

[54] **BIOMEDICAL MONITORING ELECTRODE**

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[52] **U.S. Cl.** **128/2.1 E**, 128/2.06 E, 128/417, 128/DIG. 4

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

[58] **Field of Search** 128/2.1 E, 2.06 E, DIG. 4, 128/416–418, 410, 411, 404, 405

[56] **References Cited**

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[57] **ABSTRACT**

A pregelled intensive care electrode is formed from two layers of soft, conformable foam material having a rigid plastic supporting layer between the foam layers. A conductive connector is in contact with an open-celled spongy material filled with an electrolyte which provides means for connecting the electrode to monitoring devices and measuring the electrical impulses from a patient's skin. The biomedical monitoring electrode is held in place on the patient's skin by means of a hypo-allergenic pressure sensitive adhesive.

5 Claims, 3 Drawing Figures

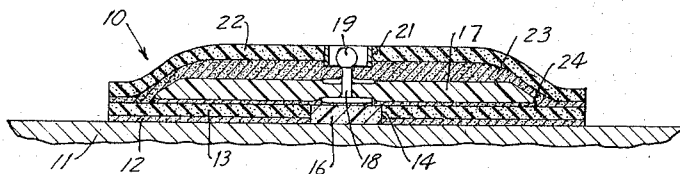


FIG. 1

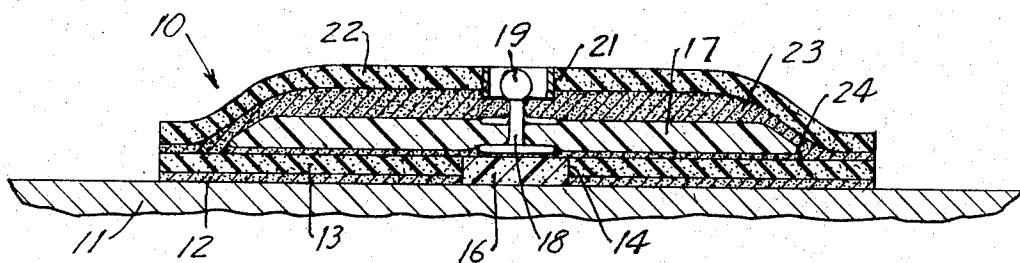


FIG. 2

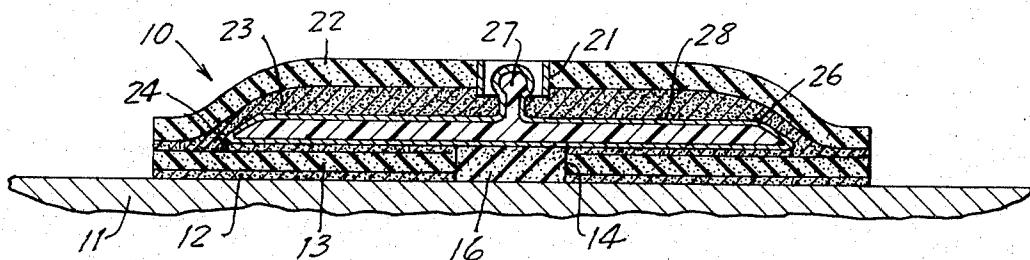
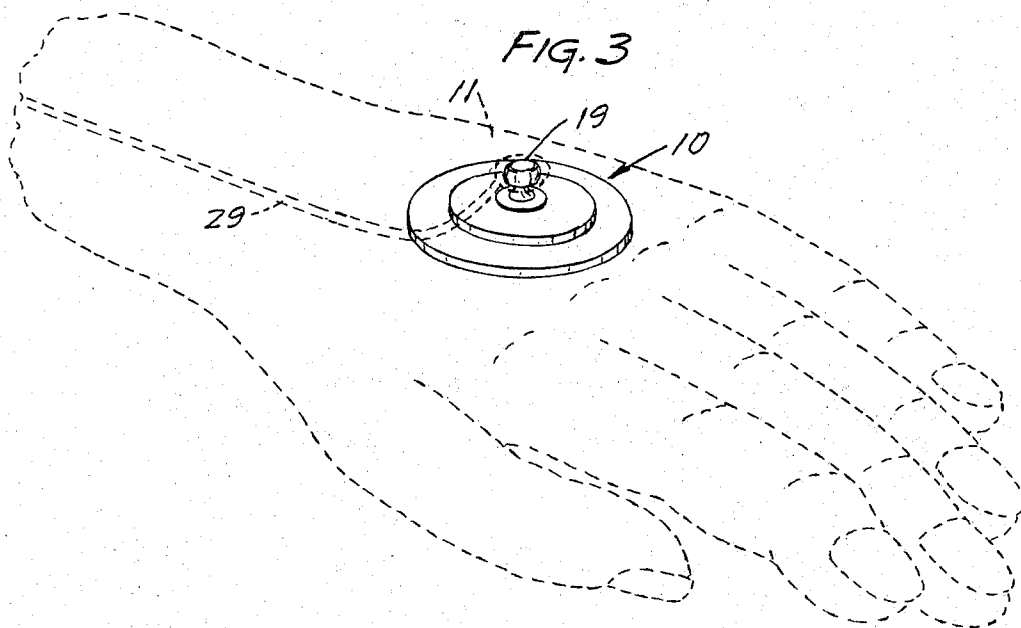


FIG. 3



BIOMEDICAL MONITORING ELECTRODE

BACKGROUND OF THE INVENTION

This invention relates to a biomedical monitoring electrode of the type used to detect electrical signals from the skin of a patient. In another aspect, this invention relates to a medical electrode of the type designed for use over a period of several days such as in the intensive or coronary care facilities. In a still further aspect, this invention relates to medical electrodes designed to be used for several days without interfering with the patient's normal activities and without becoming dislodged from this original position. In yet a further aspect, this invention relates to medical electrodes of the pregelled type useful in detecting electrical signals from the skin of the patient.

It is known that the conductor portion of electrodes should be maintained away from the skin of the subject by the electrolyte or an electrolyte-filled pad to obtain an electrical contact having minimal resistance and also to minimize the noise caused by motion of the conductive electrolyte with relation to the patient's skin.

Pregelled electrodes have been made of rigid plastic cups wherein a cup containing a sponge filled with electrolyte is held against the skin by an elastic sheet. The elastic sheet is attached to the skin by means of a pressure-sensitive adhesive depressing the rigid cup into the patient's skin. These electrodes provide an electrode having a broad area of electrolyte contact with the skin. However, the rigid plastic cup of these electrodes is hard and unyielding and the hard plastic cup is uncomfortable when lain on and may irritate the skin of many patients when the electrode is left in place for extended periods. Also the pregelled pad can move in relation to the patient's skin and thus cause some noise and inaccuracies in the measurement. Generally, this hard rigid cup construction requires a larger electrode since the adhesive on the elastic sheet next to the rigid cup is not in contact with the patient's skin, making this type of electrode bulky.

Briefly, the electrode of this invention comprises a soft, conformable layer of foam having an aperture therethrough and having on one side of the foam a layer of hypoallergenic adhesive for securing the electrode of this invention to the patient's skin. Partially covering the foam on the other side is a hard, rigid disc preferably plastic, which covers the aperture and gives rigidity to the electrode configuration. This rigid plastic disc has a conductive snap which is in contact with an open celled sponge filled with an electrolyte in the aperture of the foam layer. The electrolyte filled sponge serves to conduct the electrical signals from the skin of the patient to the conductive snap or coating of the electrode which is designed for attachment to an external lead suitable for monitoring the patient's bodily functions, e.g. an electrocardiogram. The rigid plastic disc and a portion of the first foam layer can be covered by a second soft conformable foam layer which improves the appearance, serves to protect the patient, medical personnel and their clothing from snagging on the exposed edges of the plastic disc and also helps strengthen the total construction.

A better understanding of the invention may be had by reference to the drawing in which:

FIG. 1 is a side view in section of a biomedical monitoring electrode of this invention;

FIG. 2 is a side view in section of a second embodiment of the electrode of this invention;

FIG. 3 is a perspective view of an electrode in place.

Referring to the accompanying drawing, and initially to FIG. 1, reference No. 10, designates generally an intensive care electrode attached to a patient's skin 11 by means of a pressure-sensitive adhesive layer 12. The adhesive 12 adheres a soft foam layer 13 having an aperture 14 to the patient's skin. A soft, open-celled sponge pad 16 containing an electrolytic gel or cream is contained in the cavity formed by the patient's skin 11, the soft foam layer 13 and the rigid plastic supporting disc 17 which overlays a portion of the foam layer 13. An electrically conductive, e.g., silver or silver chloride-treated, snap 18 passes through the plastic disc and makes contact with the electrolyte filled sponge 16 providing a low resistance electrical pad for impulses from the patient's skin to an external monitoring device which can be attached to the snap connector 19 which projects through an aperture 21 in a second layer of soft foam 22 which covers the disc 17. The layers of foam 13, 22 and the rigid disc 17 are adhesively bonded together by means of adhesive layers 23, 24, said layers also serving to adherently bond the foam layers 13, 22 together at the periphery of the intensive care electrode. Adhesive layer 24 also serves to bond the electrolyte-filled sponge 16 to rigid disc 17 minimizing motion between the patient's skin 11 and the conductive snap 18.

FIG. 2 denotes another embodiment of the intensive care electrode of this invention wherein the soft foam layers 13, 22 are adherently bonded by means of adhesive layers 23, 24 to a molded plastic disc 26 with a plastic knob 27 forming a snap connector, the rigid plastic disc 26 and knob 27 being coated with a continuous, electrically coherent conductive layer 28. There exists a conductive path from the patient's skin 11 through the electrolyte-filled gel pad 16 to the snap connector 27 which can be attached to external monitoring means such as an electrocardiogram machine.

In FIG. 3, a disc electrode 10 is shown in place on the skin 11 of a patient. The electrode shown is a circular electrode as shown in section in FIG. 1 and is attached firmly to the patient's skin 11 by adhesive layer 12. In use, electrical signals from the skin are amplified and sensed by an apparatus (not shown) connected to the male snap connector 19, by a conductive lead and co-operative snap fastener shown by phantom lines 29.

The foams chosen for the practice of this invention are soft and nonirritating to the human skin when left in place for extended periods of time. It is desirable that the foams chosen to make the biomedical monitoring electrode of this invention be substantially closed-cell foams which are not readily permeable to moisture so as to maintain the electrolyte-filled pad in a moistened condition. Use of an open cell foam can result in the gel pad drying out and becoming nonconductive during extended monitoring, resulting in a loss of electrical signals and erroneous readings. Examples of closed cell foams suitable for use in the electrode of this invention are crosslinked polyethylene, polyethylene modified with ethylene vinyl acetate, polyvinyl chloride, etc. These foams normally have a density of about 1 to 6 pounds per cubic foot with the preferred range of foams being about 2 to 4 pounds per cubic foot. Other closed cell foams having similar resistance to set and

strength will form suitable intensive care electrodes of this invention.

The plastic disc laminated in the electrode of this invention provides a support for the electrical connection to the external monitoring means and also serves to rigidify the electrode to maintain adequate spacing between the electrical conductor and the patient's skin.

Examples of plastics having suitable properties are polystyrene, polypropylene, acrylonitrile-butadienestyrene copolymers, or rigid polyvinyl chloride. The plastics useful include those having a Rockwell Hardness of about M65-100 and which do not react with silver and other conductive metals or the ingredients used in the conventional electrolyte gels presently available. Plastics having these characteristics will maintain their structural ability when perforated with a snap connector as shown in FIG. 1. The rigid disc and snap connector can be injection molded as a unitary body and then treated with silver, silver chloride, or other conductive materials to provide a conductive path around said disc as shown in FIG. 2 without impairing the accuracy and stability of the electrode of this invention. The disc could also be formed of other materials such as metals, or glass which will accept a conductive snap connector and will not react when used in contact with the conductive gel.

The pregelled electrode of this invention is designed for use with sodium chloride-based electrolytes such as those which are commercially available and sold in the form of electrolytic pastes or gels. Examples of such gels are "EKG-Sol," "Redux," and "G.E. Jel," although other electrolyte gels and creams can also be used.

The adhesives useful in constructing the intensive electrode of this invention are chosen from those adhesives which are nonirritating to the human skin when left in contact therewith over extended periods of time. Preferable adhesives are the hypoallergenic, acrylate-based adhesives such as those of Ulrich U.S. Pat. No. Re. 24,906. The adhesive holding the electrode of this invention to the skin surfaces the entire bottom of the electrode with the exception of the sponge filled aperture. Because of the construction of this electrode, the skin and the electrolyte-filled sponge, and the electrolyte-filled sponge and rigid disc are held in intimate contact. Therefore, there is little or no opportunity for the skin to shift in relationship to the electrolyte-filled sponge and conductor producing a low noise electrical connection of little variability.

Example 1

A coating of acrylate adhesive was applied to a strip of 0.075-inch thick by 2 inches wide polyethylene foam having a density of 2 pounds per cubic foot ("Volara" Type A). The adhesively treated surface of the foam was placed on a silicone release liner and 2-inch squares having a five-eighths-inch diameter hole in the center were cut from the resulting laminate.

A coating of the acrylate adhesive was applied on one side of 1-inch diameter polystyrene discs 0.040-inch

thick. Brass studs having a silver-silver chloride coating and silver eyelets having a silver chloride coating were attached to the centers of the polystyrene discs with the silver eyelets on the adhesively treated surface.

A 0.025-inch polyethylene foam was treated with adhesive as above and 2-inch square pieces having a one-fourth-inch diameter hole in the center were cut from the treated foam.

Electrodes were assembled by placing a polystyrene disc adhesive side down on the untreated surface of a 0.075 inch thick foam square such that the silver-silver chloride eyelet was in the hole formed in the polyethylene foam. Next a 0.025-inch layer of the treated polyethylene foam was placed adhesive side down on top of the polystyrene disc with the coated brass stud protruding through the hole in the foam forming a laminate similar to FIG. 1 but without the gelled pad.

A 1½-inch diameter preform was cut from the laminate concentrically around the center. A five-eighths-inch diameter piece of open celled polyurethane foam having a thickness of three-sixteenths-inch and having a density of about 1.1 pounds per cubic foot was placed into the cavity formed by the polystyrene disc and the 0.075-inch thick polyethylene foam. The foam was adhesively bonded in place by the adhesive on the polystyrene disc. Sodium chloride electrolyte ("EKG-SOL") was injected into the foam disc; about 0.3 cubic centimeters of electrolyte being injected into the foam.

The electrodes were then packaged in an airtight container to prevent the electrolyte from drying out.

What is claimed is:

1. A medical monitoring electrode for attachment to external monitoring means, said electrode comprising a soft resilient layer having an aperture therethrough, said layer having on one side thereof a coating of hypoallergenic adhesive for securing said electrode to a patient's skin and having within said aperture a spongy, open-celled foam filled with a conductive electrolyte, a rigid plastic disc adhered to said layer opposite said adhesive coating and overlying said aperture, said open-celled foam being adhesively retained within said aperture, and an electrically conductive snap carried by said plastic disc and extending above the top face thereof for connection with an external monitoring means and being in electrical contact with said electrolyte at the opposite face of said disc.

2. The electrode of claim 1 having in addition a layer of foam covering the rigid plastic disc and having an aperture therethrough for the connection of the conductive snap to the external monitor.

3. The electrode of claim 1, where said electrically conductive snap passes through said plastic disc.

4. The electrode of claim 1, where said snap and said disc are a unitary plastic body and have a conductive layer disposed thereon.

5. The electrode of claim 1 wherein the means for adhesively retaining said open-celled foam within said aperture comprises a coating of adhesive on the undersurface of said disc overlying said aperture.

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