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(54) **Title**: RELEASABLE LINER FOR SENSOR DEVICE

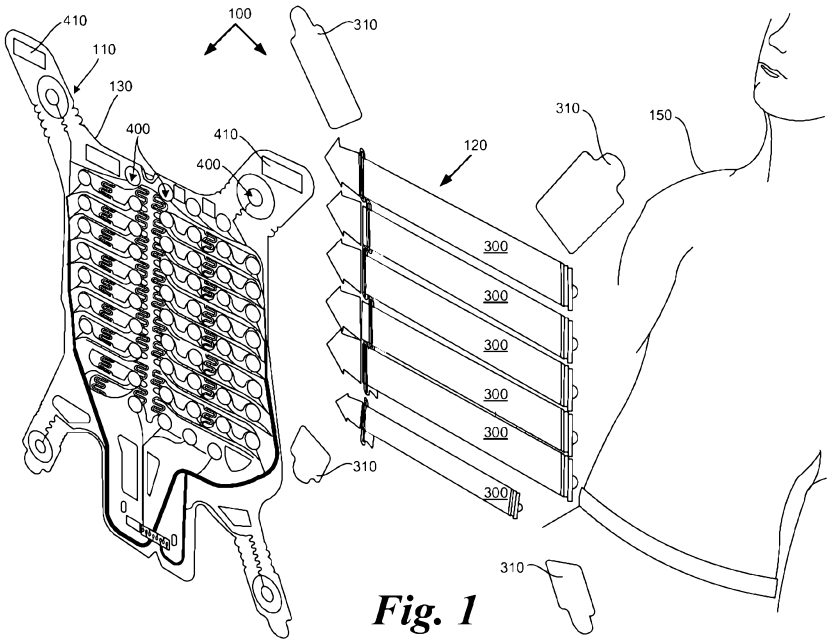

Fig. 1

(57) **Abstract**: A releasable liner for a sensor device having adhesive and conductive gel portions includes a flexible sheet having a free end and a fixed end, and a portion of the flexible sheet that is releasably attached to the sensor device, wherein the flexible sheet is folded upon itself so that the fixed end is generally adjacent the free end. Exerting a pulling force on the free end releases the liner in a controlled manner to uncover the adhesive and conductive gel portions of the sensor device.

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RELEASABLE LINER FOR SENSOR DEVICE

PRIORITY CLAIM

This application claims priority to U.S. Patent Application Serial No. 13/183,310 filed July 14, 2011. The foregoing application is hereby incorporated by reference in its entirety as if fully set forth herein.

FIELD OF THE INVENTION

[0001] This invention relates generally to a protective liner for a sensor device and, more specifically, to a protective liner that may be controllably and systematically removed from a sensor device.

BACKGROUND OF THE INVENTION

[0002] Electrocardiogram (ECG) devices, using twelve (12) or more leads are known. Twelve-lead systems typically utilize individual leads that are connected to a patient, whereas ECG systems employing more than 12-leads are likely to be deployed in the form of an electrode vest, which is applied to the patient's torso. By way of example, one type of electrode vest is described in U.S. Patent No. 6,055,448.

[0003] Electrodes for sensing bioelectric data or signals from a patient, whether connected to individual leads or in a multi-electrode vest require a conductive coupling gel placed between

each electrode and the patient's skin. The gel better enables signal transfer between the patient's body and the electrode. The electrodes may also have an adhesive section to allow the electrodes to stay connected to the patient's skin during an ECG test. In addition, or alternatively, the conductive gel may have adhesive properties to allow the electrodes to adhere to the patient. Both the gel and adhesive section of an electrode must be protected from the environment until such time that the electrode is to be placed onto the patient. Individual protective patches that cover individual electrodes are known. The protective patches are removed by a medical clinician immediately prior to applying the electrodes to a patient. Alternatively, a single protective sheet may cover all of the electrodes on a vest. The protective sheet is removed immediately prior to placing the vest on a patient. Electrode vests may be unwieldy and difficult to apply to the patient and removing the individual protective patches or the larger protective sheet further complicates the utilization of such vests, making it difficult to place the vest and accompanying electrodes on the patient without the electrodes sticking to other parts of the vest or at the wrong locations on the patient.

SUMMARY OF THE INVENTION

[0004] According to an embodiment of the invention, a releasable liner for a sensor device having a plurality of electrodes includes a first strip portion configured to overlay and adhere to at least one of the plurality of electrodes, the first strip portion having a fixed end attached to the sensor device, and a second strip portion extending approximately parallel to the first strip portion and positioned adjacent thereto, the second strip portion having a free end movable relative to the fixed end of the first strip portion, the second strip portion coupled to the first strip portion such that a pulling force applied to the free end causes the first strip portion to separate from at least one of the plurality of electrodes.

[0005] According to another embodiment of the invention, a releasable liner for a sensor device includes a flexible sheet having a free end and a fixed end, and a portion of the flexible sheet that is releasably attached to the sensor device, wherein the flexible sheet is folded upon itself so that the fixed end is generally adjacent the free end. The liner is released from the sensor device when pulling force is exerted on the free end.

[0006] In accordance with yet another example of the invention, a sensor device for positioning on a human patient, includes a patient-facing surface with at least a portion of the patient-facing surface having an adhesive characteristic that may be removably attached to the patient's body and a protective liner folded upon itself and releasably affixed to the patient-facing surface of the sensor device. Exerting a pulling force on the liner causes the liner to release from the patient-facing surface of the sensor device.

[0007] In accordance with still another embodiment of the invention, a method for placing a sensor device in contact with a patient's anatomy includes the steps of positioning the sensor device on the patient in a desired position and releasing a protective sheet between the patent and a portion of the sensor device such that the releasing step exposes the sensor device to the patient's anatomy.

[0008] These and other examples of the invention will be described in further detail below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] Preferred and alternative examples of the present invention are described in detail below with reference to the following drawings:

[0010] FIGURE 1 is an exploded perspective view showing a sensor device and protective liner according to an embodiment of the present invention in relation to the front of a patient's body;

[0011] FIGURE 2A is a perspective view of the sensor device and protective liner of FIGURE 1 placed onto a patient;

[0012] FIGURE 2B is a perspective view of the sensor device and liner of FIGURE 2A showing portions of the liner at various states of removal;

[0013] FIGURE 2C is a perspective view of the sensor device and liner of FIGURE 2A showing the liner entirely removed;

[0014] FIGURE 3A is a schematic view of a portion of the liner covering electrodes on a sensor device;

[0015] FIGURE 3B is a schematic view of a portion of the liner partially removed to partially expose electrodes on the sensor device;

[0016] FIGURE 3C is a schematic view of a portion of the liner more fully removed to expose electrodes but still attached to the sensor device;

[0017] FIGURE 4A is a schematic side view of the sensor device and liner of FIGURE 3A;

[0018] FIGURE 4B is a schematic side view of the sensor device and liner of FIGURE 3B;

[0019] FIGURE 4C is a schematic side view of the sensor device and liner of FIGURE 3C; and,

[0020] FIGURE 5 is an exploded perspective view showing various components of the liner.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0021] As previously discussed, conventional, single sheet protective liners for electrode vests used with electrocardiogram (ECG) devices are cumbersome and unwieldy to use, making the

vest difficult to apply to a patient. Accordingly, there is a need for a releasable liner for such an electrode vest that may be easily and quickly removed from the electrodes in a controlled manner and which does not complicate the attachment of the vest or otherwise disturb the placement of the electrodes on the patient.

[0022] FIGURE 1 illustrates an ECG sensor device 100 according to an embodiment of the present invention. Sensor device 100 includes an electrode vest 110 and protective liner 120. Vest 110 includes a plurality of sensors, or electrodes, 400 and conductive traces on a flexible dielectric membrane 130. The electrodes 400 are positioned on a patient-facing surface of the vest 110. For purposes of clarity, FIGURE 1 is an exploded perspective view of the sensor device 100 that shows the liner 120 separated from the vest 110. However, it is to be understood that before the sensor device 100 is affixed to the patient 150, the liner 120 is in contact with the patient-facing side of vest 110 and covers the electrodes 400. In this way, the liner 120 protects the electrodes 400 until they are affixed to the patient 150.

[0023] Figures 2A-C illustrate how the sensor device 100 may be attached to the patient 150 who is about to undergo a medical test, such as an ECG exam. In FIGURE 2A, sensor device 100 is positioned over the front torso of the patient 150. The liner 120 is in contact with the patient-facing surface of the vest 110 and, as illustrated in FIGURE 2A, the liner 120 is between the patient's skin and the electrode vest 110. Accordingly, the electrodes 400 in FIGURE 2A are not in contact with the patient.

[0024] Turning to FIGURE 2B, the sensor device 100 is shown partially attached to the patient 150. Portions of the liner 120 near the top of the vest 110, closest to the patient's head, have been removed from the vest 110 and the electrodes 400 in this area of the vest 110 are in contact with the patient's skin. FIGURE 2C shows the remaining portions of liner 120 removed from the

sensor device 100 and all of the electrodes 400 on the vest 110 are in contact with the patient 150. As depicted in FIGURE 2C, the sensor device is now ready to be connected to a remote device, such as an ECG base unit 190. The electrodes 400 are electrically coupled to the ECG base unit 190 through connector 180 and cable 185.

[0025] As will be more fully appreciated from the following discussion and with reference to (FIGURE 2C), the vest 110 and electrodes 400 in one embodiment of the present invention are held in place on the patient by adhesive patches 200 and adhesive gel 220 on or in the general vicinity of the electrodes 400. Conventional, conductive gel, such as Katecho KM10T or Covidien RG-63B, is suitable for coupling the electrodes to the patient and allowing electrical conductivity there between. Once the ECG or other medical test utilizing the sensor device 100 is completed, the vest 110 may be removed from the patient 150 by pulling the vest 110 away from the patient and, thus, peeling the electrodes 400 from the patient 150. The vest 110 may then be discarded.

[0026] As previously discussed, liner 120 is left attached to the vest 110 until the electrodes 400 are to be attached to the patient 150, thus preserving the cleanliness and integrity of the adhesive patches 200 and electrode gel 220.

[0027] As illustrated in FIGURES 2A-C, and more fully described below, liner 120 provides a quick and simple way to attach the electrode vest 110 in the proper position on the patient 150. Once the sensor device 100 is properly oriented on the patient (FIGURE 2A), portions of the protective liner 120 are removed to allow the medical personnel to attach the vest 110 and electrodes 400 to the patient 150 in a controlled manner.

[0028] FIGURE 2B shows the vest 110 partially affixed to the patient 150. Preferably, the clinician removes some or all of patches 310 and affixes the associated adhesive patches and gel

200, 220 to the patient 150 to hold the vest 110 in the proper orientation. Starting near the top of the sensor device 100, closest to the patient's head, portions of the liner 120, illustrated as a series of strips, are removed and the corresponding portions of the vest 110 and electrodes 400 are pressed into place onto the patient's skin by the medical clinician. Continuing to work down the vest 110, away from the patient's head, the medical personnel removes the strips of the liner 120 and affix the vest 110 and the uncovered electrodes 440 to the patient 150. Once the liner 120 is completely removed, that is, once all of the strips have been removed (FIGURE 2C), the vest 110 may then be connected to the remote equipment, such as the ECG base unit 190 to begin the desired medical test. After the test is completed, the medical personnel may remove the vest 110 from the patient 150 and discard it in an appropriate and conventional manner.

[0029] In one embodiment, as briefly discussed above, liner 120 includes a number of releasable, protective strips 300 (FIGURE 1). The liner 120 may also include additional, releasable patches 310 positioned on extensions of the vest 110 that may cover electrodes 400 and/or adhesive patches 410 for securing the vest 110 to the patient 150. When medical personnel apply the vest 110 to the patient 150, the patches 310 near the patient's head may be removed first to allow the medical technician to place the vest 110 on the patient 150 and hold it in proper orientation. Similarly, the patches 310 near the bottom of the vest 110, farthest away from the patient's head, may be removed next to further secure the vest 110 and electrodes 400 to the patient 150. The patches 310 may be removed in this or a different order relative to each other and the liner strips 300 as preferred by the medical technician.

[0030] FIGURES 3A-C show one of the protective liner strips 300 during various stages of release from the vest 110. FIGURES 4A-C are schematic side views of the liner strip 300 in the various stages of removal illustrated in corresponding FIGURES 3A-C, and further illustrate the

release of the liner strip 300 from the vest 110. FIGURES 3A-C illustrate the liner strip 300 as viewed from the patient's side of the vest 110 while FIGURES 4A-4C illustrate corresponding side elevational views of the liner strip 300.

[0031] In FIGURE 3A, the liner strip 300 is placed on the vest 110 covering rows of electrodes 400. The liner strip 300 includes a fixed end 320 releasably attached to the vest 110 by a fastening device 330, which may take the form of, but is not limited to, adhesive tape, wax, hook and loop fasteners, magnets, *etc*.. The liner strip 300 further includes a free end 340 that passes through a retainer 350 located distally from the fixed end 320 and then passes through a guide 360 located proximate the free end 340, thus forming an open loop as best shown in FIGURE 4A. As illustrated in FIGURES 3A-C and as discussed with reference to FIGURE 5, retainer 350 and guide 360 are attached to vest 110.

[0032] Referring specifically to FIGURE 4A, liner strip 300 is positioned between electrodes 400 and the patient's skin 155. The liner strip 300 is attached at its fixed end 320 to dielectric membrane 130 by the fastening device 330 and passes through the retainer 350. As previously discussed, the liner strip 300 is folded back on itself after passing through retainer 350 and may pass through a slot 365 in guide 360 so that free end 340 is looped back to the general proximity of, and even extending past, the fixed end 320.

[0033] Turning to FIGURES 3B and 4B, free end 340 has been pulled away from the fixed end 320. As oriented in FIGURES 3B and 4B, free end 340 has moved to the left. This motion is accomplished by the medical technician pulling on free in 340. As the free end 340 is pulled, the liner strip 300 disengages from the retainer 350. The material properties and mechanical design of the retainer 350 allow it to give way and release the strip 300 when a sufficient pulling force is applied to end 340. As end 340 is pulled, the strip 300 pulls away from retainer 350 and

sequentially and controllably releases from, and exposes, electrodes 400. As the strip 300 continues to be pulled, eventually, all electrodes 400 previously covered by strip 300 are uncovered and exposed to the patient 150 (FIGURES 3C and 4C). Continued pulling by medical personnel causes the liner strip 300 to eventually release completely from vest 110. As discussed above, and with reference to FIGURE 2B, a medical technician may apply pressure to the vest 110 in the area of the exposed electrodes 400 so that they better adhere to the patient 150.

[0034] As the free end 340 of liner strip 300 is pulled, arms 351 of retainer 350 flex and release the liner strip 300 (FIGURE 3B). As the medical personnel continues to pull the liner strip 300, the strip releases from, and uncovers electrodes 400. The uncovered electrodes 400 may be pressed into contact with the patient's skin 155. In FIGURE 3C, the liner strip 300 has been pulled sufficiently far to uncover all previously covered electrodes 400, but is still attached to the vest 110 at its fixed end 320 by tape 330. Continued pulling of strip 300 releases the end 320 from the vest 110. The tape may either remain on the vest 110 or on the liner strip 300. All electrodes 400 previously covered by strip 300 are now uncovered and are in contact with the patient 150.

[0035] FIGURE 5 illustrates one embodiment of a liner strip 300. In this embodiment, retainer 350 and guide 360 are elements affixed to vest 110 (FIGURES 1 and 2A) by adhesive strips 375. Alternatively, the retainer 350 and guide 360 may be attached to the vest 110 by other means, including but not limited to gluing or sonic welding. In the embodiment illustrated in FIGURE 5, free end 340 has an arrowhead shape and is attached to the liner strip 300 by adhesive 380. Free end 340 may have other shapes and may be attached to the liner strip 300 by other means, such as gluing or sonic welding. Further, end 340 may be formed as an integral part of liner strip 300. One benefit of the arrowhead shape of end 340 is that the width of end 340 is larger than the

width of slot 365 in guide 360 through which the liner strip 300 passes. This geometry prevents the free end 340 of liner strip 300 from unintentionally pulling back through the guide 360. It is further understood that retainer 350 and guide 360 may be formed as part of, and integral with, vest 110. For example, the retainer 350 and guide 360 may be laser cut into the dielectric substrate 130 of vest 110.

[0036] Preferably, a surface 315 (FIGURE 5) of liner strip 300 has sufficiently low adhesive properties that allow it to release from the adhesive gel on the electrodes 400 when an appropriate pulling force is applied to free end 340. For example, silicone coated polyester release liner materials may offer these properties. Also preferably, the opposite surface 325 of liner strip 300 has sufficiently low coefficient of friction properties to allow it to slide easily against itself when a pulling force is applied to free end 340 (also FIGURE 5).

[0037] While the preferred embodiment of the invention has been illustrated and described, as noted above, many changes can be made without departing from the spirit and scope of the invention. For example, the protective liner may be shaped other than as a series of strips and there may be more than one guide element along the liner strip. The characteristics of the protective liner material may be such that there is no need for a retainer or guide. For example, the liner may be stiff enough to hold its place on the vest without the need for a retainer. By way of further example, the length of the liner strip may be short enough that a guide is not required. Accordingly, the scope of the invention is not limited by the disclosure of the preferred embodiment. Instead, the invention should be determined entirely by reference to the claims that follow.

[0038] The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A releasable liner for a sensor device having a plurality of electrodes, the releasable liner comprising:
a first strip portion configured to overlay and adhere to at least one of the plurality of electrodes, the first strip portion having a fixed end attached to the sensor device; and
a second strip portion extending approximately parallel to the first strip portion and positioned adjacent thereto, the second strip portion having a free end movable relative to the fixed end of the first strip portion, the second strip portion coupled to the first strip portion such that a pulling force applied to the free end causes the first strip portion to separate from at least one of the plurality of electrodes.

2. The releasable liner of Claim 1, further comprising:
a first surface of the first strip portion and the second strip portion positioned between the fixed end and free end having a first section and a second section that face each other when the flexible sheet is folded upon itself.

3. The releasable liner of Claim 2, wherein the first surface has a low coefficient of friction and the first and second sections are in slidable contact with each other.

4. The releasable liner of Claim 1, wherein the free end is slidably attached to the sensor device

5. The releasable liner of Claim 1, wherein the fixed end is releasably attached to the sensor device.

6. The releasable liner of Claim 1, further comprising:
a second surface of the first strip portion and the second strip portion positioned between the free and fixed ends having a first section and a second section that face away from each other when the flexible sheet is folded upon itself.

7. The releasable liner of Claim 6, wherein the second surface has a low adhesion characteristic for releasable engagement with at least one of the plurality of electrodes.

8. A sensor device for a human patient, the sensor device comprising,
a patient-facing surface with at least a portion of the patient-facing surface having an adhesive member that is removably attachable to the patient's body;
a protective liner folded upon itself and releasably affixed to the patient-facing surface of the sensor device; and,
wherein the sensor device is attachable to the patient once the protective liner is at least partially released from the sensor device.

9. A method for placing a sensor device in contact with a patient's anatomy, the method comprising the steps of:
positioning the sensor device on the patient in a desired position; and;
releasing a protective sheet between the patent and a portion of the sensor device
such that the releasing step exposes the sensor device to the patient's anatomy.

10. The method of Claim 9, wherein releasing the protective sheet includes pulling on an end of the sheet in a direction in which the pulling force is generally coplanar with the portion of the sheet between the patient and the sensor device.

11. The method of Claim 10, wherein pulling on the end of the sheet includes
pulling a free end of the sheet in a direction away from a fixed end of the sheet;
causing the sheet to loop back upon itself as it releases from the sensor device.

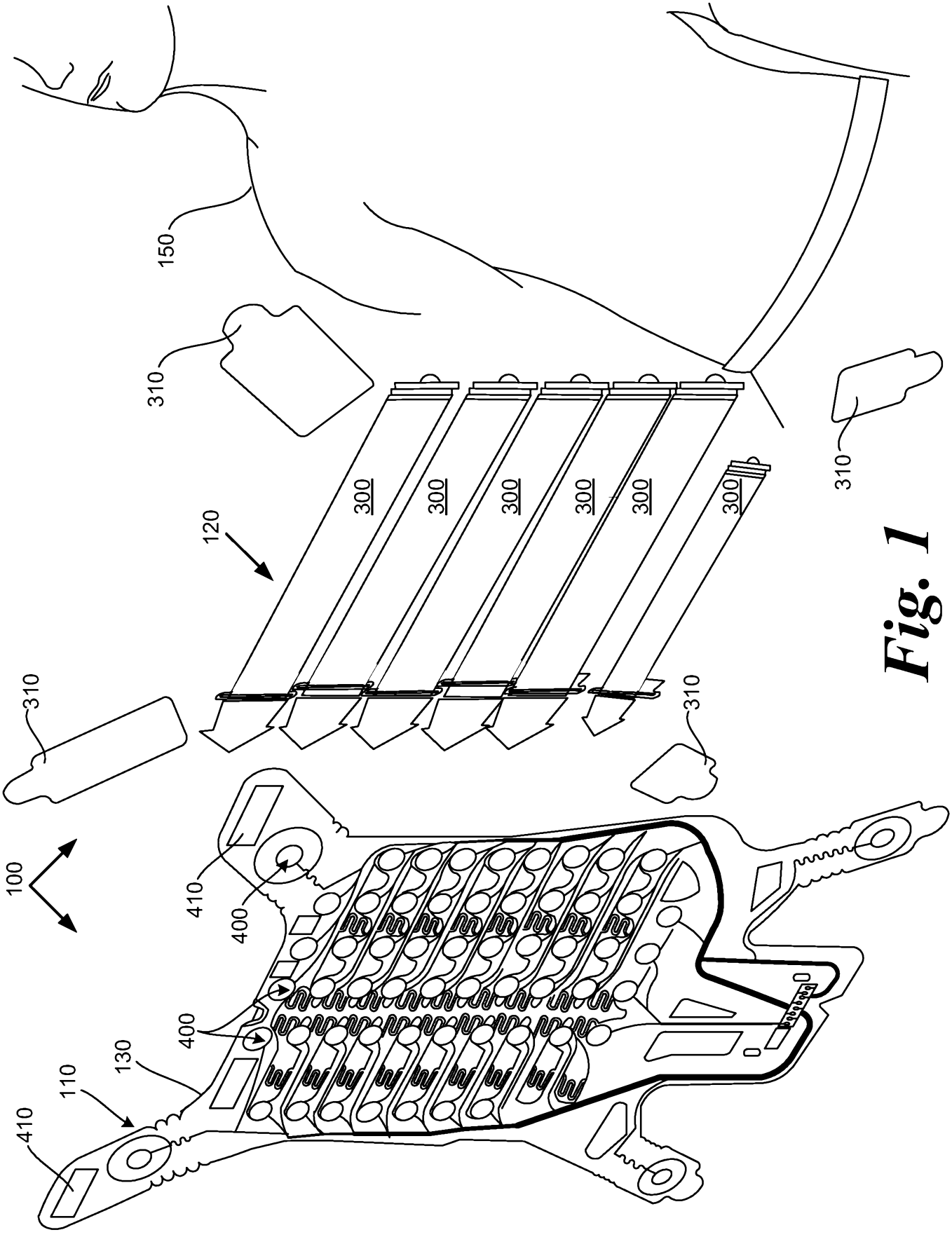
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Fig. 1

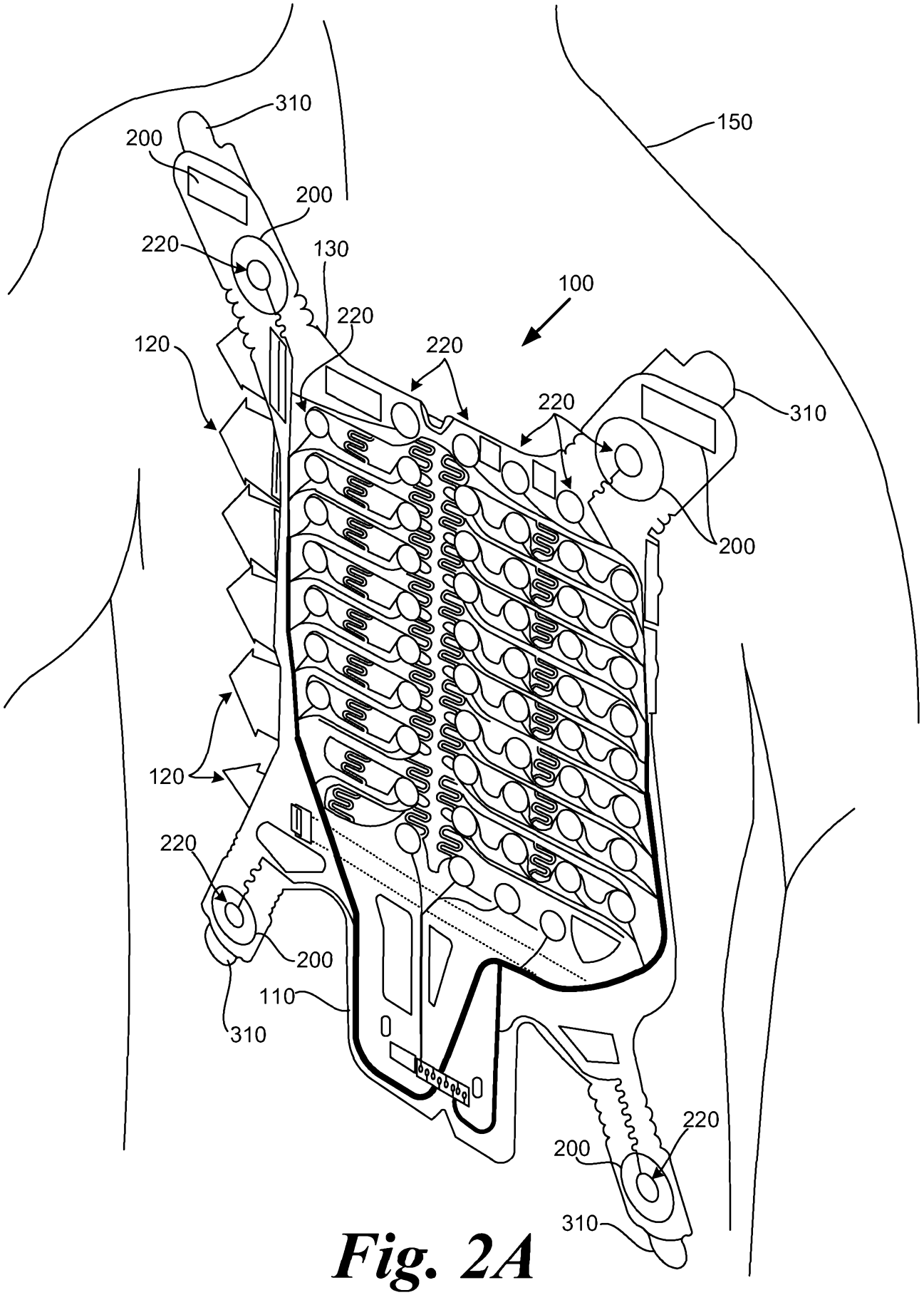
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Fig. 2A

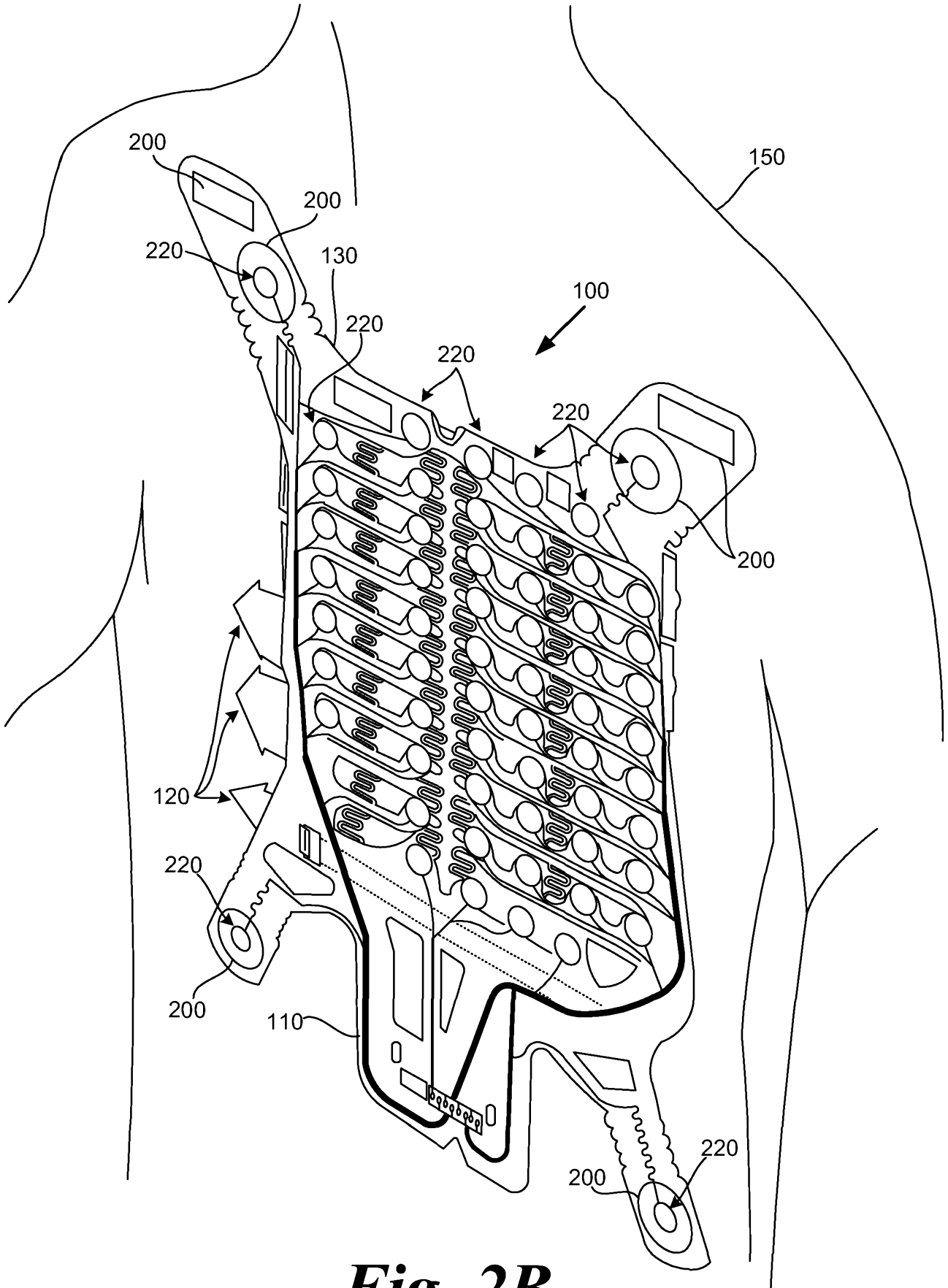

Fig. 2B

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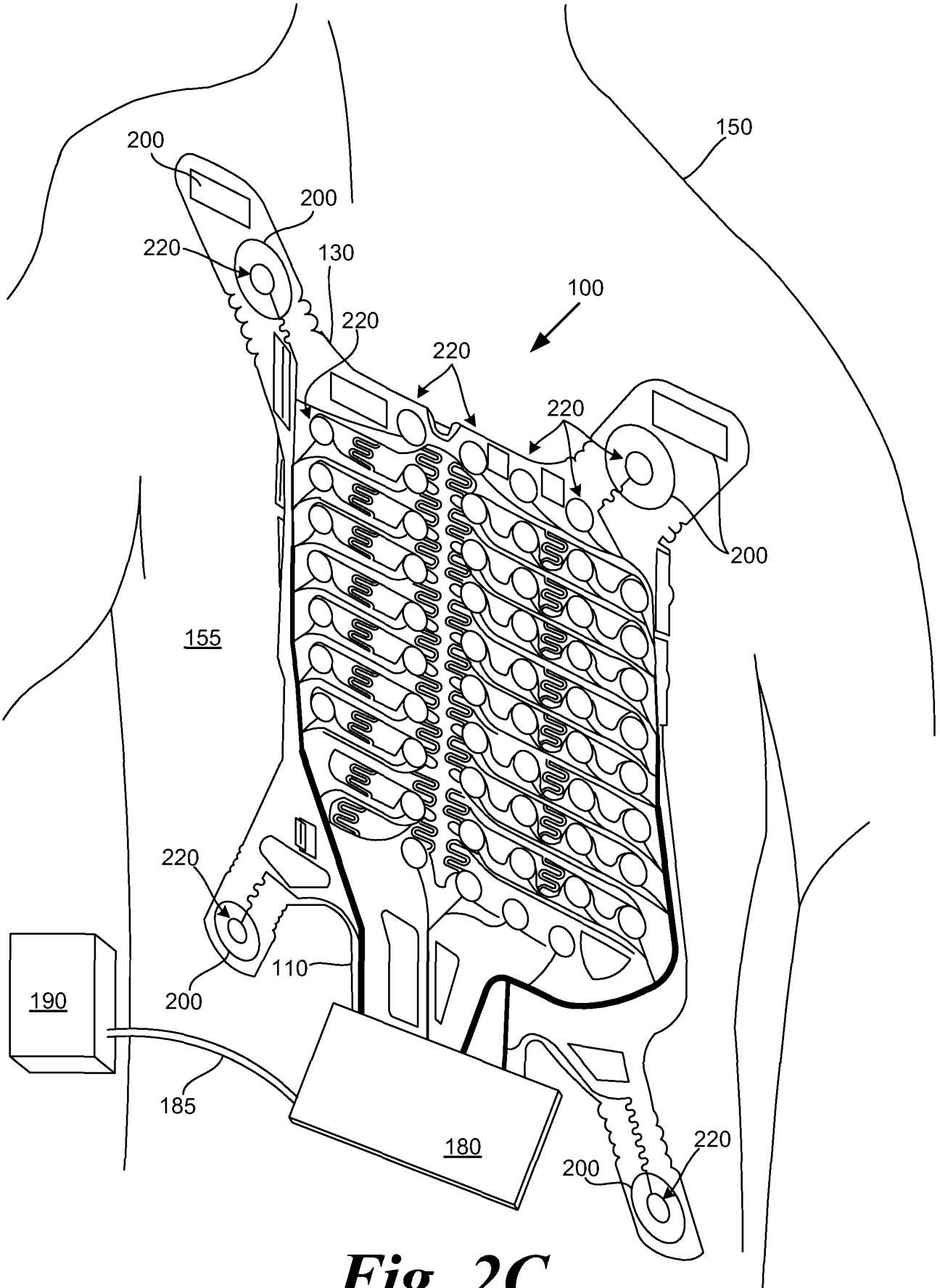

Fig. 2C

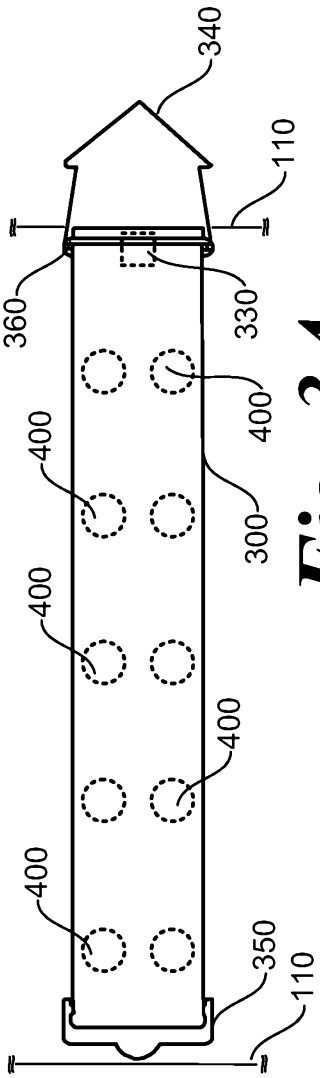

Fig. 3A

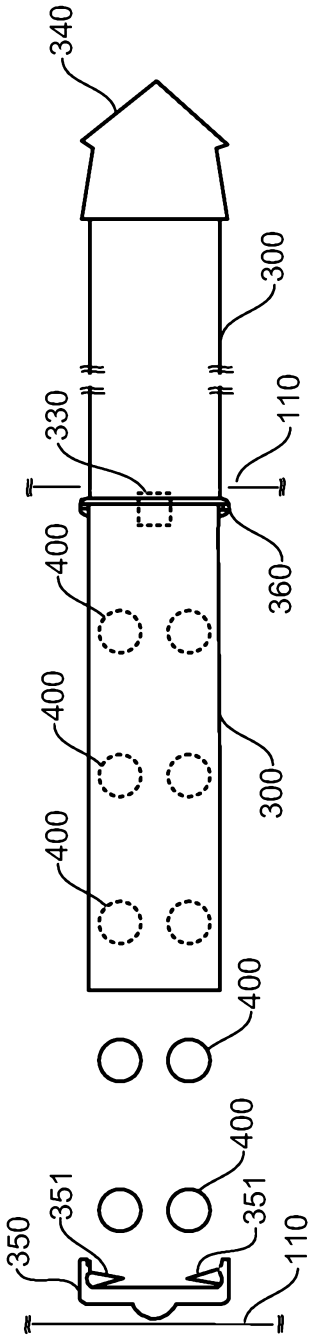

Fig. 3B

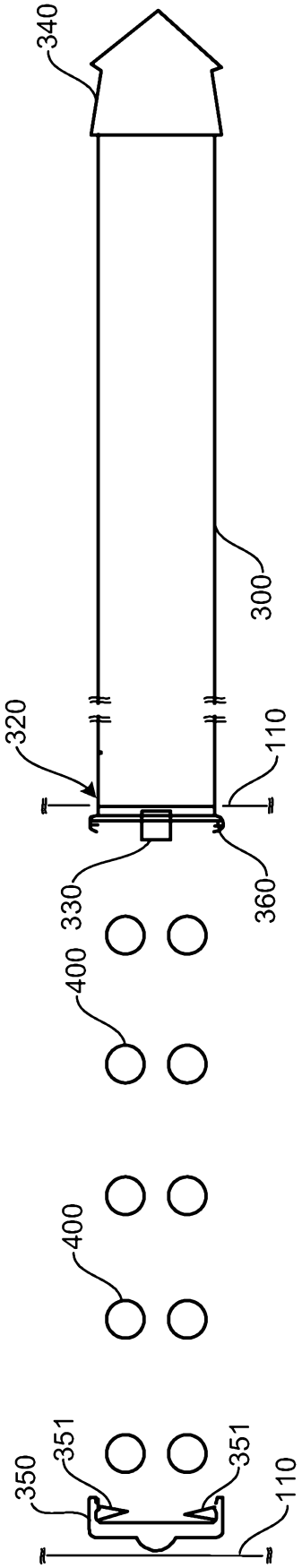

Fig. 3C

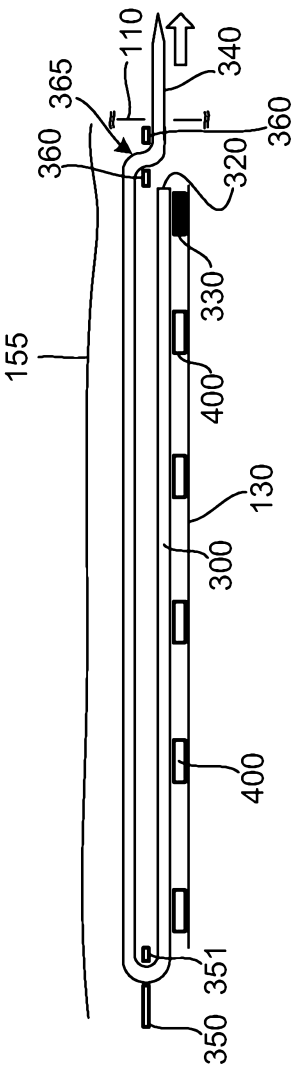

Fig. 4A

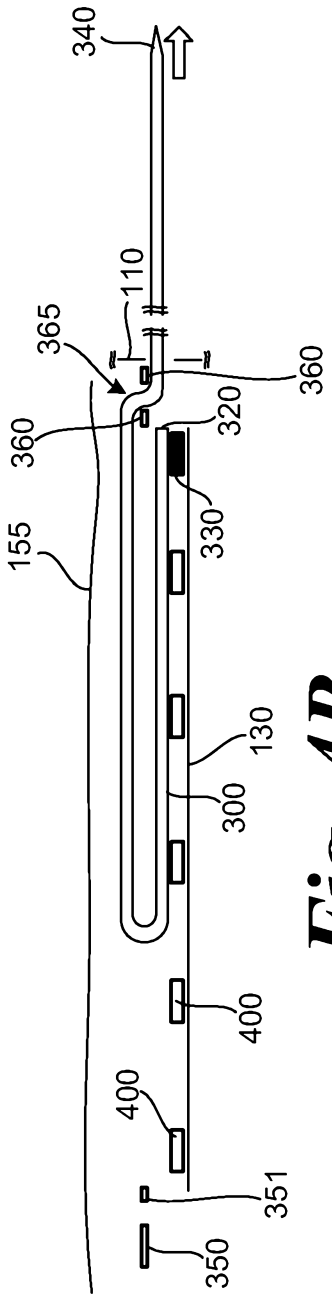

Fig. 4B

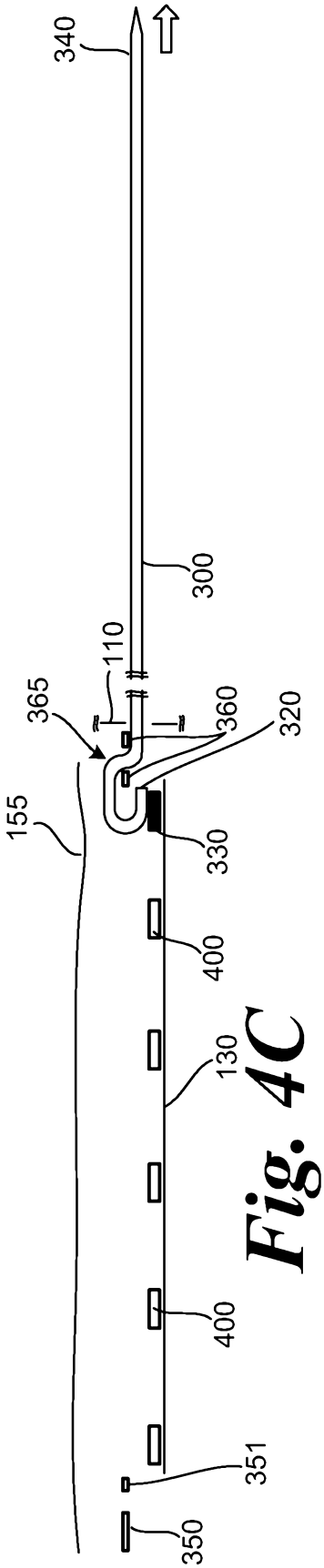

Fig. 4C

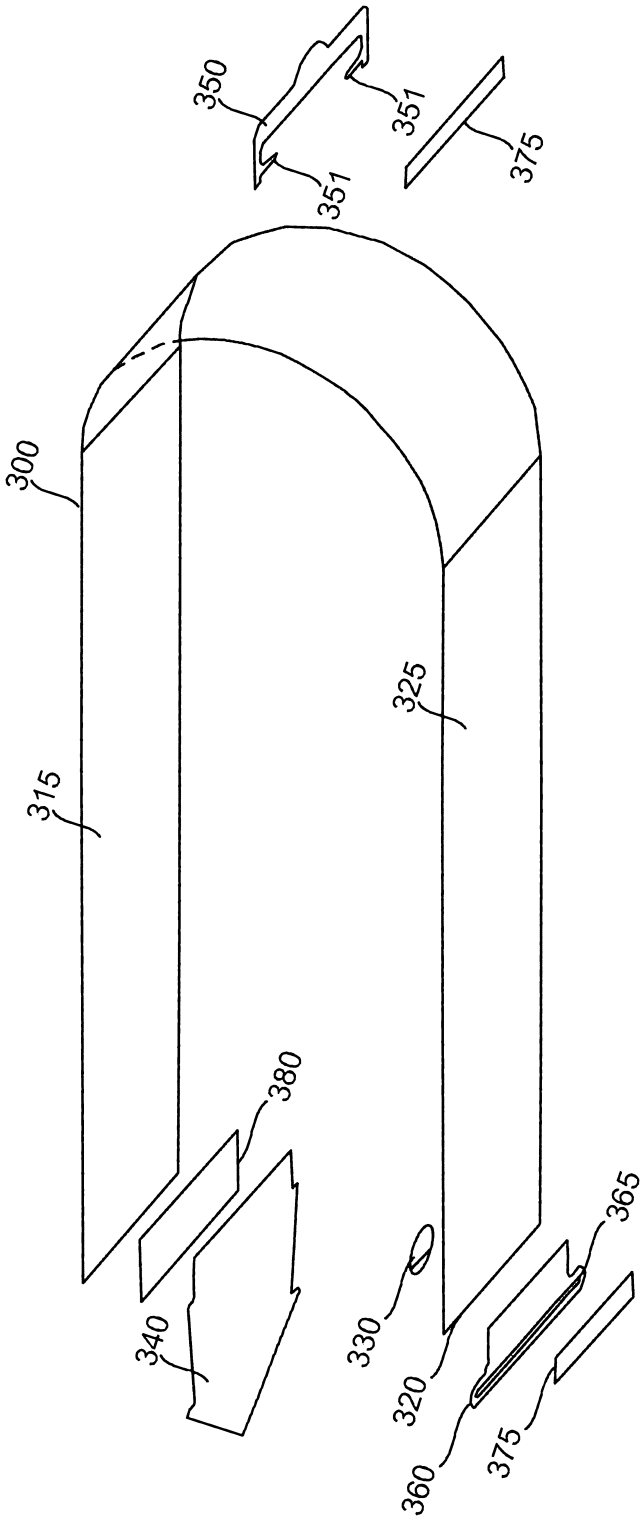

Fig. 5