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BIO-MEDICAL INSTRUMENTATION ELECTRODE

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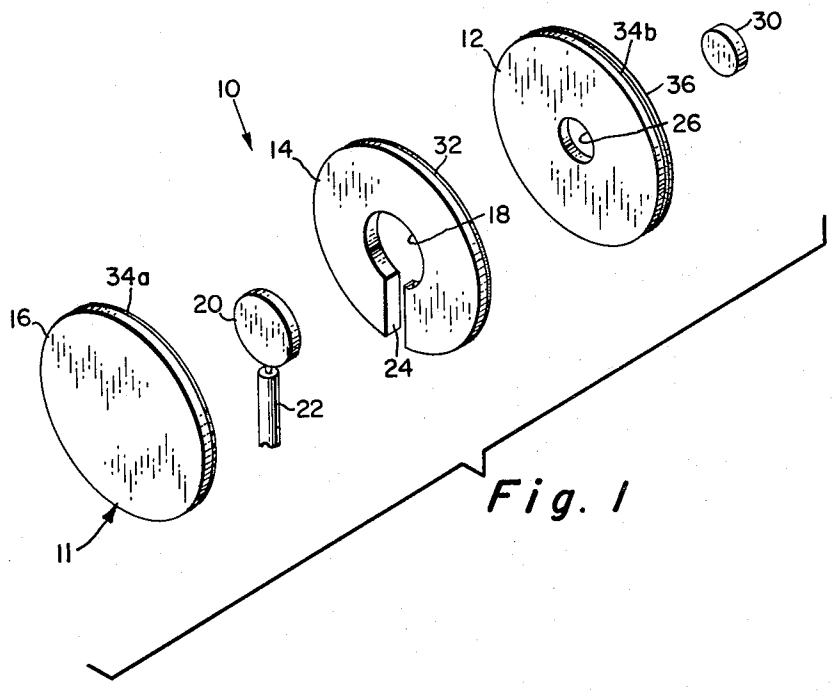

Fig. 1

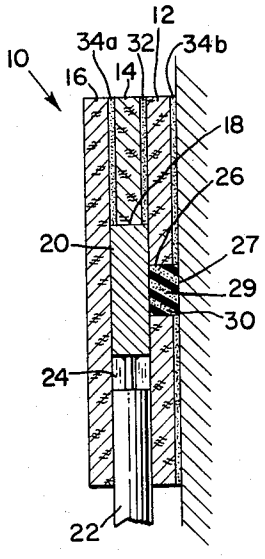

Fig. 2

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BIO-MEDICAL INSTRUMENTATION ELECTRODE

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The invention described herein may be manufactured and used by or for the Government of the United States of America for governmental purposes without the payment of any royalties thereon or therefor.

This invention relates to medical instrumentation, and more particularly to an instrumentation electrode capable of intercepting minute bio-electrical potentials which appear on the body surface of a subject and suitable for use in a dynamic environment.

Comparatively recent aerospace advances have accelerated the requirement for improved designs of electrodes for electroencephalograph and electrocardiograph devices that can be used in dynamic environments, and that will operate with a high degree of dependability.

Standard clinical electrodes presently in use consist for the most part of a relatively large metal plate, such as copper or stainless steel, maintained by clamps, elastic straps, adhesive tape, etc. in intimate contact with a skin area of the subject where the potential is to be measured. Such a design has been found to be satisfactory for laboratory use where the subject is in a static environment and the sensitivity to pressure artifacts is not a factor in the electrical recording of the data.

However, under a dynamic environment, such as for a pilot occupying a full-pressure flight suit in an airborne vehicle, these prior art electrodes present several serious disadvantages. It has been found that use of the clinical electrode which relies on direct metal-to-skin contact normally presents relatively large contact potentials. These contact potentials are further increased by pressures, both positive and negative, that may be caused by various artifacts, which reduce the intimacy of the contact between the electrode and skin and adversely affect the quality of the recorded bio-electrical potentials. Heretofore, clinical electrodes were usually limited to limb extremities where they were subjected to excessive muscle potential artifacts. Attempts to use the clinical electrodes as torso leads, in an attempt to minimize muscle artifacts, were unsatisfactory because these prior art electrodes are too large, uncomfortable, and too difficult to releasably attach to the body surface in a routine manner. These considerations become critical when it is required to instrument inside a high-altitude, full pressure, flight suit to be occupied by a pilot where freedom of movement is an important factor.

The present invention presents advantages over the prior art electrodes mechanically and electrically in nature. Mechanically, the present electrode is small, light in weight, and presents a thin profile which contributes to improved comfort to the subject, and reduces susceptibility to displacement by various pressures and friction. The electrode assembly is in the form of a patch comprising a series of superimposed layers of cork, or like insulating material, secured together and supporting therebetween a metal pellet electrode in fixed spaced distance from the skin thus avoiding metal-to-skin contact. The pellet is provided with an electrical conductor for connection into the recording circuit. The hollow space between the pellet and the skin, being of optimum size, is filled with a conductive paste which creates a conductive path therebetween, the composition of the paste being

compatible with the body saline electrolyte. The conductive paste may be retained in position within the patch by impregnating a resilient sponge-like material. A pressure sensitive adhesive on the face of the cork layer adjacent the skin not only provides an effective and simple means of attaching the electrode patch to the desired skin area thereby eliminating the requirement for adhesive plaster strips, but more important it also serves to hermetically seal the paste within the electrode assembly as well as maintaining the fixed spacing between the electrode pellet and the skin which defines the electrical bridge.

An object of the invention is to provide a bio-medical electrode device which is small, compact and sufficiently thin to be used in dynamic environments, such as by a pilot under flight conditions, and under a variety of external forces.

Another object of the invention is to provide such an electrode device which will maintain a constant or fixed conductive path with the skin throughout the application of either a negative or positive pressure to the skin area supporting the electrode, and a corollary object is to provide such a device which is insensitive to displacement.

Still another object is to provide a medical electrode which can be readily installed and removed; simply manufactured; which is salvageable for reuse to reduce the cost per application; and which can be used over relatively long periods of time without developing instabilities.

Other objects and many of the attendant advantages of this invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings wherein:

FIG. 1 is an exploded perspective elevation view of the electrode patch assembly; and

FIG. 2 is an enlarged vertical section through an assembled electrode unit adhered to a skin surface of a subject.

Referring to the figures where like reference numerals refer to similar parts throughout the drawing there is illustrated in FIGS. 1 and 2 a bio-medical electrode patch assembly 10 comprising a housing 11 of a plurality of thin discs, three being illustrated, namely 12, 14, and 16, arranged in a sandwiched relation. The term "disc" is not intended to limit the use to circular layers, although such a shape is preferred as a matter of avoiding sharp corners that may catch clothing, etc., as well as increased structural strength since the discs will be fabricated with openings for purposes later to be described. In the preferred embodiment, disc 12 is a base member, disc 14 is a spacer member, and disc 16 is a cover member. The discs are made of insulating material, such as cork, which is light in weight, relatively incompressible, and has the desired flexibility for compliance with the selected skin area. The various dimensions thereinafter noted are of one sample electrode patch assembly that in practice has been found to be completely satisfactory, and while these dimensions can be varied, it is believed that certain considerations must be accounted for. In the example, the discs are all 23 millimeters in diameter; base and spacer discs being 2 millimeters in thickness while cover disc is 1 to 2 millimeters in thickness. Since the electrode patch is to be used under flight suits, etc., the smallest thickness of the assembly consonant with satisfactory structural integrity is desired. Spacer disc 14 has a central hole 18, which in the example has been made 9 millimeters in diameter, to accommodate snugly a metallic electrode pellet 20 of a corresponding diameter, the pellet having attached thereto a conductor 22 adapted to be

connected in a recording circuit, not shown. The pellet is the same thickness, namely 2 millimeters as spacer disc **14** to insure a tight fit on the edge and top with the respective disc for sealing purposes. Spacer **14** is also slotted at **24** from the outer edge to the hole to accommodate snugly the conductor, being 2 millimeters in diameter. The electrode pellet **20** is preferably made of a mixture of equal weights of silver and silver chloride, although it is believed that each ingredient could be varied from 30 to 70% and still provide satisfactory results.

Base disc **12** is also provided with a central hole **26**, the example having a 5 millimeter diameter, being smaller than hole **18** to provide a 2 millimeter circular lip to ensure that electrode pellet **20** is firmly and tightly supported between the cover disc and the base disc when assembled. Hole **26** in the base disc defines the area **27** of the subject's skin from which the potential is to be measured, and the size has optimum limits as will be explained. Electrical conductivity through hole **26**, a distance of 2 millimeters, between the electrode pellet and the skin area is bridged by a conductive paste or gel **29**, such as the commercially available "graphojel" manufactured by Tablax Company, New York, New York which is inserted in the cup-like area. Where the electrode device is to be applied for relatively long periods of time or where the device is subjected to various external pressures, it may be desirable to reinforce the electrical bridge by using a fine-celled sponge **30** which fits into base hole **26**, the sponge being impregnated with the conductive paste which is retained therein. The fitting, assembly, and application of the assembled electrode device to the subject's skin are all important to achieve a near-hermetic sealed space for the conductive gel.

As a production step, spacer disc **14** may be permanently cemented by **32** to a base disc **12**, so that electrode pellet **20** and lead **22** may be readily seated in their respective openings in the spacer disc. As previously described, the fit is very snug, and as the electrode pellet is flush with the surrounding cork disc, the electrode pellet is firmly fixed and sealed therein when cover disc **16** is secured thereto by integral contact adhesive layers on the contacting faces of the cover and spacer discs, represented by adhesive **34***a* on the cover disc. However, as will be later described, cover disc **16** is applied as the last step in the procedure of applying the electrode patch. The open face of the base disc is also provided with an integral contact adhesive **34***b* suitably protected by a thin cloth air tight layer **36** with which the cork disc is manufactured to preserve the contact adhesive until ready for use, such a protective layer may also be provided on the adhesively coated face of cover **16**, not shown. Adhesive **34***b* on the base disc has other functions in addition to securing the electrode patch to the skin which will be hereinafter described.

The selected skin area on the subject is first cleansed with alcohol to remove surface oils and easily removable foreign matter. The area is then scrubbed with the conductive paste until the area develops a redness. The area is then washed with a detergent solution. Next a ring of tincture of benzoin compound approximately the size of the electrode patch is applied with at least a 5 mm. centered hole left uncovered. With protective layer **36** removed, the spacer and base disc assembly is then pressed on the skin with the uncovered skin area concentric with hole **26** of the base disc. The conductive paste is then inserted into hole **26**. When sponge **30** is to be employed, the paste is filled to a depth of approximately 1 mm. prior to insertion of the paste impregnated sponge. Any remaining space is filled with additional conductive paste. The undercontacting surface of electrode pellet **20** is then next coated with a thin layer of the conductive paste and inserted in hole **18** of the spacer disc with conductor **22** firmly seated in groove **24**. Finally, cover disc **12** is adhesively pressed over spacer disc **14**.

It is believed that improved electrical characteristics of the invention electrode assembly are achieved primarily by maintaining a fixed electrical bridge through the conductive paste between the electrode pellet and the skin area. This is achieved by firmly supporting the electrode pellet in the assembly without play, and also by preventing any relative movement between the electrode pellet and the skin. For example, increasing the diameter of hole **26** substantially greater than 5 mm. would allow the skin area to bulge in, or move out of, hole **26** depending on whether there was a positive, or negative pressure on the applied electrode patch, respectively. Decreasing the diameter of hole **26** substantially less than 5 mm. unduly limits the potential that can be transmitted. The maintenance of the fixed electrical path is further achieved by adhesive **34***b* which secures base disc **12** firmly and completely around skin area **27** reducing to a minimum any displacement of the skin with respect to the electrical patch assembly. In other words, skin area **27** is displaced piston-like by any external force, and the electrode pellet follows by the same distance. In event there is a slight relative displacement between the encircled skin area and the electrode pellet, the resilient characteristics of the impregnated sponge will maintain good electrical continuity even if some of the conductive paste escapes.

Adhesive **34***b* also functions to seal the electrical patch assembly to the skin to prevent the escape and evaporation of the conductive paste in base disc hole **26**, the tight fit of electrode pellet in spacer disc **14** and cover **16** preventing the escape of the conductive paste through the patch assembly.

Low values of skin/electrode resistance are desirable because of the tendency to resistance modulate the amplifier of the recording circuit, not shown, by instabilities due to displacement of the electrode assembly by external forces is minimized. These forces are normal to, or lateral to, the plane of the skin. It is important that the electrode patch assembly be insensitive to these forces. Reduced potential difference across the electrode patch assembly is achieved through the interface functions consisting of a pellet-paste couple and the paste skin couple, compatibility existing in the ionic structure of the electrode pellet, the conductive paste, and the skin.

After one application of the electrode patch assembly, the cork disc components can be stripped away and discarded, and the electrode pellet and conductor reused in a new cork assembly.

According to the present invention there is provided an improved bio-medical electrode suitable for use in dynamic environments. The assembly is small, compact, light weight and has a low profile less subject to lateral displacement that may upset the applied patch. These factors are important to attenuate discomfort and fatigue for the user, especially over extended periods. Elimination of the metal-to-skin contact by use of a conductive paste bridge, and maintaining this electrical bridge constant, that is, supporting the electrode pellet at an unvarying distance from the skin throughout use, reduces adverse effects of varying the resistance in the recording circuit and eliminates pressure artifacts as a trouble source in the system. Securing the electrode patch assembly to the skin area directly by an adhesive helps to achieve the constant electrical path; to obtain a hermetically sealed enclosure for the conductive paste; and reduces the effects of lateral forces on the patch.

Obviously many modifications and variations of the present invention are possible in the light of the above teachings. It is therefore to be understood that within the scope of the appended claims the invention may be practiced otherwise than as specifically described.

We claim:

1. A bio-medical electrode assembly for attaching to a subject's skin, comprising a housing composed of a plurality of superimposed flat layers of flexible insulation mate-

rial adhesively secured together, one of said layers having a face portion adapted physically to contact the skin, an electrode supported between said layers in fixed, spaced relation to said skin, said housing having a central opening capable of containing a conductive paste for creating a single conductive path between said electrode and the subject's skin, and adhesive means on the face portion of the body for adhering the assembly including the entire edge of the opening completely around the skin area opposite said housing opening so as to maintain a fixed electrical path of constant resistance between the electrode and the subject's skin.

2. The electrode assembly of claim 1 wherein said electrode is firmly supported in a central opening in an adjacent layer, said opening being in juxtaposition to the opening containing the conductive paste.

3. A bio-medical electrode assembly for attaching to a subject's skin, comprising a housing composed of a plurality of superimposed cork discs including a base disc having a first central opening, the remaining portion of the base disc facing the skin having a coating of a pressure sensitive adhesive, an intermediate disc having a central opening larger than said first opening and a narrow slot extending from said second central opening to the outer edge of said intermediate disc, a metal electrode pellet and an associated conductor snugly fitting into said second opening and slot, respectively, a cover disc, adhesive means for securing and sealing said intermediate disc to the cover disc, and the intermediate disc to the base disc with the electrode and conductor fixed in position, said first opening capable of containing a conductive paste to create an electrical bridge between said electrode and the skin area,

the adhesive on the face of the base disc capable of adhering the electrode assembly to the skin and of sealing the conductive paste within said first opening.

4. The electrode assembly of claim 3 wherein a sponge-like member is housed within said first opening and impregnated with conductive paste.

5. The method of securing a bio-medical electrode assembly to a subject's skin, said assembly including a body member having a plurality of flexible insulation discs, one disc being a cover disc and another disc being a base disc having a central opening to receive an electrically conductive paste and an electrode adjacent said opening and in contact with said paste, the steps of first adhesively securing the base disc to a selected area of the skin completely around at least the entire edge of said base opening for the paste, filling said opening in the base with the conductive paste and then with the electrode in position adhesively applying said cover disc on top of said base disc to secure the electrode within the base disc.

References Cited by the Examiner

UNITED STATES PATENTS

562,765	6/96	Horton	128—418 X
1,583,087	5/26	Morse	128—417
2,895,479	7/59	Lloyd	128—417
2,943,628	7/60	Howell	128—418

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