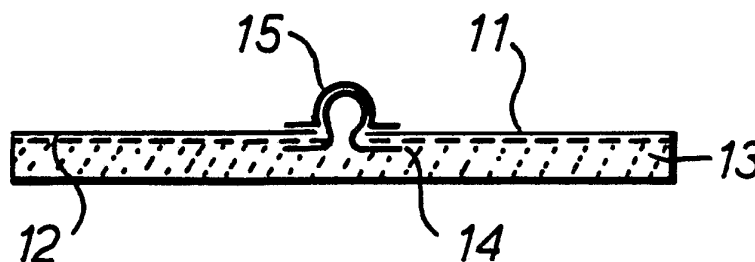




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(54) Title: ELECTRICALLY-CONDUCTIVE DEVICE FOR MEDICAL PURPOSES AND A MATERIAL FOR USE IN THE SAME



(57) Abstract

An electrically-conductive device for medical purposes. The device comprises a three-dimensional conductive polymeric network (14) supported on one face of a backing member (11). The backing member (11) includes an electrically-conductive contact (15) passing through the member (11) from said one face of the member, and the network has a conductive medium interspersed therethrough (13). The medium (13) provides an electrical path through the device (via the medium (13), the network (14) and the contact (15)) when placed on the skin. Also provided is an electrically-conductive material, which material comprises a three-dimensional conductive polymeric network (14) having a conductive medium (13) interspersed throughout the interstices thereof.

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**ELECTRICALLY-CONDUCTIVE DEVICE FOR
MEDICAL PURPOSES AND A MATERIAL
FOR USE IN THE SAME**

The present invention relates to an electrically-conductive device for medical purposes, in particular to those such medical devices commonly known as "electrodes". Also provided is an electrically
5 conductive material for use in the same.

In International Publication No. WO 84/02423 there is disclosed a formable polymer composition having electrically-conductive properties. The earlier composition is broadly defined as one which comprises a
10 formable polymeric material having dispersed therein an electrically-conductive material in particulate form comprising metal or metal coated particles, the conductive material being present in an amount to provide an overall specific conductivity in the
15 composition of at least about 2 mho cm^{-1} . Furthermore, in one preferred aspect the earlier composition includes one or more components to provide a composition having contact adhesive properties which can be used to produce a transducer or so-called "electrode". Such a
20 transducer is said to comprise a backing member through which is mounted an electrically-conductive contact so that an electrical lead can be connected to one part of the contact at the rear of the backing member. The contact then provides an unbroken electrical path
25 through the backing member to a portion of the said electrically-conductive adhesive composition forming at least part of an adhesive layer disposed on the front of the backing member through which the front of the transducer may be adhered to the skin. The earlier
30 transducer device is disclosed as useful in e.c.g.

measurement applications and as a cardiac stimulator.

In using the transducer of the earlier invention difficulties can be encountered in arriving at interface characteristics with skin tissue which are satisfactory. Often the initial impedance is too high and, although the system eventually settles down, it often takes an undesirably long time to reach equilibrium as evidenced by a stable e.c.g. signal. Also, materials and production costs are high.

In U.S. Specifications Nos. 4,391,278 and 4,581,821 there is disclosed an improved medical electrode particularly adaptable to tape-like configurations for use in sensing and stimulation applications in which the electrode is applied to the skin and a method of preparing the same. An essential electrode component comprises a mixture of a polymerized form of 2-acrylamido-2-methylpropanesulphonic acid or one of its salts with water and/or an alcohol. The mixture possesses electrically conductive properties, flexible properties and adhesive properties particularly lending itself to skin contact and adhesion.

In its most preferred form, as shown in the Figures, the earlier electrode includes an electrical current distribution member which also electrically contacts an electrical conductor lead as well as a substrate member of said mixture. The current distribution member is preferably formed of a metallic foil, such as stainless steel foil, which is said to be readily available in very thin configuration or form such as 0.001 inches (0.025 mm). Such a foil may be included in the electrode without having any substantial effect on its flexibility. Due to the adhesive nature of the substrate the foil readily adheres thereto. Other forms of distribution member may also be used, such as wire mesh, conductive cloth or the like.

The earlier invention is predicated on the provision of a skin contacting component which is homogeneous and creep resistant and thus (according to the generalities of that disclosure) is able to avoid the development of "hot spots". Nevertheless, we have found that electrode arrangements, such as the disclosed arrangement which depend on pure metal (or metal alloy) in the form of say a sheet or wire mesh to distribute the charge over the electrode, suffer from the disadvantage that the charge distribution is uneven. This in fact leads to the formulation of "hot spots" especially at the outer edge(s) of the electrode, which is especially pronounced when electrodes are used as defibrillation electrodes and/or under defibrillation conditions.

However, we have also found quite surprisingly that the various disadvantages of the earlier inventions can be overcome by providing a three-dimensional conductive polymeric network coated with a conductive material (preferably silver or silver/silver chloride) as a carrier matrix for a conductive medium. In that manner, good interface characteristics can be obtained (both in an e.c.g. measurement and in a defibrillation use situation), a much wider variety of conductive media can be employed, and an "electrode" which has a good storage life can be produced at a lower cost. Also, the conductive polymeric network and conductive medium construction can provide low and constant polarisation potentials and good current distribution, whereas known electrodes are deficient in one or both of these.

Accordingly, the present invention provides an electrically-conductive device for medical purposes, and especially a defibrillation or defibrillation/e.c.g. electrode, which device comprises a three-dimensional conductive polymeric network supported on one face of a backing member, the backing member including an

5 electrically-conductive contact passing through the member from said one face of the member, and the network having a conductive medium interspersed therethrough to provide an electrical path through the device (via the medium, the network and the contact) when placed on the skin.

10 In the device of the present invention, the three-dimensional conductive network may be any polymeric network which is conductive per se or has been treated to render it conductive. Thus, for example, it may be based on a polymeric material which is conductive such as a polyacetylene or a carbon fibre filled polymer. Preferably, however, it is based on a polymeric material which has surfaces coated with a conductive material.

15 Thus, the network may be any polymeric network capable of providing either surface or inherent electronic conductivity.

20 In particular, the network may be any random or regular collection or collocation of strands or filaments or the like of conductive coated or conducting polymeric material, which are linked together to provide a three-dimensional network structure comprising said strands etc. and a multiplicity of interstices. Preferably, the network is a woven or unwoven mesh comprising strands of polymer, typically which form a regular network, and more preferably an open weave mesh, or a network based on an expanded reticular structure such as a sponge defining interstices in the case of a mesh or capillaries in the case of a sponge.

25 In any of the networks used in the present invention, the various strands etc. which form the network may be woven together, fused together, or in any other way linked, such as by adhesion, into a three-dimensional polymeric network structure. Also, the network may be formed by selective cutting of a polymeric sheet material followed by stretching.

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So that any chosen three-dimensional polymeric network based on a non-conductive polymer may function as an electrically-conductive material, the network is provided with a conductive coating. Such a coating may
5 comprise any material which can provide the necessary conducting properties, but generally speaking the network will be coated with a thin coating or a film of a metal or of a metal and a metal salt. Desirably the metal or metal and metal salt should be non-corroding,
10 non-corrosive, non-toxic and neither exhibit nor afford any adverse side effects when placed in close contact with the human skin for extended periods of time. In that respect, metallic silver or an equilibrium mixture of silver/silver chloride/chloride ions are preferred
15 as materials to provide the coating for the polymeric network, the latter being the most preferred.

Furthermore, the non-conductive polymer on which a network may be based may comprise a thermoplastics material or a thermo- or cold-setting material. Again, however, the polymeric material preferably should be one
20 which neither exhibits nor affords any adverse side effects when placed in close contact with the human skin for extended periods of time. On the other hand, apart from that consideration a variety of polymeric materials may be employed, for example, polyvinyl compounds;
25 polyalkenes, e.g. polyethylenes, polypropylenes and polyisobutenes; polyacrylates; polymethacrylates; polyamides, e.g. nylon; and polyurethanes. One especially preferred polymeric network is based on nylon and comprises an open weave nylon mesh coated with
30 silver or silver/silver chloride. Another especially preferred polymeric network comprises a sponge (e.g. polyurethane sponge) coated with silver or silver/silver chloride.

It will be appreciated, of course, that in the
35 device of the invention the network may be employed as a

single layer or as a plurality of superimposed layers. In addition, each such layer may comprise either the same or a different network material. Also, the interstices of the network may be regular or irregular and of any suitable shape such as square, hexagonal, circular, or the like, and of any suitable size. Typically, the largest dimensions of the interstices will be of the order of below about 5 mm, more preferably of from about 0.5 mm to about 3 mm, for example, about 1.5 to about 2 mm.

Furthermore, variations in size of the interstices across the device may be employed to vary electronic characteristics in the final device. Thus, in order to increase resistance towards the outer edge(s) of the device, the size of the interstices preferably may be increased towards the edge(s), and/or to decrease the resistance towards the centre of the device the size of the interstices preferably may be decreased towards the centre. For example, in the case of say a mesh network, strands may be cropped from those areas of the mesh adjacent the outer edge(s) to increase mesh size and/or a finer mesh network may be superimposed e.g. as a disc of mesh, at the centre of the device.

Generally speaking the backing member of the device of the invention will comprise a sheet material, which most usefully (in some instances) may be a conductive sheet material, although typically it will comprise non-conductive sheet material. Thus, a wide variety of sheet materials may be employed, preferably polymeric sheet materials which exhibit at least a degree of flexibility. As examples of such sheet materials there may be cited polyvinylchloride, polyethylene, polypropylene and like materials.

Preferably, the electrically-conductive contact is a stud or ball pillar or the like compatible with existing e.c.g. or defibrillation leads or the like,

which provides a means of connecting the leads to the device of the invention. Such a stud or pillar may be formed of metal e.g. silver, or of a coated metal e.g. silver coated with silver chloride, the latter being preferred. Preferably also, the contact is mounted at or about the centre of the backing member and, in order to avoid uncomfortable corners, the backing member may be a disc or, more preferably to keep waste to a minimum, a square with rounded corners.

In the device of the invention, the conductive medium may be selected from a number of media as more fully described below. Such media in themselves may be adhesive and, by virtue of that property, may provide in the device overall the necessary adhesive-properties to enable the device to be adhered to the skin in a satisfactory manner. Nevertheless, in some instances it may be preferred (whatever the conductive medium employed) to include an annulus of non-conducting contact adhesive material surrounding a central portion or plug comprising said polymeric network and conductive medium disposed on the backing member. More preferably, such an annulus may be formed of a hypoallergenic pressure-sensitive skin adhesive material. Most preferred is an annulus comprising a hypoallergenic composition based on polyisobutene.

As to the conductive medium, that may be any medium which can be interspersed through the interstices of the three-dimensional polymeric network so as to provide the necessary electrical path through the device via the medium etc. when the device is placed on the skin, and any required or desired degree of skin adhesion. In that manner there can be provided an electronically conducting network interfaced with an ionically conducting medium, which in turn is compatible with the conducting medium naturally provided at the skin surface.

Generally speaking, the medium used in the invention will be a relatively viscous material so that it does not readily flow out of the polymeric network. Thus, for example, the conductive medium may be a gel or the like, typically one based on an aqueous conducting system; or a formable conductive polymer composition as described and claimed in International Publication No. WO 84/02423 (European Application No. 84-90-0090 and U.S. Patent Application No. 841,169) the disclosures of which are hereby incorporated by way of reference; or a modification of such a composition wherein the metal particles or the like are replaced by other conductive materials.

Thus, generally speaking preferably the conductive medium may be as follows:

A. An aqueous- and/or alcohol-based conductive gel, for example, one having a gel structure based on a sulphonic acid or one of its salts. Typically, such a gel may be one based on a polymer of 2-acrylamido-2-methylpropanesulphonic acid or a salt thereof and water and/or an alcohol e.g. glycerol, such as that sold as "Hydrogel" by Promean.

B. A formable polymer composition comprising a formable polymeric material having randomly dispersed therein an electrically conductive material in particulate form. The particulate material is one comprising metal or metal-coated particles having a narrow spectrum of particle size and being present in an amount to provide an overall specific conductivity of at least about 2 mho cm^{-1} , and in a proportion which at least exceeds that of the critical percolation volume. Preferably, such a material will be based on silver-coated glass spheres, e.g. ballotini, as described in the above-mentioned International Publication. Preferably also, such a composition will be based on polyisobutene, which may be mixed with one or more phase

structure, flow and/or moisture permeability modifiers, for example, low molecular weight polyalkenes, e.g. polyethylene, or hydroxyalkyl celluloses, e.g. hydroxymethyl cellulose. In such a composition the polyisobutene typically may have a viscosity average molecular weight in the range of from about 40,000 to about 100,000.

Furthermore, such a composition in accordance with the preferred aspects of the earlier invention more preferably includes an additive to reduce contact resistance with the skin when applied to unprepared skin. Preferably, such an additive is one which provides an aqueous medium within the composition to provide the necessary electrical continuity through the skin keratin layer. Thus, the composition preferably includes an additive comprising a mixture of:

1. Water,
2. A hygroscopic agent such as glycerine or glycerol or polyvinyl alcohol, and
3. A thickening agent, for example, carboxymethyl-cellulose,

which mixture may be used in an amount of, for example, from about 1% to about 5% by weight of the total composition.

In preparing one of the earlier compositions containing an additive to reduce skin contact resistance, it is convenient to prepare a first mixture comprising additive and electrically-conductive material, and a second mixture comprising polymer and electrically-conductive material, those mixtures then being blended to form the final composition. When that method is employed, preferred ranges of the various components for the first mixture are:

- (i) A ratio of hygroscopic agent e.g. glycerol, to water of from about 20:80 to about 80:20 by weight,
- (ii) A proportion of thickening agent e.g. CMC, to

hygroscopic agent/water mixture of from about 2% to about 10% by weight, and

(iii) A percentage of electrically-conductive material, e.g. silver-coated glass spheres, in the overall mixture of from about 70% to about 80% by weight.

Generally, the overall composition will include no more than about 20% by weight of such a first mixture including said additive since the use of more than about 20% by weight could result in a composition that is both too soft and which could leave a heavy residual deposit on the skin when the transducer is removed after use. Preferably, the upper limit for the first mixture is about 15% by weight based on the total weight of the composition.

Furthermore, in the earlier compositions the additive may be modified so that it comprises:

- (a) Water,
- (b) A hygroscopic agent, and
- (c) A water-soluble salt, for example, sodium chloride.

Typically in that case there may be used glycerol saturated with a saturated solution of sodium chloride in water e.g. distilled water.

C. A composition comprising:

1. A formable polymer, for example, polyisobutene,
2. A hygroscopic agent, for example, as described above, and
3. A water-soluble salt, for example, sodium chloride.

Again, typically, in that case there may be used glycerol saturated with a saturated solution of sodium chloride in water e.g. distilled water.

The device of the present invention can be constructed and arranged as an "electrode" or transducer intended for use in a wide variety of medical applications. For example, the device of the invention

may be constructed and arranged as an e.c.g. monitoring and/or diagnosis electrode, as a neo-natal electrode, as a defibrillation electrode or the like. The device of the invention provides electrical conductivity both in terms of taking a signal from a patient and in terms of directing a signal into a patient. In particular, the device of the invention has significant advantages over the usual metal paddles used as defibrillation devices which must be used in a somewhat harsh manner, and with great skill, otherwise the patient can be burnt. Since the device of the present invention provides good electrical contact with the skin, it can be used in a more gentle manner without burning.

Furthermore, while known silver/silver chloride defibrillation electrodes can be used in a less harsh manner than paddles, they exhibit other disadvantages not possessed by the device of the invention. Thus, such known (disposable) electrodes are designed as ones having a large surface area to avoid burning of the patient and must be stored flat otherwise the conducting medium in them leaks out. Also, they are relatively costly for items to be used only once.

Thus, in a particularly preferred aspect, the invention provides a device as defined or described herein which is a defibrillation or a defibrillation/e.c.g. electrode. Such an electrode affords a more uniform charge distribution than with known electrode arrangements such as that of U.S. Specification No. 4,581,821.

The invention will now be further described by way of example with reference to the accompanying drawings, in which:

Figure 1 is a diagrammatic cross section through one form of device in accordance with the invention, and

Figure 2 is a diagrammatic cross section through another form of device in accordance with the invention.

Referring to Figure 1, the device shown comprises a backing member 11 which on one face 12 carries a layer of a viscous conducting medium 13. In that conducting medium 13 is embedded a polymeric network material comprising a mesh 14. Also, a stud and eyelet contact 15 provides electrical contact through the backing member 11 to the medium 13 and mesh 14, and secures together the mesh and backing member.

Referring to Figure 2, that shows a similar device, except that the conductive medium is now carried in the interstices or capillaries 16 of a sponge 17 disposed on face 12 of the backing member 11.

Based on the structures generally described above with reference to the drawings, devices illustrating specific electrodes in accordance with the invention may be prepared according to the details in the following Examples:

Example 1

An electrode was prepared using the following materials and formulations, namely:

1. Backing member 11 - a pvc sheet material.
2. A silver/silver chloride stud and eyelet 15 - obtained from TRW Fasteners, Cambridge, Mass., U.S.A.
3. Mesh 13 - silver-coated nylon mesh Type 1037 (described as a warp knitted from 10 filament 40 denier nylon 6 yarn with a hole count of 20 x 20 per square inch) obtained from Croxton & Garry. This mesh has square holes of approximate dimensions 1.5 mm to 2 mm.
4. Conductive medium (and adhesive) 14 - a gel medium sold by Promean under the name "Hydrogel RG 63A" - typically a layer of about 1 mm in thickness.

Using the above materials an electrode device having a backing member of 4 x 4 cm overall dimensions and a mesh of the same dimensions was produced. Such an electrode device has good defibrillation characteristics, can be produced at a low cost and has

good storage properties. The device also has high quality reproducible e.c.g. signal characteristics.

Example 2

A device is produced in accordance with the details of Example 1 except that the nylon mesh is replaced by a silver-coated polyurethane sponge, i.e. to provide a sponge 17 as shown in Figure 2, the interstices of which are filled with the Promean "Hydrogel". The sponge can be attached to the backing sheet either via the "Hydrogel" or by using a suitable adhesive such as the acrylic adhesive Fasson S277 made by John Cleland.

Example 3

A device is produced in accordance with the details of Example 1 except that the Promean "Hydrogel" is replaced by a polyisobutene composition in accordance with International Publication No. WO 84/02423, for example, a composition as described in Example 1 of that publication, namely one formulated as follows:

| <u>Component</u> | <u>Percent by weight of the total composition</u> |
|--|---|
| Silver-coated glass spheres prepared as described in the International Publication | 72 |
| Polyisobutene (viscosity average molecular weight of about 50,000) | 28 |

By using an adhesive composition based on polyisobutene as described above the silver-coated nylon mesh can be embedded in a thin film of the composition and attached to the final backing member without the use of an intervening separate adhesive.

Example 4

Example 3 is repeated except that there is used a conductive medium as follows:

| <u>Component</u> | <u>Percent by weight of the total composition</u> |
|--|---|
| 5 Silver-coated glass spheres prepared as described in the International Publication mentioned above | 70 |
| 10 Polyisobutene (viscosity average molecular weight of about 50,000) | 25 |
| 15 Glycerol (BP grade) saturated with a saturated solution of sodium chloride in distilled water | 5 |

Example 5

Example 4 is repeated except that the silver-coated glass spheres are omitted and the composition is thus formulated as follows:

| <u>Component</u> | <u>Percent by weight of the total composition</u> |
|--|---|
| 20 Polyisobutene (viscosity average molecular weight of about 50,000) | 90 |
| 25 Glycerol (BP grade) saturated with a saturated solution of sodium chloride in distilled water | 10 |

Example 6

Example 2 is repeated except that the conductive medium is glycerol (BP grade) saturated with a saturated solution of sodium chloride in distilled water.

Example 7

5 Example 6 is repeated except that the conductive medium is based on polyvinyl alcohol rather than glycerol and has the following composition:

| 10 | <u>Component</u> | <u>Percent by weight of the total composition</u> |
|----|---|---|
| | Polyvinyl alcohol | 90 |
| | Saturated solution of sodium chloride in distilled water | 10 |

Example 8

15 A defibrillation electrode was prepared using the materials and formulations of Example 1 except that the stud and eyelet 15 was replaced by a Newey-Goodman ball pillar, and the backing member was 4 inches x 4 inches (about 10 cm x about 10 cm).

20 It will be appreciated from the above specific description that the invention provides a device through which electrical signals can be received from or transmitted to living tissue by means of an electrode comprising a three-dimensional conductive polymeric network functioning as an interface membrane embedded in
25 and/or carrying a conductive medium. Also, it will be

appreciated that the specific details mentioned above may be varied to a wide degree within the spirit and scope of the following claims provided only that the device is based on the said network as defined and the
5 said conductive medium.

Furthermore, it will be appreciated from the above description that the device of the invention in some embodiments can use a novel material insofar as it employs a conductive polymeric network, and especially
10 a sponge, having a conductive medium interspersed throughout the interstices thereof. Accordingly, in one other aspect of the invention, there is provided an electrically-conductive material, which material comprises a three-dimensional conductive polymeric
15 network, especially in the form of a sponge, having a conductive medium interspersed throughout the interstices thereof. In particular, such a material may comprise a polymeric sponge comprising a material such as polyurethane in which the capillaries of the sponge
20 have an electrically-conductive coating such as one provided by silver or silver/silver chloride/chloride, with a conductive medium as described above interspersed therethrough.

CLAIMS

1. An electrically-conductive device for medical purposes, which device comprises a three-dimensional conductive polymeric network supported on one face of a backing member, the backing member including an electrically-conductive contact passing through the member from said one face of the member, and the network having a conductive medium interspersed therethrough to provide an electrical path through the device (via the medium, the network and the contact) when placed on the skin.
2. A device according to claim 1, wherein the conductive polymeric network is based on a conductive polymer.
3. A device according to claim 1, wherein the conductive polymeric network is a polymeric network having a conductive coating.
4. A device according to any one of the preceding claims, wherein the network is a woven or unwoven mesh comprising strands of polymer.
5. A device according to claim 4, wherein the network is a regular network comprising an open weave mesh.
6. A device according to any one of claims 1 to 3, wherein the network is a sponge structure.
7. A device according to any one of claims 3 to 6, wherein the network is a polymeric network which is coated with a thin coating or a film of a metal or of a metal and a metal salt.
8. A device according to claim 7, wherein the network is coated with metallic silver or silver/silver chloride/chloride ions.
9. A device according to any one of claims 3 to 8, wherein the network is one based on a polyvinyl compound; a polyalkene; a polyacrylate; a

polymethacrylate; a polyamide; or a polyurethane.

10. A device according to claim 9, wherein the polymeric network is based on nylon and comprises an open weave nylon mesh coated with silver.
- 5 11. A device according to claim 9, wherein the polymeric network is based on a polyurethane and comprises a sponge coated with silver.
12. A device according to any one of the preceding claims, wherein the network is a single layer or a
10 plurality of superimposed layers comprising either the same or a different network.
13. A device according to any one of the preceding claims, wherein the largest dimensions of the interstices of the network are from about 0.5 mm to
15 about 3 mm.
14. A device according to any one of the preceding claims, wherein the backing member comprises a non-conductive flexible sheet material.
15. A device according to claim 14, wherein the
20 backing member comprises polyvinylchloride.
16. A device according to claim 15, wherein the contact is formed of metal or of a formable electrically-conducting composition.
17. A device according to any one of the preceding
25 claims, wherein the conductive medium is an aqueous- and/or alcohol-based conductive gel.
18. A device according to claim 17, wherein the medium is one based on a sulphonic acid structure.
19. A device according to any one of claims 1 to 5, 7
30 to 10 or 12 to 16, wherein the conductive medium is a formable polymer composition comprising a formable polymeric material having randomly dispersed therein an electrically conductive material in particulate form comprising metal or metal-coated particles having a
35 narrow spectrum of particle size and being present in an amount to provide an overall specific conductivity of at

least about 2 mho cm^{-1} , and in a proportion which at least exceeds that of the critical percolation volume.

20. A device according to claim 19, wherein the particulate material comprises silver-coated glass spheres.

21. A device according to claim 19 or claim 20, wherein the composition is based on polyisobutene, which may be mixed with one or more phase structure, flow and/or moisture permeability modifiers.

22. A device according to any one of claims 19 to 21, wherein the composition includes an additive to reduce contact resistance with the skin when applied to unprepared skin.

23. A device according to claim 22, wherein the composition includes an additive comprising water, a hygroscopic agent, and a thickening agent.

24. A device according to claim 22 or claim 23, wherein the composition includes an additive comprising water, a hygroscopic agent and a water-soluble salt.

25. A device according to any one of claims 1 to 16, wherein the conductive medium comprises a formable polymer, a hygroscopic agent and a water-soluble salt.

26. A device according to claim 24 or claim 25, wherein the salt is sodium chloride.

27. A device according to any one of the preceding claims, which includes an annulus of non-conducting contact adhesive material surrounding a central portion or plug comprising said polymeric network and conductive medium disposed on the backing member.

28. A device according to claim 27, wherein the annulus is formed of a hypoallergenic pressure-sensitive skin adhesive material.

29. A device according to any one of the preceding claims which is an e.c.g. and/or defibrillation electrode.

30. An electrically-conductive material, which

material comprises a three-dimensional conductive polymeric network having a conductive medium interspersed throughout the interstices thereof.

5 31. A material according to claim 30 having one or more of the features defined in any one of claims 2 to 13 or 17 to 26.

FIG. 1

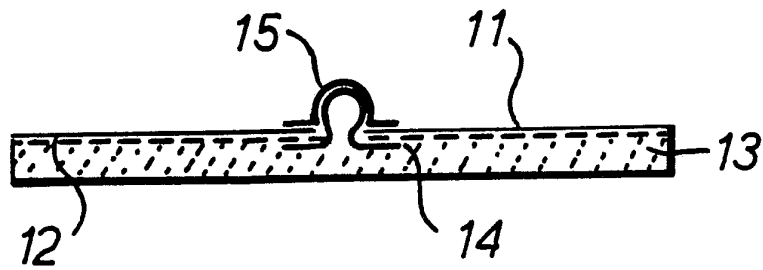
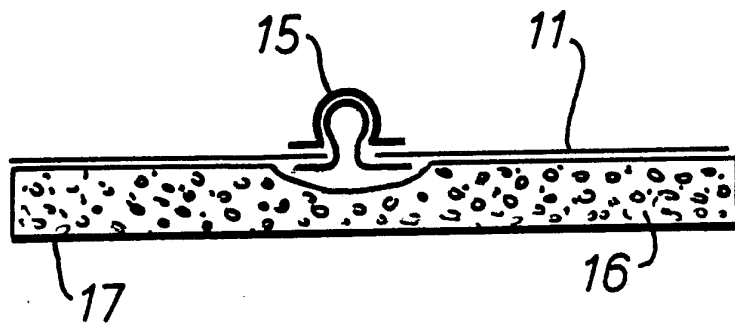


FIG. 2



INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 87/00835

| I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶ According to International Patent Classification (IPC) or to both National Classification and IPC IPC ⁴ : A 61 N 1/04 | | | | | | | | | | | | | | | | | |
|--|--|---|--|--|-------------------------------------|--------|--|------|---|--|------|---|---|-------------------------------|---|---|--------|
| II. FIELDS SEARCHED <div style="text-align: right; margin-right: 100px;">Minimum Documentation Searched ⁷</div> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%; padding: 5px;">Classification System</td> <td style="padding: 5px;">Classification Symbols</td> </tr> <tr> <td style="padding: 5px;">IPC⁴</td> <td style="padding: 5px;">A 61 N</td> </tr> </table> <p style="text-align: center; margin-top: 10px;">Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸</p> | | | Classification System | Classification Symbols | IPC ⁴ | A 61 N | | | | | | | | | | | |
| Classification System | Classification Symbols | | | | | | | | | | | | | | | | |
| IPC ⁴ | A 61 N | | | | | | | | | | | | | | | | |
| III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹ <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%; padding: 5px;">Category ¹⁰</th> <th style="width: 70%; padding: 5px;">Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²</th> <th style="width: 20%; padding: 5px;">Relevant to Claim No. ¹³</th> </tr> </thead> <tbody> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">Y</td> <td style="padding: 5px;">EP, A, 0085327 (MEDTRONIC, INC.) 10 August 1983 see the whole document --</td> <td style="text-align: center; vertical-align: top; padding: 5px;">1-31</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">Y</td> <td style="padding: 5px;">WO, A, 84/02423 (KENNEDY) 21 June 1984 see the whole document cited in the application --</td> <td style="text-align: center; vertical-align: top; padding: 5px;">1-31</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">A</td> <td style="padding: 5px;">FR, A, 2291732 (KAUFMAN) 18 June 1976 see page 3, line 31 - page 4, line 32 --</td> <td style="text-align: center; vertical-align: top; padding: 5px;">1-6,11, 14,16,17, 29-31</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">A</td> <td style="padding: 5px;">US, A, 4066078 (BERG) 3 January 1978 see column 3, line 18 - column 6, line 36 -----</td> <td style="text-align: center; vertical-align: top; padding: 5px;">1-7,29</td> </tr> </tbody> </table> | | | Category ¹⁰ | Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹² | Relevant to Claim No. ¹³ | Y | EP, A, 0085327 (MEDTRONIC, INC.) 10 August 1983 see the whole document -- | 1-31 | Y | WO, A, 84/02423 (KENNEDY) 21 June 1984 see the whole document cited in the application -- | 1-31 | A | FR, A, 2291732 (KAUFMAN) 18 June 1976 see page 3, line 31 - page 4, line 32 -- | 1-6,11, 14,16,17, 29-31 | A | US, A, 4066078 (BERG) 3 January 1978 see column 3, line 18 - column 6, line 36 ----- | 1-7,29 |
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| Y | WO, A, 84/02423 (KENNEDY) 21 June 1984 see the whole document cited in the application -- | 1-31 | | | | | | | | | | | | | | | |
| A | FR, A, 2291732 (KAUFMAN) 18 June 1976 see page 3, line 31 - page 4, line 32 -- | 1-6,11, 14,16,17, 29-31 | | | | | | | | | | | | | | | |
| A | US, A, 4066078 (BERG) 3 January 1978 see column 3, line 18 - column 6, line 36 ----- | 1-7,29 | | | | | | | | | | | | | | | |
| <p>¹⁰ Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> | | <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"A" document member of the same patent family</p> | | | | | | | | | | | | | | | |
| IV. CERTIFICATION <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 5px;"> Date of the Actual Completion of the International Search 24th February 1988 International Searching Authority EUROPEAN PATENT OFFICE </td> <td style="width: 50%; padding: 5px;"> Date of Mailing of this International Search Report 07 APR 1988 Signature of Authorized Officer P.C.G. VAN DER PUTTEN </td> </tr> </table> | | | Date of the Actual Completion of the International Search 24th February 1988 International Searching Authority EUROPEAN PATENT OFFICE | Date of Mailing of this International Search Report 07 APR 1988 Signature of Authorized Officer P.C.G. VAN DER PUTTEN | | | | | | | | | | | | | |
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ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.

GB 8700835
SA 19572

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
The members are as contained in the European Patent Office EDP file on 16/03/88
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

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