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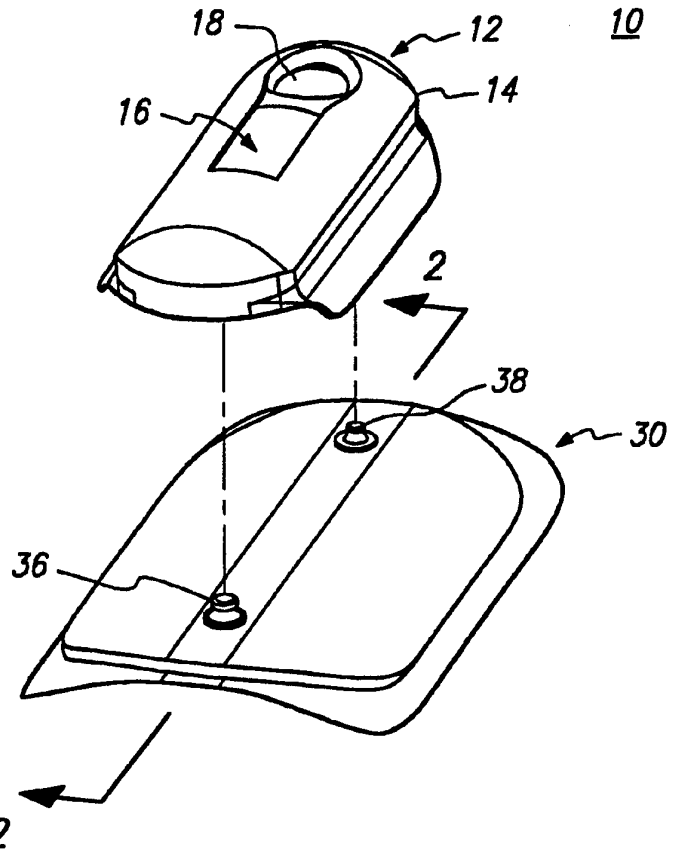
(57) Abstract

An electrotransport system (10) includes a reusable controller (12) having a power source (20) and a separable disposable drug-containing unit (30) which contain both a donor electrode (32) and a counter electrode (34). A coupling means (26, 28, 36, 38) physically and electrically connects together the controller (12) and the drug unit (30) such that the controller (12) provides electrical current to the drug unit (30) for electrotransport delivery of the drug to a body surface (e.g., the skin) of a patient. The coupling means (26, 28, 36, 38) ensures correct polarity connection of the donor and counter electrodes (32, 34) to the outputs of the controller (12).



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ELECTROTRANSPORT DEVICE HAVING REUSABLE CONTROLLER

TECHNICAL FIELD

The invention relates to electrotransport drug delivery systems having a drug containing assembly and a reusable controller having an electrically powered control circuit, the assembly and the controller being separably connected by a coupler which establishes electrical connection of the assembly to the controller.

BACKGROUND ART

The term "electrotransport" as used herein refers generally to the delivery of an agent (e.g., a drug) through a membrane, such as skin, mucous membrane, or nails. The delivery is induced or aided by application of an electrical potential. For example, a beneficial therapeutic agent may be introduced into the systemic circulation of a human body by electrotransport delivery through the skin. A widely used electrotransport process, electromigration (also called iontophoresis), involves the electrically induced transport of charged ions. Another type of electrotransport, electroosmosis, involves the flow of a liquid, which liquid contains the agent to be delivered, under the influence of an electric field. Still another type of electrotransport process, electroporation, involves the formation of transiently-existing pores in a biological membrane by the application of an electric field. An agent can be delivered through the pores either passively (i.e., without electrical assistance) or actively (i.e., under the influence of an electric potential). However, in any given electrotransport process, more than one of these processes may be occurring simultaneously to a certain extent. Accordingly, the term "electrotransport", as used herein, should be given its broadest

possible interpretation so that it includes the electrically induced or enhanced transport of at least one agent, which may be charged, uncharged, or a mixture thereof, whatever the specific mechanism or mechanisms by which the agent actually is transported.

Electrotransport devices use at least two electrodes that are in electrical contact with some portion of the skin, nails, mucous membrane, or other surface of the body. One electrode, commonly called the "donor" or "active" electrode, is the electrode from which the therapeutic agent is delivered into the body. The other electrode, typically termed the "counter" or "return" electrode, serves to close the electrical circuit through the body. For example, if the agent to be delivered is positively charged, i.e., a cation, then the anode is the active or donor electrode, while the cathode serves to complete the circuit. Alternatively, if an agent is negatively charged, i.e., an anion, the cathode is the donor electrode. Additionally, both the anode and cathode may be considered donor electrodes if both anionic and cationic agent ions, or if uncharged or neutrally charged agents, are to be delivered.

Furthermore, electrotransport delivery systems generally require at least one reservoir or source of the agent to be delivered, which is typically in the form of a liquid solution or suspension. Examples of such donor reservoirs include a pouch or cavity, a porous sponge or pad, and a hydrophilic polymer or a gel matrix. Such donor reservoirs are electrically connected to, and positioned between, the anode or cathode and the body surface, to provide a fixed or renewable source of one or more agents or drugs. Electrotransport devices also have an electrical power source such as one or more batteries. Typically, one pole of the power source is electrically connected to the donor electrode, while the opposite pole is electrically connected to the counter electrode. In addition, some electrotransport devices have an electrical controller that controls the current applied through the electrodes, thereby regulating the rate of agent delivery. Furthermore,

passive flux control membranes, adhesives for maintaining device contact with a body surface, insulating members, and impermeable backing members are other optional components of an electrotransport device.

All electrotransport agent delivery devices utilize an electrical circuit to electrically connect the power source (e.g., a battery) and the electrodes. In very simple devices, such as those disclosed in Ariura et al US Patent 4,474,570, the "circuit" is merely an electrically conductive wire used to connect the battery to an electrode. Other devices use a variety of electrical components to control the amplitude, polarity, timing, waveform shape, etc. of the electric current supplied by the power source. See, for example, McNichols et al US Patent 5,047,007.

To date, commercial transdermal electrotransport drug delivery devices (e.g., the Phoresor, sold by Iomed, Inc. of Salt Lake City, UT; the Dupel Iontophoresis System sold by Empi, Inc. of St. Paul, MN; the Webster Sweat Inducer, model 3600, sold by Wescor, Inc. of Logan, UT) have generally utilized a desk-top electrical power supply unit and a pair of skin contacting electrodes. The donor electrode contains a drug solution while the counter electrode contains a solution of a bio-compatible electrolyte salt. The "satellite" electrodes are connected to the electrical power supply unit by long (e.g., 1-2 meters) electrically conductive wires or cables. Examples of desk-top electrical power supply units which use "satellite" electrode assemblies are disclosed in Jacobsen et al US Patent 4,141,359 (see Figures 3 and 4); LaPrade US Patent 5,006,108 (see Figure 9); and Maurer et al US Patent 5,254,081 (see Figures 1 and 2). The power supply units in such devices have electrical controls for adjusting the amount of electrical current applied through the electrodes. Existing commercial electrotransport devices are approved for operation only by trained medical technicians. One important consideration when connecting the "satellite" electrodes to the power supply unit is to make sure that the electrodes are connected with the correct polarity, i.e., a satellite donor electrode which contains a cationic

therapeutic agent must be connected to the positive output of the controller whereas a satellite donor electrode which contains an anionic therapeutic agent must be connected to the negative output of the controller. In order to assist the medical technician to make the correct polarity connections, two approaches have been used. In the first approach, the outputs of the controller have been color coded to the appropriate satellite electrode. In the second approach (used in the CF Indicator sold by ScandiPharm, Inc.), the controller is provided with electrodes in the form of metal (e.g., stainless steel) plates which are positioned on one side of the controller housing. The two electrode plates have different geometric shapes (e.g., one square and one circular). The drug-containing donor gel and the electrolyte-containing counter gel each have a different shape which corresponds to the respective electrode plate shape in order to ensure that the donor and counter gels are placed in contact with the correct (i.e., correct polarity) electrodes.

More recently, small self-contained electrotransport delivery devices adapted to be worn on the skin, sometimes unobtrusively under clothing, for extended periods of time have been proposed. The electrical components in such miniaturized electrotransport drug delivery devices are also preferably miniaturized, and may be either integrated circuits (i.e., microchips) or small printed circuits. Electronic components, such as batteries, resistors, pulse generators, capacitors, etc., are electrically connected to form an electronic circuit that controls the amplitude, polarity, timing, waveform shape, etc. of the electric current supplied by the power source. Such small self-contained electrotransport delivery devices are disclosed for example in Tapper US Patent 5,224,927; Sibalis et al US Patent 5,224,928 and Haynes et al US Patent 5,246,418.

There have recently been suggestions to utilize electrotransport devices having a reusable controller which is adapted to be used with multiple drug-containing units. The drug-containing units are simply disconnected from the controller when the drug becomes depleted and a fresh drug-containing unit is thereafter connected to the controller. In this way, the relatively more expensive hardware components of the device (e.g., batteries, LED's, circuit hardware, etc.) can be contained within the reusable controller, and the relatively less expensive donor reservoir and counter reservoir matrices can be contained in the disposable drug containing unit thereby bringing down the overall cost of electrotransport drug delivery. Examples of electrotransport devices comprised of a reusable controller adapted to be removably connected to a drug-containing unit are disclosed in Sage, Jr. et al, US Patent 5,320,597; Sibalis, US Patent 5,358,483; Sibalis et al, US Patent 5,135,479 (Fig. 12); and Devane et al UK Patent Application 2 239 803.

Electrotransport devices having reusable controllers and which are adapted to be used with multiple drug-containing units are particularly well suited for drug administration to patients outside of clinic/doctor's office settings (e.g., for those patients requiring long term medication). Unfortunately, the existing schemes for ensuring that the drug reservoir of an electrotransport device is connected to the electrode of the correct polarity are not foolproof. This becomes an even greater problem in settings outside of the clinic/doctor's office where the patient is expected to periodically replace the drug-containing unit him/herself. The problem becomes still greater in cases where the patient population tends to be more elderly.

DESCRIPTION OF THE INVENTION

It is an aspect of the present invention to ensure correct polarity electrical connection between the drug reservoir of a drug-containing assembly and the reusable controller of an electrotransport device comprised of a reusable controller adapted to be used with a plurality of drug-containing assemblies.

The present invention is directed to ensuring correct polarity electrical connections in an electrotransport device comprised of a reusable electronic controller adapted to be used with a plurality of single use (e.g., disposable) drug-containing units. After the drug has been depleted from the drug-containing unit, the unit is disconnected from the controller and discarded, and then replaced with a fresh one. The controller includes a bipolar power source (e.g., one or more batteries), and optionally a circuit for controlling the timing, frequency, magnitude, etc. of the current applied by the device. The drug-containing unit has first and second electrodes, at least one of which contains the therapeutic agent (i.e., drug) to be delivered.

In accordance with one embodiment of the present invention, the reusable controller is adapted to be electrically coupled to a more limited use (e.g., a single use) drug-containing unit by at least two electrically conductive snap connectors. The snap connectors have different sizes and/or are arranged with different male/female parts in the different respective units, so that the controller and the drug-containing unit may be coupled in only one way, i.e., with the correct polarity connections.

In an alternative embodiment of the present invention, a projecting member is provided on either the controller or the drug-containing unit with a correspondingly shaped hole on the other unit. The positioning of the projecting member and the correspondingly shaped hole are such that the controller and the drug-containing unit may be coupled in only one way, i.e., with the correct polarity connections.

BRIEF DESCRIPTION OF THE DRAWINGS

In the figures, wherein like parts are given like reference numerals and wherein;

Fig. 1 is a perspective view of an electrotransport device comprised of a reusable controller and a separate drug-containing unit, in an uncoupled configuration, which controller and unit are couplable in accordance with this invention;

Fig. 2 is a cross sectional view of the device shown in Fig. 1, showing the controller and the drug-containing unit in a coupled configuration;

Fig. 3 is a perspective view of an electrotransport device comprised of a reusable controller and a separate drug-containing unit, in an uncoupled configuration, which controller and drug unit are couplable in accordance with another embodiment of this invention;

Fig. 4 is a perspective view of an electrotransport device comprised of a reusable controller and a separate drug-containing unit, in an uncoupled configuration, which controller and drug unit are couplable in accordance with yet another embodiment of this invention;

Fig. 5 is a perspective view of another electrotransport device with the controller and the drug-containing unit in an uncoupled configuration, the drug-containing unit adapted to slidably engage the controller;

Fig. 6 is a bottom view of the device shown in Fig. 5 with the controller and the drug-containing unit in a coupled configuration;

Fig. 7 is a sectional view of the device shown in Figs. 5 and 6, taken along line 7-7 shown in Fig. 6;

Fig. 8 is a perspective view of an electrotransport device comprised of a reusable controller and a separate drug-containing unit, in an uncoupled configuration, which controller and drug-containing unit are couplable in accordance with another embodiment of this invention;

Fig. 9 is a top view of a drug-containing unit in accordance with another embodiment of the present invention;

Fig. 10 is a side view of the drug-containing unit shown in Fig. 9;

Fig. 11 is a perspective view showing the coupling of a reusable controller to the drug-containing unit illustrated in Figs. 9 and 10;

Fig. 12 is a top view of the coupled system shown in Fig. 11;

Fig. 13 is a top view of a coupled electrotransport system in accordance with another embodiment of the present invention;

Fig. 14 is a top view of the drug-containing unit shown in Fig. 13;

Fig. 15 is a side view of the drug-containing unit shown in Fig. 14, with parts shown in section;

Fig. 16 is a top view of another electrotransport system in accordance with the present invention;

Fig. 17 is a top view of the drug-containing unit of the system shown in Fig. 16; and

Fig. 18 is a perspective view showing the coupling of the reusable controller to the drug-containing unit of the system shown in Figs. 16 and 17.

MODES FOR CARRYING OUT THE INVENTION

Fig. 1 is a perspective view of electrotransport device 10 having a reusable electronic controller 12 which is adapted to be coupled to and uncoupled from, drug-containing unit 30. The controller 12 is reusable, i.e., it is adapted to be used with a plurality of drug units 30, e.g., a series of identical and/or similar drug units 30. On the other hand, drug unit 30 typically has a more limited life and is adapted to be discarded after use, i.e., when the drug contained therein has been delivered or has been depleted.

The controller 12 is comprised of a housing 14, typically formed of a molded plastic material. With reference to Fig. 2, there is shown a sectional view of the device 10 with the drug unit 30 coupled to the controller 12. The controller 12 includes a battery 20, e.g. a button cell battery, for powering the circuit board 22. The circuit board 22 is formed in a conventional manner, having conductive traces patterned for interconnecting component(s) 24 thereon. Electrical component(s) 24 control the magnitude, timing, frequency, waveform shape, etc., of the electric current applied by device 10. Although not critical to the invention, controller 12 includes a push button switch 18 which can be used to start operation of device 10 and a liquid crystal display (LCD) 16 which can display system information such as current level, dosing level, number of doses delivered, elapsed time of current application, battery strength, etc.

The drug unit 30 is configured to be removably coupled to the controller 12, with the top of drug unit 30 adjacent to and facing the bottom of the controller 12. The top of drug unit 30 is provided with the male parts of two snap type connectors, the male parts being posts 36 and 38 which extend upwardly from drug unit 30. The bottom of housing 14 is provided with receptacles 26 and 28 (shown in Fig. 2) which are electrically connected to the outputs of the circuit on circuit board 22 by through-board connectors 23 and 25, respectively. Receptacle 26 is positioned and sized to receive donor post 36 and receptacle 28 is positioned and sized to receive counter post 38. Receptacles 26, 28 and posts 36, 38 are made from an electrically conductive material (e.g., a metal such as silver, brass, stainless steel, platinum, gold, nickel, beryllium, copper, etc. or a metal coated polymer, e.g., ABS with a silver coating). The donor post 36 is electrically connected to the donor electrode 31, which in turn is electrically connected to the donor reservoir 32 which typically contains a solution of the therapeutic agent (e.g., a drug salt) to be delivered. The counter post 38 is electrically connected to the counter electrode 33, which in turn is electrically connected

to the counter reservoir 34 which typically contains a solution of a biocompatible electrolyte (e.g., buffered saline). The electrodes 31 and 33 are typically comprised of electrically conductive materials, most preferably a silver (e.g., silver foil or silver powder loaded polymer) anodic electrode and a silver chloride cathodic electrode. The reservoirs 32 and 34 typically include hydrogel matrices which hold the drug or electrolyte solutions and are adapted to be placed in contact with the body surface (e.g., skin) of a patient (not shown) when in use. The electrodes 31,33 and the reservoirs 32,34 are isolated from each other by foam member 35. The bottom (i.e., patient contacting) surface of foam member 35 is preferably coated with a skin contact adhesive. A release liner 39 covers the body contacting surfaces of the two reservoirs 32 and 34 and the adhesive coated surface of foam member 35 before the unit 30 is put in use. The release liner 39 is preferably a silicone coated polyester sheet. The release liner 39 is removed when the device 10 is applied to the skin of a patient (not shown).

Thus, the donor post 36 and the receptacle 26 comprise a snap type connector which electrically connects an output of the circuit on circuit board 22 to the drug-containing donor electrode 32. Similarly, the counter post 38 and the receptacle 28 comprise a snap type connector which electrically connects an output of the circuit on circuit board 22 to the electrolyte containing counter electrode 34. In addition to providing the above described electrically connections, the two snap connectors also provide a separable (i.e., not permanent) mechanical connection of the drug unit 30 to the controller 12.

The two outputs of the circuit on circuit board 22 have different polarities, i.e., one output is positive and is adapted to be connected to the anodic electrode in drug unit 30 whereas the other circuit output is negative and is adapted to be connected to the cathodic electrode in drug unit 30. It is important to ensure that the connections of the two electrodes in drug

unit 30 are connected to the controller outputs of the correct polarity, since if the connections are reversed (i.e., if the positive circuit output is connected to the cathodic electrode and the negative circuit output is connected to the anodic electrode), little if any drug would be delivered by electrotransport. The present invention ensures correct polarity connections by making it substantially impossible to make incorrect (i.e., reversed) polarity connections between the controller 12 and the drug unit 30. As is clearly shown in Figs. 1 and 2, the diameter of post 36 is larger than the diameter of post 38. Similarly, the inside diameter of receptacle 26 is larger than the inside diameter or receptacle 28. Preferably, the inside diameter of receptacle 28 is smaller than the diameter of post 36 so that it is not possible to insert post 36 into receptacle 28.

In accordance with this embodiment of the present invention, each of posts 36 and 38 has a different size. Those skilled in the art will appreciate that in addition to the size (i.e., diameter) of posts 36, 38 being made different, the shape (e.g., cross-sectional or other shape) of posts 36, 38 could be made sufficiently different to ensure only correct polarity connections between controller 12 and drug unit 30.

An alternate means for ensuring correct polarity connections between a drug unit having donor and counter electrodes and a controller is illustrated in Fig. 3. Reusable controller 12' is adapted to be separably connected to one or more drug units 40. Drug unit 40 has a donor post 42 which performs a similar function as donor post 36 illustrated in Figs. 1 and 2. However, unlike drug unit 30, drug unit 40 has a receptacle 44 which is electrically connected to the counter electrode (not shown) in the drug unit 40. Receptacle 44 is adapted to engage a post (not shown) extending from the underside of controller 12'. Thus, drug unit 40 contains both a male part (i.e., post 42) of a first snap connector and a female part (i.e., receptacle 44) of a second snap connector. The two snap connectors provide both electrical and mechanical coupling of the drug unit 40 to controller 12'. By having a

male connector and a female connector in each of the drug unit 40 and the controller 12', the coupling of the controller 12' to the drug unit 40 can only be accomplished in one way, i.e., with the correct polarity connections.

Referring now to Fig. 4, there is shown an electrotransport device comprised of a reusable electronic controller 12" and a drug unit 50. Unlike device 10 illustrated in Figs. and 2, the reusable controller 12" has a third snap type receptacle adapted to receive a third post 56 on drug unit 50. Thus, posts 52 and 54 perform substantially the same function as posts 36, 38 in device 10. The positioning of the third post 56, as well as the positioning of the receptacle (not shown) for post 56 in the bottom of controller 12", should not be equidistant from posts 52 and 54 assuming that the posts and receptacle are all the same size and shape. By positioning post 56 closer to post 54 than to post 52, there is only one way to connect the drug unit 50 to the controller 12", i.e., with correct polarity connections.

An alternative way to ensure correct polarity connections between a controller 62 and a drug unit 80 is illustrated in Figs 5 to 7. Electrotransport device 60 is comprised of a reusable controller which is adapted to be coupled to a plurality of same or similar drug units 80 in succession. The body of the controller 62, shown in section in Fig. 7, is shown as a solid cross section to simplify the drawing. Those skilled in the art will appreciate that controller 62 contains an electrical power source and a current control circuit similar to that illustrated in Fig.2. Controller 62 has two circuit outputs 68 and 70 which need to make electrical connection to electrode contacts 82 and 84, respectively in order to ensure correct polarity electrical connection of electrodes 88 and 90 to controller 62. Controller 62 includes a clasp 64. The drug unit 80 is adapted to be slid into the space between clasp 64 and the body of controller 62. A post 66 engages notch 86 in drug unit 80 when the drug unit 80 is slid into place and helps position drug unit 80 relative to controller 62 so that circuit output 68 touches electrode contact 82 and circuit output 70 contacts electrode contact 84. In addition to the siding

engagement of drug unit 80 with controller 62, there is also provided a snap type connector which provides secure, but separable, mechanical connection of drug unit 80 to controller 62. The snap connector is comprised of a receptacle 72 in the body of controller 62 and a post 92 on drug unit 80. The post 92 snaps into receptacle 72 as best shown in Fig. 7.

An alternative way to ensure correct polarity connections between a controller 112 and a drug unit 130 is illustrated in Fig. 8. Electrotransport device 110 is comprised of a reusable controller 112 which is adapted to be coupled to a plurality of same or similar drug units 130 in succession. Controller 112 contains an electrical power source and a current control circuit similar to controller 12 illustrated in Figs. 1 and 2. Controller 112 has two receptacles (not shown in Fig. 8) adapted to engage posts 136 and 138 in drug unit 130. Unlike the device illustrated in Figs. 1 and 2, posts 136 and 138 have the same size. In order to ensure that the posts 136 and 138 are snapped into the correct receptacles on the underside of controller 112, a projecting member 134 is provided on the surface of drug unit 130 which abuts against the underside of controller 112. As shown in Fig. 8, projecting member 134 has a square shape which engages a square shaped hole (not shown in Fig. 8) on the underside of controller 112. Those skilled in the art will appreciate that projecting member 134 may have any number of different shapes such as triangular, rectangular, circular, half-moon, etc. and should preferably project out a sufficient distance from the surface of drug unit 130 to ensure that post 138 cannot engage the incorrect receptacle in controller 112 in the event the patient attempts to couple the drug unit 130 to the controller with incorrect polarity connections. Preferably, the projecting member 134 is provided on a spine member 132 having increased rigidity. It is important that projecting member 134 be positioned on spine 132 at a location other than the midpoint between the two posts 136 and 138 in order to ensure that only one (i.e., the correct) polarity connection between the drug unit 130 and the controller 112 can be made.

Referring now to Figs. 9 through 12, there is shown an alternate embodiment of an electrotransport device 210 comprised of a controller 212 which is adapted to be coupled to a plurality of same or similar drug units 230 in succession. As best shown in Figs. 9 and 10, drug unit 230 has a pair of posts 236, 238 adapted to engage receptacles (not shown) in the underside of controller 212. The posts 236, 238 are preferably provided on a rigid spine member 232. Also provided on spine member 232 is a wedge-shaped projecting member 234. As best shown in Figs. 11 and 12, the controller 212 has a wedge-shaped opening 235 with a size and shape which is adapted to mate with the wedge-shaped projecting member 234. The projecting member 234 and the opening 235 provide a visual lock and key mechanism which visually guides the user to couple the controller 212 to the drug unit 230 with the correct polarity connections therebetween. If further certainty is required, the controller 212 may be made in a manner wherein the projecting member 234 engages and closes a switch contained in controller 212 thereby closing a circuit pathway which enables the device to deliver electrotransport drive current to the patient. When the projecting member 234 is disengaged from the opening 235, the switch is opened and electrotransport drug delivery is not possible.

Referring now to Figs. 13 through 15, there is shown an electrotransport device 310 comprised of a reusable controller 312 adapted to be coupled to a series of same or similar drug units 330. The drug unit 330 has a receptacle 334 which is adapted to accept and engage an end of controller 312. The snap connections are provided in a position which insures that the controller 312 can be electrically coupled to drug unit 330 only when one of the two ends of controller 312 is inserted into receptacle 334. Alternatively, the receptacle 334 can be sized and/or shaped to accept only one of the two ends of controller 312. The selective engagement of controller 312 can be accomplished through any number of known means including appropriately varying the size and/or shape of the respective ends of

controller 312 and/or providing some type of appropriate keying mechanism (not shown). In this way, only one end of the controller 312 may be engaged within receptacle 334, thereby ensuring correct polarity connections between the controller 312 and the drug unit 330 by means of the two snap connectors of the kind described hereinbefore.

Referring now to Figs. 16 through 18, there is shown another embodiment of the present invention. Like the system shown in Figures 13 through 15, electrotransport device 410 is comprised of a controller 412 which is adapted to fit in a single orientation within receptacle 434 on drug unit 430 due to the dissimilarly shaped ends (one end is flat and the other end is rounded) of controller 412 and receptacle 434. By shaping the receptacle 434 to "match" the shape of only one of the two ends of controller 412, only one (i.e., the correct) polarity connection between controller 412 and the drug unit 430 can be made.

While the foregoing detailed description has described several embodiments for ensuring correct polarity coupling of an electrotransport controller to a drug unit having donor and counter electrodes, it is to be understood that the above description is illustrative only and not limiting of the disclosed invention. It will be appreciated that it is possible for one skilled in the art to modify the materials, dimensions, type and shape of the couplers disclosed herein, or to include or exclude various elements, and yet remain within the scope and spirit of this invention. Thus the invention is to be limited only by the following claims.

Claims:

1. An electrotransport device (10) for delivering a therapeutic agent through a body surface of a patient, the device (10) including an assembly (30) having first and second electrodes (31, 32 and 33, 34), at least one of the electrodes containing the therapeutic agent to be delivered, and a controller (12) having a bipolar electrical power source (20) for providing electric current to the electrodes (31, 32 and 33, 34), and coupling apparatus (36, 26 and 38, 28) for electrically coupling and uncoupling the controller (12) and the assembly (30), the device being characterized by a coupling apparatus which permits the first electrode (31, 32) to be electrically connected to a predetermined pole of the bipolar power source (20) and prevents the first electrode (31, 32) from being electrically connected to the other pole of the bipolar power source (20).

2. The device of claim 1, wherein the coupling apparatus permits the second electrode (33, 34) to be electrically connected to the other pole of the bipolar power source (20) and prevents the second electrode (33, 34) from being electrically connected to the predetermined pole of the bipolar power source (20).

3. The device of claim 1, wherein the predetermined pole of the bipolar power source (20) is a positive pole, the electrode electrically connected to the predetermined pole is an anode, and the therapeutic agent is cationic.

4. The device of claim 1, wherein the predetermined pole of the bipolar power source (20) is a negative pole, the electrode electrically connected to the predetermined pole is a cathode, and the therapeutic agent is anionic.

5. The device of claim 1, wherein the coupling apparatus comprises a pair of electrically conductive snap connectors (36, 26 and 38, 28).

6. The device of claim 5, wherein the snap connectors (36, 26 and 38, 28) are comprised of a material selected from the group consisting of metal and carbon.

7. The device of claim 6, wherein the metal is selected from the group consisting of silver and stainless steel.

8. The device of claim 1, wherein the coupling apparatus also provides a mechanical coupling of the assembly (30) to the controller (12).

9. The device of claim 1, wherein the coupling apparatus comprises a first coupler (36, 26) having male (36) and female (26) mating members, the first electrode (31, 32) being electrically connected to the power source (20) when the first coupler mating members (32, 26) are mated, and a second coupler (38, 28) having male (38) and female (28) mating members, the second electrode (33, 34) being electrically connected to the power source (20) when the second coupler mating members (38, 28) are mated, and wherein the male mating member (36) of the first coupler is unable to mate with the female mating member (28) of the second coupler.

10. The device of claim 1, wherein the coupling apparatus comprises a first coupler having first and second pairs (52, 54) of male and female mating members, the first electrode (31, 32) being electrically connected to the power source (20) when the two pairs (52, 54) of male and female mating members are mated, and a second coupler having a third pair (56) of male and female mating members, the second electrode being electrically connected to the power source when the third pair of male and female mating members are mated, and wherein the positioning of the three pairs of male and female mating members permits only one electrical connection of the assembly (50) and the controller (12").

11. The device of claim 10, wherein both of the first and second pairs of mating members must be mated in order to electrically connect the first electrode to the power source.

12. The device of claim 10, wherein only the first pair of mating members must be mated in order to electrically connect the first electrode to the power source, the second pair of mating members providing a mechanical coupling of the assembly and the controller.

13. The device of claim 1, wherein the coupling apparatus comprises a first coupler (44) having male and female mating members, the first electrode (31, 32) being electrically connected to the power source (20) when the first coupler (44) mating members are mated, and a second coupler (42) having male and female mating members, the second electrode (33, 34) being electrically connected to the power source (20) when the second coupler (42) mating members are mated, and wherein the male mating member of the first coupler is positioned on the controller (12') and the male mating member (42) of the second coupler is positioned on the assembly (40).

14. The device of claim 1, wherein the coupling apparatus comprises a first coupler having male and female mating members, the first electrode being electrically connected to the power source when the first coupler mating members are mated, and a second coupler having male and female mating members, the second electrode being electrically connected to the power source when the second coupler mating members are mated, and wherein the female mating member of the first coupler is positioned on the controller and the female mating member of the second coupler is positioned on the assembly.

15. The device of claim 1, wherein the coupling apparatus comprises a first coupler having male and female mating members, the first electrode being electrically connected to the power source when the first coupler mating members are mated, and a second coupler having male and female mating members, the second electrode being electrically connected to the power source when the second coupler mating members are mated,

the mating members being positioned to achieve an overhang/non-alignment orientation of the controller with the assembly when the first coupler male mating member is mated to the second coupler female mating member and the first coupler female mating member is mated to the second coupler male mating member.

16. The device of claim 1, wherein the bipolar power source (20) comprises a battery.

17. The device of claim 1, wherein the assembly (30) is adapted to be discarded after a single use.

18. The device of claim 1, wherein the controller (12) is adapted to be coupled to a plurality of assemblies (30) in succession.

19. A method of electrically coupling an assembly (30) to a controller (12), the assembly (30) having first and second electrodes (31, 21 and 33, 34) and at least one of the electrodes containing a therapeutic agent to be delivered, the controller (12) having a bipolar electrical power source (20) for providing electric current to the electrodes (31, 32 and 33, 34), the method comprising electrically coupling and uncoupling the controller (12) and the assembly (30) by means of a coupling apparatus (36, 26 and 38, 28) which permits the first electrode (31, 32) to be electrically connected to a predetermined pole of the bipolar power source (20) and prevents the first electrode (31, 32) from being electrically connected to the other pole of the bipolar power source (20).

20. The method of claim 19, wherein the coupling of the controller (12) and the assembly (30) is achieved by means of an electrically conductive snap connector (36, 26).

21. The method of claim 19, wherein the coupling of the controller (12) the assembly (30) is achieved by means of a pair of electrically conductive snap connectors (36, 26 and 38, 28).

22. The method of claim 19, wherein the bipolar power source (20) comprises a battery.

23. The method of claim 19, including discarding the assembly (30) after the assembly (30) is uncoupled from the controller (12).

24. The method of claim 19, including coupling the controller (12) to a plurality of assemblies (30), one at a time in succession.

25. The device of claim 1, wherein the coupling apparatus comprises a projecting member on one of the controller (112) and the assembly (130).

26. The device of claim 25, wherein the projecting member engages an opening on the other of the assembly (130) and the controller (112).

27. The device of claim 1, wherein the coupling apparatus comprises a receptacle (334, 434) on the assembly (330, 430) and wherein the controller (312, 412) is adapted to engage the receptacle (334, 434) in only a single orientation.

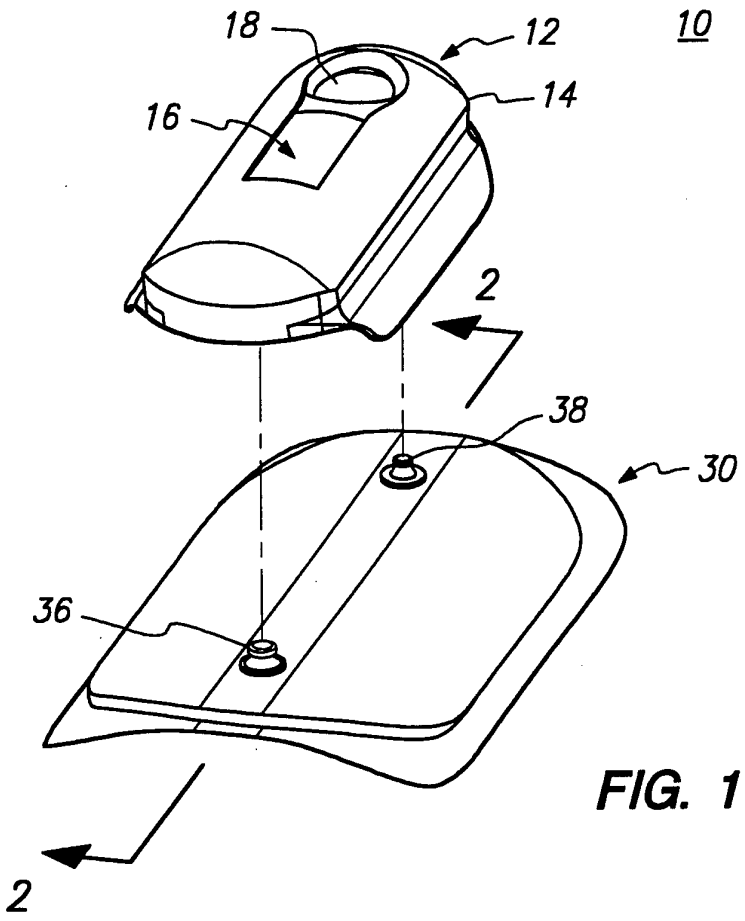
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FIG. 1

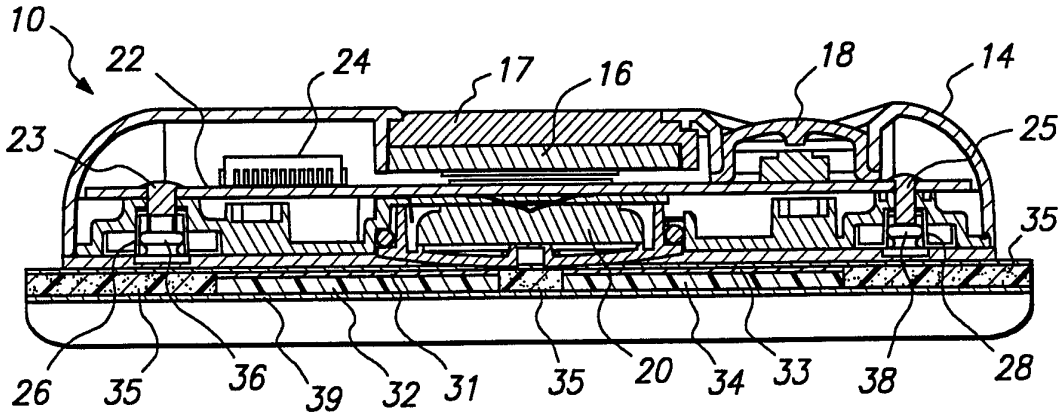
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FIG. 2

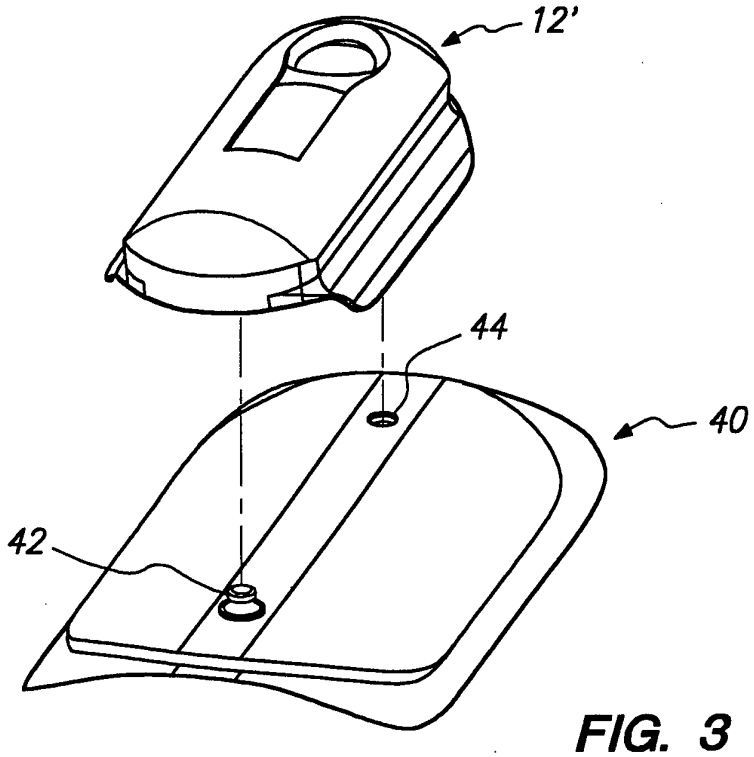


FIG. 3

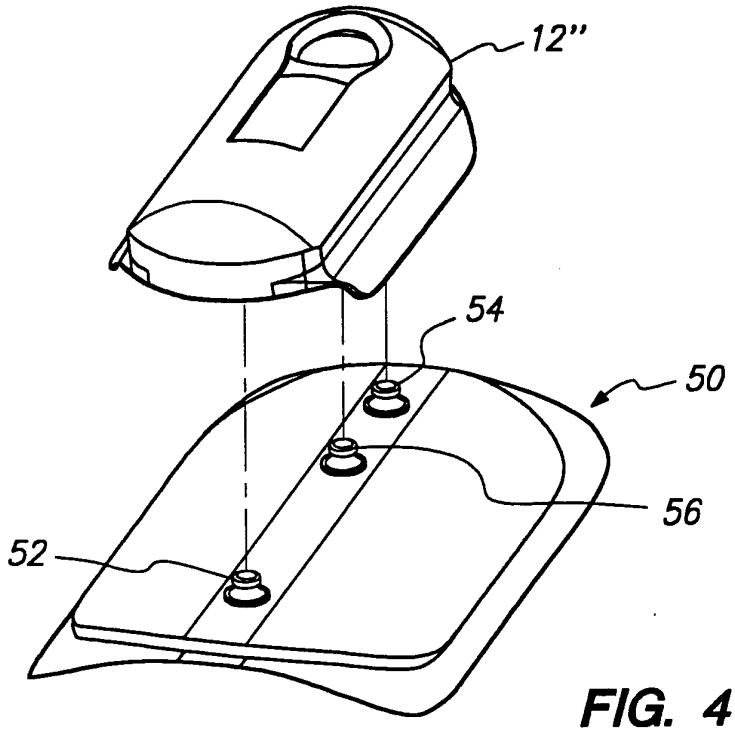


FIG. 4

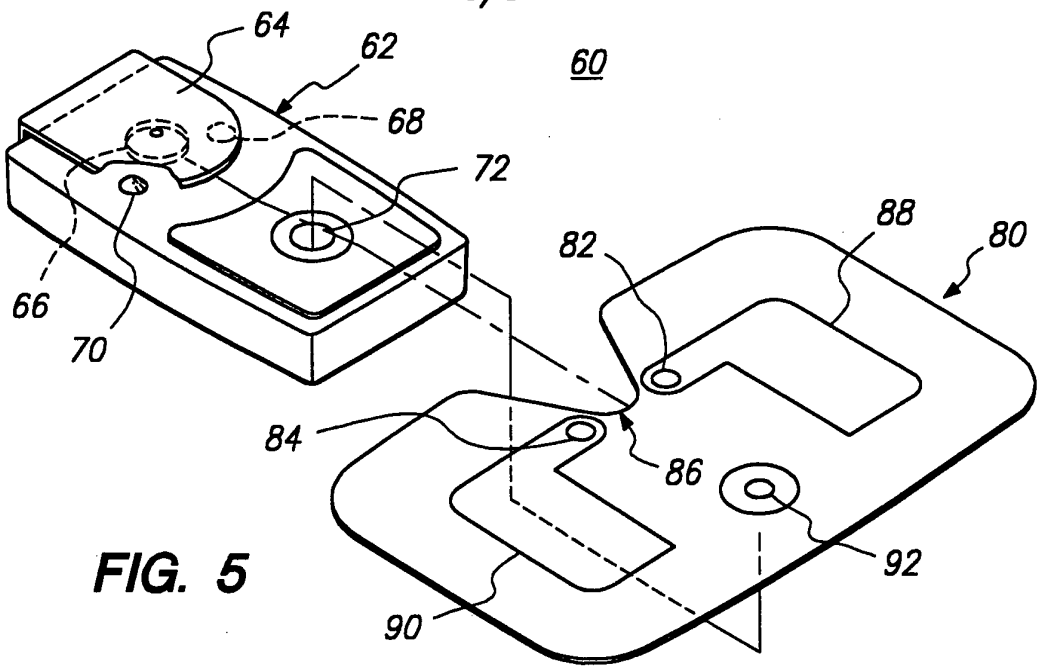


FIG. 5

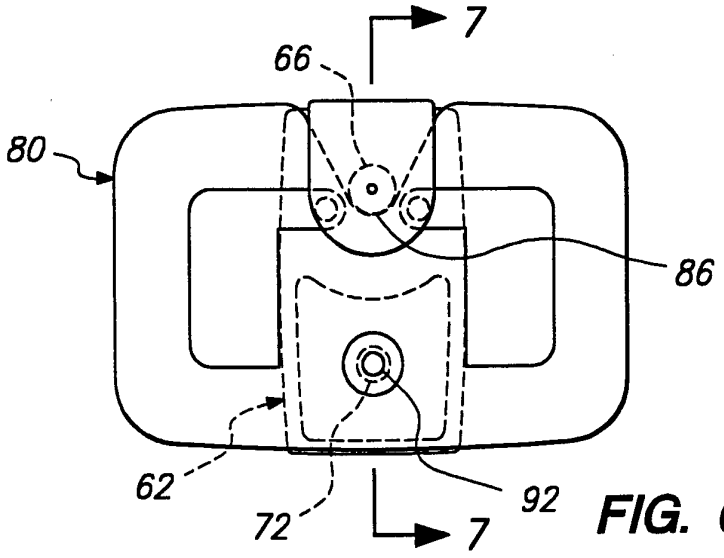


FIG. 6

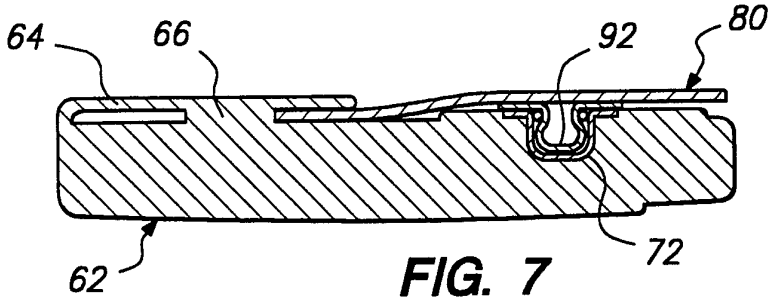


FIG. 7

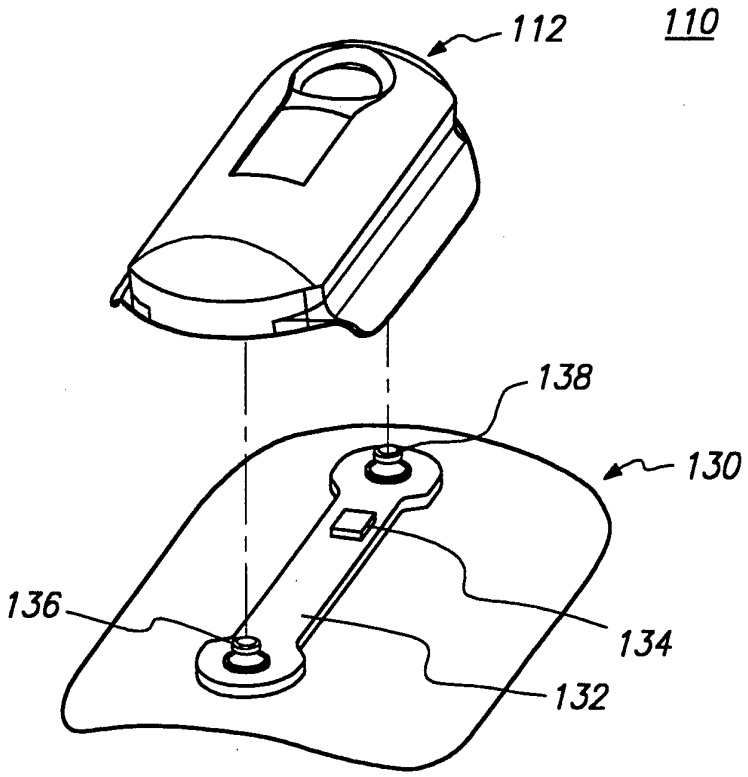


FIG. 8

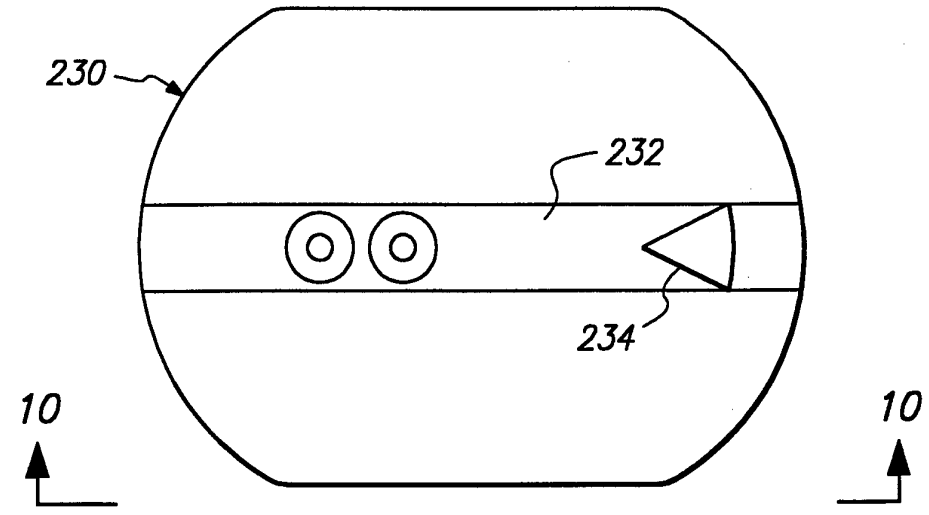
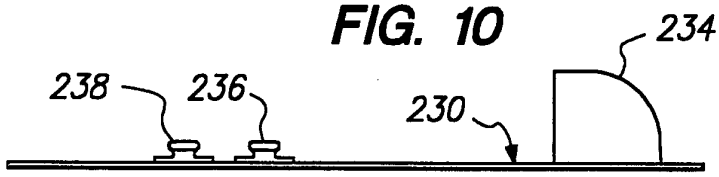


FIG. 9

FIG. 10



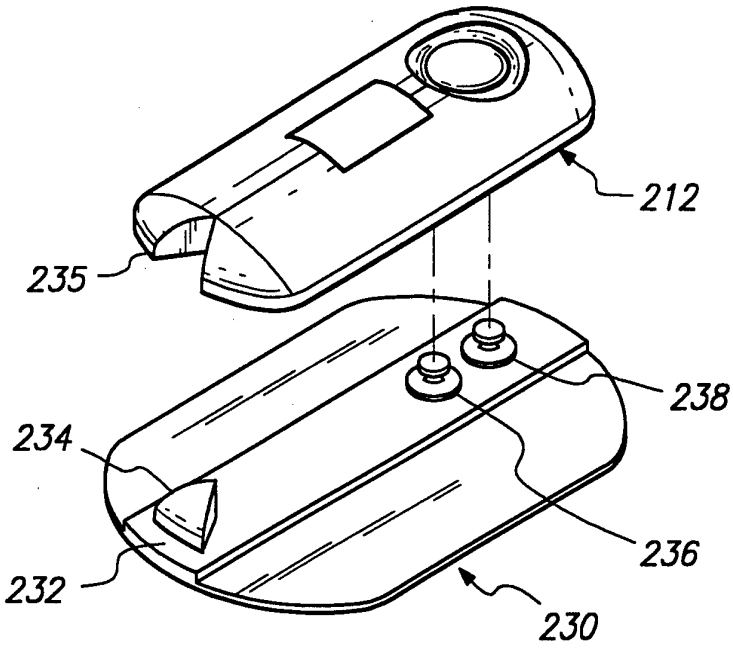


FIG. 11

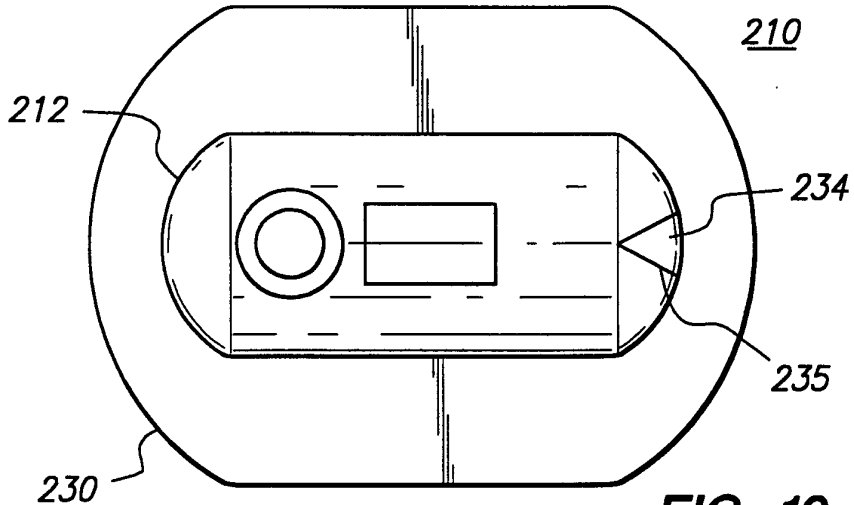


FIG. 12

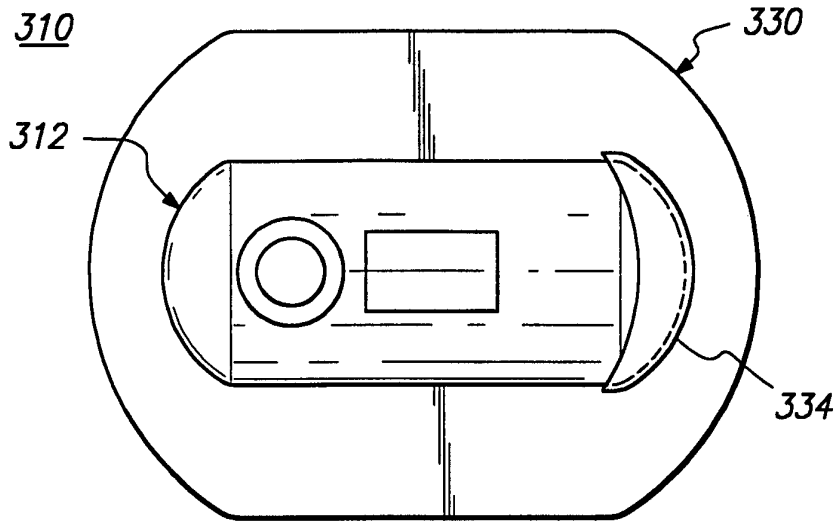


FIG. 13

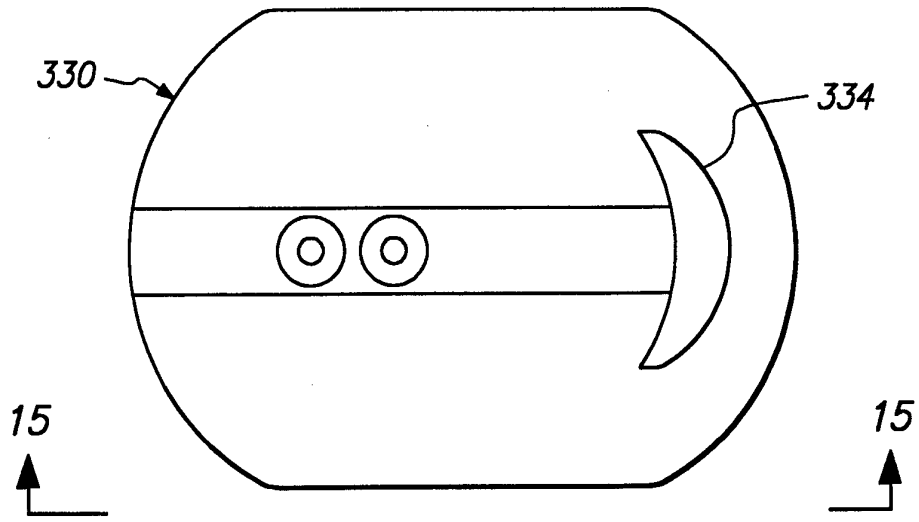
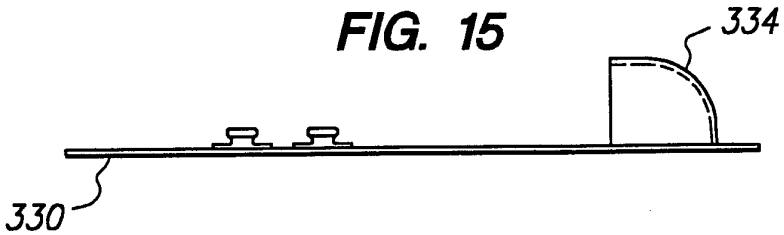


FIG. 14

FIG. 15



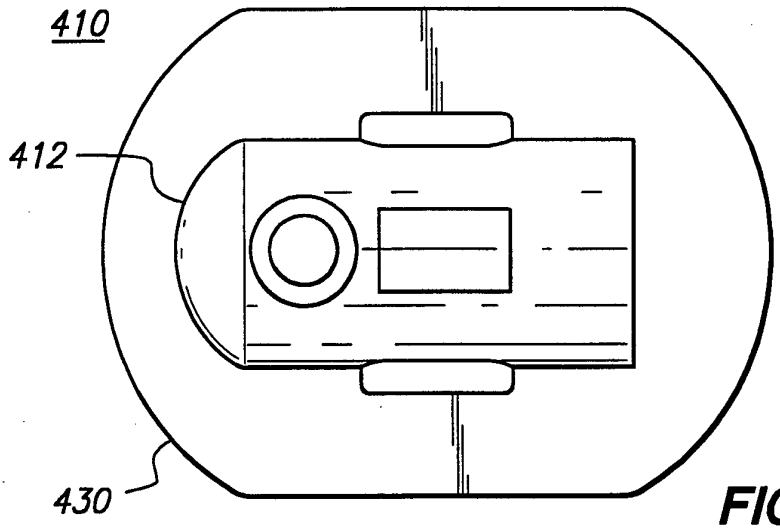


FIG. 16

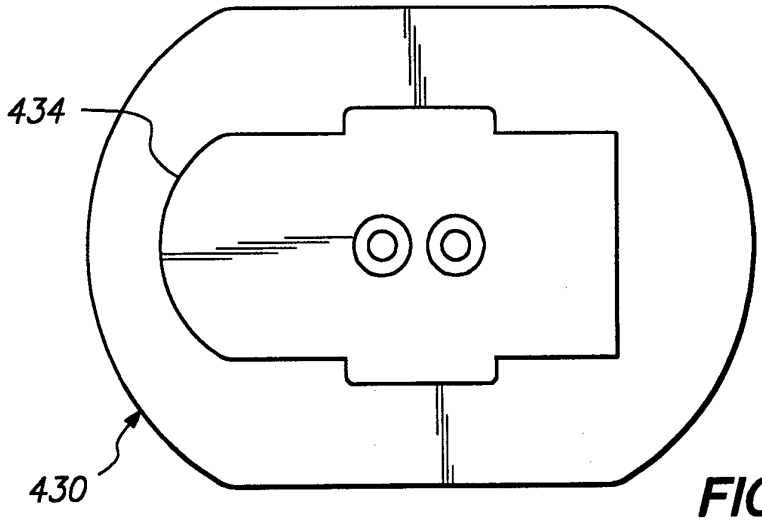


FIG. 17

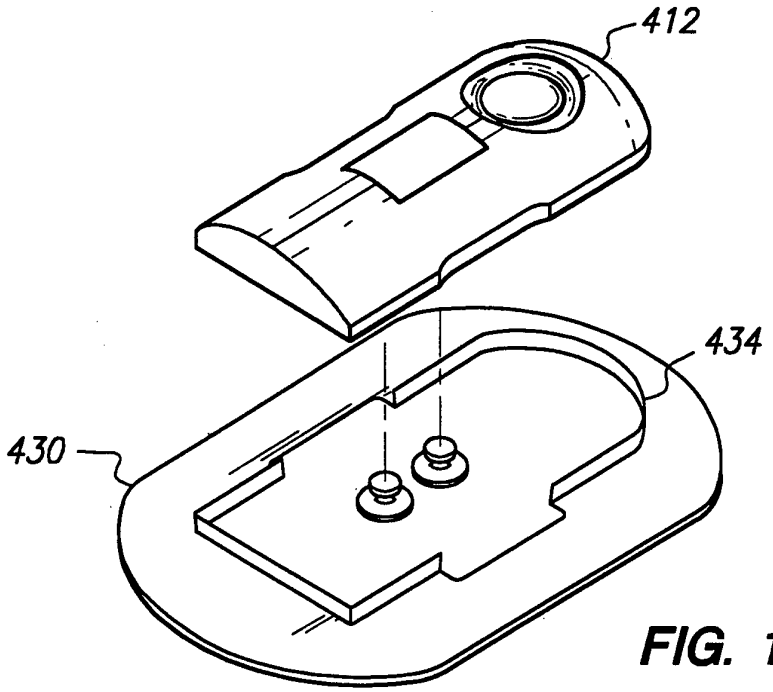


FIG. 18

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCI/US 96/06098

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61N1/30 A61N1/32

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)
IPC 6 A61N

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 practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	EP,A,0 337 642 (INVENTOR S FUNDING CORP LTD) 18 October 1989 see the whole document ---	1-6,8,9, 13-24 7,10-12
A	GB,A,2 239 803 (ELAN CORP PLC) 17 July 1991 cited in the application see page 14, line 5 - page 23, line 3; figures ---	1-8,11, 12,16-27
A	EP,A,0 642 808 (ASULAB SA) 15 March 1995 see page 4, column 5, line 23 - page 5, column 8, line 51; figures --- -/--	1-8, 16-27

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"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

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"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
7 August 1996	21.08.96
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Authorized officer Rakotondrajaona, C

Form PCT/ISA/210 (second sheet) (July 1992)

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Inter nal Application No
PCT/US 96/06098

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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