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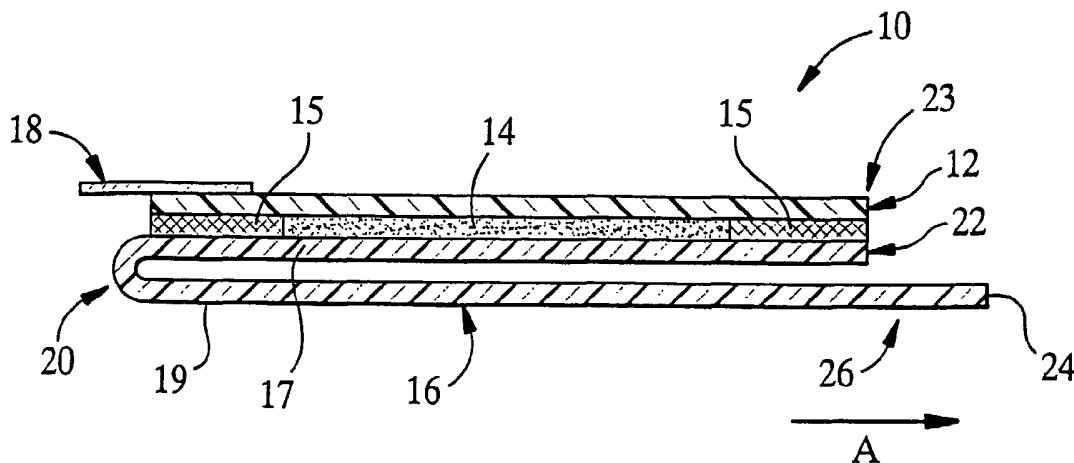
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(54) Title: SKIN-APPLIED ELECTRODE PADS



(57) Abstract: Skin-applied electrodes (10) are provided that are suitable for use in applications such as pacing and defibrillation. The electrodes have a release sheet (16) that is configured to allow the electrode to be accurately positioned on a patient.

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# Skin-Applied Electrode Pads

## TECHNICAL FIELD

This invention relates to skin-applied electrode pads, e.g., for use with  
5 defibrillators.

## BACKGROUND

Skin-applied electrode pads are well known for use in medical applications such as cardiac pacing, ECG monitoring, and defibrillation. Typically, these electrode pads are attached to a wire lead or cable that is attached at its opposite end to the connector  
10 of a medical device or medical device instrumentation. Electrode pads generally include an electrode, e.g., a conductor such as a thin layer of tin or another metal, resting on a foam backing. The electrode typically is covered with a conductive gel that contacts a patient's skin and electrically connects the electrode to the patient, and the electrode pad includes a ring of adhesive surrounding the conductive gel to adhere  
15 the electrode to the patient's skin.

For one or more reasons, e.g., to prevent the adhesive gel from drying out, to maintain the electrodes in a sanitary condition, and to cover the adhesive until a caregiver is ready to adhere the electrode to the patient, a release sheet, e.g., a plastic cover, is positioned over the adhesive and/or conductive gel of each electrode.

20 To use the electrode pads, a caregiver connects the wire leads to an appropriate medical device such as a defibrillator (if they are not pre-connected), removes the release sheets from the electrode pads, and applies the electrode pads to the patient. If the caregiver does not correctly position the electrode pads on the first try, it may be difficult to reposition the electrode pads if the adhesive has adhered to the patient's  
25 skin. If the caregiver is able to remove and reposition the electrodes, adhesion may not be as good as it would have been had the electrode pads not been previously adhered. Also, if the electrodes are large in size and flexible, some of the electrode's adhesive surfaces may inadvertently adhere to each other during handling of the (release sheetless) electrode requiring the clinician to separate the stuck together portions prior  
30 to application to the patient. This "untangling" of the electrode can be frustrating, time consuming, difficult and may degrade the electrode's ability to adhere to the patient.

## SUMMARY

Generally, the invention features an electrode pad in which an adhesive area is covered by a release sheet that is configured to be removed while the release sheet is in contact with or closely adjacent to a patient's skin. This arrangement allows the caregiver to carefully position the electrode pad with the release sheet in place, and then remove the release sheet without moving the electrode pad.

Because the release sheet can be removed from the electrode pad after the electrode pad has been properly positioned, without moving the electrode pad, accurate and precise placement can be achieved. Moreover, the need to remove, reposition and attempt to re-adhere an electrode pad that has already adhered to a patient's skin is eliminated and the likelihood that the electrode's adhesive surfaces will stick together during application is reduced. The time saved can literally be the difference between life and death in an emergency situation. For example, when defibrillation is required, every second of delay in applying the electrode pads can be critical.

In one aspect, the invention features a generally planar skin-applied electrode pad including: (a) an electrode, (b) an adhesive configured to adhere the electrode to a patient's skin, and (c) a release sheet, a first portion of the release sheet covering the adhesive, and a second portion of the release sheet extending from the first portion and being folded so that the release sheet can be peeled away from the adhesive by pulling the second portion in a direction substantially parallel to the plane of the electrode pad.

Some implementations may include one or more of the following features. The electrode pad includes a conductive gel, and the conductive gel is covered by the release sheet. The adhesive is non-conductive. The adhesive surrounds the gel. The release sheet is folded in a substantially U-shaped configuration. An edge of the second portion of the release sheet extends beyond an adjacent edge of the electrode, providing a pull-tab that can be grasped during removal of the release sheet. The release sheet is selected from the group consisting of release-coated papers, plastic sheet materials and polymeric films. The electrode pad includes a cable constructed to connect the electrode pad to a defibrillator control box. The electrode pad is configured for use with an automatic external defibrillator (AED), or a manual or semi-automatic external defibrillator.

In another aspect, the invention features a skin-applied electrode pad having a release sheet that is configured to be removed while the electrode pad is held in a

desired position on the patient with a portion of the release sheet in contact with the patient's skin.

The invention also features, in another aspect, a defibrillator including a skin-applied electrode pad of the invention.

5           Some implementations may include one or more of the following features. The defibrillator is an automatic external defibrillator. Two or more electrode pads are integrally connected, forming an electrode pad assembly. The release sheet is folded in a substantially U-shaped configuration. An edge of the second portion of the release sheet extends beyond an adjacent edge of the electrode, providing a pull-tab that can be  
10 grasped during removal of the release sheet.

In yet another aspect, the invention features a method of applying an electrode to a patient, the electrode including an adhesive portion covered by a release sheet. The method includes (a) positioning the electrode on the patient's skin with the release sheet facing the skin and in contact with or closely adjacent to the skin, (b) without  
15 lifting the electrode from the patient's skin, removing the release paper to expose the adhesive portion, and (c) adhering the adhesive portion to the patient's skin.

Other features and advantages of the invention will be apparent from the detailed description and drawings, and from the claims.

### DESCRIPTION OF DRAWINGS

20           Fig. 1 is a top view of a prior art electrode pad.

Fig. 2 is a cross-sectional view of an electrode pad according to one embodiment of the invention. Figs. 2A and 2B are similar cross-sectional views, illustrating removal of the release sheet.

Fig. 3 is a drawing of an electrode pad assembly according to one embodiment  
25 of the invention, positioned over the chest of a patient.

Fig. 4 is a cross-sectional view of an electrode pad according to an alternate embodiment of the invention.

Fig. 5 is a back planar view of an electrode pad similar to that shown in Fig. 2.

### DETAILED DESCRIPTION

30           An electrode pad 10 is shown in Fig. 1. When in use, electrode pad 10 is connected to a defibrillator control box 13 (not shown to scale) by cable 11.

Electrode pad 10 is relatively large, rendering it suitable for use in defibrillation. Typically, the surface area of electrode pad 10 is at least 50 cm<sup>2</sup>, more preferably from about 50 cm<sup>2</sup> to 100 cm<sup>2</sup>. Smaller medical electrodes, such as EKG electrodes, are generally much easier to place than the large defibrillator electrodes described above.

5 This is in part due to the flexibility of the electrode, which makes the electrode difficult to control after the release paper is removed and can result in the sticking together problem discussed above in the Background.

Referring to Fig. 2, electrode pad 10 includes an electrode 12, a conductive gel layer 14, an adhesive ring 15, and a release sheet 16. Optionally, electrode pad 10 may  
10 include a stabilizing tab 18 (not shown in Fig. 1), the function of which will be described below. Electrode 12 includes a foam backing or other suitable backing material (not shown), as is well known.

Release sheet 16 is folded, at fold 20, to define a generally U-shaped configuration, defining a portion 17 that is initially adhered to the adhesive and gel, and  
15 a portion 19 that extends freely beyond fold 20. The release sheet is folded in a manner so that it will not unfold to any significant extent during storage or prior to use. As shown in Figs. 5 and 5A, the release sheet may also be held in place by a pair of tabs 25 extending from portion 17, under which pull tab 26 is disposed prior to use. Alternatively, a small area of pressure sensitive adhesive can be positioned in the same  
20 general area, on portion 17 or portion 19, to adhere the two portions together until use. Referring to Fig. 2, the end 22 of the release sheet that is adjacent the gel layer 14 is generally substantially aligned with the edge 23 of the electrode pad. The opposite end 24 of the release sheet extends beyond the edge 23 of the electrode pad, providing a pull-tab 26 which can be grasped by a user. Pull tab 26 preferably extends far enough  
25 beyond the edge 23 to provide a good grasp between the thumb and forefinger, typically at least about 1 inch.

To apply electrode pad 10 to a patient, a caregiver positions the electrode pad on the patient's chest in a desired position. When the caregiver is sure that the electrode pad is in the correct position, the caregiver holds the electrode pad in place,  
30 e.g., by grasping stabilizing tab 18, grasps pull tab 26, and peels the release sheet 16 out from underneath the electrode pad as indicated by arrow A in Fig. 2. Grasping stabilizing tab 18 while pulling on the pull tab 26 stabilizes the electrode and helps the caregiver to maintain the electrode in the desired position on the patient as the release

sheet is removed. If stabilizing tab 18 is omitted, the same result may be obtained by lightly pressing the far side of the electrode (the side opposite the pull tab) against the patient while pulling the pull tab.

As the release sheet 16 is peeled off (Figs. 2A and 2B), the fold 20 moves  
5 across the electrode pad in the direction of arrow A, so that the gel layer 14 is exposed and brought into contact with the patient's skin. As the gel layer and adhesive are exposed, the electrode pad adheres to the patient's skin and electrical contact is established. Light pressure may be applied to the electrode pad by the caregiver to ensure good adhesion.

10 The release sheet may be a release-coated paper, a plastic sheet material (including non-polymeric films having the properties of plastics), a polymeric film, or any other suitable sheet material having release properties sufficient to release from the gel layer and adhesive. Suitable sheet materials for use in the embodiment described above are also foldable. Examples of suitable sheet materials include polystyrene,  
15 polyester and paper.

Other embodiments are within the scope of the following claims. For example, the electrode pad may have any desired shape and size, including square, circular, or oval.

The adhesive ring may be formed of a non-conductive or conductive adhesive,  
20 and the adhesive may be provided in any other desired shape or configuration.

The electrode pad may be integrally attached to one or more other electrode pads to form an electrode pad assembly, allowing a pair of electrodes to be easily applied to a patient, e.g., as disclosed in copending U.S. Serial No. 09/794,320, filed February 27, 2001, the complete disclosure of which is incorporated herein by  
25 reference. Such an electrode pad assembly is shown in Fig. 3. Referring to Fig. 3, electrode pad assembly 110 includes a pair of electrode pads 112, 114. Electrode pad assembly 110 is connected by a cable 111 to a resuscitation control box (not shown). In this case, the pull-tabs 126 of the two electrode pads 112, 114 extend from opposite edges 123a, 123b of the electrode pad assembly so that they are exposed for use.

30 Moreover, the electrode pad or electrode pad assembly may include text or other indicia to help a caregiver locate the electrode, e.g., as disclosed in U.S. Serial No. 09/794,320.

In another embodiment, shown in Fig. 4, an electrode pad 200 includes a pair of U-folded release sheets 216a, 216b. Each release sheet is folded at a fold 220 (220a, 220b), to define a generally U-shaped configuration. The end 222 of each release sheet that is adjacent the gel layer 14 is generally substantially aligned with the edge 23 of the electrode pad. The opposite end 224 of each release sheet extends beyond the edge 23 of the electrode pad, providing a pull-tab 226 which can be grasped by a user. This option may be desirable when the electrode is circular or oval.

Portion 19 of the release sheet may be any desired shape. For example, portion 19 may be tapered as shown in Fig. 5. This taper facilitates removal of portion 19 and pull tab 26 from the tabs 25.

**WHAT IS CLAIMED IS:**

1. A generally planar skin-applied electrode pad comprising:  
an electrode;  
5 an adhesive configured to adhere the electrode to a patient's skin; and  
a release sheet, a first portion of the release sheet covering the adhesive, and a  
second portion of the release sheet extending from the first portion and being folded so  
that the release sheet can be peeled away from the adhesive by pulling the second  
portion in a direction substantially parallel to the plane of the electrode pad.  
10
2. The electrode pad of claim 1 wherein the electrode pad further comprises a  
conductive gel.
3. The electrode pad of claim 1 wherein said adhesive is non-conductive.  
15
4. The electrode pad of claim 2 wherein said adhesive surrounds said gel.
5. The electrode pad of claim 1 wherein the release sheet is folded in a  
substantially U-shaped configuration.  
20
6. The electrode pad of claim 1 wherein an edge of the second portion of the  
release sheet extends beyond an adjacent edge of the electrode, providing a pull-tab that  
can be grasped during removal of the release sheet.
- 25 7. The electrode pad of claim 1 wherein said release sheet is a sheet material  
selected from the group consisting of release-coated papers, plastic sheet materials, and  
polymeric films.
8. The electrode pad of claim 1 further comprising a cable constructed to  
30 connect the electrode pad to a defibrillator control box.



9. The electrode pad of claim 1 wherein said electrode pad is configured for use with an automatic, semi-automatic or manual external defibrillator.

5           10. The electrode pad of claim 1 wherein the release sheet is configured so that, as the release sheet is peeled away, a fold about which the release sheet is folded travels in the direction in which the second portion is pulled.

10           11. A skin-applied electrode pad comprising:  
an electrode;  
an adhesive configured to adhere the electrode to a patient's skin; and  
a release sheet covering the adhesive, the release sheet being configured to be removed while the electrode pad is held in a desired position on or against the patient's skin with a portion of the release sheet in contact with the patient's skin.

15           12. The electrode pad of claim 11 wherein the electrode pad further comprises a conductive gel.

20           13. The electrode pad of claim 11 wherein said adhesive is non-conductive.

14. The electrode pad of claim 12 wherein said adhesive surrounds said gel.

25           15. The electrode pad of claim 11 wherein the release sheet is folded in a substantially U-shaped configuration.

30           16. A defibrillator comprising:  
a defibrillator control box;  
a pair of electrode pads; and  
leads connecting the electrode pads to the defibrillator control box;  
wherein each electrode pad comprises:  
          (i) an electrode;  
          (ii) an adhesive configured to adhere the electrode to a patient's skin;  
and

(iii) a release sheet, a first portion of the release sheet covering the adhesive, and a second portion of the release sheet extending from the first portion and being folded so that the release sheet can be peeled away from the adhesive by pulling the second portion in a direction substantially parallel to the plane of the electrode pad.

5

17. The defibrillator of claim 16 wherein the defibrillator comprises an automatic, semi-automatic or manual external defibrillator.

10 18. The defibrillator of claim 16 wherein the electrode pads are integrally connected, forming an electrode pad assembly.

19. The defibrillator of claim 16 wherein the release sheet is folded in a substantially U-shaped configuration.

15

20. The defibrillator of claim 16 wherein an edge of the second portion of the release sheet extends beyond an adjacent edge of the electrode, providing a pull tab that can be grasped during removal of the release sheet.

20 21. The defibrillator of claim 16 wherein the release sheet is configured so that, as the release sheet is peeled away, a fold about which the release sheet is folded travels in the direction in which the second portion is pulled.

22. The defibrillator of claim 16 wherein the electrode pad further comprises a  
25 conductive gel.

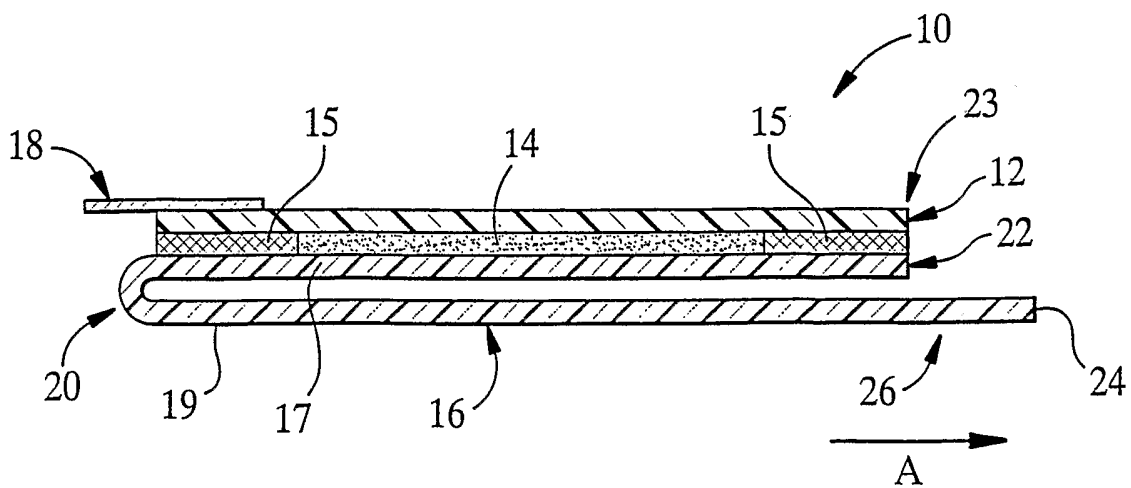
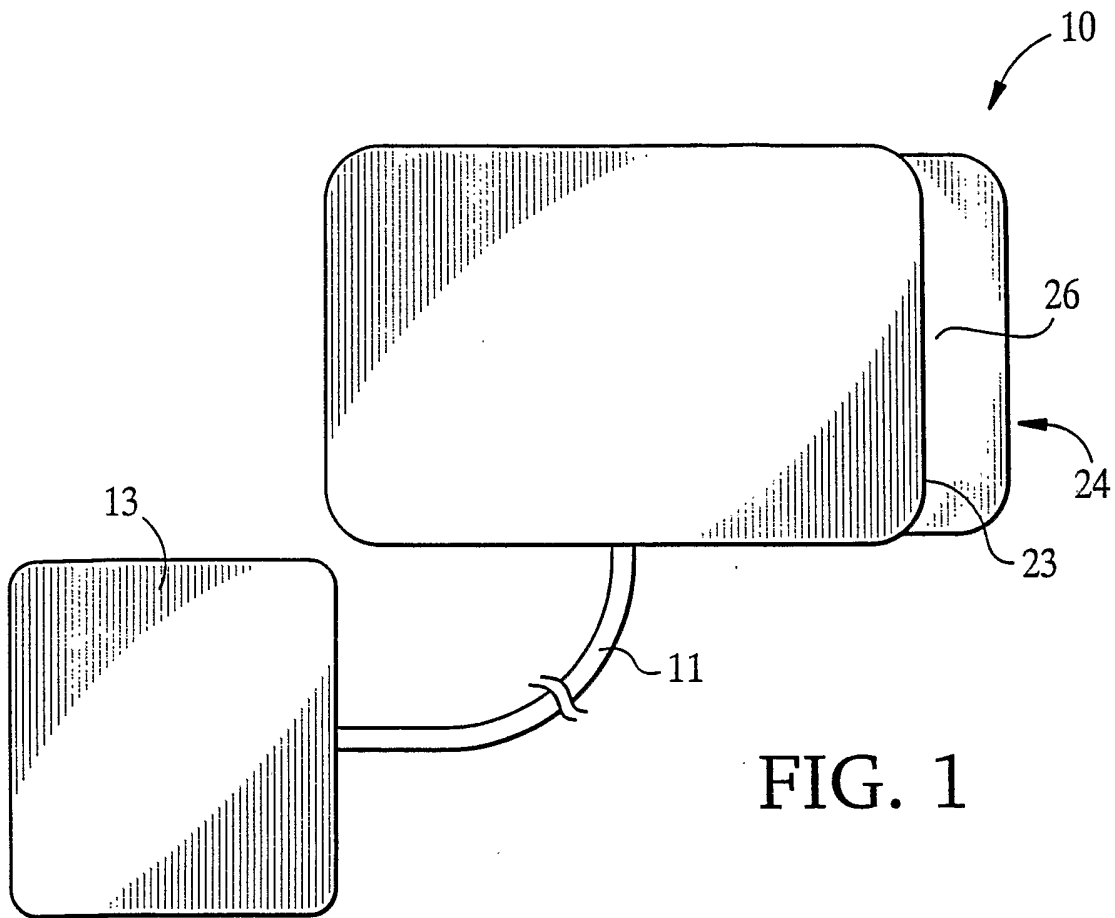
23. The defibrillator of claim 16 wherein said adhesive is non-conductive.

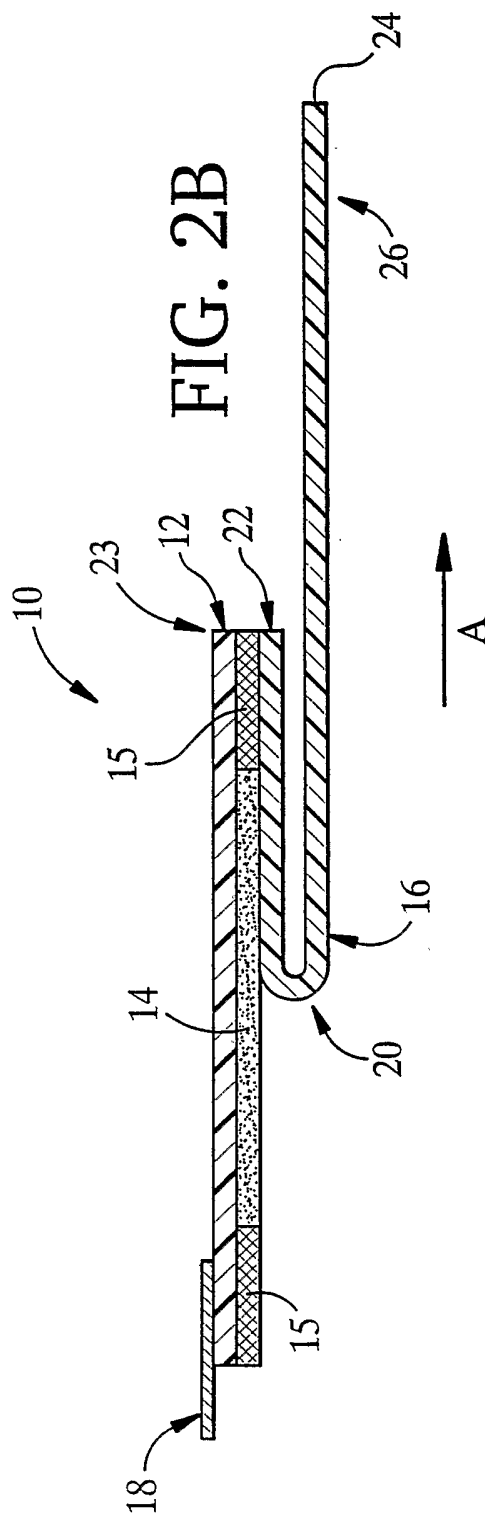
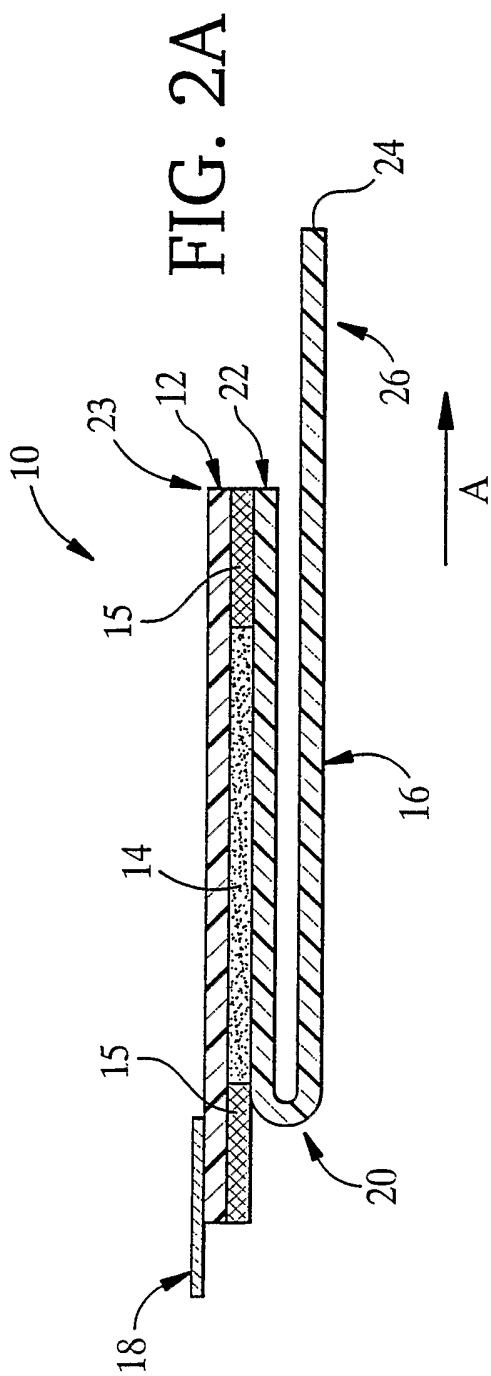
24. The defibrillator of claim 22 wherein said adhesive surrounds said gel.

30

25. A method of applying an electrode to a patient, the electrode including an adhesive portion covered by a release sheet, comprising:

- positioning the electrode on the patient's skin with the release sheet facing the  
5 skin and in contact with or closely adjacent the skin;
- without lifting the electrode from the patient's skin, removing the release paper  
to expose the adhesive portion; and
- adhering the adhesive portion to the patient's skin.





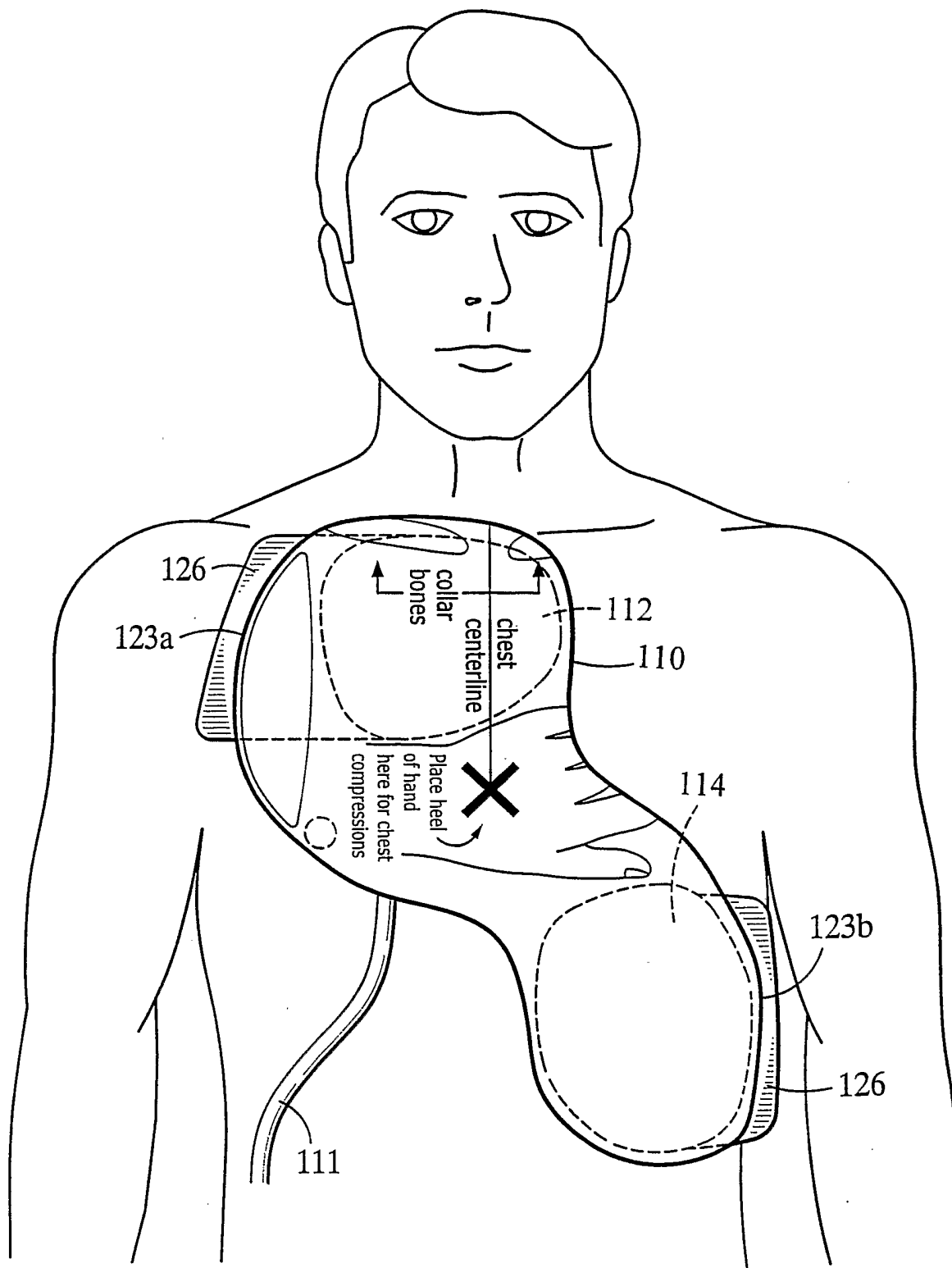


FIG. 3

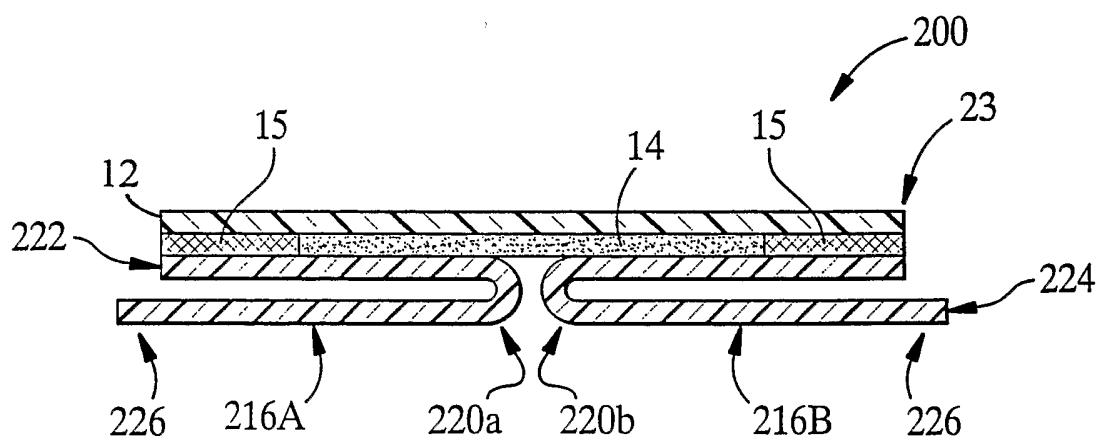


FIG. 4

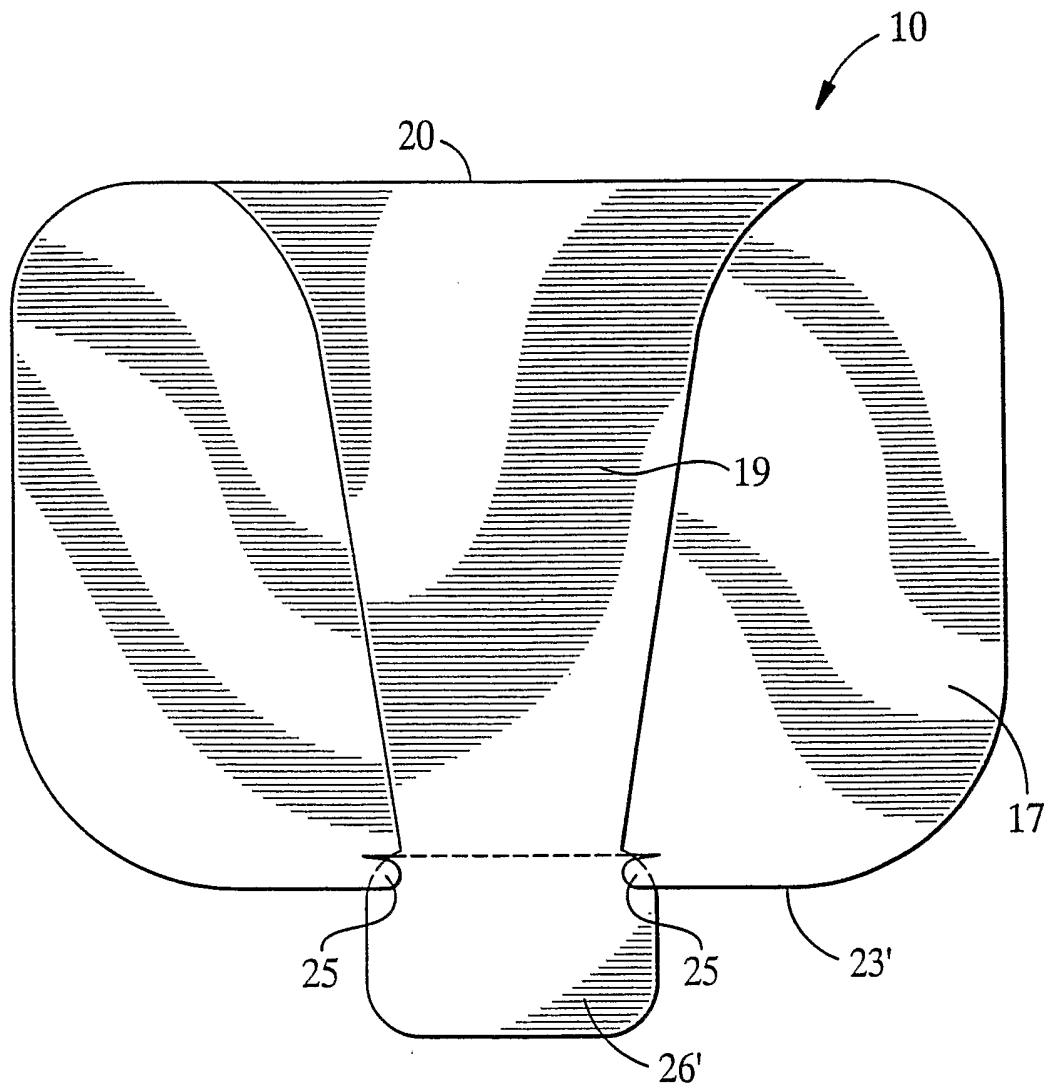


FIG. 5

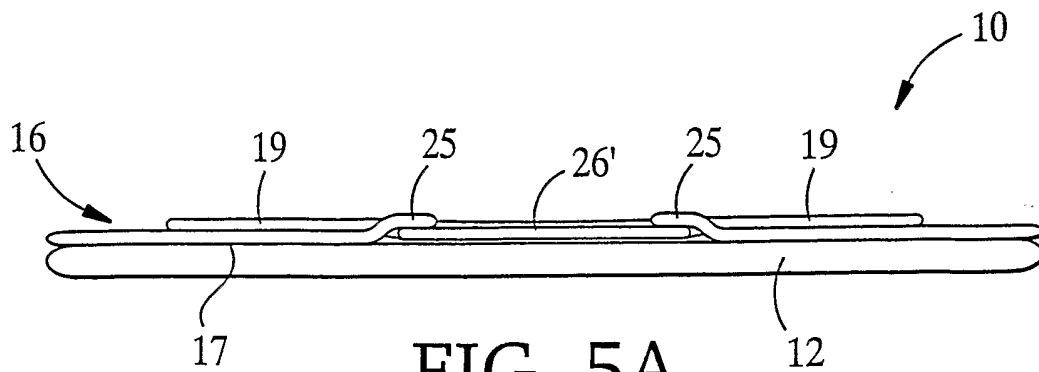


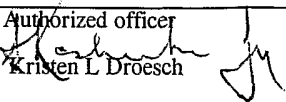
FIG. 5A



# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US02/23404

<b>A. CLASSIFICATION OF SUBJECT MATTER</b>		
IPC(7) : A61N 1/04 US CL : 607/142		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b>		
Minimum documentation searched (classification system followed by classification symbols) U.S. : 600/372,382,386,391,392; 602/57; 607/115,142,149,152,153		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6,178,357 B1 (GLINER et al) 23 January 2001 (23.01.2001), whole document.	1-25
Y	US 5,713,842 A (KAY) 03 February 1998 (03.02.1998), whole document.	1-25
Y	EP 0 434 258 A2 (SMITH INDUSTRIES PLC) 26 June 1991 (26.06.1991), whole document.	1-25
A	US 6,272,385 B1 (BISHAY et al) 07 August 2001 (07.08.2001), whole document.	1-25
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
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"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family	
Date of the actual completion of the international search		Date of mailing of the international search report
19 October 2002 (19.10.2002)		<b>18 DEC 2002</b>
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230		Authorized officer  Kristen L Droesch Telephone No. 703-605-1185