

1 567 962

- (21) Application No. 27766/78 (22) Filed 11 Jul. 1977
- (62) Divided out of No. 1567961
- (31) Convention Application No. 709140 (32) Filed 27 Jul. 1976 in
- (33) United States of America (US)
- (44) Complete Specification Published 21 May 1980
- (51) INT. CL.³ H01R 17/00 //
A61B 5/40

(19)



- (52) Index at Acceptance
H2E 10B 19 20 3A1 3A2 3A5 3A6C 3C6C 3C7 3D4 3E22 5

(54) ELECTRICAL CONNECTOR FOR MEDICAL ELECTRODES

(71) We, C.R. BARD, INC., a corporation of the State of New Jersey, United States of America, of Murray Hill, New Jersey, United States of America, do hereby declare the invention for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:-

5 This invention relates to electrical connectors for medical electrodes, and more particularly pregelled disposable medical electrodes used to detect biological or physiological electrical potentials such as those associated with muscular activity. In more detail, this invention relates to electrical connectors for low cost, high quality pregelled electrocardiogram (ECG) electrodes for detecting the muscular activity of the human heart.

10 Most ECG electrodes in routine use today depend on a metal-electrolyte interface with the body surface. Many electrodes use extremely pure silver as the metallic component. Those in which a moist, ready-to-use electrolytic paste is packaged as part of the electrode are termed pre-gelled. Electrodes intended for single patient use only are considered disposable. Those that can be reused many times are termed permanent.

15 In the past, the only high quality electrodes available contained pure silver as the metallic component of the electrode, with the surface often chlorided to achieve optimum performance. The process of chloriding involves coating, either by electrodeposition or reaction with chlorine gas, of the active surface of the silver with a thin layer of silver chloride.

20 Conventional permanent ECG electrodes are available in many styles and configurations, but all share several negative characteristics:

- a) They are often relatively expensive, since most employ high cost construction materials and methods.
- b) They must be reprocessed (cleaned carefully) between uses.
- 25 c) They must be attached to the skin with separate straps, suction cups, glue, tape, adhesive pads, or similar means.
- d) Most require that electrolytic gel or fluid be applied to the skin (or electrode) at time of use.
- e) Most are "short term" electrodes (in the sense that they cannot be left on a patient for more than a few hours before the gel desiccates and loses its electrical contact with the skin).

30 On the positive side, the best properly-prepared permanent ECG electrodes are capable of delivering extremely high resolution, nearly artifact-free signals. Hence, they are used whenever very high quality "Type 1" ECG recordings are necessary. Further if preparation and preprocessing costs are ignored, the cost/use is low, compared to pre-gelled, single-use electrodes. Suction or strap-attached permanent electrodes are often used when short-term ECG's are needed, since the electrodes can be repositioned or moved as often as necessary without resorting to the use of tape or glue.

35 Conventional disposable ECG electrodes offer increased convenience over permanent electrodes. Disposable ECG electrodes are usually pregelled, self-adhesive, and clean. Since they cannot be reused, cross-contamination is minimized and postuse cleanup is minimal. Most electrodes of this type provide reasonably accurate transduction of ECG data and are a fairly cost-effective approach to routine diagnostic ECG's and heart rate monitoring. Most will function adequately for one to several days, depending on the patient.

45

Pregelged electrodes typically consist of a thin, adhesive coated disc of open or closed cell foam or microporous tape. A centrally located gel reservoir consisting of a molded cup, such as shown in U.S. Patents 3,696,807, 3,701,346, 3,713,435, 3,820,531 or 3,830,229, or a die cut hole in the foam, such as shown in U.S. Patent 3,868,946, encapsulates a gel-saturated open cell compressible foam column. In the alternative, the gel-saturated, open cell foam column may be adhered directly to the face of the disc of foam, such as in U.S. Patent 3,828,766, or to an impermeable backing material as in U.S. Patent 3,805,769. The consistency of the gel is maintained by scaling the opening of the gel reservoir in one of several ways, which include: an injection molded or thermo-formed cap removably attached to the gel cup or an adhesive coated film on the disc in conjunction with a moisture-proof backing paper attached to the film and covering the gel saturated foam column or a combination of these. In spite of the use in these electrodes of such means for sealing the gel reservoir, most also require a secondary air-tight foil pouch or plastics bag to contain the electrode in an air-tight way and preserve the gel in a usable condition.

All pregelged electrodes known to be presently available, incorporate a metallic component in contact with the gel. This component can be silver coated plastics, silver, nickel, or stainless steel. In some types of electrodes, lead wires are permanently attached to the electrode. In the majority, however, a male snap fastener of silver, stainless steel, nickel, etc., is incorporated as a part of the electrode. A lead wire having a mating metallic female snap fastener on one end is connected to the male snap fastener of the electrode. The opposite end of such lead wire is then secured to a diagnostic instrument, such as a cardiograph. As an alternative, a silver-coated plastics snap fastener, such as shown in U.S. Patent 3,841,312 may be used. Use of mating snap fasteners have the disadvantage that relative movement between the electrode and the lead may cause motion artifacts. Further, use of a coated plastics male snap in conjunction with a metallic female snap may result in the silver coating on the male snap being scratched off during application or usage, causing faulty readings.

U.S. Patent 3,599,629 shows an electrode which does not employ a snap fastener. Instead, this device has a flat, wafer-like top composed of an electrically insulating material coated with a thin film of metallic silver having a surface layer that has been converted to silver chloride. Rather than using a wire lead having a mating snap fastener, this electrode employs a tubular plug dimensioned to snugly fit into a corresponding silver chloride coated socket in the wafer-like top, electrical continuity resulting from intimate contact between the socket and the plug.

In all of the above instances, the pregelged electrodes are sold ready for use having an electrically conductive material, such as metal or a metal chloride, in contact with the electrolyte gel. Such contact presents the possibility of chemical reaction between the two during storage of the electrode prior to usage. In addition, in all known conventional pregelged electrodes, especially those containing silver or silver chloride, the metal component represents a considerable portion of the cost of the electrode. As the electrodes are disposed of after only one use, the cost of the metal adds considerably to the cost of usage of same.

According to the invention, there is provided an electrical connector for a medical electrode and for transmission of an electrical signal, the connector being of the type wherein an electrically conductive probe is attached to an electrically conductive wire and a boot of electrically insulating material encloses the point of attachment of the wire to the probe, characterised in that the probe has a core of electrically nonconductive material within said boot and a pair of sharp pointed blades also of nonconductive material extending from the core and the boot, and a continuous coating of an electrically conductive material on the core and on the blades, one end of said wire being in electrical connection with said conductive coating on the core and on the blades.

Preferably the probe consists of an electrically nonconductive plastics having a coating of silver thereover and a film of silver chloride covering that portion of the silver coating extending beyond the boot.

A pregelged electrode pad and the connector of the invention together form a low cost disposable electrode system which has high fidelity signal transduction, negligible baseline drift, offset, and polarization and minimal distortion, artifacts or noise in the ECG output recording made during use of the electrode system, even after several continuous days of usage.

The following is a more detailed description of an embodiment of the invention by way of example, reference being made to the accompanying drawings in which:-

Figure 1 is a perspective exploded view of an electrode pad and of a connector in accordance with the invention.

Figure 2 is a cross sectional view of the electrode pad, taken along line 2-2 of *Figure 1* prior to insertion of the connector.

Figure 3 is a top view of the connector of the invention to be used with the electrode pad.
Figure 4 is a partly cutaway cross sectional view of the connector taken along line 4-4 of Figure 3.

5 Figure 5 is a cross sectional view of the probe taken along line 5-5 of Figure 3. The dimensions of the coatings shown therein are not to scale but are exaggerated for clarity. 5

Figure 6 is a top view of a second embodiment of the electrode pad.

Figure 7 is a top view of the electrode pad of Figure 1 with the connector of the invention attached.

10 Figure 8 is a cross sectional view of the electrode pad, taken along line 8-8 of Figure 7 after insertion of the connector. 10

Figure 9 is a cross sectional view of the electrode pad taken along line 9-9 of Figure 7 after insertion of the connector.

15 Figure 10 is a bar chart comparing D.C. offset for the electrode with five different commercially available disposable pregelled electrodes. 15

Referring now to the drawings, an electrode pad 10 is shown in Figures 1 and 2 in conjunction with a connector according to the invention generally designated as 40. The electrode pad 10 consists of a disc 12, a gel matrix 14 located in a cavity 18 positioned in the centre of said disc 12 and a release backing 16 covering the adhesive 38 coated lower face 72 of the disc 12 and the uncoated gel matrix 14. After removal of the release backing 16 the adhesive coated lower face 72 of the electrode is placed on a patient's skin, thus interfacing the gel matrix to the skin for ECG readings. 20

25 The disc 12 is formed of a thermoplastic material which preferably is flexible, can be readily molded to fit the contour of the patient's skin, and has low moisture absorption and high electrical resistance. Suitable materials include silicone rubber, natural rubber, thermoplastic rubber, polyvinyl chloride, polyurethane, or other flexible polymers. As an added feature, this material can be transparent so that the patient's skin can be continuously observed through the electrode pad 10 to detect possible skin changes and to permit easy inspection during usage of the adhesive/skin interface. The gel matrix 14 and a gel-connector-interface caused by mating of the electrode pad 10 and electrolead 40 is also readily observable. 30

35 The disc 12 is provided with a central cavity 18 defined by a cap 20, a vertically depending wall 22 and an annular ring 24 extending outward from the wall 22. The annular ring 24 may correspond in thickness to the height of wall 22 or preferably may be a tapered flange 24 extending from the lower edge of the wall 22 as shown in Figure 2. The cavity in combination with the release backing 16 provides a moistureproof space capable of protecting electrolyte gel enclosed therein for extended periods of time. Elongated semi-circular slot 26 extends through the vertical wall 22 and into the inner surface of the cap 20. In the preferred embodiment two parallel slots 26 are used. However, one slot or more than two slots can be used. Until the electrode pad is put into service the slot or slots 40 26 extending through the wall 22 are maintained closed and impervious to moisture by membranes 28 or portions of the wall 22 having reduced thickness.

45 The gel matrix 14 consists of an electrically non-conductive porous material of limited compressibility, such as compacted felt, non-woven fabric, a molded or extruded honeycomb of plastics, or other similar material. In the preferred embodiment, the gel matrix is formed of sintered thermoplastic, such as polyethylene foam, having a void volume of 20 to 60% of the total matrix volume. The gel matrix 14 is saturated with a suitable conductive electrolyte gel 30 conventionally used with electrocardiograph instruments, for example a gel of sodium chloride in agar. The gel matrix 14 is positioned in the cavity 18 by an indexing pin 32 which extends from the inner surface of the cap 20 into a central hole 34 in the matrix 14. The matrix 14 is retained in the cavity 18 by an annular lip 50 36 molded into wall 22, near the lower surface 72. To further retain the matrix 14 in the cavity 18 a small amount of adhesive material may be applied to the interface between the indexing pin 32 and the central hole 34 in the matrix 14.

55 Medical grade pressure sensitive adhesive 38, preferably transparent and moistureproof, is applied to the lower face 72 of the disc 12. A protective cover or backing 16 of an impervious release material, such as a polymer coated paper, completely covers the adhesive 38 and encloses the gel saturated matrix 14 in the cavity. 55

60 Referring to Figures 3, 4 and 5, the connector 40 consists of an insulation boot 66, probe 42 mounted in the insulation boot 66, the probe 42 having blades 44 extending from one end of the insulation boot 66 and an electrical wire 43 extending from the other end of insulation boot 66, the electrical wire 48 and the probe 42 being secured to each other within insulation boot 66. 60

65 The electrically conductive probe 42 is designed to pierce thin sections of the wall 22, such as membrane 28, so that it fits snugly into the blade slot 26. In the preferred embodiment, the electrically conductive probe is a unit having two parallel blades 44 and a 65

central portion 46 connected to an insulated wire 48. Connection of the wire 48 to the probe 42 is made by stud 50 attached to or molded onto the lower surface of central portion 46 of the probe 42. As shown in Figures 3, 5 and 9, the blades 44 have sharp tips 52, a broad or flattened bottom surface 54 and a rounded upper surface 56. The sharp tips 52 are designed to readily puncture the membrane 28 when the connector 40 is connected to the electrode 10. The broad bottom surface 54 of the blade 44 provides maximum contact with the gel matrix 14 while the rounded upper surface 56 and the resultant semi-circular cross-section of each blade functions to give the blades strength and stiffness and to hold the blades 44 in the slots 26 to prevent movement artifacts. The electrically conductive probe 42 is formed of a non-conductive plastics material having a conductive metal coating. In the preferred embodiment shown in Figure 5 the probe is made of a non-conductive thermoplastic material 58, for example ABS (acrylonitrile butadiene styrene polymer) having a silver coating 60 applied thereto, preferably electrodeposited thereon after the surface of the thermoplastic material is made conductive by known coating techniques. This electroplated silver forms a tough, crack-resistant conductive surface on the plastic. Using conventional methods a silver chloride layer 62 is then formed on at least part of the silver coating 60. The silver chloride layer 62 may be formed by chemically converting the outer portion of the silver coating to silver chloride, such as by treatment with hydrochloric acid, or may be electrodeposited on top of the silver coating 60. In the preferred embodiment, the electrodeposited silver-chloride layer 62 has a uniform thickness of 20 - 5000 mA sec/cm², preferably 100 - 1000 mA sec/cm². The silver-chloride layer 62 has a dark color while the underlying silver coating 60 has a shiny appearance. Because of the hardness of the silver chloride layer 62 the connector 40 can be reused through several ECG procedures. However, extensive use or repeated cleaning may damage the silver chloride layer. Damage is readily apparent by the shiny silver showing through the dark colored silver chloride layer.

The design of the electrode pad 10 and connector 40 in combination makes possible high quality recording ECG data. The first use of each connector provides a Type I recording with diagnostic accuracy similar to that previously obtained only with the highest quality hand made research electrodes. Depending on care taken in cleaning the connector, this Type I performance can be repeated through several subsequent uses of the same connector. Connectors 40 used as many as 25 times still exhibit Type II recording performance, required for routine monitoring. Optimum performance continues through at least the first 10 usages. Eventually the silver chloride layer 62 will be worn away exposing the shiny underlying silver coating 60 thus signalling the operator to dispose of the connector.

Referring to Figures 3 and 4 the wire 48 is a standard multi-strand conductor commonly used for ECG leads. One end of the wire 48 terminates in a fitting 64 adapted to connect with probe 42. In the preferred embodiment, the wire 48 has a brass ring tongue fitting 64 which is sized to fit over the silver coated stud 50 in such a manner that when mated with stud 50 an electrical conductive path is formed between the probe 42 and the wire 48. The fitting 64 is securely attached to the stud 50 by staking or flattening of the stud and to the wire 48 by crimping or soldering.

The central portion 46 and the fitting 64 are encapsulated in a boot 66 composed of a thermoplastic electrically insulating material. This boot may be formed as two separate mating pieces designed to enclose the central portion 46 and the fitting 64 in which case central portion 46 and fitting 64 are assembled, the assembly is placed between the separate portions of boot 66 and the portions are securely attached together. Preferably, boot 66 is formed in one piece and is directly molded around the assembled central portion 46 and fitting 64. When the probe 42 is formed from ABS a suitable material for forming the boot is polyvinylchloride polymer (PVC). Molding the boot directly on to the central portion 46 and fitting 64 makes permanent the assembled unit and has the added advantage of hermetically sealing the junction between the connector 64 and central portion 46.

The other end of the wire 48 is secured to a plug 68 compatible with cardiograph equipment commonly used for ECG procedures.

Referring to Figure 6, there is shown an electrode pad, generally designated as 110 having two blade slots 112 that extend completely across the cap 114 of the electrode. Membranes 116 correspond in function and design to the membranes 28, of the embodiment shown in Figures 1-2. Aside from the above all the other features of this embodiment correspond to the first embodiment described above. This embodiment has the additional advantage that blades 44 can be inserted from either side.

In use the electrode pad 10 and the connector 40 are connected by gripping the boot 66 of the connector in one hand and the electrode pad 10 in the other hand, aligning the sharp tips 52 of the blades 44 with the blade slots 26 and advancing the blades 44 forward into the slots 26 piercing the membranes 28 resulting in apertures 82, which are completely filled by

blades 44 and which conform closely to the outer shape of the blades 44 so that electrode gel is prevented from exiting from cavity 18 through slots 26, and tight fitting flaps 80 that act to wipe the blade surfaces 54 and 56. Further advancement of the blade 44 forces portions of the gel matrix 14 down out of contact with the inner surface 67 of the cap 20.

Because the gel matrix is not readily compressible, the insertion of the blades 44 pushes the lower portion or surface 70 of the gel matrix beyond the lower surface 72 of the electrode pad 10 as shown in Figures 8 and 9. Also as shown in Figures 8 and 9, the insertion of blades 44 stretches that portion of the flexible cap 20 that is over the blades. The elastic, flexible nature of the cap 20 and the secure mounting of the gel matrix 14 cooperate to tightly hold the broad bottom surface 54 of blades 44 in intimate contact with the gel matrix 14 resulting in an electrically conductive path through the electrolyte gel 30 which fills the matrix 14, and the silverchloride layer 62 on the blade 44. In addition the tight mating of the blades 44 in the slots 26 serves to hold the connector 40 securely in the electrode pad 10. Use of indexing pin 32 further prevents relative movement between the electrode components and the connector 40, thus preventing disturbances of the ECG reading, known as motion artifact, which are common in electrodes which employ a snap type electrode connector.

The patient's skin is then prepared for attachment of the electrode pad 10 by standard cleaning procedures, possibly including shaving of the area. It is generally not necessary to abrade the skin surface to reduce skin impedance prior to application of the electrode pad, as is suggested procedure for use of many electrodes which employ compressible foam-like gel pads. The slightly abrasive lower surface 70 of the gel matrix 14 continuously performs the same function during usage of the electrode as is accomplished by abrasion of the skin prior to application of the electrode.

The release backing 16 is then removed from the lower face 72 of the electrode pad 10 and the electrode pad is applied to the patient's skin, the adhesive 38 firmly securing the electrode pad thereto and forcing the gel saturated matrix 14 into intimate contact with the skin. As indicated above, insertion of the blades 44 forces the gel matrix 14 to extend beyond the lower face 72 of the electrode pad 10 so that upon adhesive application of the electrode to the skin the gel matrix is forced into contact with the skin. The assembled combination of the electrode pad and connector forms a system uniquely designed to effect intimate and secure contact between the skin and all electrically conductive components so that artifact-free transmission of physiological potentials results.

Tests of electrode characteristics for quality control purposes were conducted on an electrode of the kind described above with reference to the accompanying drawings and on various models of commercially available electrodes. These tests included AC impedance, DC offset and rectification. To perform the tests, the release backing 16 was removed from two like electrodes and these electrodes were placed face to face. The data obtained was for the pair; however, the resultant data is typical of normal usage, since the electrodes are normally applied in pairs.

AC impedance was determined by measuring the AC voltage drop across the electrode pair under test when a reference AC voltage is applied through the electrodes. DC offset was measured as the DC potential existing across the electrode pair when no AC or DC current is flowing. DC rectification was assessed by measuring the DC offset before and after application of a voltage, with rectification being defined as the difference between the two measurements.

No well established "ideal" values exist for any of these parameters. However, continuing tests show that "good" electrodes have AC impedance values of under 500 Ω , depending on specific electrode configuration. DC offset values should be less than 10 mV, preferably less than 1mV for Type I (diagnostic) monitoring. A number of commercial electrodes have DC offsets which are only a few mV and others are as high as 100 mV. DC rectification should be as small as possible, never exceeding 5mV for Type I (diagnostic) monitoring electrodes.

The electrode pair of the type illustrated herein consistently demonstrates an AC impedance of less than 100 Ω , a DC offset of about 1mV and a rectification of less than 0.2mV. Table 1 lists DC offset values for paired electrodes of the present embodiments compared with values obtained on several commercially obtained disposable pregelled electrodes measured using a Keithley Model 168 Digital Multimeter. The mean and median values obtained for the present embodiments are markedly superior to those obtained for the other samples tested. In addition, the commercially available samples, with the exception of Product 3, all showed a wide distribution of offset values. Figure 10 is a bar chart showing the distribution of DC Offset Values obtained on all samples tested. From this Figure it is evident that the present embodiments would give more consistent and reliable readings. In addition, the electrode system of the embodiments show a low frequency (0.5Hz) capacitive polarization significantly less than that exhibited by any other

commercially available pregelled electrode, approximately the performance of a pure resistive element at 0.5Hz. This property permits more accurate transduction of low-frequency ECG wave components than any other commercially available disposable pregelled electrode.

5 This application is divided from our British patent application No. 29052/77 (Serial No. 5
1567961) which is directed to a medical electrode pad having no metallic components for
use on the skin for detecting biological electrical potentials comprising a disc of flexible
10 electrically insulating thermoplastic material having a central cover element, a vertical wall
depending from said central cover element, said central element and vertical wall defining a
central cavity, and a peripheral element having a lower surface extending out from said
15 wall; an electrically non-conductive porous matrix received in said central cavity; an
electrolyte gel saturating said porous matrix and together therewith substantially filling said
central cavity; an adhesive covering said lower surface of said peripheral element; a release
backing covering said adhesive and enclosing and hermetically sealing said porous matrix
and electrolyte gel in said cavity; and means in said disc for receiving and guiding a
20 removable electrically conductive probe into intimate contact with said electrolyte gel.

The combination of the medical electrode pad and connector described above is the
subject of our British patent application No 27767/78 (Serial No. 1567963) also divided from
our application No 29052/77 (Serial No 1567961) and directed to the combination of a
25 medical electrode pad having no metallic components for attachment to the skin,
comprising a disc of electrically non-conductive material having a planar base and a
centrally located cup-shaped cavity therein, an electrolyte saturated porous matrix received
in said cavity, an adhesive on the surface of said planar base, and a release backing covering
the adhesive surface and enclosing the matrix in the cavity; puncturable membrane means
25 in said disc for puncture by a connector, and a reusable, removable electrically conductive
connector insertable through said membrane means by puncture of the membrane means
and into intimate contact with said electrolyte saturated porous matrix.

30 TABLE 1
D.C. Offset (millivolts) of Electrode Pairs* 30

Electrode	SAMPLE SIZE (Pairs)	MEAN	MEDIAN	MODE	RANGE	
Embodiment	N=28	1.03mV	0.7mV	1mV	0-5mV	35
Product 2	25	15.02mV	1.8mV	1mV	0-164mV	
Product 1	22	12.48mV	2.3mV	2mV	0-162mV	
Product 5	37	4.21mV	3.7mV	1mV	0-12mV	
40 Product 4	40	12.43mV	7.8mV	4mV	0-79mV	40
Product 3	42	45.24mV	20.7mV	20mV	0-265mV	

* Measured using Keithly Model 168 Digital Multimeter

45 WHAT WE CLAIM IS:- 45

1. An electrical connector for a medical electrode and for transmission of an electrical
signal, the connector being of the type wherein an electrically conductive probe is attached
to an electrically conductive wire and a boot of electrically insulating material encloses the
point of attachment of the wire to the probe, characterised in that the probe has a core of
50 electrically non-conductive material within said boot and a pair of sharp pointed blades also
of non-conductive material extending from the core and the boot, and a continuous coating
of an electrically conductive material on the core and on the blades, one end of said wire
being in electrical connection with said conductive coating on the core and on the blades.

2. The connector of claim 1 wherein the core non-conductive material is a thermoplastic
55 and the conductive coating is silver with an additional silver chloride coating covering at
least part of said silver coating.

3. The connector of claim 1 wherein the blades are parallel and coplanar and are
formed with a flat bottom surface and a curved upper surface.

4. An electrical connector constructed and arranged substantially as herein particularly
60 described with reference to the accompanying drawings.

BREWER & SON,
Chartered Patent Agents,
5-9 Quality Court,
Chancery Lane,
65 London, WC2A 1HT. 65

FIG. 1

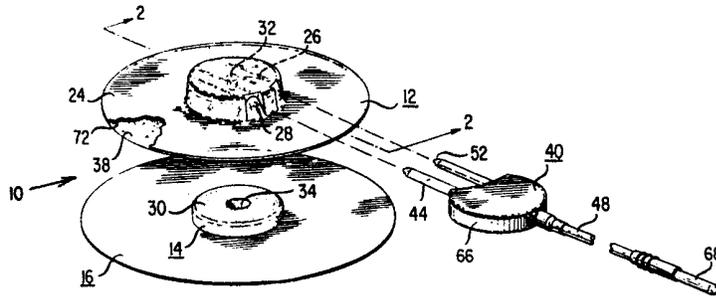


FIG. 2

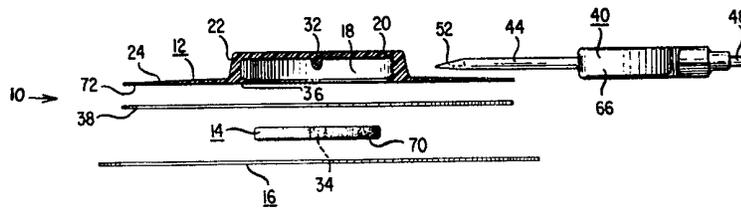


FIG. 3

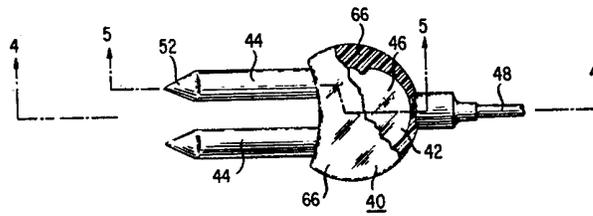


FIG. 4

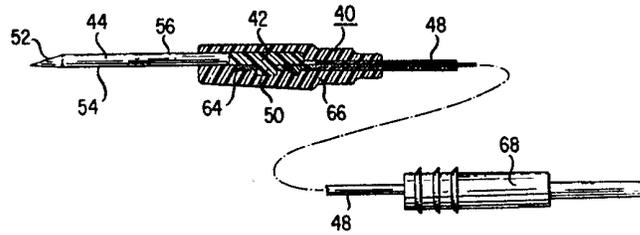


FIG. 5

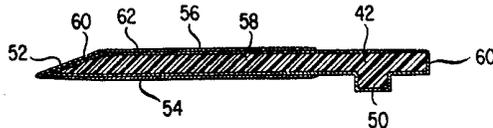
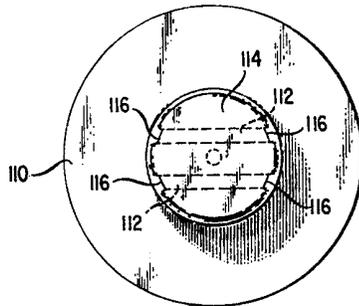


FIG. 6



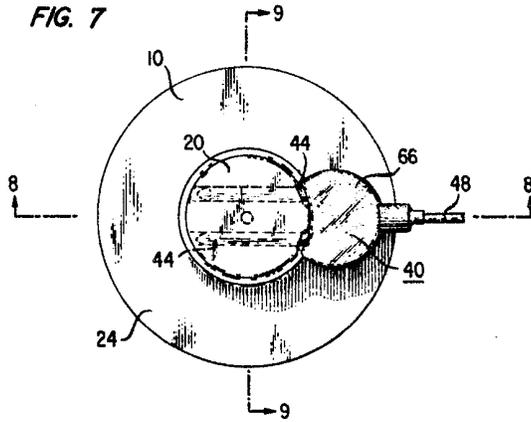


FIG. 8

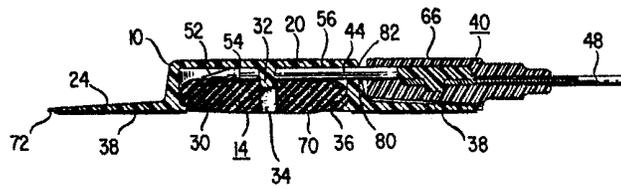


FIG. 9

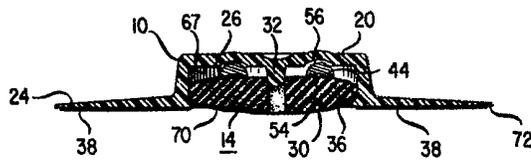


FIG. 10

DC. OFFSET VALUES FOR VARIOUS ELECTRODES

