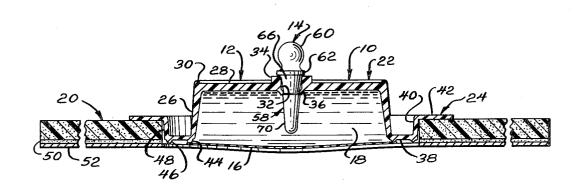
[54]	ELECTRO	DDE
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[52] [51] [58]	Int. Cl	128/2.06 E, 128/417, 128/DIG. 4
[56]		References Cited
[56]	UNIT	References Cited FED STATES PATENTS
2,555 3,027 3,580 3,590 3,602 3,659	,037 5/19 ,333 3/19 ,240 5/19 ,810 7/19 ,216 8/19	7ED STATES PATENTS 51 Jenson 128/417 62 Friedman 128/417 71 Cosentino 128/2.06 E 71 Kopecky 128/2.06 E 71 Moe, Jr 128/2.06 E
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Primary Examiner—William E. Kamm Attorney, Agent, or Firm—Anthony S. Zummer

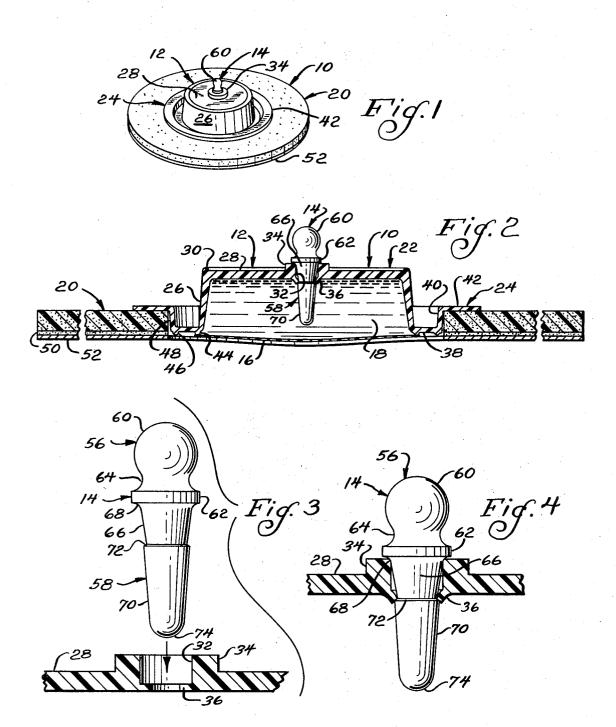
[57] ABSTRACT

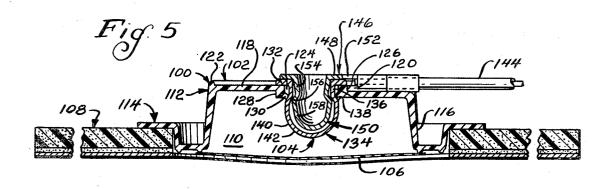
A biomedical electrode for use in cooperation with a signal-receiving apparatus is the subject matter of this invention. The instant electrode is one which is particularly adapted for use in observing certain phenomena of the subject by observing electrical signals on the surface of the subject. The electrode includes an open-sided, resilient container, with a microporous diaphragm closing the open side. An electrolyte is contained in the container and permeates the diaphragm to unite with skin fluids of the subject. The container contains a filling aperture on the side opposite the open side. An annular sealing flange is formed integral with the container and extends into the filling aperture. A terminal plug is positioned in the filling aperture in sealing engagement with the annular sealing flange to seal closed the filling aperture.

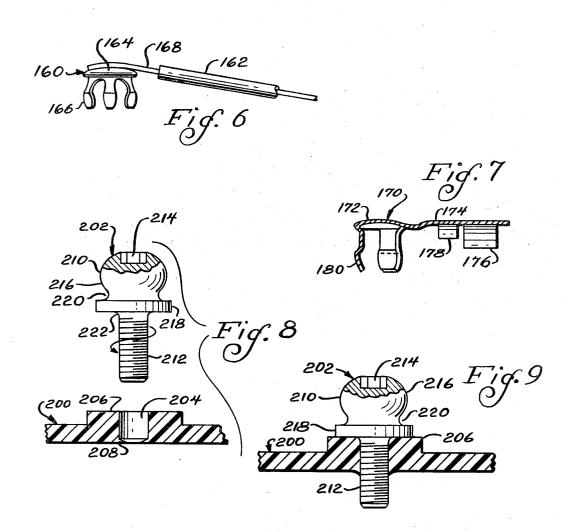
14 Claims, 9 Drawing Figures



SHEET 1 OF 2







BACKGROUND OF THE INVENTION

The general construction of a biomedical electrode such as that which is the subject matter of this invention is well-known in the art and is disclosed in U.S. patent application Ser. No. 303,335, filed on Nov. 3, 1972. The specific construction of such an electrode is adequate for short-run production. However, when large quantities of electrodes are required, the construction of the electrode is such that it is difficult to fill the electrode container with an electrolyte and then quickly and inexpensively seal closed the container to retain the electrolyte in the container.

SUMMARY OF THE INVENTION

The present electrode is a specific improvement of an electrode which has a container having a permeable diaphragm on one side of the container. The container is filled with an electrolyte through a filling aperture. The container has an annular sealing flange formed integral therewith and extending into the filling aperture. Once the container is filled with electrolyte, a terminal plug is inserted into the filling aperture and into sealing en- 25 gagement with the container and with the annular sealing flange to seal closed the filling aperture. The terminal plug performs three functions in the electrode. One function is to provide a terminal for connection of the electrode to a lead; the second function is to seal closed 30 the filling aperture; and the third function is to provide the necessary metal in contact with the electrolyte to form an electrical half cell for operation of the electrode. It is therefore a principal object of this invention to provide an improved biomedical electrode construc- 35 tion, which electrode may be quickly and easily assembled.

It is another object of the present invention to provide an improved construction of a biomedical electrode in which the various parts of the electrode may be quickly and easily manufactured.

It is a still further object of the herein-disclosed invention to provide a biomedical electrode which has a minimum of parts.

Other objects and uses of the instant invention will become readily apparent to those skilled in the art upon a perusal of the following specification in light of the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a biomedical electrode embodying the present invention;

FIG. 2 is an enlarged cross-sectional view of the biomedical electrode shown in FIG. 1, with portions bro- 55 ken away;

FIG. 3 is an enlarged side elevational view of a filling aperture in a container of the electrode of FIG. 2, showing a terminal plug in position for insertion into the filling aperture;

FIG. 4 is an enlarged cross-sectional view of the parts of FIG. 3, but showing the terminal plug in its sealing position in the filling aperture;

FIG. 5 is a cross-sectional view of a biomedical electrode similar to that shown in FIGS. 1 and 2, but showing a modified container and terminal plug construction;

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FIG. 6 is a side elevational view of a connector which is particularly adapted for use with the biomedical electrode shown in FIG. 5;

FIG. 7 is a side elevational view of another form of connector which may be quickly attached to a lead, which connector may be used in connection with the biomedical electrode shown in FIG. 5;

FIG. 8 is a fragmentary cross-sectional view of a portion of a container of a biomedical electrode having a slightly modified form and a terminal plug particularly adapted for mounting in a filling aperture of the container; and

FIG. 9 is a cross-sectional view of the parts shown in FIG. 8, but showing the terminal plug positioned in a 15 sealing attitude in the filling aperture.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the drawings, and especially to FIG.

20 2, an electrode which is a specific embodiment of the instant invention is shown therein and is generally indicated by numeral 10. The electrode generally includes a container 12 and a terminal plug 14 mounted in the container. A microporous diaphragm 16, made of a thin sheet of plastic material, such as, polypropylene, is mounted on the open side of container 12. The container is filled with an electrolyte 18, which is an 0.25 percent sodium chloride solution having a wetting agent, a bacteria inhibitor, and glycerine to control evaporation. A mounting pad 20 is secured to the container for attaching the electrode to a subject.

Container 12 is a resilient injection-molded part, which in this instance is a polypropylene part, though any other suitable material may be used. The container generally consists of two integral parts, a cup 22 and a mounting flange 24. Cup 22 includes an annular sloping wall 26, with a top 28 formed integral with the smaller portion of sloping wall 26. A bead 30 is formed integral with the outer periphery of the top 28. In the center of the top 28, there is a filling aperture 32, with a terminal boss 34 formed integral with the top around the aperture 32. Formed interiorly of filling aperture 32, there is a resilient annular sealing flange 36, having its outer periphery formed integral with the container. Flange 36 extends inward of the sealing aperture for engagement with the terminal plug 14, as will be described in detail hereinafter.

Mounting flange 24 includes an annular cup flange 38, having its interior formed integral with the lower portion of sloping wall 26. A cylindrical wall 40 is formed integral with the outer periphery of the flange 38. An annular pad flange 42 has its inner edge formed integral with the cylindrical wall 40. An annular diaphragm bead 44 is formed integral with an inner edge of the flange 38 for receipt of the diaphragm. A sealing bead 46 is formed integral with the outer edge of flange 38.

Mounting pad 20 is a thin piece of reticulated polyurethane foam, in which there are 50 to 150 pores per linear inch. The pad had a container aperture 48 receiving a portion of the container 12. A network of adhesive 50 is placed on one side of the pad 20, with a conventional release paper 52 positioned over the adhesive. The pad 20 is secured to the flange 42 by heat sealing. A conventional sealing sheet (which is not shown herein) is mounted on the annular bead 46 to prevent the electrode from drying out in storage. How-

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ever, when the electrode is in use, the sealing sheet is removed from the bead so that the diaphragm may contact the surface of a subject.

Terminal plug 14, in this instance, is a solid piece of tin-plated brass. The plug generally consists of a connector head 56 and a sealing body 58 formed integral with the head. The head includes a spherical portion 60, with an annular shoulder 62 formed therein and an annular fillet 64 between the portion 60 and the shoulder 62. The body includes a tapered shank 66 formed 10 integral with the shoulder and having a fillet 68 between the shank and the shoulder. The body also includes a tapered nose 70 formed integral with the shank 66. The nose 70 terminates in a rounded end portion 74. A beveled seal face 72 is integrally formed 15 between nose 70 and shank 66.

There is a very specific interrelationship of the sizes of the terminal plug 14 and filling aperture 32 and sealing flange 36. The diameter of the sealing shoulder 62 is greater than the diameter of the filling aperture 32. 20 The maximum diameter of the nose 70 is less than the diameter of the filling aperture. The minimum diameter of the tapered shank 66 is less than the diameter of the filling aperture 32, but greater than the interior diameter of the sealing flange 36. The distance from the 25 shoulder 62 to the beveled seal face 72 is slightly greater than the distance from the top of the boss 34 to the bottom of the top 38, as viewed in FIGS. 2, 3 and 4, but less than the length of the filling aperture plus the width of one side of the annular sealing flange 36. The 30 length of the nose 70 is slightly less than the height of the sloped wall 36, for reasons which will become apparent hereinafter.

Electrode 10 is assembled by securing the diaphragm 16 to the diaphragm bead 44 and securing the pad 20 35 to the flange 42. A sealing sheet (which is not shown) is placed over the diaphragm, into sealing engagement with bead 46. Cup 22 is filled with electrolyte 18 through the filling aperture 32. Once the cup is sufficiently filled, the terminal plug 14 is inserted into the filling aperture to seal closed the filling aperture.

The terminal plug 14 is inserted into the filling aperture with the longitudinal axes of the plug and the filling aperture being aligned. The tapered nose 70 is inserted into the upper portion of the aperture; and an 45 axial force is applied to the plug so that the rounded end portion 74 first engages the sealing flange 36. The sealing flange 36, being resilient, is deformed by the rounded end portion; and the outside walls of the tapered nose 70 then are moved into engagement with the sealing flange 36. The sealing flange is disposed downward as the tapered nose slides through the sealing flange. The plug is moved downward until the sealing shoulder 62 is placed adjacent to the upper surface 55 of boss 34; and the tapered nose, in its entirety, passes through the sealing flange until the sealing flange engages the beveled seal face 72. The diameter of the tapered shank 66 is greater than the diameter of the aperture through the sealing flange, so that the sealing flange is held downward in engagement with the seal face 72, thus locking the plug in position, with the fillet 68 in sealing engagement with the interior of the boss 34. It may be appreciated that the fillet deforms the boss slightly so that there is a double seal on the terminal plug.

There is one seal between the sealing flange 36 and the seal face 72, as may be best seen in FIG. 4. There

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is a secondary seal between the fillet 68 and the upper portion of the boss 34. The sealing action also serves to lock the plug into position, so that the plug is held securely in place.

The nose 74 extends downward into the cup, toward the diaphragm 16, but does not touch the diaphragm 16. However, the plug is immersed in electrolyte 18. The terminal plug, having its nose tin-coated, forms an electrical half cell with the electrolyte.

The electrode is applied to the skin of a subject by first removing the sealing sheet from bead 46. The release paper 52 is also removed from the pad. The electrode is adhesively secured to the patient by positioning the electrode at a desired location and applying a load to the mounting pad 20. Thus, diaphragm 16 is placed into contact with the skin of a patient. The diaphragm 16, being microporous, has electrolyte 18 permeating the diaphragm to wet slightly the exterior surface of the diaphragm so that, as soon as the diaphragm is placed into contact with a subject's skin, good contact is made between the diaphragm and the subject's skin fluids without the use of any other material or scraping the subject's skin. As is conventional, a lead is attached to the terminal plug.

Measurements are taken in a conventional fashion, using conventional equipment. The electrical condition is observed on electrical measuring equipment. There is a faithful reproduction of a signal since there is ionic conduction through diaphragm 16 since the electrolyte permeates the microporous diaphragm uniting with the skin fluids providing a conductive path directly between the electrode and the inner layer of the subject's skin. The amount of noise and other electrical disturbances is held to a minimum, thereby giving a high-fidelity signal.

The electrolyte is a physiological saline solution, thus allowing the electrode to remain on a patient's skin for a prolonged period of time. As the subject perspires, the perspiration does not affect the operation of the electrode.

It is a simple matter to move the electrode by pulling the pad off the skin of the subject. The electrode, being inexpensive to manufacture, may then be discarded.

Another form of an electrode embodying the present invention is shown in FIG. 5. The modified form of electrode is generally indicated by numeral 100. The electrode 100 generally consists of a resilient polypropylene container 102, a terminal plug 104 mounted in the container, a microporous thin sheet polypropylene diaphragm 106 mounted on an open side of container 102, and a polyurethane foam mounting pad 108 secured to the container. The container is filled with an electrolyte 110, which is identical to electrolyte 18.

Electrode 100 is identical to electrode 10, except for the construction of the container 102 and the terminal plug 104. Container 102 generally consists of two parts, a cup 112 and a mounting flange 114, which mounting flange is identical to mounting flange 24. The cup 112 includes an annular sloping wall 116, with a top 118 formed integral with the smaller portion of the sloping wall 116. A terminal groove 120 is formed in the top 118. A discontinuous bead 122 is formed integral with the top. The bead 122 is discontinuous only at the portion where the groove 120 extends through the bead. A filling aperture 124 is formed in the center of the top, with a wall 126 forming a part of a terminal portion adjacent to the groove 120. An interior boss 128 is

formed on the interior surface of the top, surrounding aperture 124. A sealing flange 130 is formed integral with the boss 128 and extends inwardly into the filling

The terminal plug 104 is a stamped brass hollow tin- 5 plated plug, which includes an annular head 132, with a hollow body 134 formed integral therewith. The hollow body includes a shank 136, having one end formed integral with the annular head 132. A seal face 138 is formed integral with one end of the shank. A hollow 10 as the electrode 10, which is described in detail above. nose 140 is formed integral with the face 138, and has a rounded end portion 142.

A lead wire 144 is connected to the terminal plug by a connector 146. The connector 146 includes a connector head 148 and a connector body 150. The con- 15 nector head has formed integral therewith a conventional gripping portion 152. The connector body 150 has a conical connector shank 154, with a locking face 156 formed integral therewith and a connector snout 158 formed integral with the face 156.

The electrode 100 is assembled in much the same manner that electrode 10 is assembled. After the container 102 is filled with the electrolyte 110, the terminal plug 104 is forced into the filling aperture 124. The construction of the terminal plug is such that the exte- 25 rior diameter of the nose 104 is less than the diameter of the filling aperture 124, but greater than the interior diameter of the sealing flange 130. As the terminal plug is forced into the container, the sealing flange is forced into the container and outward. Then, when the nose 30 passes entirely through the sealing flange, the sealing flange engages the seal face 138 and tends to push the plug into the container. However, the annular head 132 engages the top 118 so that the terminal plug is held securely in place. It follows that there are two seals be- 35 tween the housing and the terminal plug. One seal exists between the sealing flange 130 and the seal face 138. The second seal exists between the annular head 132 and the top 118. The tin-plated nose 140 is immersed in the electrolyte to form a half cell.

The electrode 100 gives a low profile in that the electrode does not have its terminal plug extending upward and outward of the electrode. The connector 146, which is electrically connected to the terminal plug, also provides a low profile. It may be appreciated that the connector 146 is connected to the terminal plug by inserting its connector body 150 into the terminal plug and snapping the connector body in so that the face 156 engages the interior of the seal face 136, while the connector head 148 is in engagement with the annular head 132. The gripping portion 152 and the lead 144 lie in the groove 120, so that the overall height of the connector positioned in the electrode is not substantially higher than the electrode.

Other forms of connectors may be used with the electrode 100, such as those shown in FIGS. 6 and 7. A button connector 160 is shown connected to a lead 162. The button connector has a conventional head 164, with a plurality of spring legs 166 formed integral with the head. The lead 162 has a wire 168 soldered to the head 164. The connector 160 is snapped into the terminal plug 104 by positioning the spring legs 166 into the opening of the terminal plug and pushing the button downward so that the spring legs engage the interior 65 surface of the nose 140 to make contact. A solderless connector 170 is shown in FIG. 7. The solderless connector has a head 172, with an elongated ribbon por-

tion 174 formed integral with the head. The ribbon portion has a pair of clamping arms 176 and 178 for engagement with the lead. The head 172 has a plurality of spring legs 180 formed integral therewith, which spring legs also fit into the aperture of the terminal connector. Whether connector 160 or 170 is mounted in electrode 100, each provides a low profile.

Irrespective of which connector is used with the electrode 100, the electrode operates in the same manner

Another improved electrode construction is shown in FIGS. 8 and 9. Only a portion of a top 200 of a container, with a terminal plug 202, is shown therein inasmuch as the remainder of the electrode is identical to electrode 10. The top 200 has a filling aperture 204; and a boss 206 is formed integral with the top. Adjacent to the interior surface of the top, there is an annular tapered sealing flange 208 extending inwardly of the filling aperture. The terminal plug 202 includes a head 210 and a threaded body 212. The head 210 includes a generally spherically shaped portion 216, having a conventional tool recess 214, for receipt of a tool (in this instance, an Allen wrench). Head 210 also includes a shoulder 218 formed integral with portion 216, with a fillet 220 therebetween. A fillet 222 is formed at the junction of the shoulder and the threaded body. The terminal plug is, in this instance, made of tin-plated

Terminal plug 202 is inserted into filling aperture 204 after the container has been filled with electrolyte. Terminal plug 202 is positioned in the filling aperture and then turned with an appropriate instrument positioned in recess 214 until the threads pass through sealing flange 208. The plug is rotated until the bottom of shoulder 218 engages boss 206 and fillet 222 deforms the boss slightly so that there is a seal between the upper surface of the boss 206 and fillet 222. The filling aperture is completely sealed by the sealing flange 208 engaging body 212 and by the engagement of fillet 222 with boss 206. The operation of the electrode is the same as that described in connection with electrode 10.

Although a specific embodiment of the present invention has been shown and described in detail above, it is readily apparent that those skilled in the art may make various modifications and changes in the specific disclosure without departing from the spirit and scope thereof. It is to be expressly understood that the instant invention is limited only by the appended claims.

What is claimed is:

1. A biomedical electrode for use on a subject for receiving electrical signals from said subject, comprising: a resilient container having an open side, a thin microporous diaphragm sealingly secured to the container closing said open side, an electrolyte in the container in contact with the diaphragm permeating the diaphragm to wet the outside surface of the diaphragm to have direct contact with the surface of a subject through the diaphragm between the surface and the electrolyte in the container, said container having a fill-60 ing aperture, a resilient annular sealing flange formed integral with the container and extending inwardly to the filling aperture, and a terminal plug mounted in said filling aperture in sealing engagement with the annular sealing flange and having a portion in contact with the electrolyte to form a half cell therewith, said terminal plug locked in said filling aperture by said sealing flange, said terminal plug including a head extending

exteriorly of the container, and a body positioned in the filling aperture and in sealing engagement with the resilient annular sealing flange to seal closed the filling

- 2. A biomedical electrode for use on a subject for receiving electrical signals from said subject as defined in claim 1 wherein the terminal plug is elongated, said head defines a portion of a sphere and is adapted for connection to a lead for electrical connection to an inportion of a sphere; and said body includes a tapered shank having its wider portion formed integral with the shoulder, a seal face formed integral with the tapered shank adjacent to the narrower end of said tapered shank, said seal face being adapted for sealing engage- 15 form a secondary seal therewith for the filling aperture. ment with the resilient annular sealing flange, and a nose formed integral with the seal face and being adapted for contact with the electrolyte, said nose having its free end rounded to facilitate insertion of the terminal plug through the annular sealing flange.
- 3. A biomedical electrode for use on a subject for receiving electrical signals from said subject as defined in claim 2 wherein the distance from the shoulder to the seal face is greater than the length of the filling aperthe width of the sealing flange, and said diameter of the tapered shank adjacent to the seal face is greater than the internal diameter of the annular sealing flange.
- 4. A biomedical electrode for use on a subject for receiving electrical signals from said subject as defined in 30 claim 1 wherein the terminal plug is an elongated terminal plug, said head of the terminal plug is adapted for connection to a lead for electrical connection to an instrument, and said body includes a tapered shank having its wider portion adjacent to the head.
- 5. A biomedical electrode for use on a subject for receiving electrical signals from said subject as defined in claim 4 wherein the body has a seal face formed integral with the tapered shank adjacent to the narrower sealing engagement with the resilient annular sealing flange.
- 6. A biomedical electrode for use on a subject for receiving electrical signals from said subject as defined in claim I wherein the terminal plug has a connector re- 45 ceptacle for receipt of a connector to make electrical contact therewith.
- 7. A biomedical electrode for use on a subject for receiving electrical signals from said subject as defined in nal groove in the side spaced away from said open side for receipt of a lead.
- 8. A biomedical electrode for use on a subject for receiving electrical signals from said subject as defined in claim 1 wherein the head of the terminal plug is held 55 in sealing engagement with the container to form a seal therebetween, thereby forming a secondary seal for the filling aperture.
- 9. A biomedical electrode for use on a subject for receiving electrical signals from said subject as defined in 60 claim 1 wherein the terminal plug is an elongated terminal plug; said head of the terminal plug is adapted for connection to a lead for electrical connection to an instrument; and said body includes a tapered shank hav-

ing its wider portion adjacent to the head, a seal face formed integral with the tapered shank adjacent to the narrower end of the tapered shank, said seal face being adapted for sealing engagement with the resilient annular sealing flange, and an elongated nose formed integral with the seal face and being adapted for contacting the electrolyte.

- 10. A biomedical electrode for use on a subject for receiving electrical signals from said subject as defined strument, and a shoulder is formed integral with said 10 in claim 1 wherein the head is solid and has a rounded exterior, said body is threaded over a portion of its length for threaded sealing engagement with the resilient annular sealing flange to seal closed the filling aperture, and the head sealingly engages the container to
 - 11. A biomedical electrode for use on a subject for receiving electrical signals from said subject as defined in claim 1 wherein the annular sealing flange is tapered and has its thinner portion adjacent to the interior 20 thereof, and said body is threaded for threaded sealing engagement with the annular sealing flange.
- 12. A biomedical electrode for use on a subject for receiving electrical signals from said subject as defined in claim 1 wherein the annular sealing flange is tapered ture but less than the length of the filling aperture plus 25 and having its thinnest portion adjacent to the interior thereof, said head is solid and has a rounded exterior surface, said head includes a tool recess in its surface spaced away from the body for receipt of a tool for rotating said plug, and said body is threaded over a portion of its length for threaded sealing engagement with the resilient annular sealing flange to seal closed the filling aperture.
- 13. A biomedical electrode for use on a subject for receiving electrical signals from said subject as defined 35 in claim 1 wherein the container includes a radial terminal groove in the side spaced away from the open side for receipt of a lead, said terminal plug has a connector receptacle for receipt of a connector to make electrical contact therewith, a flat head connector end of the tapered shank, said seal face is adapted for 40 mounted in the connector receptacle, and a lead electrically connected to the connector and having a portion lying in the radial terminal groove to provide a low profile for the biomedical electrode.
- 14. A biomedical electrode for use on a subject for receiving electrical signals from said subject as defined in claim 1 wherein the container includes a radial terminal groove in the side spaced away from the open side for receipt of a lead; said terminal plug has a connector receptacle for receipt of a connector to make claim 6 wherein the container includes a radial termi- 50 electrical contact therewith; said head of the terminal plug is flat and adapted for engagement with the container; said terminal plug body includes a tapered shank having its wider portion adjacent to the head, a seal face formed integral with the tapered shank adjacent to the narrower end of the tapered shank, said seal face being adapted for sealing engagement with the resilient annular sealing flange, and an elongated nose formed integral with the sealing face and adapted for contacting the electrolyte; a flat head connector mounted in the connector receptacle; and a lead electrically connected to the connector and having a portion lying in the radial terminal groove to provide a low profile for the biomedical electrode.