

United States Patent

Patrick, Jr. et al.

[15] 3,701,346

[45] Oct. 31, 1972

[54] MEDICAL ELECTRODE

[72] Inventors: Charles T. Patrick, Jr.; Roman Szpur, both of Dayton, Ohio

[73] Assignee: Bionetics Inc., Dayton, Ohio

[22] Filed: Jan. 4, 1971

[21] Appl. No.: 103,498

[52] U.S. Cl.: 128/2.06 E, 128/2.1 E, 128/417, 128/DIG. 4, 206/63.2 R

[51] Int. Cl.: A61b 5/04

[58] Field of Search: 128/2.06 E, 2.1 E, 404, 417, 128/418, DIG. 4; 206/63.2 R

[56] References Cited

UNITED STATES PATENTS

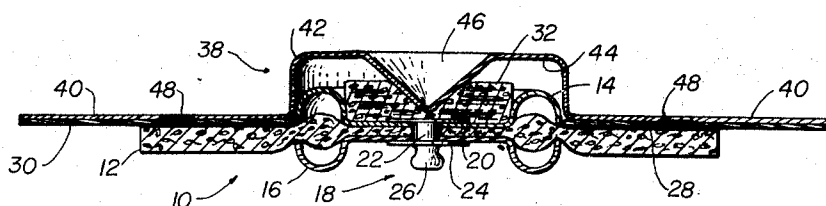
3,187,745	6/1965	Baum et al.	128/2.06 E
2,782,786	2/1957	Krasno	128/417
3,170,459	2/1963	Phipps et al.	128/2.06 E
3,085,577	4/1963	Berman et al.	128/418

Primary Examiner—William E. Kamm
Attorney—H. Talman Dybvig

[57] ABSTRACT

An electrode for attachment to the skin includes a pad of foamed material soaked with electrode jelly positioned in a low profile cup member and engaging an electrical conductor at the base of the cup member. Because the pad is wetted by the jelly, it adheres to the cup member and conductor. The cup member and soaked pad are protected by a cover, a projecting portion of which engages and holds the pad in the cup member. The area of the projecting portion engaging the pad has a relatively small area in comparison to the area of the pad engaging the cup member base and conductor. The pad therefore has comparatively little adhesion to the projecting portion and the cover can be removed from the electrode without pulling the pad away from the cup member.

9 Claims, 5 Drawing Figures



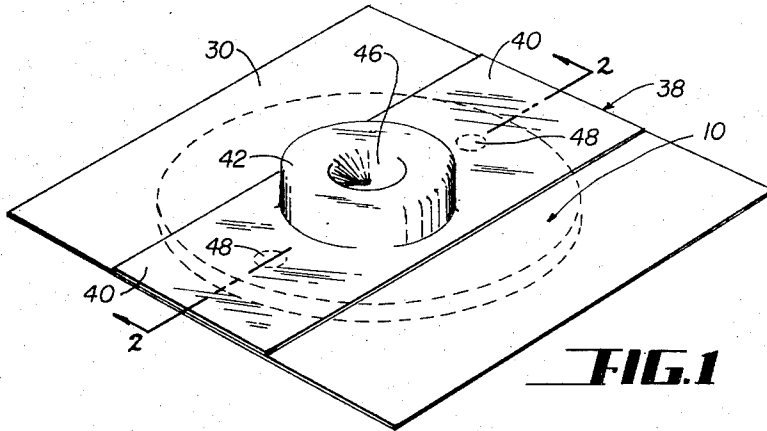


FIG. 1

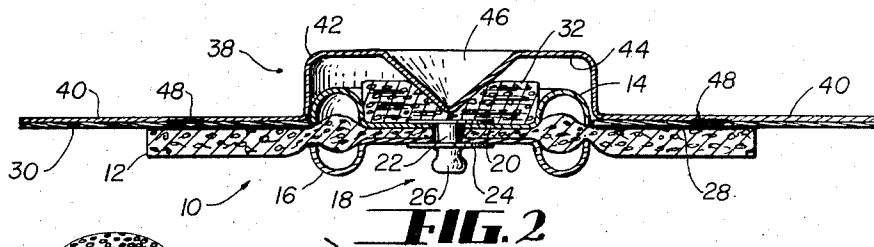


FIG. 2

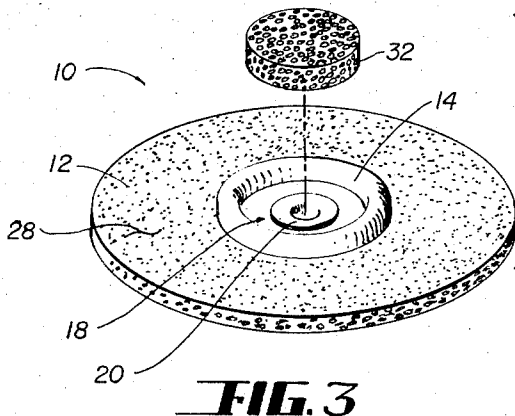


FIG. 3

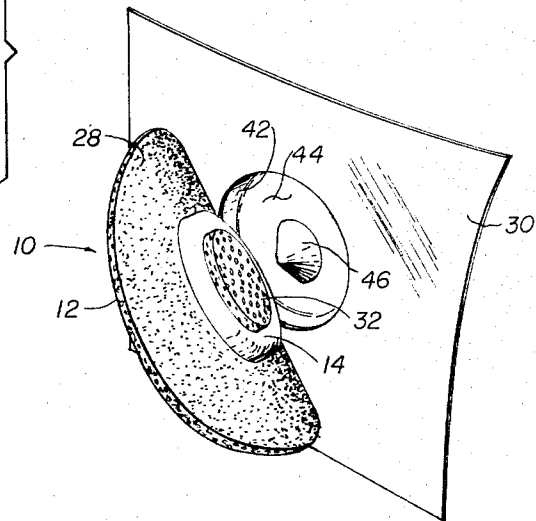


FIG. 4

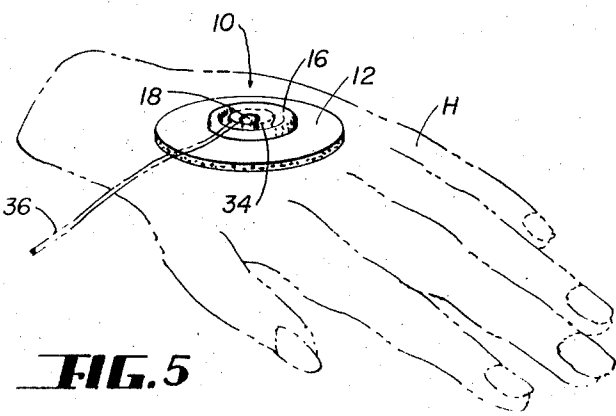


FIG. 5

INVENTOR,
ROMAN SZPUR
CHARLES T. PATRICK JR.
BY *Lybryg and Lybryg*
THEIR ATTORNEYS

MEDICAL ELECTRODE

BACKGROUND OF THE INVENTION

This invention relates to medical electrodes of the type used to detect signals from the skin of a living subject and more particularly to a disposable medical electrode which can be placed in immediate use for emergency and other purposes.

In the application of Roman Szpur, Ser. No. 11,208, filed in the United States Patent Office on Feb. 13, 1970, a disposable medical electrode is disclosed having a low profile cup member held by a conductive snap fastener to an elastic, foamed plastic sheet. In use, the sheet is applied to the skin with the aid of a pressure-sensitive adhesive surrounding the cup member. Because the sheet is elastic, the cup member is held firmly against the skin to seal an electrolyte within the cup member. The snap fastener is positioned remote from the skin to minimize motion artifacts or noise. One embodiment of the electrode shown in the aforementioned application Ser. No. 11,208 includes electrode gel or paste loaded in the cup member and covered by a protective member which would be removed prior to use. It has been found that such an arrangement is undesirable because of the difficulties in sealingly confining a sufficient quantity of electrode gel or paste in the cup member.

Other electrodes have been proposed or used wherein the skin and the conductive member are spaced by a gap filled with foamed material loaded or soaked with an electrolyte. Immediately prior to use, an electrolyte in the form of a conductive paste is embedded in a piece of foamed material, this piece being then inserted into contact with the conductor portion of the electrode. Such a device is shown in the Phipps et al. U.S. Pat. No. 3,170,459.

Edmark U.S. Pat. No. 3,487,827 shows a snap fastener type electrode provided with a removable plastic bubble containing electrode jelly. In preparation for use, the bubble is squeezed and then removed along with a backing paper. The squeezing of the bubble causes the jelly to be smeared over a non-conductive screen and a conductive plate located behind the screen.

SUMMARY OF THE INVENTION

All of the known prior devices require special preparation immediately prior to use and the need still exists for a simple, inexpensive and thus disposable electrode which can be used without special preparation. It is the primary object of this invention to provide such an electrode.

More specifically, it is an object of this invention to provide an electrode having the advantages of the electrode shown in the aforementioned Szpur application, Ser. No. 11,208, which is readied for use merely by peeling away a protective covering, such an electrode being as easy to use as well known types of first aid bandage strips. To this end, a low profile medical electrode is provided by this invention with a foamed pad soaked or loaded with an electrode jelly, the pad being positioned within a cup member and, when in use, substantially filling the chamber formed between the skin and the base of the cup member. This assembly is packaged together and a protective covering is provided for the cup member and the soaked pad.

A simple protective cover sheet for the cup member and the pad is unsatisfactory because the moistness of the soaked pad would cause it to adhere to both the cup member and the protective cover sheet. In view of the fact that the cup member has a very low profile (low height in relation to its diameter) the area of contact of the pad with the cup member is not significantly greater than the area of the exposed surface of the pad. Therefore, if a cover sheet is provided engaging the pad over substantially all of its exposed surface, the pad would frequently be peeled away with the protective covering. Of course, such an event would be quite undesirable, especially in emergency situations.

In accordance with this invention, the only portion of the protective covering engaging the pad is a projection located generally over the center of the pad and spaced from the base of the cup member appropriately to hold the pad against the base. The projection is formed so that the area of contact between the projection and the soaked pad is considerably smaller than the area of contact between the pad and the cup member. Accordingly, the adhesion between the jelly filled pad and the cup member is inherently greater than the adhesion between the pad and the protective covering. Therefore, the protective covering may be removed simply by peeling it away from the electrode without accidentally removing the pad.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is a perspective view of the underside of an electrode provided with a protective covering made in accordance with this invention.

FIG. 2 is a cross sectional view of the electrode and protective covering taken along 2—1 of FIG. 1.

FIG. 3 is a partially exploded perspective view of the underside of the electrode with the protective covering removed.

FIG. 4 is a perspective view illustrating the manner in which the protective covering is peeled from the electrode.

FIG. 5 is a perspective view of the electrode shown applied to the hand of a subject.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The drawing illustrates an electrode, generally designated 10, consisting of a circular elastic pad or sheet 12 overlying a centrally located, inverted cup member 14 and sandwiched between a clamp plate 16 located on top of the sheet 12 which is of the same form and in alignment with the inverted cup member 14. The inverted cup member 14 is in the form of a cavity washer having a circular flat base with a semi-circular or U-shaped annular flange. The diameter of the cup member 14 is substantially greater than its height. These parts are held together by a metallic conductor formed from a male snap fastener member, generally designated 18, and which includes a lower, circular plate portion 20, from the center of which a hollow stud 22 projects upwardly, and an upper plate portion 24 having an upwardly protruding hollow socket portion 26 receiving the stud 22.

The parts are assembled and held together by centrally locating and aligning the cup member 14 and the clamp plate 16 on opposite sides of the sheet 12. The

stud 22 is then inserted through aligned apertures in the centers of the sheet 12 and the members 14 and 16 and into the socket 26. The pressing together of the snap fastener portions causes the upper end of the stud 22 to fold inwardly and its side walls to collapse outwardly whereupon the snap fastener parts are tightly wedged together.

The bottom surface of the sheet 12 has a commercially available, medical grade acrylic pressure sensitive adhesive coating 28. Until the electrode 10 is to be used, the adhesive coating 28 is covered by a protective paper sheet 30 having a release coating on its face which engages the adhesive coating 28.

The sheet 12 is preferably formed of a foamed plastic, such as polyvinyl chloride, which provides for adequate aeration or ventilation of the skin. Such a sheet is quite flexible, readily conforming to skin contours and permitting free movement of the skin to which it is applied. The cup member 14 may be vacuum formed from a thermoplastic sheet material which is slightly flexible but sufficiently rigid to prevent its collapse. A variety of plastic materials may be used to form the cup member 14, examples being vinyl, linear polyethylene, and cellulose acetate butyrate.

The parts as thus far described may be identical to the electrode shown in the aforementioned Szpur application, Ser. No. 11,208. As therein described, the electrode has numerous advantages resulting primarily from its low profile and from the fact that the elastic sheet 12, when applied to the skin, maintains a resiliently applied pressure between the skin and the rim of the cup member 14. Although the electrode 10 has a low profile rendering it useful over extended periods without interfering with the patient's movements, a spacing is invariably maintained between the patient's skin and the conductive plate portion 20. Persons to which the electrode 10 is applied do not experience any unusual discomfort because of the U-shaped configuration of the cup member flange. However, the cup member flange does cooperate with the surrounding adhesively coated sheet 12 to cause a circular depression in the skin and the skin will bulge slightly into the cup member cavity. Artifacts are kept to a minimum because a substantially uniform spacing is maintained at all times between the area of the skin contacted by the electrolyte and the conductive plate portion 20 of the snap fastener 18.

In accordance with this invention, the electrolyte is preassembled with the electrode 10 by soaking a disc-shaped pad 32 of non-conductive, open-cell material with an electrode jelly. The pad 32 preferably has a diameter substantially equal to the diameter of the base of the cup member 14 and a thickness greater than the depth of the cup member 14. It is sufficiently heavily laden with electrode jelly that, when the electrode 10 is pressed on the skin, the jelly fills the entire volume of the cavity between the skin and the conductive plate portion 20 whereupon good electrical contact between the skin and the conductor plate portion 20 through the jelly is assured.

The pad 32 may be manufactured from open-cell polyurethane foam material although other cellular materials would be suitable. The electrode jelly may be of an entirely conventional formulation which, as those familiar with the art will understand, is formulated to

make good electrical contact with the skin and which, provided that the plate member 20 comprises or is plated with silver or another suitable metal, will make good contact therewith. The pad 32 may be soaked with the jelly by immersing it in a quantity of jelly, squeezing it under pressure and then gradually releasing the pressure before removing it from the jelly in the same manner that one would load a sponge with water. Of course it could be soaked with jelly by other methods.

Since wetted by the jelly, the soaked pad 32 tends to adhere to the conductive plate portion 20 and the base of the cup member 14. The adhesion is sufficient that the soaked pad 32 may simply be placed into position on the conductive plate portion 20 and the cup member 14 without the use of additional adhesives. When so placed, the electrode 10 is ready for use.

In FIG. 5 the electrode 10 is shown adhered to the hand H with a female snap fastener member indicated by phantom lines 34 snap connected to the male snap fastener member 18. Since the pad 32 is preferably thicker than the depth of the cup member 14, it is compressed when the electrode 10 is applied to the skin. Accordingly, the pad 32 is tightly confined against movement in the cup member 14 and artifacts which would result from movements of the pad 32 are avoided. Additionally the compressing of the pad 32 desirably assists in causing the electrode jelly to thoroughly coat the entire area of the skin surrounded by the cup member flange and insures that a complete electrical path is provided by the jelly from the skin to the conductive plate portion 20. The electrical path is completed through the interconnected snap fastener members 18 and 34 and thence to a conductive lead shown by phantom lines 36. Electrical signals from the skin are carried by the lead 36 to an amplifier and sensing apparatus (not shown).

Further in accordance with this invention, a protective cover 38 is provided for the cup member 14 and the jelly soaked pad 32 so that the electrode 10 may be stored ready for immediate use. With reference to FIGS. 1 and 2, the cover 38 comprises an essentially flat strip of non-conductive plastic sheet having coplanar flat ends 40 and a raised center portion 42 formed as a cylinder, the inner diameter of which is substantially the same as the outer diameter of the cup member 14. The height of the cylindrical center portion 42 is greater than the combined height of the cup member 14 and the pad 32 whereupon the inside base surface, designated 44, of the center portion 42 is spaced from the pad 32. However, the base of the center portion 42 has a centrally located, inwardly directed conical projection 46, the lowermost end of which is spaced from the plane of the flat ends 40 by considerably less than the thickness of the pad 32. For reasons discussed below, the projection 46 is so designed that, when the parts are assembled, the area of contact between the projection 46 and the pad 32 is considerably less than the combined area of contact between the pad 32 and the conductive plate portion 20 and the base of the cup member 14.

The cover 38 is assembled on the back face of the sheet 30 with the cylindrical center section 42 slipped over the cup member 14 and secured to the sheet 30 as by adhesive tacking 48. The protective cover 38 serves

not only to prevent soiling of the pad 32 but also, because the conical projection 46 engages the pad 32, it holds the pad 32 firmly in the cup member 14 and against the conductive plate portion 20. When the electrode 10 is to be used, the protective sheet 30 is merely peeled away from the sheet 12, taking with it the protective cover 38, in the manner shown in FIG. 4. There it will be noted that the cellular pad 32 has, due to its elasticity, returned to its original disc shape.

Importantly, it will also be noted in FIG. 4 that the pad 32 remains nestled in the cup member 14 and is not peeled away with the cover 38 because, as mentioned above, the area of contact and, hence, the adhesion between the projection 46 and the soaked pad 32 is less than that between the pad 32, the conductive plate portion 20 and the cup member 14.

The protective cover 38 is desirably sufficiently flexible that it will naturally follow along with the sheet 30 as the sheet 30 is removed from the sheet 12. However, it should also have a self-supporting shape so that its center section 42 will not collapse when stored, thereby causing an undesirably large area of contact with the pad 32. As apparent a variety of plastic materials could be used for this purpose. Polyvinyl butyrate vacuum-formed to the illustrated shape has been found satisfactory.

After the electrode and protective covering have been assembled they may be stored for indefinite periods of time until needed. However, to avoid an undesirable collection of moisture within the chamber formed between the cup member 14 and the center section 42 of the protective cover 38, and also to avoid dehydration of the electrode jelly, the assembled electrode 10 and coverings 30, 38 are preferably packaged in a suitable air and watertight envelope.

The dimensions of the electrode 10 are not critical but a model made in accordance with this invention has been successfully tested with both the cup member 14 and the clamp member 16 having a depth on the order of 0.094 inch assembled on an elastic sheet 12 having a thickness of 0.125 inch. The overall height of the assembled electrode 10 is on the order of only 0.3 inch. The diameter of the cup member and, accordingly, the clamp member was approximately 0.875 inch, the diameter of the cup member base being approximately 0.5 inch and the snap fastener plate portion 20 having a diameter of 0.4 inch. The diameter of the plastic sheet is preferably on the order of two to three times the diameter of the cup member 14 to provide a broad area for skin contact by the pressure sensitive adhesive 28, whereupon the electrode 10 is held fast to the skin.

The diameter of the pad 32 is preferably the same as the diameter of the cup member base, that is, 0.5 inch in the model discussed above. Its thickness is not critical and will depend in part upon the nature of the pad material and especially whether or not it is a relatively open or relatively closed cell material. In any event the pad 32 should be as thick as the depth of the cup member so that the skin bulging into the cup member will in all cases compress the pad 32 to prevent motion artifacts. It presently is believed that the pad 32 should be on the order of one-half again as thick as the depth of the cup member 14 so that its compression results in a positive pressure on the pad 32 against the skin and against the cup member tending to hold the pad 32 in a

fixed position. However, the pad 32 should not be so thick that the pressure overcomes the adhesive 28 and causes the rim of the cup member 14 to be displaced from the skin. Generally speaking the pad 32 may have a thickness on the order 0.1 to 0.14 inch in the model described above. The area engagement of the pad 32 by the conical projection 46 is significantly less than the diameter of the pad 32 and preferably on the order of one-half the pad diameter. The height of the raised center section 42 overlying the pad 32 need only be sufficient to avoid contact therewith; 0.2 inch is ample.

Aside from the electrolyte, the only part of the electrode 10 and the protective coverings 30, 38 made from conductive material is the snap fastener 18. Since all other parts are non-conductive, all may be made from inexpensive, readily available plastic materials. Accordingly, and for the added reason that the electrode is simple to fabricate, it may be manufactured at minimal costs.

As used in this application, the term "electrolyte" refers to pastes or jellies primarily intended to conduct electrical current at bio-potentials.

Although the presently preferred embodiment of this invention has been described, it will be understood that within the purview of this invention various changes may be made within the scope of the appended claims.

Having thus described our invention, we claim:

1. A medical electrode of the type adapted to be adhered to the skin and having means defining a cavity opening to the skin and a conductive member at the base of the cavity, wherein the improvement comprises a pad of resilient cellular material loaded with electrolyte and substantially filling said cavity, said pad having a thickness greater than the depth of said cavity whereupon said pad projects outwardly of said cavity when said electrode is stored and is compressed into said cavity when said electrode is adhered to the skin whereupon said pad is held against movement within said cavity during use of the electrode, and a removable covering for said pad when stored, said covering comprising sheet material having a raised portion overlying said pad and accommodating said greater thickness of said pad.

2. A medical electrode of the type adapted to be adhered to the skin and having means defining a cavity opening to the skin and a conductive member at the base of the cavity, wherein the improvement comprises a pad of cellular material loaded with electrolyte and substantially filling said cavity, said pad having a thickness greater than the depth of said cavity whereupon said pad is compressed when said electrode is adhered to the skin whereupon said pad is held against movement within said cavity during use of the electrode, and a removable protective covering for said pad when stored, said removable protective covering comprising sheet material having a raised portion overlying said pad, said raised portion having a projection engaging said pad for holding said pad in said cavity, the surface area of said projection engaging said pad being less than the surface area of said pad engaging said means, defining said cavity.

3. A medical electrode for use on the skin including an inverted cup member; an elastic sheet member overlying said cup member; an adhesive layer on the same side of said elastic sheet as said cup member; means

securing said elastic sheet to said cup member including an electrically conductive member projecting through the base of said cup member adapted to be electrically connected to an external electrically responsive member; a pad of cellular material soaked with electrode jelly located in and substantially filling the interior of said cup member; and a protective cover for said jelly-soaked pad comprising a plastic sheet surrounding the open end of said cup member and having a raised portion confronting said pad and spaced therefrom, and a projection extending from said raised portion into engagement with said pad for retaining said pad in said cup member.

4. The medical electrode of claim 3 wherein said pad has a thickness at least as great as the depth of said cup member.

5. The medical electrode of claim 3 wherein said pad has a thickness exceeding the depth of said cup member.

6. The medical electrode of claim 3 wherein the surface area of said projection engaging said pad is significantly less than the surface area of said pad engaging said cup member and said conductive member, whereupon the tendency of said soaked pad to adhere to said projection is less than the tendency of said pad to adhere to said cup member and said protective cover may be removed without removing said pad from said cup member.

7. The medical electrode of claim 3 further including

a cover sheet releasably secured to said adhesive layer and means securing said protective cover to said cover sheet.

8. A medical electrode for use on the skin including an inverted cup member; a flexible elastic sheet overlying and surrounding said cup member; an adhesive layer on the same side of said elastic sheet as said cup member; means securing said elastic sheet to said cup member including an electrically conductive member projecting through the base of said cup member adapted to be electrically connected to an external electrically responsive member; and a pad of resilient cellular material soaked with electrode jelly located in and substantially filling the interior of said cup member, said pad having a thickness exceeding the depth of said cup member whereby said pad is compressed between said electrically conductive member and the skin of a subject to which said elastic sheet is applied, whereby said pad is held in a substantially fixed position during use of the electrode, and a removable covering to protect said pad prior to use of said electrode, said protective covering comprising sheet material and having a raised portion overlying said pad and accommodating the thickness of said pad which exceeds the depth of said cup member.

9. The medical electrode of claim 8 wherein said raised portion has a projection engaging said pad for holding said pad in said cup member.

* * * * *

35

40

45

50

55

60

65

Disclaimer

3,701,346.—*Charles T. Patrick, Jr.*; and *Roman Szpur*, Dayton, Ohio. MEDICAL ELECTRODE. Patent dated Oct. 31, 1972. Disclaimer filed Dec. 20, 1984, by the assignee, *NDM Corp.*

Hereby enters this disclaimer to claims 1 and 8 of said patent.
[*Official Gazette March 12, 1985.*]