



(51) International Patent Classification:

A61B 5/02 (2006.01) *A61B 5/026* (2006.01)
A61B 5/022 (2006.01) *A61B 5/00* (2006.01)

(21) International Application Number:

PCT/EP2018/055940

(22) International Filing Date:

09 March 2018 (09.03.2018)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

1703775.5	09 March 2017 (09.03.2017)	GB
1703781.3	09 March 2017 (09.03.2017)	GB
1703783.9	09 March 2017 (09.03.2017)	GB

(71) Applicant: **SMITH & NEPHEW PLC** [GB/GB]; 15
Adam Street, London WC2N 6LA (GB).

(72) Inventors: **BROWNHILL, Varuni, Rachindra**; PO Box 81, 101 Hessle Road, Hull HU3 2BN (GB). **GRUBB, Scott**; Carlyle House, Carlyle Road, Cambridge CB4 3DN (GB). **HUNT, Allan, Kenneth, Frazer, Grugeon**; PO Box 81, 101 Hessle Road, Hull HU3 2BN (GB). **KNIGHT, Reece**; PO Box 81, 101 Hessle Road, Hull HU3 2BN (GB). **LAITENBERGER, Peter**; Carlyle House, Carlyle Road, Cambridge CB4 3DN (GB). **PARTINGTON, Lee**; PO Box 81, 101 Hessle Road, Hull HU3 2BN (GB). **PHILLIPS, Marcus, Damian**; PO Box 81, 101 Hessle Road, Hull HU3 2BN (GB).

(74) Agent: **ELLYATT, William**; Smith & Nephew, 101 Hessle Road, Hull East Yorkshire HU3 2BN (GB).

(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP,

(54) Title: DEVICE, APPARATUS AND METHOD OF DETERMINING SKIN PERFUSION PRESSURE

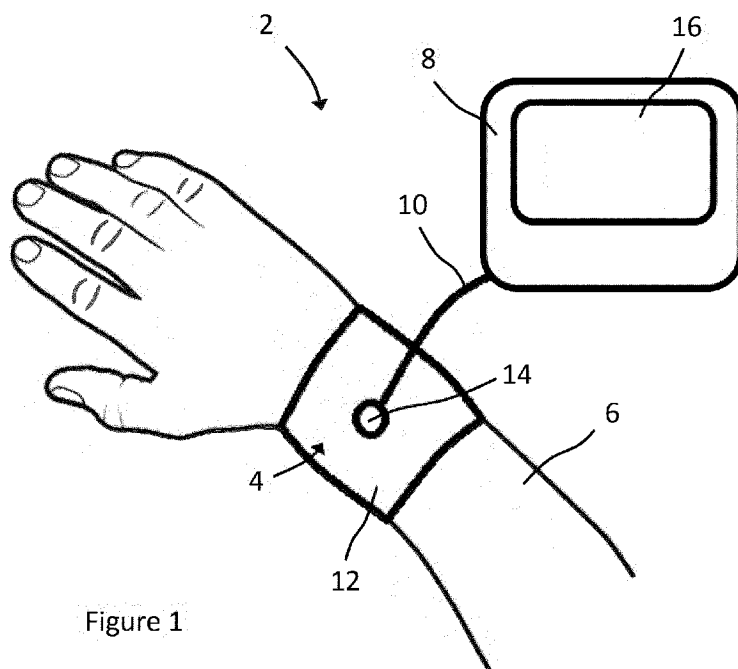


Figure 1

(57) Abstract: Disclosed embodiments relate to apparatuses and methods for a skin perfusion pressure determination device. In some embodiments, a skin perfusion pressure determination device can include a sensor module having a first sensor for sensing a first parameter associated with a pressure exerted on a target area by the sensor module and a second sensor for sensing a second parameter associated with an amount of blood perfusion at the target area. In some embodiments, the first sensor and the second sensor can be arranged such that, when the sensor module is pressed against the target area the first sensor produces an output corresponding to the sensed first parameter and the second sensor produces an output corresponding to the sensed second parameter.

KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

- with international search report (*Art. 21(3)*)
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (*Rule 48.2(h)*)

(88) Date of publication of the international search report:

18 October 2018 (18.10.2018)

DEVICE, APPARATUS AND METHOD OF DETERMINING SKIN PERFUSION PRESSURE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to Patent Application No. GB 1703775.5, filed on March 9, 2017, Patent Application No. GB 1703781.3, filed March 9, 2017, and Patent Application No. GB 1703783.9, filed on March 9, 2017. All of these applications are hereby incorporated by reference in their entireties and made part of this disclosure.

FIELD

[0002] Embodiments described herein relates to a skin perfusion pressure determination device, apparatus and method of determining skin perfusion pressure.

BACKGROUND

[0003] Wound healing is natural process performed by the human body in response to injury. The amount of time taken for a wound to heal is dependent on many different factors which include the human body's ability to heal itself and any treatments that are applied to the wound to accelerate wound healing. Understanding the healing status of a wound and being able to monitor the healing process helps to inform decisions on further treatment of the wound and can also assist in the development of future wound therapies.

[0004] One factor that is known to be correlated with wound healing is the Skin Perfusion Pressure (SPP) in tissue adjacent the wound. SPP is the amount of pressure required to restore blood flow to blood vessels within skin tissue following a controlled occlusion of the blood vessels using a blood pressure cuff.

[0005] Techniques for detecting the restoration of blood flow include radioisotope clearance, laser doppler flow measurement and photoplethysmography. Such techniques are typically performed by clinicians and require instrumentation that is often bulky, complicated and expensive.

[0006] Additionally, a wound dressing is typically applied to a wound in order to protect the wound from pathogens, assist healing of the wound and to protect the area of the wound from further injury. In order to assess healing, the tissue in and around the wound may be inspected periodically. Inspection can be carried out by a clinician using the naked eye, but may also be carried out using optical devices that analyze the appearance of the wounded area to determine the state of the wound. To access the wounded area, the wound dressing

must be removed. This is time consuming, inconvenient and often uncomfortable for the patient. Moreover, the original dressing is usually replaced by a fresh dressing even though the old dressing may not have needed replacing at the time of inspection

[0007] In order to assess healing, a probe or other form of inspection device may be used to measure a parameter associated with wound healing at various points about the perimeter of the wound dressing. One example is the measurement of the amount of blood perfusion in the tissue surrounding the wound. The amount of blood perfusion will, however, vary about the periphery of the wound dressing. For example, the amount of blood perfusion of tissue at the periphery of a wound to a forearm may be greater in tissue closer to the elbow than in tissue closer to the wrist. Repeated measurements at different locations by clinicians can therefore produce results which are inconsistent and unreliable for determining the status of the healing process.

SUMMARY

[0008] It is an aim of the embodiments described herein to at least partly mitigate the above-mentioned problems.

[0009] It is an aim of certain embodiments to provide a skin perfusion pressure determination device, apparatus and a method of determining skin perfusion pressure for determining skin perfusion pressure at a target area.

[0010] Additionally, certain embodiments include a wound dressing which facilitates convenient inspection of the area of a wound without the inspection process being time consuming or uncomfortable for the patient.

[0011] Certain embodiments can provide a wound dressing which can be applied to a patient's wound in a predetermined orientation such that inspection of skin tissue in the vicinity of the wound can be conducted reliably, consistently and repeatedly.

[0012] Embodiments of the present disclosure relate to apparatuses and methods for wound treatment. Embodiments of the present disclosure provide a skin perfusion pressure determination device, apparatus and a method of determining skin perfusion pressure for determining skin perfusion pressure at a target area.

[0013] According to a some embodiments, there is provided a skin perfusion pressure determination device comprising a sensor module having a first sensor for sensing a first parameter associated with a pressure exerted on a target area by the sensor module and a second sensor for sensing a second parameter associated with an amount of blood perfusion at the target area, wherein the first sensor and the second sensor are arranged such that, when

the sensor module is pressed against the target area the first sensor produces an output corresponding to the sensed first parameter and the second sensor produces an output corresponding to the sensed second parameter.

[0014] The first sensor may comprise a force sensor arranged to determine the force exerted by the sensor module on the target area.

[0015] The force sensor may be arranged such that when the sensor module is pressed against the target area, the second sensor is disposed between the target area and the force sensor.

[0016] The second sensor may comprise a light source and an optical detector arranged to receive light emitted by the light source which has been reflected by the target area.

[0017] The light source may comprise at least one light emitting diode and the optical detector comprises at least one photodetector. The second sensor may be a pulse sensor.

[0018] The device may be a portable device comprising a probe portion. The probe portion may comprise the sensor module.

[0019] The probe portion may comprise a pad portion having a lower surface which, in use, is pressed against the target area.

[0020] The device may be a portable device comprising a cuff portion for wrapping about a limb of a patient, the sensor module is arranged on an inner portion of the cuff.

[0021] The cuff may be inflatable. The cuff may be configured such that inflation of the cuff presses the sensor module against the target area.

[0022] The cuff may be manually actuated. The cuff may be configured to be inflated by an electromechanical actuator or fluid-based inflation device.

[0023] The device may comprise a wound dressing. The sensor module may be integral with the wound dressing.

[0024] The wound dressing may comprise an actuator arranged to press the sensor module against the target area.

[0025] The skin perfusion pressure determination device may further comprise a processor for processing an output of the first sensor and an output of the second sensor. The processor may be configured to determine that the output of the second sensor satisfies a predetermined condition associated with a predetermined amount of blood perfusion at the target area.

[0026] The predetermined condition may be a condition which corresponds to an amount of blood perfusion at the target area which exceeds a predetermined threshold.

[0027] The predetermined condition may be a condition that corresponds to the presence of a pulsatile component of blood flow at the target area.

[0028] The processor may be configured to produce an output which represents a pressure exerted on the target area by the sensor module when the second parameter satisfies the predetermined condition.

[0029] The skin perfusion pressure determination device may further comprise a memory for storing at least one of the predetermined condition and the output of the processor.

[0030] According to some embodiments, there is provided apparatus comprising the skin perfusion pressure determination device of the first aspect of the disclosure, wherein the apparatus comprises a display for displaying information representing at least one output of the first sensor and the second sensor.

[0031] According to some embodiments, there is provided a method of determining skin perfusion pressure comprising the steps: pressing a sensor module against a target area, wherein the sensor module has a first sensor for sensing a first parameter associated with a pressure exerted on a target area by the sensor module and a second sensor for sensing a second parameter associated with an amount of blood perfusion at the target area; subsequently reducing the pressure exerted on the target area by the sensor module; processing with a processor a first sensor output corresponding to the sensed first parameter and a second sensor output corresponding to the sensed second parameter to determine that the output of the second sensor satisfies a predetermined condition corresponding to an amount of blood perfusion at the target area and outputting an output from the processor which corresponds to the pressure exerted by the sensor module on the target area when the second parameter satisfies the predetermined condition.

[0032] The predetermined condition may be a condition which corresponds to an amount of blood perfusion at the target area which exceeds a predetermined threshold.

[0033] The predetermined condition may be a condition that corresponds to the presence of a pulsatile component of blood flow at the target area.

[0034] The step of reducing the pressure exerted by the sensor module on the target area may comprise the steps of: processing with the processor the second sensor output to determine that the second parameter satisfies a further predetermined condition associated

with an amount of blood perfusion at the target area and subsequently reducing the pressure exerted by the sensor module on the target area.

[0035] The further predetermined condition may be a condition which corresponds to an amount of blood perfusion at the target area which is below a predetermined threshold.

[0036] According to some embodiments, there is provided a method of determining skin perfusion pressure comprising the steps: processing with a processor a first sensor output representing a sensed first parameter associated with a pressure applied to a target area and a second sensor output representing a sensed second parameter associated with an amount of blood perfusion at the target area to determine that the output of the second sensor satisfies a predetermined condition associated with an amount of blood perfusion at the target area and outputting an output from the processor which corresponds to the pressure exerted by the sensor module on the target area when the second parameter satisfies the predetermined condition.

[0037] The predetermined condition may be a condition which corresponds to an amount of blood perfusion at the target area which exceeds a predetermined threshold.

[0038] The predetermined condition may be a condition that corresponds to the presence of a pulsatile component of blood flow at the target area.

[0039] The method may further comprise the steps of: processing with the processor the second sensor output to determine that the second parameter satisfies a further predetermined condition associated with an amount of blood perfusion at the target area and subsequently reducing the pressure exerted by the sensor module on the target area.

[0040] The further predetermined condition may be a condition which corresponds to an amount of blood perfusion at the target area which is below a predetermined threshold.

[0041] Certain embodiments of the present disclosure allow a parameter associated with the amount of blood perfusion in skin tissue to be measured at the same location at which a pressure to occlude blood vessels in the skin is applied during measurement of skin perfusion pressure. An accurate measurement of skin perfusion pressure can therefore be determined at the location at which the pressure is applied.

[0042] Certain embodiments of the present disclosure allow for blood perfusion pressure to be determined using a device comprising a single sensor module for sensing parameters associated with applied pressure to a target area and the amount of blood

perfusion at the target area simultaneously. The device can therefore be made compact, portable and easy to operate.

[0043] According to some embodiments, there is provided a wound dressing comprising:

a wound protecting portion which, in use, overlies a wound, and a peripheral portion which extends around at least part of the wound protecting portion, wherein the peripheral portion comprises at least one window which is arranged to locate a measurement probe having an optical sensor configured to sense light at a predetermined wavelength, wherein the window is transparent to light at the predetermined wavelength.

[0044] The predetermined wavelength may be a wavelength that corresponds to visible, ultraviolet or infrared light.

[0045] The predetermined wavelength may be between 495nm and 1350nm. In particular, the predetermined wavelength may be between 650nm and 1350nm.

[0046] The or each window may comprise an opening through the peripheral portion. The or each window may comprise an optically transparent material.

[0047] The optically transparent material may comprise at least one of polyvinyl chloride (PVC), cellulose acetate or acrylic or silicone or polyurethane or acrylate.

[0048] The peripheral portion may have a lower surface and an adhesive on the lower surface for securing the wound dressing to a patient's skin.

[0049] The wound dressing may be an island-type dressing in which the wound protecting portion is disposed centrally and the peripheral portion extends around a perimeter of the wound protecting portion.

[0050] The peripheral portion may further comprise at least one lobe which projects away from the wound protecting portion, wherein the or each window is provided at least partially in the or each lobe respectively. The or each window may be circular or ovoid.

[0051] The wound dressing may comprise at least two windows adjacent the wound protecting portion. The wound protecting portion may be disposed between the windows.

[0052] The wound protecting portion may have four sides and the four windows which are disposed adjacent each of the sides respectively.

[0053] According to some embodiments, there is provided apparatus comprising: the wound dressing and a measurement probe comprising an optical sensor configured to sense light at the predetermined wavelength.

[0054] The measurement probe may comprise a pad portion having a lower surface which, in use, is pressed against a patient's skin, and the window has a size and shape which corresponds to the size and shape of the pad portion.

[0055] According to some embodiments, there is provided a method of sensing at least one characteristic associated with a wound or a region of tissue proximate to a wound, comprising the steps of: locating a wound dressing comprising a wound protecting portion over a wound whereby the wound protecting portion overlies the wound, locating a pad portion of a measurement probe at a window region of a peripheral portion of the wound dressing, and transmitting light from the measurement probe through the window.

[0056] The method may further comprise preventing light from the measurement probe penetrating through the wound dressing at remaining regions of the wound dressing away from the window.

[0057] The method may further comprise: one-by-one, locating the measurement probe consecutively at each of a plurality of windows on the wound dressing and taking respective probe measurements at each location.

[0058] Certain embodiments of the present disclosure allow for consistent inspection of a region of tissue at or proximate a wound using a measurement probe.

[0059] Certain embodiments of the present disclosure allow for repeated measurements at a region of tissue at or proximate a wound to be made at one or more predetermined locations by a measurement probe such that a record of measurements associated with wound healing can be compiled for each of the predetermined locations.

[0060] Certain embodiments of the present disclosure allow for inspection of a region of tissue at or proximate a wound without having to remove a wound dressing.

[0061] According to some embodiments, there is provided a wound dressing comprising an upper surface, and at least one indicium for determining the orientation of the wound dressing, about an axis which is orthogonal to the upper surface, relative to a surface on which the wound dressing is securable.

[0062] At least one indicium may be provided on the upper surface.

[0063] The wound dressing may comprise a wound protecting portion; and a peripheral portion which extends around at least part of the wound contacting portion, wherein the wound protecting portion comprises the at least one indicium.

[0064] The peripheral portion may have a lower surface and an adhesive on the lower surface for securing the wound dressing to a surface.

[0065] A plurality of indiciums may be provided on the upper surface. Each indicium may comprise at least one graphical marker which is different from each of the other graphical markers.

[0066] The wound dressing may have at least two poles and at least one graphical marker may be provided at each of the poles. Each marker may comprise an alphanumeric character. Each marker may comprise a directional marker.

[0067] The wound dressing may be an island-type dressing.

[0068] Each indicium may be a printed element or a recessed region or a protruding region of the wound dressing. Each indicium may comprise at least one of a color patch, a metal element, a magnetic element and a resonant tag. Each indicium may comprise an RFID tag.

[0069] The wound dressing may further comprise at least one sensor site and said at least one indicium provides a visible cue for locating the sensor site at a desired location with respect to a wound. Each sensor site may be associated with a respective at least one indicium.

[0070] Each sensor site may comprise a location where a wound dressing sensor is located, a location of a window configured to receive a portion of a probe portion of an inspection device, or a target area of the wound dressing configured to receive a portion of a probe portion of an inspection device.

[0071] Each indicium may comprise of an RFID tag and a graphical marker which are configured to be uniquely associated with a respective sensor site of the wound dressing.

[0072] According to some embodiments, there is provided a method of orientating a wound dressing to a desired orientation with respect to a surface, comprising the steps of: locating a wound dressing proximate to a wound, rotating the wound dressing about an axis orthogonal to an upper surface of the wound dressing to align at least one indicium on the upper surface at a desired rotatory orientation, and urging the wound dressing towards the wound thereby dressing the wound via the wound dressing.

[0073] The method may further comprise rotating the wound dressing to align at least one indicium on a peripheral portion of the wound dressing at a desired positional relationship with respect to a wound or a predetermined patient feature.

[0074] The method may further comprise the wound dressing further comprising at least one sensor site and the step of rotating the wound dressing comprises locating each sensor site at a desired location with respect to the wound.

[0075] The step of locating each sensor site may comprise locating a wound dressing sensor at the desired location or at a window portion of the wound dressing that locates a wound dressing sensor.

[0076] Certain embodiments of the present disclosure allow inspection of skin tissue in the vicinity of the wound to be conducted reliably, consistently and repeatedly.

[0077] Certain embodiments of the present disclosure allow for measurements of a parameter associated with wound healing to be compiled for specific locations in the vicinity of a wound such that progress of wound healing can be monitored accurately over a desired period of time.

[0078] According to some embodiments, there is provided a wound dressing comprising an upper surface; and at least one indicium for determining the orientation of the wound dressing, about an axis which is orthogonal to the upper surface, relative to a surface on which the wound dressing is securable; a wound protecting portion; and a peripheral portion which extends around at least part of the wound contacting portion, wherein the wound protecting portion comprises the at least one indicium, wherein a plurality of indiciums are provided on the upper surface, each indicium comprising at least one graphical marker which is different from each of the other graphical markers.

[0079] According to some embodiments, there is provided a wound dressing comprising: an upper surface; at least one indicium for determining the orientation of the wound dressing, about an axis which is orthogonal to the upper surface, relative to a surface on which the wound dressing is securable; a wound protecting portion; and a peripheral portion which extends around at least part of the wound contacting portion, wherein the wound protecting portion comprises the at least one indicium.

[0080] According to some embodiments, there is provided a wound dressing comprising an upper surface and at least one indicium for determining the orientation of the wound dressing, about an axis which is orthogonal to the upper surface, relative to a surface on which the wound dressing is securable, wherein each indicium comprises an RFID tag.

[0081] According to some embodiments, there is provided a wound dressing comprising an upper surface; at least one indicium for determining the orientation of the wound dressing, about an axis which is orthogonal to the upper surface, relative to a surface on which the wound dressing is securable; at least one sensor site, wherein said at least one indicium provides a visible cue for locating the sensor site at a desired location with respect to a wound, and wherein each indicium comprises of an RFID tag and a graphical marker

which are configured to be uniquely associated with a respective sensor site of the wound dressing.

[0082] According to some embodiments, there is provided an apparatus comprising a wound dressing; a skin perfusion pressure determination device comprising a sensor module, the sensor module including a sensor configured to sense at least one characteristic associated with a wound or a region of tissue proximate to a wound; and a display configured to indicate at least one condition relating to the at least one characteristic associated with a wound or a region of tissue proximate to a wound sensed by the sensor module.

[0083] The skin perfusion pressure determination device can comprise a hand-held device.

[0084] The display can comprise a computer monitor, laptop, tablet, or smart phone.

[0085] The display can be configured to provide a visual indication of a measurement location, an applied force, an occlusion reached indication, high force warning, speed of movement indication, perfusion measurement result, or a measurement quality indication.

[0086] The display can be positioned on the skin perfusion pressure determination device.

[0087] The display can comprise one or more visual indicators.

[0088] The one or more visual indicators can comprise a multi-segment gauge type indicator, a symbol, a text and/or numeric indication, graphical indication, or circumferential indicators.

[0089] The one or more visual indicators can comprise one or more light emitting diodes (LED).

[0090] The one or more visual indicators can comprise an LED indicator, organic light emitting diodes (OLED) indicator, and/or EINK indicators.

[0091] The one or more visual indicators can comprise a multi-segment gauge type indicator, a symbol, a text and/or numeric indication, graphical indication, or circumferential indicators.

[0092] The sensor module can be configured to apply a pressure on a target area.

[0093] The sensor module can comprise a first sensor for sensing a first parameter associated with the pressure exerted on the target area by the sensor module and a second

sensor for sensing a second parameter associated with an amount of blood perfusion at the target area.

[0094] The display can be configured to provide user instructions to increase the applied pressure or to reduce the applied pressure during a measurement process.

[0095] According to some embodiments, there is provided an apparatus comprising a wound dressing, a skin perfusion pressure determination device comprising a sensor module, the sensor module including a sensor configured to sense at least one characteristic associated with a wound or a region of tissue proximate to a wound, and an audible and/or tactile indicator configured to indicate at least one condition relating to the at least one characteristic associated with a wound or a region of tissue proximate to a wound sensed by the sensor module.

[0096] According to some embodiments, there is provided a method of determining at least one characteristic associated with a wound or a region of tissue proximate to a wound comprising: locating a wound dressing comprising a wound protecting portion over a wound whereby the wound protecting portion overlies the wound; positioning a skin perfusion pressure determination device comprising a sensor module at a target area on or adjacent to the wound dressing, wherein the sensor module includes a sensor configured to detect at least one characteristic associated with a wound or a region of tissue proximate to a wound; and receiving a visual, audible, or tactile indicator relating to the at least one characteristic associated with a wound or a region of tissue proximate to a wound detected with the sensor of the skin perfusion pressure determination device.

[0097] A visual indicator can be incorporated into a display.

[0098] The skin perfusion pressure determination device can comprise a hand-held device.

[0099] The display can comprise a computer monitor, laptop, tablet, or smart phone.

[0100] The skin perfusion pressure determination device can comprise the visual, audible, or tactile indicators.

[0101] The display can comprise one or more visual indicators.

[0102] A visual indicator can comprise one or more light emitting diodes (LED).

[0103] A visual indicator can comprise an LED indicator, organic light emitting diodes (OLED) indicator, and/or EINK indicator.

[0104] A visual indicator can comprise a multi-segment gauge type indicator, a symbol, a text and/or numeric indication, graphical indication, or circumferential indicators.

[0105] The at least one characteristic associated with a wound or a region of tissue proximate to a wound can comprise a skin perfusion pressure.

[0106] The method can further comprise applying pressure to the skin perfusion pressure determination device to exert a pressure on a target area.

[0107] The sensor module can have a first sensor for sensing a first parameter associated with the pressure exerted on the target area by the sensor module and a second sensor for sensing a second parameter associated with an amount of blood perfusion at the target area.

[0108] The visual, audible, or tactile indicator can provide user instructions to increase the applied pressure or to reduce the applied pressure of the skin perfusion pressure determination device on the target area.

[0109] The visual, audible, or tactile indicator can provide an indication of a measurement location, an applied force, an occlusion reached indication, high force warning, speed of movement indication, perfusion measurement result, or a measurement quality indication.

BRIEF DESCRIPTION OF THE DRAWINGS

[0110] Embodiments of the present disclosure will now be described, by way of example only, with reference to the accompanying drawings in which:

[0111] Figure 1 is a schematic representation of a skin perfusion pressure determination device in use;

[0112] Figure 2 is a schematic representation of components of the skin perfusion pressure determination device shown in Figure 1;

[0113] Figure 3 is a schematic representation of a sensor for sensing a parameter associated with blood perfusion;

[0114] Figure 4 is a flow chart depicting a method for determining skin perfusion pressure;

[0115] Figure 5 is an example of a display derived from an output of the skin perfusion pressure determination device shown in Figure 1;

[0116] Figure 6 shows an alternative embodiment of a skin perfusion pressure determination device comprising a probe portion;

[0117] Figure 7A shows the skin perfusion pressure determination device shown in Figure 6 in use with a wound dressing;

[0118] Figure 7B illustrates an embodiment of a hand-held skin perfusion pressure determination device;

[0119] Figure 7C-7D illustrates an embodiment of a hand-held skin perfusion pressure determination device with an illumination source;

[0120] Figures 7E-7K illustrate embodiments of optical pattern indicia;

[0121] Figures 7L-7O illustrate embodiments of a wound dressing with indicia;

[0122] Figures 7P-7Q illustrate embodiments of a cross section of a wound dressing;

[0123] Figure 7R illustrates an embodiment of a wound dressing with notches;

[0124] Figure 8 shows a further embodiment of a skin perfusion pressure determination device comprising a wound dressing;

[0125] Figure 9A shows an example of a skin perfusion pressure determination device comprising a wound dressing;

[0126] Figure 9B shows an example of an arrangement comprising a wound dressing and a separate skin perfusion pressure determination device;

[0127] Figure 10A shows a display device for use with the skin perfusion pressure determination device shown in Figure 9A;

[0128] Figure 10B shows a wireless display device for use with the skin perfusion pressure determination device shown in Figure 9B;

[0129] Figure 11 shows a further embodiment of a skin perfusion pressure determination device comprising a wound dressing and multiple sensor modules;

[0130] Figure 12 shows an example display output for the device shown in Figure 11;

[0131] Figure 13 shows a handheld skin perfusion pressure determination device incorporating a display;

[0132] Figure 14 is a schematic representation of a further embodiment of an apparatus comprising a skin perfusion pressure determination device;

[0133] Figure 15 is a schematic representation of a further embodiment of an apparatus comprising a skin perfusion pressure determination device;

[0134] Figure 16 is a schematic representation of a further embodiment of an apparatus comprising a skin perfusion pressure determination device;

[0135] Figures 17A-17B and 18A-18B illustrate embodiments of a skin perfusion pressure determination device in use;

[0136] Figures 19A-19F illustrate embodiments of a display for use with a skin perfusion pressure determination device and a skin perfusion pressure determination device in use with a wound dressing;

[0137] Figures 20A-20F illustrate embodiments of a display for use with a skin perfusion pressure determination device; and

[0138] Figures 21A-21G, 22A-22E, and 23 illustrate embodiments of a display or user interface on the hand-held skin perfusion pressure determination device.

DETAILED DESCRIPTION

[0139] Figure 1 shows an apparatus 2 for determining skin perfusion pressure comprising a skin perfusion pressure determination device 4 secured to a patient's arm 6 and a monitoring device 8 connected via a lead 10 to the skin perfusion pressure determination device 4. The skin perfusion pressure determination device 4 comprises a wound dressing 12 and a sensor module 14 formed integrally with the wound dressing 12. The wound dressing 12 is in the form of a detachable band that may be secured to the arm 6 of the patient by wrapping it around the arm 6 and securing opposite end portions together using a fastener, such as an adhesive strip or hook and loop fastener or the like. In other embodiments the skin perfusion pressure determination device may be a detachable band that does not comprise a wound dressing but may be secured adjacent a wound if desired. Bands may be secured to other parts of an animal or person's body including other limbs, such as a leg, or a torso. The lead 10 is connected to the sensor module 14 at one end and to the monitoring device 8 at the other end. The lead 10 provides a means for communication between the sensor module 14 and the monitoring device 8 and also provides a means for supplying power to the sensor module 14.

[0140] The monitoring device 8 is configured to receive and process a signal received from the sensor module 14 and display processed information on an integrated display 16.

[0141] Figure 2 is a system diagram representing components of the apparatus 2 shown in Figure 1.

[0142] Figure 2 depicts components of the skin perfusion pressure determination device 4 and the monitoring device 8 which are enclosed, respectively, by broken lines. The sensor module 14 comprises a first sensor in the form of a force sensor 18 for sensing a force transmitted through the sensor module 14 to the patient's arm 6, and a second sensor in the form of an optical sensor 20 for sensing a parameter which corresponds to the amount of

blood perfusion in the skin tissue of the arm 6 underneath the sensor module 14. In the present embodiment, the optical sensor 20 is a pulse sensor, but other suitable sensors may be used such as a reflective pulse oximeter sensor or the like. The force sensor 18 is a thin-film micro-force sensor with a diameter of 15mm and a force range of 45N. The force sensor 18 also comprises associated read-out electronics.

[0143] The force sensor 18 is disposed on an upper portion of the optical sensor 20 and the optical sensor 20 is arranged such that it faces away from the force sensor 18 towards the arm 6.

[0144] The sensors 18, 20 are connected via respective electrical wires 10a, 10b, which comprise the lead 10, to an input of the monitoring device 8.

[0145] Figure 3 is a schematic representation of the optical sensor 20 in isolation wherein the optical sensor 20 is located against the arm 6. The optical sensor 20 comprises a light emitter in the form of a light emitting diode (LED) 22 which emits light at a predetermined wavelength (or emits light across a predetermined range of wavelengths) and a light detector in the form of a photodiode 24 which is configured to detect light emitted by the LED 22.

[0146] The LED 22 and the photodiode 24 are disposed within a housing 26 and separated by a shield 28 which is opaque to the wavelength or range of wavelengths of light detectable by the photodiode 24. The shield 28 prevents emitted light from the LED being transmitted directly to the photodiode 24. The lower portion of the housing 26 is open or transparent so that light emitted by the LED 22 can pass through the lower portion to the skin tissue of the arm 6 and light reflected or scattered by the skin tissue of the arm 6 can pass back through the lower portion of the housing 26 to the photodiode 24. The shield 28 is spaced slightly from the skin tissue so that it does not contact the skin and so does not prevent light from passing underneath the shield 28. Light received by the photodiode 24 is therefore light which has been emitted by the LED 22 and either reflected, scattered or absorbed and reemitted by the skin tissue of the arm 6.

[0147] In the embodiment shown, the LED 22 emits light in the green band of the visible spectrum having a wavelength between 495nm and 570nm. Green light is known to be absorbed highly by hemoglobin within blood and so the amount of absorption of green light is correlated with the amount of blood in the skin tissue. Measuring the amount of absorption of green light emitted by the LED 22 can therefore be used to determine the amount of blood, and hence indicate the amount of blood perfusion, in a target area of tissue beneath the sensor module 14.

[0148] Referring again to Figure 2, the monitoring device 8 comprises signal processing electronics 30 connected to the leads 10a, 10b and a processor 32 for processing signals received from the force sensor 18 and the optical sensor 20. The processor 32 is configured to display data representing the processed signals on the display 16. The signal processing electronics 30 are further configured to supply power to the sensor module 14. However, it will be appreciated that a separate power source may be provided, and that a power source may be integrated into the wound dressing. In other embodiments, the skin perfusion pressure determination device may comprise the processor and the processor may be configured to provide a digital output to the monitoring device.

[0149] A method of determining skin perfusion pressure using the apparatus 2 will now be described with reference to Figures 1 to 5.

[0150] The sensor module 14 is placed against the arm 6 of a patient so that the lower portion of the housing 26 of the sensor module 14, which is open or transparent, is adjacent the target area of skin tissue, as shown in Figure 3. The lower portion of the housing 26 may be in contact with the target area. The skin perfusion pressure determination device 4 is then secured to a patient's arm 6 by wrapping the wound dressing 12 about the arm 6 and securing end portions of the wound dressing 12 together, as shown in Figure 1. The sensor module 14 is connected to the monitoring device 8 by the lead 10 so that the sensor module 14 is in communication with the monitoring device 8.

[0151] Outputs from the force sensor 18 and the optical sensor 20 are then monitored and displayed on the display 16. Examples of outputs from the force sensor 18 and the optical sensor 20 are shown in the respective lower and upper traces of Figure 5.

[0152] The upper trace is a photoplethysmogram (PPG) which provides an indication of the amount of light emitted by the LED 22 that is absorbed by the skin tissue at the target area (i.e. the trace is inversely proportional to the amount of light reflected by the skin tissue at the target area and received by the photodiode 24). Therefore, a relatively large amount of blood in the skin tissue, which absorbs a relatively large amount of light emitted by the LED 22, produces a relatively high output trace value, and vice versa. Of course, the trace could be inverted such that the amount of light reflected by the skin tissue is plotted in which case, a large amount of blood within the skin tissue would produce a relatively low output trace value.

[0153] The upper trace will typically have a pulsatile component and a non-pulsatile component. The pulsatile component represents light absorbed by pulsatile arterial blood whereas the non-pulsatile component represents light absorbed by non-pulsatile arterial

blood, venous blood and skin tissue. The pulsatile component arises due to the change in blood volume caused by the pressure pulse of the cardiac cycle pushing blood through the blood vessels and capillaries and is therefore associated with blood flow. The pulsatile component can therefore be monitored to obtain an indication of the amount of blood perfusion in the underlying tissue.

[0154] The amount of light absorbed by the skin tissue initially once the skin perfusion pressure determination device 4 has been secured to the patient's arm 6 is shown between times t_1 and t_2 of the upper trace in Figure 5. Each peak represents a pulse of arterial blood through the skin tissue at the target area.

[0155] Time t_2 is the time at which a skin perfusion pressure measurement is commenced and corresponds to initiation of the first step of the method depicted by the flow diagram in Figure 4.

[0156] In use, a clinician (or the patient themselves) presses the sensor module 14 against the arm 6 to occlude the blood vessels within the tissue below the target area. The amount of force is increased until the pulsatile component of the trace drops below a predetermined level or ceases to be evident, as shown at time t_3 . Once the trace drops below the predetermined level, the clinician continues to hold the sensor module 14 against the arm 6 to ensure that the pulsatile arterial blood flow has ceased in the tissue at the target area, as shown between times t_3 and t_4 . In the example shown, there remains a non-zero noise component of the trace which fluctuates at a level below the predetermined level. At time t_4 , the clinician begins to reduce the force applied to the sensor module 14 slowly until time t_5 at which time the pressure module 14 has been released completely and pulsatile arterial blood flow in the tissue at the target area is completely restored.

[0157] The force exerted by the clinician on the tissue at the target area via the sensor module 14 is recorded by the lower trace. As can be seen from the lower trace, no force is recorded between times t_1 and t_2 . The force increases relatively rapidly between times t_2 and t_3 as the clinician presses the sensor module 14 against the arm 6 of the patient and then plateaus while the clinician holds the sensor module 14 against the arm 6 between times t_3 and t_4 . As the clinician begins to slowly release the sensor module 14 at time t_4 , the applied force reduces steadily back to zero at time t_5 and pulsatile arterial blood flow returns to the skin tissue.

[0158] Pulsatile arterial blood flow returns when the blood pressure is sufficient to overcome the occlusion pressure on the blood vessels within the tissue which is applied by the clinician pressing on the sensor module 14. The return of blood flow is represented by a

return of the pulsatile component in the upper trace, as shown at time t_{SPP} . Different criteria can be used to determine the return of pulsatile arterial blood flow. For example, return of blood flow could be determined by the return of the value of the upper trace to a predetermined threshold I_{SPP} value such as a value greater than a maximum expected noise value. Alternatively, the threshold value I_{SPP} may be a value that is determined based on the pulse amplitude observed before a force is applied to occlude the blood vessels (i.e. the pulse amplitude between times t_1 and t_2). In one example, a threshold value I_{SPP} may be used which is a predetermined percentage of the pulse amplitude observed before a force is applied to occlude the blood vessels. Other algorithms may be used to determine return of the pulsatile component of the trace.

[0159] The magnitude of the force F_{SPP} of the lower trace at time t_{SPP} is then recorded. The recorded force F_{SPP} can subsequently be used to determine a skin perfusion pressure. This may be done by calculation, look-up tables or based on a pre-calibration of the force sensor 18. For example, if the contact area of the portion of the sensor module 14 pressed against the skin tissue is known, the pressure applied to the skin tissue can be calculated. In this instance, the target area corresponds to the contact area of the sensor module 14. In the described embodiment, the contact area of the sensor module 14 is circular and has a diameter of 10mm and therefore a surface area of approximately 80mm^2 . The larger the contact area, the greater the force required to stop blood flow. The smaller the contact area, the greater the fluctuations in pressure caused by fluctuations in the force applied so that, for very small contact areas it becomes difficult for a clinician to release the applied force in a controlled manner in order to determine the force at which blood flow returns. A very small contact area can also make it difficult for an accurate reading to be taken by the blood perfusion sensor. The contact area of the sensor module 14 may therefore be between 1mm^2 and 1000mm^2 , for example between 10mm^2 and 400mm^2 .

[0160] A benefit of the arrangement is that contemporaneous measurements of the pressure exerted by the sensor module 14 on the target area and the amount of blood perfusion are made at the target area. The measurements can be taken and recorded simultaneously to produce an accurate and reliable measurement of blood perfusion pressure at a desired location on a patient's body.

[0161] Measurement of skin perfusion pressure may be performed as a single measurement or determined from trends evident from repeated measurements over time. Such measurements may be used to aid the prediction of wound healing.

[0162] Use of an LED light source, in particular a surface-mount LED, provides a compact, widely available, inexpensive, very reliable and a low power consumption light source. In the embodiment described above an LED which emits light in the green band of the visible spectrum is used. However, other suitable light sources could be used which emit light having a wavelength that is absorbed or reflected by blood. Light sources which emit light having a wavelength (or range of wavelengths) between 600nm and 1350nm may be used. In particular, light sources which emit light in the red band of the visible spectrum having a wavelength of between 600nm and 750nm or which emit light in the near-infrared band of the visible spectrum having a wavelength of between 850nm and 1000nm may be used. Light sources which emit light in the near-infrared window of biological tissue having a wavelength of between 650nm and 1350nm are beneficial because light has its maximum depth of penetration in tissue at these wavelengths and so a greater proportion of the emitted light will reach the blood vessels within the tissue.

[0163] Alternative light detectors may be used. For example, phototransistors or complementary metal-oxide semiconductor (CMOS) based sensors may be used. These sensors, and the photodiodes of the described embodiment, are preferred because they are inexpensive, compact and widely available.

[0164] Alternative sensors for determining a parameter associated with a pressure exerted on the target area may be used. In particular, sensors which have a thickness which corresponds to, or is less than, the thickness of a typical wound dressing may be used. Suitable capacitive, resistive thin-film or micromachined sensors or strain gauges or the like may be used. Such sensors are suitable for incorporation onto wound dressings, as described below. It will be appreciated that although the embodiment described above comprises a force sensor, alternative types of sensor which produce an output which can be used to determine a parameter associated with the pressure exerted on or stress created at the target area by a sensor module may be used. Such sensors may include sensors configured to output a pressure applied by the sensor or the sensor module to the target area.

[0165] In the embodiment described above, a simple trace showing the outputs from the sensor module 14 is provided to aid the clinician or patient. The processor may, however, be configured to display instructions to a patient/clinician on the display 16 such as instructions to increase the applied force or to reduce the applied force at each stage of the measurement process. An audible signal may be generated to inform a clinician/patient of the pulse strength. The audible signal may be continuous or a series of beeps that vary in frequency or volume depending on the magnitude of the pulsatile component of the trace.

For example, an audible beep pattern may become silent when the pulsatile component drops below a threshold value and re-emerges when the pulsatile component returns indicating the return of blood flow in the tissue at the target area. In addition to written instructions, a light or a symbol or a color signal or an audible signal could be used to instruct a user to increase or decrease a force applied.

[0166] Figure 6 shows an example of an alternative embodiment of part of an apparatus 102 comprising a hand-held skin perfusion pressure determination device 104 comprising a grip portion 106 and a probe portion 108. The probe portion 108 has a pad portion 110 in which a sensor module (not shown) is housed. The sensor module is in accordance with the sensor module 14 shown in Figure 2. The hand-held device 104 is connected to a monitoring device similar to that shown in Figure 1 by a lead 112.

[0167] In use, the grip portion 106 is held by a clinician and used to press the pad portion 110 against a target area of a patient's skin. The method shown in Figure 4 and described above is then followed to determine the skin perfusion pressure at the target area.

[0168] Figure 7A shows the hand-held device 104 in use with a wound dressing 202. The wound dressing 202 comprises a central wound protecting portion 204 and a peripheral securing portion 206. As illustrated in Figure 7A, the peripheral securing portion 206 extends around the perimeter of the central wound protecting portion 204 and forms the perimeter of the wound dressing 202. The securing portion 206 has an adhesive, such as an acrylic adhesive or silicone adhesive or the like, on its lower surface for securing the wound dressing 202 to a patient's skin.

[0169] Four circular windows 208A, 208B, 208C, 208D are provided in respective lobes 210A, 210B, 210C, 210D of the securing portion 206. The lobes 210A, 210B, 210C, 210D are spaced apart about the wound protecting portion 204 so that each lobe 210A, 210B, 210C, 210D is positioned opposite one of the other lobes 210A, 210B, 210C, 210D. Each window 208A, 208B, 208C, 208D is defined by an opening through which the pad portion 110 can be pressed directly against a patient's skin. Each window 208A, 208B, 208C, 208D has a size and shape which corresponds to the size and shape of the pad portion 110 in order to help locate the pad portion 110 as it is pressed against a patient's skin. The windows 208A, 208B, 208C, 208D provide a convenient way in which blood perfusion pressure can be measured at a target area close to the location of a wound without having to remove a wound dressing. The fixed location of the windows 208A, 208B, 208C, 208D also ensures that measurements of skin perfusion pressure can be repeatedly and reliably made at the same location or locations to assess wound healing. This facilitates consistent and robust

tracking of wound healing. Other shapes of windows that help locate a suitably shaped pad portion of a hand-held device could of course be utilized. At least some of the lobes 210A, 210B, 210C, 210D may be detachable, for example, by being connected to the remainder of the wound dressing 202 via one or more perforated sections. Furthermore, the windows 208A, 208B, 208C, 208D could be revealed and/or created at the time of use by removing detachable portions of the wound dressing 202 immediately before application of the wound dressing 202. The detachable portions may be connected to the remainder of the wound dressing 202 via one or more perforated sections. The quantity, location and size of the lobes may be tailored in accordance with requirements such as body location for the wound dressing or wound size or wound type.

[0170] The wound dressing 202 has an upper surface on which indicia are provided in order to determine the orientation of the wound dressing 202. In some embodiments, the indicia can be used to determine orientation, detect the target area or location of measurement, and/or identify the wound dressing. Since the time between measurements can be between about one day to about seven days, the indicia can assist the user in assuring accurate and repeated measurements can be taken from the same location and/or dressing.

[0171] In some embodiments, the indicia can comprise alphanumeric characters A, B, C and D, as shown in Figure 7A, but may comprise directional markers or the like for determining the orientation of the wound dressing and for uniquely identifying each of the windows 208A, 208B, 208C, 208D of the wound dressing 202. Each indicium may comprise a symbol or one of more color patches or folds in the dressing material or dimples or indentations or holes or metal elements or magnetic elements or resonant tags. As used herein, the upper surface of the wound dressing refers to the surface of the wound dressing that is furthest from or distal to the wound bed.

[0172] Other indicia and patterns can be used to determine orientation, detect the target area or location of measurement, and/or identify the wound dressing. In some embodiments, locations on the wound dressing can be color-coded. In some embodiments, the wound dressing can have color patches or be color-coded to identify the orientation, location, and/or identify the wound dressing. The coloring can be used to identify the target area for taking a skin perfusion pressure measurement. Color patches can be used next to or on the intended measurement location. In some embodiments, the color can be detected using a color sensor on or in the measurement device. The probe portion 108 of the hand-held skin perfusion pressure determination device or other device with a sensor module can include a

color sensor which can be used to detect a color patch on or near the wound dressing 202. In some embodiments, the hand-held skin perfusion pressure determination device 104 can include an illumination source. As shown in Figures 7B and 7C, the illumination source 109 of the hand-held skin perfusion pressure determination device 104 can illuminate an area 115 on the upper surface of the wound dressing. In some embodiments, the wound dressing can be marked with a color patch that is visible when illuminated by the illumination source. For example, the color patch could be a color that is visible on an ultraviolet spectrum and can be visible when illuminated by an ultraviolet light from the illumination source 109. In some embodiments, the illumination source can illuminate the upper surface of the wound dressing and the reflected light can be detected by the color sensor or other sensor as illustrated in Figure 7D. In some embodiments, such imaging or illumination can be used to detect bacteria in wounds (for example systems such as MolecuLight).

[0173] In some embodiments, the wound dressing can include an optical pattern to identify the target area on the wound dressing. Figures 7E-7K illustrate various optical patterns that can be used. Figure 7E illustrates an embodiment of a bar code. Figure 7F illustrates an embodiment of a dot pattern. Figure 7G and 7H illustrate embodiments of line patterns that can be used including grid pattern (shown in Figure 7G) or parallel lines (shown in Figure 7H). In some embodiments, directional indicators similar to those shown in Figure 7I can be used on the wound dressing. In some embodiments, symbols or drawings similar to those shown in Figures 7J and 7K can be used.

[0174] As shown in Figures 7L and 7M the wound dressing 202 can have one or more of a color 701 (shown in Figure 7L) or a pattern 703 (shown in Figure 7M) similar to those described herein positioned on a location of the wound dressing to determine orientation, detect location of measurement, and/or identify the wound dressing. The hand-held skin perfusion pressure determination device can be positioned over the wound dressing and can utilize a camera to detect the color, pattern, or other indicia on the wound dressing. The hand-held skin perfusion pressure determination device 104 can include a camera to detect the pattern and to identify the measurement location. In some embodiments, the hand-held skin perfusion pressure determination device can include an illumination source to assist in capturing the color, pattern, or other indicia on the surface of the wound dressing.

[0175] The orientation of the wound dressing, the location of measurement, and/or the identity of the wound dressing can be determined by observing the indicia on the upper surface of a wound dressing. In some embodiments, the indicia can be positioned on the dressing in an asymmetrical way. For example, the indicia 714 can be positioned in three

of the four corners of a square dressing 202 as illustrated in Figure 7N. Since the wound dressing can be sided (including a top backing layer and a wound contact layer) the orientation can be determined by simply using the indicia in three of the corners.

[0176] In some embodiments, as illustrated in Figure 7O, the wound dressing 202 can have indicia of different shapes, styles, and/or sizes positioned at different locations of the wound dressing to determine orientation, detect location of measurement, and/or identify the wound dressing. The wound dressing 202 can have unique indicium at each location. For example, the wound dressing 202 can have a circle indicium 715, a triangle indicium 716, and a square indicium 717. In some embodiments, the unique indicium at each location can assist the user to confirm that readings and/or measurements have been consistently taken from the same location for each measurement time.

[0177] While Figures 7L-7O illustrate the use of a pattern or a color indicium, any colors, pattern, code, and/or notch in the sides of the dressings can be used instead or in addition to the patterns or colors to identify a location or to identify the dressing.

[0178] In some embodiments, magnetic encoding can be utilized to assist the user to identify the location for measurement on the wound dressing. A magnetic material or pattern in the wound dressing can be used next to or on the intended measurement location, a location used to determine orientation, and/or a location used to identify the wound dressing. The hand-held device can include a magnetic sensor (for example, a magnetometer) to detect the magnetic material or pattern in the wound dressing. In some embodiments, the magnetic material can utilize different amounts of magnetic material in different locations to generate a different size of signal detected by the detection device or hand-held device. In some embodiments, the different size of signal detected can be subject to the sensitivity of the magnetometer or magnetic sensor. In some embodiments, various patterns of magnetic material can be used to identify locations on the wound dressing.

[0179] Each indicium may comprise an RFID identification tag that is configured to communicate information, such as the location of the RFID tag and/or a window associated with the RFID tag to the hand-held device 104 when the pad portion 110 is located at the respective window. In other embodiments, a combination of an RFID tag and a visible marker could be used in which the visible marker and the RFID tag store information that, when combined, can be used to identify a wound dressing and/or a patient to which a wound dressing is applied. For example, a dressing may have an identifier in the form of a serial number. At least a portion of the serial number may be obtainable from the RFID tag and a different portion of the serial number may be obtainable from the visual marker. The two

portions can be combined to enable anonymous identification of a wound dressing, and hence a patient to which the wound dressing has been applied.

[0180] The hand-held device may comprise a suitable RFID reader or camera module for acquiring information about the indicia of the wound dressing. The apparatus may be configured to associate a measurement with a wound dressing or a certain window/lobe of the wound dressing.

[0181] It will be appreciated that the windows 208A, 208B, 208C, 208D could be formed of a material that is transparent to a wavelength of the light used by the optical sensor of the sensor module. For example, each window 208A, 208B, 208C, 208D may be made of a material that is transparent, or substantially transparent, to green light having a wavelength of between 495nm and 570nm. The windows may comprise, for example, at least one of polyvinyl chloride (PVC), cellulose acetate or acrylic or silicone or polyurethane or acylate or other suitable material.

[0182] Figures 7P-7Q illustrates a cross-sectional view of the wound dressing 720 with a window 721. The wound dressing 720 of Figures 7P and 7Q illustrates a cross section of an embodiment of the wound dressing described herein with reference to Figure 7A. As described previously, the wound dressing 720 can include a peripheral securing portion 725 and a central wound protecting portion 728. As illustrated in Figures 7P and 7Q, the wound dressing 720 can include a wound contact layer 722, an absorbent or foam layer 723, and a top film or backing layer 724.

[0183] In some embodiments, the windows 208A, 208B, 208C, 208D shown in Figure 7A could be formed of the material of a wound contact layer from the wound dressing that extends under the window portion of the dressing. As illustrated in Figure 7P, the wound contact layer 722 can extend across the peripheral securing portion 725 of the dressing 720 and across the window 721. The backing layer 724 can include an opening 726 in the window portion 721 of the wound dressing. In such embodiments, the hand-held skin perfusion pressure determination device can be positioned over the wound contact layer 722 in the window 721.

[0184] Figure 7Q illustrates an embodiment of the wound dressing 720 with an opening 727 in the wound contact layer 722 and an opening 726 in the backing layer 724 in the window portion 721 of the wound dressing. In the embodiment of Figure 7Q, the hand-held skin perfusion pressure determination device would be positioned in the window 721 and no material would be present in the window portion of the wound dressing between the hand-held skin perfusion pressure determination device and the skin of the patient. In such

embodiments, the hand-held skin perfusion pressure determination device can make direct contact with the skin in the window. In some embodiments, the wound contact layer and absorbent or foam layer is optional.

[0185] In some embodiments, the backing layer 724 can be formed from a thermoplastic polyurethane. The wound contact layer 722 can be a perforated layer and can optionally include an adhesive. In some embodiments, the absorbent or foam layer 723 can be any dressing construction material, for example, a spacer layers, super absorbers, non-wovens, foams, masking layers, and/or any combination thereof.

[0186] In some embodiments, a separate dressing layer can be used to form the material of the window. For example, a wound contact layer can be used under the absorbent and/or foam layer or the central wound protecting portion 728. A separate non-perforated and/or non-adhesive film can be used around the peripheral securing portion 725 of the dressing and/or within the windows. In some embodiments, the material used within the window can be selected for pressure and/or optical transmission.

[0187] Figure 7R illustrates a wound dressing 702 with notches 730 along the peripheral securing portion 731 of the dressing. The notches 730 can indicate the measurement locations for measurements by the hand-held skin perfusion pressure determination device. For example, instead of detaching lobes 210A, 210B, 210C, 210D from the dressing as described with reference to Figure 7A, the dressing could be designed with the notches illustrated in Figure 7R.

[0188] Figure 8 shows a skin perfusion pressure determination device 302 comprising a wound dressing 304 having an integrated sensor module that is in accordance with the sensor module 14 shown in Figure 2. The wound dressing 304 is shown attached to the leg 306 of a patient. A lead 308 connects the sensor module to a monitoring device (not shown) such as that shown in Figure 1.

[0189] Figure 9A shows an embodiment a skin perfusion pressure determination device 402 comprising a wound dressing 404 having an integrated sensor module 406 that is in accordance with the sensor module 14 shown in Figure 2. The wound dressing 404 comprises a central wound protecting portion 408 and a peripheral securing portion 412. The securing portion 412 has an adhesive on its lower surface for securing the wound dressing to a patient's skin. The sensor module 406 is formed integrally with the peripheral securing portion 412 and is connected to a lead 414 which connects the sensor module 406 to a monitoring device, such as that shown in Figure 10A (described below). In the described embodiment, the wound dressing 404 is an island-type dressing. The thickness of the central

portion 408 may include one or more component parts between a lower wound contact layer and the upper layer (seen in Figures 9A and 9B).

[0190] Figure 9B shows an embodiment a skin perfusion pressure determination device 502 comprising a sensor module 504, that is in accordance with the sensor module 14 shown in Figure 2, and a securing portion 506 with which the sensor module 504 is formed integrally. The device 502 can be secured to a patient's skin adjacent a wound dressing 508 comprising a wound protecting portion 510 and a peripheral securing portion 512, as shown in Figure 9B. An advantage of the arrangement is that the wound dressing 508 can be changed periodically without having to disturb the skin perfusion pressure determination device 502. In the embodiment shown, the skin perfusion pressure determination device 502 is wireless, and may be configured to communicate with a monitoring device such as that shown in Figure 10B (described below).

[0191] Figure 10A shows an example of a monitoring device 416 in the form of a personal hand-held device which is connected to a sensor module by the lead 414 which may be used in conjunction with the skin perfusion pressure determination device 402 shown in Figure 9A. The monitoring device 416 has an integrated display 418 and may be a portable computer having an integrated display such as a tablet, smartphone or the like. The monitoring device 416 may be carried by a clinician and connected to a wound dressing 404 during a consultation with a patient. The device 416 can then be used to display information about the wound to a clinician and/or stored on the device for future reference or subsequent transfer to a remote database.

[0192] Figure 10B shows an example of a monitoring device 514 in the form of a personal hand-held device that is similar to the device shown in Figure 10A, but is configured to communicate wirelessly with the skin perfusion pressure determination device 502 shown in Figure 9B.

[0193] Figure 11 shows a skin perfusion pressure determination device 602 comprising a wound dressing 604 having four integrated sensor modules 606A, 606B, 606C, 606D which are each in accordance with the sensor module 14 shown in Figure 2. The wound dressing 604 comprises a central wound protecting portion 608 and a peripheral securing portion 610. The securing portion 610 has an adhesive on its lower surface for securing the wound dressing to a patient's skin. The sensor modules 606A, 606B, 606C, 606D are formed integrally with the peripheral securing portion 610 and are located at respective lobes 612A, 612B, 612C, 612D. The lobes 612A, 612B, 612C, 612D are spaced apart about the wound protecting portion 608 so that each lobe 612A, 612B, 612C, 612D is

spaced opposite one of the other lobes 612A, 612B, 612C, 612D. Other protruding element distribution patterns could of course be utilized.

[0194] Figure 12 is an example of a graphical display of information derived from outputs from three of the sensor modules 606A, 606B, 606C (represented by columns A, B and C of the display) shown in Figure 11. The display provides an indication of how blood perfusion pressures derived from each of the sensor modules 606A, 606B, 606C modules can be displayed together to provide an indication of how blood perfusion pressure may vary about the periphery of a wound to which the dressing 604 is applied.

[0195] Figure 13 shows an example of a further embodiment of hand-held skin perfusion pressure determination device 702 comprising a grip portion 704 and a probe portion 706. The device 702 is similar to the device shown in Figure 6 in that the probe portion 706 comprises a pad portion 708 in which a sensor module is housed. The grip portion 704 comprises an integrated display 710 for displaying information derived from the output of the sensor module.

[0196] Figure 14 shows a further apparatus 802 for determining skin perfusion pressure comprising a skin perfusion pressure determination device 804, a monitoring device 806 and an inflatable cuff 808. The skin perfusion pressure determination device 804 comprises a wound dressing 810 and a sensor module 812 formed integrally with the wound dressing 810. The sensor module 812 is in accordance with the sensor module 14 shown in Figure 1. The monitoring device 806 comprises signal processing electronics 814, a processor 816, a power source in the form of a battery 818 and a display 820. The battery 818 is arranged to supply power to the sensor module 812, processor 816 and display 820. The monitoring device 806 is formed integrally with the wound dressing.

[0197] The inflatable cuff 808 is arranged so that, in use, the cuff 808 surrounds the wound dressing 810 and a patient's limb 822 or other region of a patient's body to which the wound dressing is to be secured. The cuff 808 is configured so that the display 820 is visible to a clinician or other such healthcare professional. For example, a window (not shown) may be provided in the cuff 808 in the vicinity of the display 820. The display 820 may be a thin-film display having a thickness which corresponds to, or is less than, the thickness of the wound dressing 810 and which is suitable for incorporation into the wound dressing.

[0198] The cuff 808 may be inflated and deflated using an external pump, such as a hand pump, or a pump integrated into the apparatus 802. Inflation of the cuff 808 presses the sensor module 812 against the patient's limb. The cuff 808 can then be deflated in order

to reduce the force applied to the sensor module 812 in accordance with the method outlined above with respect to the apparatus shown in Figure 1 in order to obtain a skin perfusion pressure measurement. Deflation may be done manually by the user or automatically and follow a predetermined sequence of steps and/or in accordance with other sensed parameters.

[0199] Figure 15 shows an alternative arrangement of an apparatus comprising a wound dressing and a monitoring device which correspond to the wound dressing and a monitoring device shown in Figure 14. The same reference signs for the same components have therefore been used. The apparatus further comprises a pneumatic actuator in the form of an inflatable air cushion 902 which is located on top of the sensor module 812 and integrated with the wound dressing 810 such that the air cushion 902 can be inflated to press the sensor module 812 against a patient's skin 822. The apparatus may be configured to automatically take measurements in a predetermined time sequence and store the results to compile data between visits by a clinician or caregiver. The device could further be configured to calculate trends and store them for subsequent retrieval by a caregiver.

[0200] Figure 16 shows a further apparatus 1002 for determining skin perfusion pressure comprising a skin perfusion pressure determination device 1004, a monitoring device 1006 and a force actuator 1008. The skin perfusion pressure determination device 1004 comprises a wound dressing 1010 and a sensor module 1012 formed integrally with the wound dressing 1010. The sensor module 1012 is in accordance with the sensor module 14 shown in Figure 1. The monitoring device 1006 comprises signal processing electronics 1014, a processor 1016, a data storage device in the form of a memory 1018 and a power source in the form of a battery 1020. The battery is arranged to supply power to the sensor module 1012, the processor 1016 and the memory 1018. The monitoring device 1006 is formed integrally with the wound dressing 1010. The force actuator 1008 may be an electromechanical actuator, a thermal actuator or a pneumatic actuator such as an air cushion as described with respect to the arrangement shown in Figure 15, which is arranged to press the sensor module 1012 against a patient's skin 1022. Examples of suitable actuators include: motors, solenoids, shape-memory actuators, wax actuators and piezo-electric actuators or the like. The force actuator 1008 may be calibrated such that the force applied can be determined from the a drive signal supplied to the force actuator. In such embodiments, no additional force sensor may be required.

[0201] The processor is configured to both drive the force actuator 1008 and to process outputs from the sensor module 1012 (although separate processors may be used instead) and is programmed to conduct a series of skin perfusion pressure measurements

automatically in accordance with a predetermined requirement such as a predetermined time pattern or on an ad hoc basis when initiated by a user. The memory is configured to store data obtained from the sensor module 1012. The stored data can be subsequently transmitted to a further device for storage and/or processing, for example, during consultations with a clinician. This may be done via a wired link or wirelessly.

[0202] Figures 14, 15 and 16 show a power source in the form of a battery. However, alternative power sources may be used such as one or more capacitors, fuel cells or energy generators, which generate energy, for example, from the movement of the wearer, e.g. based on some piezo elements or the like, from temperature differences and heat generated by the user or the environment, using, for example, thermopiles, or from light, using, for example, photovoltaic cells, or other energy generating systems, for example clockwork type mechanisms which can be charged by the user. Any battery used may be non-rechargeable or rechargeable. Recharging may be conducted using wired or contactless charging techniques.

[0203] Figure 17A illustrates an embodiment of a cuff 1202. As used herein, the terms cuff and detachable band can be used interchangeable to refer to a detachable band that may be secured to the limb or body of a patient by wrapping it around the limb or body and securing opposite end portions together using a fastener, such as an adhesive strip or hook and loop fastener or the like. The cuff 1202 can have a sensor module 1212 similar to and is in accordance with the sensor module 14 shown in Figure 1. In some embodiments, manual actuation can be used to apply pressure to the cuff 1202 and press the sensor module 1212 against a patient's limb or other region of a patient's body to which the device is to be secured. The manual actuation can utilize a user's hand and/or fingers to control the amount of force applied to the device and/or patient's skin. Figure 17A illustrates a cuff 1202 surrounding a patient's limb 1222. The user can press the cuff 1202 at the position of the sensor module 1212 as shown in Figure 17A. The sensor module 1212 can be pressed against the patient's limb 1222. The pressure asserted on the sensor module 1212 can be released in order to reduce the force applied to the sensor module 1212. These steps can be conducted in accordance with the method outlined above with respect to the apparatus shown in Figure 1 and the method shown in Figure 4 in order to obtain a skin perfusion pressure measurement. Release of the manual pressure may follow a predetermined sequence of steps and/or in accordance with other sensed parameters. As illustrated in Figure 17A, in some embodiments, the device can communicate with a remote device 1223 which displays the results and provides user feedback as described in more detail herein.

[0204] In some embodiments, the sensor module (not shown) can be integrated into the wound dressing 1210. A user can press the sensor module within the wound dressing 1210 to carry out a measurement as illustrated in Figure 17B.

[0205] Figures 18A and 18B illustrates embodiments of a cuff 1302 with a sensor module 1312 to be used against a patient's limb 1322 or other region of a patient's body to which the device is to be secured. In some embodiments, the cuff 1302 can apply pressure and release pressure against a patient's skin in accordance with the method outlined above with respect to the apparatus shown in Figure 1 and the method shown in Figure 4 in order to obtain a skin perfusion pressure measurement.

[0206] In some embodiments, the application and release of pressure on a sensor module can be fully automated in order to obtain a skin perfusion pressure measurement. The cuff can use electromechanical actuators which can control the cuff as it shrinks around a patient's limb. Once the appropriate pressure has been applied to the patient's limb, the cuff can automatically release the pressure. In other embodiments, the cuff 1302 can use fluid-based inflatable pads or devices to control the inflation and/or release of pressure on the cuff 1302 by inflating and deflating the cuff 1302 as shown in Figure 18B. Figure 18B illustrates the cuff 1302 in an inflated state around a patient's limb 1322. The automated application and/or release of pressure may follow a predetermined sequence of steps and/or can occur in accordance with other sensed parameters.

[0207] As described previously, the hand-held skin perfusion pressure determination device or other device with a sensor module can be used to obtain a skin perfusion pressure measurement. The hand-held skin perfusion pressure determination device or other device with a sensor module described herein can be placed either above, below, to the left, and/or to the right of the wound bed to obtain a measurement. In some embodiments, the hand-held skin perfusion pressure determination device or other device with a sensor module can be placed 5cm from the edge of the wound bed. In some embodiments, the hand-held skin perfusion pressure determination device or other device with a sensor module can be placed about 2cm to 10cm from the edge of the wound bed. In some embodiments, measurements can be taken up to the edge of the wound. In some embodiments, measurements can be taken any distance from the wound or from a location on the patient's body not associated with a wound. The skin perfusion measurement can be obtained from one or more locations near or on the wound bed. In some embodiments, the skin perfusion measurement can be obtained from each location, one at a time.

[0208] The hand-held skin perfusion pressure determination device or other device with a sensor module can be placed in a first location and measurements can be obtained from the first location in accordance with the methods described herein. Then the hand-held skin perfusion pressure determination device or other device with a sensor module can be placed in a second location and measurements can be obtained from the second location in accordance with the methods described herein. The process can be repeated at each location where a measurement is desired.

[0209] In some embodiments, the hand-held skin perfusion pressure determination device or other device with a sensor module can include or be in communication with signal processing electronics and a processor for processing signals received from the sensors in the sensor module. In some embodiments, the hand-held skin perfusion pressure determination device or other device with a sensor module can be connected to or in communication with a monitoring device similar to that shown in Figure 1. In some embodiments, the processor can display data representing the processed signals on a display. The processor may be configured to display instructions to a patient/clinician on the display such as instructions to increase the applied force or to reduce the applied force at each stage of the measurement process. In some embodiments, the display can be located on a remote device. For example, the display can be located on a computer monitor, laptop, tablet, smart phone, and/or other device with a user interface. In other embodiments, the display can be on the device comprising the sensor module. For example, the display can be located on the hand-held skin perfusion pressure determination device.

[0210] Figures 19A-19F illustrate embodiments of a display that can provide a user instructions to increase the applied force or to reduce the applied force at each stage of the measurement process. The display 1916 can include an indicator bar 1917. The indicator bar 1917 can rise or increase in size as force is applied to the measurement location or applied with the sensor module. The indicator bar 1917 can fall or decrease in size as the applied force is reduced. In some embodiments, the display can be a computer monitor, laptop, tablet, smart phone, and/or other device with a user interface. Figures 19A-19F illustrate a display 1916 with an indication bar 1917 and a hand-held skin perfusion pressure determination device 1902 positioned above or on a wound dressing 1901. While the hand-held skin perfusion pressure determination device 1902 is shown above or on the wound dressing 1901, in some embodiments, the hand-held skin perfusion pressure determination device 1902 could be positioned proximal to the wound dressing 1901. The indication bar 1917 can move between a bottom portion 1918 and a top portion 1919 of the display 1916.

Figures 19A-19F illustrate embodiments of a wound dressing 1901 and a hand-held device 1902 throughout the steps of the measurement method as described herein. As illustrated in Figures 19A-19F, the interaction between the wound dressing 1901 and the hand-held device 1902 can correspond to the movement or location of the indication bar 1917 of the display 1916.

[0211] Figure 19A illustrates a hand-held device 1902 placed on a measurement location or target area 1911 of a wound dressing 1911. As used herein, the measurement location and/or target area are used herein interchangeably to refer to the location where the skin perfusion pressure measurement is taken. The display 1916 shows the indicator bar 1917 near the bottom 1918 of the display 1916. The location of the indicator bar 1917 on the display provides feedback to the user that little to no pressure is applied to the measurement location 1911 by the hand-held device 1902. Pressure can be applied to the measurement location 1911 until the indicator bar 1917 on the display 1906 fills up or rises to the top portion 1919 of the display 1916.

[0212] As shown in Figure 19B, the hand-held device 1902 can be positioned on the measurement location 1911 and a force can be applied to the measurement location 1911. As the force applied to the measurement location 1911 is increased, the indicator bar 1917 on the display 1916 can rise as illustrated in Figure 19B. In some embodiments, the display 1916 can provide an indicator, symbol, or color change when the incorrect amount or correct amount of force is applied to the measurement location 1911 by the hand-held device 1902.

[0213] Force can continue to be applied until the indicator bar 1917 on the display 1916 reaches the top 1919 of the display as shown in Figure 19C. In some embodiments, the indicator bar 1917 can change colors or pattern to indicate the appropriate amount of force has been or is being applied to the measurement location 1911. In other embodiments, a symbol or indicator can be displayed to indicate the appropriate amount of force has been or is being applied to the measurement location 1911.

[0214] Once the appropriate amount of force has been applied to the measurement location 1911 to conduct the perfusion measurement according to the methods described herein, the force applied by the hand-held device 1902 can be decreased as the hand-held device 1902 is removed from the measurement location 1911 as illustrated in Figure 19D. In some embodiments, the hand-held device 1092 is slowly removed from the measurement location 1911 to obtain the appropriate measurements. As the hand-held device 1902 is removed from the measurement location 1911, the indicator bar 1917 can begin to decrease or fall as illustrated in Figure 19D and Figure 19E. In some embodiments, the indicator bar

1917 can assist the user in slowly removing the hand-held device 1902 from the measurement location. For example, if the indicator bar falls or decreases too quickly the user can adjust to remove the hand-held device 1902 at a slower rate. In some embodiments, the display 1916 can provide an indicator, symbol, or color change if the hand-held device 1902 is removed too quickly or too slowly. As illustrated in Figure 19F, once the hand-held device 1902 is completely removed from the measurement location 1911, the indicator bar 1917 is no longer present or visible on the display 1916.

[0215] The display 1916 can give live or real time feedback on the current amount of pressure being applied versus the pressure that should be applied. The display 1916 and indication bar 1917 can give helpful, education feedback to improve performance for the next use if the first use was insufficient to collect data.

[0216] Once the measurement is taken at a first location, the hand-held device 1902 can be applied to a second measurement location and the process can be repeated with the force application instructions provided by the user on the display 1916 as illustrated in Figures 19A-19F.

[0217] In some embodiments, the display or user interface can be used to provide guidance and/or feedback to a user. In some embodiments, the display or user interface can provide guidance and/or feedback with respect to the measurement location and the applied force to conduct the perfusion measurement according to the methods described herein. In some embodiments, the display can indicate various conditions. For example, the display can provide a visual indication of a measurement location, an applied force, an occlusion reached indication, high force warning, speed of movement indication, perfusion measurement result, and/or a measurement quality indication. In some embodiments, these conditions or indicators can be displayed on a remote display such as a computer monitor, laptop, tablet, smart phone, and/or other device with a user interface. In some embodiments, these conditions or indicators can be displayed on a device comprising a sensor module, for example, a hand-held skin perfusion pressure determination device.

[0218] Figure 20A illustrates an embodiment of a display indicating the location of measurement 2011 with respect to the wound 2010. Figure 20B illustrates an embodiment of a display or user interface with a force indicator used to indicate the force applied by a skin perfusion pressure determination device or other measurement device to the measurement location. The force indicator can assist the user by indicating when the appropriate amount of force is applied to the measurement location. As illustrated in Figure 20B, the force indicator display can provide a visual indication of the force applied to the measurement location. The

visual indication of the force applied can be indicated with a multi-segment gauge type indicator 2012 as illustrated in Figure 20B.

[0219] Figure 20C illustrates an embodiment of an occlusion pressure indicator. The occlusion pressure indicator can provide a visual indication of the occlusion pressure and/or when the occlusion pressure is reached. The occlusion pressure indicator can assist the user by indicating when the appropriate amount of pressure has been applied to the measurement location to cause occlusion. In some embodiments, the visual indication of the force applied can be indicated with multi-segment gauge type indicator 2013 as illustrated in Figure 20C.

[0220] Figure 20D illustrates an embodiment of a display with a visual indicator used to indicate when a force is above a critical level. In some embodiments, the visual indication of the force applied can be indicated with multi-segment gauge type indicator 2014 as illustrated in Figure 20C.

[0221] In some embodiments, the display can be a high force warning indicator with a two-level indication. The two-level indication can include an indication when occlusion pressure is reached and when the force is above a critical level. In other embodiments, the high force warning can have a three-level indication. The three-level indication can include an indication when occlusion pressure is reached, when force has reached a desired level, and when the force is above a critical level.

[0222] Figure 20E illustrates an embodiment of a display with a visual indication of the speed of movement of the hand-held device. In some embodiments, the speed of movement indicator can include an indication if the speed is appropriate (for example, target speed), if the speed is too slow, and/or if the speed is too high or fast. In some embodiments, the speed of movement indicator can be a graphical representation of the speed as illustrated in Figure 20E.

[0223] Figure 20F illustrates a display with a visual indication of a perfusion level and/or perfusion measurement result. In some embodiments, the visual indication of perfusion level and/or perfusion measure results can be displayed with a text and/or numeric indication display as shown in Figure 20F. For example, perfusion measure result can be expressed in units of pressure.

[0224] In some embodiments, the display can include an indication of the quality of the measurement obtained from the measurement location.

[0225] Figures 21A-21G illustrate embodiments of a display or user interface on a hand-held skin perfusion pressure determination device 2102. Figure 21A illustrates a hand-

held device 2102 with a display 2116. In some embodiments, the display 2116 can include one or more visual indicators 2120. In some embodiments, the visual indicators 2120 can include a light source, for example, a light emitting diode (LED). The visual indicators 2120 can be different colors, can change colors, and/or can illuminate in a pattern or sequence to provide guidance or feedback to the user. In some embodiments, multiple visual indicators 2120 can be used to indicate one or more conditions or parameters of the wound dressing or hand-held device. In some embodiments, the light source can be a single color, multi-color, and/or blinking light source.

[0226] Figure 21B illustrates a hand-held device 2102 with a visual indicator 2120 for signaling if the device is powered on or off. In some embodiments, the indicator 2120 can display different colors depending on the condition or can switch between being illuminated or not illuminated depending on the condition. Figure 21C illustrates a hand-held device 2102 with a visual indicator 2123 for indicating that a particular force has been applied. For example, the visual indicator 2123 can indicate when an occlusion force is reached. The visual indicator 2123 can have a force indication displayed with a multi-segment gauge type indicator including a column of light sources that can be illuminated one by one as the force applied to the dressing is increased. As shown in Figure 21C, the hand-held skin perfusion pressure determination device 2102 can include two types of visual indicators. The display 2016 of the hand-held skin perfusion pressure determination device 2102 can include a circular visual indicator 2120 and the multi-segment gauge type indicator 2123.

[0227] Figure 21D and 21E illustrates a hand-held skin perfusion pressure determination device 2102 with two visual indicators 2120a and 2120b. In some embodiments, the two visual indicators 2120a and 2120b can indicate when the appropriate speed for application and withdrawal or force is used. To indicate different conditions, the indicators can be illuminated or not illuminated. For example, Figure 21D illustrates an embodiment of a hand-held device 2102 with indicator 2120b not illuminated and Figure 21E illustrates an embodiment of a hand-held device 2102 with indicator 2120b illuminated. In other embodiments, one of the two visual indicators 2120b can display a first color when the speed is correct and a second color as when the speed is too high. In some embodiments, the two visual indicators can be used in combination to display or indicate a certain condition. The two visual indicators can display different color combinations and/or illumination combinations depending on the condition.

[0228] In some embodiments, the two visual indicators 2120a and 2120b can be used to indicate two different conditions. As illustrated in Figure 21F, the visual indicator 2120a can be used to indicate if the device is on or off and the visual indicator 2120b can be used to indicate that the force applied to the measurement location has reached a desired level.

[0229] Figure 21G illustrates an embodiment of a hand-held device 2102 with multiple indicators. Visual indicator 2120e can be a caution symbol or other symbol that is illuminated when a condition has occurred. The indicators can be any shape or symbol, a light source, a multi-segment gauge type indicator, and/or any other indicator type.

[0230] As illustrated in Figure 22A and 22B a hand-held skin perfusion pressure determination device 2202 can include a display 2216 that provides a text and/or numeric indication of various conditions of the hand-held skin perfusion pressure determination device, measurement technique, and/or measurement information. For example, the display 2216 can provide a text and/or numeric indication of the force (shown in Figure 22A), the withdrawal speed (shown in Figure 22B), or a measurement result.

[0231] In some embodiments, the hand-held device 2202 can include a display 2216 that provides a graphical indication of various conditions of the hand-held device 2202, measurement technique, and/or measurement information. In some embodiments, the graphical indicator can include multiple visual indicators. In some embodiments, as shown in Figure 22C, the graphical indicator can be a multi-segment gauge type indicator 2217. In some embodiments, the graphical indicator can be an analogue display 2218 as illustrated in Figures 22D and 22E.

[0232] In some embodiments, the visual indicators can be LED indicators, organic light emitting diodes (OLED) indicators, and/or electronic paper display technology (EINK) indicators.

[0233] An audible and/or tactile indicators can be used in addition to or in place of the visual indicators on the hand-held device. In some embodiments, the audible and/or tactile indicators can provide an audible and/or tactile signals to indicate and/or monitor the force level and/or withdrawal speed. The audible signal or tactile indicator may be generated to inform a clinician/patient of a condition or parameter. In some embodiments, an audible and/or tactile signal can be used to provide warnings or alerts including a warning when the occlusion pressure is reached and/or a high force warning. In some embodiment, the audible signal may be continuous or a series of beeps that vary in frequency or volume depending on the magnitude of the pulsatile component of the trace or when a condition is reached. The

tactile signal may be a continuous or series of vibrations that vary in frequency or volume depending on the magnitude of the pulsatile component of the trace or when a condition is reached. For example, an audible beep pattern or vibration pattern may stop when the pulsatile component drops below a threshold value and re-emerges when the pulsatile component returns indicating the return of blood flow in the tissue at the target area.

[0234] In some embodiments, the indicators can be circumferential indicators. Figure 23 illustrates an embodiment of a hand-held skin perfusion pressure determination device 2302 with a circumferential indicator 2322. The circumferential indicator 2322 can be located on the distal end 2323 of the hand-held skin perfusion pressure determination device 2302 furthest from the proximal sensor end 2324 of the hand-held device 2302. The circumferential indicator 2322 can indicate one or more characteristics or parameters of the hand-held skin perfusion pressure determination device 2302, the sensor, the measurement location, the measurement method, and/or any other characteristics that can provide guidance or feedback to the user. In some embodiments, the hand-held skin perfusion pressure determination device 2302 can include one or more circumferential indicators 2322 to provide visual force feedback to the user. The visual force feedback can be real time or substantially real time feedback. In some embodiments, each circumferential indicator 2322 can provide guidance or feedback with respect to a different characteristic. For example, a first circumferential indicator can provide guidance to the user regarding a first characteristic and a second circumferential indicator can provide guidance to the user regarding a second characteristic, and so on. In some embodiments, the circumferential indicators 2322 can be used to display the different levels of the same characteristic. For example, a first circumferential indicator can illuminate or provide a visual indication when a first characteristic reaches a first threshold and a second circumferential indicator can illuminate or provide a visual indication when a first characteristic reaches a second threshold, and so on. The circumferential indicators 2022 can be color changing indicators. In some embodiments, the circumferential indicators 2022 can be LED indicators and one or more LED colors can be used. As illustrated in Figure 23, the hand-held skin perfusion pressure determination device 2302 can have three circumferential indicators 2322.

[0235] Although, Figures 7A-7C, 7L-7O, 7R, 8, 9A-9B, 11, and 17B illustrate a square, rectangular, substantially rectangular, or substantially rectangular dressing with lobes, in some embodiments, various dressing shapes and sizes can be used. In some embodiments, the dressing can be rectangular, square, round, oval, rounded rectangle, triangular, and/or any other shape. In some embodiments, multi-lobe dressings can be used. For example,

quadrilobe, trilobe, and/or sacral dressings such as dressings available for ALLEVYN™ or ALLEVYN Life™ product line available from Smith & Nephew can be used with the embodiments described herein. In some embodiments, the dressing can include an asymmetrical lobed or notched dressing with no line of symmetry so that the measurement device can determine the orientation.

[0236] It will be appreciated that the blood perfusion sensor may comprise other types of optical sensor or may be a non-optical sensor, the monitoring device could comprise other types of data storage devices. It will also be appreciated that, where applicable, each embodiment described previously could be modified so that recorded data is processed and/or stored locally on a skin perfusion pressure determination device or transmitted for remote processing and/or storage and vice versa.

[0237] The embodiments described above comprise a sensor module which is configured such that an optical sensor can be positioned adjacent the skin and a force sensor is located above the optical sensor. Other possible arrangements include a sensor module in which a force sensor and an optical sensor are arranged such that, in use, the force sensor is placed next to a target region of skin tissue and the optical sensor is positioned above the force sensor. In such an arrangement, the force sensor may comprise through-holes or transparent portions through which light can be transmitted.

[0238] It will be appreciated that throughout this specification reference is made to a wound. 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 superficial 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 include, but are not limited to, abdominal wounds or other large or incisional wounds, either as a result of surgery, trauma, sterniotomies, fasciotomies, or other conditions, dehiscent wounds, acute wounds, chronic wounds, subacute and dehiscent 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.

[0239] It will be understood that embodiments of the present disclosure are generally applicable for use in topical negative pressure ("TNP") therapy systems, such as be incorporated into a TNP dressing. 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. As is used herein, reduced or negative pressure levels, such as -X mmHg, represent pressure levels relative to normal ambient atmospheric pressure, which can correspond to 760 mmHg (or 1 atm, 29.93 inHg, 101.325 kPa, 14.696 psi, etc.). Accordingly, a negative pressure value of -X mmHg reflects absolute pressure that is X mmHg below 760 mmHg or, in other words, an absolute pressure of (760-X) mmHg. In addition, negative pressure that is "less" or "smaller" than X mmHg corresponds to pressure that is closer to atmospheric pressure (e.g., -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 (e.g., -80 mmHg is more than -60 mmHg). In some embodiments, local ambient atmospheric pressure is used as a reference point, and such local atmospheric pressure may not necessarily be, for example, 760 mmHg. 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 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.

[0240] In the drawings like reference numerals refer to like parts.

[0241] Throughout the description and claims of this specification, the words "comprise" and "contain" and variations of them mean "including but not limited to" and they are not intended to (and do not) exclude other moieties, additives, components, integers or steps. Throughout the description and claims of this specification, the singular encompasses the plural unless the context otherwise requires. In particular, where the indefinite article is used, the specification is to be understood as contemplating plurality as well as singularity, unless the context requires otherwise.

[0242] Features, integers, characteristics or groups described in conjunction with a particular aspect, embodiment or example of the disclosure 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), and/or all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of the features and/or steps are mutually exclusive. The disclosure is not restricted to any details of any foregoing embodiments. The disclosure extends to any novel one, or 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.

[0243] The reader's attention is directed to all papers and documents which are filed concurrently with or previous to this specification in connection with this application and which are open to public inspection with this specification, and the contents of all such papers and documents are incorporated herein by reference.

WHAT IS CLAIMED IS:

1. A skin perfusion pressure determination device comprising:
a sensor module having a first sensor for sensing a first parameter associated with a pressure exerted on a target area by the sensor module and a second sensor for sensing a second parameter associated with an amount of blood perfusion at the target area, wherein the first sensor and the second sensor are arranged such that, when the sensor module is pressed against the target area the first sensor produces an output corresponding to the sensed first parameter and the second sensor produces an output corresponding to the sensed second parameter.
2. The skin perfusion pressure determination device of claim 1, wherein the first sensor comprises a force sensor arranged to determine the force exerted by the sensor module on the target area.
3. The skin perfusion pressure determination device of claim 2, wherein the force sensor is arranged such that when the sensor module is pressed against the target area, the second sensor is disposed between the target area and the force sensor.
4. The skin perfusion pressure determination device of any one of the preceding claims, wherein the second sensor comprises a light source and an optical detector arranged to receive light emitted by the light source which has been reflected by the target area
5. The skin perfusion pressure determination device of claim 4, wherein the light source comprises at least one light emitting diode and the optical detector comprises at least one photodetector.
6. The skin perfusion pressure determination device of any one of the preceding claims, wherein the second sensor is a pulse sensor
7. The skin perfusion pressure determination device of any one of the preceding claims, wherein the device is a portable device comprising a probe portion, the probe portion comprising the sensor module.
8. The skin perfusion pressure determination device of claim 7, wherein the probe portion comprises a pad portion having a lower surface which, in use, is pressed against the target area.
9. The skin perfusion pressure determination device of any one of claims 1 to 6, wherein the device is a portable device comprising a cuff portion for wrapping about a limb of a patient, the sensor module is arranged on an inner portion of the cuff.

10. The skin perfusion pressure determination device of claim 9, wherein the cuff is inflatable and the cuff is configured such that inflation of the cuff presses the sensor module against the target area.

11. The skin perfusion pressure determination device of claim 9, wherein the cuff is manually actuated

12. The skin perfusion pressure determination device of claim 10, wherein the cuff is configured to be inflated by an electromechanical actuator or fluid-based inflation device.

13. The skin perfusion pressure determination device of any one of claims 1 to 6, wherein the device comprises a wound dressing and the sensor module is integral with the wound dressing.

14. The skin perfusion pressure determination device of claim 13, wherein the wound dressing comprises an actuator arranged to press the sensor module against the target area.

15. The skin perfusion pressure determination device of any one of the preceding claims, further comprising a processor for processing an output of the first sensor and an output of the second sensor, wherein the processor is configured to determine that the output of the second sensor satisfies a predetermined condition associated with a predetermined amount of blood perfusion at the target area.

16. The skin perfusion pressure determination device of claim 15, wherein the predetermined condition is a condition which corresponds to an amount of blood perfusion at the target area which exceeds a predetermined threshold.

17. The skin perfusion pressure determination device of claim 15 or 16, wherein the predetermined condition is a condition that corresponds to the presence of a pulsatile component of blood flow at the target area.

18. The skin perfusion pressure determination device of any one of claims 15 to 17, wherein the processor is further configured to produce an output which represents a pressure exerted on the target area by the sensor module when the second parameter satisfies the predetermined condition.

19. The skin perfusion pressure determination device of any one of claims 15 to 18, further comprising a memory for storing at least one of the predetermined condition and the output of the processor.

20. Apparatus comprising the skin perfusion pressure determination device of any one of the preceding claims, wherein the apparatus comprises a display for displaying information representing at least one output of the first sensor and the second sensor.

21. A method of determining skin perfusion pressure comprising the steps:

pressing a sensor module against a target area, wherein the sensor module has a first sensor for sensing a first parameter associated with a pressure exerted on a target area by the sensor module and a second sensor for sensing a second parameter associated with an amount of blood perfusion at the target area;

subsequently reducing the pressure exerted on the target area by the sensor module;

processing with a processor a first sensor output corresponding to the sensed first parameter and a second sensor output corresponding to the sensed second parameter to determine that the output of the second sensor satisfies a predetermined condition corresponding to an amount of blood perfusion at the target area and outputting an output from the processor which corresponds to the pressure exerted by the sensor module on the target area when the second parameter satisfies the predetermined condition.

22. The method of claim 21, wherein the predetermined condition is a condition which corresponds to an amount of blood perfusion at the target area which exceeds a predetermined threshold.

23. The method of claim 21 or 22, wherein the predetermined condition is a condition that corresponds to the presence of a pulsatile component of blood flow at the target area.

24. The method of any one of claims claim 21 to 23, wherein the step of reducing the pressure exerted by the sensor module on the target area comprises the steps of:

processing with the processor the second sensor output to determine that the second parameter satisfies a further predetermined condition associated with an amount of blood perfusion at the target area and subsequently reducing the pressure exerted by the sensor module on the target area.

25. The method of claim 24, wherein the further predetermined condition is a condition which corresponds to an amount of blood perfusion at the target area which is below a predetermined threshold.

26. The method of any one of claims 21 to 25, wherein the method comprises a step of determining a skin perfusion pressure based on the output from the processor which corresponds to the pressure exerted by the sensor module on the target area.

27. A method of determining skin perfusion pressure comprising the steps:

processing with a processor a first sensor output representing a sensed first parameter associated with a pressure applied to a target area and a second sensor output representing a sensed second parameter associated with an amount of blood perfusion at the target area to determine that the output of the second sensor satisfies a predetermined condition associated with an amount of blood perfusion at the target area and outputting an output from the processor which corresponds to the pressure exerted by the sensor module on the target area when the second parameter satisfies the predetermined condition.

28. The method of claim 27, wherein the predetermined condition is a condition which corresponds to an amount of blood perfusion at the target area which exceeds a predetermined threshold.

29. The method of claim 27 or 28, wherein the predetermined condition is a condition that corresponds to the presence of a pulsatile component of blood flow at the target area.

30. The method of any one of claims 27 to 29, further comprising the steps of:

processing with the processor the second sensor output to determine that the second parameter satisfies a further predetermined condition associated with an amount of blood perfusion at the target area and subsequently reducing the pressure exerted by the sensor module on the target area.

31. The method of claim 29, wherein the further predetermined condition is a condition which corresponds to an amount of blood perfusion at the target area which is below a predetermined threshold.

32. A wound dressing comprising:

a wound protecting portion which, in use, overlies a wound; and

a peripheral portion which extends around at least part of the wound protecting portion, wherein the peripheral portion comprises at least one window which is arranged to locate a measurement probe having an optical sensor configured to sense light at a predetermined wavelength, wherein the window is transparent to light at the predetermined wavelength.

33. The wound dressing of claim 32, wherein the predetermined wavelength is a wavelength that corresponds to visible, ultraviolet or infrared light.

34. The wound dressing of claim 33, wherein the predetermined wavelength is between 495nm and 1350nm.

35. The wound dressing of claim 34, wherein the predetermined wavelength is between 650nm and 1350nm.

36. The wound dressing of any one of claims 32 to 35, wherein the or each window comprises an opening through the peripheral portion.

37. The wound dressing of any one of claims 32 to 36, wherein the or each window comprises an optically transparent material.

38. The wound dressing of claim 37, wherein the optically transparent material comprises at least one of polyvinyl chloride (PVC), cellulose acetate or acrylic or silicone or polyurethane or acylate.

39. The wound dressing of any one of claims 32 to 38, wherein the peripheral portion has a lower surface and an adhesive on the lower surface for securing the wound dressing to a patient's skin.

40. The wound dressing of one of claims 32 to 39, wherein the wound dressing is an island-type dressing in which the wound protecting portion is disposed centrally and the peripheral portion extends around a perimeter of the wound protecting portion.

41. The wound dressing of claim 40, the peripheral portion further comprising at least one lobe which projects away from the wound protecting portion, wherein the or each window is provided at least partially in the or each lobe respectively.

42. The wound dressing of any one of claims 32 to 41, wherein the or each window is circular or ovoid.

43. The wound dressing of any one of claims 32 to 42, comprising at least two windows adjacent the wound protecting portion, wherein the wound protecting portion is disposed between the windows.

44. The wound dressing of claim 43, wherein the wound protecting portion has four sides and the four windows which are disposed adjacent each of the sides respectively.

45. Apparatus comprising:

the wound dressing of any one of claims 32 to 44; and

a measurement probe comprising an optical sensor configured to sense light at the predetermined wavelength.

46. The apparatus of claim 45, wherein the measurement probe comprises a pad portion having a lower surface which, in use, is pressed against a patient's skin, and the window has a size and shape which corresponds to the size and shape of the pad portion.

47. A method of sensing at least one characteristic associated with a wound or a region of tissue proximate to a wound, comprising the steps of:

locating a wound dressing comprising a wound protecting portion over a wound whereby the wound protecting portion overlies the wound, locating a pad

portion of a measurement probe at a window region of a peripheral portion of the wound dressing, and transmitting light from the measurement probe through the window.

48. The method as claimed in claim 47 further comprising:

preventing light from the measurement probe penetrating through the wound dressing at remaining regions of the wound dressing away from the window.

49. The method as claimed in claim 47 or 48, further comprising:

one-by-one, locating the measurement probe consecutively at each of a plurality of windows on the wound dressing and taking respective probe measurements at each location.

50. A wound dressing comprising:

an upper surface; and

at least one indicium for determining the orientation of the wound dressing, about an axis which is orthogonal to the upper surface, relative to a surface on which the wound dressing is securable.

51. The wound dressing of claim 50, wherein the at least one indicium is provided on the upper surface.

52. The wound dressing of claim 50, wherein the wound dressing comprises:

a wound protecting portion; and

a peripheral portion which extends around at least part of the wound contacting portion, wherein the wound protecting portion comprises the at least one indicium.

53. The wound dressing of any one of claims 50 to 52, wherein the peripheral portion has a lower surface and an adhesive on the lower surface for securing the wound dressing to a surface.

54. The wound dressing of any one of claims 50 to 53, wherein a plurality of indiciums are provided on the upper surface, each indicium comprising at least one graphical marker which is different from each of the other graphical markers.

55. The wound dressing of claim 54, wherein the wound dressing has at least two poles and at least one graphical marker is provided at each of the poles.

56. The wound dressing of claim 54 or 55, wherein each marker comprises an alphanumeric character.

57. The wound dressing of any one of claims 54 to 56, wherein each marker comprises a directional marker.

58. The wound dressing of any one of claims 50 to 57, wherein the wound dressing is an island-type dressing.

59. The wound dressing of any one of claims 50 to 58, wherein each indicium is a printed element or a recessed region or a protruding region of the wound dressing.

60. The wound dressing of any one of claims 50 to 59, wherein each indicium comprises at least one of a color patch, a metal element, a magnetic element and a resonant tag.

61. The wound dressing of any one of claims 50 to 60, wherein each indicium comprises an RFID tag.

62. The wound dressing of any one of claims 50 to 61, wherein the wound dressing further comprises at least one sensor site and said at least one indicium provides a visible cue for locating the sensor site at a desired location with respect to a wound.

63. The wound dressing of claim 62 wherein each sensor site is associated with a respective at least one indicium.

64. The wound dressing of claim 62 or claim 63 wherein each sensor site comprises a location where a wound dressing sensor is located, a location of a window configured to receive a portion of a probe portion of an inspection device, or a target area of the wound dressing configured to receive a portion of a probe portion of an inspection device.

65. The wound dressing of any one of claims 62 to 64, wherein each indicium comprises of an RFID tag and a graphical marker which are configured to be uniquely associated with a respective sensor site of the wound dressing.

66. A method of orientating a wound dressing to a desired orientation with respect to a surface, comprising the steps of:

 locating a wound dressing proximate to a wound, rotating the wound dressing about an axis orthogonal to an upper surface of the wound dressing to align at least one indicium on the upper surface at a desired rotatory orientation, and urging the wound dressing towards the wound thereby dressing the wound via the wound dressing.

67. The method as claimed in claim 66, further comprising:

 rotating the wound dressing to align at least one indicium on a peripheral portion of the wound dressing at a desired positional relationship with respect to a wound or a predetermined patient feature.

68. The method of claim 66 or claim 67, further comprising:

the wound dressing further comprises at least one sensor site and the step of rotating the wound dressing comprises locating each sensor site at a desired location with respect to the wound.

69. The method of claim 68 wherein the step of locating each sensor site comprises locating a wound dressing sensor at the desired location or at a window portion of the wound dressing that locates a wound dressing sensor.

70. A wound dressing comprising:

- an upper surface; and

- at least one indicium for determining the orientation of the wound dressing, about an axis which is orthogonal to the upper surface, relative to a surface on which the wound dressing is securable;

- a wound protecting portion; and

- a peripheral portion which extends around at least part of the wound contacting portion, wherein the wound protecting portion comprises the at least one indicium,

- wherein a plurality of indiciums are provided on the upper surface, each indicium comprising at least one graphical marker which is different from each of the other graphical markers.

71. A wound dressing comprising:

- an upper surface;

- at least one indicium for determining the orientation of the wound dressing, about an axis which is orthogonal to the upper surface, relative to a surface on which the wound dressing is securable;

- a wound protecting portion; and

- a peripheral portion which extends around at least part of the wound contacting portion, wherein the wound protecting portion comprises the at least one indicium.

72. A wound dressing comprising:

- an upper surface; and

- at least one indicium for determining the orientation of the wound dressing, about an axis which is orthogonal to the upper surface, relative to a surface on which the wound dressing is securable,

- wherein each indicium comprises an RFID tag.

73. A wound dressing comprising:

an upper surface;

at least one indicium for determining the orientation of the wound dressing, about an axis which is orthogonal to the upper surface, relative to a surface on which the wound dressing is securable;

at least one sensor site,

wherein said at least one indicium provides a visible cue for locating the sensor site at a desired location with respect to a wound, and

wherein each indicium comprises of an RFID tag and a graphical marker which are configured to be uniquely associated with a respective sensor site of the wound dressing.

74. An apparatus comprising:

a wound dressing;

a skin perfusion pressure determination device comprising a sensor module, the sensor module including a sensor configured to sense at least one characteristic associated with a wound or a region of tissue proximate to a wound; and

a display configured to indicate at least one condition relating to the at least one characteristic associated with a wound or a region of tissue proximate to a wound sensed by the sensor module.

75. The apparatus of claim 74, wherein the skin perfusion pressure determination device comprises a hand-held device.

76. The apparatus of any one of claims 74 to 75, wherein the display comprises a computer monitor, laptop, tablet, or smart phone.

77. The apparatus of any one of claims 74 to 76, wherein the display is configured to provide a visual indication of a measurement location, an applied force, an occlusion reached indication, high force warning, speed of movement indication, perfusion measurement result, or a measurement quality indication.

78. The apparatus of any one of claims 74 to 77, wherein the display is positioned on the skin perfusion pressure determination device.

79. The apparatus of any one of claims 74 to 78, wherein the display comprises one or more visual indicators.

80. The apparatus of claim 79, wherein the one or more visual indicators comprise a multi-segment gauge type indicator, a symbol, a text and/or numeric indication, graphical indication, or circumferential indicators.

81. The apparatus of any one of claims 79 to 80, wherein the one or more visual indicators comprise one or more light emitting diodes (LED).

82. The apparatus of any one of claims 79 to 80, wherein the one or more visual indicators comprise an LED indicator, organic light emitting diodes (OLED) indicator, and/or EINK indicators.

83. The apparatus of any one of claims 79 to 82, wherein the one or more visual indicators comprise a multi-segment gauge type indicator, a symbol, a text and/or numeric indication, graphical indication, or circumferential indicators.

84. The apparatus of any one of claims 74 to 83, wherein the sensor module is configured to apply a pressure on a target area.

85. The apparatus of claim 84, wherein the sensor module comprises a first sensor for sensing a first parameter associated with the pressure exerted on the target area by the sensor module and a second sensor for sensing a second parameter associated with an amount of blood perfusion at the target area.

86. The apparatus of any one of claims 84 to 85, wherein the display is configured to provide user instructions to increase the applied pressure or to reduce the applied pressure during a measurement process.

87. An apparatus comprising:

a wound dressing;

a skin perfusion pressure determination device comprising a sensor module, the sensor module including a sensor configured to sense at least one characteristic associated with a wound or a region of tissue proximate to a wound; and

an audible and/or tactile indicator configured to indicate at least one condition relating to the at least one characteristic associated with a wound or a region of tissue proximate to a wound sensed by the sensor module.

88. A method of determining at least one characteristic associated with a wound or a region of tissue proximate to a wound comprising:

locating a wound dressing comprising a wound protecting portion over a wound whereby the wound protecting portion overlies the wound;

positioning a skin perfusion pressure determination device comprising a sensor module at a target area on or adjacent to the wound dressing, wherein the sensor module includes a sensor configured to detect at least one characteristic associated with a wound or a region of tissue proximate to a wound; and

receiving a visual, audible, or tactile indicator relating to the at least one characteristic associated with a wound or a region of tissue proximate to a wound detected with the sensor of the skin perfusion pressure determination device.

89. The method of claim 88, wherein a visual indicator is incorporated into a display.

90. The method of any one of claims 88 to 89, wherein the skin perfusion pressure determination device comprises a hand-held device.

91. The method of any one of claims 89 to 90, wherein the display comprises a computer monitor, laptop, tablet, or smart phone.

92. The method of any one of claims 88 to 91, wherein the skin perfusion pressure determination device comprises the visual, audible, or tactile indicators.

93. The method of any one of claims 89 to 92, wherein the display comprises one or more visual indicators.

94. The method of any one of claim 88 to 93, wherein a visual indicator comprises one or more light emitting diodes (LED).

95. The method of claim 88 to 94, wherein a visual indicator comprises an LED indicator, organic light emitting diodes (OLED) indicator, and/or EINK indicator.

96. The method of any one of claims 88 to 95, wherein a visual indicator comprises a multi-segment gauge type indicator, a symbol, a text and/or numeric indication, graphical indication, or circumferential indicators.

97. The method of any one of claims 88 to 96, wherein the at least one characteristic associated with a wound or a region of tissue proximate to a wound comprises a skin perfusion pressure.

98. The method of any one of claims 88 to 97, further comprising applying pressure to the skin perfusion pressure determination device to exert a pressure on a target area.

99. The method of claim 98, wherein the sensor module has a first sensor for sensing a first parameter associated with the pressure exerted on the target area by the sensor module and a second sensor for sensing a second parameter associated with an amount of blood perfusion at the target area.

100. The method of claims 98 to 99, wherein the visual, audible, or tactile indicator provides user instructions to increase the applied pressure or to reduce the applied pressure of the skin perfusion pressure determination device on the target area.

101. The method of any one of claims 88 to 100, wherein the visual, audible, or tactile indicator provides an indication of a measurement location, an applied force, an

occlusion reached indication, high force warning, speed of movement indication, perfusion measurement result, or a measurement quality indication.

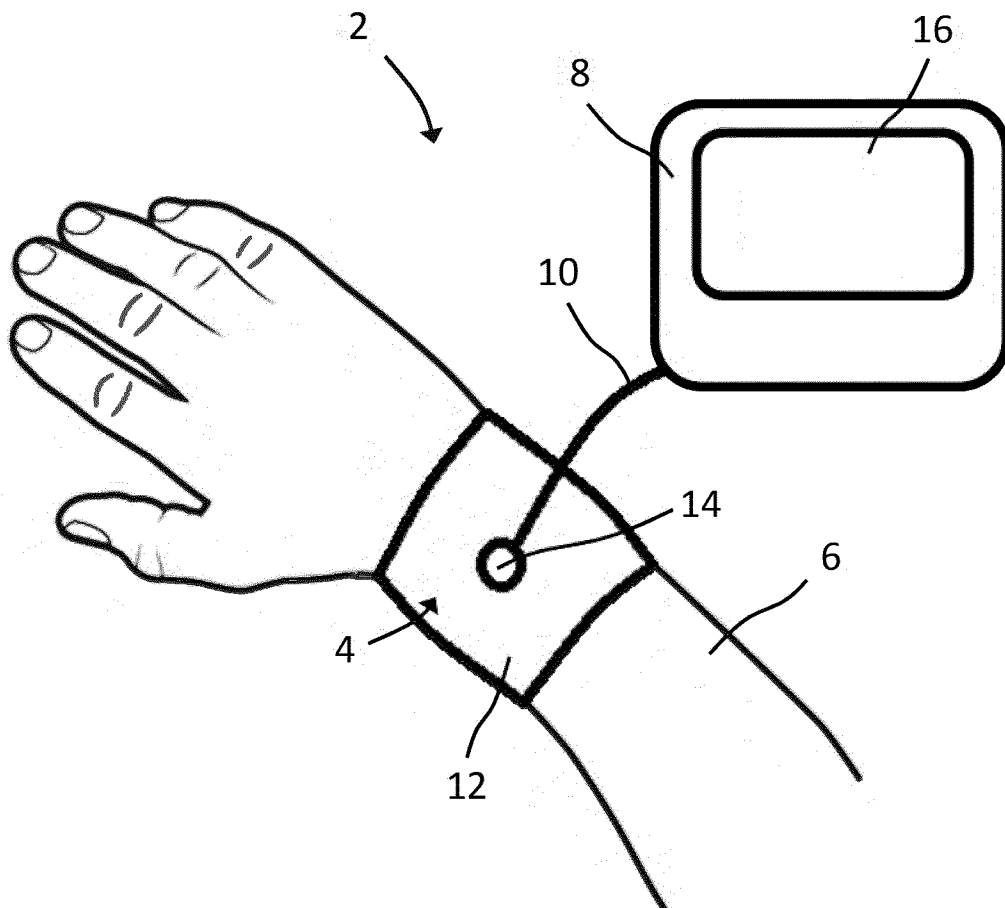


Figure 1

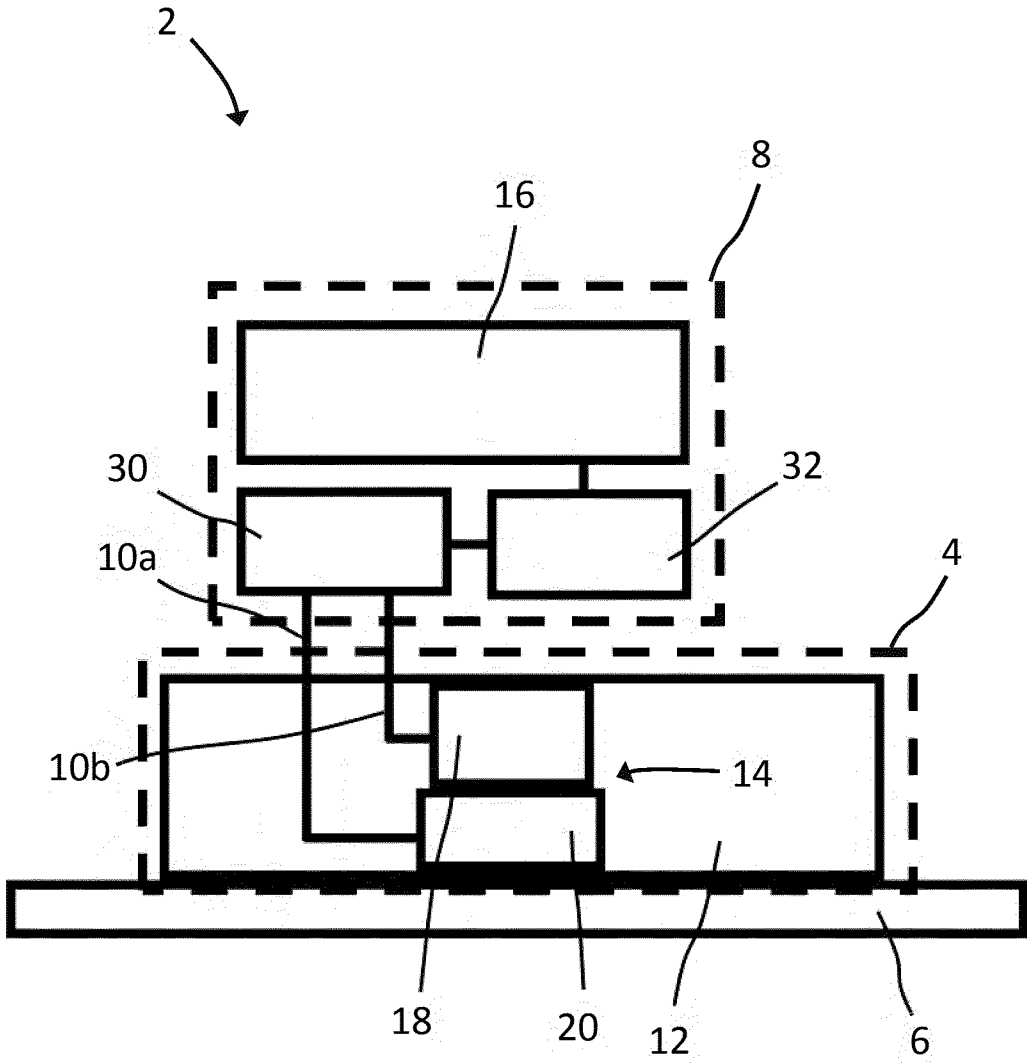


Figure 2

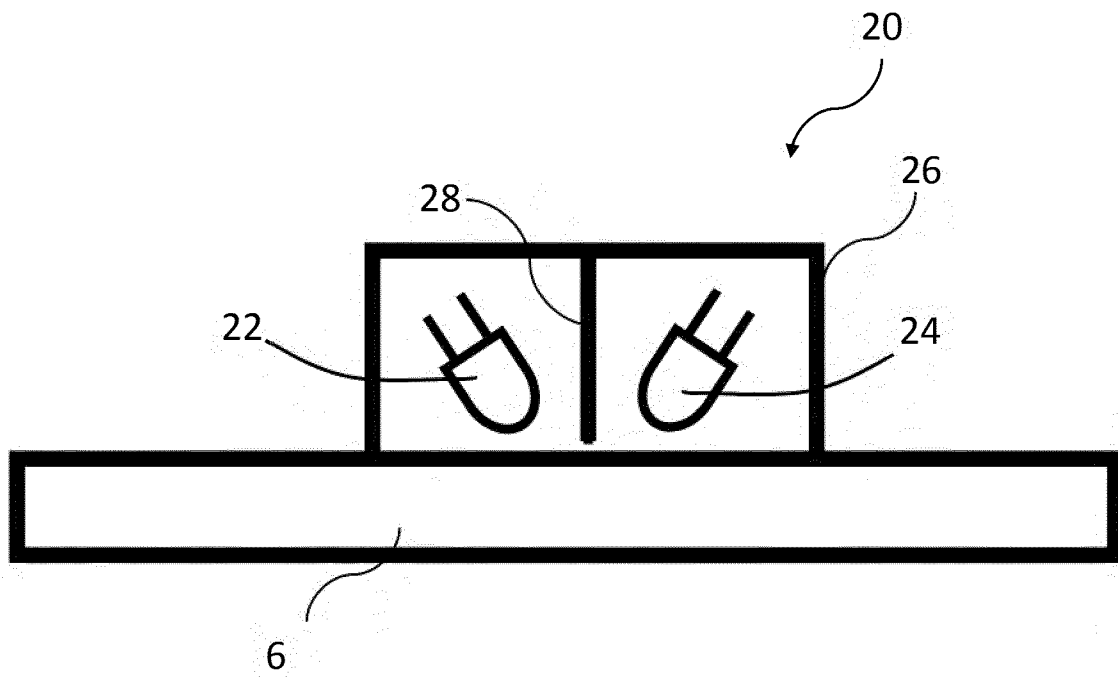


Figure 3

4/47

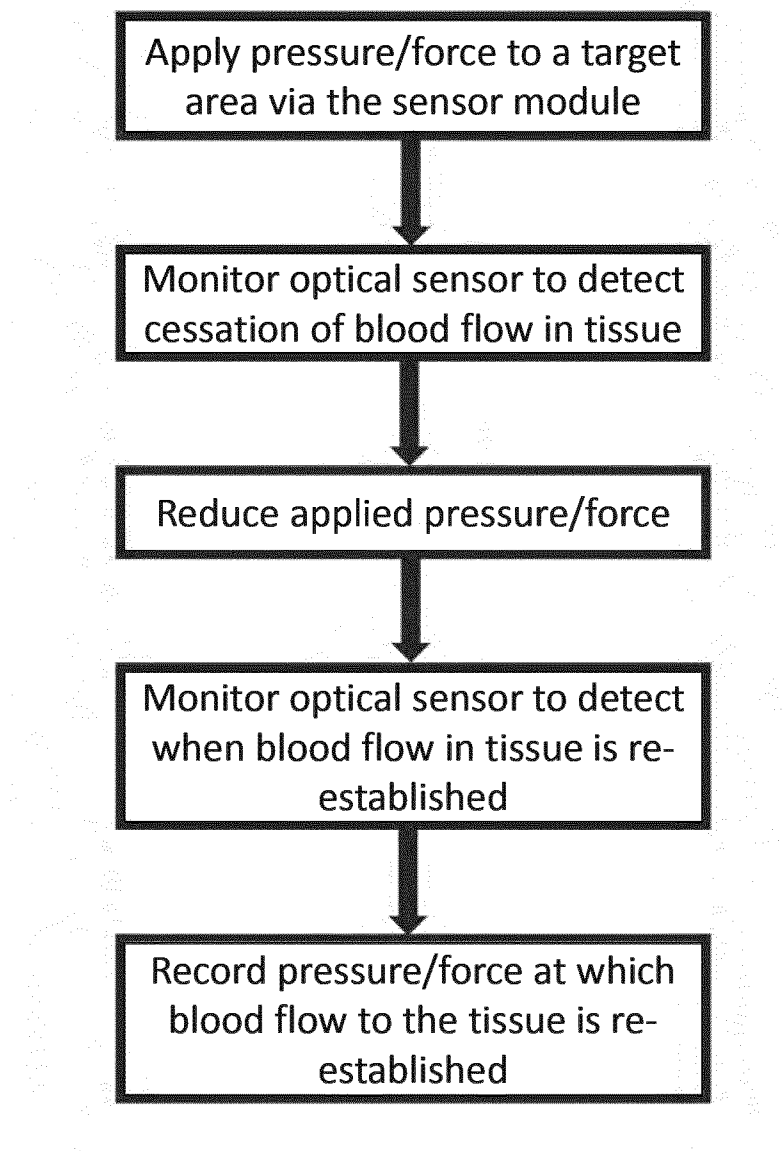


Figure 4

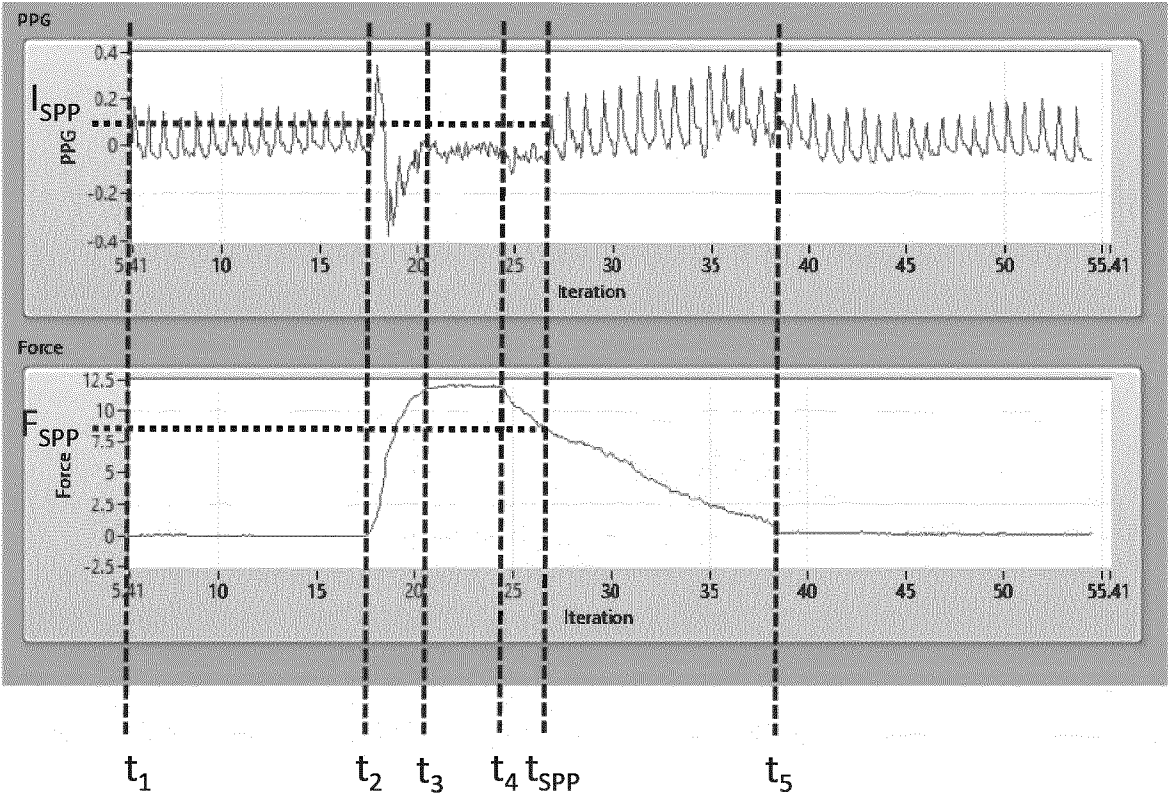


Figure 5

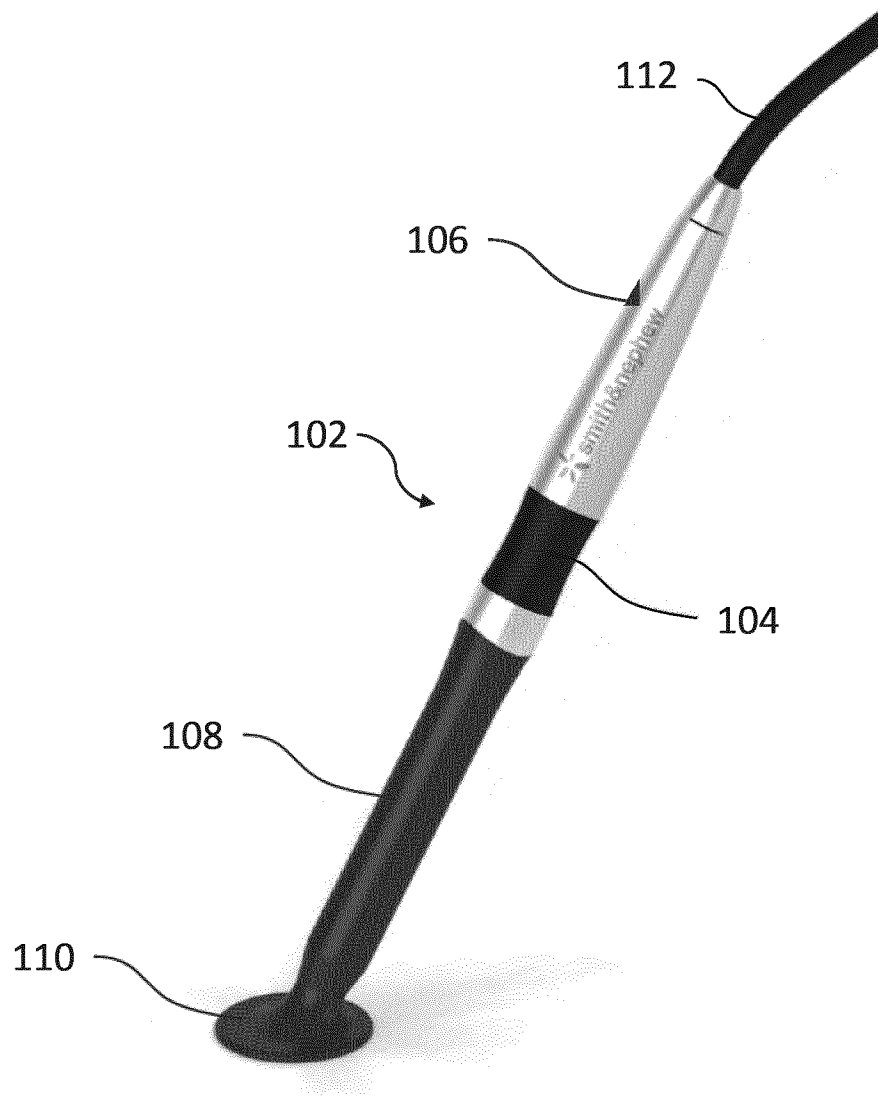


Figure 6

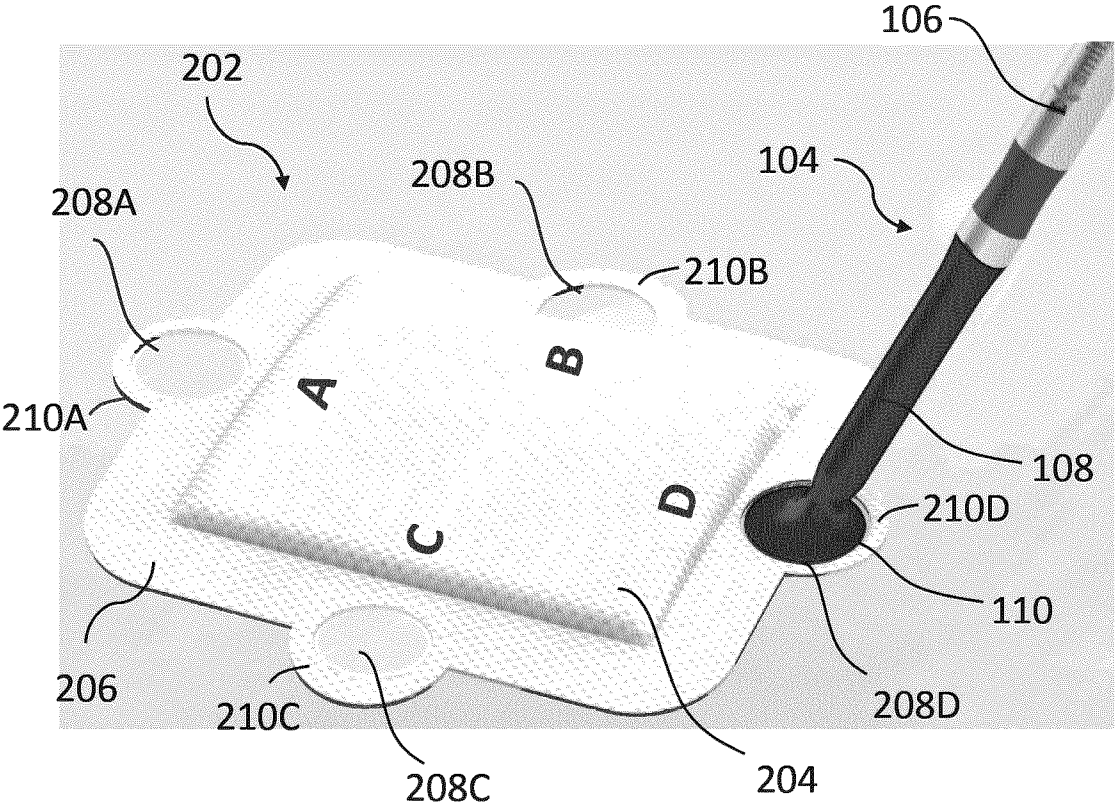


Figure 7A

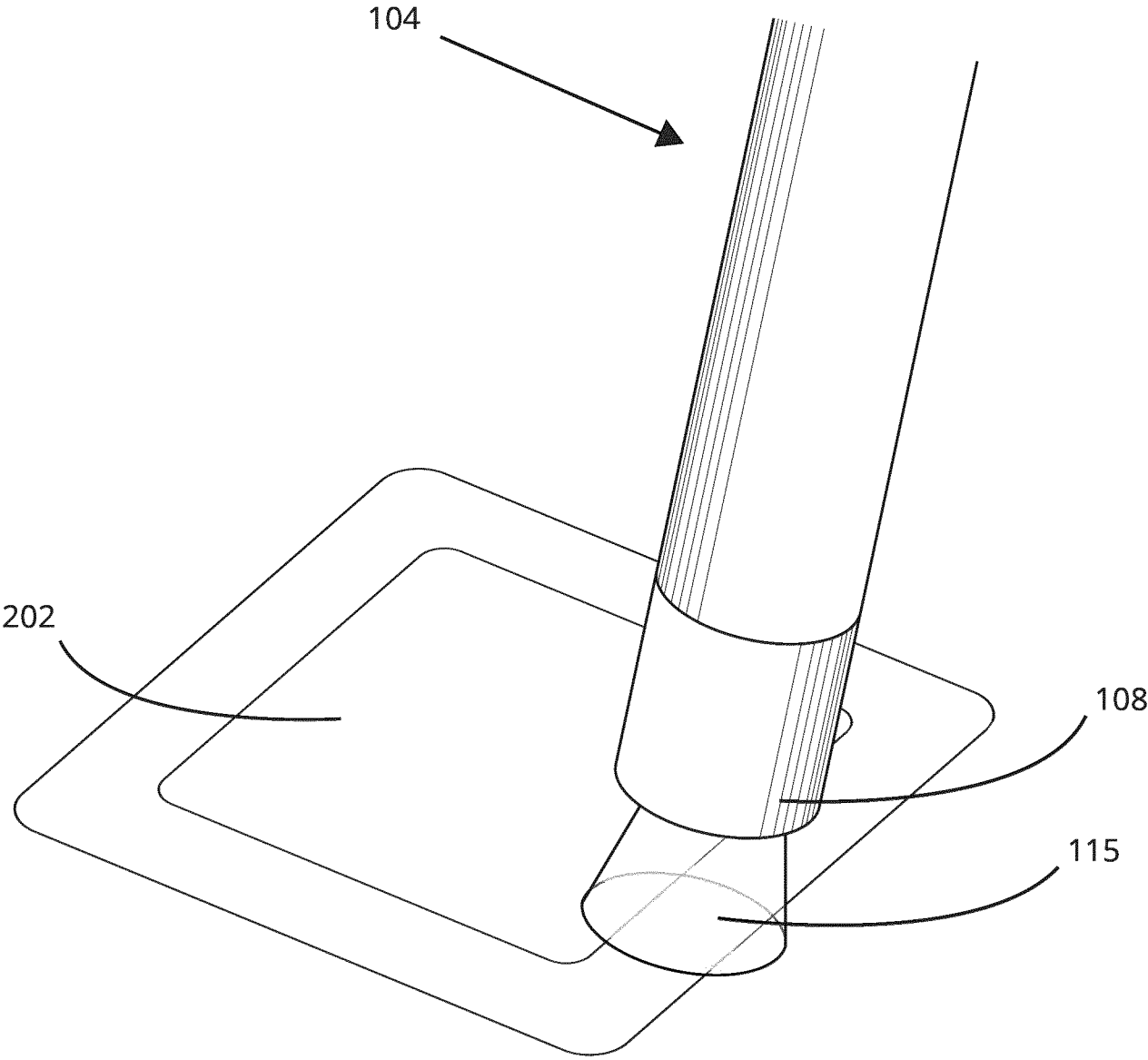


Figure 7B

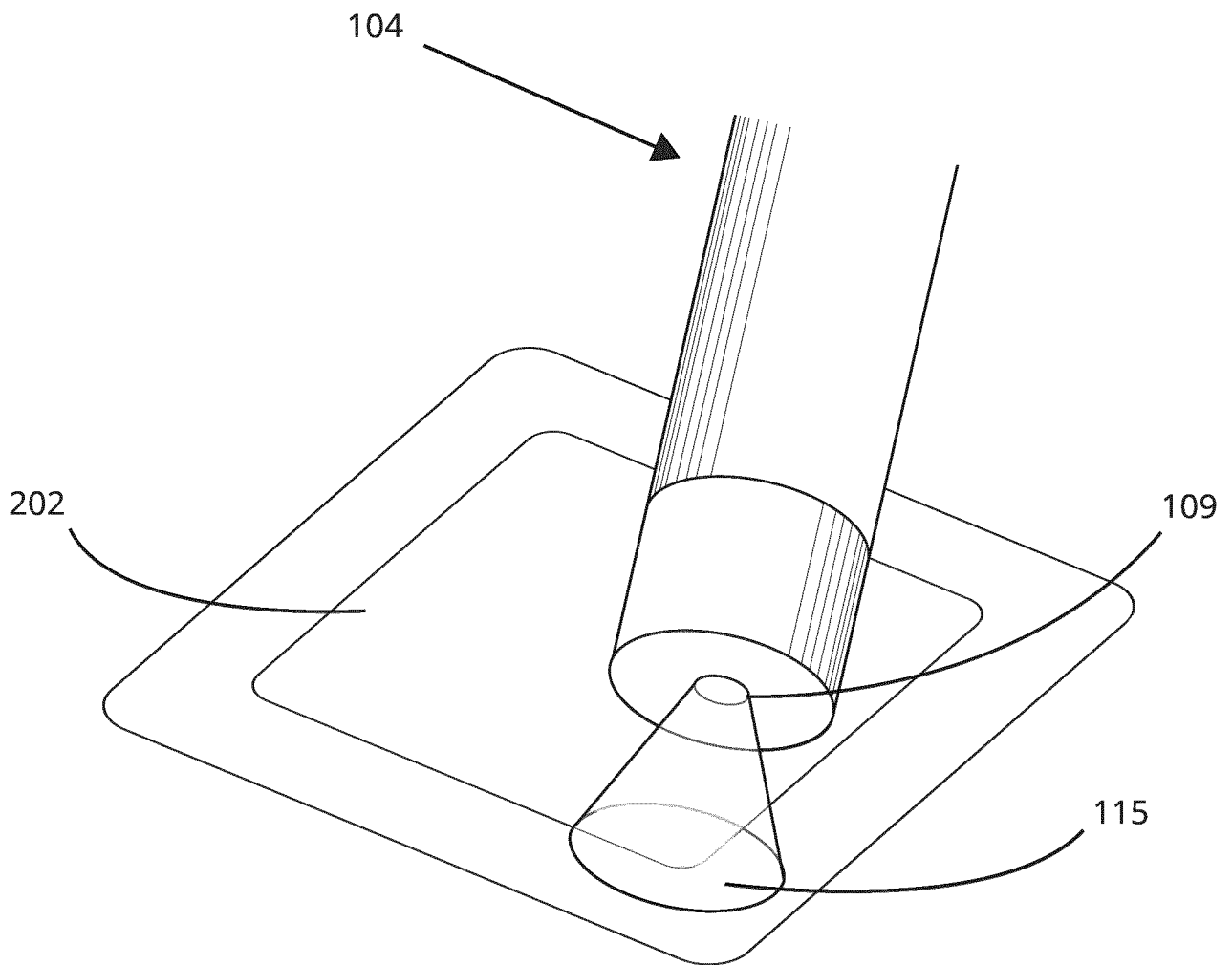


Figure 7C

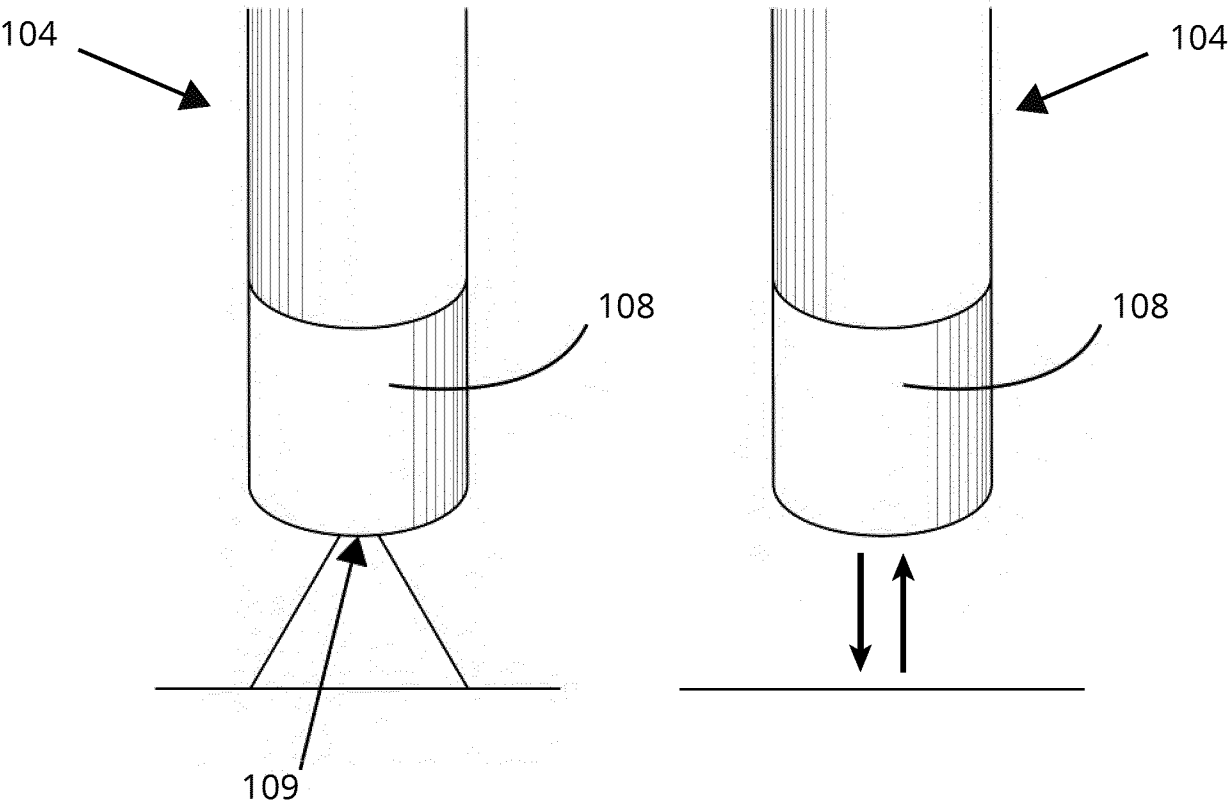


Figure 7D

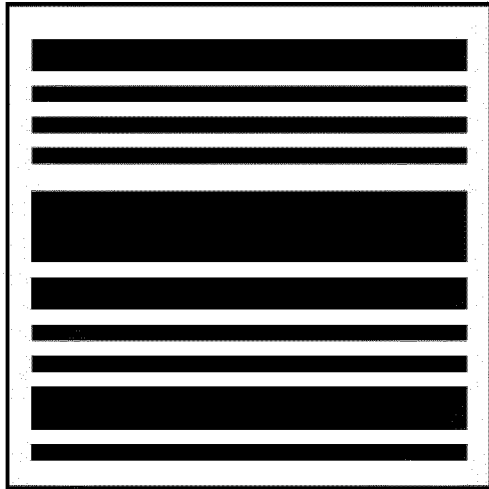


Figure 7E

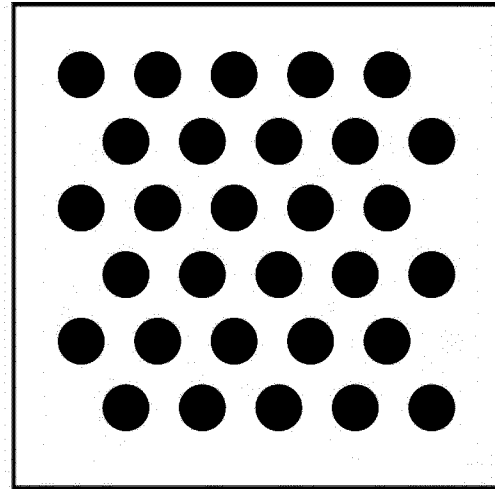


Figure 7F

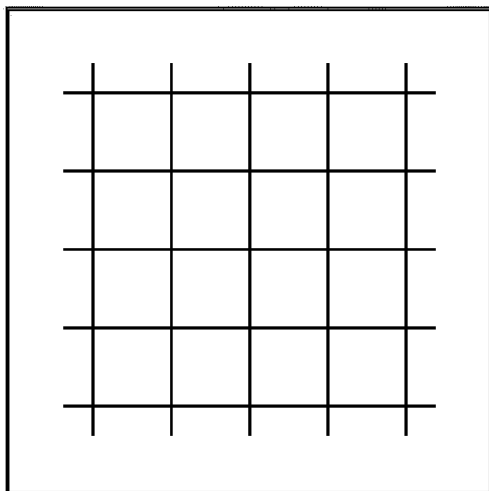


Figure 7G

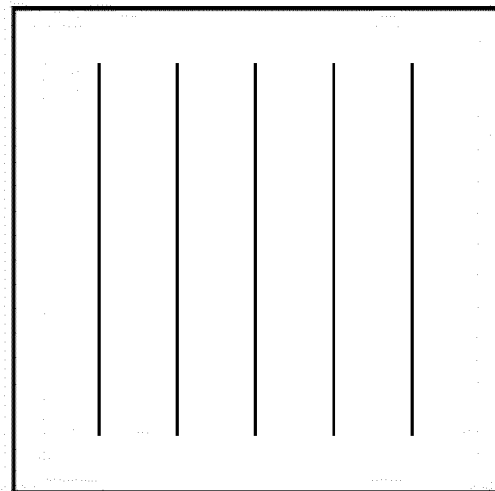


Figure 7H

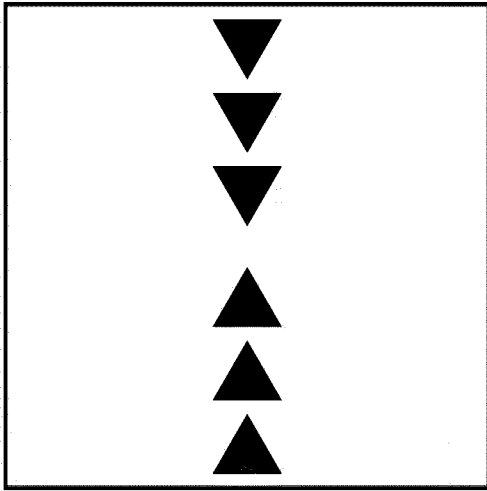


Figure 7I

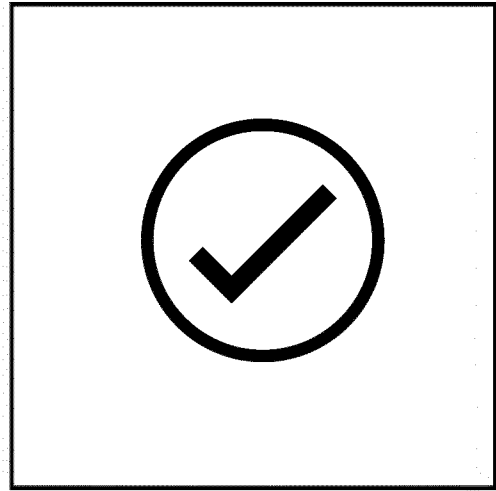


Figure 7J

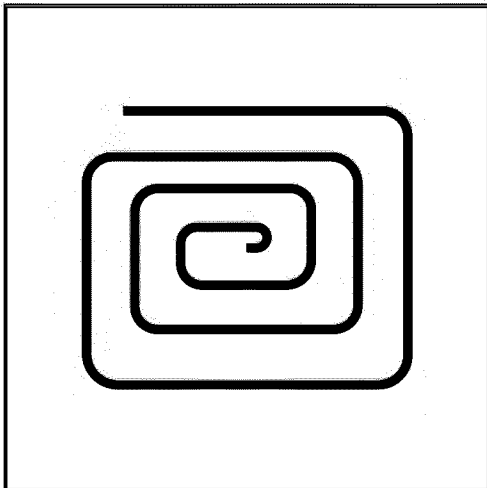


Figure 7K

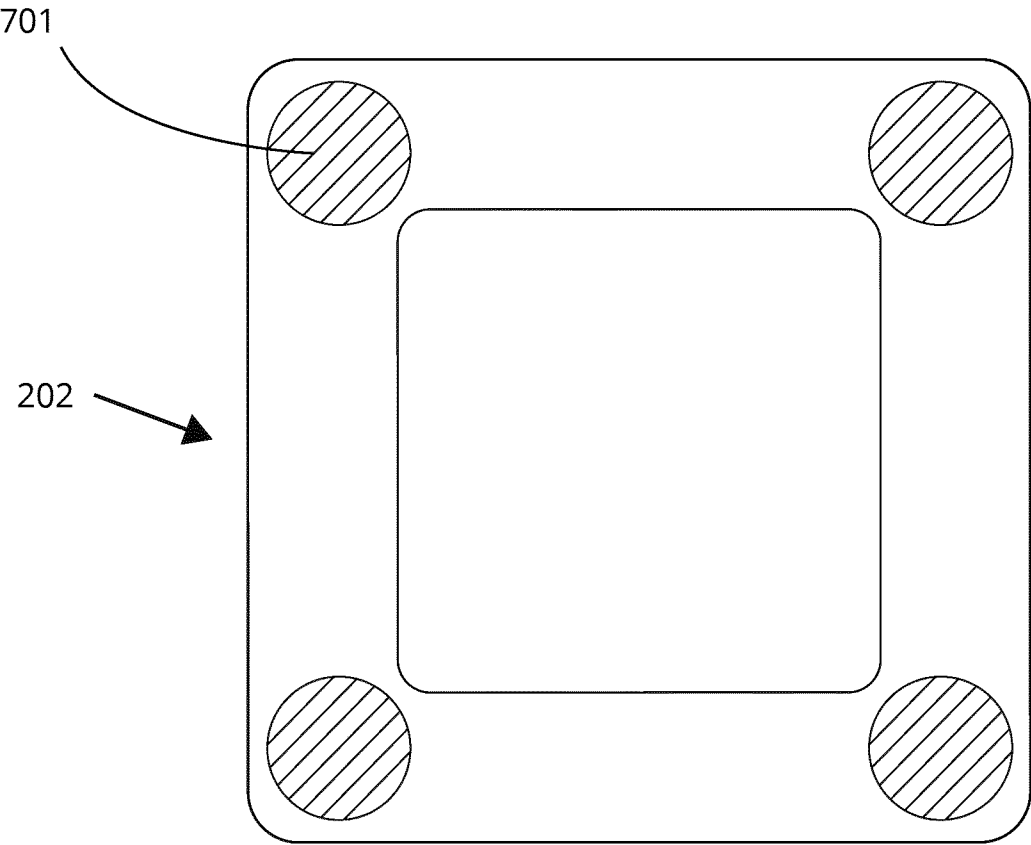


Figure 7L

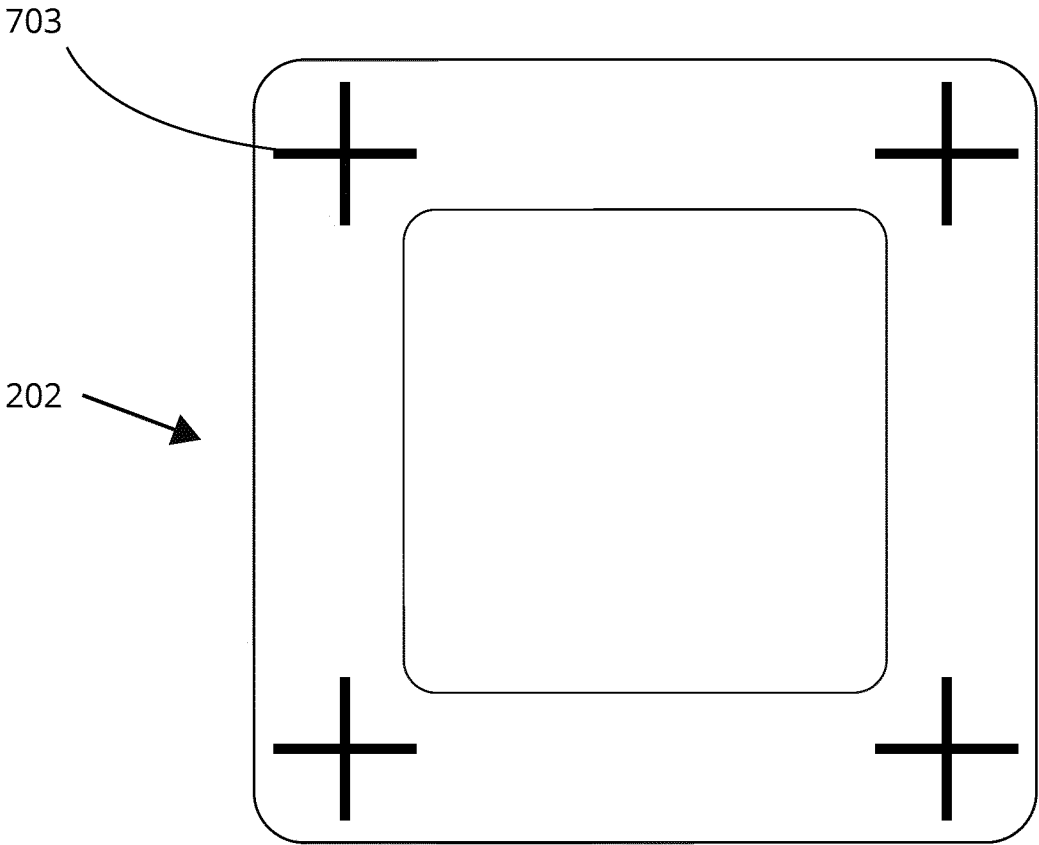


Figure 7M

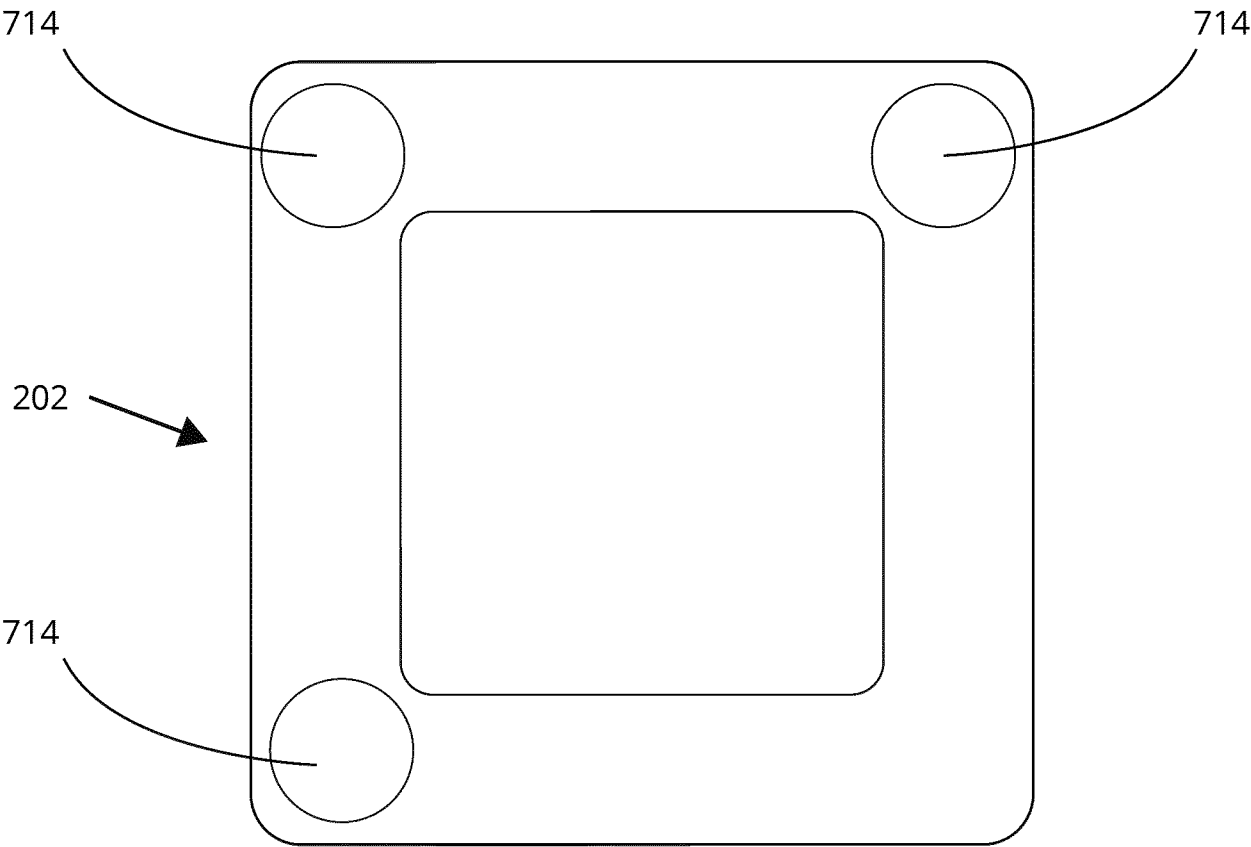


Figure 7N

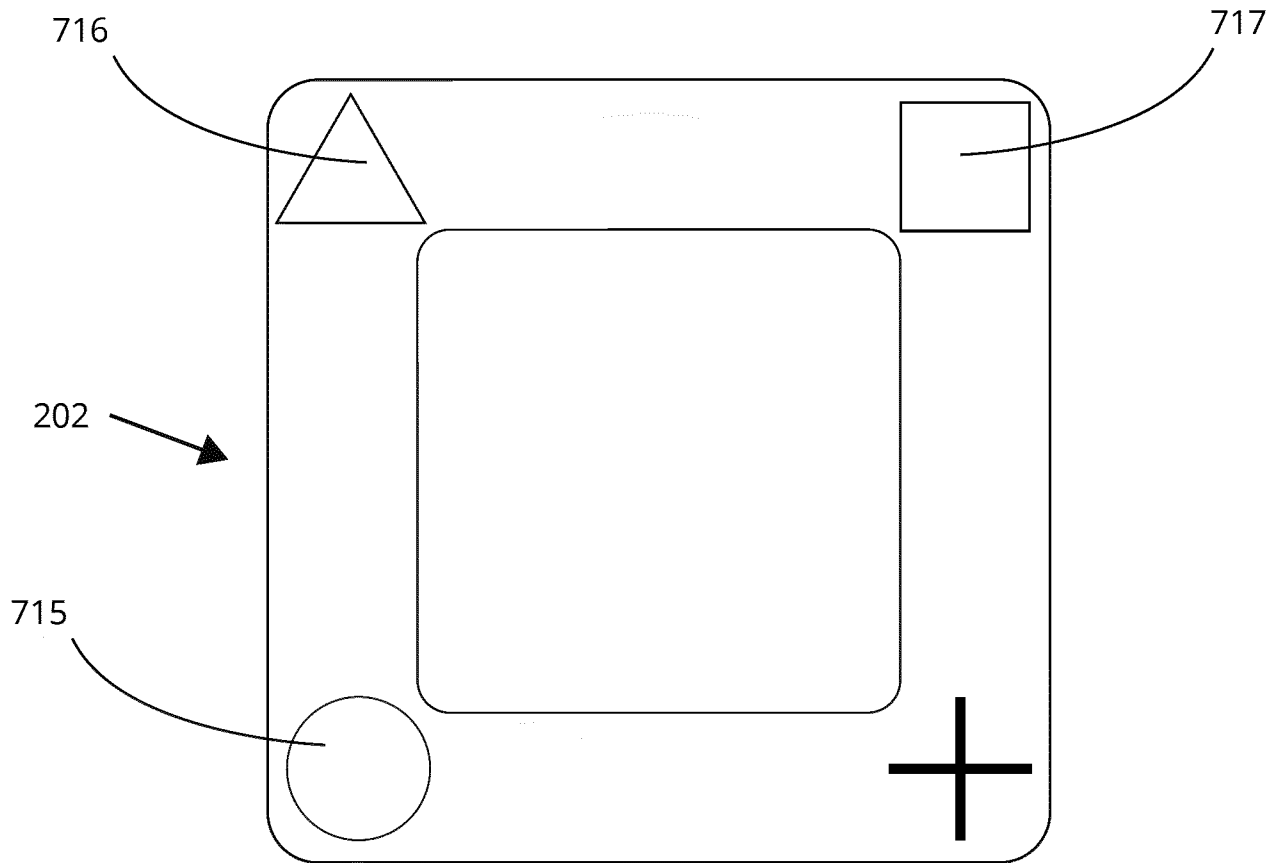


Figure 70

17/47

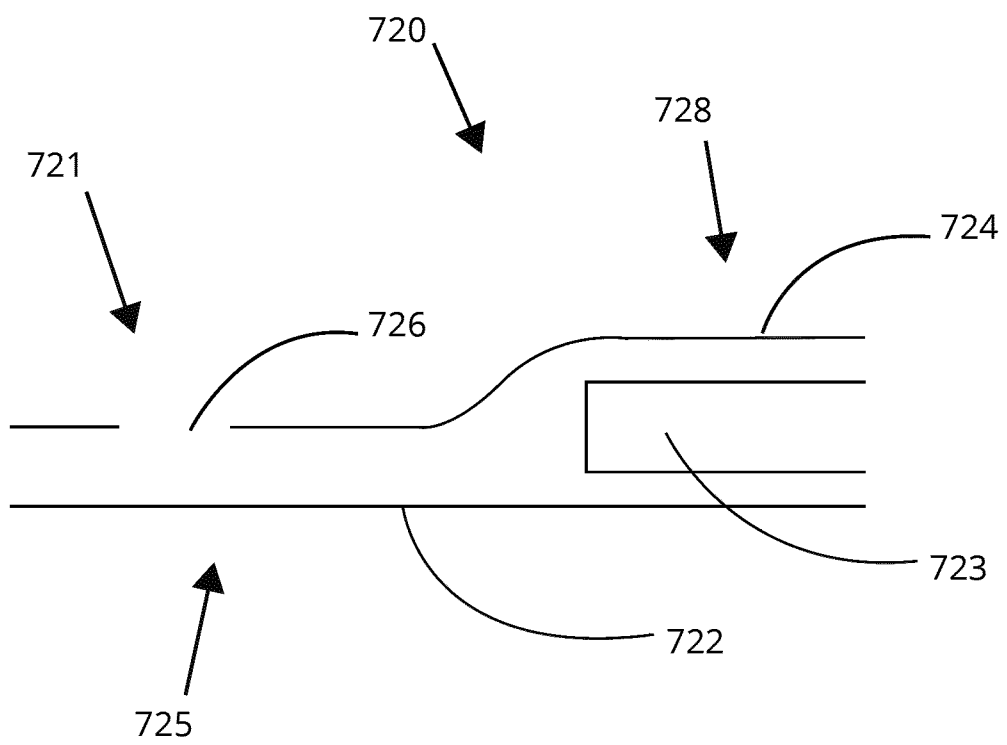


Figure 7P

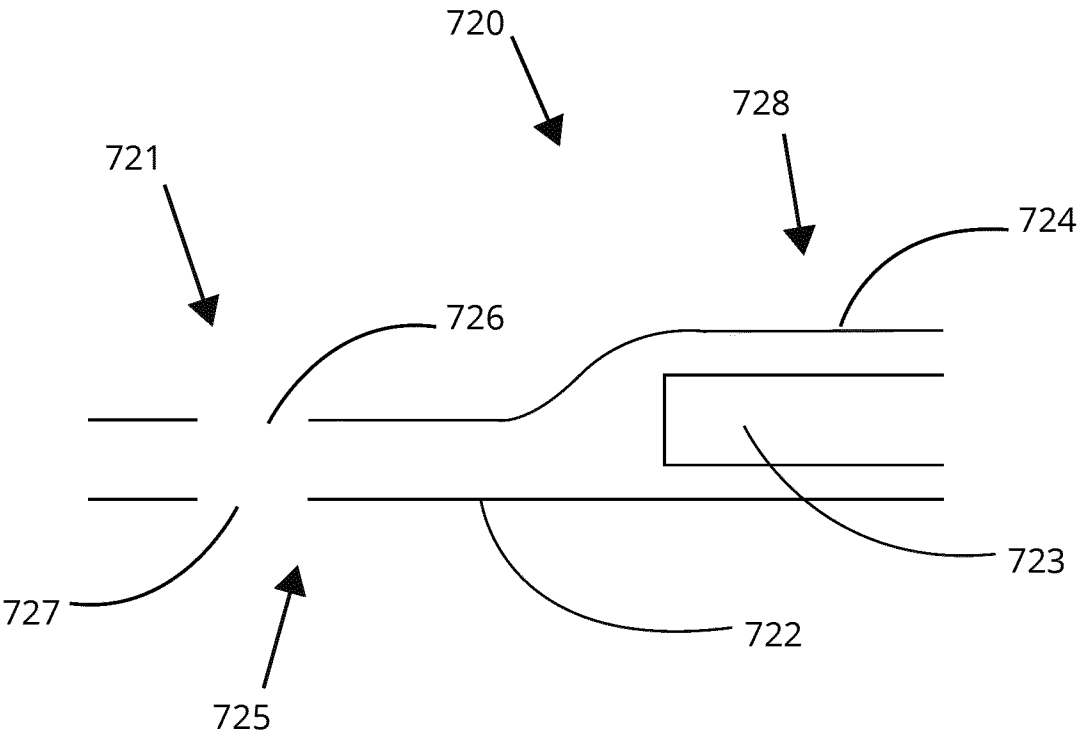


Figure 7Q

19/47

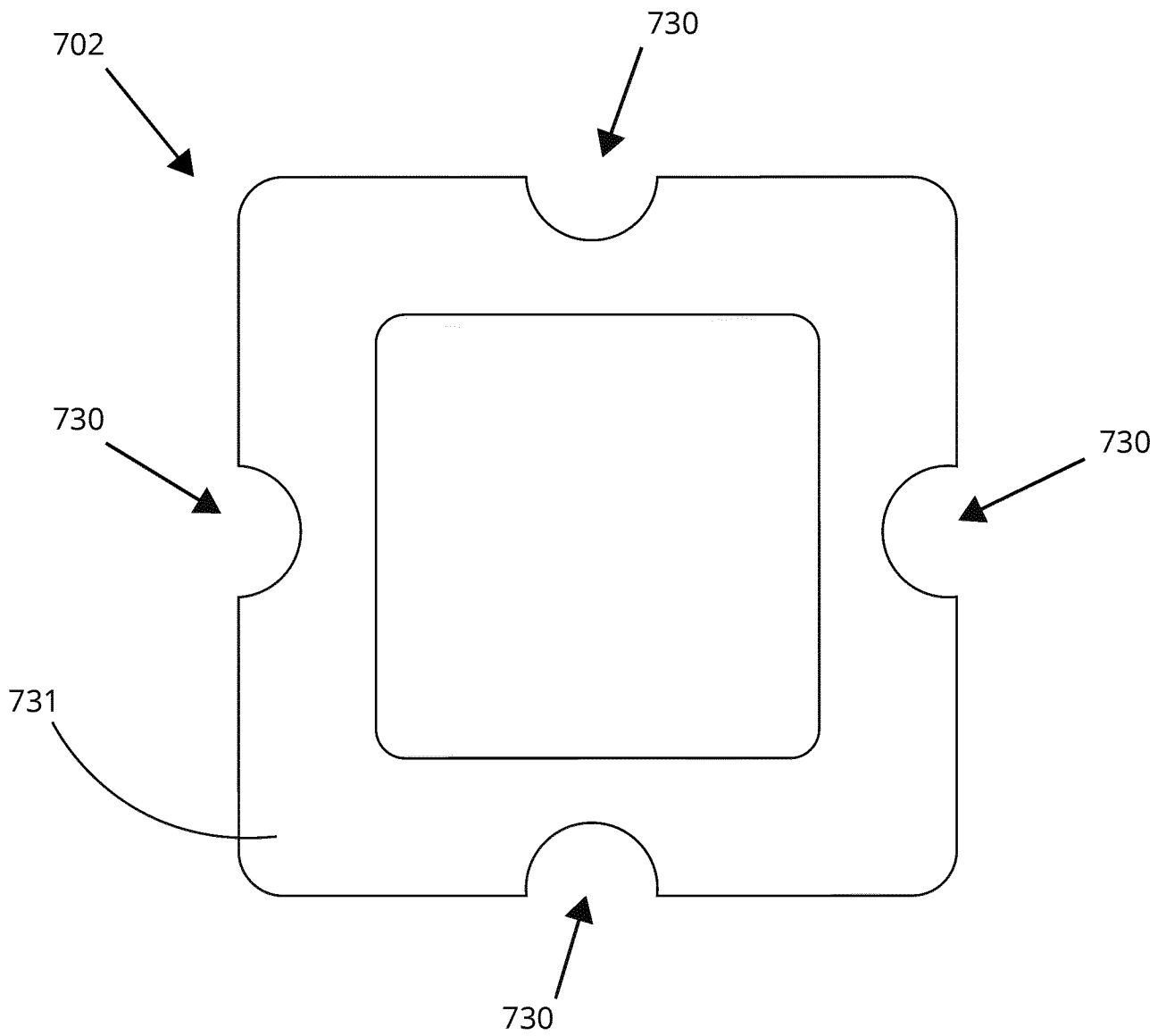


Figure 7R

20/47

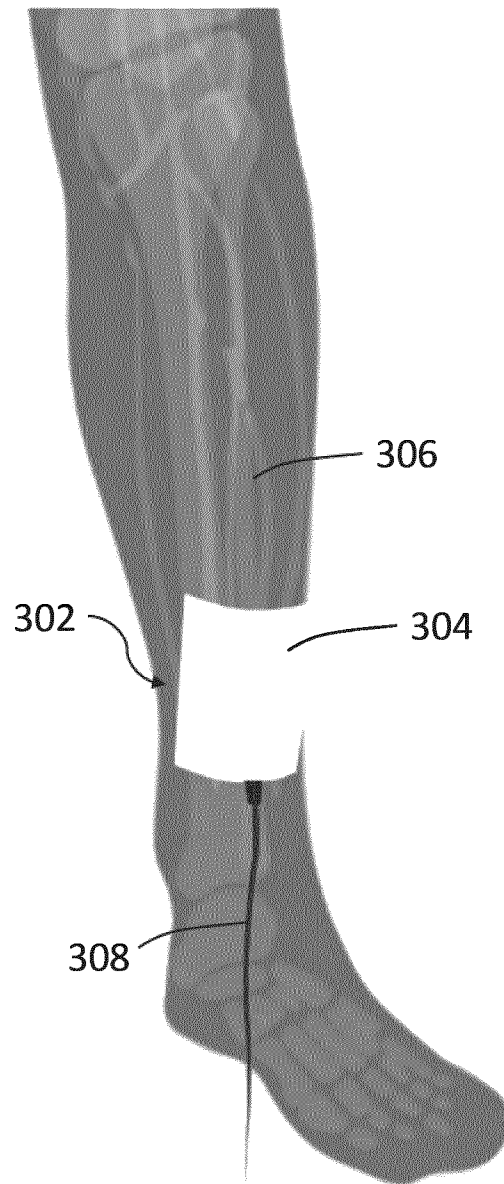


Figure 8

21/47

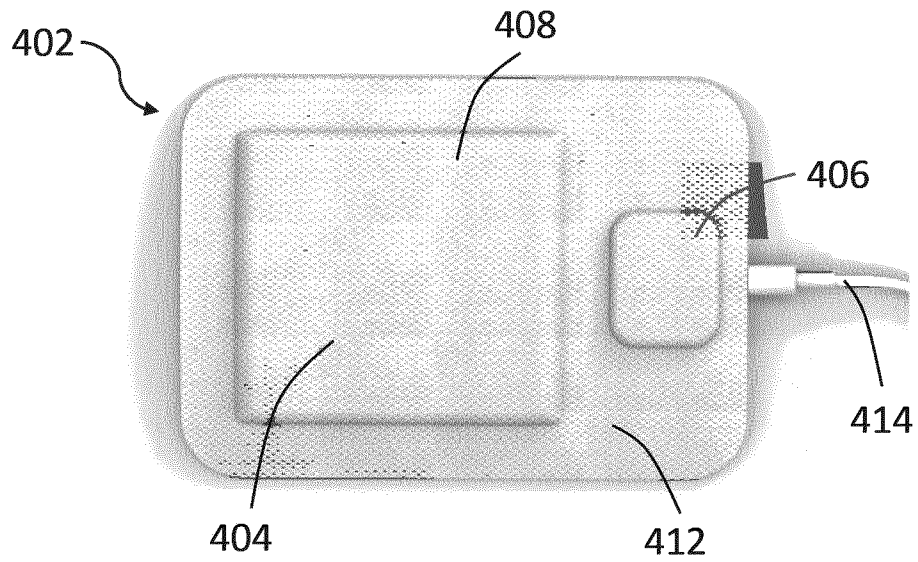


Figure 9A

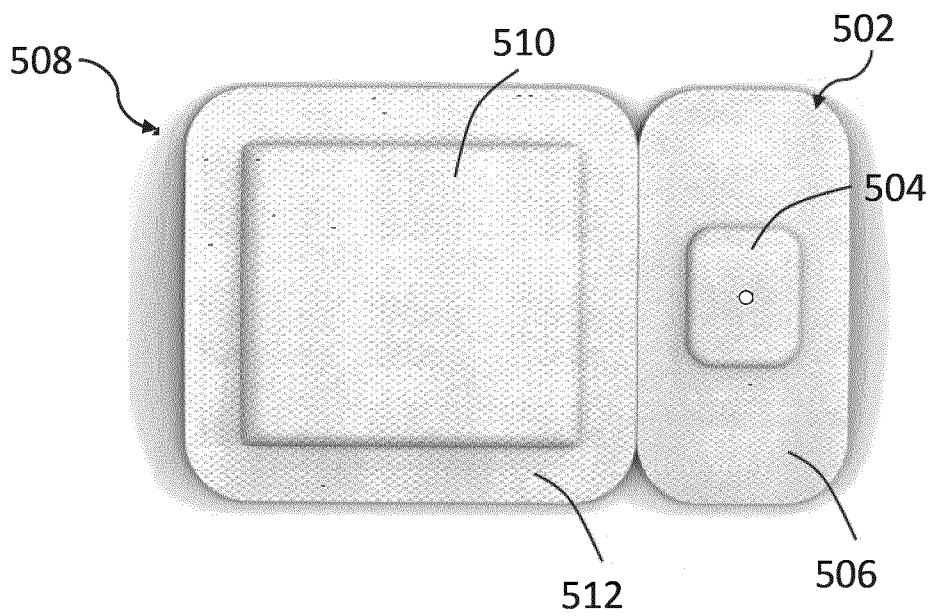


Figure 9B

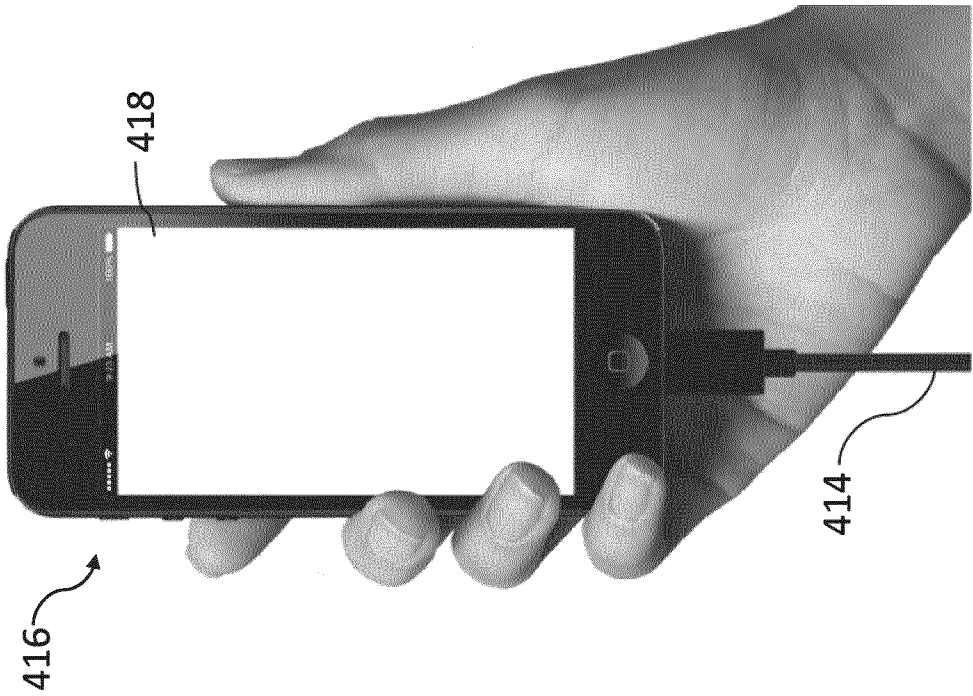


Figure 10A



Figure 10B

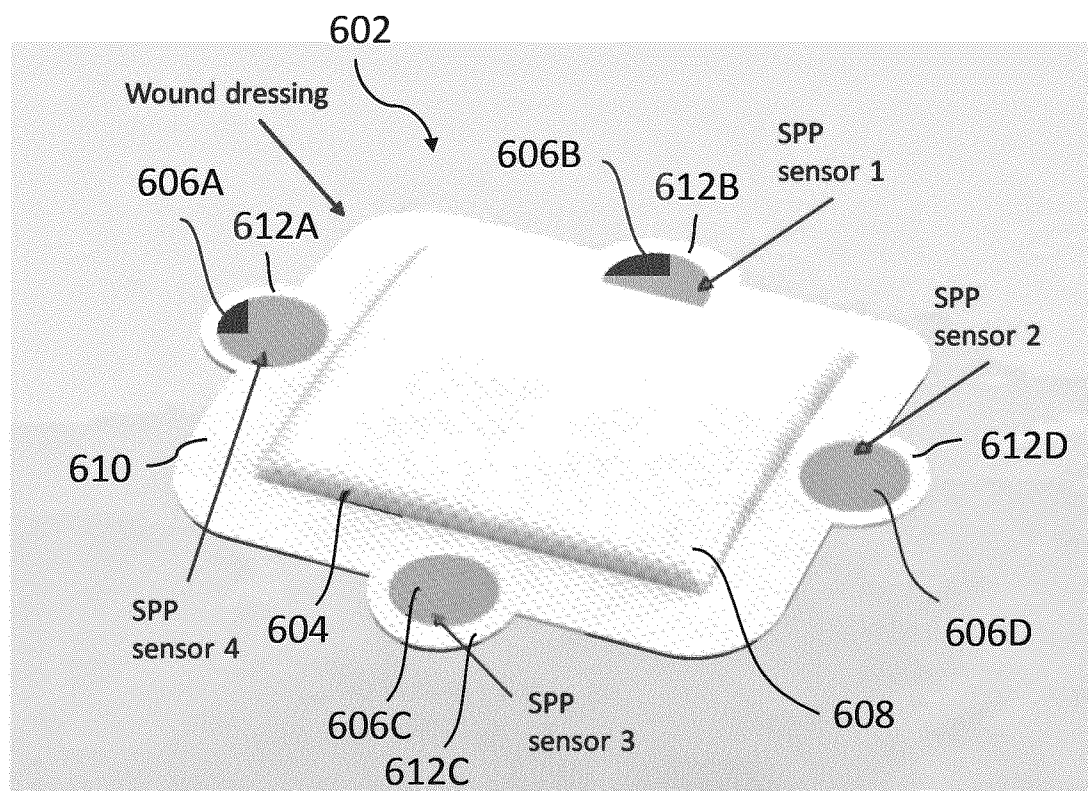


Figure 11

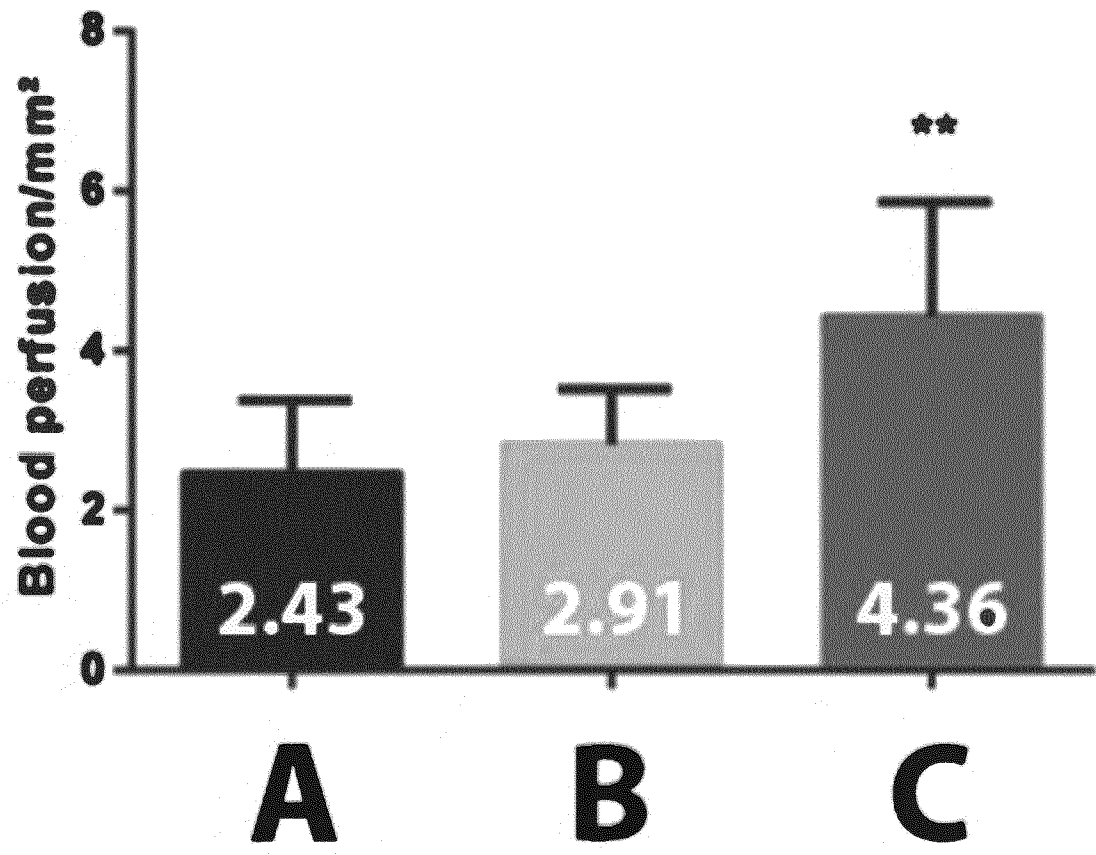


Figure 12

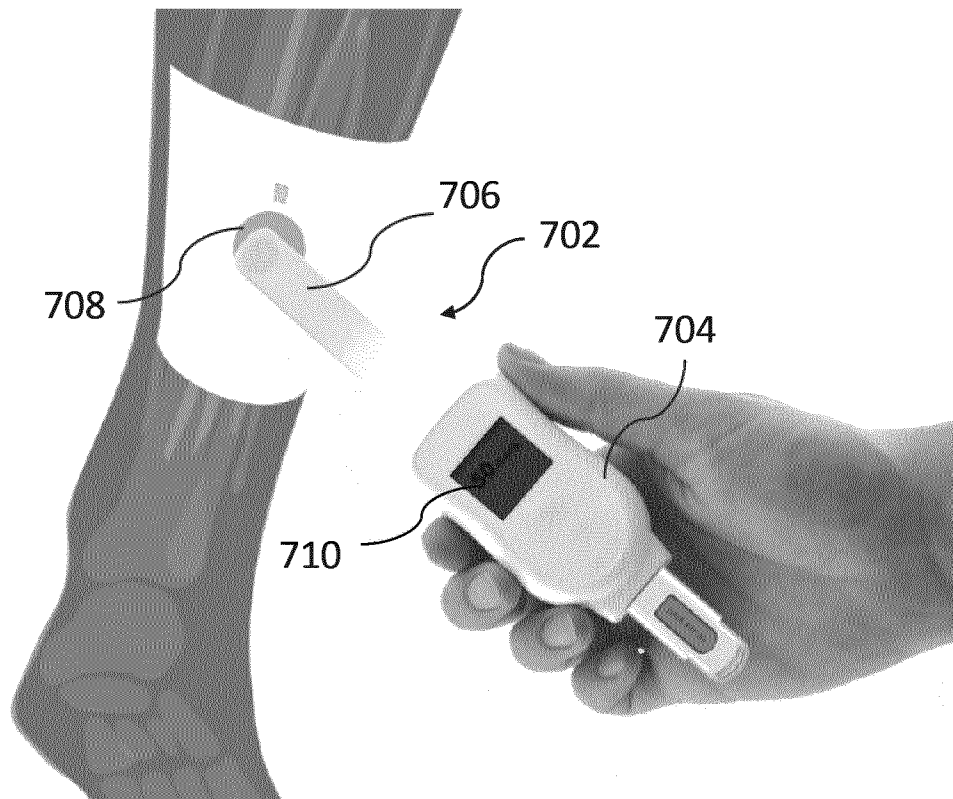


Figure 13

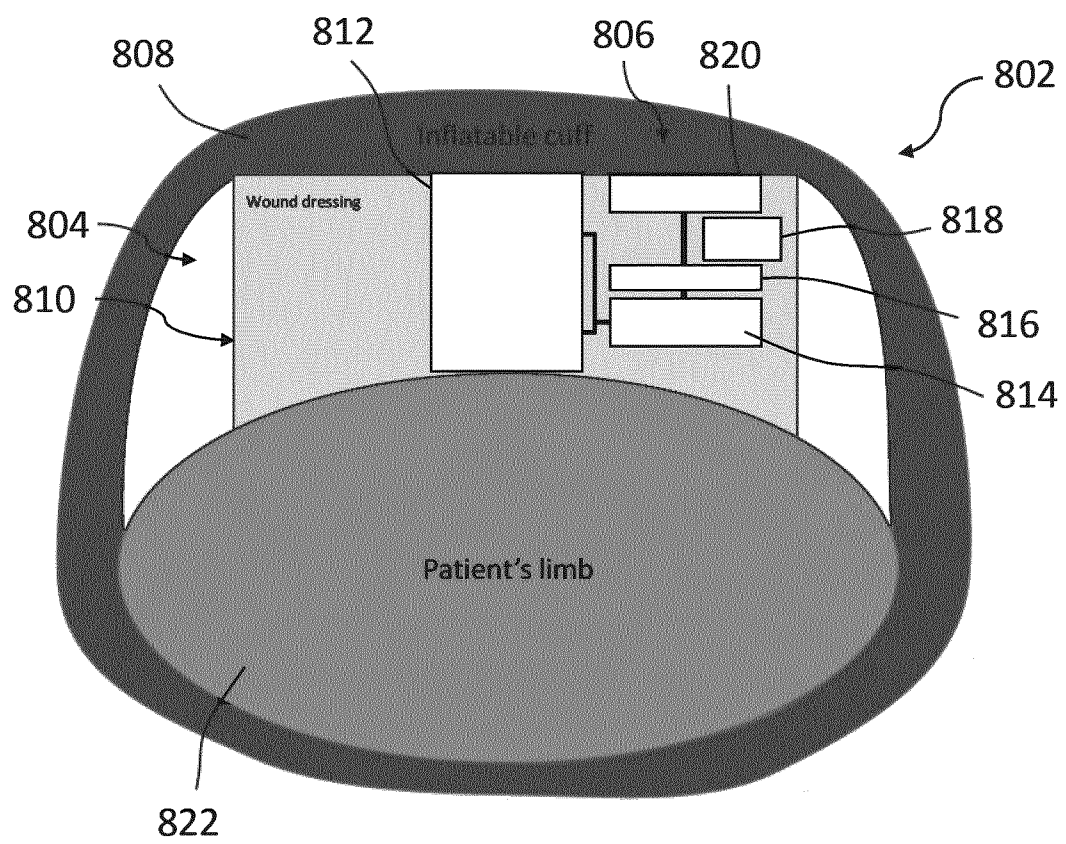


Figure 14

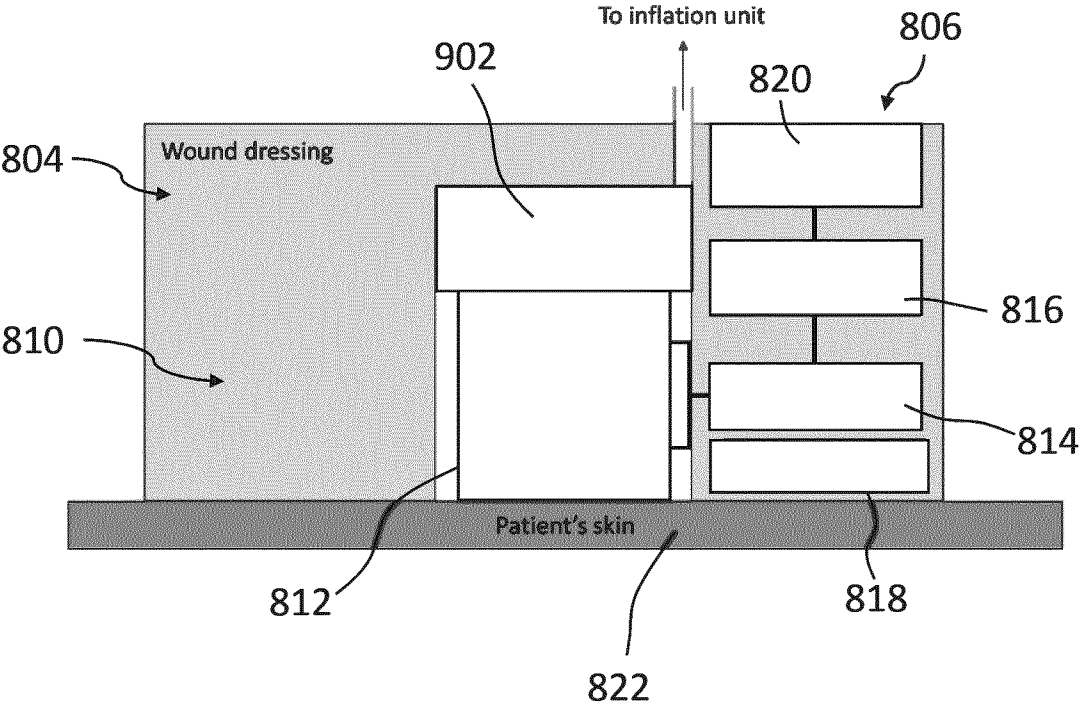


Figure 15

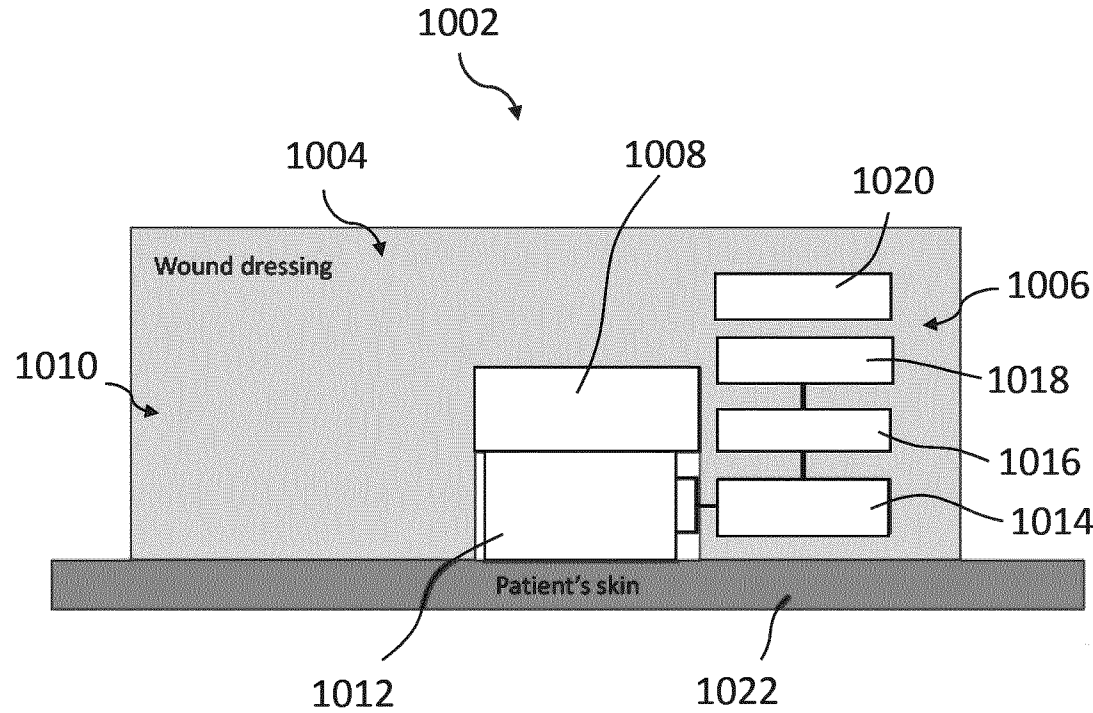


Figure 16

29/47

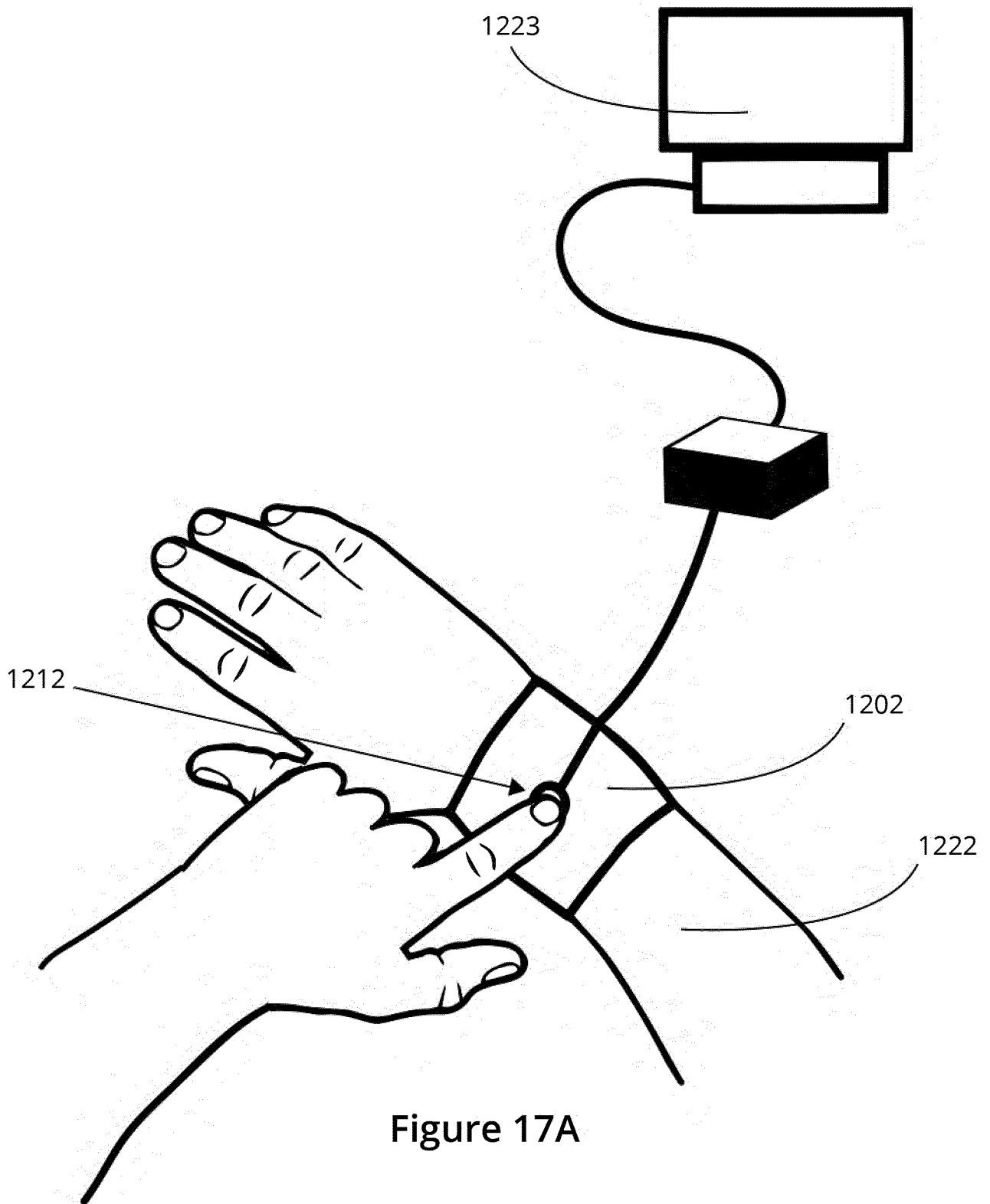


Figure 17A

30/47

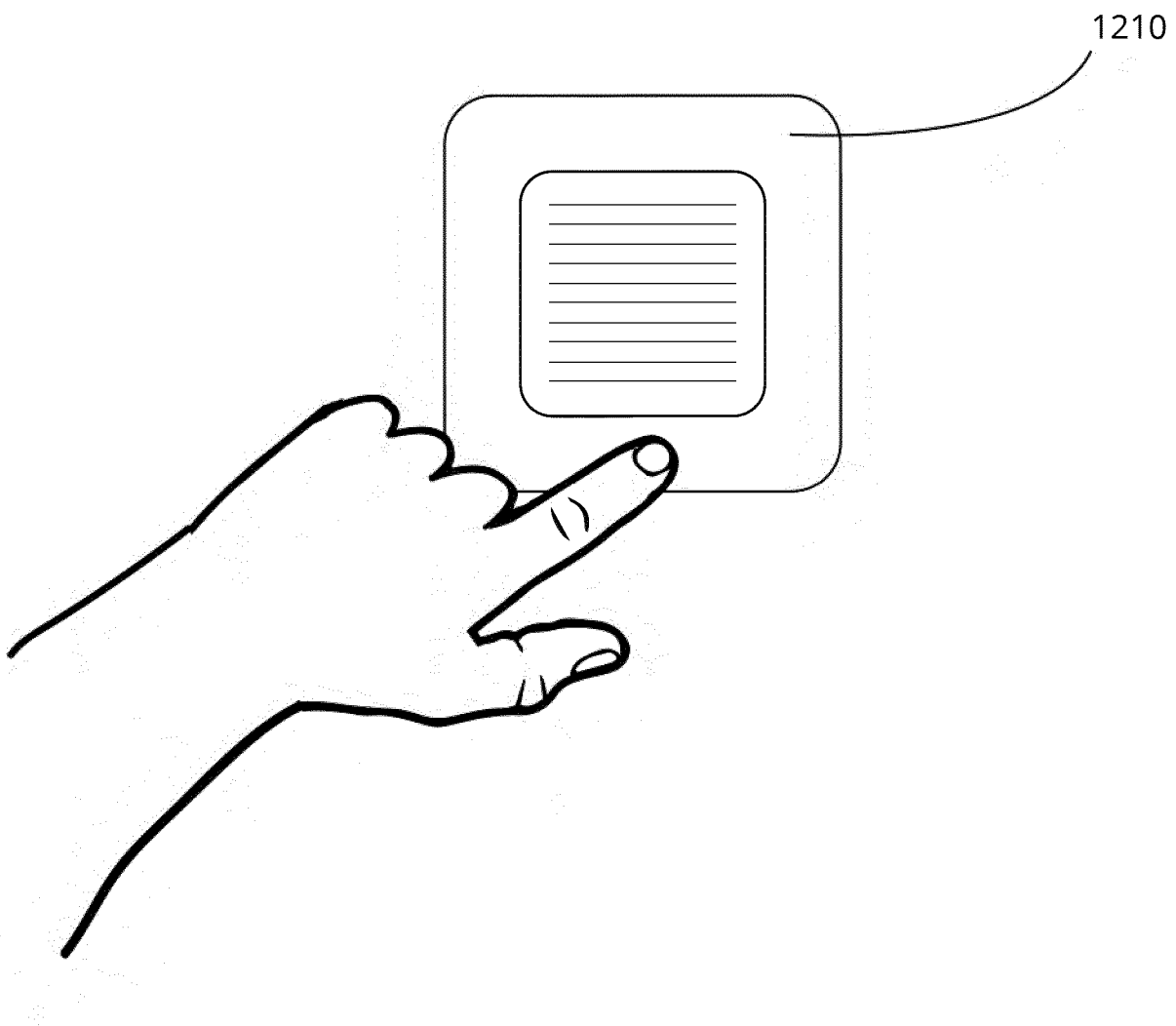


Figure 17B

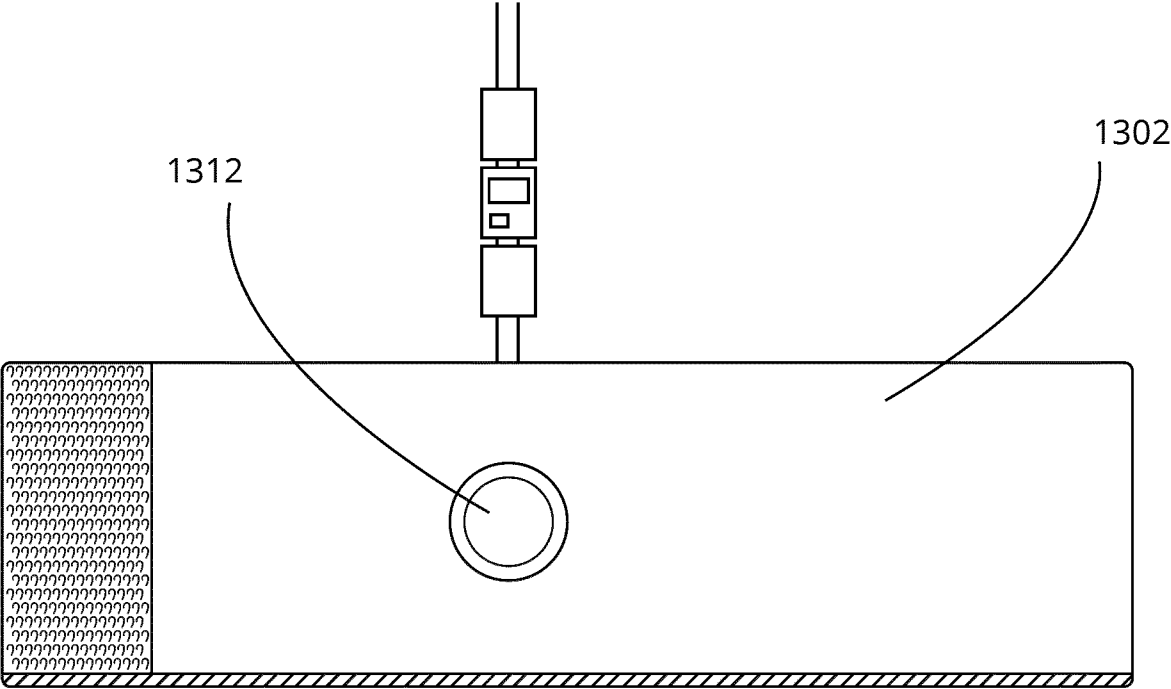


Figure 18A

32/47

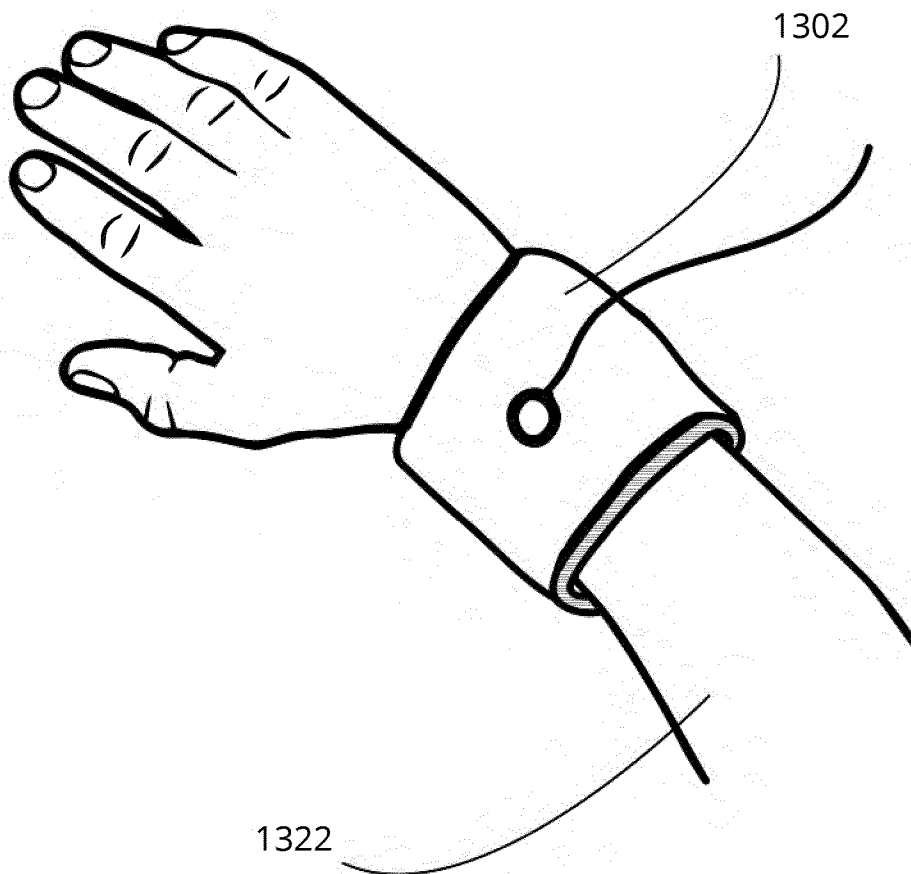


Figure 18B

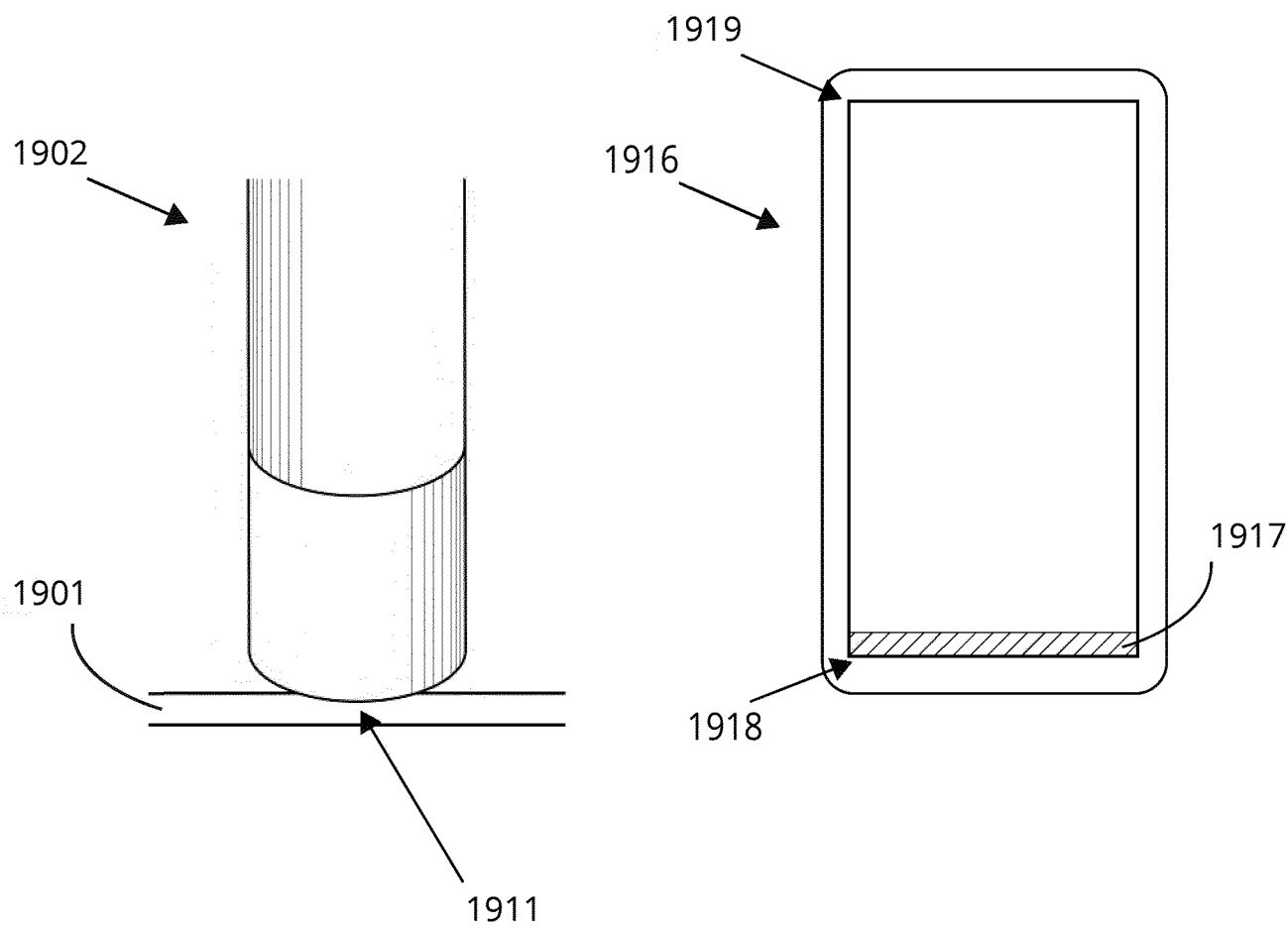


Figure 19A

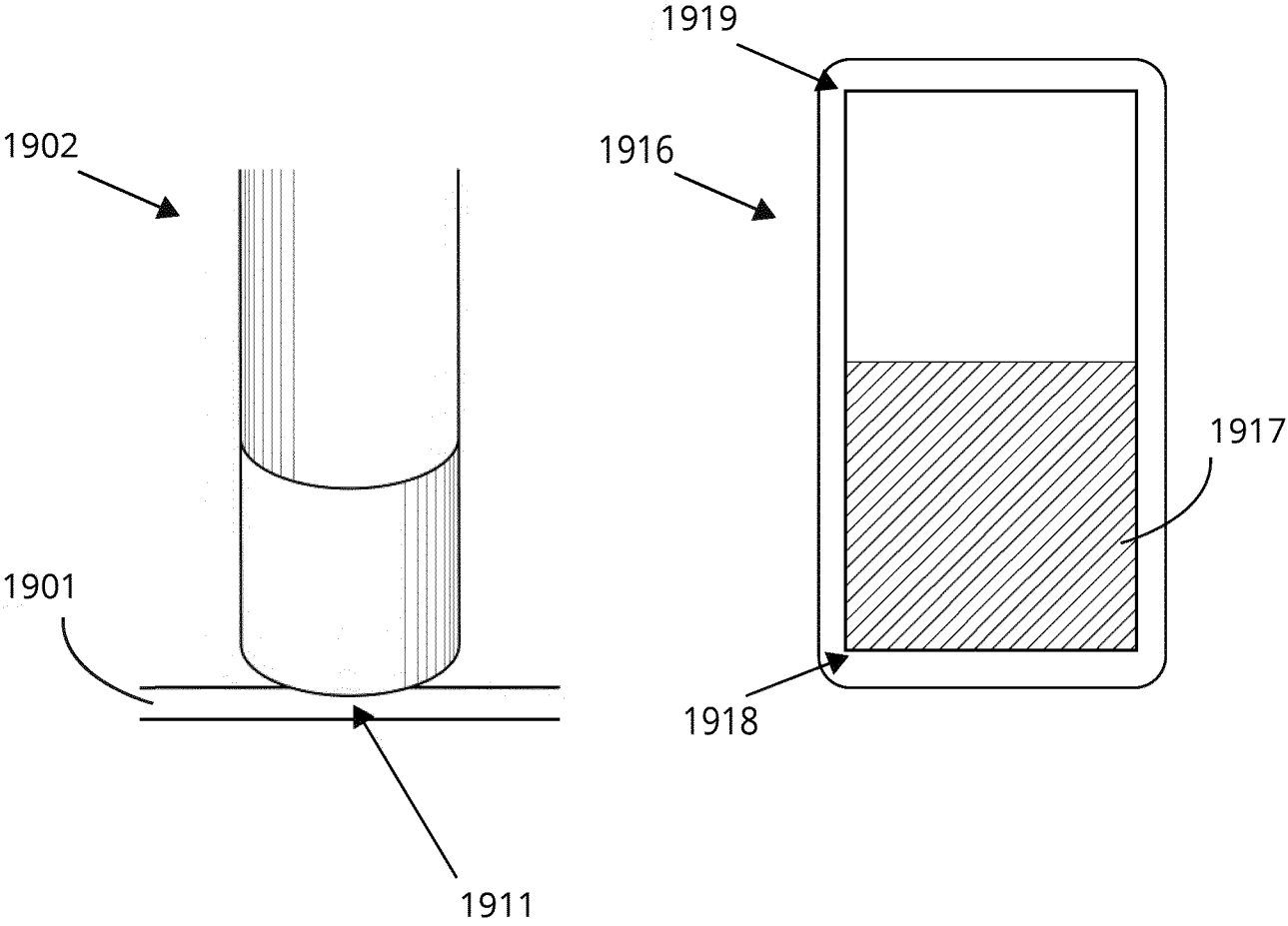


Figure 19B

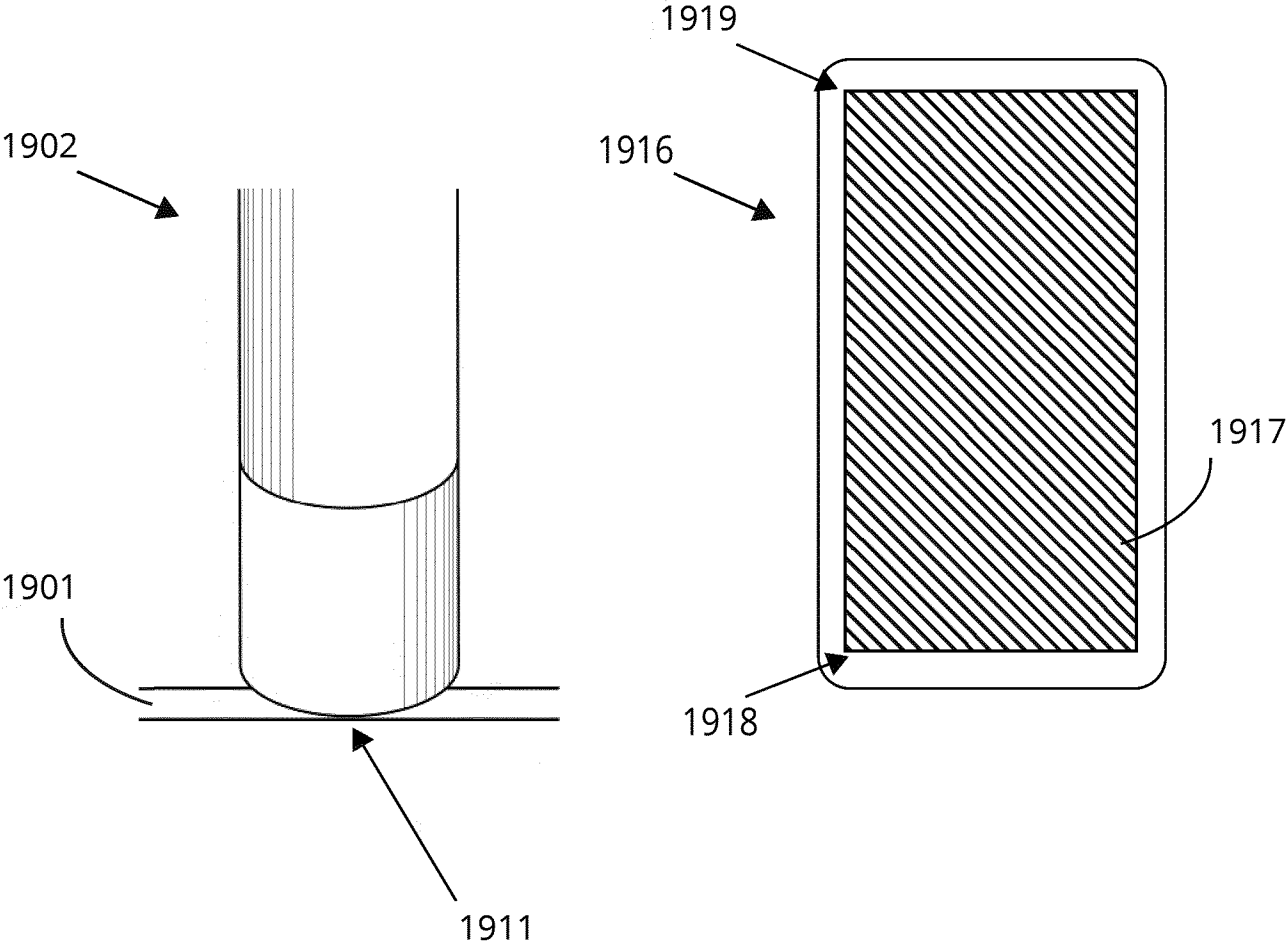


Figure 19C

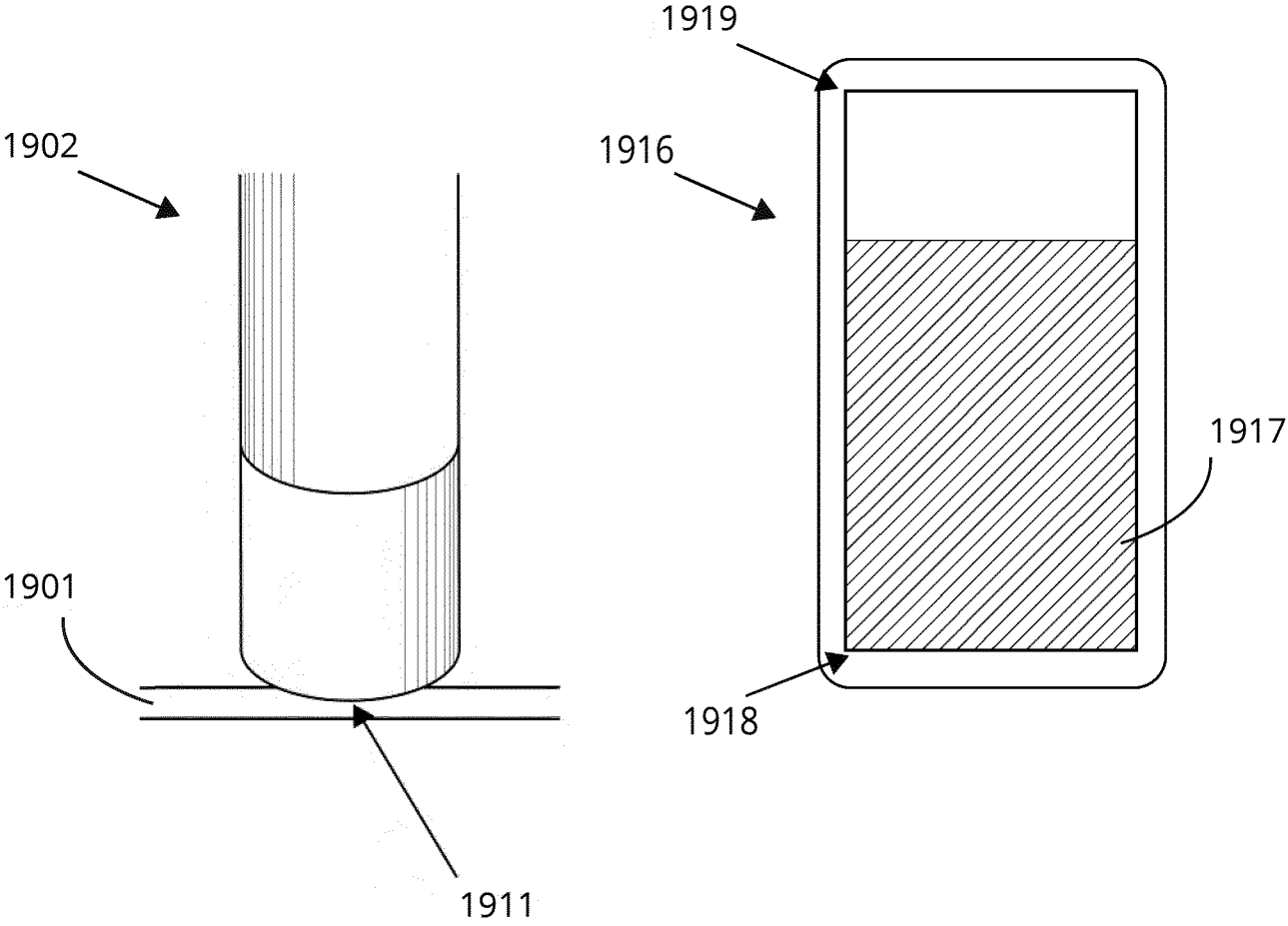


Figure 19D

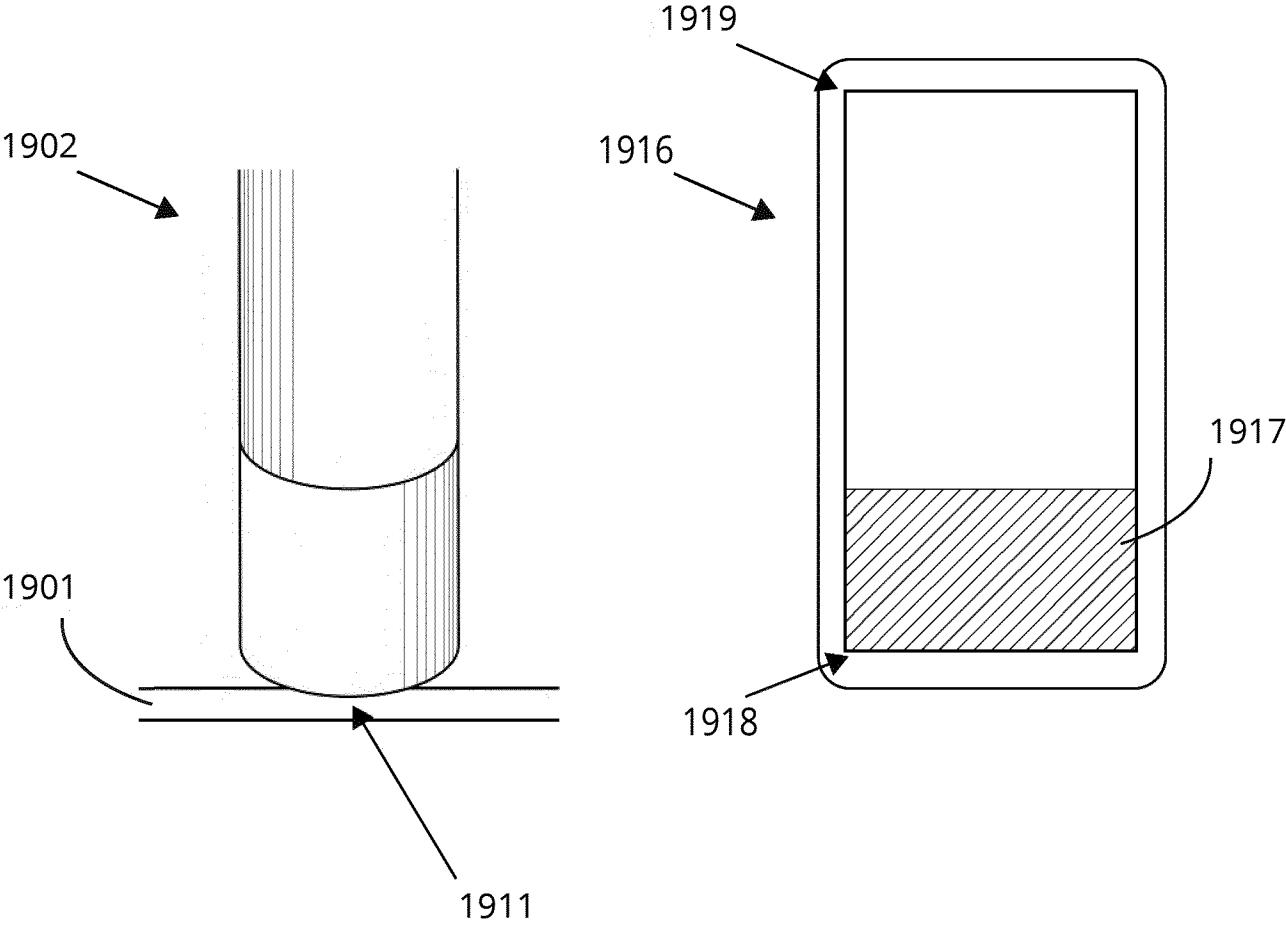


Figure 19E

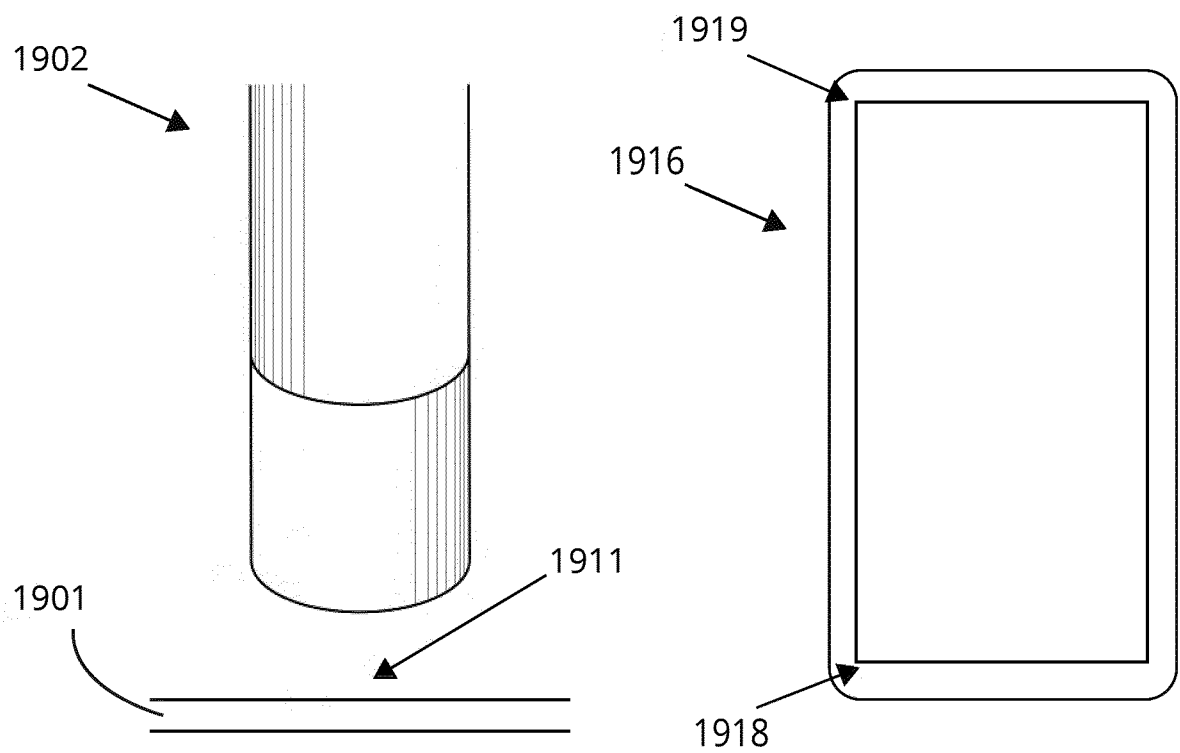


Figure 19F

39/47

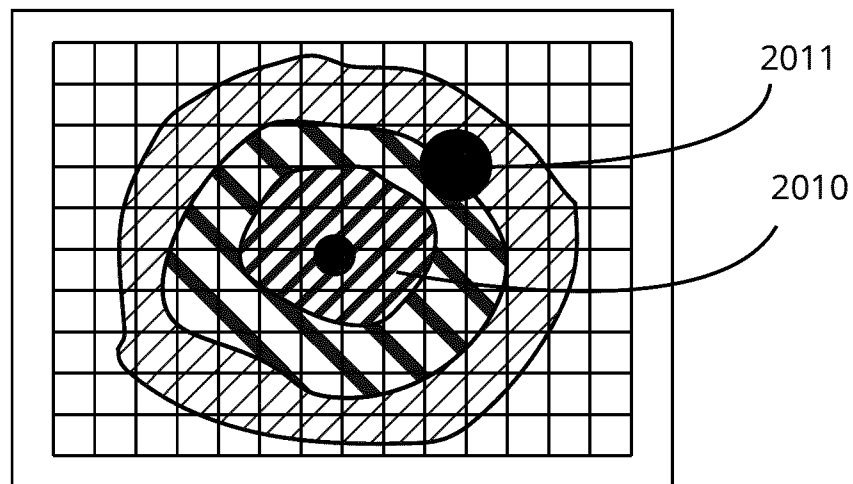


Figure 20A

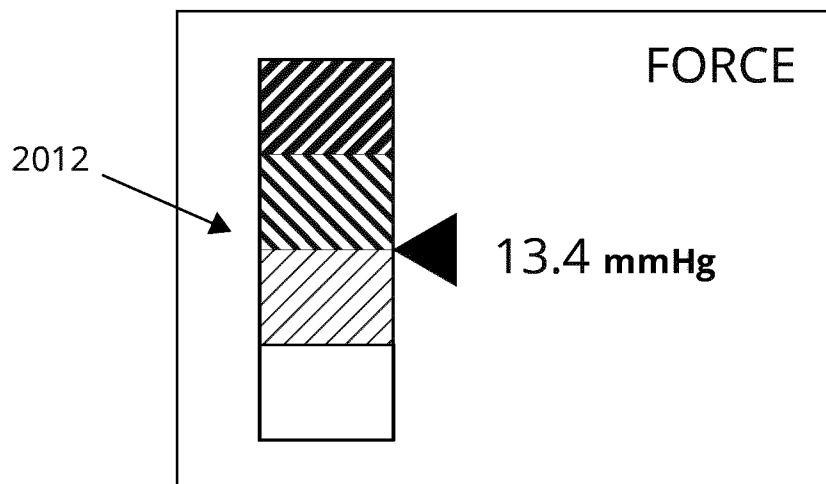


Figure 20B

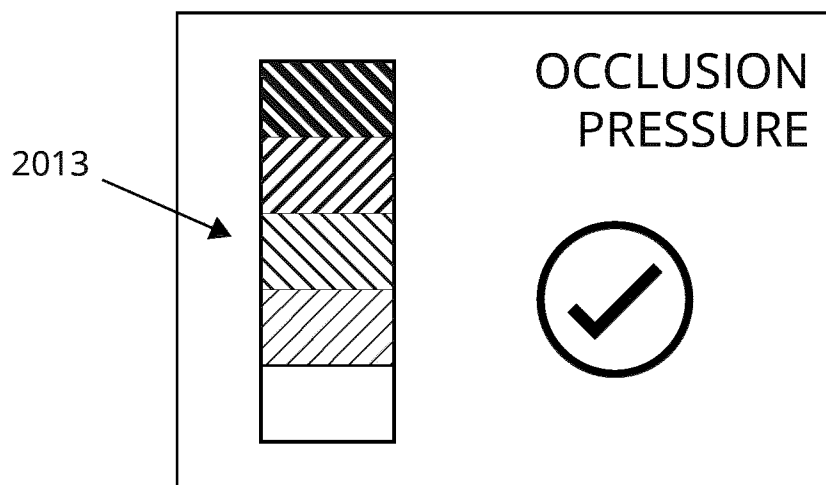


Figure 20C

40/47

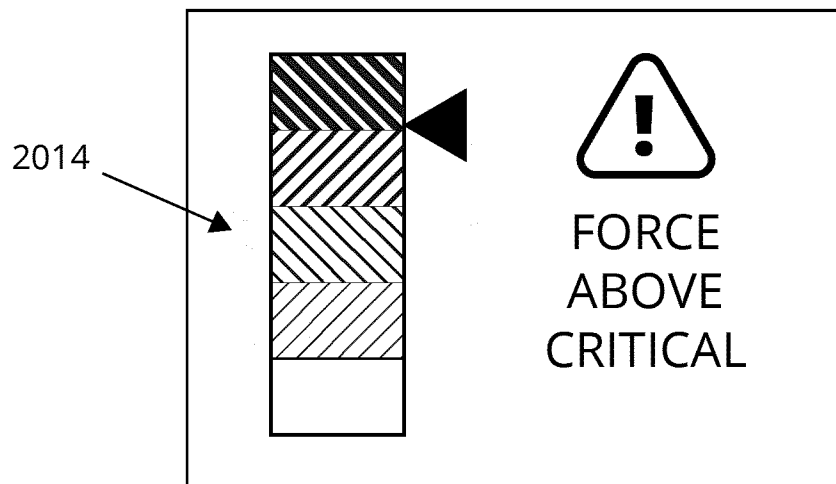


Figure 20D

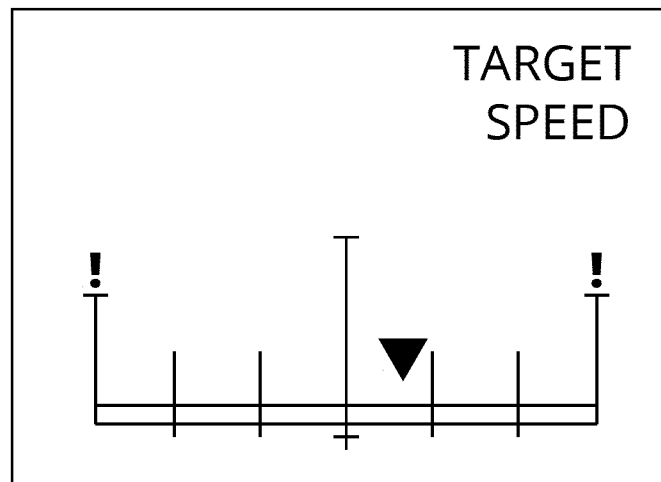


Figure 20E

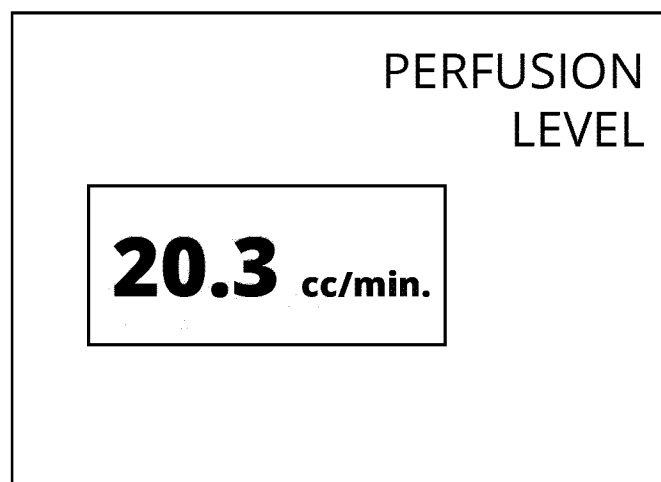


Figure 20F

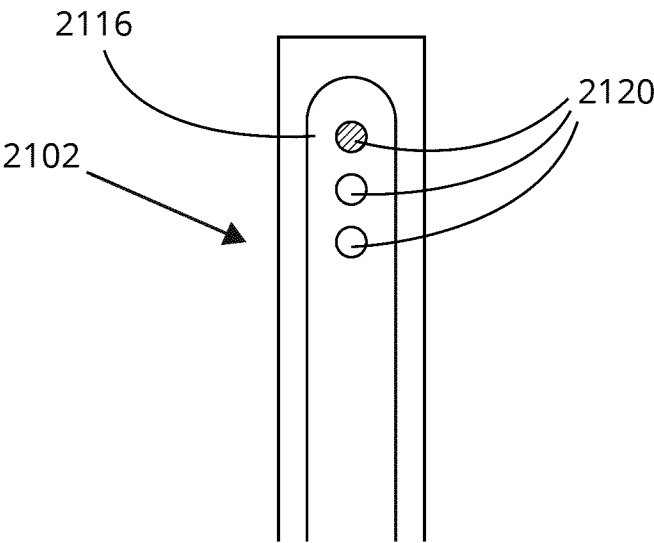


Figure 21A

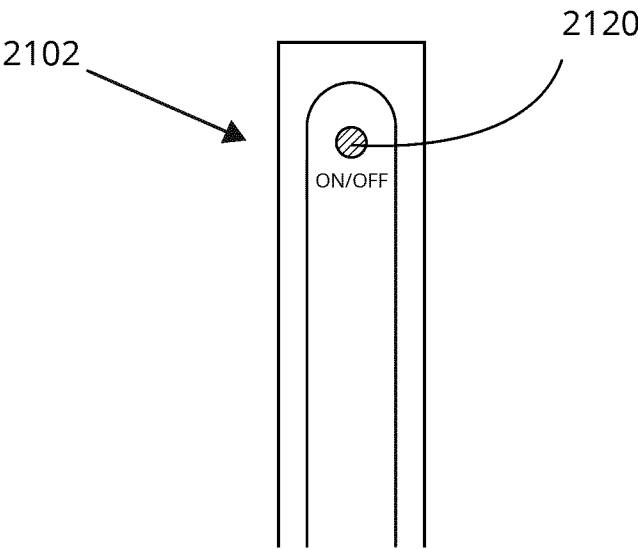


Figure 21B

42/47

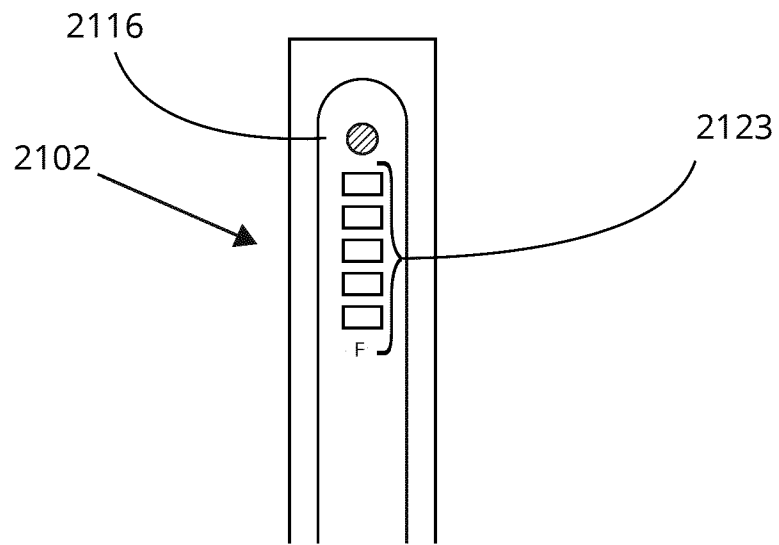


Figure 21C

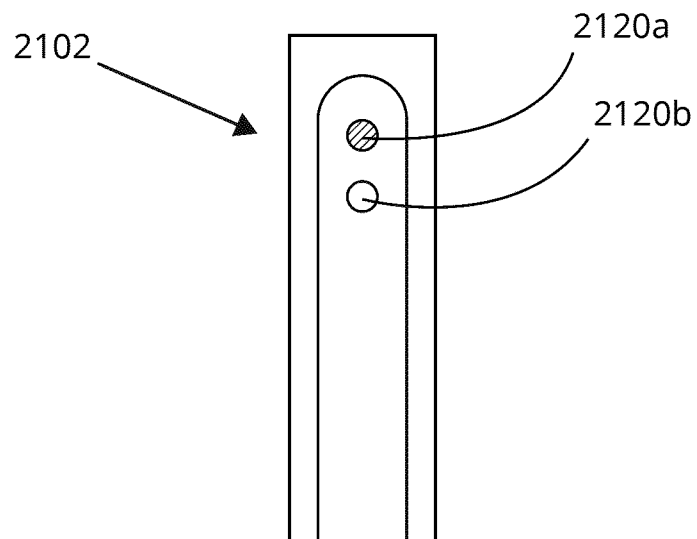


Figure 21D

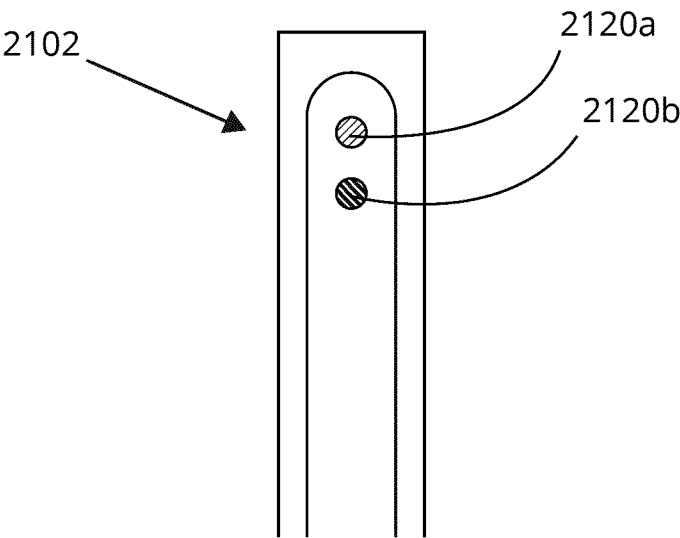


Figure 21E

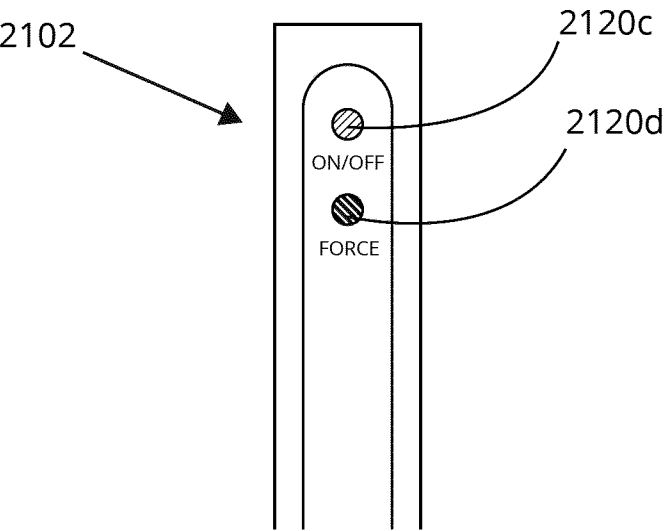


Figure 21F

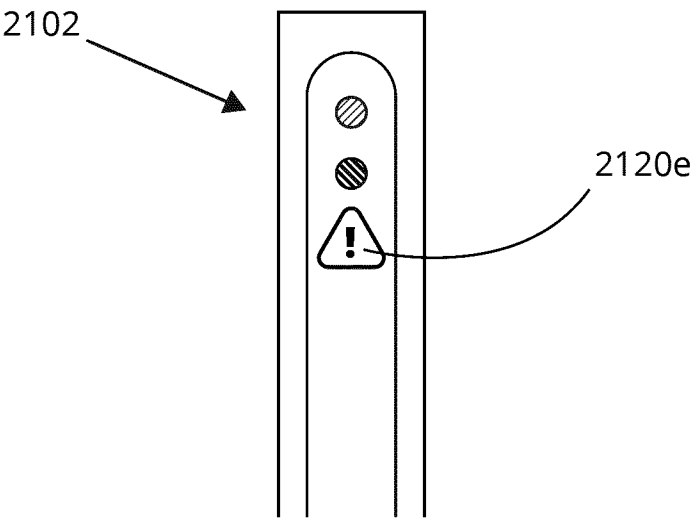


Figure 21G

45/47

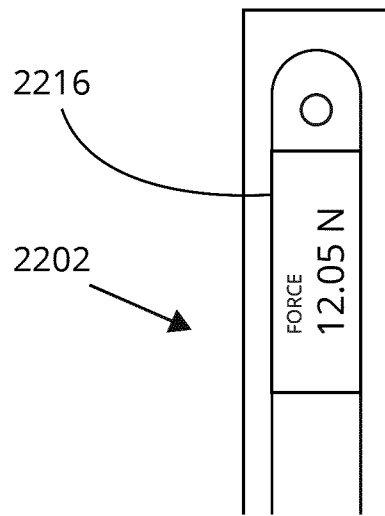


Figure 22A

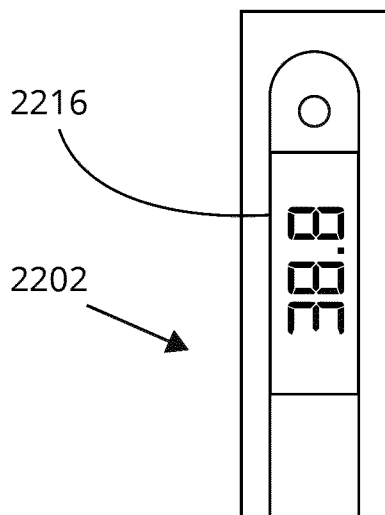


Figure 22B

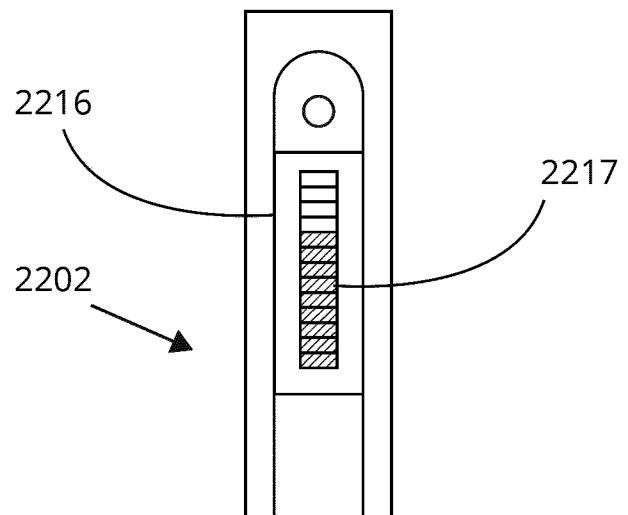


Figure 22C

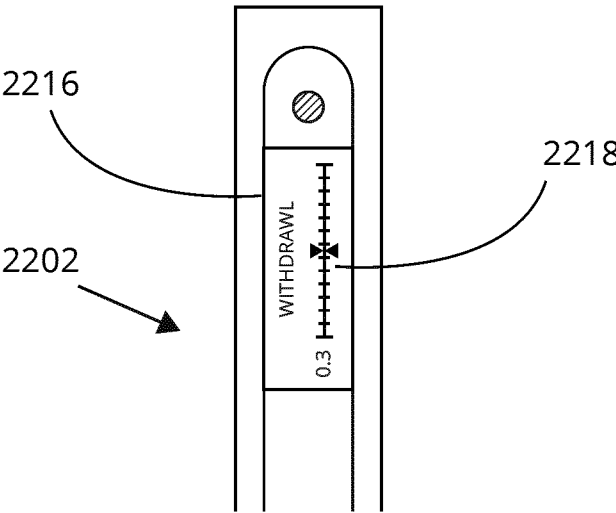


Figure 22D

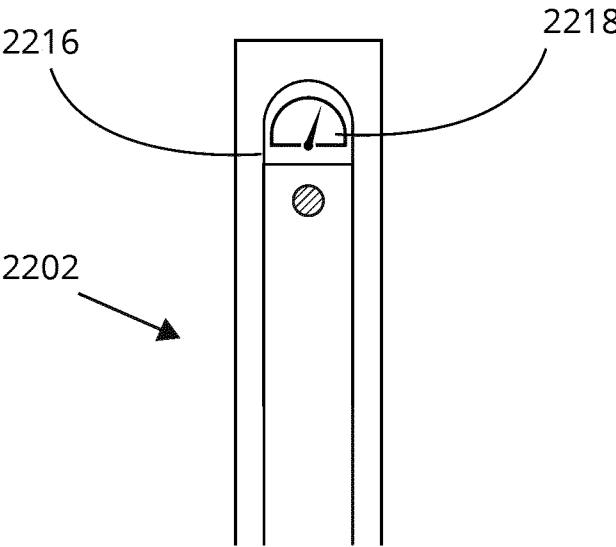


Figure 22E

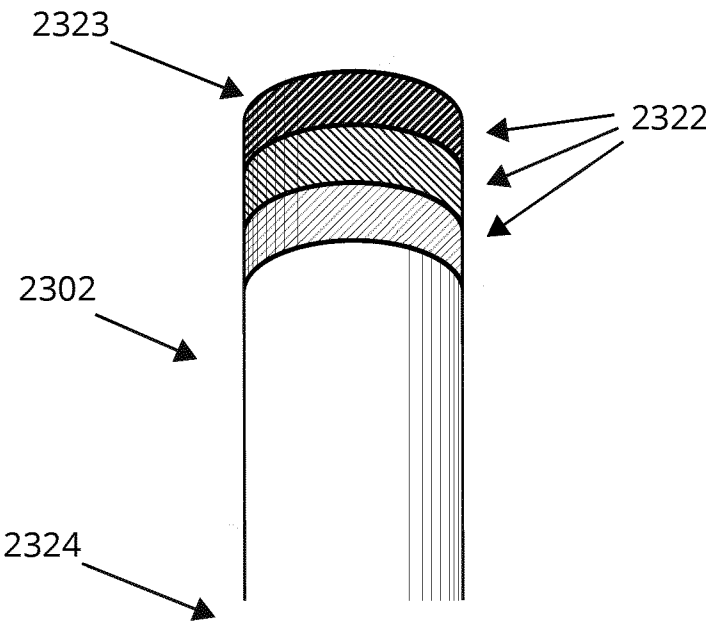


Figure 23