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Reinhold, Jr.

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[54] **DRY APPLIED AND OPERABLY DRY ELECTRODE DEVICE**

[75] Inventor: **Herbert E. Reinhold, Jr.**, Rockville, Md.

[73] Assignee: **Survival Technology, Inc.**, Bethesda, Md.

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[52] **U.S. Cl.** ..... **128/2.06 E**; 128/2.1 E; 128/DIG. 4

[51] **Int. Cl.**[2] **A61B 5/04**

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

[56] **References Cited**

UNITED STATES PATENTS

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FOREIGN PATENTS OR APPLICATIONS

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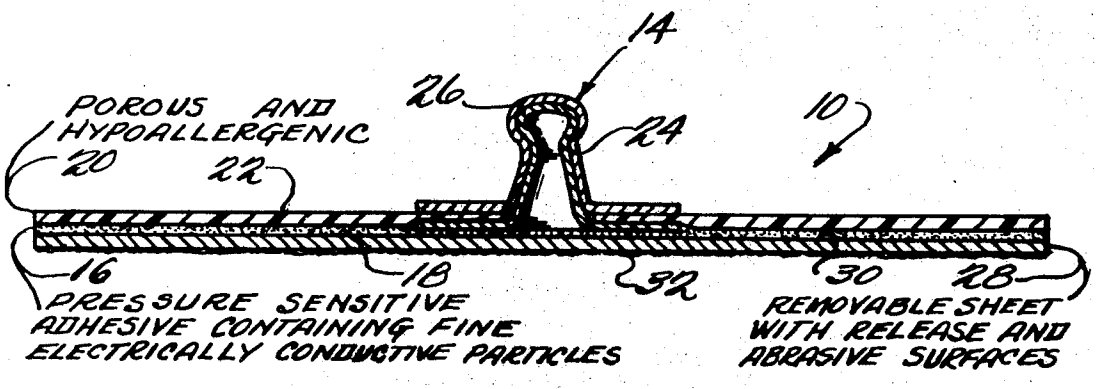
Primary Examiner—William E. Kamm
Attorney, Agent, or Firm—Cushman, Darby & Cushman

[57] **ABSTRACT**

An electrode device for establishing an electrical connection between electromedical apparatus and the skin of the human anatomy comprising a composite electrode body for self-adhering engagement with a substantial surface area of the skin to establish the electrical connection throughout substantially the entire engaged area of the skin without the use of conductive pastes, gels or other liquids, such as solvents or the like, the composite electrode body being porous and hypoallergenic and including a carrier layer and a thin flexible layer of pressure sensitive adhesive material having fine electrically conductive particles dispersed throughout providing a tacky skin-engaging surface the particles being provided in an amount sufficient to effect the electrical connection with the engaged area of the skin through the layer by particle to particle contact while permitting the skin-engaging surface of the layer to remain tacky prior to skin engagement. A removable sheet having a release surface engaging the tacky skin-engaging surface of the layer is operable to be separated therefrom prior to application without substantially reducing the tackiness thereof.

8 Claims, 2 Drawing Figures



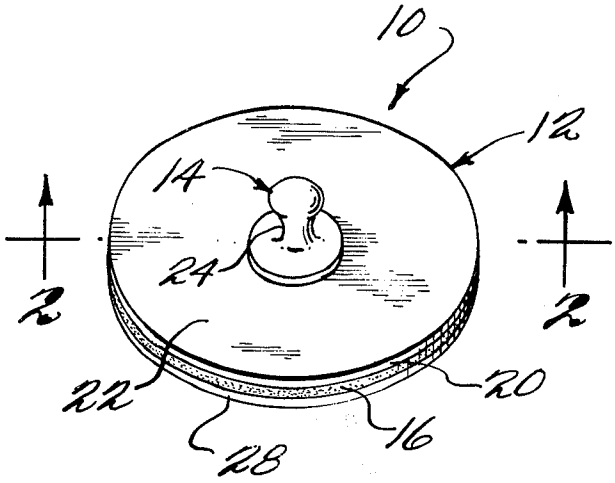

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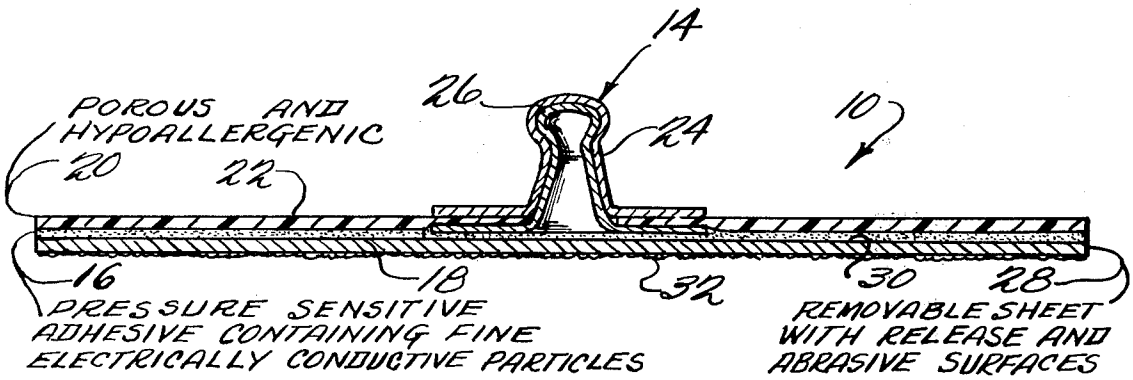
Fig. 1


14
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POROUS AND
HYPOALLERGENIC
20
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16
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PRESSURE SENSITIVE
ADHESIVE CONTAINING FINE
ELECTRICALLY CONDUCTIVE PARTICLES
REMOVABLE SHEET
WITH RELEASE AND
ABRASIVE SURFACES

Fig. 2

DRY APPLIED AND OPERABLY DRY ELECTRODE DEVICE

This invention relates to electrodes of the type adapted to establish an electrical connection between electromedical apparatus, such as an electrocardiograph or the like, and the skin of the human anatomy and more particularly to an electrode of this type which is especially suitable for long term monitoring.

Typical electrodes now available for use in long term monitoring usually rely upon the utilization of a conductive paste or gel to establish the actual electrical connection with the patient's skin. A typical example of an electrode of this type is disclosed in U.S. Pat. No. 3,713,435. The disclosed arrangement is one in which a central electrolyte paste receiving structure providing an exterior terminal, such as a male snap fastener element, is fixedly secured to a surrounding sheet-like member having a pressure sensitive adhesive thereon which serves to adhere the central structure to the skin.

Electrodes of this type have proven quite reliable in effecting the required electrical connection, however, there are disadvantages and inconveniences presented. The primary disadvantage resides in the utilization of the electrolyte gel which requires that such gel be extraneously supplied during application or that the electrode be packaged individually with the gel in a liquid tight container. The necessity to provide extraneous gel during application is an obvious inconvenience. Where this inconvenience is obviated by packaging the gel with the electrode structure, overall costs are increased by the cost of packaging. Moreover, any premature exposure of the packaged electrode to atmospheric conditions will result in the drying out of the gel.

In addition to the above application disadvantages, the use of an electrolyte gel in contact with the skin, especially for long periods of time, can cause skin irritation and sores to develop. Another possible source of skin irritation during use is the adhesive which contacts the larger area of the skin surrounding the area of electrolyte contact. Thus, with electrodes of this type the total skin contact area subject to irritation is substantially greater than the area through which the electrical connection is made since the area of electrical contact is separate and distinct from the area of securement. Moreover, because of this separation the area of electrical contact is capable of surface to surface shifting which may produce artifact.

Another type of electrode construction is disclosed in U.S. Pat. No. 3,547,105. The opening paragraphs of the specification of this patent, by way of background information, refer to NASA Technical Note D-3414, May 1966 "Dry Electrodes for Physiological Monitoring", which discusses an electrode which is sprayed on the skin in the form of a solution of Duco cement made by the DuPont Company having an acetone solvent and a powdered silver therein. The electrode of the patent is disclosed as an improvement, set against this background, in which the Duco cement solution is used to perform an electrode construction rather than to form the same on the patient by the spray-on technique. The preformed electrode consists essentially of two thin disks punched from a thin dried layer of Duco cement solution which are cemented together with a terminal lead therebetween. The electrode is referred to as dry but cannot be applied without utilizing an extraneous

supply of acetone solvent or the like. Thus in applying the electrode, the solvent is wiped or dabbed on the patient's skin and the electrode is also wetted with solvent, then immediately pressed upon the wet area and held for a second or two until the electrode has started to adhere. The small layer of solvent is then rapidly absorbed into the skin and dry electrode.

This electrode obviates many of the above-mentioned disadvantages of the first-mentioned type of electrode. Thus, the electrode is dry, in the sense of not utilizing an electrolyte paste or gel to effect the electrical connection during use, and hence the disadvantages inherent in the use of such electrolytes is obviated. Moreover, the disadvantages previously discussed in relation to the provision of separate electrical contact and skin securement areas are obviated, since skin adherence is obtained coextensively in the area where electrical contact is made.

While these disadvantages in the first-mentioned type of electrode are overcome, the second-mentioned type of electrode presents other disadvantages which are related to the necessity of utilizing a solvent to apply the electrode. This necessity essentially raises the same type of problems which are presented with the use of electrolyte gels. Thus, application cannot be effectively accomplished unless a supply of solvent is available. A substantial inconvenience is presented where the solvent supply is separate from the electrode supply. The packaging problems presented to integrate the two are even more formidable than those presented by electrolyte gels because of the inherent volatile nature of the solvent. There exists the need for an electrode which will obtain all of the advantages of both of the above-mentioned types of electrodes without securing the attendant disadvantages thereof.

An object of the present invention is to provide an electrode which will fill such need by securing all of the advantages of the prior art electrodes without any of the attendant disadvantages. In accordance with the principles of the present invention this objective is obtained by providing a composite electrode body having a tacky skin-engaging surface formed by a thin flexible layer of pressure sensitive adhesive material having fine electrically conductive particles dispersed throughout including the skin-engaging surface in an amount sufficient to provide an effective electrical connection with the engaged area of the skin through the layer by particle to particle contact while permitting the skin-engaging surface of the layer to remain tacky prior to skin engagement. The tacky surface is protected prior to use by a removable sheet having a release surface engaging the tacky surface which, when the sheet is removed, does not substantially reduce the tackiness of the surface. The composite electrode body also includes a thin flexible carrier layer or layers coextensively connected with the tacky surface layer and with an appropriate terminal structure capable of detachable connection to the electromedical apparatus. The carrier layer or layers may be either non-conductive, in which case the terminal structure directly contacts the conductive particles of the pressure sensitive adhesive layer, or conductive, in which case the conductive layer may be interposed in series between the conductive particles of the pressure sensitive adhesive layer and the terminal structure. An electrode constructed in accordance with these principles is truly dry in that no liquid solvent is necessary to effect application and no

electrolyte paste or gel is necessary to effect a reliable low resistance electrical connection throughout the entire area of the skin to which the electrode is adhered.

While it can be readily understood that an electrode constructed in accordance with the principles enunciated above effectively solves the problems which have been experienced over the years in the long term monitoring art, such understanding should not imply an assertion that the present invention resides in the principles applied. Quite to the contrary, the invention resides in solving the problems of the long term electrode monitoring art and the principles, enunciated above, in that solution are derived from a hind-sight analysis of that solution. These principles derived from such hindsight analysis are known per se. See, for example, the following U.S. Pat. Nos. 2,498,493; 2,670,306; 2,797,370; 2,808,352; 2,822,509; 3,475,213; 3,762,946; and 3,778,306. However, such knowledge per se does not suggest the solution of the present invention. Indeed, the separate co-existence of the principles per se and the problem for an extended period indicates just the opposite.

Another object of the present invention is the provision of an electrode of the type described which is simple in construction, easy and convenient to apply, efficient in operation and economical to manufacture.

These and other objects of the present invention will become more apparent during the course of the following detailed description and appended claims.

The invention may best be understood with reference to the accompanying drawings, wherein an illustrative embodiment is shown.

In the drawings:

FIG. **1** is a perspective view of an electrode construction embodying the principles of the present invention; and

FIG. **2** is an enlarged, sectional view taken along the line **2—2** of FIG. **1.**

Referring now more particularly to the drawings, there is shown therein an electrode device, generally indicated at **10,** for establishing an electrical connection between electromedical apparatus, such as an electrocardiograph or the like, and the skin of the human anatomy. The electrode device consists essentially of a composite electrode body, generally indicated at **12,** for self-adhering engagement with a substantial surface area of the skin, to establish the electrical connection therewith throughout substantially the entire engaged area of the skin without the use of conductive pastes, gels or other liquids, such as solvents or the like, and a terminal structure, generally indicated at **14,** for enabling the electrode device to be detachably electrically connected with the electromedical apparatus.

In accordance with the principles of the present invention it is essential that the composite body **12** provide a tacky skin-engaging surface **16** which is formed by a thin flexible layer **18** of pressure-sensitive adhesive material having fine electrically conductive particles dispersed throughout, including the tacky surface **16** in an amount sufficient to provide an electrical connection from the surface **16** through the layer **18** by particle to particle contact while permitting the surface **16** to remain tacky prior to skin engagement. A further critical characteristic of the composite structure is that the adhesive layer is coextensively secured with a carrier structure of thin flexible sheet-like form which in the preferred embodiment shown is a carrier layer **20** laminated to the pressure sensitive adhesive layer **18** by the adhesive qualities of the latter. The carrier layer **20** provides a non-tacky exterior surface **22** opposed to the tacky surface **16.**

While the preferred embodiment of the composite body is of laminar construction with a clearly defined interface, it will be understood that the term composite contemplates constructions other than the aforesaid clearly defined laminar one and specifically one in which there are layers of different material characteristics with merging interfaces which are not well-defined, as distinguished from interfaces which are sufficiently well-defined as to be capable of delamination.

Preferably the composite body is thin and flexible to the extent of readily following the skin movements of the patient to which it is applied without any portion of the surface **16** losing adherence with the skin. Moreover, the composite body is preferably hypoallergenic and porous so as to substantially eliminate any allergic reaction due to the application of the electrode device to the skin of the patient and virtually eliminate skin maceration caused by moisture build-up. These characteristics are greatly preferred where the electrode device **10** of the present invention is to be used for long term monitoring. A further highly desirable characteristic is that the composite body is capable of removal after use without leaving residue from the layer **18** on the skin.

While the composite body may be formed of any desired materials capable of providing the above-mentioned essential characteristics, the preferred construction shown, which admirably meets the essential characteristics as well as the preferred characteristics noted above, utilizes the backing layer and pressure sensitive adhesive material embodied in the surgical tape marketed by 3M Company under the trademark MICROPORE with fine powder carbon being utilized as the electrically conductive particles. Thus, the carrier layer **20** is a thin flexible highly porous non-woven fabric and the adhesive material is a synthetic acrylic copolymer. A preferred amount of fine carbon powder to be included in the adhesive is 25%, although it will be understood that more or less can be used in accordance with the principles enunciated above. The composite body is constructed in accordance with known procedures including specifically those commercially utilized in the formation of MICROPORE surgical tape with the fine carbon particles in the above amount being initially mixed uniformly in the syntehtic acrylic copolymer while in liquid form.

Layer thicknesses are preferably the same as those provided in the aforesaid MICROPORE tape although either or both may be increased or decreased if desired. The preferred shape of the composite body **12** is the circular configuration shown in the drawings since the terminal construction can be centered therein. A preferred diameter size is 2 inches. However, it will be understood that the composite body **12** may assume other shapes and sizes. With respect to size, the contact area provided by the above-preferred diameter dimension should not be greatly reduced in order to insure a low resistance connection, while size increase is limited only by practical considerations. Square and rectangular shape variations are specifically contemplated as well as elliptical and any others considered desirable.

As previously stated, it will be understood that the invention is not limited to the above-preferred specific construction. With respect to the conductive particle loaded pressure sensitive adhesive layer **16** per se, any of the known per se constructions in the aforementioned patents may be utilized and the disclosure of each is hereby incorporated by reference into the present specification for that specific purpose per se. Other specific constructions which clearly meet the essential and preferred characteristics include a carrier layer and adhesive material such as embodied in the TRANSPORE and DURAPORE surgical tapes marketed by 3M Company. Thus, the carrier layer **20** may be a porous Polyethylene/Ethylene Vinyl Acetate film or a porous woven cloth or fabric. Also, as previously indicated, porosity in the layer **16** and **20** is not essential where the electrode device is not contemplated for use in long term monitoring, indeed a carrier layer of thicker polyethylene may be desirable for short term disposable use since it is easier to handle. For long term monitoring use, the porous and hypoallergenic characteristics are practically necessary.

The terminal structure **14** may assume a variety of forms including the simple wire construction of the aforesaid U.S. Pat. No. 3,547,105. A male snap fastener construction such as that shown in the aforesaid U.S. Pat. No. 3,713,435 is preferred. The male snap fastener terminal structure **14** shown in the drawings consists essentially of two similarly shaped metallic elements **24** and **26** crimped together. Each element includes a generally flange-shaped mounting portion and a projecting generally knob-shaped terminal portion. As shown, the terminal structure is fixedly connected to the carrier layer **20** prior to lamination with the layer **16,** the connection being effected by suitably perforating the layer, extending the knob portion of the smaller element upwardly through the perforation while the larger element is held thereover and effecting the crimping action. The mounting flange portions of the two elements thus grip the marginal portions of the layer **20** defining the perforation. By effecting securement of the terminal with the layer **20** prior to the lamination with the layer **16,** electrical connection between the conductive particles of the layer **16** and mounting portion of the terminal is simply effected in a manner which effectively prevents direct contact of the metal of the terminal with the skin during use. Avoidance of metal-to-skin contact is desirable because of the battery effect, as is well known. This effect may be likewise avoided by constructing the terminal of carbon loaded plastic in which case the terminal may extend through the skin engaging surface **18,** if desired.

The above construction of the terminal also suggests the utilization of carbon loaded plastic as the carrier layer in which case a single unitary terminal could be secured to the exterior surface of the carrier layer or even made integral therewith. Thus, it will be apparent that while the preferred embodiments of the carrier layer **20** are constructed of nonconductive material, it is within the contemplation of the present invention to form the carrier layer of conductive material such as carbon loaded plastic, metallic foil, etc.

In accordance with the principles of the present invention, the tacky surface **18** of the carbon loaded pressure sensitive adhesive layer **20** is protected prior to the application of the electrode device **10** with removable sheet means, a preferred form of which is shown in the drawings as a paper sheet **28** having a release surface **30** of silicone or other well-known release material disposed in coextensive engagement with the tacky surface **18.** The exterior surface of the paper sheet **28** is preferably provided with abrasive granules **32** or similar substances which will perform the usual known function of such granules. The removable sheet **28** is formed essentially of very fine sand paper with the non-abrasive surface thereof coated with silicone.

Since the construction is dry and application can be effected dry, elaborate packaging is not required. Application is readily effected by first rubbing the area of the skin to which the electrode device is to be applied with the abrasive surface **32** in the usual manner in which sand paper or the like is normally used. As would be expected, this operation has the effect of removing a layer of dead cells from the skin area. This removal enhances the electrical connection to be effected and is preferable as a dry pretreatment which is consistent with the dry construction and operation of the electrode itself. Abrasive pretreatment is often performed together with sterilization of the skin area b y swabs containing alcohol and pumice. It will be understood that abrasive pretreatment of the skin, whether wet or dry, is not at all essential to the pretreatment. Next, the removable sheet **28** is separated and then the composite body **12** is simply pressed onto the abraded skin area so that the tacky surface **18** is firmly adhered thereto. Connection with the electromedical apparatus is effected simply by detachably connecting the lead thereof to the terminal structure **14** in conventional fashion. While the application has been described above in a sequence in which the rubbing of the skin with the abrasive surface **32** is performed prior to the removal of the sheet, the sequence of these procedures may be reversed. Moreover, the removable sheet means may be formed of two sheets, rather than one as shown, with each sheet having removal tabs, as is well known.

It thus will be seen that the objects of this invention have been fully and effectively accomplished. It will be realized, however, that the foregoing preferred specific embodiment has been shown and described for the purpose of illustrating the functional and structural principles of this invention and is subject to change without departure from such principles. Therefore, this invention includes all modifications encompassed within the spirit and scope of the following claims.

What is claimed is:

1. An electrode device for establishing an electrical connection between electromedical apparatus and the skin of the human anatomy, said electrode device comprising composite electrode body means for self-adhering engagement with a substantial surface area of the skin to establish the aforesaid electrical connection throughout substantially the entire engaged area of the skin without the use of conductive pastes, gels or other liquids, such as solvents or the like, said composite electrode body means including a tacky skin-engaging surface formed by a thin flexible layer of pressure sensitive adhesive material having fine non metallic electrically conductive particles dispersed throughout including said tacky skin-engaging surface in an amount sufficient to provide the aforesaid electrical connection with the engaged area of the skin through said layer by particle to particle contact while permitting the skin-engaging surface of said layer to remain tacky prior to

skin engagement, removable sheet means having a release surface engaging the tacky skin-engaging surface of said layer operable to be separated therefrom without substantially reducing the tackiness thereof in response to the removal of said removable sheet means, said composite electrode body means further including carrier layer means disposed in substantially coextensive connected relation with said adhesive layer and presenting a non-tacky exterior surface generally opposed to said skin-engaging surface and electrical terminal means carried by said carrier means and forming an exterior terminal part of the aforesaid electrical connection with which a detachable electrical connection with the electromedical apparatus can be effected.

2. An electrode device as defined in claim **1** wherein said composite body means is porous and hypoallergenic.

3. An electrode device as defined in claim **1** wherein said fine conductive particles are carbon particles.

4. An electrode device as defined in claim **1** wherein said terminal means comprises a male snap fastener element.

5. An electrode device as defined in claim **4** wherein said male snap fastener element is metal.

6. An electrode device as defined in claim **4** wherein said electrode body means is circular and said male snap fastener element is concentrically connected therewith.

7. An electrode device as defined in claim **1** wherein said carrier layer means is formed of a porous nonwoven fabric.

8. An electrode device as defined in claim **7** wherein said adhesive material is a synthetic acrylic copolymer.

* * * * *