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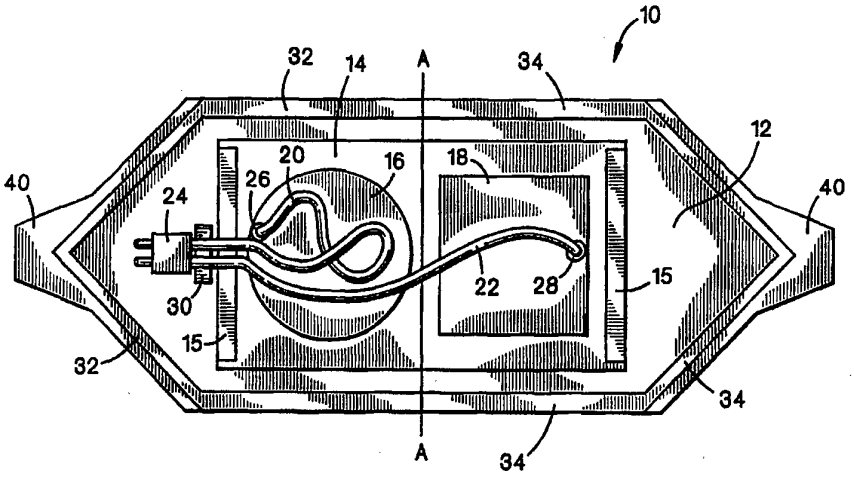
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**Published**
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**(54) Title:** ELECTRODE PACKAGE




**(57) Abstract**

An electrode package (100) in which one or more adhesively applied skin electrodes (106, 108) may be sealed has an envelope that includes a sheet of material (102) and a releasable seal (120) joining portions (122) of the envelope to provide a sealed first compartment in which an electrode may be isolated from the external environment. The envelope includes a first wall that defines a first interior surface (104) facing the interior of the sealed first compartment. The first interior surface includes an electrode mounting surface for direct attachment of an adhesive portion (110) of the electrode. The envelope is releasably sealed so that, when the envelope is sealed, the first interior surface is isolated from an external environment and, when the envelope is unsealed, the first interior surface is not isolated from the external environment.

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# ELECTRODE PACKAGE

## Background of the Invention

The invention relates to electrode packages.

Skin-applied electrodes used in medical applications such as cardiac pacing or defibrillation are well known. Typically, these electrodes consist of a wire lead that is attached at one end to a connector for a medical device and, at the other end, to a conductor such as a thin layer of tin or another metal resting on a foam backing. The conductor is covered with a water-based, conductive adhesive gel that contacts a patient's skin and electrically connects the electrode to the patient.

To prevent the adhesive gel from drying out, and to maintain the electrodes in a sanitary condition, the electrodes are stored in a package prior to use. In some such packages, plastic covers are positioned over the conductive adhesive gel of each electrode. The covered electrodes are then positioned within a sealed bag. To use the electrodes, medical personnel must tear open the bag, pull out and separate the electrodes, connect the electrodes to an appropriate medical device such as a defibrillator, remove the plastic covers, and apply the electrodes to the patient.

## Summary of the Invention

In one aspect, generally, the invention features an electrode package in which the conductive adhesive gel of an electrode is attached directly to an electrode mounting surface located on an interior surface of a wall of a releasably sealed envelope. When sealed, the envelope isolates the electrode from the external environment and thereby prevents the adhesive gel from drying out. To use the electrode, medical personnel tear open the envelope and expose the electrode.

Because the electrode is attached directly to the interior surface of the envelope, the steps of pulling the electrode out of the bag and removing the plastic cover that were required when using prior electrode packages are condensed into a single step of detaching the electrode from the interior surface of the package. The time saved by the elimination of a step 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 can be critical. Moreover, attaching the electrode to the interior of the envelope eliminates the risk of dropping the electrode that occurs when the electrode is loosely packaged within a bag or other container.

Typically, a second electrode is directly attached to an electrode mounting surface of a second interior surface of the envelope so that, when the envelope is sealed, the first and second interior surfaces face each other. The envelope is then unsealed in a manner similar to that of opening a book so that the two electrodes, like the facing pages of a book, are located on a single surface. This arrangement, which makes both electrodes readily accessible by medical personnel, further simplifies and accelerates the process of applying the electrodes to the patient. In addition, it provides a compact, efficient package.

For ease of assembly and use, the envelope is formed from a single sheet of material that is folded to form a first edge of the envelope and releasably heat sealed to form the remaining edges. This construction ensures that, when the envelope is opened, the electrode is fully exposed and readily available to medical personnel.

To further ease opening of the package, a pair of tabs are located opposite the folded edge of the

envelope. To open the envelope, medical personnel need only grasp these tabs and pull them apart. This releases the heat seal and exposes the electrode.

The envelope also includes a reinforcing layer located at the electrode mounting surface. The reinforcing layer provides structural rigidity and protects the electrode.

Finally, to temporarily secure a wire lead of the electrode during assembly and to prevent the wire lead from becoming tangled, the envelope includes an adhesive strip located on its interior surface.

In another aspect, generally, the invention features an electrode package that has a first compartment in which an electrode is sealed, a second compartment in which a connector of the electrode is sealed, and a barrier element between the compartments that provides an electrically conductive path between the electrode and the connector. The barrier element allows the second compartment to be opened, and the connector exposed, without affecting the seal of the first compartment or exposing the electrode.

Because the connector can be exposed without exposing the electrode, the electrode can be preconnected to a medical device without the risk of contaminating the electrode or drying out its conductive adhesive layer. Thus, the electrode can be connected to the medical device before an emergency arises, and the step of connecting the electrode to the device, and its associated delay, can be eliminated from the electrode application procedure in an emergency situation such as when defibrillation is required.

The barrier element can also be employed in an electrode package having only a single compartment to similarly allow preconnection of the electrode to a medical device.

One method of implementing the barrier element includes forming a layer of material around a wire lead that is attached between the connector and the electrode. The layer is formed so that it includes an arcuate upper portion and an arcuate lower portion. To form the barrier element and seal the compartment, a first wall of the compartment is heat sealed to the arcuate upper portion, a second wall of the compartment is heat sealed to the arcuate lower portion, and the first and second walls are heat sealed to each other.

Another method of implementing the barrier element involves using the connector body as a portion of the barrier element. Typically, the body is formed from a single piece of material and includes an integral hinge. The body also includes strain relief posts that arranged so as to relieve strain on a wire lead located between the electrode and the connector. To ease formation of the barrier element and sealing of the compartment, the body includes a first end located in the compartment, a second end located outside of the compartment, and a central section that is used as part of the barrier element. The central section includes an arcuate upper portion and an arcuate lower portion and the barrier element is formed by heat sealing a first wall of the compartment to the arcuate upper portion, heat sealing a second wall of the compartment to the arcuate lower portion, and heat sealing the first and second walls to each other.

When the features of attaching electrodes to interior surfaces of the envelope and using an envelope having two compartments are combined, the process of applying the electrode to a patient is greatly simplified. Medical personnel no longer have to tear open a bag, pull out the electrodes, separate them, connect them to an appropriate medical device, remove

plastic covers from them, and apply them to the patient. Instead, because the electrodes are preconnected to the medical device, the medical personnel need only tear open the package, detach the electrodes from the package, and attach them to the patient.

Other features and advantages of the invention will be apparent from the following description of the preferred embodiments and from the claims.

Brief Description of the Drawings

Fig. 1 is a top view of an electrode package in an unsealed configuration.

Fig. 2 is a top view of the electrode package of Fig. 1 in a sealed configuration.

Fig. 3 is a cutaway top view of a dual-compartment electrode package in a sealed configuration.

Fig. 4 is a cross-sectional view of the dual-compartment electrode package of Fig. 3.

Fig. 5 is a cutaway top view of an electrode package in a sealed configuration.

Fig. 6 is a cross-sectional view of the electrode package of Fig. 5.

Fig. 7 is a top view of an electrode connector in an open configuration.

Fig. 8 is a left side view of the electrode connector of Fig. 7.

Fig. 9 is a right side view of the electrode connector of Fig. 7.

Fig. 10 is a top view of a portion of the electrode connector of Fig. 7, with wires inserted.

Fig. 11 is a front view of the electrode connector of Fig. 7 in a closed configuration.

Fig. 12 is a right side view of the electrode connector of Fig. 11.

Fig. 13 is a cross sectional view of the electrode connector of Fig. 11.

Description of the Preferred Embodiments

Referring to Fig. 1, an electrode package 10 (shown in an unsealed configuration) includes an outer sheet 12 on which is mounted a liner 14 that provides structural rigidity. Outer sheet 12 is made of a polyester, aluminum, TYVEK laminate. Liner 14 is made from styrene and is approximately two millimeters thick. Liner 14 is secured to outer sheet 12 by a pair of adhesive strips 15 that are implemented using double-sided adhesive tape attached between outer sheet 12 and liner 14.

In use, electrodes 16, 18 are attached to liner 14. Wire leads 20, 22, which are attached at one end to a connector 24, and at the other end, respectively, to terminals 26, 28 on electrodes 16, 18, are temporarily secured by an adhesive strip 30. Adhesive strip 30 is implemented using double-sided adhesive tape.

Referring also to Fig. 2, which shows electrode package 10 in a sealed configuration, electrode package 10 is sealed by folding sheet 12 along an axis A so that electrodes 16, 18 face each other. In this configuration, regions 32 contact regions 34. Thereafter, regions 32, 34 are heated to form heat seals 36.

Tabs 40, which are not sealed together, are used in opening electrode package 10. Tabs 40, focus, in a region 42 of heat seals 36, a force applied to tabs 40 by, for example, an emergency medical technician pulling tabs 40 away from each other. By focusing the force, tabs 40 minimize the force needed to break heat seals 36. Once seals 36 are broken at region 42, additional force on tabs 40 splits the remainder of heat seals 36 until electrode package 10 folds entirely open to expose electrodes 16, 18 as shown in Fig. 1.

Referring to Fig. 3, a dual-compartment electrode package 50 includes an outer sheet 52 on which is mounted a liner 54. As with electrode package 10, electrodes 56, 58 are attached to liner 54 and, when, as shown, dual-compartment electrode package 50 is sealed, face each other. Line 54 is attached to outer sheet 52 by a pair of adhesive strips 55. As shown in the cutaway portion, electrode 58 attaches to liner 54 via a layer of adhesive gel 60 on electrode 58.

Wire leads 62, 64, which are attached at one end to a connector 66, and at the other end, respectively, to electrodes 56, 58, are temporarily secured by an adhesive strip 68.

Referring also to Fig. 4, sheet 52 is folded along an axis A so that regions 70 contact corresponding regions 72 from the opposite end of sheet 52 and are heated to form heat seals 74. In addition, heat seals 76 are formed from regions 78 and corresponding regions from the opposite end of sheet 52; heat seals 80 are formed between regions 82 and corresponding regions from the opposite end of sheet 52; and heat seals 84 are formed between a gasket 88 and regions 86 of sheet 52.

Gasket 88 is produced by forming a layer of RTV or a so-called "hot-melt" adhesive around wire leads 62, 64. Gasket 88 has an arcuate upper surface 90 and an arcuate lower surface 92.

Gasket 88, in combination with heat seals 76, 80 and 84, forms a barrier element between a first compartment 94 and a second compartment 96 of dual-compartment electrode package 50. The barrier element allows second compartment 96 to be opened without opening first compartment 94.

As shown in Fig. 4, gasket 88 simultaneously maintains a seal between compartments 94, 96 and allows wire leads 62, 64 to pass between compartments 94, 96.

Thus, gasket 88 provides an electrically conductive path between connector 66 and electrodes 56, 58 even when electrodes 56, 58 are sealed in compartment 94.

As with electrode package 10, dual-compartment electrode package 50 includes a pair of tabs 98 that are used in opening dual-compartment electrode package 50.

Referring to Fig. 5, an electrode package 100 includes an outer sheet 102 on which is mounted a liner 104. Electrodes 106, 108 are attached to liner 104 and, when, as shown, electrode package 100 is sealed, face each other. Liner 104 is attached to outer sheet 102 by a pair of adhesive strips 105. As shown in the cutaway portion, electrode 108 attaches to liner 104 via a layer of adhesive gel 110 on electrode 108.

Wire leads 112, 114, which are attached at one end to a connector 116, and at the other end, respectively, to electrodes 106, 108, are temporarily secured by an adhesive strip 118.

Referring also to Fig. 6, sheet 102 is folded along an axis A and heated to form heat seals 120 between regions 122 from opposite ends of sheet 102, heat seals 124 between regions 126 from opposite ends of sheet 102, and heat seals 128 between connector 116 and regions 130 of sheet 102.

Referring also to Fig. 13, in a central region 134 between heat seals 128, connector 116 has an arcuate upper surface 136 and an arcuate lower surface 138. Connector 116, in combination with heat seals 124 and 128, forms a barrier element between a compartment 140 of electrode package 100 and the external environment. Connector 116 provides a seal for compartment 140 and an electrically conductive path between electrodes 106, 108 and terminals 142, 144, which are connected, respectively, to wire leads 112, 114.

Referring to Figs. 7-13, connector 116, shown in an open configuration in Figs. 7-9, includes a body 146 that is a single piece of molded plastic. Body 146 includes a base 148 in which terminals 142, 144 are positioned and a cover 150. Base 148 and cover 150 are connected by an integral hinge 152. Base 148 includes three pairs of strain relief posts 154, 156, 158, a pair of semicircular wire lead cutouts 160, and a pair of male locking tabs 161. Cover 150 includes a pair of semicircular wire lead cutouts 162, and a pair of female locking tabs 163.

At assembly, as shown in Fig. 10, wire leads 112, 114 are connected, respectively, to terminals 142, 144. Wire leads 112, 114 are then threaded around posts 154, between posts 156, and around posts 158 before passing through cutouts 160.

Once wire leads 112, 114 are in place, body 146 is folded along hinge 152 so that cover 150 is positioned on base 148 so that locking tabs 161 engage locking tabs 163. Cover 150 is then sealed to base 148.

Other embodiments are within the following claims. For example, connector 116 could replace gasket 88 in dual-compartment electrode package 50. Similarly, gasket 88 could replace connector 116 in electrode package 100. In addition, rather than mounting electrodes on the interior surfaces of dual-compartment electrode package 50 and electrode package 100, the electrodes could be loosely placed within the packages.

What is claimed is:

1. An electrode package in which one or more adhesively-applied skin electrodes may be sealed, said electrode package comprising

an envelope comprising a sheet of material,

a releasable seal joining portions of said envelope to provide a sealed first compartment in which a said electrode may be isolated from an external environment,

said envelope comprising a first wall that defines a first interior surface facing the interior of said sealed first compartment, said first interior surface including a first electrode mounting surface for direct attachment of an adhesive portion of a first said electrode,

said first interior surface being isolated from an external environment when said releasable seal is in a sealed mode and exposed to the external environment when said releasable seal is in an unsealed mode.

2. The electrode package of claim 1, wherein said envelope further comprises:

a second wall that defines a second interior surface facing the interior of said sealed first compartment, said second interior surface including a second electrode mounting surface for direct attachment of an adhesive portion of a second said electrode,

wherein said second interior surface is isolated from the external environment when said releasable seal is in the sealed mode and exposed to said second interior surface when said releasable seal is in the unsealed mode.

3. The electrode package of claim 2, wherein, when said releasable seal is in the sealed mode, said first and second interior surfaces face each other.

4. The electrode package of claim 3, wherein, when said releasable seal is in the unsealed mode, said first and second electrode mounting surfaces both face upward and are approximately coplanar.

5. The electrode package of claim 2, wherein

a first edge of said envelope comprises a fold in said sheet of material,

each of said first and second interior surfaces are located on opposite sides of said fold, and

said first edge, said first interior surface, said second interior surface, and said releasable seal are located so that said envelope can be opened by breaking said releasable seal and folding back said envelope at said first edge, so that said envelope lays in a generally flat configuration with said first and second interior surfaces facing upward.

6. The electrode package of claim 5, wherein said envelope further comprises a pair of tabs for aiding in breaking said releasable heat seal, said tabs being located opposite said first edge of said envelope.

7. The electrode package of claim 1, further comprising an adhesive layer for temporarily securing a wire lead of the first said electrode to said first interior surface, said adhesive layer being located on said first interior surface.

8. The electrode package of claim 1, wherein said envelope further comprises:

a second compartment for containing a connector of the first said electrode, and

a barrier element between said first and second compartments, said barrier element providing an

electrically conductive path between the first said electrode and the connector of the first said electrode.

9. The electrode package of claim 8, wherein,

when said second compartment is in a sealed mode, the connector of the first said electrode is isolated from the external environment and,

when said second compartment is in an unsealed mode, the connector of the first said electrode is not isolated from the external environment and the mode of said the envelope is unaffected.

10. The electrode package of claim 8, wherein said barrier element comprises a layer of material formed around a wire lead of the first said electrode, the wire lead providing the electrically conductive path between the first electrode and the connector of the first electrode.

11. The electrode package of claim 8, wherein said barrier element comprises a body of the connector of the first said electrode, the body providing the electrically conductive path between the first said electrode and the connector of the first said electrode.

12. An electrode package in which one or more adhesively-applied skin electrodes may be sealed, said electrode package comprising:

a first compartment for maintaining a first said electrode in either a sealed mode in which the first said electrode is not exposed to an external environment or an unsealed mode in which the first said electrode is exposed to the external environment,

a second compartment for maintaining a connector of the first said electrode in either a sealed mode in

which the connector is not exposed to an external environment or an unsealed mode in which the connector is exposed to the external environment, and

a barrier element between said first and second compartments, said barrier element maintaining the first compartment in the sealed mode when the second compartment is in the unsealed mode and providing an electrically conductive path between the electrode and the connector.

13. The electrode package of claim 12, wherein said barrier element comprises a layer of material formed around a wire lead of the electrode, the wire lead providing the electrically conductive path between the electrode and the connector.

14. The electrode package of claim 12, wherein said barrier element comprises a body of the connector, the body providing the electrically conductive path between the electrode and the connector.

15. An electrode package in which one or more adhesively-applied skin electrodes may be sealed, said electrode package comprising:

a compartment for maintaining a first said electrode in either a sealed mode in which the first said electrode is not exposed to an external environment or an unsealed mode in which the first said electrode is exposed to the external environment, and

a barrier element between said compartment and the external environment, said barrier element providing an electrically conductive path between the first said electrode and a connector of the first said electrode that is located in the external environment.

16. The electrode package of claim 15, wherein said barrier element comprises a layer of material formed around a wire lead of the first said electrode, the wire lead providing the electrically conductive path between the first said electrode and the connector.

17. The electrode package of claim 16, wherein the layer of material includes an arcuate upper portion and an arcuate lower portion,

said barrier element being formed by heat sealing a first wall of the compartment to the arcuate upper portion, heat sealing a second wall of the compartment to the arcuate lower portion, and heat sealing the first and second walls to each other.

18. The electrode package of claim 15, wherein said barrier element comprises a body of the connector, the body providing the electrically conductive path between the first said electrode and the connector.

19. The electrode package of claim 18, wherein the body comprises a single piece of material and includes an integral hinge.

20. The electrode package of claim 18, wherein the body includes a plurality of strain relief posts for relieving strain on a wire lead located between the first said electrode and the connector.

21. The electrode package of claim 18, wherein the body includes a first end located in the external environment, a second end located in said compartment, and a central section that comprises said barrier element and includes an arcuate upper portion and an arcuate lower portion,

said barrier element being formed by heat sealing a first wall of the compartment to the arcuate upper portion, heat sealing a second wall of the compartment to the arcuate lower portion, and heat sealing the first and second walls to each other.

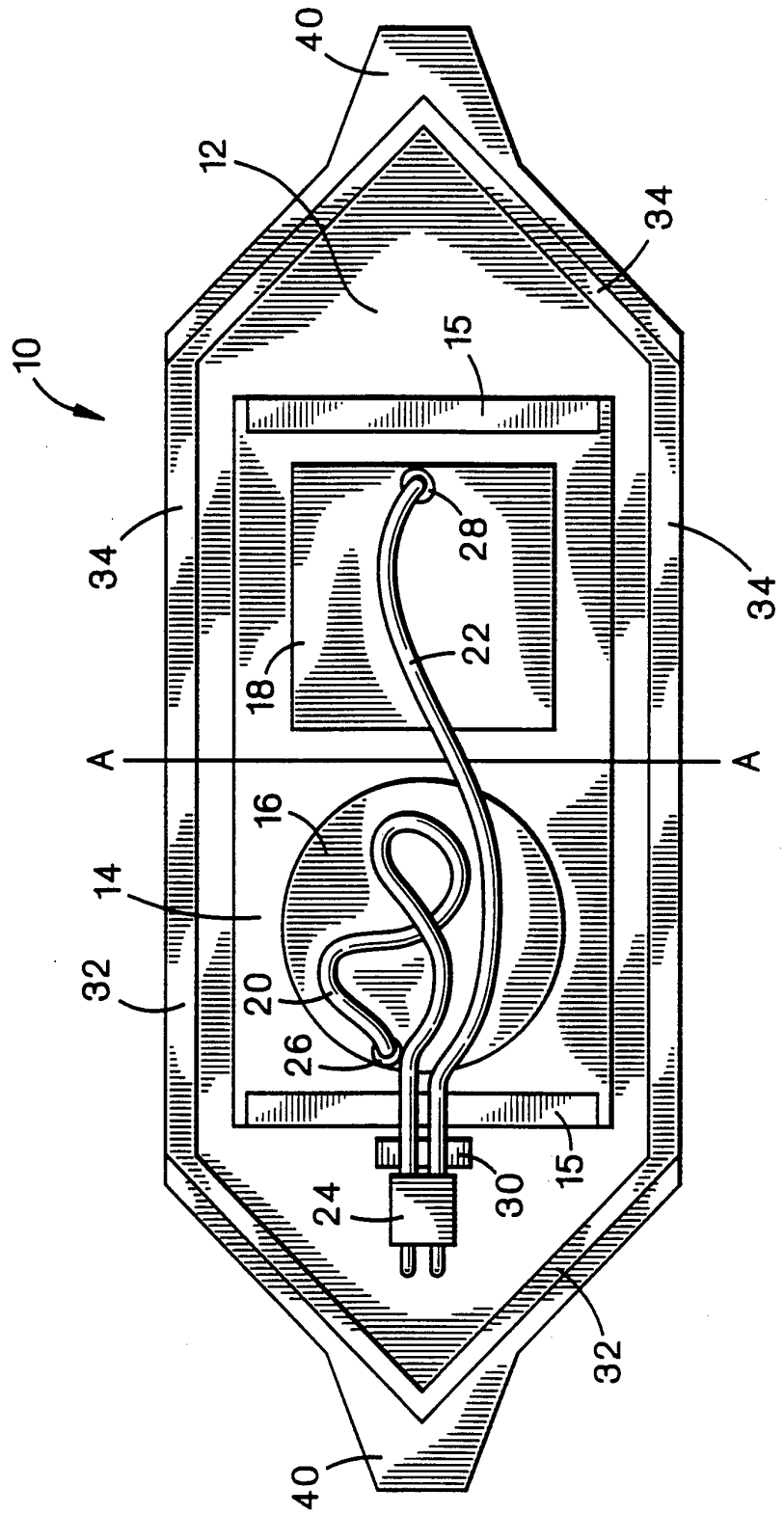



FIG. 1

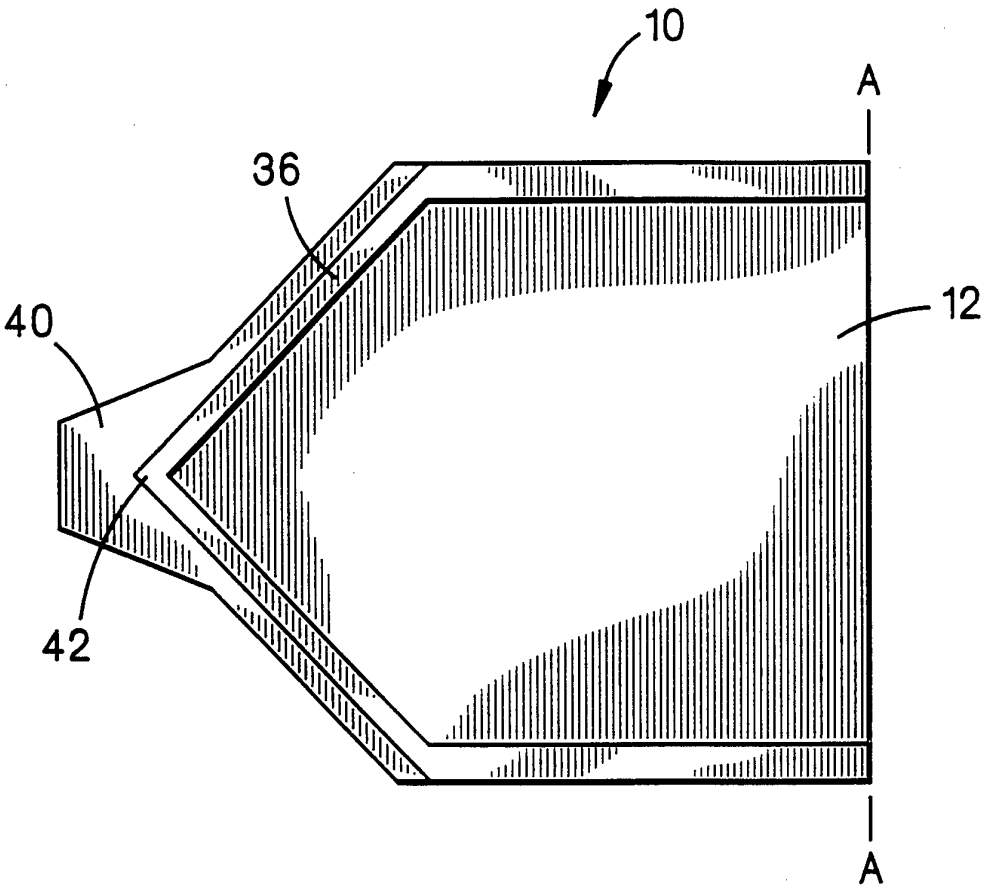



FIG. 2

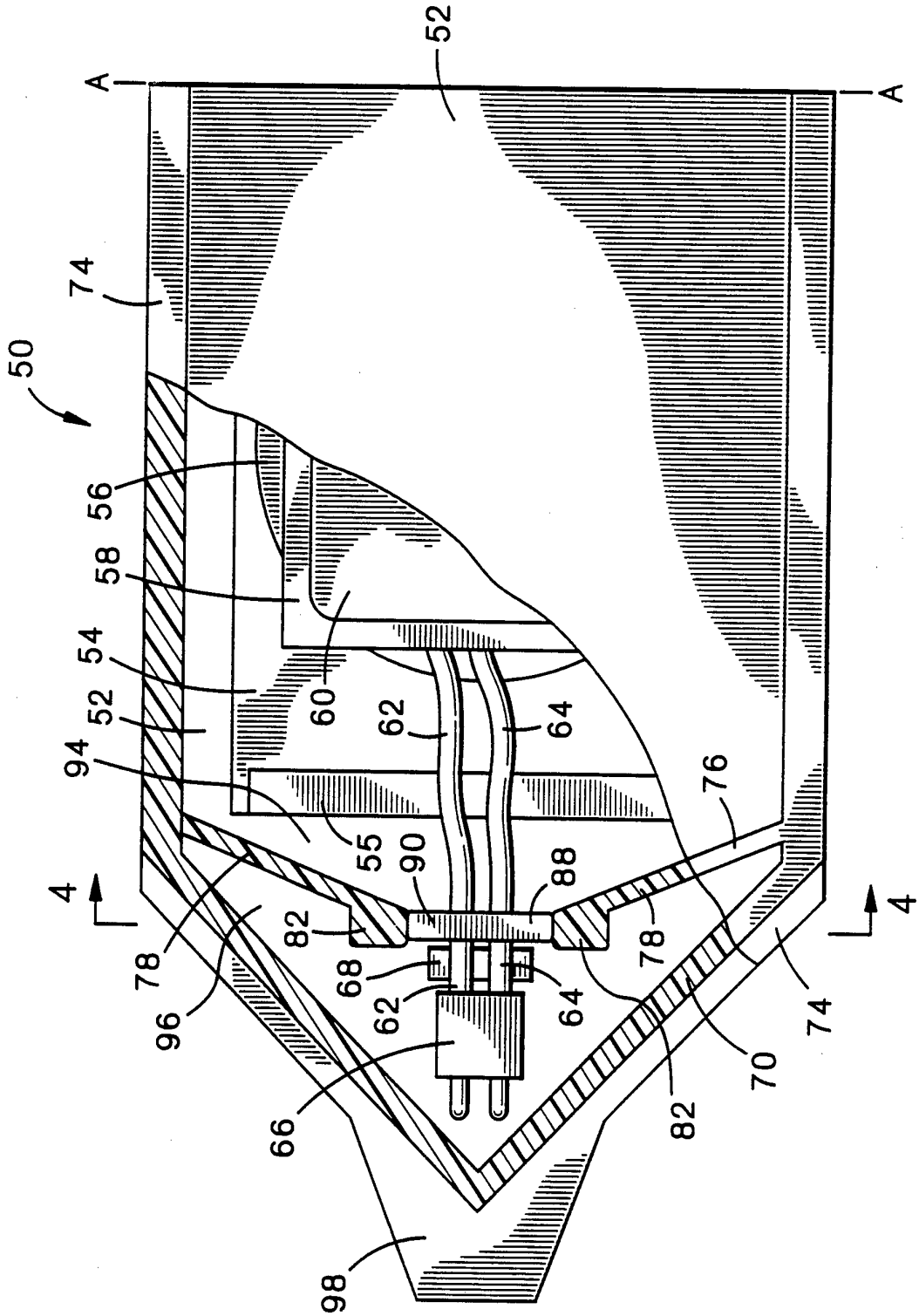

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FIG. 3

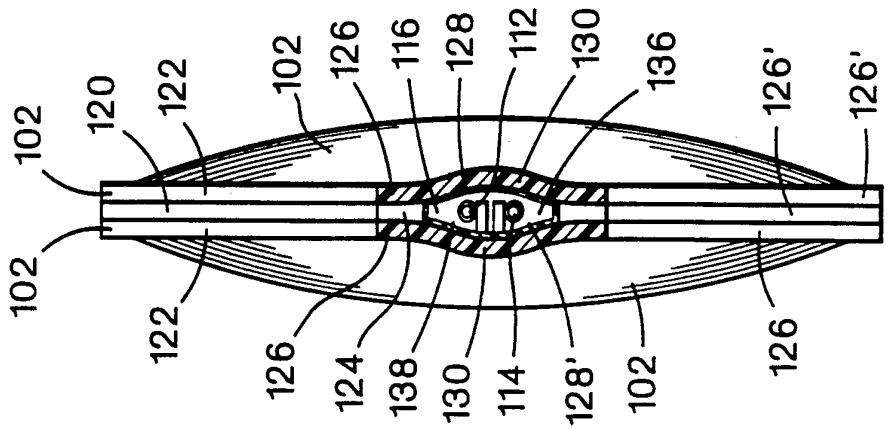

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FIG. 6

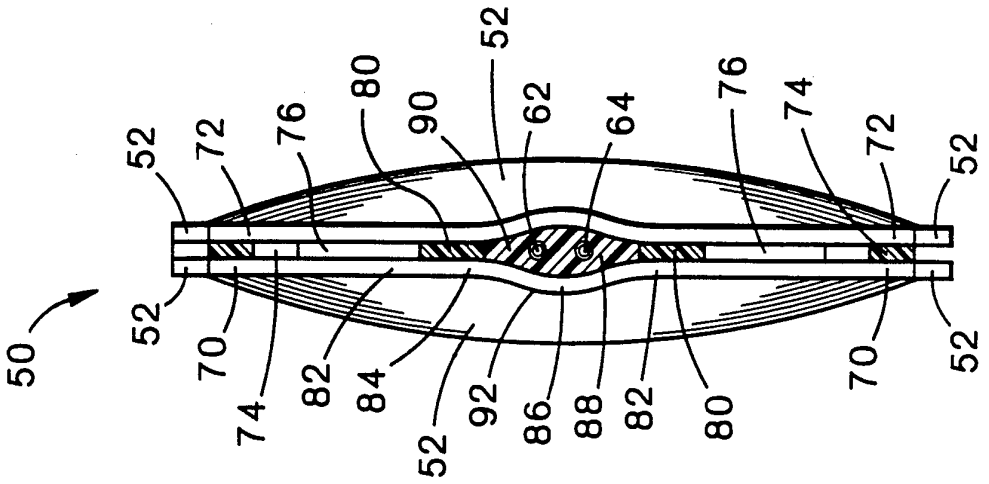

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FIG. 4

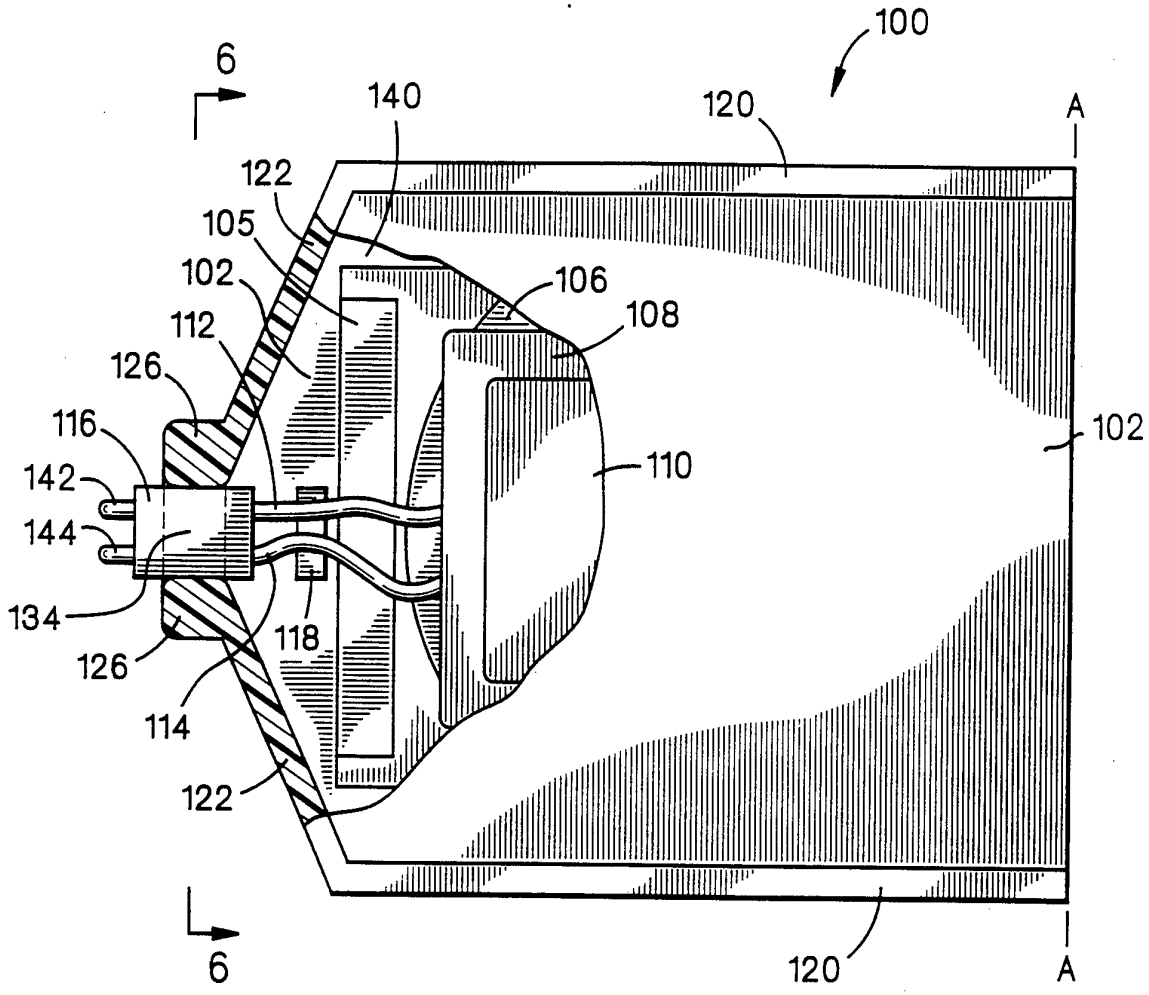

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FIG. 5

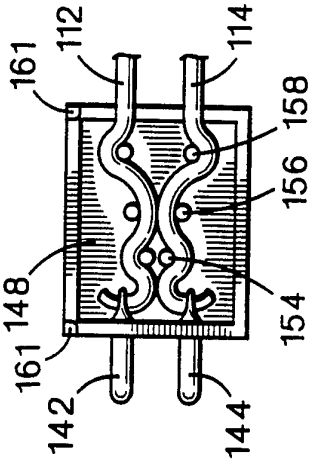



FIG. 10

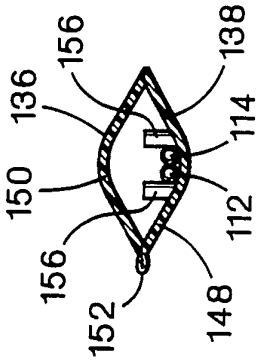



FIG. 13

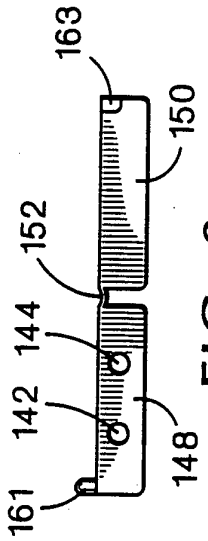



FIG. 8

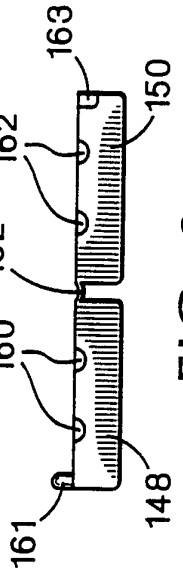



FIG. 9

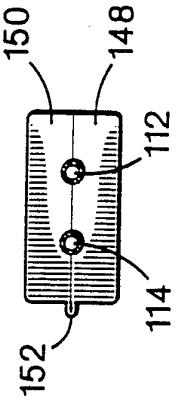



FIG. 12

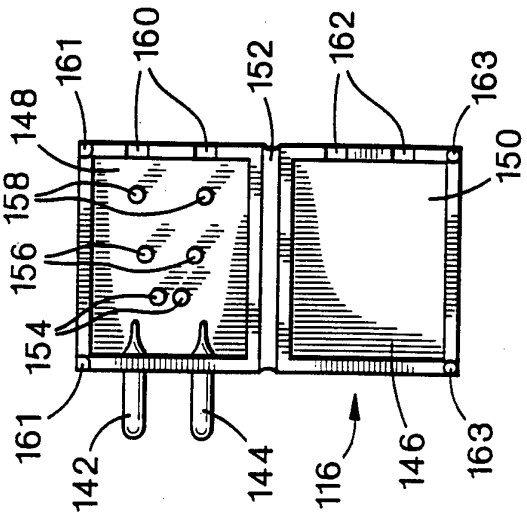



FIG. 7

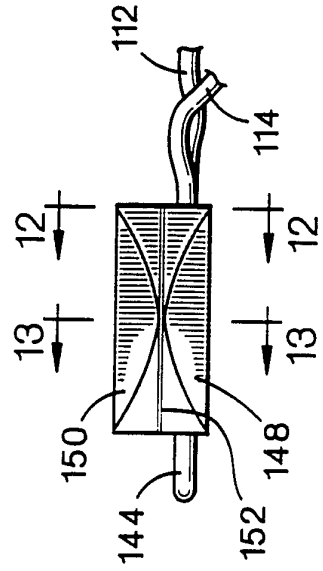



FIG. 11

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/12355

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) :B65D 85/38
US CL :128/640; 607/152,153; 206/438
According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/640; 607/152,153; 206/205, 210, 328-334, 438, 460, 461, 570

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

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US, A, 3,698,549 (Glassman) 17 October 1972, column 1, line 53 through column 2, line 19. | 1, 2, 5-7 |
| Y | US, A, 4,362,165 (Carmon et al) 07 December 1982, Figures 1 and 2, column 4, line 51 through column 6, line 30. | 1-4, 8-18 |
| Y | US, A, 4,176,746 (Kooi) 04 December 1979, column 5, lines 7-31. | 1-4, 8-14 |
| Y | US, A, 4,082,086 (Page et al) 04 April 1978, Figure 1, column 3, lines 2-4. | 2-4 |
| Y | US, A, 4,365,634 (Bare et al) 28 December 1982, Figure 22. | 15-18 |
| A | US, A, 3,685,645 (Kawaguchi) 22 August 1972. | 1-21 |

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

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| * | Special categories of cited documents: | "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 |
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|---|---|
| Date of the actual completion of the international search<br>23 NOVEMBER 1994 | Date of mailing of the international search report<br>DEC 14 1994 |
| Name and mailing address of the ISA/US<br>Commissioner of Patents and Trademarks<br>Box PCT<br>Washington, D.C. 20231<br>Facsimile No. (703) 305-3230 | Authorized officer<br>for JIMMY G. FOSTER<br>Sheila H. Veney<br>Paralegal Specialist<br>Group 2400<br>Telephone No. (703) 308-0771 |

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# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/12355

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | US, A, 5,191,887 (Cartmell) 09 March 1993. | 1-21 |
| A | US, A 5,203,330 (Schaefer et al) 20 April 1993 | 1-21 |