

Imredy et al.

[15] **3,682,159**

[45] *Aug. 8, 1972

[54] **CATHETER ELECTRODE FOR OXYGEN POLAROGRAPHY**

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[*] Notice: The portion of the term of this patent subsequent to Sept. 15, 1987, has been disclaimed.

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[21] Appl. No.: 26,006

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 525,926, Feb. 8, 1966, Pat. No. 3,528,403.

[52] U.S. Cl.....128/2 E, 204/195 B

[51] **Int. Cl.** **A61b 5/00**

[58] **Field of Search...**128/2 R, 2.05 D, 2.05 F, 2.05 R, 128/2.1 E, 2.1 R; 204/195 B, 195 L, 195 M, 195 P, 195 R

[56] **References Cited**

UNITED STATES PATENTS

3,528,403	9/1970	Imredy et al.	128/2 E
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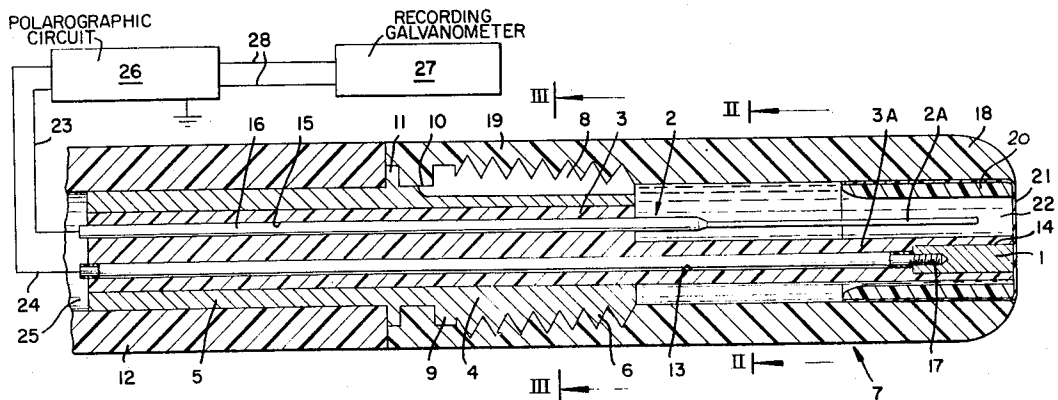
Primary Examiner—William E. Kamm

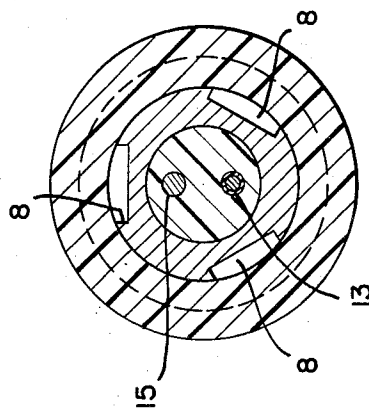
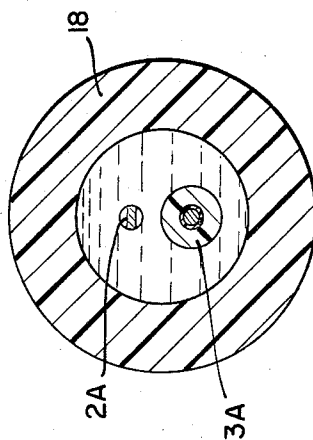
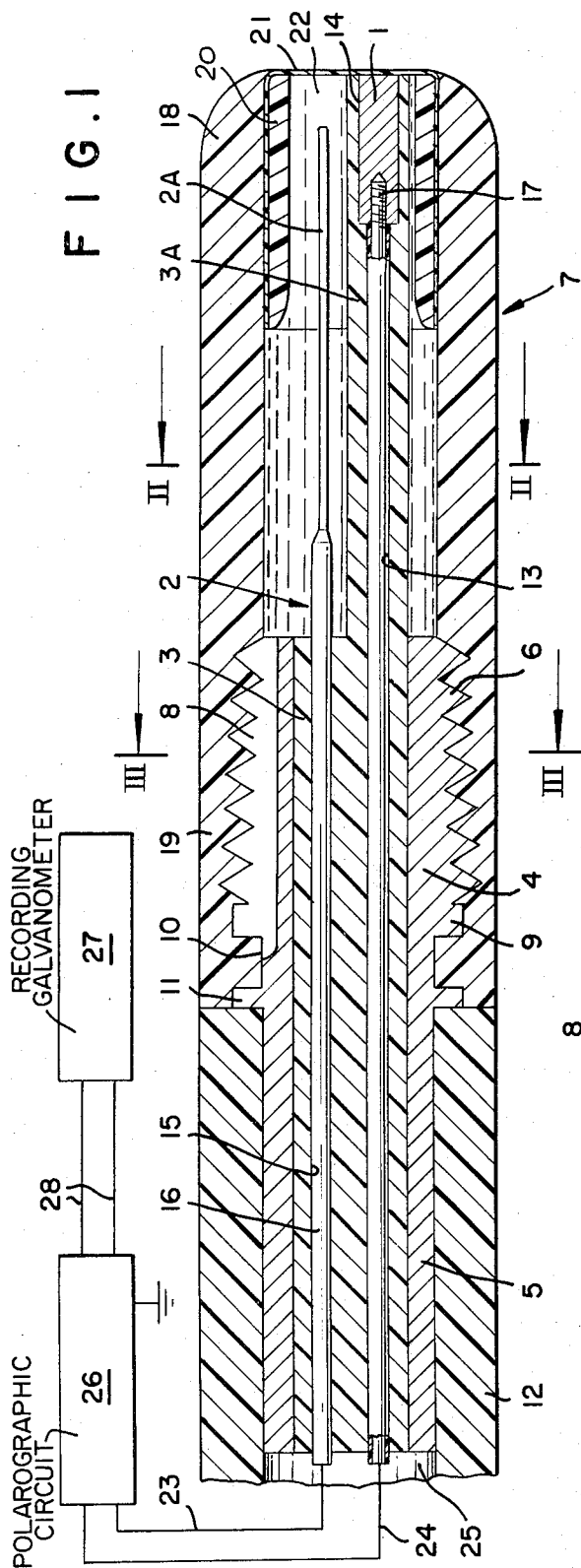
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[57] **ABSTRACT**

A miniature electrode comprising cathode, anode, electrolyte and oxygen-permeable diaphragm, with a shell and housing adapted for secure attachment to the end of a catheter, to be introduced into positions where in vivo oxygen tension determinations can be made in blood or other body fluids.

9 Claims, 6 Drawing Figures





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FIG. 4

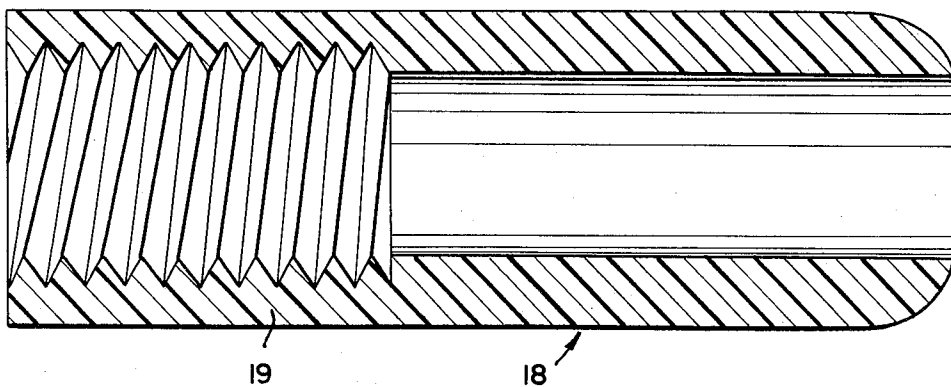


FIG. 5

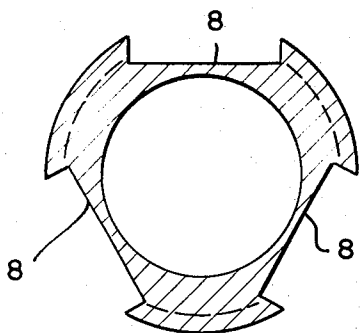
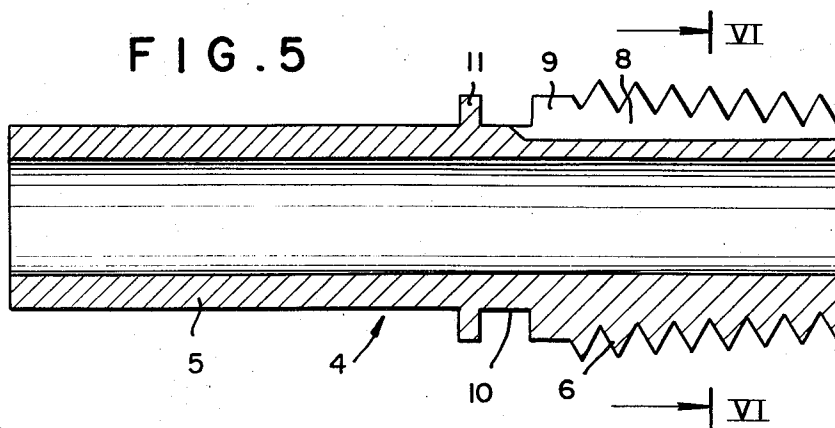


FIG. 6

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CATHETER ELECTRODE FOR OXYGEN POLAROGRAPHY

This application is a continuation-in-part of application Ser. No. 525,926, filed Feb. 8, 1966 now U.S. Pat. No. 3,528,403.

It is broadly old to employ polarographic cells in the in vitro determinations of oxygen tension in human blood and other biological fluids. Such cells, or electrodes, generally consist of a platinum cathode and a silver reference anode enclosed within a unit containing an electrolyte bridge and covered at one end by a gas-permeable plastic membrane. The unit is maintained at 0.6 volt potential and the membrane, which is an insulator and is not permeable to fluids, separates the specimen from the electrodes so no current can flow into the specimen. When oxygen molecules diffuse from the specimen through the membrane to the polarized cathode surface, the cathode becomes depolarized allowing a current to flow which is directly proportional both to the amount of oxygen contacting the cathode and to the oxygen content of the specimen. This current can be measured and read off or recorded by any suitable indicating device such as a galvanometer.

However, the size, shape and construction of the electrode described above prohibits or severely limits any practical application to in vivo clinical use, in sharp contrast to the fact that in addition to the indispensability of in vitro oxygen polarography there is a steadily increasing demand for measuring the oxygen tension directly and continuously in vivo.

Therefore, an object of this invention is to provide a miniaturized electrode that will function satisfactorily and safely when attached to or in a catheter for in vivo determinations of oxygen tension in blood, lung gases and other biological fluids.

Another object of this invention is to provide an electrode of the character stated in which the cathode and anode supporting element and the capsule cover therefor are fabricated from an inert insulating plastic, said supporting element including an inert plastic tube and plug press fitted into an insulated stainless steel housing provided with improved means for securely interconnecting the parts and mounting the electrode on the catheter.

A practical embodiment of the invention is shown in the accompanying drawings, wherein:

FIG. 1 represents a longitudinal axial section of an electrode as attached to a catheter, the electrical circuit being shown diagrammatically;

FIG. 2 represents a sectional view on the line II — II of FIG. 1;

FIG. 3 represents a sectional view on the line III — III of FIG. 1;

FIG. 4 represents a detail longitudinal axial section of the outer shell;

FIG. 5 represents a detail longitudinal axial section of the catheter base; and

FIG. 6 represents a greatly enlarged detail sectional view on the line VI — VI of FIG. 5.

Referring to the drawings, the electrode is shown as comprising a platinum cathode 1 and a silver anode 2 embedded in a one piece plastic base 3 which in turn is press fitted into an insulated stainless steel tubular housing tube 4. This tube has an extended cylindrical proximal end portion 5 for the purpose of affixing the

tube 4 permanently to the tip of the catheter 12, and bears external threads 6 for affixing the outside capsule 7. The threads 6 are tapered and have three equally spaced axially extending slots 8 (FIGS. 1, 3, 5, 6) serving as vents during assembly. A solid flange 9 is located at the rearward end of the threads 6; this flange 9 is slightly larger in diameter than the root of the threads 6 and acts as a lock binding additionally the outside capsule 7 to the stainless tube 4. Immediately adjacent to flange 9 is an annular recess 10 bounded rearwardly by a shoulder 11 located approximately midway between the ends of the tube. The recess 10 permits the threaded portion 19 of outside capsule 7 to shrink into recess 10 after passing over flange 9, tightening the grip of outside capsule 7 onto steel tube 4. The shoulder 11 serves as a stop for precise positioning of steel tube 4 with respect to the end of catheter 12.

The plastic base 3 is made of a suitable plastic material having good chemical resistance, electric insulating properties and resistance to wetting, such as "Kel-F", a polymer of trifluorochloroethylene marketed by 3-M. The larger cylindrical end of base 3 is snugly fitted into tube 4. The stem end 3A of base 3 protrudes beyond the end of tube 4 and contains a longitudinal bore 13 extending the entire length of base 3 and being enlarged near its end, as shown at 14, to receive the cathode 1. The larger end of base 3 contains another longitudinal bore 15 in spaced parallel relation to bore 13 to receive the extension 16 of anode 2, which portion 16 is not part of the polarographic cell called electrode area.

The cathode 1 is a short bar of platinum connected at its base by soft solder to the end of a fine copper wire 17, preferably vinyl acetal enameled, of the type sold as "Formvar" by Acme Wire Co., New Haven, Conn. The cathode 1 has its end squarely even and flush with the end of the stem 3A of base 3.

The anode 2, constituted by a silver wire, is securely mounted with its extension 16 in the second longitudinal bore 15 of base 3 and protrudes freely alongside the stem 3A to a distance slightly less than the length of said stem, the protruding part being flattened as shown at 2A.

The parts just described are assembled with the tubular outside capsule 7 which consists of an outer shell 18, a proximal portion 19 of which is internally threaded, an inner shell 20 equal only to about one-fourth the length of outer shell 18, and a gas-permeable plastic membrane 21. The membrane 21 is stretched over the end of inner shell 20 and inserted, press-fitted and cemented into the outer shell 18, lying flush with the end of same. The void between outside capsule 18, base 3, distal end of tube 4, and membrane 21, and not occupied by anode 2 and stem 3A, is filled with electrolyte 22, such as a half saturated KCl, that is, 18 grams of Potassium Chloride per 100 ml. H₂O.

Before assembling, the outside capsule 7 should be filled, free of air, with electrolyte 22 and screwed onto the threaded steel housing tube 4 for establishing an electrolyte bridge between cathode 1 and anode 2. The distal end of tube 4 extends to a point approximately midway between the ends of shell 18. Since cathode 1, anode 2, plastic base 3, and stainless steel tube 4 are permanently assembled as a unit and screwed into outer capsule 7 as such, means must be provided to

permit the escape of excess electrolyte and trapped air, if any, from the void mentioned above during the screwing procedure. The means is shown in FIGS. 1, 3 and 6 as comprising longitudinally extending grooves or slots 8 in the threaded surface of the tube 4 from its forward end through the lock flange 9, terminating in the recess 10; permitting excess fluid to escape through the grooves eliminates any pressure within the electrode area and insures the proper electro-chemical function of the cell. Furthermore, when the outside capsule is fully seated, with its proximal the shoulder 11 at a point midway between the ends of the tube 4, in the position shown in FIG. 1, there is no force tending to cause leakage and none takes place. This portion of the electrode assembly is further sealed by snugly fitting the forward end of catheter 12 over the rearwardly extending portion 5 of steel tube 4 and also against shoulder 11 and securing the catheter 12 thereto by means of a suitable epoxy cement.

In use, the ends of the silver anode extension 16 and wire 17 are extended to constitute, or are connected to, separate insulated leads 23, 24, which extend through the lumen 25 of catheter 12 and connect to a polarographic circuit indicated at 26 (which includes a dry cell), the current in this circuit being monitored by a recording galvanometer 27 or the like, connected to circuit 26 by leads 28. The catheter 12 may have one or more lumens as indicated for the areas or fluids where O_2 determination is to be effected.

The actual electrode, constructed as described above, has a diameter of about 0.080 inch and length of about 0.450 inch, being fitted on the end of a catheter having the same diameter (6 F.) and of any suitable length. The instrument can be used to determine O_2 content and variations thereof within the heart, blood vessels, brain, spinal fluid, lungs or any cavity or area of the body that the electrode can reach.

The space 22 holds a substantial quantity of the electrolyte and the flattened end 2A of the anode provides a relatively large surface area in contact with the electrolyte, for stability and durability. The layer of electrolyte between the cathode 1 and membrane 21 is very thin so that it responds readily to variations in the rate of penetration of O_2 through the membrane, such responses being immediately reflected in the current flow through the polarographic circuit, as previously explained. Since the electro-chemical aspects of oxygen polarography are well known, they need not be further discussed.

What is claimed is:

1. An electrode assembly for use in oxygen polarography comprising an elongated tubular insulating

plastic shell, a gas-permeable plastic membrane closing the distal end of said shell, an elongated tubular metal housing screw-threaded adjacent its distal end, said shell being correspondingly screw-threaded from its proximal end and said tubular housing being screwed into said shell to a point approximately midway between the ends of said shell, the proximal end of said shell being at a point approximately midway between the ends of said tubular housing, whereby approximately half of said tubular housing projects proximally from said shell, a cylindrical insulating electrode base having a larger portion fitting and secured in the bore of said tubular housing and a cylindrical stem integral with said larger portion and projecting distally therefrom, a first passage extending axially of said base and stem, a second passage extending axially of said larger portion, a cathode mounted at the distal end of said stem and having a lead extending through said first passage, an anode projecting distally from said larger portion adjacent to said stem and having a lead extending through said second passage, and a quantity of electrolyte confined within a space bounded by said shell, said membrane and the distal ends of said base and said tubular housing, the proximally extending portion of said tubular housing being adapted to fit within and be secured to a substantial distal portion of a catheter.

2. An electrode according to claim 1, wherein the screw-threaded portion of the housing is bounded proximally by an integral unthreaded flange.

3. An electrode according to claim 1, wherein the screw-threaded portion of the housing is traversed axially by at least one groove.

4. An electrode according to claim 1, wherein the screw-threaded portion of the housing is bounded proximally by an integral flange and an integral shoulder spaced to define an annular recess.

5. An electrode according to claim 2, wherein the screw-threaded portion of the housing and the flange are traversed axially by at least one groove.

6. An electrode according to claim 4, wherein the screw-threaded portion of the housing and the flange are traversed axially by at least one groove.

7. An electrode according to claim 1, which includes an inner shell fitted within the first named shell adjacent the distal end thereof, the plastic membrane being held in place by engagement between said shells.

8. An electrode according to claim 1, wherein the cathode is entirely encapsulated by the said stem with only its distal end surface exposed to electrolyte.

9. An electrode according to claim 1, wherein the anode is flattened.

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