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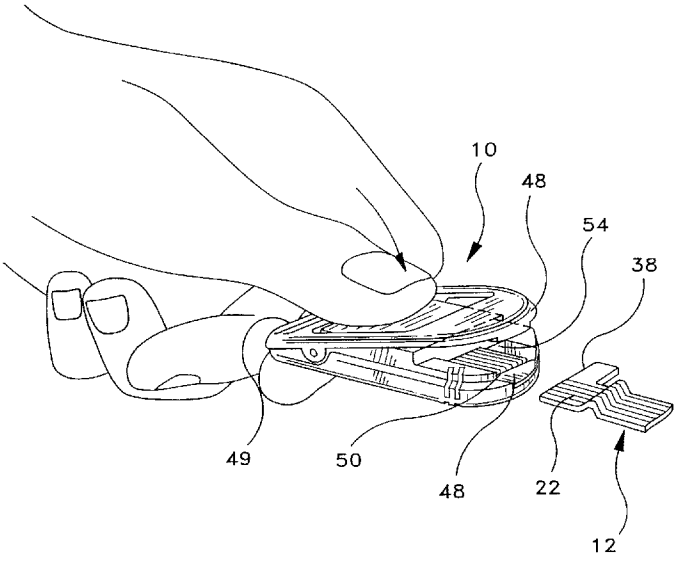
(54) **SYSTEME D'ADMINISTRATION IONTOPHORETIQUE DE MEDICAMENTS COMPRENANT UN DISPOSITIF REUTILISABLE**

(54) **IONTOPHORETIC DRUG DELIVERY SYSTEM, INCLUDING REUSABLE DEVICE**



(57) Cette invention concerne un système d'administration iontophorétique de médicaments, lequel comprend une unité de commande réutilisable (10) pouvant être connectée de manière fiable à un timbre (12) contenant un médicament. Cette unité de commande (10) contrôle et commande l'alimentation en courant électrique du timbre (12) contenant le médicament lors de l'administration d'au moins un médicament. L'interconnexion électrique entre le timbre (12) et l'unité de commande (10) se fait en ouvrant la partie avant (48) de l'unité de commande (10) à l'aide du pouce, de sorte qu'une languette (22) dépassant du

(57) An iontophoretic drug delivery system of the present invention includes a reusable controller (10) reliably interconnectable with a drug-filled patch (12). The controller (10) monitors and controls the supply of electrical current to the drug-filled patch (12) during delivery of at least one drug. Electrical interconnection between the patch (12) and the controller (10) is established by opening the front end (48) of the controller (10) under thumb actuation so that a tab (22) extending from the patch (12) can be inserted into the opened front end (48), and the front end (48) closed with the tab (22) therein. The tab (22) of the drug-filled patch

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timbre (12) puisse être insérée dans ladite partie avant (48) ouverte qui est ensuite refermée avec la languette (22) à l'intérieur. La languette (22) du timbre (12) contenant le médicament comporte une patte (38) conçue pour rentrer dans une entaille correspondante (54) pratiquée dans la partie avant (48) de l'unité de commande (10), ceci de manière à offrir un logement de type clé pour la languette (22) et pour la patte (38). Cette structure de clé, qui se trouve tant sur la partie avant (48) du boîtier que sur la patte (38), permet d'éviter tout mauvais positionnement du timbre (12) par rapport à l'unité de commande (10). Dans un mode de réalisation préféré, la partie avant (48) et l'entaille (54), ainsi que la languette correspondante (22) et la patte (38), possèdent une section globalement en forme de L.

(12) includes an extending leg (38) designed to fit in a corresponding notch (54) formed in the front end (48) of the controller (10) so as to provide keyed accommodation of the tab (22) and leg (38). The key structure included on both the housing front end (48) and the leg (38) prevents incorrect positioning of the patch (12) with respect to the controller (10). In the preferred embodiment, both the front end (48) and the notch (54), and the corresponding tab (22) and the leg (38) have a generally L-shaped cross section.

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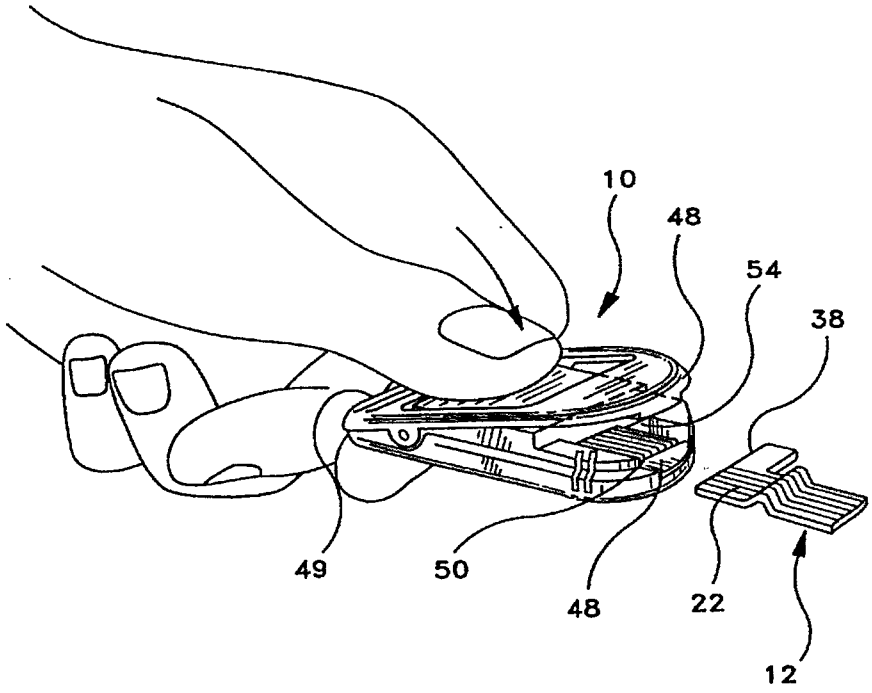
(54) Title: IONTOPHORETIC DRUG DELIVERY SYSTEM, INCLUDING REUSABLE DEVICE

(57) Abstract

An iontophoretic drug delivery system of the present invention includes a reusable controller (10) reliably interconnectable with a drug-filled patch (12). The controller (10) monitors and controls the supply of electrical current to the drug-filled patch (12) during delivery of at least one drug. Electrical interconnection between the patch (12) and the controller (10) is established by opening the front end (48) of the controller (10) under thumb actuation so that a tab (22) extending from the patch (12) can be inserted into the opened front end (48), and the front end (48) closed with the tab (22) therein. The tab (22) of the drug-filled patch (12) includes an extending leg (38) designed to fit in a corresponding notch (54) formed in the front end (48) of the controller (10) so as to provide keyed accommodation of the tab (22) and leg (38). The key structure included on both the housing front end (48) and the leg (38) prevents incorrect positioning of the patch (12) with respect to the controller (10). In the preferred embodiment, both the front end (48) and the notch (54), and the corresponding tab (22) and the leg (38) have a generally L-shaped cross section.



IONTOPHORETIC DRUG DELIVERY SYSTEM, INCLUDING REUSABLE DEVICE

FIELD OF THE INVENTION

The present invention generally relates to iontophoretic systems for delivering drugs, medicines and the like to patients transdermally, i.e., through the skin, and more specifically relates to a reusable iontophoretic drug delivery device such as a controller attachable to a disposable drug-filled patch.

BACKGROUND OF THE INVENTION

Transdermal drug delivery systems have, in recent years, become an increasingly important means of administering drugs and like therapeutic agents.

Presently, there are two types of transdermal drug delivery systems, i.e., "Passive" and "Active." Passive systems deliver drug through the skin of the user unaided, an example of which would involve the application of a topical anesthetic to provide localized relief, as disclosed in U.S. Patent No. 3,814,095 (Lubens). Active systems on the other hand deliver drug through the skin of the user using, for example, iontophoresis, which according to Stedman's Medical Dictionary, is defined as "the introduction into the tissues, by means of an electric current, of the ions of a chosen medicament." Such systems offer advantages clearly not achievable by any other methods of administration, such as avoiding introduction of the drug through the gastro-intestinal tract or punctures in the skin to name a few.

Conventional iontophoretic devices, such as those described in U.S. Patent Nos. 4,820,263 (Spevak et al.), 4,927,408 (Haak et al.) and 5,084,008 (Phipps), the disclosures of which are hereby incorporated by reference, for delivering a drug or medicine transdermally through iontophoresis, basically consist of two electrodes, which are in contact with a portion of a patient's body. A first

electrode, generally called the active electrode, delivers the ionic substance or drug into the body by iontophoresis. The second electrode, generally called the counter electrode, closes an electrical circuit that includes the first electrode and the patient's body. Generally, the circuit includes a source of electrical energy, such as a battery. The ionic substance to be driven into the body may be either positively charged or negatively charged. In the case of a positively charged ionic substance, the anode of the iontophoretic device becomes the active electrode and the cathode serves as the counter electrode to complete the circuit. Alternatively, if the ionic substance to be iontophoretically delivered is negatively charged, the cathode will be the active electrode and the anode will be the counter electrode.

In practice, this process is typically achieved by placing the ionic drug either in solution or in gel form on a carrier and placing the drug-containing carrier, for example, in the form of a drug-filled adhesive patch, into contact with the skin. The pair of electrodes is placed in contact with the skin and with the carrier. Direct current is applied between the two electrodes. Under the influence of the electric field present, the drug molecules migrate through the skin. As current flows between the two electrodes placed at spaced apart locations on the skin, the current path carries the drug with it.

In order to deliver the drug to the patient, the adhesive patch may be applied to the desired portion of the patient's body and the controller attached to the patch. Oftentimes the controller is as large as, or larger than, the patch. It also should be somehow secured in place on the patient so that the patient may remain mobile and carry both the patch and controller with him as he moves about.

Delivery of a drug to the patient iontophoretically may be accomplished either at a constant rate over a long period of time, or periodically at various intervals and in some situations, upon demand. As can be seen, it may be necessary

for the drug-containing carrier to be maintained in contact with the patient's skin over a long period of time, either for continuous drug delivery, or to permit frequent interval delivery over a period of time.

One of the problems with an iontophoretic drug delivery device such as described above, especially one that is compact and portable to provide patient mobility, is how to attach the controller to the patient and yet be as unobtrusive as possible and comfortable for the patient where the system is to be applied for an extended period of time. A side-by-side arrangement of patch and controller may occupy too much space on the patient's skin and limit the choices where the transdermal device may be attached to the patient. Also, the controller may then have to be fastened to the patient's skin by adhesive or a strap, for example, which may be uncomfortable to the user.

As previously noted, it may be necessary to use an iontophoretic drug delivery device over an extended period of time i.e., longer than 24 hours to delivery the necessary dosage of drug. As the length of delivery time increases, there is a need to develop small, unobtrusive iontophoretic delivery devices which can be easily worn on the skin under clothing.

In addition to the need for developing smaller iontophoretic devices, there is need to reduce the cost of these devices in order to make them more competitive with conventional forms of therapy such as pills and subcutaneous injections. One manner of improving cost effectiveness is to have a reusable controller which includes the costly electronics that provides the current to drive the patch.

Also, it is envisioned that the controller, which may contain sophisticated electronics besides just a power source to control and monitor the delivery of drug to the patient, is repeatedly used while the patch is discarded after use and replaced with new patches. The replaceable patches and controller should be so structured as to make it easy and

convenient for the patient to replace used patches with new patches on the controller.

Thus, there has been a need for an iontophoretic drug delivery system, particularly a controller which would eliminate the problems and limitations associated with the prior devices discussed above, most significant of the problems being reusability, unobtrusiveness and ease of use.

SUMMARY OF THE INVENTION

In contrast to the prior devices discussed above, it has been found that a iontophoretic drug delivery system including a controller which may be constructed in accordance with the present invention is particularly suited for reuse. In addition, the controller for the system of the present invention preferably can be used with disposable patches to easily attach the system to the patient for delivering the drug, medicament or the like.

The controller of the present invention for use in combination with a drug-filled patch to form an operable iontophoresis drug delivery system includes a housing having an upper portion and a lower portion pivotably interconnected, with the upper portion and the lower portion being biased towards one another at a openable front end by biasing means, and the housing including electronic means for monitoring and controlling electrical current and electrical connection means positioned within the front end of the housing and electrically connected to the electronics so that when sufficient force is applied to the housing to overcome the biasing means, the upper portion and the lower portion are forced away from one another to open the front end and expose the electrical connection array whereby the electrical connection array may be interconnected with the drug-filled patch.

In the preferred embodiment, the connection means is adapted to include an electrical array and also adapted so that upon opening the front end the patch may be inserted into the open front end in electrical contact with the connection means.

In addition, the open end of the housing includes a notch for keying the controller and the patch to insure proper interconnection and orientation.

The iontophoretic drug delivery system of the present invention includes a drug-filled patch removably attachable to the skin of a patient for iontophoretically delivery at least one drug to the patient, with the patch including conductive pad means for interconnection with the reusable controller, and a reusable controller removably, electrically connectable to the patch, the controller providing sufficient energy to the patch to drive the ionized medicament into the skin of the patient, with the controller including housing means having an upper portion and a lower portion pivotably interconnected, with the upper portion and the lower portion being biased towards one another at a openable front end by biasing means, and the housing including electronic means for monitoring and controlling electrical current, and with the front end of the controller housing means adapted to including electrical connection means positioned within the front end of the housing and electrically connected to the electronics so that when sufficient force is applied to the housing to overcome the biasing means, the upper portion and the lower portion are forced away from one another to open the front end and expose the electrical connection array whereby the electrical connection array may be interconnected with the conductive pad means of the drug-filled patch.

BRIEF DESCRIPTION OF THE DRAWINGS

The various features, objects, benefits, and advantages of the present invention will become more apparent upon reading the following detailed description of the preferred embodiment along with the appended claims in conjunction with the drawings, wherein like reference numerals identify corresponding components, and:

Figure 1 is a perspective, schematic view of the controller of the present invention illustrating opening of the controller for interconnecting to the patch;

Figure 2 is a perspective view of the controller shown in Figure 1 illustrating interconnection of the controller and the patch;

Figure 3 is plan view of the patch for interconnection with the controller of the present invention;

Figure 4 is an perspective view of the controller having a member for attaching the patch thereto, whereby the patch having a corresponding member may be folded and the two members brought into contact with one another; and

Figure 5 is a perspective bottom view of the controller illustrating attachment of the patch to the controller.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The iontophoretic drug deliver system of the present invention is illustrated in Figure 1-5, with the controller generally designated 10 and the patch generally designated 12.

Referring to Figures 1, 2 and 3, the controller 10 of the present invention for use in the iontophoretic drug delivery system is electrically connectable to the patch 12 to form the operable system, with the patch being attachable to the skin of a patient 14. The patch typically includes an active electrode assembly 16 and a counter electrode assembly 18. If a positively charged medicament is to be delivered to the skin 14, the medicament would be positioned in the active electrode assembly. In the preferred embodiment, an third or adjunct electrode assembly 19 is provided so that when delivering a local anesthetic such a Lidocaine, the local anesthetic may be delivered beneath the counter electrode as well as the active electrode as disclosed, for example, in International Publication No. WO 95/09032, published 6 April 1995, entitled "IONTOPHORETIC DRUG DELIVERY SYSTEM AND METHOD FOR USING SAME," which is hereby incorporated in its entirety.

As illustrated in Figures 1-4, the controller 10 is coupled to the patch 12 using well known means, for example, by printed

flexible circuits, metal foils, wires, tabs or electrically conductive adhesives as disclosed for example in International Publication No. WO 96/10442, entitled "IONTOPHORESIS ASSEMBLY INCLUDING PATCH/CONTROLLER ATTACHMENT," published 11 April 1996, the disclosure of which is hereby incorporated by reference in its entirety.

Referring to Figures 3 and 4, the patch 12 is a generally planar flexible member and may be adhesively supported on the skin 14 of the patient (Figure 5). The patch 12 includes an enlarged patch body 20 and an extending narrow tab 22. The patch body 20 includes opposed planar surfaces 24 and 26, with the planar surface 24 disposed for skin contact and including a drug reservoir 28 typically in a gel form which contains at least one drug, medicament or like active agents (hereinafter collectively referred to simply as drugs), preferably in an ionic form. While the drug reservoir 28 is shown, any other known iontophoretic drug reservoir structure for placing a medicament in contact with the skin in an iontophoretic patch may be employed, as disclosed for example in International Publication No. WO 95/09031 entitled "IONTOPHORETIC DRUG DELIVERY DEVICE AND RESERVOIR AND METHOD OF MAKING SAME," published 6 April 1995, the disclosure of which is hereby incorporated by reference in its entirety.

Each of the electrode assemblies 16 and 18 are positioned to be in contact with the skin once the patch 12 is secured, as shown in Figure 5. The positioning of the electrode assemblies 16 and 18 is such that an electrical current path is established between the electrode assemblies 16 and 18 through the skin of the patient 14. A direct current source in combination with the electrode assemblies 16 and 18 and the patient's body 14 completes the circuit and generates an electric field across the body surface or skin to which the iontophoretic device is applied, with the drug reservoir 28 assumes the same charge as the ionized drug contained in the reservoir 28. Under the influence of electrical current passing from the electrode assembly 16 through the skin 14 to the electrode assembly 18, the drug contained in the drug reservoir 28 is transcutaneously

delivered into the body of the patient by the process of iontophoresis.

Referring to Figure 4, the electrical current is supplied from the controller 10 to the electrode assemblies 16 and 18 on the patch via the electrical traces or leads 32 and 34 shown in Figure 3. Each of the traces 32 and 34 may be one or more conductive paths extending from the electrode assemblies 16 and 18 to exposed conductive pads 36 (Figure 3) positioned on a marginal edge of the patch tab 22. As described in further detail below, the pads 36 are positioned for electrical connection to the controller 10, which provides a source of electrical current.

The particular construction of the patch 12 is not essential to the present invention, and may be formed of woven or non-woven textiles or polymers or may be any other construction well known in the art. However, it is preferred that the electrode assemblies 16, 18, the electrical traces 32, 34 and the conductive pads be printed or otherwise formed on a polymeric substrate as disclosed, for example, in International Publication No. WO 94/17853 entitled "ACTIVE DRUG DELIVERY DEVICE, ELECTRODE AND METHOD FOR MAKING SAME," published 18 August 1994, the disclosure of which is hereby incorporated by reference in its entirety.

As illustrated in Figures 1 and 2, the controller 10 includes a controller housing 40 having an upper portion 42 and a lower portion 44 pivotably interconnected, with the portions being biased towards one another by a biasing means such as a spring 46. In this way, the housing 40 has a general clothespin shape and includes an biasingly openable front end 48 which accommodates the tab 22 of the patch 12. The housing 40 further accommodates a connection array 50 adjacent the electronics 52 contained within the housing 40 and schematically shown in phantom in Figure 2. The connection array 50 and the electronics 52 are preferably mounted to a common printed circuit board (not shown). The connection array 50 may include plural electrical terminals in electrical connection with the electronics 52 and may be connectable to the pads 36 of the tab 22 extending from

the patch 12. In the present illustrative embodiment, the connection array 50 is an electrical connection member having plural spaced-apart, exposed conductive surfaces separated by an insulating material. As previously discussed, it may be appreciated that any suitable electrical interconnection device may be employed in accordance with the present invention.

Referring back to Figure 2, the controller 10 houses the electronics 52 that monitor and control the supply of electric current to the electrode assemblies 16 and 18 and the user interfaces. As is known in the art, the electrical components may include a source of electrical power such as a battery and additional electronic components, such as an application specific integrated circuit, a microprocessor, used to send a controlled electrical current to electrode assemblies 16 and 18. It should be appreciated that the particular electrode assemblies and the electronic array are not essential to the present invention, with the electrode assemblies including, for example, those disclosed in International Publication No. WO 96/10440 entitled "IONTOPHORETIC DRUG DELIVERY DEVICE HAVING IMPROVED CONTROLLER," published 11 April 1996 and International Publication No. 97/07854 published 6 March 1997 entitled "IONTOPHORETIC DRUG DELIVERY DEVICE HAVING HIGH-EFFICIENCY DC-TO-DC ENERGY CONVERSION CIRCUIT," the disclosures of which are hereby incorporated by reference in their entirety.

In the preferred embodiment, as illustrated in Figures 1 and 2, the controller may be easily interconnected with the patch 12 under thumb actuation to an open position exposing the connection array 50 for electrical connection with the pads 36 of the tab 22. Specifically, by pressing the rear end 49 of the housing with sufficient force to overcome the spring 46 to open front end 48 of housing 42 (Figure 1). The tab 22 of the patch 12 may then be inserted in the open end, with the conductive pads 36 slidably engageable with the connection array 50 and the housing returned to a closed position by releasing the rear portion to cover the connection array 50 with the pads clamped or otherwise held there between.

In order to assure accurate alignment of the pads 36 of the tab 22 with the connection array 50 supported within the housing 40, the tab 22 is keyed to the housing 40. Specifically, the tab 22 includes an extending leg or like portion 38 on one side which is designed to fit in a corresponding notch 54 formed in at least one side of the front end 48 of the lower portion 42 of the housing 40. The notch 54 and the leg 38 are of similar shape so as to provide keyed accommodation of the tab 22 and the leg 38. The key structure included on both the housing front end 48 and the leg 38 insures proper orientation of the patch 12 and the controller 10 by preventing incorrect positioning of the patch 12 with respect to the controller 10. In the present embodiment, both the front end 48 and the notch 54, and the corresponding tab 22 and the leg 38 have a generally L-shaped cross-section, however, any other mating shape which would prevent incorrect alignment may be employed.

Referring to Figures 4 and 5, the controller 10 and the patch 12 include attachment means for permitting the releasable support of the controller 10 on the patch 12 after interconnection between the pads 36 and the connective array 50 is established. The surface 24 of patch 12, and the exposed upper portion 42 include cooperating fastening elements 56 and 58 thereon. In the present illustrative embodiment, the

cooperative fastening elements 56, 58 include conventional hook and loop fasteners of the type sold under the trademark VELCRO. Any other cooperating type fasteners may be employed to achieve the same objective. One cooperating fastening element 56 is secured adhesively or otherwise to patch 12 on surface 24 while the other cooperating fastening member 58 is secured by adhesive or otherwise to the exposed surface of upper portion 42 of the housing 40. As described in further detail below, attachment of the mating hook and loop fasteners 56 or 58 provide removable support for controller 10 on patch 12. It may be appreciated by those skilled in the art that the patch and controller may take any known form. The only requirement is that the patch be capable of being physically and electrically connected to the controller 10.

Operation and Use

Having described one embodiment of iontophoretic drug delivery system, including the controller 10 and the patch 12, of the present invention, its operation and use is described below.

As illustrated in Figure 5, the controller 10 and patch 12 may be adhesively secured to the skin 14 of the patient, with surface 24 of patch 12 placed in intimate contact with the skin 14 so that the electrode assemblies 16 and 18, as well as the drug containing reservoir 28, are supported in intimate contact with the skin 14. In order to iontophoretically deliver the medicament from reservoir 28 transcutaneously through the skin 14, the reusable controller 10 of the present invention is electrically connected to patch 12. The housing 40 is opened and the tab 22 of the patch 12 is inserted into the open front end 48 of the housing 40. Proper planar orientation is assured between the patch 12 and the controller 10 due to the key mateability between the notch 54 in the open front end 48 of the housing 40 and the extending leg 38 of the patch tab 22. As the controller 10 is designed to be maintained in electrical connection with the patch 12 during iontophoretic delivery of the drug contained in the reservoir 28, the controller 10 may be fastened or otherwise attached to the patch 12 so that it will be conveniently retained on the skin of the patient.

As shown in Figures 4 and 5, once the patch 12 is connected to controller 10, the controller may be flipped up so that the mating hook and loop fasteners 56 and 58 engage each other to removably fasten the controller 10 to the patch 12 as shown in Figure 5. The controller 10 is comfortably retained on the skin of the patient during iontophoretic drug delivery. At such time as a particular application of the drug is completed, the controller 10 and the patch 12 may be removed from the skin of the patient, and by separating the mating hook and loop fasteners 56 and 58, and pressing on the rear end of the housing 40, the controller 10 and the patch 12 may be

separated. In this way, the controller may be disconnected and placed aside until the next administration of the drug is needed, when it can be reused with a new patch.

In the preferred embodiment, the patch 12 of the present invention contains Lidocaine (a local anesthetic) and Epinephrine or Adrenaline (vasoconstrictors). In this way, the device can be used for anesthetizing the applied area to minimize sensation from the insertion of a needle or the like. However, it should be appreciated that other substances suitable for being applied to the area may be utilized which are well known to those skilled in the art.

Active agent, drug, formulation, medication, medicament and active compound have been used herein to mean any ethical pharmaceutical compound or agent, such as therapeutic compounds, diagnostic agents, anesthetic agents and the like.

As is well known within the field, the device can be situated on the area of the patient to which the active agent is to be applied (the applied area) such as the skin and a voltage impressed across the electrode assemblies 16, 18 to cause electrical current to flow through the skin of the patient to drive or otherwise transport the drug preferably in the form of an ionic active agent into the skin and the tissue to be absorbed by the body of the patient. The electric field lines are sufficiently long, however, so that the active agent is transported to the desired depth within the skin, and possibly to the vasculature, to provide the desired effect, e.g., anesthetic, therapeutic or diagnostic. It should also be appreciated that the device of the present invention can be applied to other areas of the body such as mucus membranes depending upon the desired therapy and drugs to be delivered.

In addition, while the present invention has been described in connection with iontophoresis, it should be appreciated that it may be used in connection with other principles of active introduction, i.e., motive forces, such as electrophoresis which includes the movement of particles in an electric field toward one or other electric pole, anode, or

cathode and electro-osmosis which includes the transport of uncharged compounds due to the bulk flow of water induced by an electric field. Also, it should be appreciated that the patient may include humans as well as animals.

While the preferred embodiment of the present invention has been described so as to enable one skilled in the art to practice the device of the present invention, it is to be understood that variations and modifications may be employed without departing from the concept and intent of the present invention as defined in the following claims. The preceding description is intended to be exemplary and should not be used to limit the scope of the invention. The scope of the invention should be determined only by reference to the following claims.

What is claimed is:

CLAIMS

1. A controller (10) for use in combination with a drug-filled patch (12) to form an operable iontophoresis drug delivery system, said controller (10) comprising:

a housing (40) including an upper portion (42) and a lower portion (44) pivotably interconnected, with said upper portion and said lower portion being biased towards one another at a openable front end (48) by biasing means (46), and said housing (40) including electronic means (52) for monitoring and controlling electrical current;

electrical connection (50) means positioned within said front end (48) of the housing (40) and electrically connected to said electronic means (52) so that when sufficient force is applied to said housing to overcome said biasing means (46), said upper portion (42) and said lower portion (44) are forced away from one another to open said front end (48) and expose said electrical connection means (50) whereby said electrical connection means (50) may be interconnected with the drug-filled patch (12).

2. The controller (10) defined in Claim 1 wherein said connection means (50) includes an array of electrical contacts.

3. The controller defined in Claim 2 wherein said connection means (50) is also adapted so that upon opening said front end (48) a tab (22) on the patch (12) may be inserted into said open front end in electrical contact with said electrical connection means (50).

4. The controller (10) defined in Claim 1 wherein the open end (48) of the housing (40) includes a notch (54) for keying said controller (10) and the patch (12) to ensure proper interconnection and orientation.

5. An iontophoretic drug delivery system including a drug-filled patch (12) electrically interconnectable with the

reusable controller (10) according to Claim 1, the system comprising:

a drug-filled patch (12) removably attachable to the skin of a patient for iontophoretically delivering at least one drug to the patient, the patch (12) including conductive pad means (36) for interconnection with the reusable controller (10); and

a reusable controller (10) removably, electrically connectable to said patch (12), the controller providing sufficient energy to said patch to drive the ionized medicament into the skin of the patient, the controller (10) including housing means (40) having an upper portion (42) and a lower portion (44) pivotably interconnected, with said upper portion (42) and said lower portion (44) being biased towards one another at a openable front end (48) by biasing means (46), and said housing (40) including electronic means (52) for monitoring and controlling electrical current;

said front end (48) of the controller housing means (40) including electrical connection means (50) positioned within said front end (48) of the housing means (40) and electrically connected to said electronic means (52) so that when sufficient force is applied to said housing means (40) to overcome said biasing means (46), said upper portion (42) and said lower portion (44) are forced away from one another to open said front end (48) and expose said electrical connection means (50) whereby said electrical connection means (50) may be interconnected with the conductive pad means (36) of the drug-filled patch (12).

FIG-1

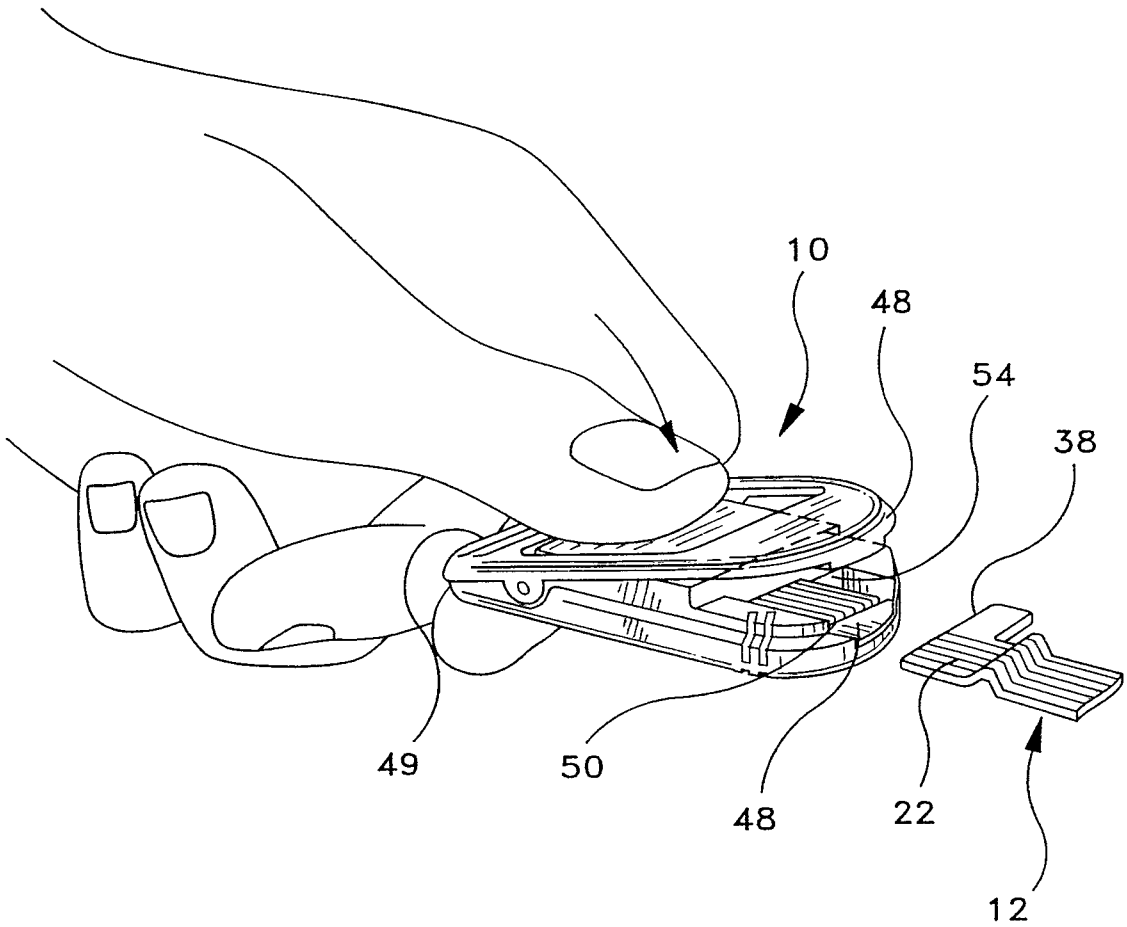


FIG-2

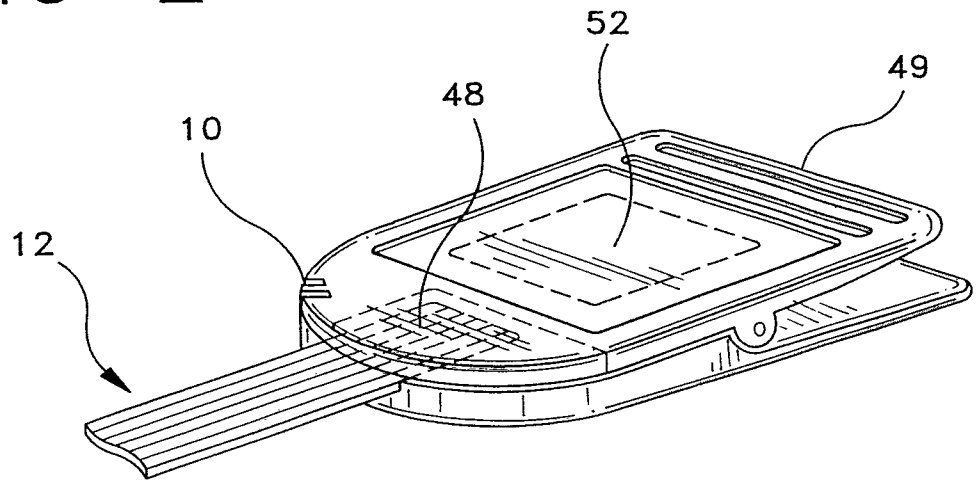
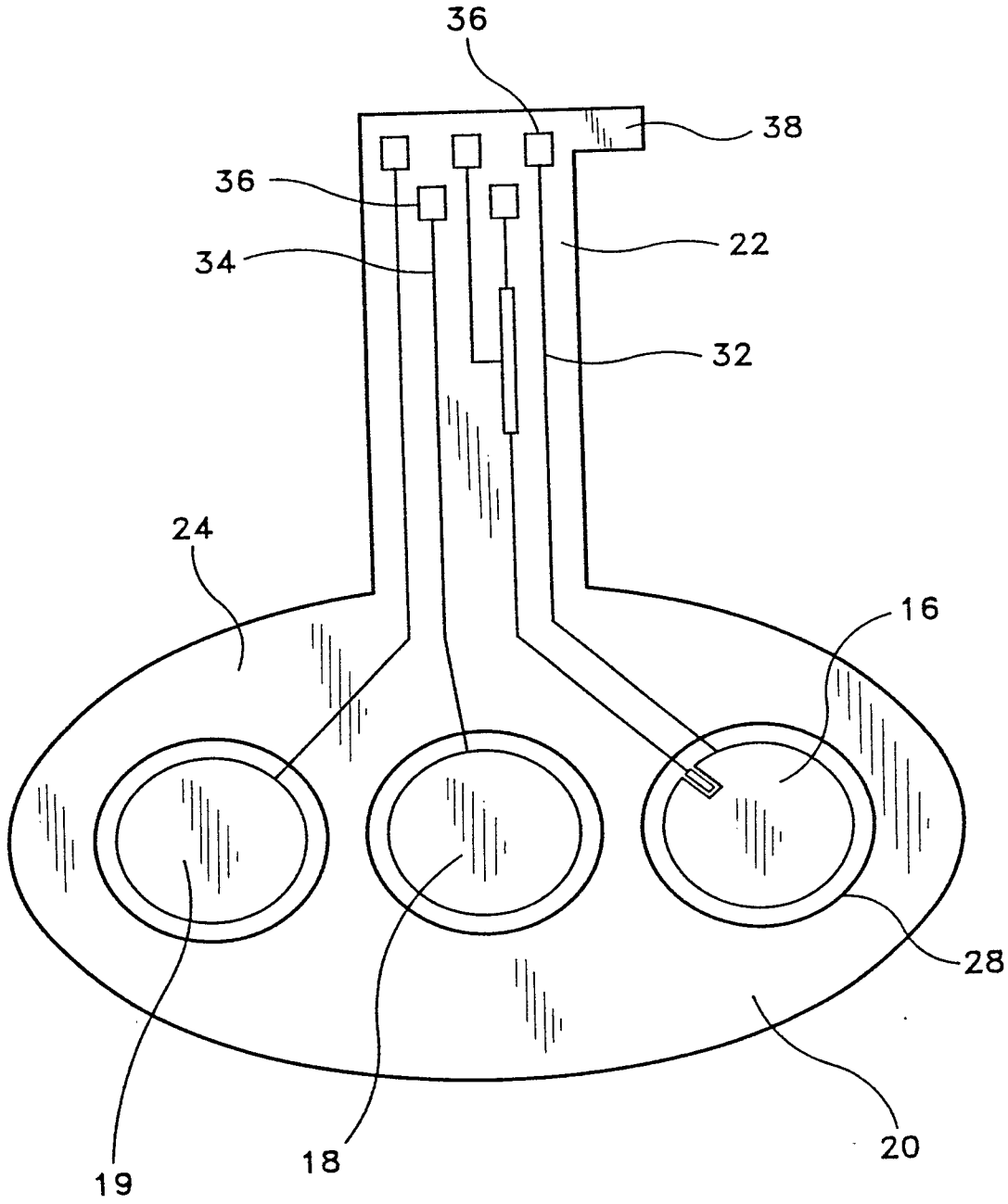


FIG-3



AMENDED SHEET

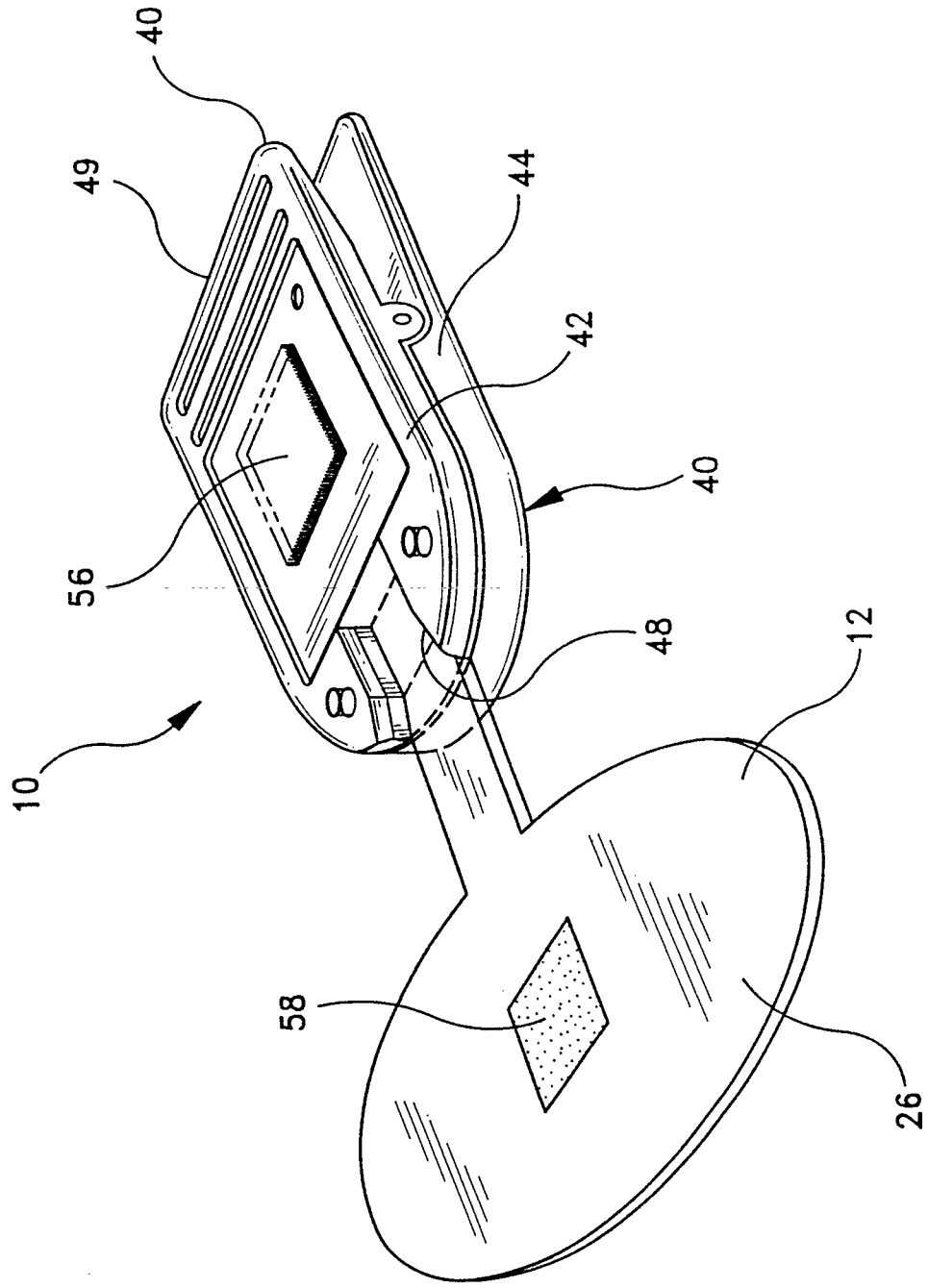


FIG-4

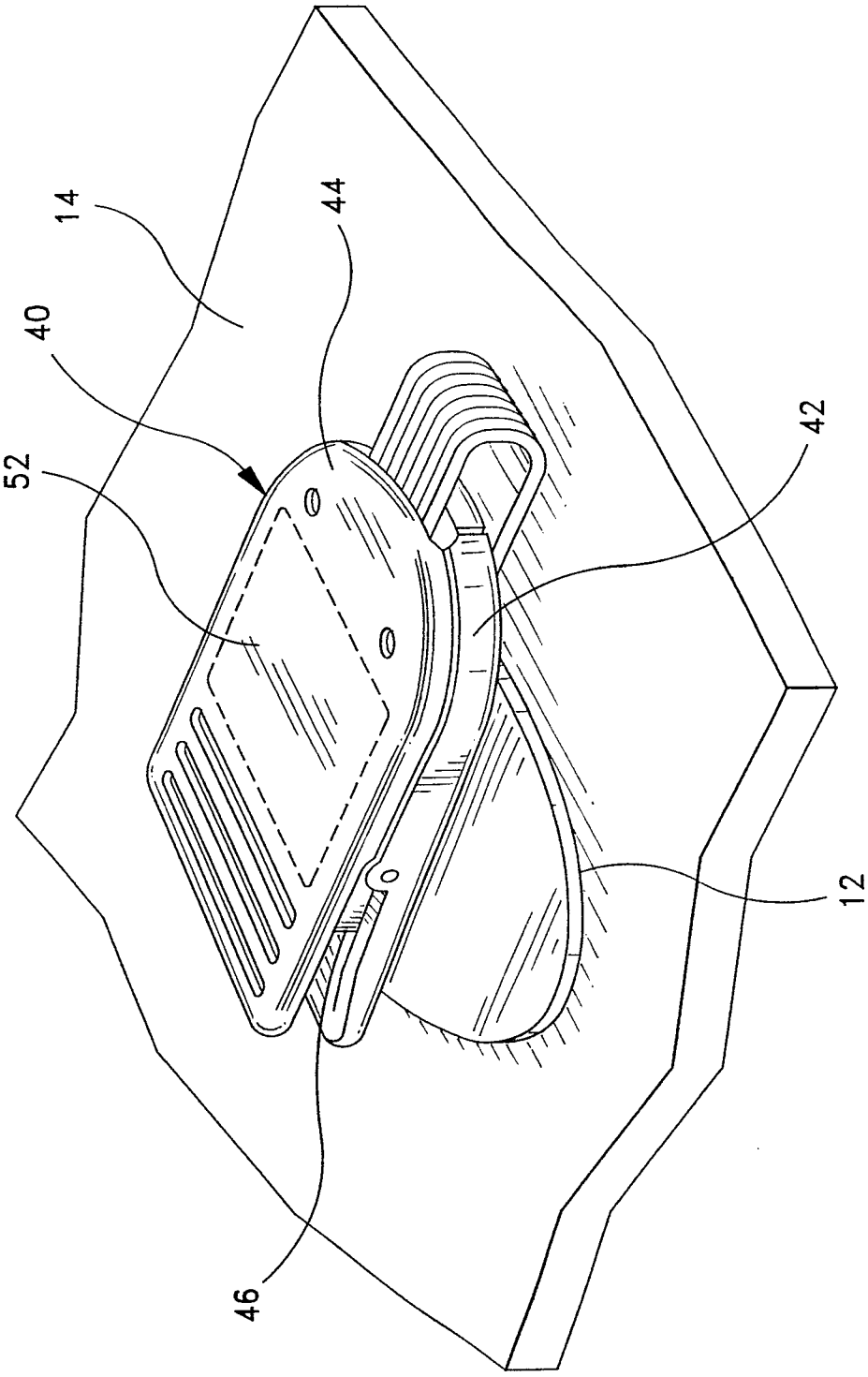
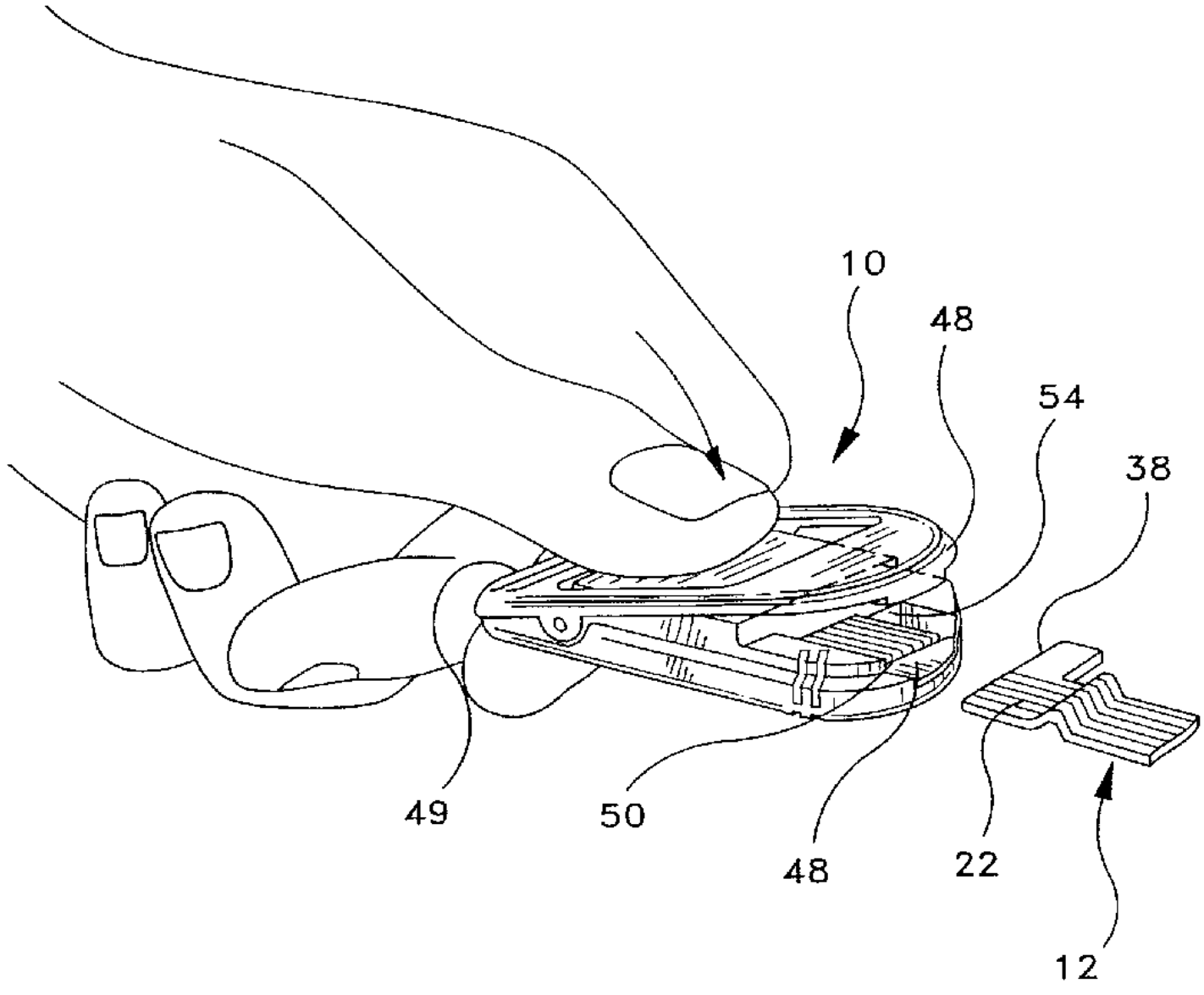


FIG-5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