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(54) OXYGEN MEASURING ELECTRODE ASSEMBLY

(71) I, BUNJI HAGIHARA, a Japanese subject, of No: 8-17 Fujishirodai 2 chome, Suita-shi, Osaka, Japan do hereby declare the invention, for which I pray that a patent may be granted to me and the method by which it is to be performed, to be particularly described in and by the following statement:-

This invention relates to an oxygen measuring electrode assembly having an improved structure which is useful for transcutaneous measurement of oxygen partial pressure in an arterial blood oxygen. The transcutaneous arterial blood oxygen measuring electrode assembly (hereafter abreviated as "transcutaneous arterial oxygen electrode") is a mechanism for detecting the oxygen partial pressure in the arterial blood of a person to be examined from his skin without directly examining the blood; therefore, the measurement is carried out non-invasively and without damage to any part of his body. Accordingly, this electrode assembly can play an important part in oxygen control of patients, especially newborn infants. Upon application of an electrode assembly of this type onto the skin of a person to be examined, the oxygen in the subcutaneous tissue diffuses through the skin and reaches to a noble metal cathode through an electrode membrane, where the oxygen is reduced to provide electrolytic current. Therefore, the oxygen partial pressure value in the tissue can be detected from the value of this electrolytic current. In this case, if the skin in contact with the electrode through the electrode membrane is heated at a temperature as high as possible within a temperature range in which the skin is not burned, the subcutaneous tissue adjacent the electrode is locally arterialized. Accordingly, the oxygen partial pressure of the tissue measured by this method is close to the oxygen partial pressure of arterial blood oxygen. The extent of closeness of the above two values, the transcutaneously measured value and the true arterial value, depends largely on the extent of arterialization of the subcutaneous tissue and partly on the properties of the electrode membrane, and the shape and size of the cathode and other structures of the electrode assembly. There are two types of transcutaneous arterial oxygen electrode assemblies known in the art. However, each of these electrode assemblies has inherent defects in the electrode structure thereof, especially in the heating mechanism of the skin, size and shape of the cathode and suporting mechanism of the electrode membrane.

In one known form of a transcutaneous arterial oxygen electrode assembly, the cathode is a thin platinum wire whose diameter is in the order of 0.015mm, and this cathode together with a silver anode arranged in association therewith is covered with an oxygen permeable membrane (polytetrafluoroethylene film 12 microns in thickness) supporting an electrolyte solution on the surfaces of the both electrodes. This electrode membrane is fixed to the electrode supporting body with an rubber "O" ring. In the case of this electrode assembly, heating of the skin is carried out by the silver anode which is heated at an constant temperature (43°C or 44°C). In this heating mechanism, arterialization of the subcutaneous tissue is not sufficient, because the heated area of skin is limited by the small surface of the anode. In addition, the signal-to-noise ratio (S/N ratio) in this electrode assembly is very low because the electrodes are extremely small. Furthermore, as the planar membrane is fixed with the "O" ring, the membrane is liable to get crinkled at the fixed portion, therefore it is difficult for the electrodes surface to be uniformly in contact with the membrane, and accordingly the electrode activity is unstable.

In a second form of transcutaneous arterial oxygen electrode assembly which is available on the market, a relatively large (3mm in diameter) gold cathode is employed, and the cathode and the anode are covered with an electrode membrane (polyester film 6 microns in thickness) which is fixed to the electrode holder with a sleeve. In this electrode assembly, heating of the skin is carried out by the gold cathode which is kept at an constant temperature (42° or 44°C). In this heating mechanism, arterialization of subcutaneous tissue is not sufficient for the reasons as described in the case of the first known example. Although the cathode has a relatively large size (3 mm in diameter) in this second form, the size is still too small for the purpose of suficient arterialization. The second significant drawback of this electrode assembly is that, as the cathode surface must be made large for heating and the amount of oxygen consumption thereof becomes large, the measured oxygen value is much less than the actual arterial value. In order to reduce the above drawback use of a membrane of very low oxygen permeability has been tried for the electrode membrane. However, this method results in a slow response of the electrode. Accompanying the large oxygen reduction on the cathode, the consumption of the electrolyte is excessive and the drift of the sensitivity of the electrode becomes considerably large. Furthermore, the peripheral portion of the cathode is different in reactivity from the central portion because these two portions are different from each other in distance from the anode and in supply of ionic components of the electrolyte.

Similarly, as in the first known form described above, the second form also has the drawback that the electrode activity is varied with the change of the contact pressure from the skin, and results in inaccurate measurement, because contact between the membrane and the electrode surface is unstable.

This invention is intended to eliminate the above-described drawbacks accompanying the conventional transcutaneous arterial oxygen electrode assemblies.

A principal object of the invention is to provide an oxygen electrode assembly having a system for heating the skin over a wide area so that the arterialization of the subcutaneous tissue is carried out satisfactorily even at a temperature causing no burning.

Another object of this invention is to provide a novel structure (ring) of the cathode whereby the reaction amount is suitably increased to improve the signal-to-noise (S/N) ratio while retaining the reaction activity over the cathode surface uniform.

Another object of the invention is to provide a novel means for supporting the electrode membrane which provides uniform and stable contact with the cathode surface.

According to the invention therefore, an oxygen measuring electrode assembly for use in making transcutaneous arterial blood oxygen measurements comprises an electrode portion having a tubular anode and a tubular cathode of a smaller diameter than the anode and disposed coaxially in said anode, an insulating support member for supporting both the anode and the cathode relative to each other, an annular holder portion made of electrically and thermally insulating material, said holder portion surrounding said anode, an oxygen permeable membrane bonded to a lower end of said holder portion so as to cover a lower end of said electrode portion and, in use, contain an electrolyte solution between said lower end surfaces of said anode and cathode and said membrane, a collar portion of a heat conductive metal having a large thermal capacity for supporting said holder portion, temperature sensing means and heating means provided in said collar portion for maintaining the collar portion at a predetermined temperature, and a membrane cover plate thermally connected to a lower end of said collar portion, said membrane cover plate having an opening through which an area of said membrane corresponding to an area of the lower end of said electrode portion is exposed, and said membrane cover plate being made of a heat conductive metal to transmit heat from said collar portion to the skin of a person when a transcutaneous arterial blood oxygen measurement is being made on the person.

Unlike the conventional transcutaneous electrode assemblies, in an assembly in accordance with the invention the heating of skin is not carried out through the cathode or the anode. Instead, a metal section occupying a greater part of the electrode assembly is kept at a constant temperature and this part is thermally connected to a metal plate at the bottom of the electrode assembly, and the skin is heated by this plate which has much larger area than that of the end surface of anode or cathode. Also, in the prior art, the skin is heated from the electrodes through the electrolyte layer and the electrode membrane, whereas there is no such obstacle as the electrolyte layer or the electrode membrane in the present assembly. By these two advantages heating of the skin is carried out more effectively and more accurately than in the prior art constructions.

Secondly, a tubular anode (preferably of silver) is arranged coaxially with an annular end of the cathode (preferably of platinum or gold) by means of the insulating support member so that the cathode surface has a uniform reactivity with respect to the anode and the electrolyte. Since the end of the cathode is annular, the cathode has a large effective area compared with a point electrode, and the electrode reactivity is sufficiently large for obtaining high S/N ratio.

Preferably the end of the cathode and the part surrounding the cathode are protruded slightly from the level of the end of the anode whereby the electrode membrane is held firmly over the protruding parts by the cover plate having an opening through which the area of the electrode membrane covering the end of the cathode is exposed. In this way the membrane can contact stably with the cathode surface as a result of a stretching force of the membrane. The cover plate is made of metal having a good heat conductivity, and is used, at the same time, for heating the skin as described before.

In each of the conventional electrode assemblies, no cover plate is employed for stretching the electrode membrane, the membrane being loosely held over the electrode surface only be weak force. Therefore, it is difficult to maintain a stable layer of the electrolyte between the membrane and the electrode surface which determines the electrode sensitivity.

The electrode membrane is bonded to an annular surface of the electrode holder, which is preferably of plastics material and of the same material as the membrane, and which is positioned outside an electrolyte storing bath located outside the tubular anode. Therefore, unlike the clamping mechanism with the "O" ring or the sleeve, the membrane is never crinkled, and therefore uniform contact with the electrode portion is obtained. The sensitivity of the present assembly is much stabilized and the leakage of the electrolyte is completely prevented. When the bonding of the membrane is carried out by an adhesive material, the replacement of the electrode membrane can be readily achieved.

The electrolyte storing bath is preferably in the form of a groove in the electrode holder around the end surface of the anode, and a sufficient amount of electrolyte is pooled here. The pressure in the electrolyte storing groove is preferably balanced with the atmospheric pressure through a thin hole vented to atmosphere. In this way, the contact condition between the electrode membrane and the electrode surface is kept constant irrespective of variation in temperature and atmospheric pressure.

A comparison of the main features of the present transcutaneous electrode with the two known constructions is summarized in TABLE I. By these structural characterstics, the present electrode shows much better accuracy (higher ratio of measured PO_2 value per actual arterial PO_2), higher stability, and other better characteristics than the prior art.

In the cases of the 1st prior art and the present invention, the skin heating area is ring shaped and has an opening in the centre. However, by making the opening small, arterialization of subcutaneous tissues is not affected by the presence of the opening in the heating area, since arterial blood spreads through the subcutaneous capillaries. It is very important, however that the heating area should be as large as possible for sufficient arterialization.

TABLE I

Comparison of the present invention with the prior art

Structures	The 1st prior art	The 2nd prior art	The present invention	
Cathode surface	point	disc	ring.	(3 in Fig.1)
Area of cathode surface	small	large	intermediate	
Heating of skin through	anode	cathode	body (collar) and plate	(8,7)
Heating area	*ring, small	disc, small	*ring, large	(7)
Membrane holding	by O-ring	by cup(sleeve)	bond to holder	(5′)
Membrane pressure to electrode	loose	loose	stable	
Membrane protector	none	none	thin plate	(7)

Two examples of the oxygen measuring electrode assembly in accordance with the invention will now be described with reference to the accompanying drawings, in which:-

Figure 1 is a sectional view showing the construction of one of the examples;

Figure 2 is a sectional view of the second example, which is a modification of the embodiment shown in Figure 1;

Figure 3 is a graphical representation showing a change in the electrolysis current, with respect to gas exchange, of the transcutaneous oxygen electrode assembly in accordance with the present invention; and

Figure 4 is a graphical representation showing a time course of electrolysis current actually measured by a transcutaneous oxygen electrode assembly (44°C) on the forearm skin of a person (♀, age 26).

Figure 1 illustrates one embodiment of a transcutaneous oxygen measuring electrode assembly in accordance with this invention. In Figure 1, the reference numeral 1 designates an electrode holder of a suitable insulating material, such as plastics, and a cylindrical silver anode 2 is held in the holder 1 so that its lower end is exposed below the holder 1. An upper end of the anode 2 is provided with a flange 2′ having a periphery exposed to an outer periphery of the holder 1. A cathode 3 is in the shape of a thin metal tube and is spaced coaxially from the anode by a glass cylinder 4 fixed to the anode 2. The peripheral outer edge of the exposed lower end of the cathode support cylinder 4 is rounded, and the cathode support is arranged in such a manner that its lower end surface protrudes from the end surface of the anode 2 by a distance substantially equal to the radius of curvature of the rounded edge. The exposed end of the cathode 3 lies in the same plane as the lower end surface of the cathode support cylinder 4.

An oxygen-permeable electrode membrane 5 is provided over the exposed ends of the electrodes 2 and 3 and the glass cylinder 4. The membrane 5 is an oxygen permeable film made of a hydrophobic polymer such as polyvinylidene chloride, polytetrafluoroethylene, or polypropylene. This membrane 5 is stuck on the peripheral part of the lower end surface of the holder 1 with a suitable adhesive. In order to obtain a good contact of the membrane 5 to the cathode end while allowing the presence of an electrolyte layer 12 therebetween, the lower ends of the anode and the holder 1 are arranged in the same plane as each other.

Further, the area of the membrane 5 covering the end of the anode 2 and the peripheral portion of the holder 1 are suitably compressed by a metal cover plate 7 having a central opening of a diameter which is slightly greater than the inner diameter of the tubular anode 2.

The cover plate 7 is supported by an outer metal collar 8 screwed on to a collar 6 fitted around the holder 1. Therefore, the membrane 5 exposed only through the area of the opening of the cover plate 7 can be brought into contact with the surface of a body to be examined.

The end portion of the electrode holder 1 which is externally in contact with the end of the anode is suitably cut like a shoulder which is employed as an electrolyte pool 9 in the form of a circumferential groove. The excess part of an electrolyte 12 covering the surfaces of the anode 2 and the cathode 3 is maintained adhered to the groove, on the silver anode side. An air evacuating hole 10 is opened on the upper surface of the plastics holder 1, extending through the holder 1 from a space outside the part of the groove where the electrolyte is maintained adhered. The opening of this hole 10 is plugged with a suitable gas permeating (porous) element 11. A number of small grooves (not shown) are provided in the end of the anode so as to stabilize the amount of electrolyte stored on the anode surface and to communicate the electrolyte balanced with the atmospheric pressure with the electrolyte layer on the end of the cathode.

A heater and a heat-sensitive element (thermistor) are arranged at a suitable part of the electrode holder collar 6, which is made of a metal of high thermal conductivity. In the example shown in Figure 1, the heater 13 is arranged in a circumferential (or peripheral) groove 14 provided in the holder collar 6, while the heat-sensitive element 15 is inserted into a hole 16 which is drilled in the holder collar 6.

Figure 2 illustrates a modified embodiment of the oxygen measuring electrode device shown in Figure 1. This assembly is quite similar in structure to the assembly shown in Figure 1, and only a part of the holder (1 in Figure 1) is different. However, by this change, the loading of the electrode membrane becomes much easier and the contact between the membrane and the electrode is much stabilized. In Figure 2, the reference numeral 1 designates a fixed part of an electrode holder of a suitable insulating material, such as plastics. The numeral 1′ designates a detachable part of the holder which is in the form of a circular tube. The detachable tube 1′ is provided at the lower end with a electrode membrane 5. A cylindrical silver anode 2 is held in the fixed part 1 of the holder. A cathode 3 in the shape of a thin metal tube is spaced coaxially from the anode 2 by a glass cylinder 4 fixed to the holder 1. A peripheral edge of an exposed lower end of the glass cylinder 4 supporting the cathode 3 is rounded and the cathode 3 is arranged in such a manner that the lower end of the glass cylinder protrudes downward from the end of the anode 2 by a distance substantially equal to the radius of curvature of the rounded edge. On the other hand, the exposed end of the cathode support cylinder 4 is in the plane including the cathode end.

An electrode membrane 5 which is made of hydrophobic oxygen permeable material is provided over the exposed ends of the electrodes 2 and 3 and the glass cylinder 4. The membrane 5 is made of an oxygen permeable hydrophobic material, and is fixed on the lower end surface of the detachable part 1′ of the holder portion with a suitable adhesive or by means of heat bonding. In order to obtain a good contact of the membrane 5 to the lower end surface of the anode while allowing a presence of an electrolyte layer inbetween, the lower end face of the anode 2 and that of the detachable part 1′ are arranged in the same plane. The area of the membrane 5 covering the lower end surface of the anode 2 is supported by a metal cover plate 7 having a central opening of a size slightly larger than that of the lower end of the cathode support cylinder 4 to assume the intimate contact of the membrane 5 with these areas.

The cover plate 7 is integral with a collar 8 made of good heat conductive metal and screwed on to the collar 6 which is also made of a metal of good heat conductivity. By the presence of the cover plate 7, only the area of the membrane 5 exposed through the opening of the plate 7 can contact the surface of a body to be examined.

The end portion of the fixed part 1 of the electrode holder, which is contact with the anode 2, suitably recedes from the end surface of the anode in order to form a circumferential space which serves as a electrolyte pool 9. An electrolyte 12 is maintained between the membrane 5 and the end surfaces of the electrodes, and its excess part is pooled in the space 9.

A heater and a heat-sensitive element (thermistor) are arranged at a suitable part of the electrode holder collar 6. The heater 13 is arranged in a circumferential (or peripheral) groove 14 provided in the holder collar 6, while the heat-sensitive element 15 is inserted into a hole which is drilled in the holder collar 6.

Since the electrode holder comprises a detachable part 1′ with the electrode membrane 5 bonded thereto, it is easy to obtain a membrane of a suitable tension which has been prefabricated by a manufacturer under a good quality control.

In the electrode assembly shown in Figure 2, the flange portion 2′ of the anode 2 shown in Figure 1 is eliminated. There is no essential difference between the presence and the absence of this flange portion as a component of the oxygen electrode assembly for the performance of transcutaneous measurement of arterial oxygen partial pressure.

Two examples of the data obtained by the transcutaneous arterial oxygen electrode assembly shown in Figure 1 will be described. The condition of constructing the electrode assembly used in these experiments are listed below:

Cathode --------------------	Material - gold
	Outside diameter of the surface - 2.0 mm
	Inside diameter of the surface - 1.5 mm
Anode ----------------------	Material - silver
	Outside diameter of the surface - 5 mm
	Inside diameter of the surface - 3 mm
Electrolyte -----------------	Water - glycerol - KCl - buffer solution (pH 10)
Electrode membrane -----	Polyvinylidene chloride film, 12 μ in thickness

Response Curve With Respect to Gas Exchange (Calibration Curve)

The curve is as shown in Figure 3. The above-described electrode assembly according to this invention was set in a calibration chamber (which is a gas exchange container approximately 5 ml in capacity having a small hole in the upper part, which is in contact with the electrode assembly). The electrolysis current of the electrode assembly was recorded while nitrogen gas, air and oxygen was supplied aternately to the chamber. The response characteristic of the electrode assembly, the linearity with respect to the oxygen partial pressure (concentration) and other properties of the assembly were examined from this curve. The results of this examination indicate the following characteristics; (1) The residual current is less than 0.2% with respect to the 1 atm. (760 mm Hg) O_2 *value*; (2) The 80% response time is 30 seconds, and the 96% response time is 70 seconds (this means that the reaction is substantially in accordance with the curve of first degree); (3) The linearity of the measurement values with respect to the O_2 concentration is substantially proportional, judging from the comparison of currents for $N_2(O_2=0)$, air (O_2=20.99%) and O_2.

In the experiment shown in Figure 3, the temperatures of the electrode assembly (set to a temperature of 44°C) was also recorded. This time course is shown in the figure as an essentially straight line parallel with the abscissa. It was known from this line that the variation of the temperature during the experiment was less than 0.02°C.

Transcutaneous Experimental Value

The person examined was a woman 26 years old. The electrode assembly according to this invention was fixed to the skin of the inside of her wrist by using a double faced adhesive tape. The electrode assembly was maintained at a temperature 43.5 ± 0.02°C. While she was allowed to make an air breathing exercise and an oxygen breathing exercise alternately, the electrolytic current values were recorded. The results are as indicated in Figure 4. Arrows A, B, C and D in the figure indicate the starting time of weak oxygen-breathing, air breathing, strong oxygen-breathing and air breathing, respectively. As is apparent from the graphical representation shown in Figure 4, the transcutaneous measured oxygen partial pressure during the air breathing exercise is about 90 mm Hg which is close to the standard value of the arterial blood oxygen partial pressure of the ordinary adult. When the oxygen inhalation was peerformed moderately, the oxygen partial pressure was about 530. When the oxygen inhalation was performed heavily, the oxygen partial pressure was 570. These values are well coincident with those of the actual arterial blood oxygen levels in the above conditions. The responses at the start and the stop of the oxygen inhalation are somewhat slower than the actual variations in the artery; however, the responses are sufficiently rapid for actual clinical treatments.

Essentially similar (or even somewhat better) results were obtained by the transcutaneous oxygen electrode assembly shown in Figure 2, as the above experiments carried out using the assembly shown in Figure 1.

The use of the conventional transcutaneous arterial oxygen electrode assembly is limited in application only to infants. However, in the electrode assembly in accordance with this invention, thearea adapted to heat a skin is markedly increased, and various improvements have been made. Accordingly, with the electrode assembly of this the invention, arterialization is satisfactorily caused even for adults, and useful and accurate measurement can be carried out. This is a significant effect of the invention.

If the above-described measurement data and the results of usage of the electrode assembly in accordance with the invention are collectively considered and are compared with those of the electrode assembly available on the market, the invention has the following merits: As the configuration and area of the cathode of the electrode assembly according to the invention are made suitable, the uniformity in reaction on the electrode surface and the S/N ratio of the electrode assembly reaction are both improved. In addition, as the holding mechanism of the electrode membrane and those of the additional components thereof are also improved in various ways, the stability in measurement is remarkably improved. These merits contribute to the stable heating operation and to the sufficient heat transmission to a surface to be examined, and make it possible to perform the transcutaneous arterial blood oxygen measurement of an adult which has been difficult before, in association with the selection of the suitable film for the electrode assembly.

An oxygen measuring electrode assembly similar to those described herein is also described and illustrated in my application No. 7909008 (Serial No. 1587880) in which I claim an oxygen measuring electrode assembly for use in measuring the partial pressure of oxygen in a fluid, the assembly comprising a first member made of an insulating material, the member having a bore therein and a flat end surface surrounding the bore at one end thereof, an oxygen permeable electrode membrane bonded to the flat end surface of the first member so that the membrane stretches across and closes the end of the bore, a second member made of an insulating material and located in the bore of the first member so that it extends along the whole length of the bore, a cathode extending co-axially through the second member, an anode mounted between the first and second members, means which supports the electrode membrane in a substantially fixed position relative to the second member, the anode, and the cathode, and an electrolyte located in a space defined by the electrode membrane and the adjacent end portions of the first and second members so that the electrolyte is in contact with the membrane and both the anode and the cathode.

WHAT I CLAIM IS:-

1. An oxygen measuring electrode assembly for use in making transcutaneous arterial blood oxygen measurements, the assembly comprising an electrode portion having a tubular anode and a tubular cathode of a smaller diameter than the anode and disposed

coaxially in said anode, an insulating support member for supporting both the anode and the cathode relative to each other, an annular holder portion made of electrically and thermally insulating material, said holder portion surrounding said anode, an oxygen permeable membrane bonded to a lower end of said holder portion so as to cover a lower end of said electrode portion and, in use, contain an electrolyte solution between said lower end surfaces of said anode and cathode and same membrane, a collar portion of a heat conductive metal having a large thermal capacity for supporting said holder portion, temperature sensing means and heating means provided in said collar portion for maintaining the collar portion at a predetermined temperature, and a membrane cover plate thermally connected to a lower end of said collar portion, said membrane cover plate having an opening through which an area of said membrane corresponding to an area of the lower end of said electrode portion is exposed, and said membrane cover plate being made of a heat conductive metal to transmit heat from said collar portion to the skin of a person when a transcutaneous arterial blood oxygen measurement is being made on the person.

2. An oxygen measuring electrode assembly as claimed in claim 1, in which the insulating support member is made of glass.

3. An oxygen measuring electrode assembly as claimed in claim 1, in which the holder portion provides an annular space for an electrolyte pool and includes an air passage communicating said electrolyte space with the atmosphere.

4. An oxygen measuring electrode assembly as claimed in claim 1, in which the lower end of the cathode and the part of the support member surrounding the cathode protrude slightly from the end of the anode, and the electrode membrane is stretched across said protruding lower end surfaces by the cover plate which presses the membrane against the lower end surfaces of the anode and the holder portion.

5. An oxygen measuring electrode assembly as claimed in claim 1, in which the electrode membrane is bonded to the lower end surface of the holder portion by an adhesive.

6. An oxygen measuring electrode assembly as claimed in claim 1, in which the holder portion and the electrode membrane are made of the same plastics material as each other, and the membrane is bonded to the lower end of the holder portion by a thermal adhesive.

7. An oxygen measuring electrode assembly as claimed in claim 1, in which the holder portion comprises a fixed part surrounding the anode, and a detachable part with the electrode membrane bonded thereto.

8. An oxygen measuring electrode assembly as claimed in claim 7, in which the detachable part and the electrode membrane are bonded to each other by an adhesive.

9. An oxygen measuring electrode assembly as claimed in claim 7, in which the detachable part and the electrode membrane are made of the same plastics material as each other and are bonded to each other by a thermal adhesive.

10. An oxygen measuring electrode assembly constructed substantially as described with reference to Figure 1 or Figure 2 of the accompanying drawings.

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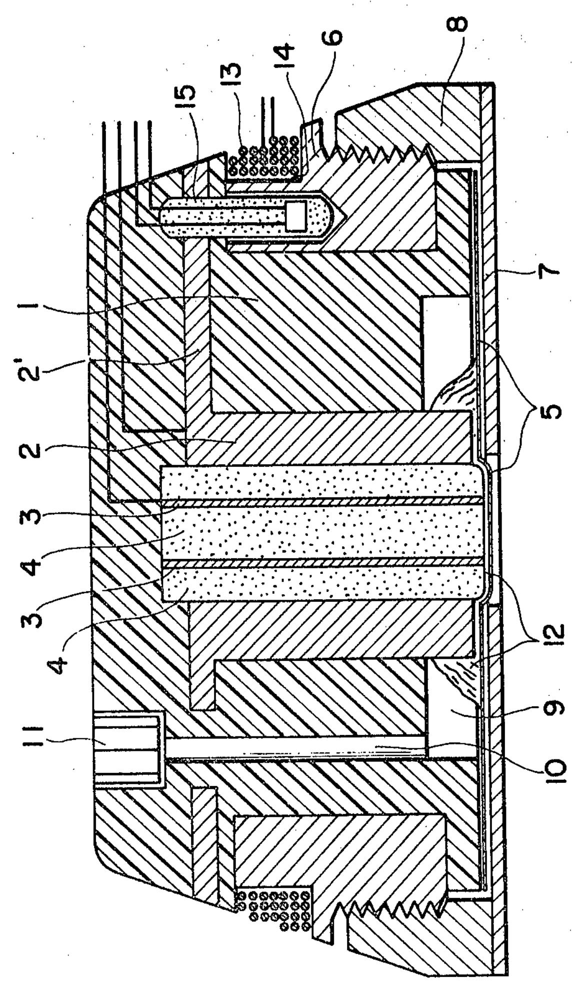
Sheet 1

FIG. 1



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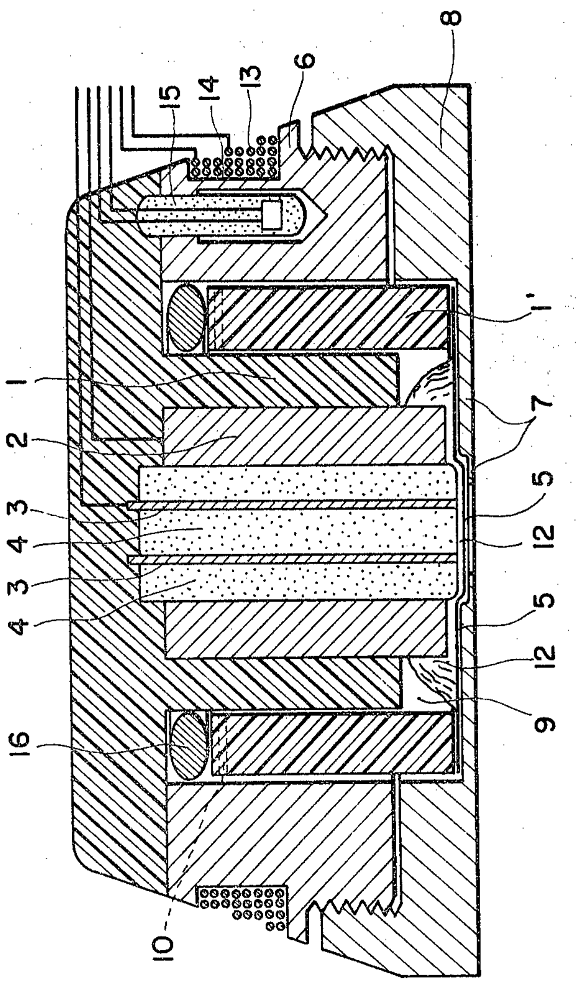

FIG. 2

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Sheet 3

FIG. 3

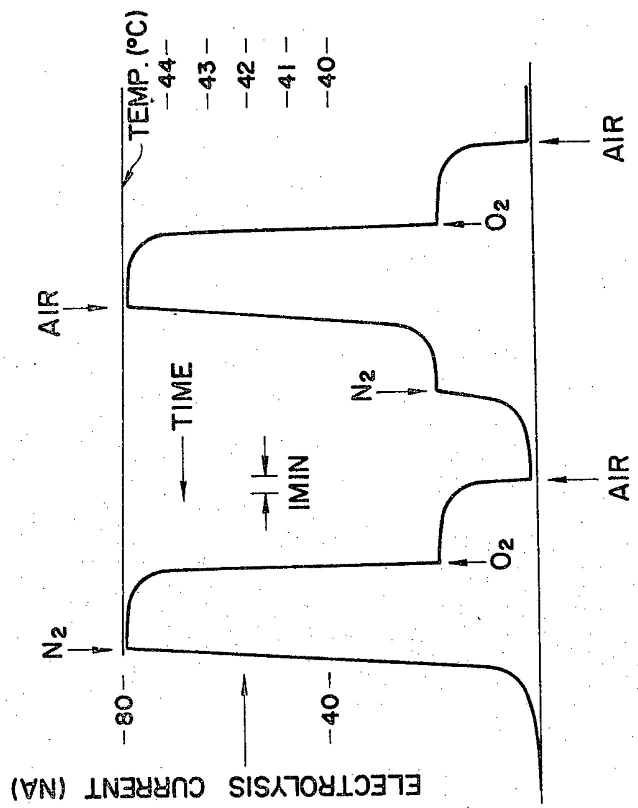
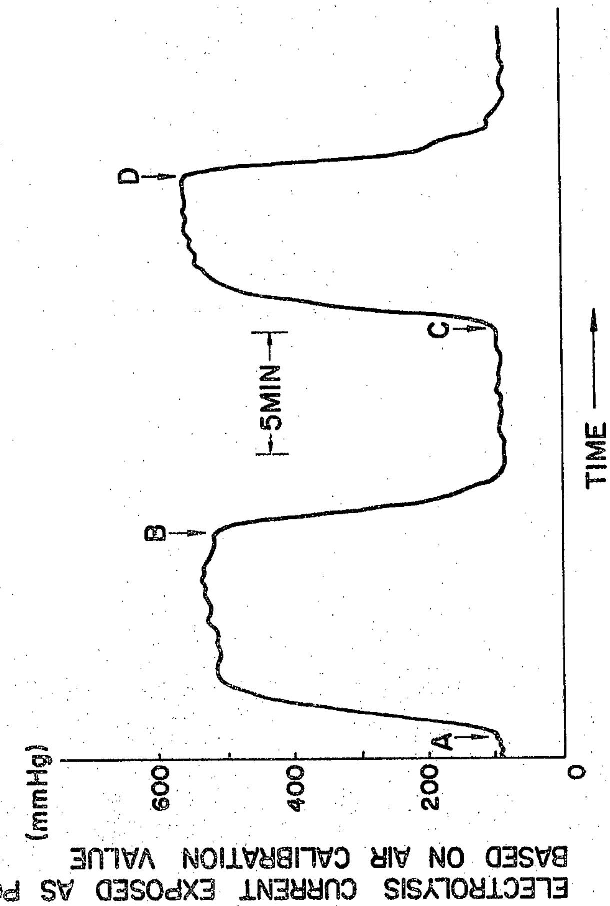


FIG. 4


ELECTROLYSIS CURRENT EXPOSED AS PO_2
BASED ON AIR CALIBRATION VALUE
(mmHg)
600
400
200
0
A
B
C
D
5MIN
TIME