

- [54] **MEDICAL ELECTRODE**
[75] Inventor: **Roman Szpur**, Dayton, Ohio
[73] Assignee: **NDM Corporation**, Dayton, Ohio
[*] Notice: The portion of the term of this patent subsequent to Oct. 10, 1989, has been disclaimed.

[22] Filed: **Jan. 30, 1973**

[21] Appl. No.: **328,000**

Related U.S. Application Data

- [63] Continuation of Ser. No. 259,563, June 5, 1972, Pat. No. 3,713,435, which is a continuation of Ser. No. 11,208, Feb. 13, 1970, Pat. No. 3,696,807.

- [52] **U.S. Cl.**..... **128/2.06 E**, 128/417, 128/DIG. 4
[51] **Int. Cl.**..... **A61b 5/04**
[58] **Field of Search** 128/2.06 E, 2.1 E, 404, 128/417, 418, DIG. 4

[56] **References Cited**
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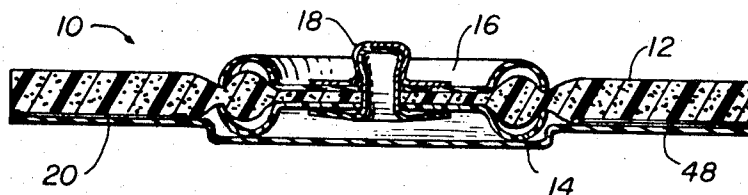
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Primary Examiner—William E. Kamm
Attorney, Agent, or Firm—Dybvig & Dybvig

[57] **ABSTRACT**

An electrode for attachment to the skin is made from an adhesively coated, elastic sheet sandwiched between a non-conducting, low profile cup member and a clamp plate fixed in assembled relation by a conductive snap fastener member extending therethrough. Both the cup member and the clamp plate are in the form of cavity washers, the confronting margins of which squeeze the sheet. In use, the cup member cooperates with the skin to form an enclosed cavity for an electrolyte. When pressed against the skin, the elastic sheet resiliently urges the cup member against the skin.

4 Claims, 4 Drawing Figures



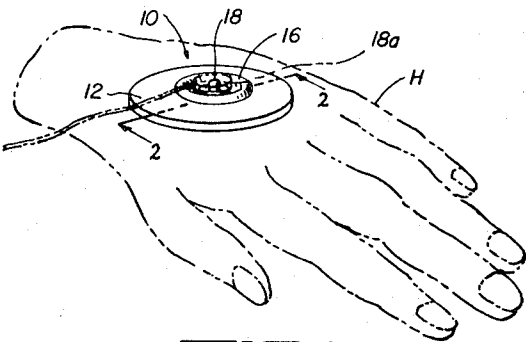


FIG. 1

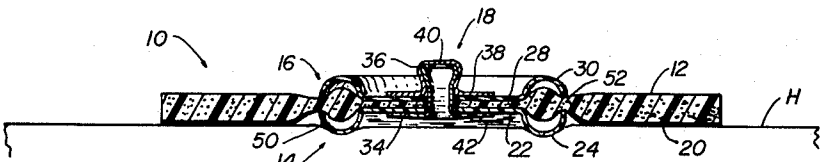


FIG. 2

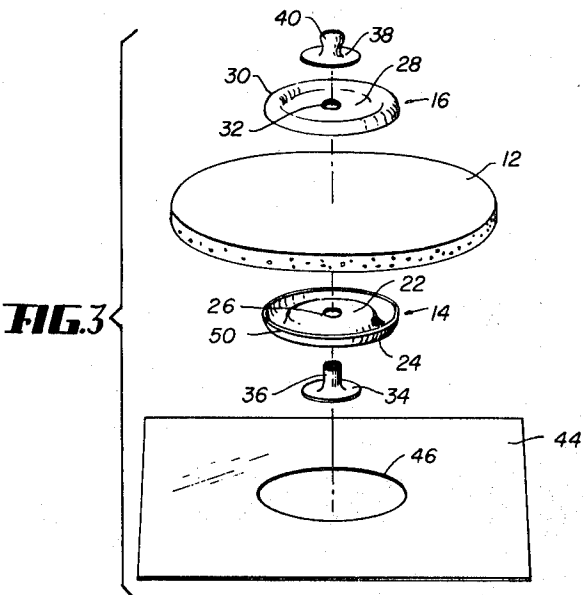


FIG. 3

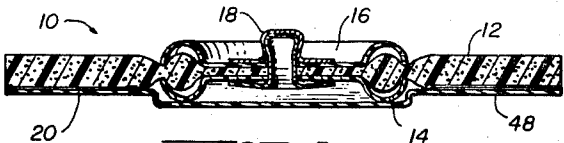


FIG. 4

MEDICAL ELECTRODE

This is a continuation of application Ser. No. 259,563 filed June 5, 1972, now U.S. Pat. No. 3,713,435 which is a continuation of application Ser. No. 11,208 filed Feb. 13, 1970, now U.S. Pat. No. 3,696,807.

BACKGROUND OF THE INVENTION

This invention relates to medical electrodes of the type used to detect electrical signals from the skin of a living subject and more particularly to the type of such electrode which is designed for use over several days without interfering with the subject's normal activities.

The electrode of this invention is designed for use with commercially available electrolytes in the form of electrode pastes or gels. It is known that the conductor portions of such electrodes should be spaced from the skin of the subject by the electrolyte to obtain the least resistance and to minimize motion artifacts or noise. Optimum results are obtained when the volume of electrolyte and its areas of contact over the skin and the conductor portion of the electrode remain constant.

Electrodes have been made with barriers to prevent contact between the skin and their conductor portions. The barriers are provided with small apertures to be filled with an electrolyte. Although such devices may minimize artifacts, they are difficult and thus costly to construct, and the imposition of the apertured barrier undesirably reduces conduction between the skin and the conductor portion of the electrode.

Other electrodes have been made without any barrier between the skin and the electrode conductor. For the most part these have been designed to provide electrical contact with only a very small skin area. One type of electrode provides for contact over a relatively large skin area. To obtain the necessary isolation between the metal conductor and the skin, these electrodes have a relatively high profile, that is, a large height to diameter ratio. However, low profile electrodes are preferred to minimize the possibility of movement of the electrolyte, which may cause spurious signals, and to minimize the inconvenience experienced by the subjects wearing the electrodes.

SUMMARY OF THE INVENTION

The electrode of this invention is provided with a relatively rigid, non-conductive, low profile cup member having a convexly curved rim and placed in an inverted position on the skin of the subject. The cup member is effectively clamped to the skin by an overlying elastic sheet having a pressure sensitive adhesive surrounding the cup member. When attached to the skin, the elastic sheet resiliently presses the cup member against the skin to firmly hold the cup member in a fixed position. Separation of the elastic sheet from the cup member is prevented by a clamp plate positioned on top of the sheet. The conductor portion of the electrode includes a thin conductive plate located in the cavity between the cup member and the skin, the conductive plate abutting the base of the cup member. The entire cup member can be filled with an electrolyte to provide a broad area of contact over the skin.

For simplicity of construction, the conductor comprises a snap fastener member projecting through the cup member, the carrier sheet and the clamp plate to hold these parts in assembled relation. Also, the clamp

plate is preferably constructed identically to the cup member, both being similar to cavity washers. The confronting margins of the cup member and the clamp plate squeeze an annular portion of the elastic sheet thereby to assist in holding the center portion of the elastic sheet under tension when the lower surface of the elastic sheet is adhered to the skin.

The elastic sheet is desirably a sponge like material, preferably open cell polyvinylchloride, because such material may be stretched in all directions and has an elastic character. When using open cell polyvinylchloride sheet or the like it is desired that both the upper and lower surfaces have a relatively closed cell construction. A partially closed cell construction is desired on the lower surface to better form a barrier layer for receiving a pressure sensitive adhesive. The top surface is preferably closed cell because closed cell surfaces do not retain dirt as readily as open cell material. The relatively closed cell surfaces also contribute to the elasticity of the sheet which is necessary to maintain the cup member pressed against the skin. A sheet made from open cell polyvinylchloride with partially closed cell upper and lower surfaces also has the advantages of being inexpensive, soft to the touch and pleasing in appearance. Air readily passes through such material to ventilate the skin. When an electrode in accordance with this invention is adhered to the skin, even for extended periods of use, substantially the only sensation experienced by the subject is the tackiness of the adhesive.

Generally stated, it is an object of this invention to provide an improved, low-profile, inexpensive medical electrode and especially one for use over extended periods of time. Other objects and advantages will become apparent from the drawing and the following description.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is a perspective view of an electrode made in accordance with this invention shown applied to the hand of a subject;

FIG. 2 is a cross sectional view of the electrode, taken along line 2—2 of FIG. 1, applied to the skin;

FIG. 3 is an exploded perspective view of an electrode in accordance with this invention and a protective sheet for the adhesive prior to assembly of these parts; and

FIG. 4 is a cross sectional view of an electrode made in accordance with this invention with a different type of protective member.

DESCRIPTION OF THE PREFERRED EMBODIMENT

An electrode generally designated 10 made in accordance with this invention is shown secured to the hand H of a subject in FIGS. 1 and 2. The electrode 10 consists of a circular, elastic pad or sheet 12 overlying a centrally located, inverted cup member 14, a clamp plate 16 located on top of the sheet 12 in alignment with the inverted cup member 14, and a metallic conductor formed from a male snap fastener member, generally designated 18. The annular area of the lower surface of the sheet 12 in surrounding relation to the cup member 14 is provided with a pressure sensitive adhesive layer 20 for attachment of the electrode 10 to the skin. In use, electrical signals from the skin are amplified and sensed by apparatus (not shown) connected to

the snap fastener member 18 by a conductive lead and cooperating snap fastener member, shown by phantom lines 18a. The electrical path is from the skin through an electrolyte confined in a chamber or cavity 42 enclosed by the cup member 14 and the skin, and thence through the snap fastener member 18.

With reference to FIGS. 2 and 3, the cup member 14 is in the form of a cavity washer and has a circular flat base 22 surrounded by an annular flange 24 which is semicircular or U-shaped in cross section. The center of the cup base 22 is apertured as indicated at 26. The cup member 14 is electrically non-conductive and can be vacuum formed from a relatively thin sheet of a suitable thermoplastic such as vinyl, linear polyethylene, cellulose acetate butyrate, or the like.

The clamp plate 16 is also non-conductive and is preferably identically constructed to the cup member 14 and accordingly includes a circular flat base 28 with a U-shaped rim or flange 30 and has a central aperture 32. As will become apparent, the shape of the clamp plate 16 is not critical but the shape illustrated is preferred because of the savings in manufacturing costs resulting from use of the same parts for both the cup member 14 and the clamp plate 16.

The male snap fastener member 18 comprises a lower circular plate portion 34 from the center of which a hollow, open ended stud 36 is formed upwardly, and an upper plate portion 38 having an upwardly protruding, hollow socket 40. To assemble the parts forming the electrode 10, the cup member 14 and the clamp plate 16 are first centrally located and aligned on opposite sides of the sheet 12. The stud 36 is then inserted through the aperture 26, pierced through the center of the sheet 12 and then through the aperture 32 into the socket 40. The parts of the snap fastener member 18 are then pressed together whereupon the upper end of the stud 36 folds inwardly and its side walls collapse outwardly, causing the fastener member parts to be tightly wedged together. The snap fastener 18 is metal and, as well known to those skilled in the art, preferably has a coating or plating of silver or the like composition to provide a satisfactory electrical interface with the electrolyte confined in the cavity or chamber 42.

The adhesive layer 20 may be applied to the lower surface of the sheet 12 either before or after assembly. After the parts are assembled and the adhesive layer 20 applied, a protective waxed paper sheet 44 having a central cutout 46 for the cup member 14 is applied to the bottom of the sheet 12. The electrode 10 with the protective sheet 44 may then be stored until ready for use. An alternative arrangement is shown in FIG. 4 wherein the cup member 14 is loaded with the electrolyte at the time of assembly and a suitably formed plastic or paper protective sheet 48 is applied in covering relation to both the lower surface of the sheet 12 and the cup member 14 to retain the electrolyte therein. Of course, the protective sheet 44 or the protective sheet 48 are easily removable at the time the electrode 10 is to be used.

As noted above, the metallic snap fastener 18, which is the only conductor portion of the electrode 10, should be supported away from contact with the skin. The area between the snap fastener 18 and the skin should be completely filled with the electrolyte. Further, the movement of the electrode relative to the skin and the electrolyte should be positively restricted. In

addition to satisfying these requirements, the electrode 10 of this invention has an unusually low profile. These characteristics result primarily from the use of the elastic sheet 12 and the design of the cup member 14.

As apparent from an inspection of FIG. 2, the semicircular or U-shaped flange 24 forms a convexly curved rim defining the mouth of the cup member 14 and an outer wall, designated 50, diverging outwardly from the rim. The upper margin of the outer wall 50 is substantially coplanar with the upper surface of the base 26. The central portion of the elastic sheet is tightly compressed between the confronting base surfaces of the cup member 14 and the clamp plate 16. Accordingly, prior to attachment of the electrode 10 to the skin, the sheet 12 and its adhesive layer 20 are axially spaced above the rim of the cup member 14. In order to attach the electrode 10 to the skin, the sheet 12 must be flexed downwardly, whereupon the annular portion of the sheet 12 immediately surrounding the outer wall 50 is stretched to span the area between the upper, marginal edge of the diverging outer wall 50 and the portion of the skin to which the adhesive layer 20 is secured. Because of its elastic nature, the stretched portion of the sheet 12 resiliently presses the convexly curved rim formed by the flange 24 into the skin, creating a slight depression therein. As a result, the cup member 14 is firmly retained in sealing relation to the skin, thereby positively confining the electrolyte within the cavity or chamber 42. Also, movement of the cup member 14 and the electrolyte relative to the skin is avoided. The U-shaped flange has a sufficient depth to create a minimal, but adequate spacing between the skin and the conductive lower plate 34 of the snap fastener member 18 within the cavity 42. Because movements of the cup member 14 are restricted, the spacing between the plate portion 34 and the skin is maintained over long periods of use.

For reasons already mentioned, the elastic sheet 12 is preferably formed from a foamed or open cell polyvinylchloride having relatively closed cell upper and lower surfaces. This type of material can be obtained at a low cost, is sufficiently flexible to conform to the skin, and has sufficient elasticity to press the cup member 14 against the skin without tearing or pulling away from the skin. As those familiar with such material are aware, the two surfaces of foamed polyvinylchloride sheets are typically of a slightly different nature, one having a more closed cell construction than the other. Although these surfaces are interchangeable in the manufacture of the electrode 10, it is presently preferred that the more open cell surface be lowermost. The more open cell surface is sufficiently porous to provide for adequate aeration or ventilation of the skin it covers, which is especially important for use over extended periods of time. Also, the more closed cell surface is preferably uppermost because this type of surface is resistant to soiling.

The various thermoplastic materials mentioned above for use in forming the cup member 14 and the clamp plate 16 are ideal for this purpose because they are inexpensive, non-conductive, and can easily be vacuum formed to the desired shape. Although of a flexible nature, a thermoplastic sheet is adequately rigid when formed to the illustrated cup shape to prevent collapse of the outer wall 50 under the force of the stretched sheet 12. The axial spacing of the rim and the upper margin of the cup member 14 are thus main-

tained. A thermoplastic sheet also has a resiliency which assists in forming a good seal with the parts of the snap fastener member 18. Accordingly, the electrolyte is retained entirely within the chamber 42 and the hollow center of the snap fastener member 18. Since both the cup member 14 and the clamp plate 16 are identically constructed of sheet material, the confronting margins of their outer walls compress the elastic sheet 12 therebetween, as indicated at 52. Therefore, substantially the only portion of the sheet 12 which is stretched when applied to the skin is that portion between the outer wall 50 and the skin.

An electrode in accordance with this invention has been made and successfully tested. The electrode had an overall height on the order of only 0.3 inch with the depth of the cup member 14 on the order of 0.094 inch and the elastic sheet 12 having a thickness of 0.125 inch. The diameter of the elastic sheet 12 was $2\frac{1}{4}$ inch. The cup member 14, and accordingly the clamp member 16, had an overall diameter of 0.875 inch with the diameter of the base 22 being $\frac{1}{2}$ inch. The lower snap fastener plate 34 has a diameter of 0.406 inch. These dimensions are not critical. For example, the overall diameter of the cup member could be between approximately $\frac{1}{2}$ inch and one inch with corresponding variations in the diameter of the cup base 22 and the snap fastener plate 34. Unless the cup member 14 is made deeper, approximately 1 inch is deemed to be the maximum acceptable cup diameter because the skin bounded by the rim of a larger diameter cup member would likely engage the conductive plate portion 34.

Commercially available medical grade acrylic pressure sensitive adhesive was applied to the lower surface of the elastic sheet 12 to form the adhesive layer 20. Because the lower surface of the elastic sheet 12 is not completely impervious, some of the adhesive may have migrated harmlessly beyond the partially closed cell surface. A sufficiently small quantity of the adhesive was applied to avoid closing the lower surface to the passage of air. Of course, the adhesive layer could be obtained in other ways. However, the adhesive layer 20 should be pressure sensitive so that the elastic sheet 12 is stretched as a natural result of the pressing of the sheet 12 onto the skin. Also, the adhesive layer should not be of such a nature that is adversely affects the skin-conforming flexibility of the elastic sheet or that it closes the pores of the lower surface of the elastic sheet

12.

The diameter of the illustrated elastic sheet 12 is approximately two and one-half times the diameter of the cup member 14. It is preferred that the diameter of the carrier sheet 12 be on the order of two to three times the diameter of the cup member 14 to provide a broad skin contact area for the pressure sensitive adhesive layer 20. Because the carrier sheet 12 is flexible it readily conforms to movements of the skin. Although the cup member 14 is relatively inflexible, it is sufficiently firmly held against the skin by the tension in the stretched portion of the carrier sheet 12 that the electrode of this invention can be used on subjects engaged in strenuous exercise.

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

Having thus described my invention, I claim:

1. In a medical electrode, low profile, nonconducting, collapse resistant means defining an electrolyte receiving, cup-shaped cavity having mutually spaced open and closed ends, the closed end of said cavity being formed by a relatively rigid base, apertured elastic sheet means connected to said base in overlying relation thereto, said sheet means having a lower surface of said sheet means adjacent and in surrounding relation to said open end of said cavity in surrounding relation to said open end of said cavity, an adhesive on said lower surface, a snap fastener projecting through said base and supported by said base remote from said open end of said cavity, said snap fastener projecting through an aperture in said sheet means, and a removable protective cover for said adhesive.

2. The medical electrode of claim 1 in which said base has an aperture therethrough, said snap fastener consisting of interfitting parts disposed on opposite sides of said base.

3. The medical electrode of claim 2 wherein said base is a flat circular member, said aperture is disposed centrally in said base and said interfitting parts each have a circular plate portion disposed concentric to said base.

4. The medical electrode of claim 3 in which said circular plate portions of said interfitting parts are smaller in diameter than said base.

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Disclaimer

3,820,531.—*Roman Szpur*, Dayton, Ohio MEDICAL ELECTRODE. Patent dated June 28, 1974. Disclaimer filed Aug. 25, 1983, by the assignee, *NDM Corp.*

Hereby enters this disclaimer to all claims of said patent.

[*Official Gazette October 18, 1983.*]

UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,820,531 Dated June 28, 1974

Inventor^(s) Roman Szpur

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

In column 5, line 22, "has" should read ----- had --.

In column 6, lines 27 and 28, delete the phrase "of said sheet means adjacent and in surrounding relation to said open end of said cavity".

In line 30, after "surface", add the phrase ---- of said sheet means adjacent and in surrounding relation to said open end of said cavity,-----

Signed and sealed this 15th day of October 1974.

(SEAL)

Attest:

McCOY M. GIBSON JR.
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents