Oct. 28, 1969 W. R. JOHNSON 3,474,775

ELECTRODE ASSEMBLY FOR SKIN CONTACT

Filed Feb. 27, 1967

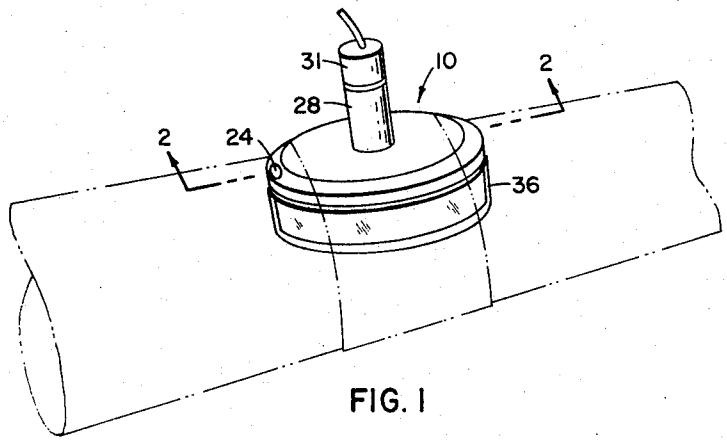

FIG. 1

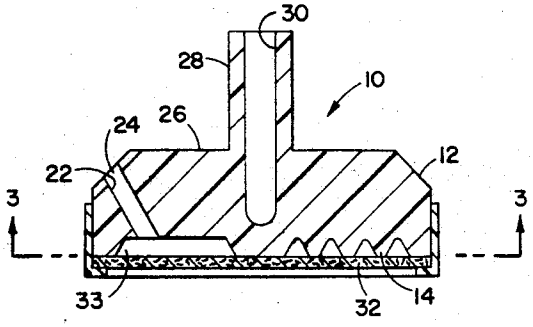

FIG. 2

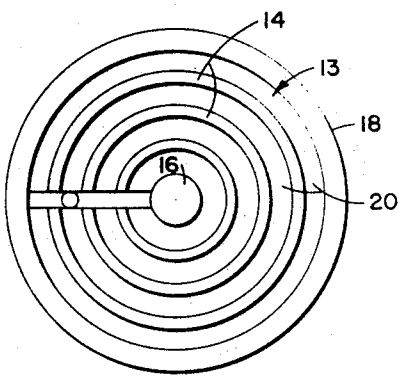

FIG. 3

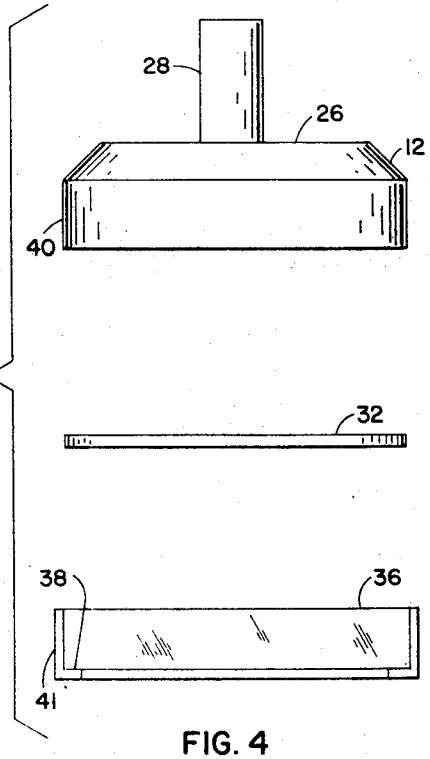

FIG. 4

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ELECTRODE ASSEMBLY FOR SKIN CONTACT

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ABSTRACT OF THE DISCLOSURE

An electrode assembly for making electrical contact with the skin consisting of a disc of conductive plastic material with a ribbed bottom side and an opening through to a top side, a wafer of soft absorbent material adapted to cover the bottom side of the disc, and a frame member adapted to fit around the side of the disc and hold the wafer clamped to cover the bottom side of the disc.

Skin contacting electrode assemblies are finding greater and greater application as knowledge of body action-reaction with respect to electrical currents existing and induced into the body increases and is applied. Present day uses of such electrode assemblies include those employed with electrocardiographs and cystic fibrosis detection equipment. With respect to the latter, to which the present invention is particularly directed, an electrode serves to produce sweat through the application of a small electrical voltage and current between two nearby but separated skin portions of the body.

The sweat glands on a localized area of the skin of the forearm are activated by the iontophoretic introduction of pilocarpine. In the process of iontophoresis, differences in electrical potential are established and pharmacologically active ions carrying a charge are introduced into the skin. In practice a positive electrode is moistened with pilocarpine nitrate and placed on the skin. A negative electrode is moistened with an electrolyte such as sodium nitrate and is applied to the opposite side of the arm. The current is applied and the positively charged pilocarpine radicals move away from the positive electrodes into the skin toward the negative electrode. After the sweat glands have been stimulated, the electrodes are removed and sweat is collected. The sodium and chloride concentrations of the sweat are then measured by known means and the findings employed as very valuable data in aid of the diagnosis of cystic fibrosis.

In the past a number of different type electrodes or electrode assemblies have been employed to induce the necessary iontophoresis and typically they are of the sintered metal type a screen mesh type, or simply of metal plate. It is to be noted that the first type of these electrodes was generally designed for electrocardiograph measurements rather than for sweat inducing iontophoresis applications. In any event they all share a common and serious problem. This problem is, as starkly noted in the "Preface to the Second Addition of Proceedings of the Seminar-Workshop on Cystic Fibrosis," as revised on Jan. 15, 1964, and as published by the American Society of Clinical Pathologists, and which states: "Electrical burns may occur with any equipment (for inducing iontophoresis) now available, and these burns may be penetrating, painful and healing may be delayed," and "Burns are caused by drying out of pads and by pressure points of the electrodes against the skin."

Test results obtained by the applicant from tests of systems employing electrodes available prior to the present invention clearly are to the same effect. It has been found that the principal reason for the difficulties with the prior devices arose out of uneven distribution of the current flow between the patient's skin and the electrode.

Such results are attributed to a variety of reasons and largely they are as suggested by the quotations, uneven distribution of conductive liquids used to perfect contact between skin and electrode, imperfect and uneven soaking of absorbent pads used between skin and electrode, and uneven pressures.

It is a general practice to place a sheet of absorbent paper or gauze between an electrode (of the same size or larger than the electrode) and the skin and to apply an appropriate conductive fluid through the top of the electrode, or to otherwise soak the gauze or paper. With this arrangement and this is the usual one, the inventor has discovered that there is a tendency for excessive pressure to be applied at the edges of the electrode and the filter paper or gauze to become indented by virtue of edge pressure. This in turn causes high edge currents at the edges with unusually high current flowing across relatively small areas. This results from the reduced thicknesses of absorbent material occurring at the indented edges, and this is particularly true as saturation of the filter paper becomes complete. In fact the filter paper tends to tear and often small holes or crevices occur through which direct metal to skin contact occurs. Likewise direct metal to skin contact occurs through compressed gauze. Further, due to wringing out of fluid from the absorbent material around the edges of the electrode, simple evaporation from material at the edges, and evaporation from any material extending beyond the edges, which material acts as a wick, portions of the absorbent material quickly dry out during the iontophoresis procedure which requires about five minutes. This necessarily results in reducing the conductive area and when sufficiently reduced, high currents result in the remaining damp and thus conductive areas producing skin burns.

It is the object of the present invention to eliminate the problem of skin burning in the process of skin iontophoresis and to generally provide an improved electrode or electrode assembly or system for this purpose.

In accordance with this invention, an electrode assembly is constructed with an electrode base member having a surface which lies generally in a plane. This surface has indentations in the form of perforations, slots or grooves extending through the surface to a top portion of the electrode base member through which a desired conductive solution is applied. A removable L-shaped frame or retaining ring support of insulating material is attached to the periphery of the bottom portion of the electrode base member and this frame extends inward over a small portion of the lower surface. A wafer of absorbent material or pad, such as filter paper, is positioned to just cover the bottom surface of the electrode and is held by the frame. In this manner the insulating frame covers the edge portion of the electrode. Thus it is impossible to effect a direct short or even significantly reduced electrical resistance path through the edge of the electrode and edge high current effects are eliminated. This feature together with its elimination of "drying out" of the absorbent material at the edges which are now sealed virtually eliminates small areas of high current concentrations and the danger of skin burns.

As a further feature of the invention the electrode assembly base portion of the electrode is made of a conductive plastic, that is of a conductive resin material with a specific resistivity much higher than steel (by a factor of at least 100) which further reduces the tendency toward high currents occurring through a single path since the smaller paths produce noticeably greater resistance and in effect produce self limiting of current flow.

As still a further feature of this invention, the skin engaging end of the electrode assembly base employs rela-

tively large concentric grooves rather than small openings, and as opposed to sintered metal, wire mesh and wire gauze for the purpose of providing a fluid path, and this in turn permits a more even saturation of the absorbent material. The effect of surface tension and tendency to bridge between sintered walls, wires, and gauze mesh walls of the fluid causing reduced flow is avoided. Further, by using the concentric grooves and the conductive plastic construction, a much simplified form of construction, with substantially reduced costs of construction is achieved.

Other objects, features and advantages of the invention will become more apparent from the following description when considered together with the drawings in which:

FIG. 1 is a pictoral view of an embodiment of the invention as used;

FIG. 2 is a section view taken along the lines **2—2** of FIG. 1;

FIG. 3 is a bottom view of the embodiment of the invention shown in FIGS. 1 and 2; and

FIG. 4 is an assembly drawing or exploded view of the embodiment of the invention shown in FIGS. 1 and 2.

Referring now to the drawings, electrode base member assembly **10** includes a base member **12** which is cast or machined from a conductive plastic type material, a resin systems material with an impregnated filler such as polyethelene with a carbon black filler. Base member **12** thus is electrically conductive but it provides significant electrical resistance. The bottom portion **13** of base member **12** of electrode assembly **10** is formed with a plurality of spaced concentric raised portions **14** extending from center post **16** outward to its periphery **18**. Between the raised portions are annular openings, indentations or grooves **20**. A passageway **22** connects between an opening **24** in the top portion **26** of base member **12** and grooves **20** through which a conductive fluid may be introduced. An upward extending member **28**, rising from the top portion of base member **12**, is provided with a circular opening **30**. Opening **30** is approximately .17 inch in diameter and .50 inch in length to provide an electrical receptacle and terminal for a standard banana plug **31**. An electrical conductor between the terminal and bottom portion of the electrode base member is provided by the natural conductivity of the base member. Further, the base, base member or body portion of the electrode assembly and terminal are thus constructed simply as a single unit. A wafer **32** of soft absorbent material such as filter paper covers the bottom portion of electrode base member **12** and fits snugly against the raised common plane surface of concentric rings or raised portions **14** and encloses annular grooves **20** which thus form a reservoir **33** for any desired conductive fluid. In this manner, wafer **32** may be readily and thoroughly saturated for effective use as a skin contacting member. Wafer **32** is held in place and its edges insulated from skin contact by insulating frame **36**. Frame **36** is constructed of an electrically non-conductive plastic, resin systems material. It is in the form of an L-shaped band or ring wherein one wall **38** is frictionally supported by the outer edge **40** of the bottom portion of electrode base member **12**. The outer wall **41**, at right angles to the first wall **38**, supports the edge of wafer **32** against electrode base member **12** and also provides, as stated above, a protective layer between the edge region of base member **12** and the skin, in addition to the wafer. In this manner indentations or perforations of wafer **32** at the normally higher pressure regions at the edges are prevented as are the resulting high density edge currents which in the past have resulted in not infrequent burns during the iontophoresis procedure.

In operation, two electrode assemblies **10** are applied to the skin of the patient at spaced points. Conductive fluids are introduced through openings **24**, e.g. a .5% pilocarpine nitrate solution, to the electrode to which a positive voltage is to be applied and e.g. a 1% sodium nitrate solution to the electrode to which a negative voltage is to be applied. The absorbent filter paper or wafer **32** saturates quickly and stays saturated throughout the iontophoresis procedure which takes about five minutes. Typically currents on the order of 1.5 milliamperes are used. Extensive testing has shown that when used in this manner burning of the skin has been eliminated. Constant attention throughout the procedure to insure that no drying out of the absorbent pad or filter paper occurs, a previous requisite, has been eliminated and dangers formerly present in this type procedure no longer need be feared.

I claim:

1. An electrode device comprising:

(A) an electrode base member having:

(1) a bottom surface comprising a planar surface interrupted by a plurality of indentations, said planar surface being electrically conductive and extending to the periphery of said base member and being adapted to provide a substantially planar supporting surface for one side of a thin wafer of soft absorbent material,

(2) a top surface including electrical terminal means for coupling an external source of power to said electrode base member and further including an opening for introducing fluid into said electrode base member,

(3) an intermediate region between said top and bottom surfaces including electrical conductive means for coupling power between said terminal means and said bottom surface and including a passageway between said opening and said indentations whereby liquid may be applied through said electrode base member to cavities formed by said indentations in said bottom surface;

(B) a wafer of thin, soft, plane absorbent material of a size and shape substantially corresponding to the area of said planar surface of said electrode base member and positioned with one side in engagement with said planar surface; and

(C) supporting frame means extending around the periphery of said bottom surface of said electrode base member, supported by said electrode base member, and in engagement with the edge of said wafer for holding said wafer in said position and including an insulating outer, bottom, surface whereby the peripheral edge region of the bottom portion of the said electrode device is electrically insulated from surfaces against which the electrode device is applied.

2. The electrode device as set forth in claim **1** wherein said supporting frame means comprises:

(A) a frame of electrically insulating material;

(B) said frame is dimensioned and positioned to extend around and frictionally engage the side of said electrode base member wherein said frame is supported by said base member;

(C) said frame includes a supporting edge extending inwardly over and covering a relatively small portion of the periphery of the lower exposed surface of said wafer.

3. The electrode device set forth in claim **2** wherein said electrode base member is constructed of a resin material impregnated with a conductive filler material.

4. The electrode device set forth in claim **3** wherein said indentations comprise a plurality of connected concentric grooves.

5. The electrode device set forth in claim **1** wherein said electrode base member is constructed of a resin material and impregnated with a conductive filler material.

6. An electrode device as set forth in claim **5** wherein said indentations comprise a plurality of concentric grooves.

7. An electrode device for uniformly saturating an ab-

sorbent wafer with a fluid and for applying an electrical potential to said wafer comprising a disc of conductive resin material and including:

(A) a bottom surface comprising a planer surface interrupted by a plurality of concentric grooves and a groove interconnecting said concentric grooves, said planar surface extending to the periphery of said base member and being adapted to provide a substantially planar supporting surface for one side of a thin wafer of soft absorbent material when positioned to cover said planer surface;

(B) a top surface including an electrical terminal for coupling an external source of power to said electrode device, and said top surface further including an opening for introducing a fluid into said electrode device, and

(C) an intermediate region between said top and bottom surfaces including a passageway between said opening and at least one of said grooves, whereby a liquid may be applied to the cavities defined by said grooves and thereby applied to a said wafer.

8. An electrode device as set forth in claim **7** further comprising a supporting frame for supporting a said wafer and wherein:

(A) said frame is of an electrically insulating material;

(B) said frame is dimensioned and positioned to extend around and frictionally engage the side of said electrode base member wherein said frame is supported by said base member; and

(C) said frame includes a supporting edge adapted to extend inwardly over and covering a portion of the periphery of the lower exposed surface of said wafer.

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