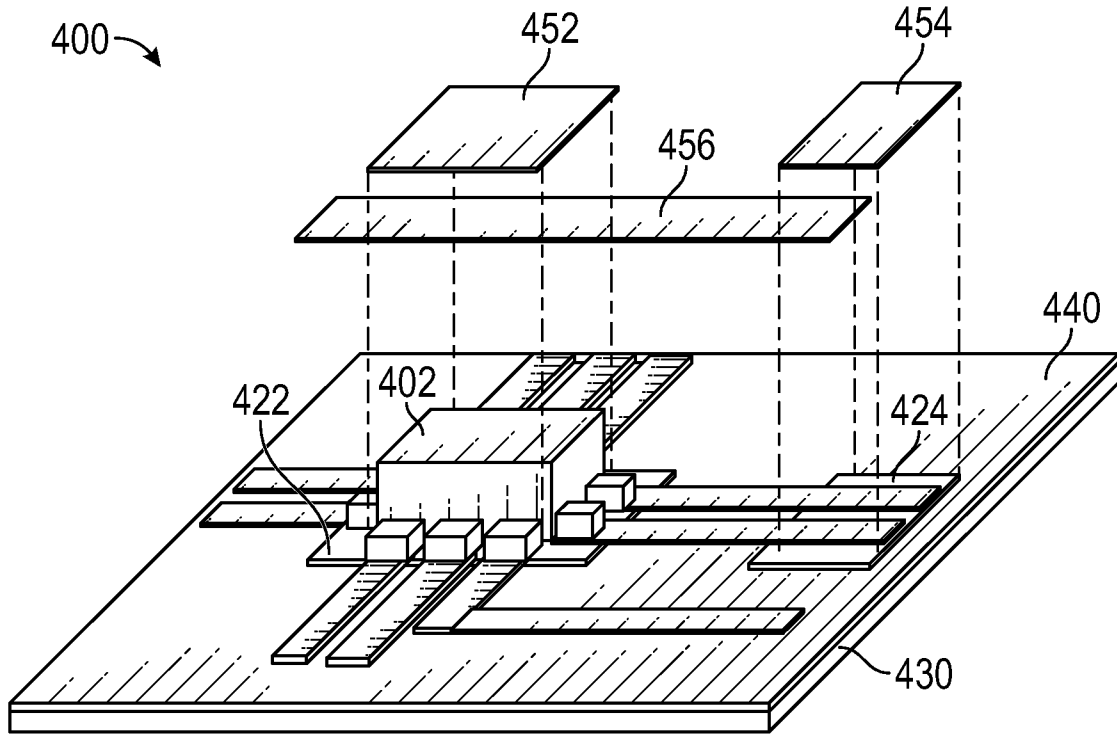


FIG. 4C

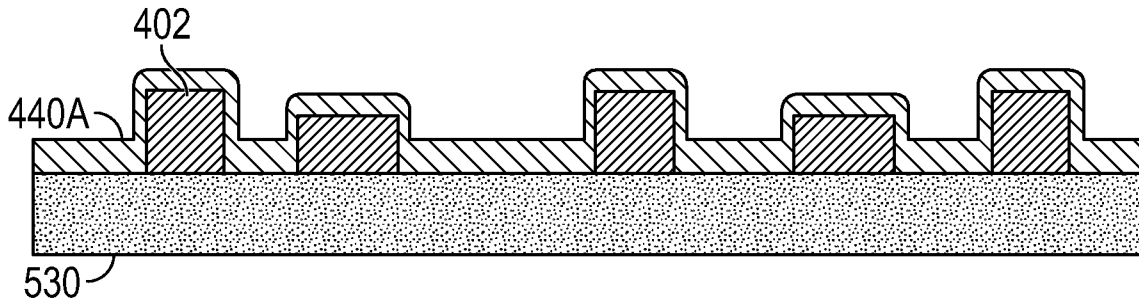


FIG. 5A

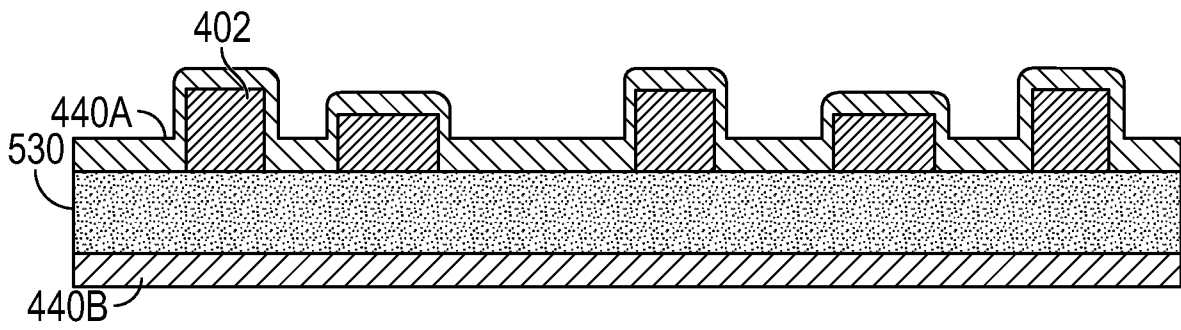


FIG. 5B

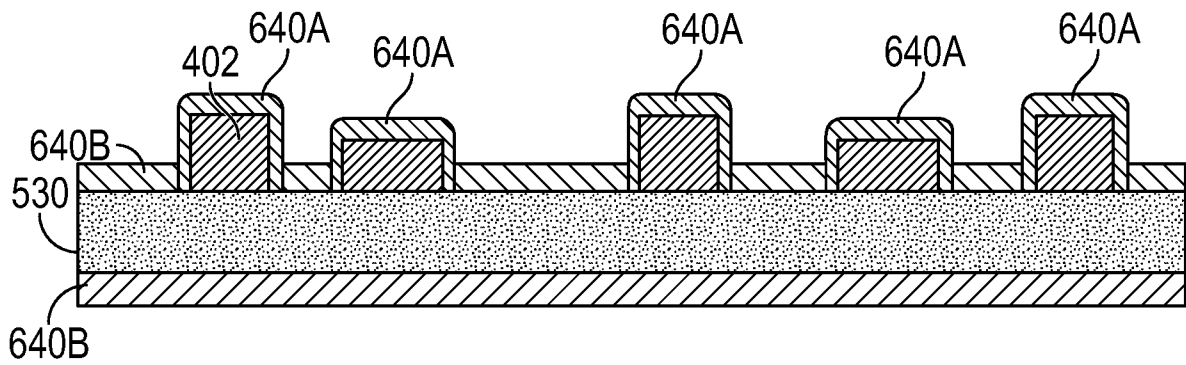


FIG. 6

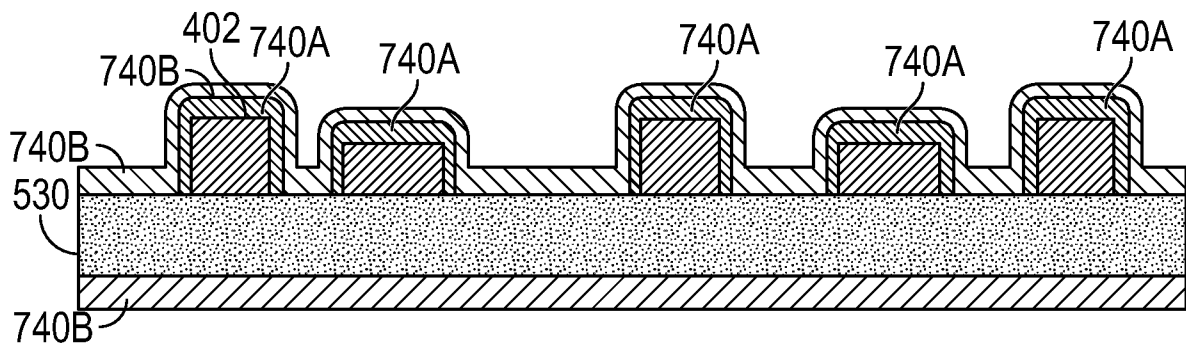


FIG. 7

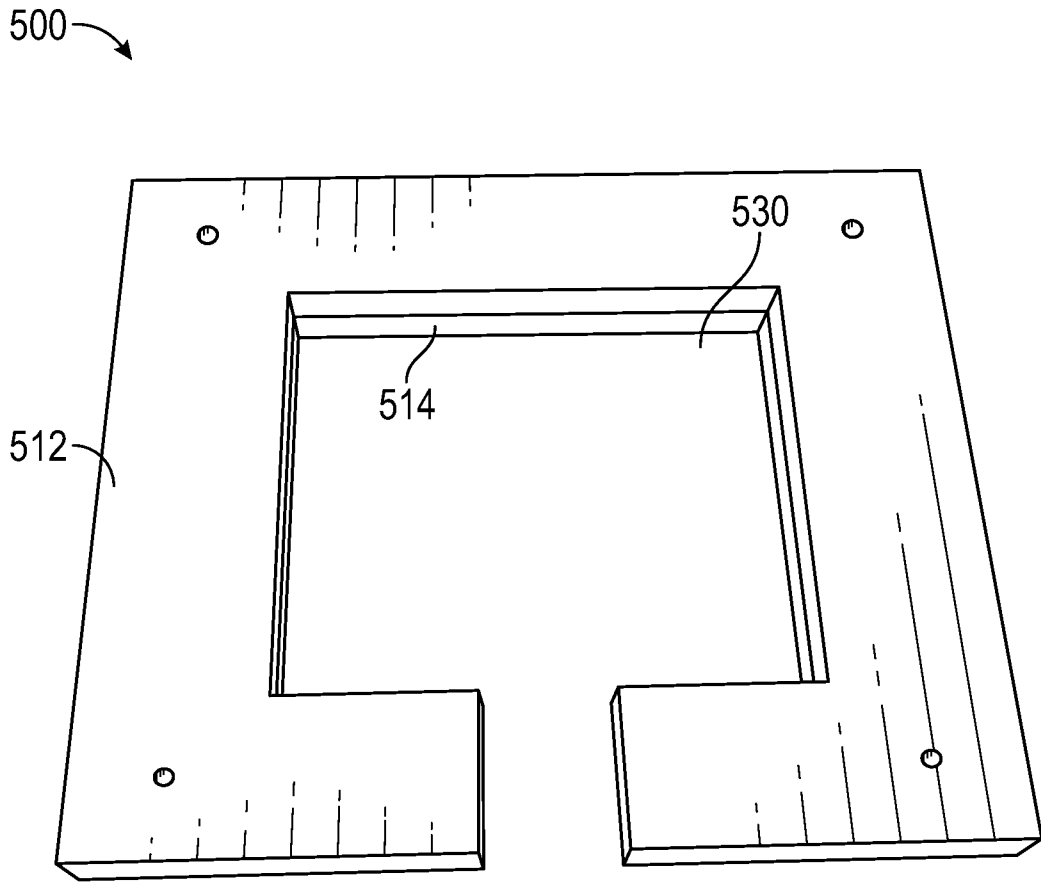


FIG. 8

600 →

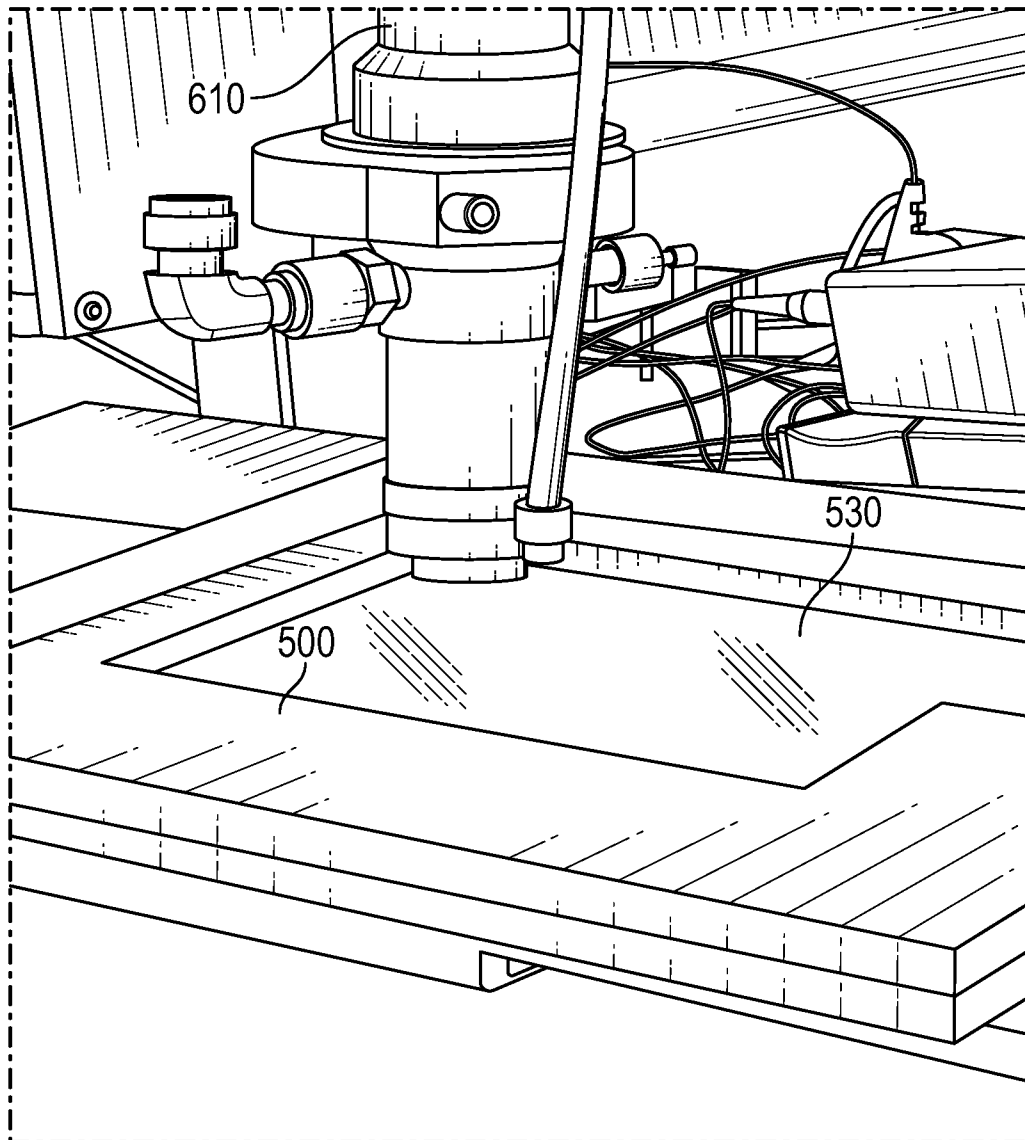


FIG. 9

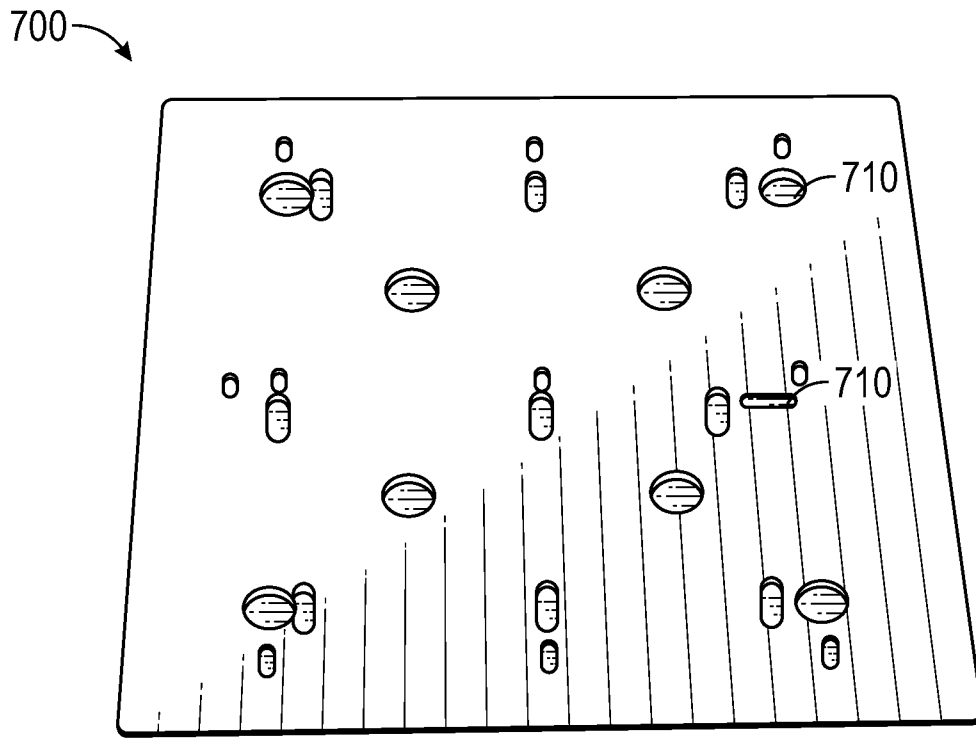


FIG. 10

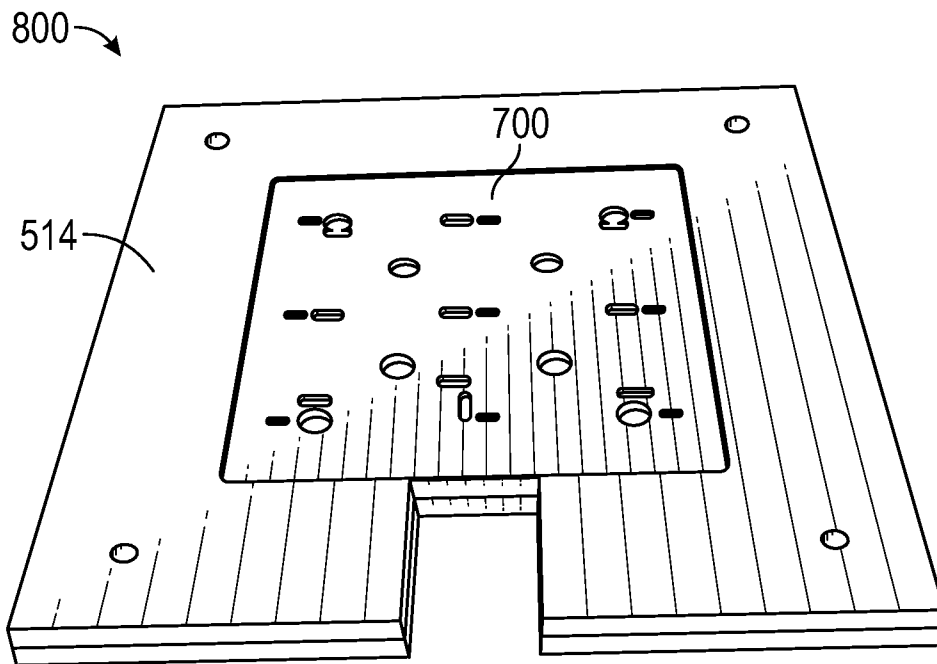


FIG. 11

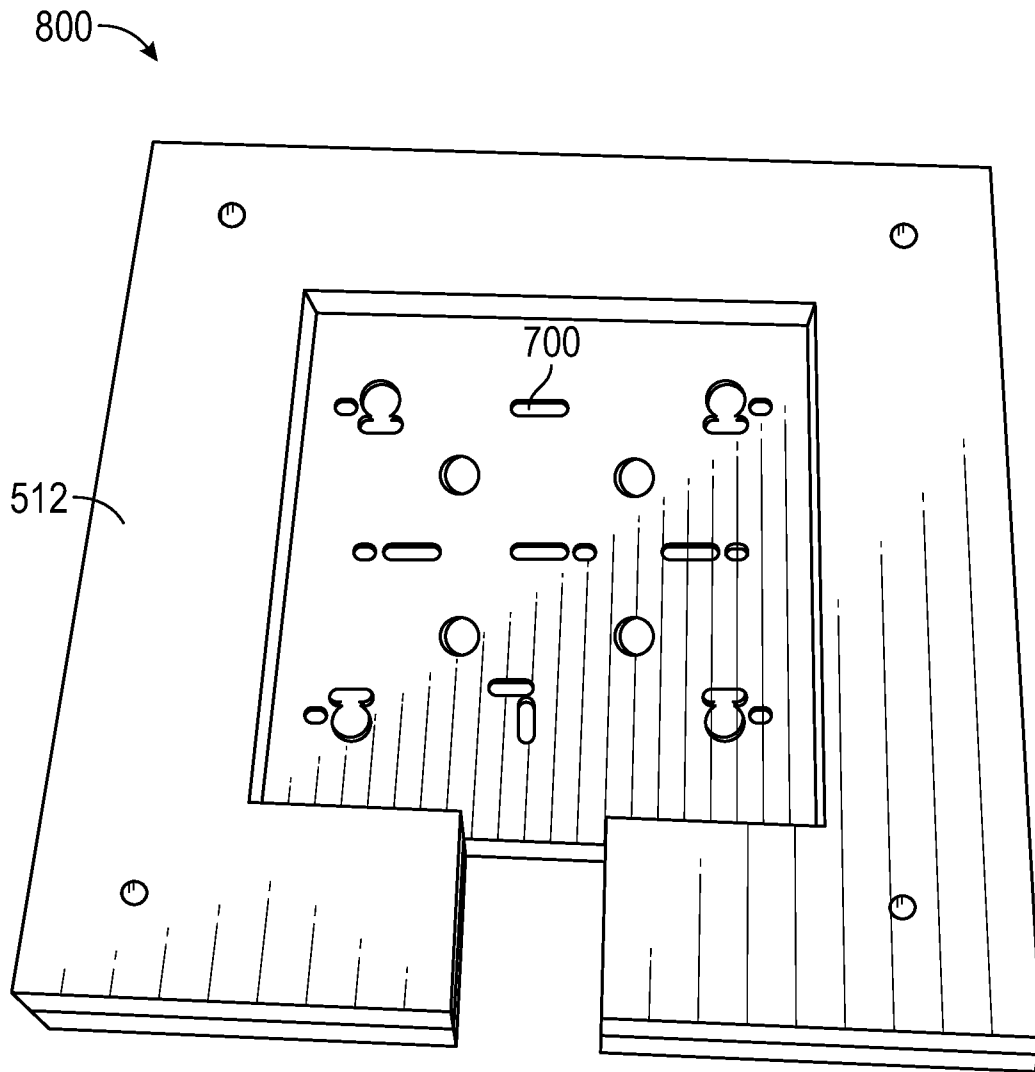


FIG. 12A

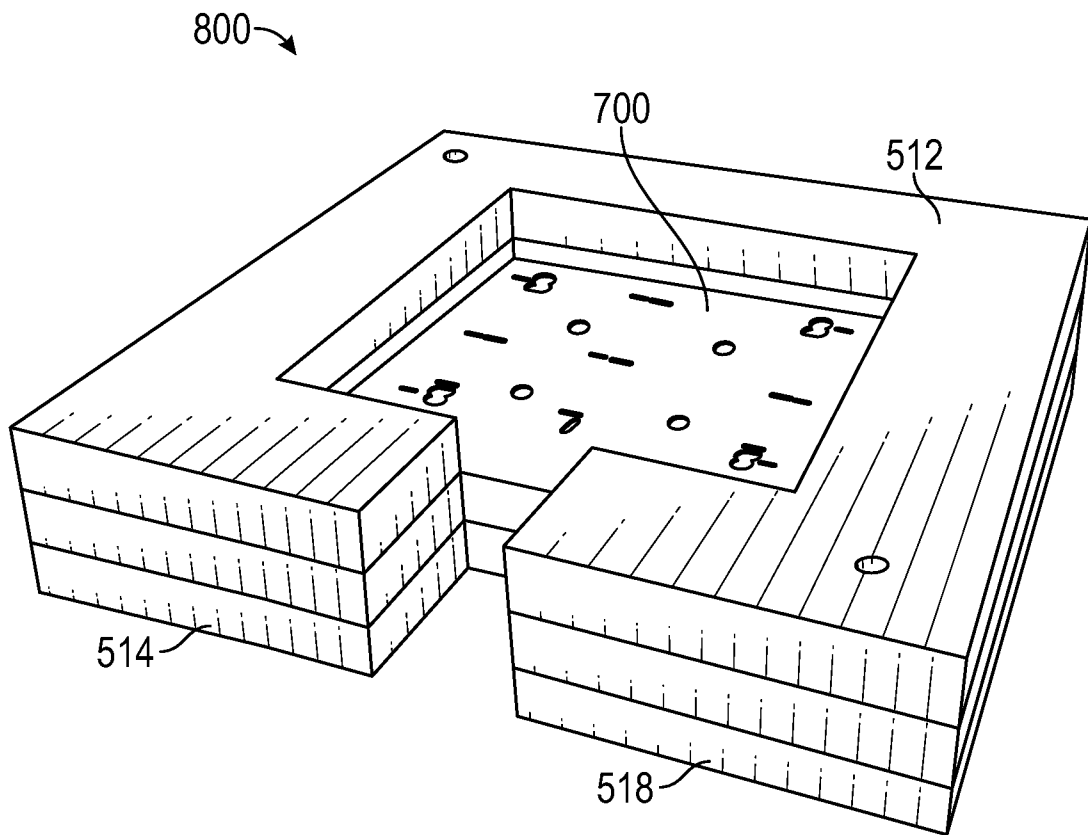


FIG. 12B

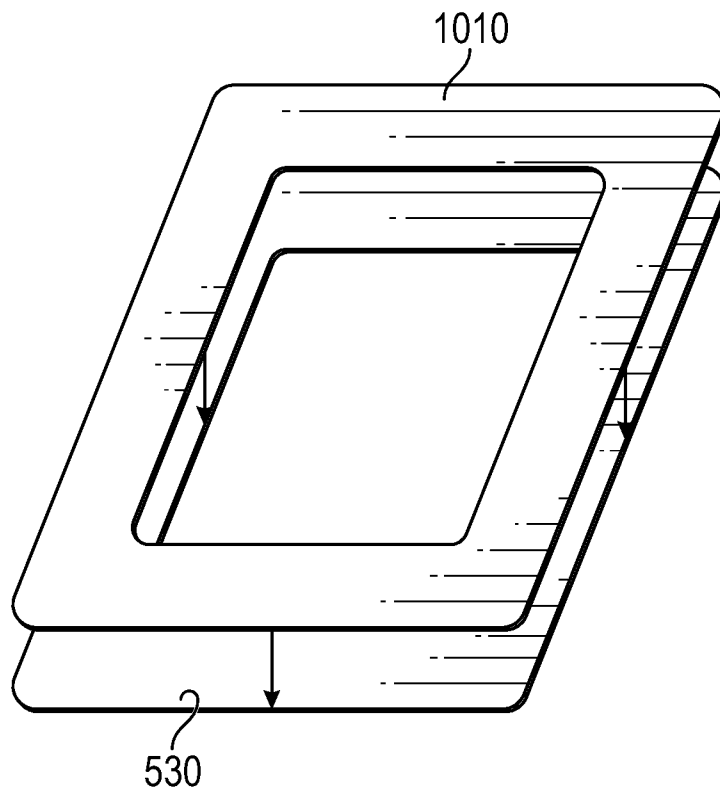


FIG. 13

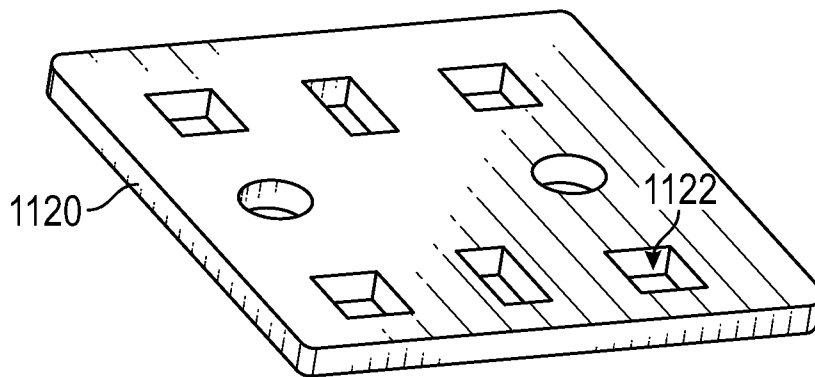
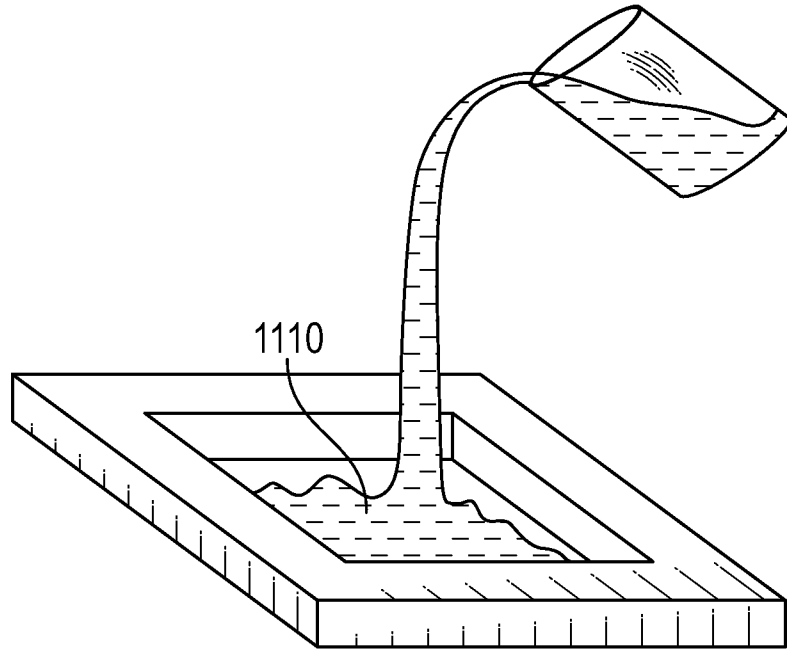


FIG. 14A

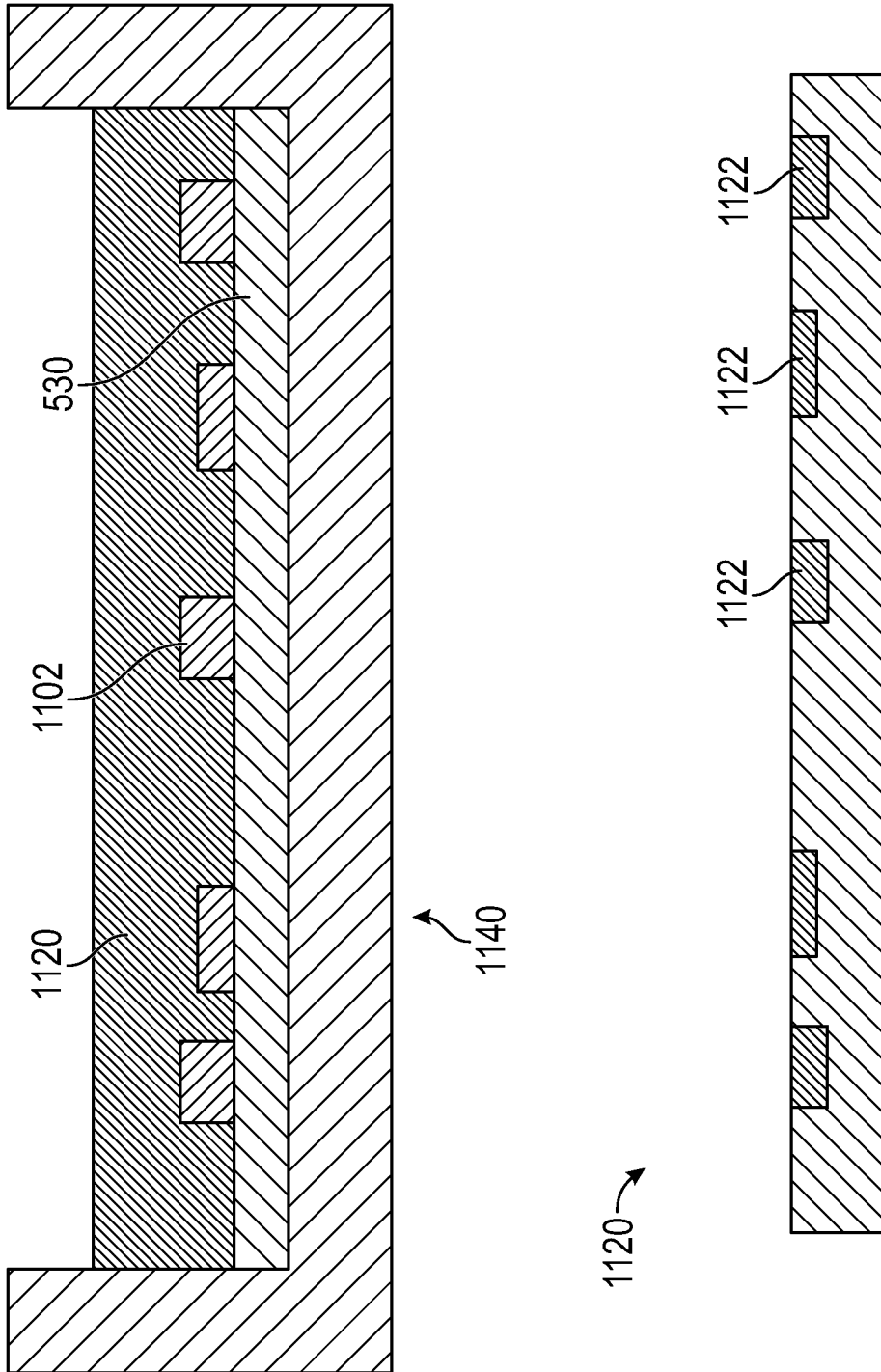


FIG. 14B

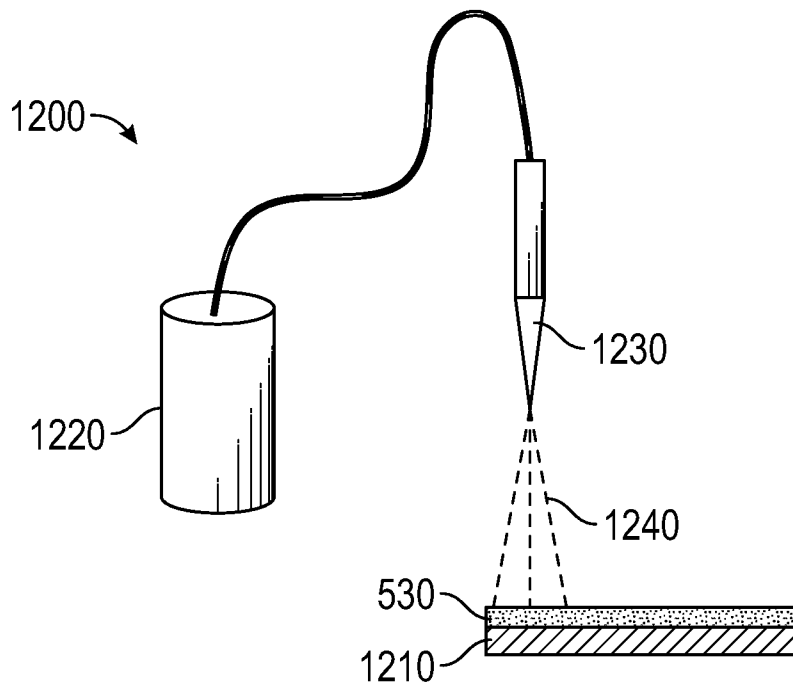


FIG. 15

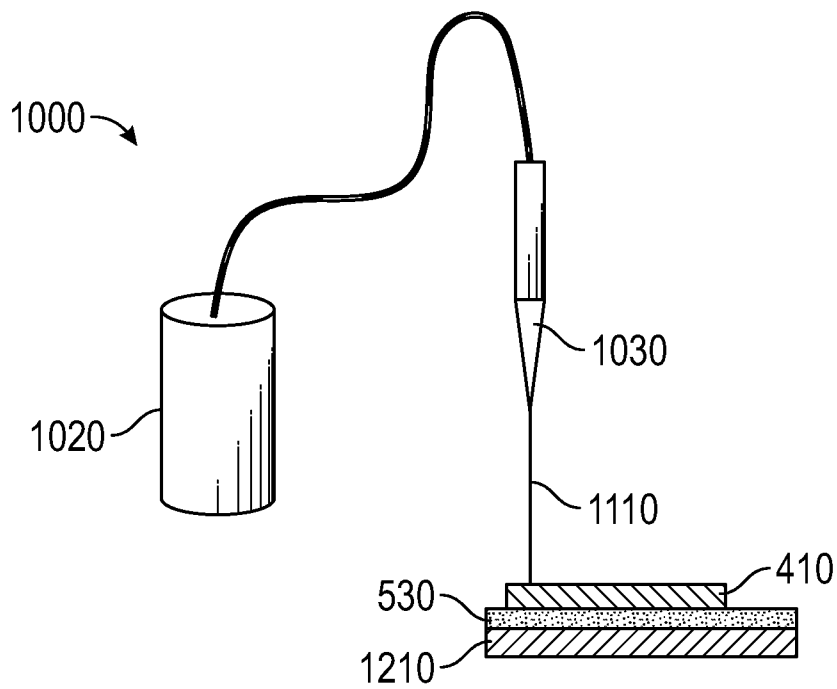


FIG. 16

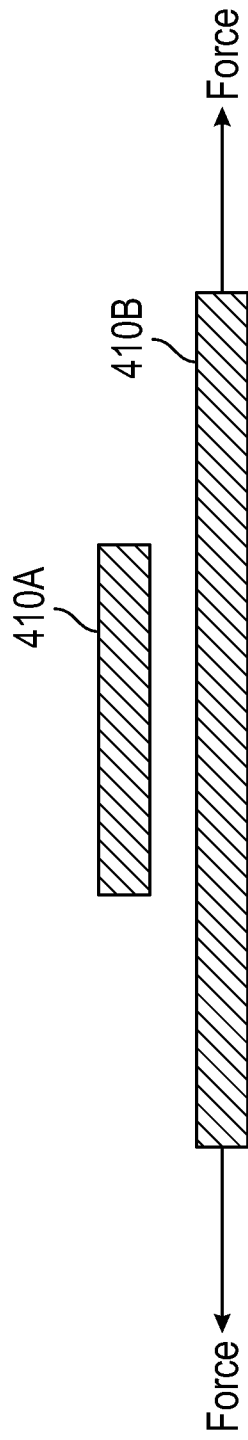


FIG. 17A

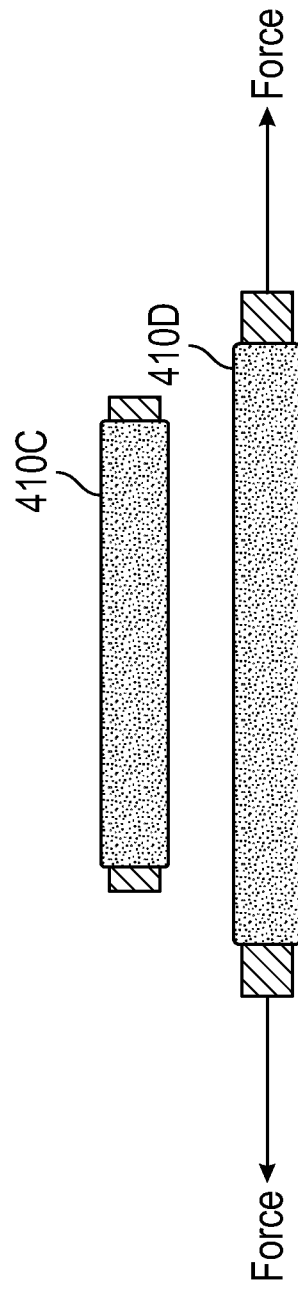


FIG. 17B

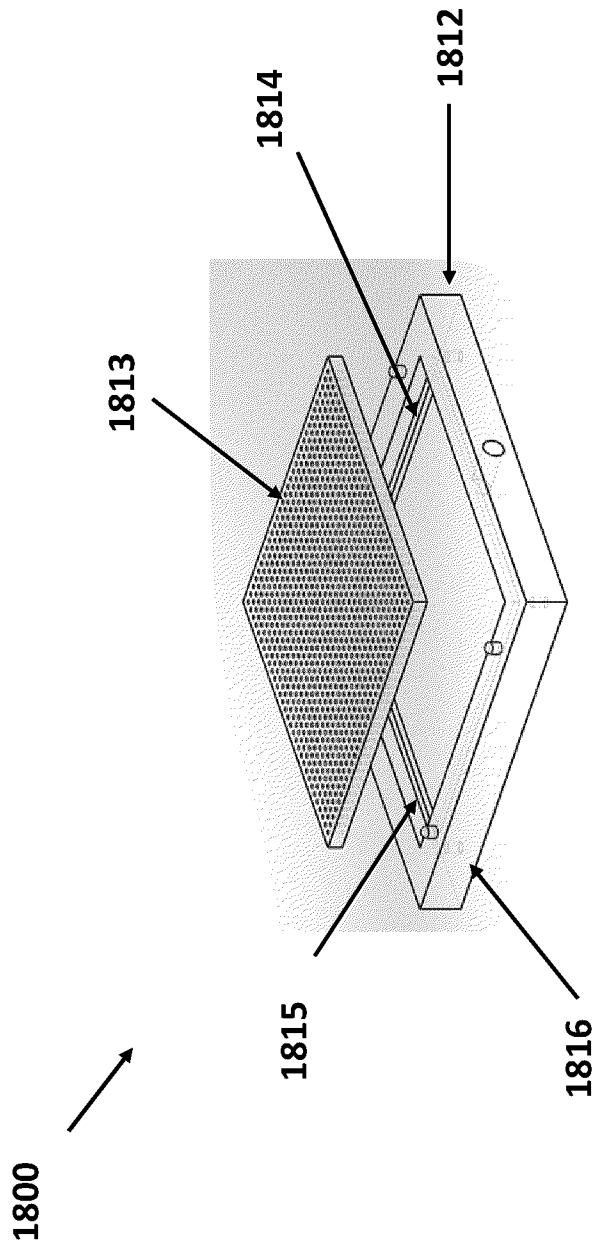


FIG. 18A

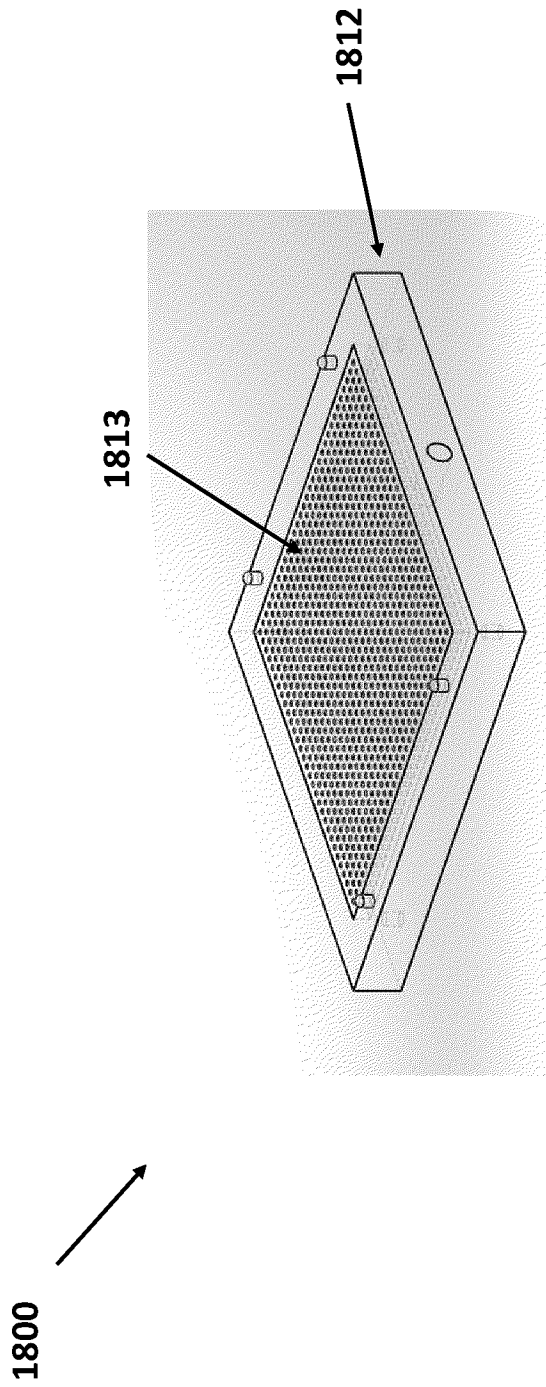


FIG. 18B

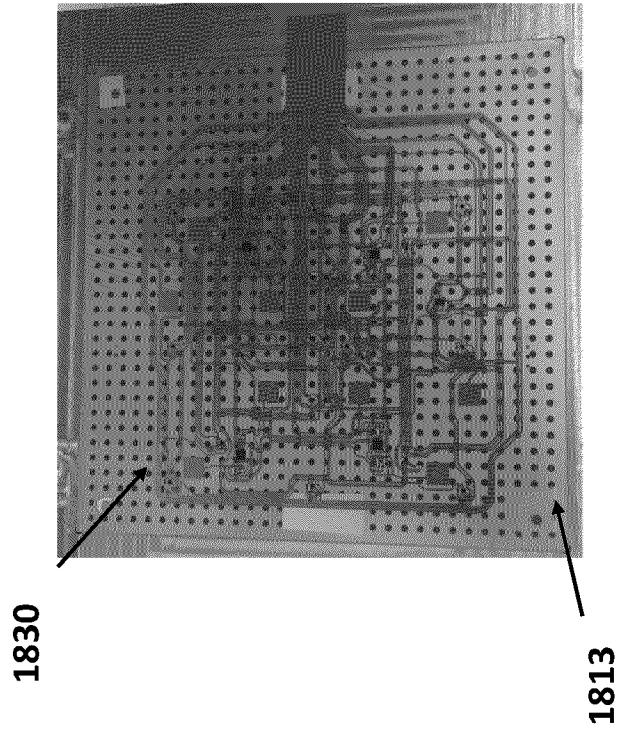


FIG. 18C

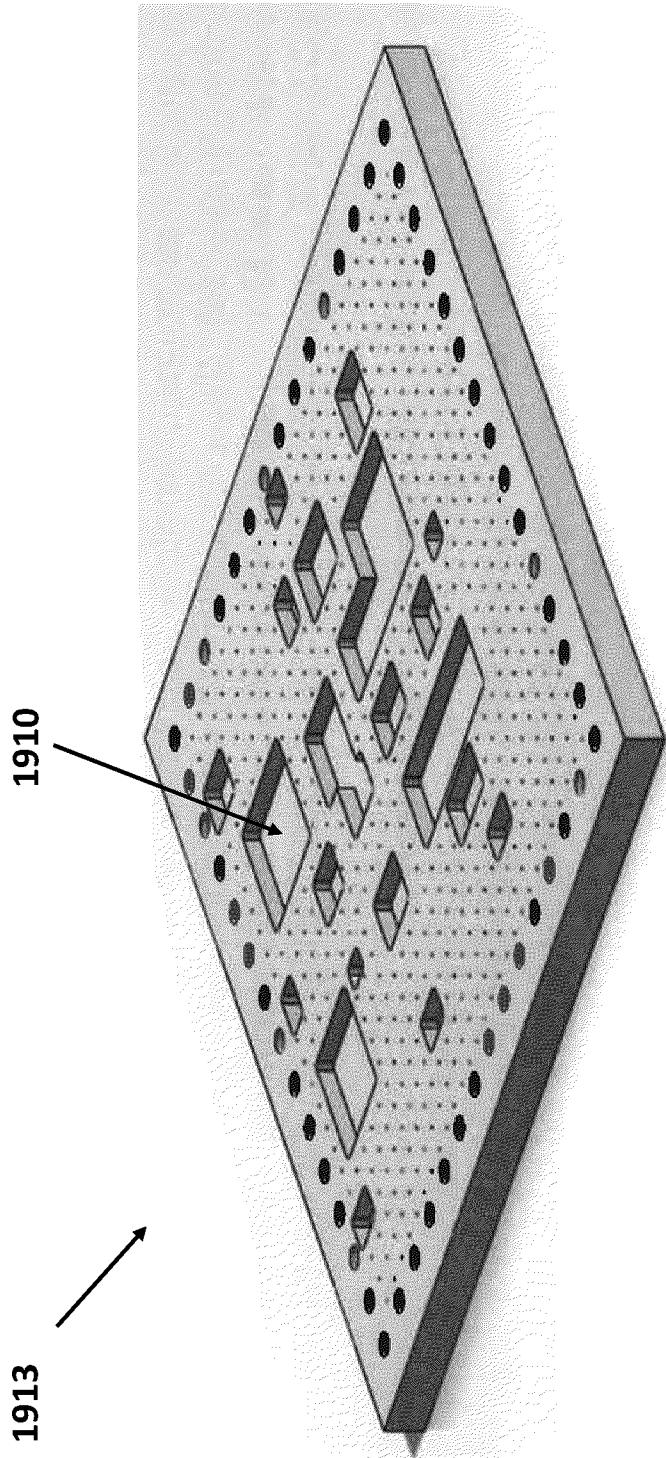


FIG. 19A

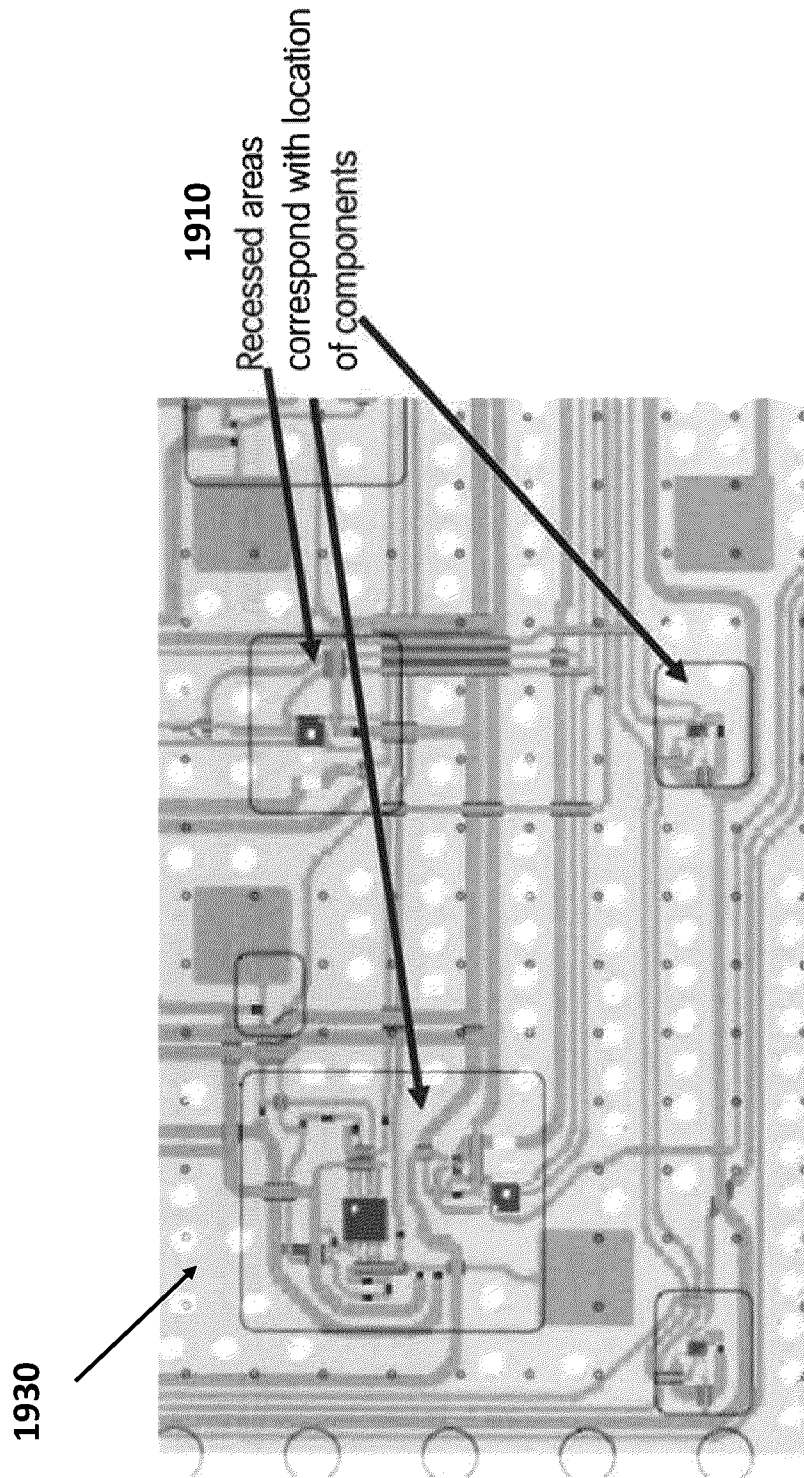


FIG. 19B

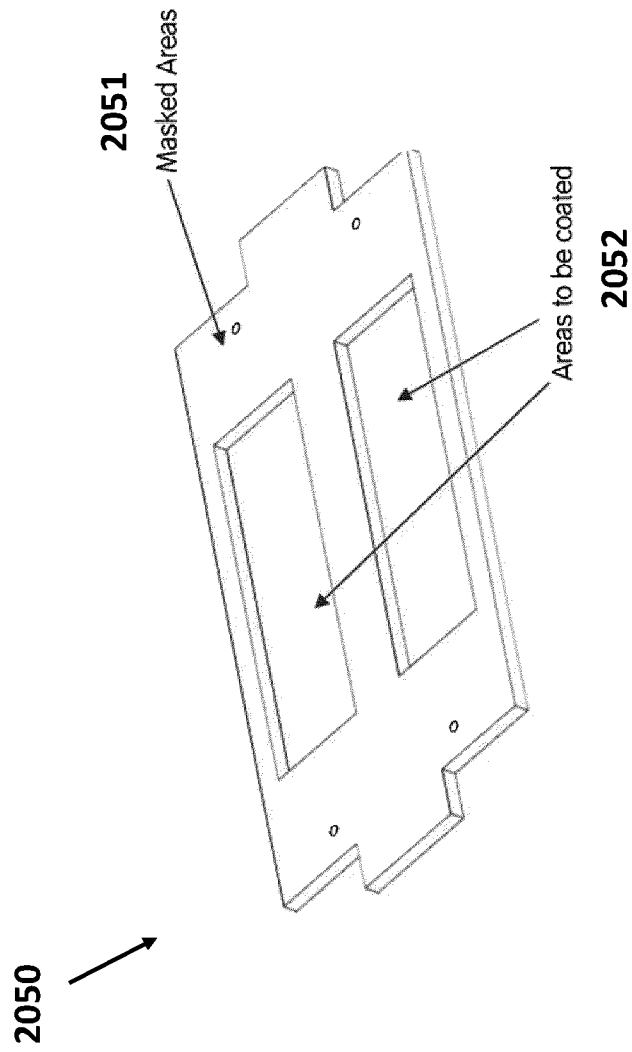


FIG. 20

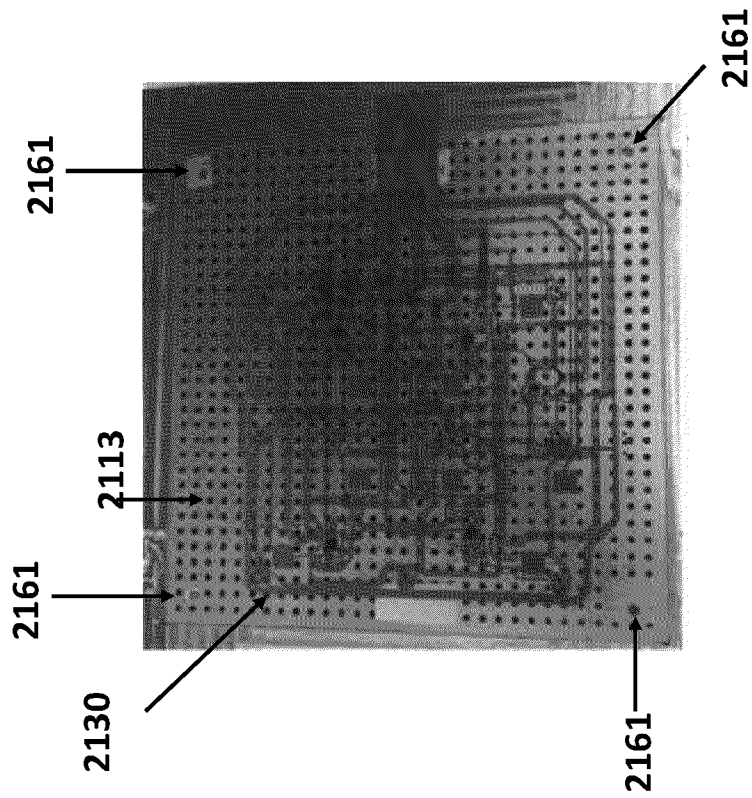


FIG. 21A

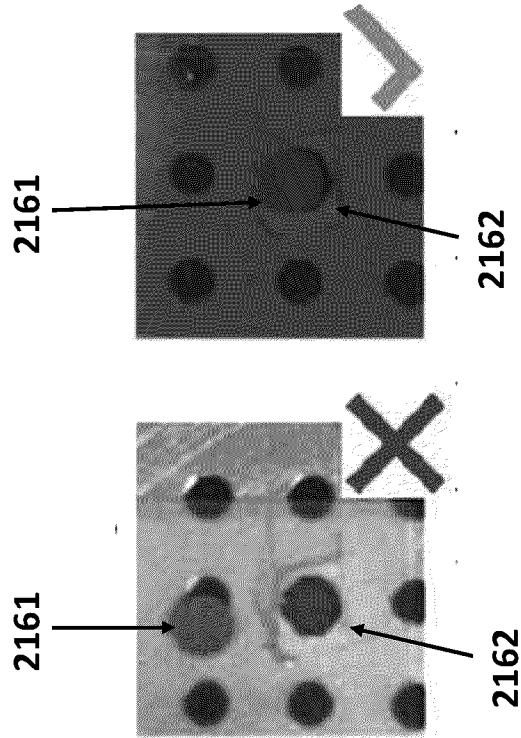


FIG. 21B

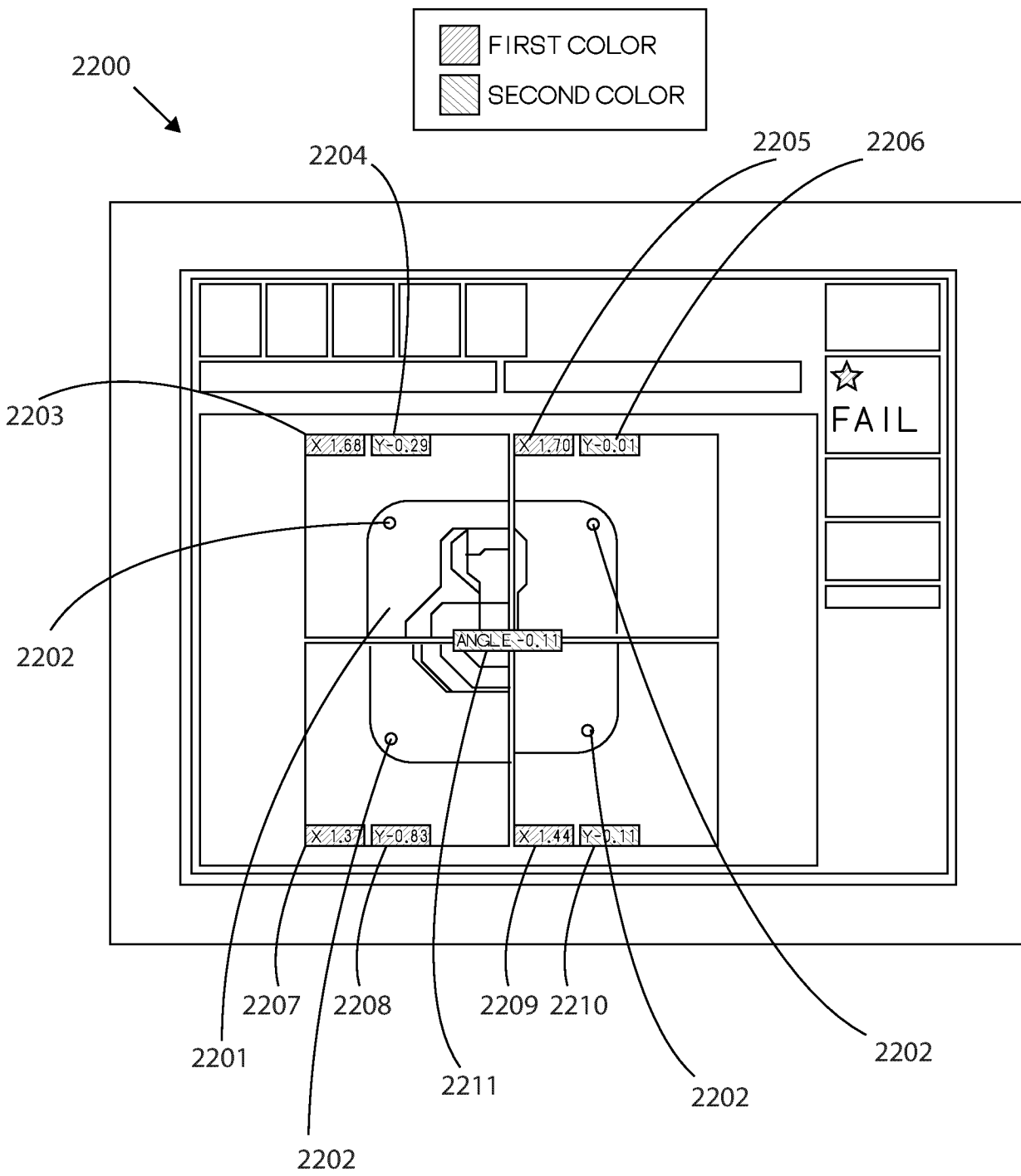


FIG. 22B

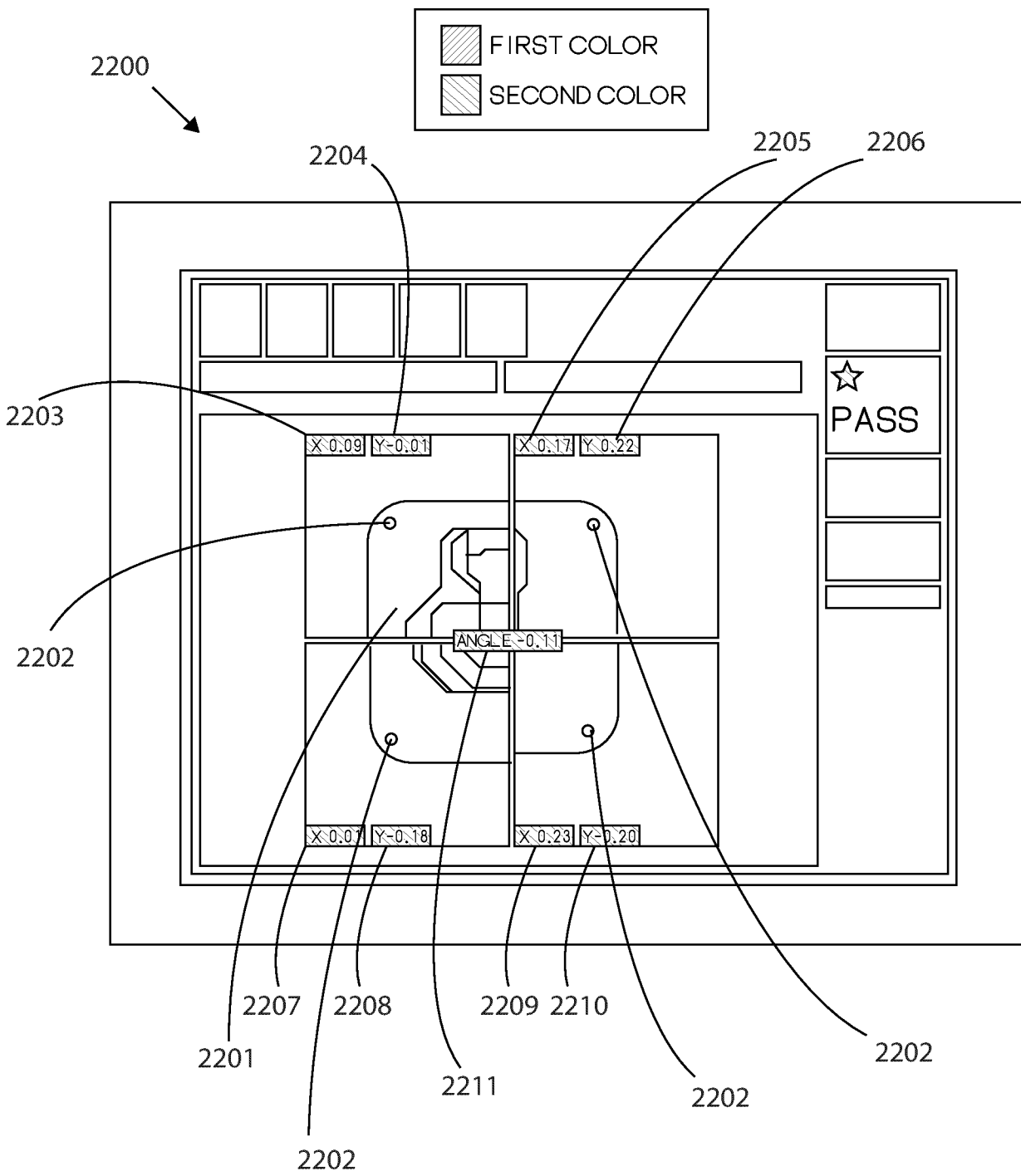


FIG. 22C