

- [54] **BIOMEDICAL ELECTRODE**
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abandoned.
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128/2.1 E
- [51] Int. Cl. A61b 5/04
- [58] Field of Search 128/2.06 E, 2.1 E, DIG. 4,
128/416-418, 410-411, 404-405, 172.1;
339/217 S, 252 P

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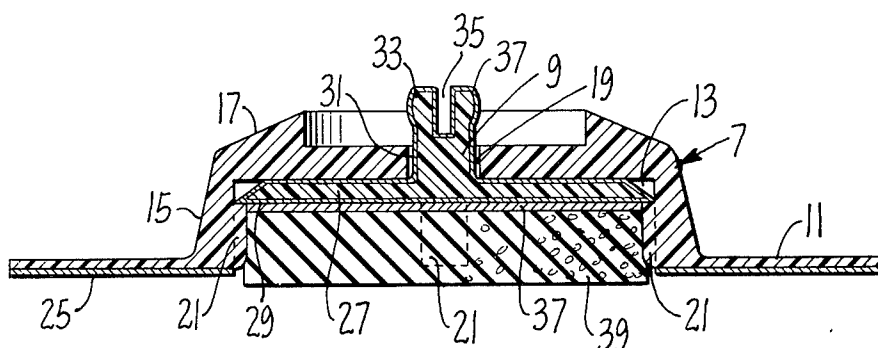
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ABSTRACT

A biomedical electrode or sensor is provided having a cup-like soft plastic base member with a solid conductive snap member therein and with a compressible sponge-like material holding a conductive paste between the solid conductive member and the body of the wearer. The device of the present invention is suitable for use as a sensor wherein it is desired to measure an electrical potential developed by the body as well as useful wherein potentials are applied to the body as in a cardiac pacemaker. The electrode was particularly designed for use with a cardiac monitor device.

8 Claims, 3 Drawing Figures



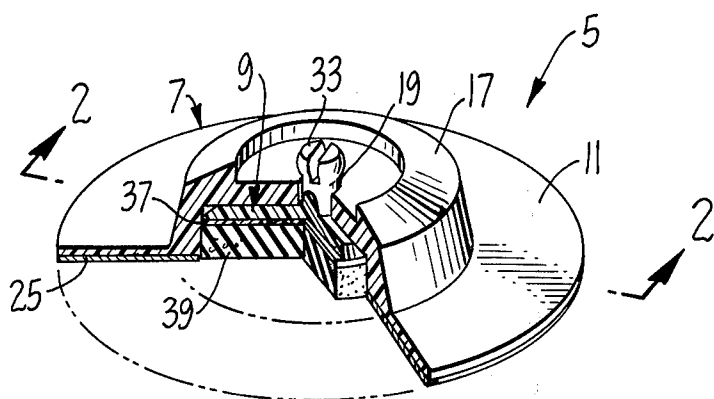


FIG. 1.

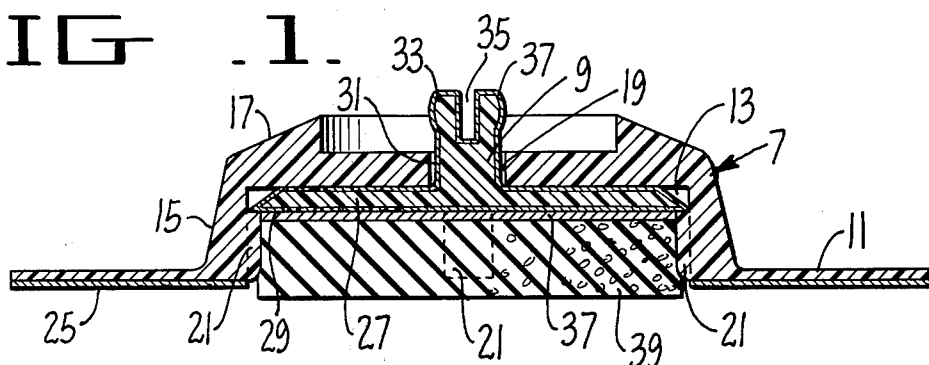


FIG. 2.

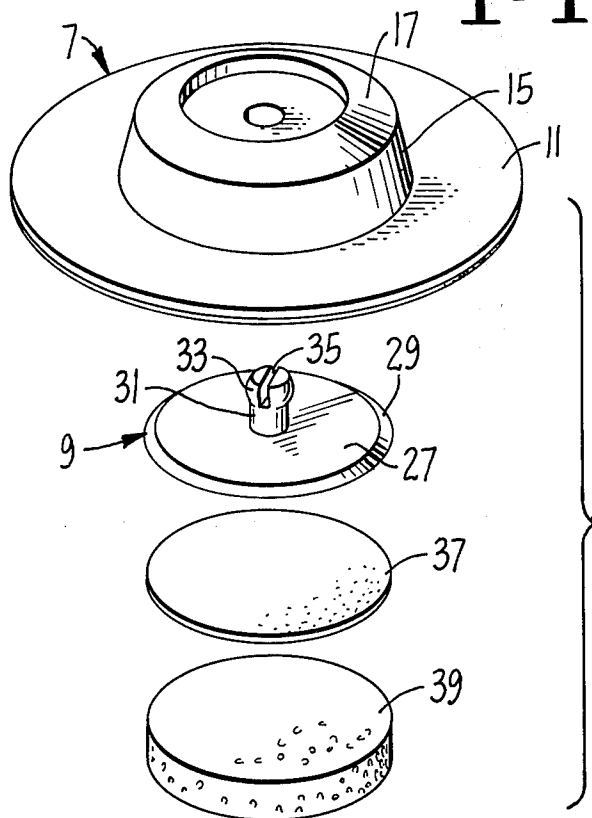


FIG. 3.

BIOMEDICAL ELECTRODE

This is a continuation, of application Ser. No. 332,720, filed Feb. 15, 1973, now abandoned.

SUMMARY OF THE INVENTION

It is frequently desired to apply an electrode to a human body either for sensing a potential developed by the body as in an EKG or for applying a potential to the body as in a cardiac pacemaker. Ordinarily when an electrode is to be applied for only a relatively short period of time to a quiescent individual, no particular problem arises. However, if it is desired that the electrode be applied for long periods of time to an active individual, many problems arise. One is that the usual electrode is of such a configuration that it could be knocked off by normal human activities. Another is that artifact noise is frequently developed because the potentials within the electrode or at the skin-electrode interface change during bodily movements. Further, there is a question of patient comfort when the electrode must be worn for extended periods of time.

In accordance with the present invention a body electrode is provided which is free from artifact noise by its novel construction wherein a conductive paste is held by a sponge-like material which is under compression between a conductive plate and the body of the wearer. Thus, as the person moves about, there is no change in potential between the electrode and the human body, thus preventing the generation of unwanted signals.

Thus, in the achievement of constant potential, this invention provides unique features in two major areas:

- a. Maintenance of constant potential, within the electrode assembly itself, even with stresses of body motion, pushes, and taps.
- b. Maintenance of constant potential in the electrode-skin interface.

The present invention is addressed to the maintenance of constant potential both in (a) and (b). These are described in detail in the following.

A. MAINTENANCE OF CONSTANT POTENTIAL IN THE ELECTRODE ASSEMBLY, EVEN WITH STRESSES

The constancy of potential of the electrode assembly is controlled by the constancy of ionic composition in the immediate environment of the metallic surface of the electrode. It is a well known law of electrochemistry that the potential of metal: metal ion is a logarithmic function of the metal ion concentration in the immediate environs of the electrode. The present invention makes possible the achievement of constancy of metal ion concentration (and activity) through the isolation of the electrode compartment from sources of variation of ionic composition. This is achieved by provision of an ionic medium in creme or gel directly in contact with the electrode metal and this is isolated by a porous material, such as blotting paper, from the remainder of the electrode assembly. The filling of the porous material with conductive creme or gel insures electrical contact between the ionic medium of the electrode compartment with the ionic medium (gel or creme) of the foam sponge which establishes the interface with the patient's skin.

The close opposition of the porous blotting material to the electrode ion compartment and its tight fit into the base itself is one key feature of the present invention which prevents movements of ions within the elec-

trode compartment, hence maintaining constant ion composition in the immediate environment of the electrode metal.

Furthermore, the non-movement of medium within the electrode compartment, achieved through the close and tight opposition of the porous blotting surface makes it possible to utilize a wide variety of electrode metals and a wide variety of metal ion concentration, including the very low concentration of metal ions achieved through electrode reactions, with no metal ions added. The present invention permits the use of all types of metals that produce a potential in contact with a conductive medium, since the isolation technique of the present invention removes limitations from type of metal. A wide range of ion concentrations is utilizable by demonstrating the invention with silver electrodes in the absence of added silver ions (thus having only the silver ions generated by electrode reaction) and with silver electrodes in contact with the very much higher silver ion concentration generated by suspension of silver chloride in the creme or gel of the electrode compartment. This is excellent proof of the efficiency of function of the isolated electrode compartment, in maintenance of constant potential, even when the ionic concentration is deliberately varied over wide limits. The invention, therefore, provides that with the principle of isolation introduced, a broad variety of metallic surfaces can be employed, and the invention therefore covers such a broad variety of metallic surfaces as electrodes.

The rigidity of the base of the central cavity, in addition to the restriction of ion movement by the porous blotting surface, is an additional key feature which maintains constancy of ion concentration in the vicinity of the electrode by prevention of any mass movement of gel or creme medium in the isolated electrode compartment, when the electrode assembly is mechanically stressed.

Because of the isolation of electrode compartment via both the porous blotting surface and the rigidity of the walls of the central cavity, such stresses as pushes on the electrode, taps on the electrode, or patient movements do not disturb the constancy of ion composition in the vicinity of electrode metal and hence constant potential is maintained at the electrode in our invention.

B. MAINTENANCE OF CONSTANT POTENTIAL IN THE ELECTRODE-SKIN INTERFACE

We have addressed in (a) the problem of maintenance of constant potential within the electrode assembly itself, an accomplishment successfully performed by the present invention. Overall performance, however, demands additionally that constancy of potential be maintained at the skin-electrode interface. It is a well-known observation that an electrical potential exists at the skin surface in humans. The precise source of such potentials is not known. Furthermore, the potential varies with depth of penetration beyond the most superficial cell layers of the skin. If a constant overall potential of a skin-electrode assembly is to be maintained, it follows that the overall assembly must not be permitted to sample varying potentials as a function of depth beyond skin surface. Such varying potentials represent a source of failure of most of the biomedical sensors (electrodes) currently available.

The present invention accomplishes the maintenance of constant interface potential in several important ways. First, we abrade the skin gently either with a sponge soaked in pumice-isopropyl alcohol (1:10 to 1:20 pumice in alcohol by volume is satisfactory) or with gentle abrasion with an emery board, or with gentle abrasion of an electrode creme (such as Redux) with abrasive in the creme. All these skin preparation modalities remove surface cornified epithelium, and bring the electrode (sensor) to the relatively deep skin layers, in which variation of potentials is minimal. Satisfactory performance of electrode sensors is achieved by establishment of contact with such deeper skin layers. The present invention guarantees such contact through use of a resilient sponge as the immediate contact between electrode assembly and the deep layers of skin. We have reduced to practice successful use of this sponge-under-pressure system with diverse materials, including latex rubber foam, polyurethane foam, neoprene, cellulose sponge, and cork. The key feature of this part of our invention is to have the sponge surface protrude from the electrode assembly. When the electrode assembly is adhered to the skin, the sponge is under compression at all times, guaranteeing maintenance of good contact with the deep layers of skin, where potential variation is at a minimum. To insure that the compression does not de-adhere the electrode assembly, we use a sufficiently large surface of adhesive to over balance the deadhering force of the compressed sponge. The area chosen for adhesion depends upon the extent to which the sponge is compressed, which in turn, depends upon the sponge density and thickness chosen.

The sponge-under-compression serves two important functions, additionally, in the present invention. First, since the sponge is soaked with electrolyte cream (and excess squeezed out), the sponge provides a very low impedance electrical contact path from skin to the electrode compartment. The sponge is under compression and hence at all times in excellent contact with the porous blotting surface of the electrode compartment as well as in excellent contact with skin. This feature of the invention obviates an important source of artifact noise, namely that due to make-break phenomena within the electrode assembly or at the skin electrode interface, especially when the electrode assembly is stressed by patient motion, by pushes on the assembly or by taps on the assembly.

The present invention has further features which prevent potential variation at the skin-electrode interface. It is essential that no mechanism of stress should alter the skin-electrode interface, since this would give rise to observation of varying potentials - such varying potentials being the essence of artifact "noise." The usually available commercial sensors are deficient in this respect in that pressure stresses on the electrode are directly transferred to the skin-electrode interface. In this way potential variation is minimized or eliminated, protecting the assembly from this source of artifact "noise."

There is still another feature of the invention which is important for minimizing voltage artifacts. The sponge, while soaked in gel or creme, is then squeezed out to eliminate excess creme or gel. Thus, the invention uses a "semi-dry" sponge, in that no excess creme is available when the electrode is mounted on the skin. This feature is important, for if excess creme or gel is

present, in the usual "wet" sponges, such excess creme can find its way between the electrode and skin including separation of the adhesive surface from skin. Once this situation is reached, pressure stresses on the electrode assembly transfer the stress to the creme-skin contact and force this creme to contact with deeper layers of skin, resulting in the sensing of the potential variation with depth. This is a source of artifact voltage. The "semi-dry" sponge does not provide such excess creme or gel and hence prevents this described source of artifact voltage.

The invention has been successfully employed with a variety of electrolyte cremes and gels, so that variation in gel or creme does not constitute a departure from our invention. Among these we have successfully utilized:

EKG Solution
 Redux Creme
 Redux Paste
 Ferris Gel
 Cam-Creme

This wide variety of cremes and gels will all work satisfactorily with the invention.

Further, the construction of the electrode base of the present invention is such that it is made of a soft plastic which conforms to the body of the wearer so that it can be worn for long periods of time without discomfort.

Another feature of the invention is that the base member is shaped in such a manner that lateral forces, which might otherwise detach the electrode from the body, are deflected.

Another feature of the present invention is that it can be made of two injection molded parts at low cost so that it can be considered an expendable item.

Other features of the invention will be brought out in the balance of the specification.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view, partly in section, of a body electrode embodying the present invention.

FIG. 2 is an enlarged section on line 2—2 of FIG. 1.

FIG. 3 is an exploded perspective view of an electrode embodying the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to the drawings by reference characters, the electrode of the present invention is generally designated 5 and consists of two main parts, namely, a base 7 and snap 9.

The base includes a wide rim portion 11 which is relatively thin so that it can conform to the shape of the body, particularly during movement. The base includes a central cavity 13 which is defined by the sidewall 15 and the top 17, both of which are relatively heavy construction. It will be noted that both the sidewall 15 and top 17 slant to form a ramp-like configuration which aids in retaining the device in the presence of lateral forces. At the center of the top a hole 19 is provided for the reception of the center post of the snap, later described. In the cup-like inner portion 13 are four bosses 21 which serve to retain the snap within the cup. The base thus far described is preferably cast from a single piece of flexible polyvinylchloride, although it could be made out of natural or artificial rubber or any relatively soft plastic. A double sided adhesive 25 is ap-

plied to the lower surface of rim 11 for attachment of the base to the body of the wearer.

The snap 9 includes a disc-like member 27 having a sharp edge 29. At the center, a post 31 is formed having a bulbous top 33. The bulbous top 33 is bifurcated as at 35 which aids in snapping the electrode to a standard clip, and which also facilitates removal of the snap piece from the injection molding tool (if the part is made by injection molding). Preferably, the snap is made of a relatively hard plastic which is platable such as No. EP-3510 acrylonitrile butadiene styrene (ABS) which is plated successively with copper, nickel and then silver. The snap could be cast from metal but the plastic is lighter weight, less expensive and provides excellent conductivity when made in this manner. The sharp edge 29 of the snap facilitates snapping it over the bosses 21 of the base and also acts as a seal, preventing leakage of the electrode jell solution out of the inner cup chamber of the base. The bosses 21 retain the snap 9 into the base 7. This retaining could be performed by any undercut in the inner cup chamber of the base 7.

In use, a disc 37 of porous paper such as blotting paper and a relatively thick disc 39 of a foam-like material such as latex or polyurethane foam is provided. The paper 37 and the foam 39 are both saturated with an electrode jell solution and, as can best be seen in FIG. 2, the foam extends slightly beyond the bottom edge of the flat portion 11. Thus, when the electrode is applied to the body, the discs 37 and 39 are under compression, maintaining a constant resistance between the body and the snap, even during vigorous body movement. The paper disc 37 and foam disc 39 are attached to each other with an adhesive. Since the paper fits tightly into the cup chamber of the base 7, the foam disc 39 is also securely retained into the assembly. Since the sides 15 and top 17 form ramp-like members, the electrode is highly resistant to lateral forces which might otherwise detach the electrode from the body.

It will be apparent to those skilled in the art that many departures can be made from the exact structure shown without departing from the spirit of this invention.

We claim:

1. A body electrode comprising in combination:
 - a. a base member made of a single piece of a flexible,

soft plastic having a thin flexible rim portion and a rigid center flat bottomed cup-like member defined by heavy sidewalls and a heavy top,

- b. a snap comprising a relatively thin flat disc of conductive material lying on the flat bottom of the cup-like member, and having a terminal extending through the face of the cup-like member,
- c. a thin sheet of porous non-conductive material of substantially the same size as the flat bottom of the cup-like member, and having one surface in contact with said disc,
- d. a thick disc of porous foam-like material in contact with said porous nonconductive material and filling the remainder of the cavity of the cup-like member and extending a substantial distance beyond the open end of the cup-like member, said foam-like material being saturated with an electrically conductive material, and
- e. means for attaching said cup to a human body by the outer thin wide rim whereby said foam-like material is brought into compression within the cup-like member by pressure from the body.

2. The structure of claim 1 wherein the outer surface of said cup-like member is formed at an angle to provide a ramp to resist lateral forces.

3. The structure of claim 1 wherein said rim is provided with a double sided adhesive on its outer surface surrounding the opening of the cup for attachment of the electrode to the body.

4. The structure of claim 1 wherein the inner surface of said cup is provided with a plurality of bosses, said snap being retained between the bosses and the flat bottom of the cup-like member.

5. The structure of claim 1 wherein the snap terminal is a center post extending through the base, said center post terminating in a bifurcated bulbous member.

6. The structure of claim 1 wherein said snap has a sharp edge at the perimeter of said disc for retaining itself within the base and acting as a seal.

7. The structure of claim 1 wherein the thin sheet of porous nonconductive material is a sheet of paper.

8. The structure of claim 7 wherein the porous paper consists of a sheet of blotting paper and the foam-like material consists of a disc of polyurethane foam.

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