United States Patent

Reeves

[15] **3,677,268**

[45] **July 18, 1972**

[54] IONTOPHORESIS ELECTRODE

[72] Inventor: **Richard A. Reeves,** Creve Coeur, Mo.

[73] Assignee: **Sherwood Medical Industries Inc.**

[22] Filed: **Nov. 28, 1969**

[21] Appl. No.: **880,767**

[52] **U.S. Cl.** **128/172.1,** 128/417

[51] **Int. Cl.** **A61n 3/06**

[58] **Field of Search** ..... 128/172.1, 405, 406, 411, 417, 128/418, 2.06 E, 2.1 E, DIG. 4, 404, 416

[56] **References Cited**

UNITED STATES PATENTS

1,573,116	2/1926	Kobayashi	128/172.1
1,585,104	5/1926	Montgomery	128/172.1
3,474,775	10/1969	Johnson	128/417 X
3,151,619	10/1964	Sullivan	128/417
2,318,207	5/1943	Ellis	128/411
3,492,216	1/1970	Riseman	128/2.1 E X

Primary Examiner—Dalton L. Truluck

Assistant Examiner—G. F. Dunne

Attorney—Donald S. Olexa, Jerome M. Teplitz, John G. Heimovics, William G. Lawler, Jr. and Hofgren, Wegner, Allen, Stellman and McCord

[57] **ABSTRACT**

A self-contained iontophoresis electrode, disposable after use on a patient, is prefilled with an inducing iontophoresis liquid completely contained within a chamber covered by a filter cover. A protective cover, impenetrable to liquids and to light energy, seals the filter cover and is removable when the electrode is to be used.

8 Claims, 3 Drawing Figures

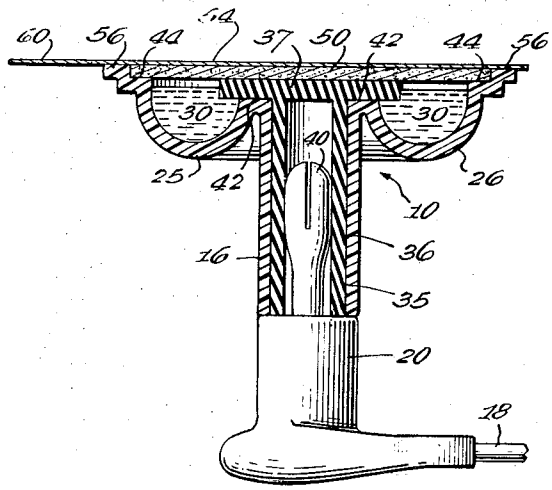


Fig. 1

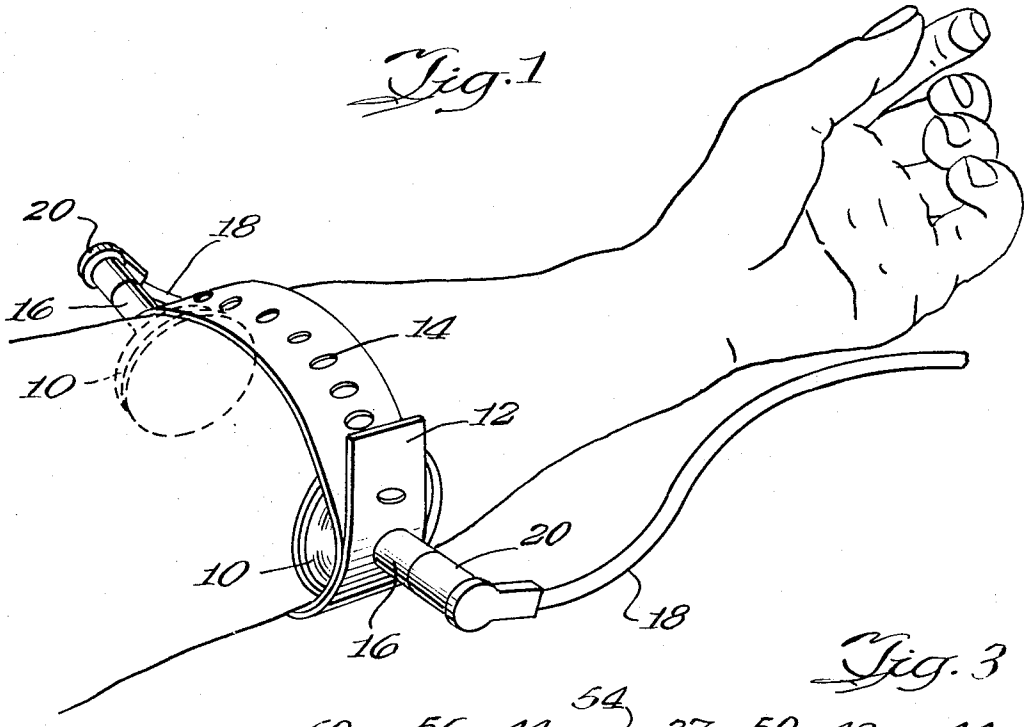


Fig. 2

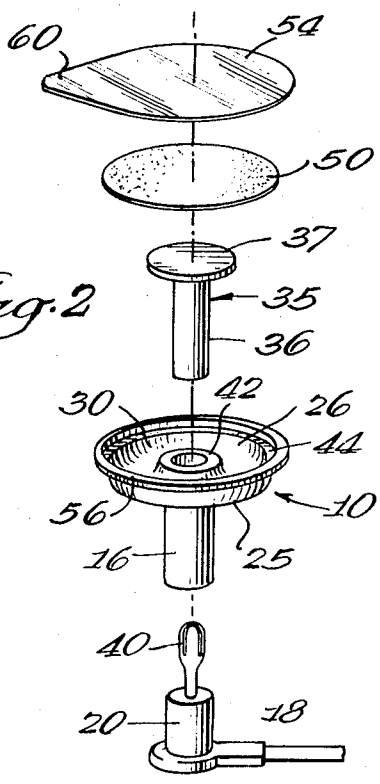
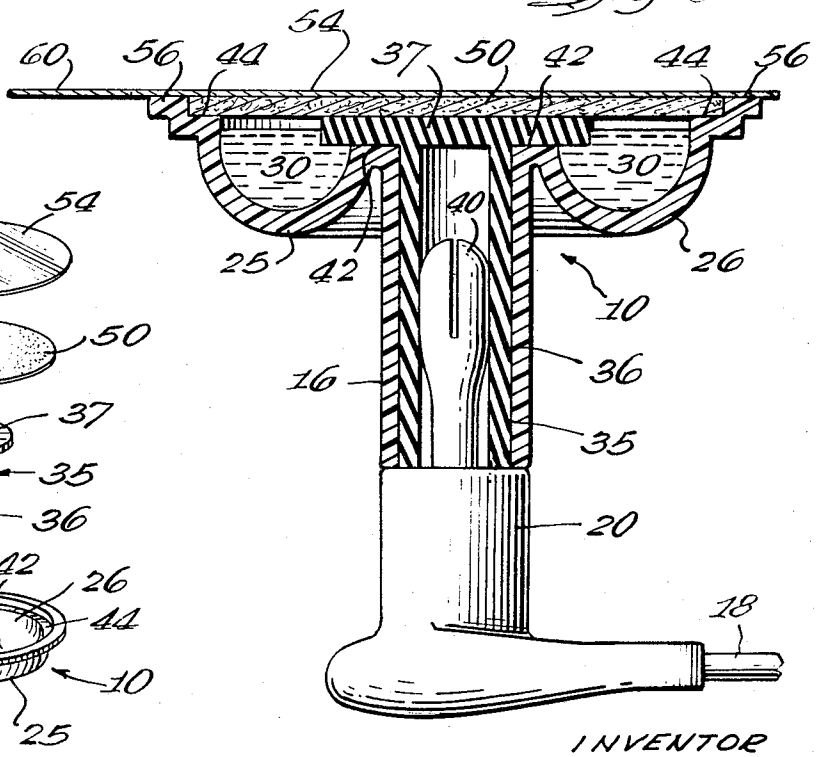


Fig. 3



INVENTOR

Richard A. Reeves

BY Jerome M. Teplitz

ATTORNEY

IONTOPHORESIS ELECTRODE

This invention relates to a self-contained iontophoresis electrode, and more particularly to a iontophoresis electrode which is prefilled with liquid and is disposable after use on a patient.

Iontophoresis is a medical technique for introducing drugs through intact skin. In the detection of cystic fibrosis in children, it is known that the great majority of children suffering with cystic fibrosis have an abnormally high concentration of sodium chloride in their sweat. An effective means of detecting such disease is to collect sweat produced by pilocarpine iontophoresis, and analyze the sweat for chloride ion concentration by using various standard methods including conductivity of the sweat sample.

Localized sweating may be induced by using iontophoresis electrodes. Such electrodes typically include a recessed area covered by filter paper held by a retaining ring. An opening through the housing of the electrode allows a technician to fill the recessed area with liquids which induce iontophoresis. For example, the technician may fill one electrode with 0.5 percent solution of pilocarpine nitrate, and the second electrode with 1 percent solution of sodium nitrate. These electrodes are strapped in contact with a patient's skin, conveniently to an arm or leg, and electrical conductors are connected to the electrodes, connecting the pilocarpine nitrate electrode to positive DC voltage and the sodium nitrate electrode to negative DC voltage. After a short time period, the electrodes are removed from the patient's skin. The skin area into which pilocarpine has been induced will now produce localized sweating, allowing the sweat to be collected in order to be analyzed by standard methods.

After removing the electrodes from the patient, the technician must disassemble the electrodes, discard the filter covers, and may clean the electrodes. When another patient is to be tested, new filter covers must be placed on the electrodes, and the electrodes must be again filled with the proper solutions. This procedure is both time consuming and subject to contamination and error, such as filling of the electrodes with the wrong solutions.

In accordance with the present invention, an improved iontophoresis electrode is provided which is completely self-contained, i.e., is prefilled with the liquids which induce iontophoresis. To use, the technician merely tears off a protective cover and straps the electrode to the patient. The electrode includes improved structure for effectuating pilocarpine utilizing iontophoresis. After use, the electrode is discarded, resulting in substantial savings in the technician's time and elimination of the problems of contamination.

One object of this invention is the provision of a self-contained iontophoresis electrode which includes all component parts and liquids for effectuating iontophoresis when connected to an external voltage source.

One feature of this invention is the provision of a self-contained iontophoresis electrode which is prefilled with a liquid for inducing iontophoresis, and includes a liquid penetrable cover for applying the liquid to the skin of a patient and a protective cover impenetrable by the liquid for sealing the electrode until use.

Another feature of this invention is the provision of a self-contained iontophoresis electrode having a completely enclosed chamber defined by a housing and a penetrable cover. The housing includes an electrically conductive element, surrounded by electrically insulated material, for connecting the liquid to an external DC voltage source.

Yet another feature of this invention is the provision of a disposable iontophoresis electrode which is prefilled with nitrate solution. The electrode includes a detachable protective cover impenetrable to liquids and impenetrable to light energy.

Further features and advantages of the invention will be apparent from the following description and from the drawings, in which:

FIG. 1 is a perspective view of a pair of iontophoresis electrodes strapped to the arm of a patient;

FIG. 2 is an exploded view of one of the iontophoresis electrodes of FIG. 1; and

FIG. 3 is a cross-sectional view of the iontophoresis electrode of FIG. 2, with the electrical connector being shown by a plane view.

While an illustrative embodiment of the invention is shown in the drawings and will be described in detail herein, the invention is susceptible of embodiment in many different forms and it should be understood that the present disclosure is to be considered as an exemplification of the principles of the invention and is not intended to limit the invention to the embodiment illustrated. The scope of the invention will be pointed out in the appended claims.

Turning to FIG. 1, a pair of iontophoresis electrodes **10** in accordance with the present invention are held in place on a patient's arm by a perforated rubber strap **12**, having perforations **14** of a size sufficient to allow insertion therethrough of a neck portion **16** of the electrodes **10**. Although the electrodes are illustrated as being strapped to the patient's arm, it will be understood that they can just as easily be attached to another portion of the patient's body, as for example, to a leg. As will appear, a protective cover has already been removed from the prefilled electrodes. After the electrodes are strapped to opposite sides of the patient's arm, connection is made to a source of DC voltage (not illustrated) by means of electrical conductors **18** which terminate in male plugs **20** insertable into an electrical receptacle within each neck **16**.

The electrode **10** illustrated in full view in the foreground is filled with 0.5 percent solution of pilocarpine nitrate, and is placed conveniently against the flexon portion of the patient's forearm. This electrode is connected by plug **20** and its associated conductor **18** to positive DC voltage. The other electrode, shown partly in dashed lines, is filled with a 1 percent solution of sodium nitrate, and is placed on the opposite side of the patient's arm. It is connected by its plug **20** and associated conductor **18** to negative DC voltage. The DC voltage may be provided from any suitable source. By way of example, the DC voltage source may take the form shown in a copending application of Donald A. Ninke and James F. La Hay, entitled "Iontophoresis and Conductivity Analysis Circuit" filed on even date herewith, Ser. No. 880,807 and assigned to the assignee of the present application.

After about 5 minutes of iontophoresis, the plugs **20** may be removed from electrodes **10** and the strap and electrodes removed from the patient's arm. The electrodes **10** are now discarded, eliminating problems of contamination and cleaning. When using the iontophoresis technique for the detection of cystic fibrosis, the forearm of the patient is then washed with distilled water and wiped dry, after which a sweat collecting cup is placed over the forearm where the electrode **10** containing pilocarpine nitrate was located.

After about a 25 minute time period, the sweat collecting cup is removed and the contents analyzed for sodium chloride, in order to detect by known methods for the presence of cystic fibrosis in a patient. By way of example, the sweat collecting cup may include an electrode for direct connection with a cystic fibrosis analyzer. Such a combination cup and electrode is shown in the copending application of James F. La Hay, entitled "Collection and Measuring Electrode", filed on even date herewith, Ser. No. 880,810 and assigned to the assignee of the present application. The ion content of the sweat may then be analyzed by the previously identified circuit of Ninke and La Hay.

The pair of electrodes **10** are identical except for the solution with which each is filled. The structure of each electrode **10** is illustrated in detail in FIG. **2** and **3**. A thin walled, electrically insulated housing **25**, formed from plastic, includes a generally cup-shaped portion **26** with an integral elongated neck portion **16** extending outwardly therefrom. The centrally located neck **16** is hollow as seen in FIG. **3**. Cup portion **26** includes an arcuate chamber **30** bounded by a generally semicircular trough surface, with an opening only along the upper termination of the trough.

For making electrical connection with chamber **30**, a conductive insert **35** is press fit through the hollow center of neck **16** in liquid-tight sealing engagement therewith. Insert **35**, which may be formed of electrically conductive plastic or other electrically conductive material, consists of a hollow tubular neck **36** which terminates in a flat, enlarged head **37**. As seen in FIG. **3**, the hollow interior of neck **36** forms the female receptacle for electrical plug **20**, and is of a size adapted to receive a compressible pin **40** of plug **20**. Pin **40** is electrically connected through plug **20** to conductor **18**. Head **37** seats on a flat ridge **42** which connects trough **26** with neck **16**. Insert **35** further encloses chamber **30**, so that the only fluid opening is confined to a space between the top portion of head **37** and a shoulder **44** on the trough surface.

The fluid penetrable opening of chamber **30** is enclosed by a disk cover **50** which is absorbent to the liquid within the chamber. Such cover **50** may take the form of filter paper which is saturable by liquid. The disk **50** seats against shoulder **44** and rests on the upper plane of head **37**, thus completely enclosing chamber **30**.

The liquid or fluid solution which is to cause iontophoresis is placed within chamber **30** before disk **50** is seated in place. As previously described, one of the pair of electrodes is filled with a 0.5 percent solution of pilocarpine nitrate, and the other electrode is filled with a 1 percent solution of sodium nitrate. Desirably, housing **25** is color coded so as to identify the solution contained within the chamber **30**. This color coding may correspond to a color coding on plug **20** and conductor **18**, in order that a technician may readily identify the correct manner to connect the electrodes to the DC voltage source.

After disk **50** is seated against shoulder **44**, a second cover **54** is placed over disk **50** and sealed around its circumference to the flat circular edge **56** of housing **25**. Cover **54** is impenetrable to fluid and further is substantially impenetrable to light energy, because solutions used for iontophoresis are typically light sensitive. Protective cover **54**, preferably a flexible foil formed by an aluminum metal, paper, polyethylene composite, is welded to edge **56** of the plastic housing **25**. The welding allows cover **54** to be peeled off edge **56** when the electrode is to be used, thereby exposing the filter cover **50** which is placed against the patient's arm. For ease in removing cover **54**, it may include a tab **60** which is not welded to housing **25** and extends beyond the circumference of edge **56**, in order to allow a technician to easily grasp the cover **54** and peel or tear it off the housing.

The above construction allows protective cover **54** to be removed without disrupting filter cover **50** from its engagement with the housing **25**. As seen best in FIG. **3**, the thickness of filter cover **50** substantially corresponds to the distance between shoulder **44** and the plane of edge **56**. This causes the exposed plane of filter cover **50** to coincide with the plane of edge **56**, allowing the electrode to be placed flat against the skin of the patient.

The electrode **10** is disposable after a single use on a patient. Because the electrode is prefilled with the nitrate solution, the technician performing the analysis does not have to handle chemicals nor fill and clean electrodes. The protective cover **54** prevents evaporation of the solution, and further protects the solution from light energy. Because the electrodes are sealed and used only once, contamination problems are reduced.

Although the electrode of the present invention has been described with particular reference to its use in pilocarpine nitrate iontophoresis, it will be understood that drugs other than pilocarpine nitrate may be used in the electrode and introduced through a patient's skin by iontophoresis in a manner similar to that described above. Moreover, the electrode of the present invention has use in applications other than iontophoresis. For example, when filled with an electrolytic fluid and held in contact with a patient's skin as described above, thereby establishing electrical connection between the patient's skin and the fluid, the electrode of this invention may be used in obtaining galvanic skin response measurements, electrocardiograms, electrooccuiograms, and various other biological voltage measurements requiring electrical contact to be made with a patient's skin.

I claim:

1. A prefilled, disposable iontophoresis electrode, comprising:

housing means including a hollow neck portion and a partial chamber portion spaced radially surrounding said hollow neck portion;

electrically conductive means extending through said hollow neck portion and into the partial chamber portion to allow external electrical connection to the partial chamber portion, said partial chamber portion and said conductive means forming a fluid impenetrable chamber with a fluid opening being the sole fluid passageway for said chamber;

first cover means completely enclosing said fluid impenetrable chamber along said fluid opening to completely contain therein an iontophoresis fluid for inducing iontophoresis on the skin of a patient, said first cover means being absorbent to said iontophoresis fluid to allow iontophoresis when said first cover means is placed against the skin of the patient and electrical connection is made to said electrically conductive means; and

second cover means impenetrable by said iontophoresis fluid for sealing said first cover means, including means attaching said second cover means to said housing for removal therefrom without disrupting said first cover means.

2. The electrode of claim **1** wherein said fluid is light sensitive, said second cover means comprising a material for preventing penetration of light energy therethrough.

3. The electrode of claim **1** wherein said second cover means comprises a material containing metal, said second cover means being welded to said housing around its periphery.

4. The iontophoresis electrode of claim **3** wherein said housing means includes a shoulder located on a different plane than the plane of the periphery to which said second cover means is welded, said first cover means being formed by filter paper of a thickness substantially corresponding to the distance between the plane of said shoulder and the plane of said periphery, said filter paper being seated against said shoulder, whereby the engagement of the filter paper with the shoulder is not disrupted when the weld of said second cover means to the housing means is broken.

5. The self-contained electrode of claim **9** in which said electrically insulated housing means includes an integral hollow neck portion contiguous with and spaced from the chamber portion defined by the housing means, the conductive neck of said electrically conductive means being contained within said hollow neck portion in liquid-tight sealing engagement therewith and extending into contact with the chamber.

6. The self-contained electrode of claim **5** wherein the conductive neck of said electrically conductive means has a hollow center defining a receptacle for an electrical plug, the electrical plug being inserted within said receptacle to allow external electrical connection to the fluid, and the electrical plug being removable from the receptacle in order to allow the electrode to be discarded after use on a subject.

7. The self-contained electrode of claim **6** wherein said electrically conductive means is formed of an electrically conductive plastic material.

8. The iontophoresis electrode of claim **1** wherein said second cover means includes a tab extending beyond the periphery of said housing, whereby said tab may be lifted to break the attaching means holding said second cover means to said housing.

* * * * *

PO-1050
(5/69)

UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,677,268 Dated July 18, 1972

Inventor(s) Richard A. Reeves

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

In the Claims: Cancel claims 5, 6 and 7.

On the title page, "8 Claims" should read -- 5 Claims --.

Column 4, line 67, "8." should read -- 5. --.

Signed and sealed this 20th day of March 1973.

(SEAL)
Attest:

EDWARD M.FLETCHER,JR.
Attesting Officer

ROBERT GOTTSCHALK
Commissioner of Patents