

Nov. 4, 1969

V. PARSONNET ET AL

3,476,116

NONPOLARIZING ELECTRODE FOR PHYSIOLOGICAL STIMULATION

Filed Nov. 3, 1967

2 Sheets-Sheet 1

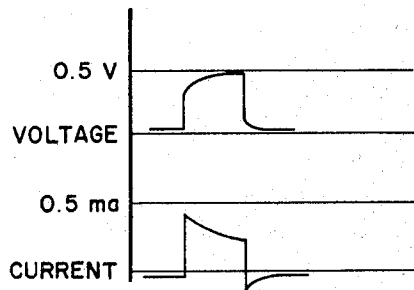


FIG. 1

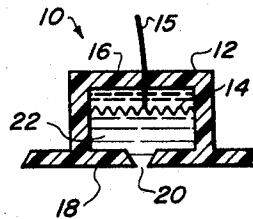


FIG. 3

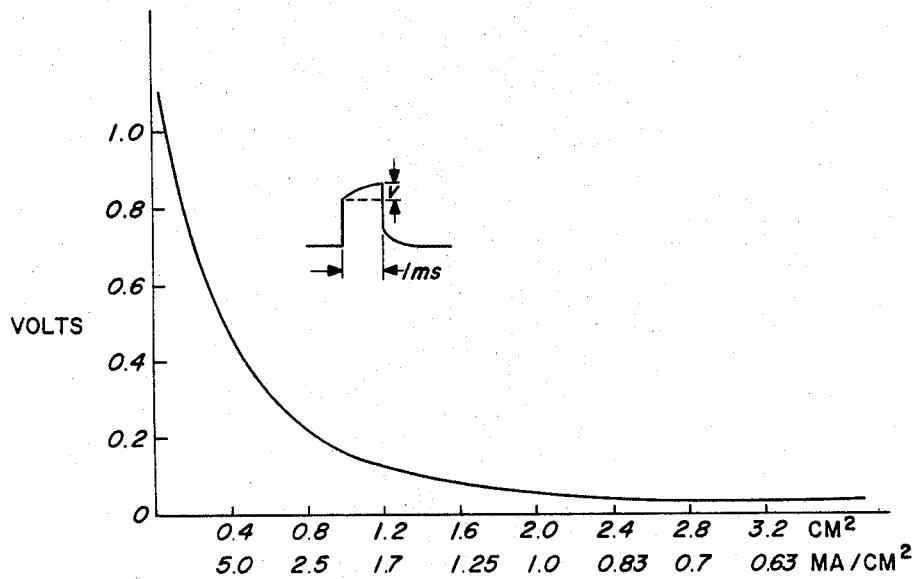


FIG. 2

INVENTORS
VICTOR PARSONNET
GEORGE H. MYERS
GERHARD LEWIN

BY

Popper, Bain, & Bobis

ATTORNEYS

Nov. 4, 1969

V. PARSONNET ET AL

3,476,116

NONPOLARIZING ELECTRODE FOR PHYSIOLOGICAL STIMULATION

Filed Nov. 9, 1967

2 Sheets-Sheet 2

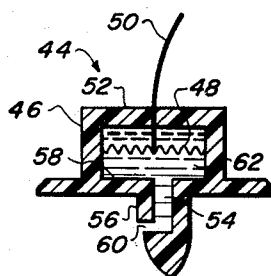
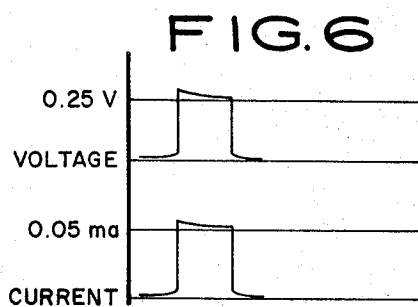
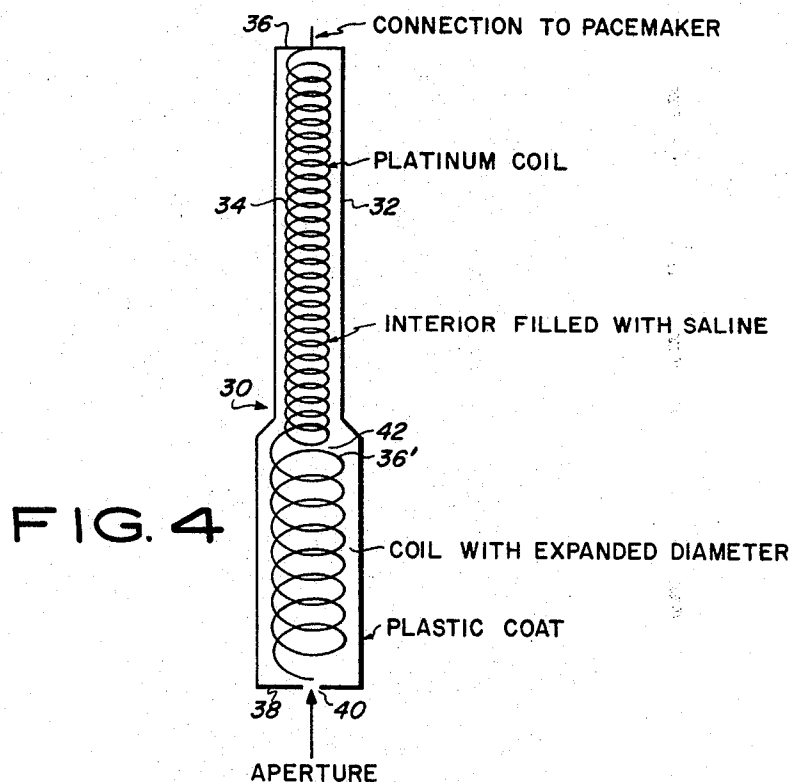
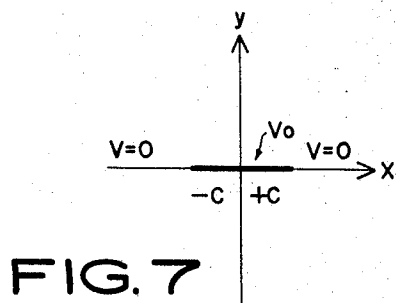


FIG. 5



INVENTORS
VICTOR PARSONNET
GEORGE H. MYERS
GERHARD LEWIN
BY
Popper, Bain, & Bolin
ATTORNEYS

1

3,476,116

NONPOLARIZING ELECTRODE FOR
PHYSIOLOGICAL STIMULATION

Victor Parsonnet, 113 Sagamore Road, Millburn, N.J.
07041; George H. Myers, 190 Wyoming Ave., Maple-
wood, N.J. 07040; and Gerhard Lewin, 21 Yale Ter-
race, West Orange, N.J. 07052

Filed Nov. 9, 1967, Ser. No. 681,872

Int. Cl. A61n 1/04, 1/36

U.S. Cl. 128-417

14 Claims

2

ABSTRACT OF THE DISCLOSURE

A nonpolarizing electrode for physiological stimulation having a large area electrode, preferably greater than one cm.² placed in a housing filled with a saline solution and having only a single hole in contact with the heart tissue to be stimulated, which hole is extremely small, approximately .5 mm.² in area so as to achieve high current densities at the tissue and to thus exceed the threshold voltage of the tissue to be stimulated while maintaining low polarizing voltages at the electrode and thus prevent heavy energy dissipation at the electrode. The electrode has biphasic excitation so as to minimize the total charge in the system.

Since Volta's first electrical stimulation of a frog leg, metallic electrodes have been used extensively for biological stimulations in demonstration and research. More recently, heart stimulation with electronic stimulator has become routine in certain types of heart diseases. Two main types of electrodes are in use: Myocardial, consisting of a wire which protrudes from the surface of the heart into the myocardium, and endocardial, consisting of a conducting tip at the end of a catheter inserted into the ventricle and in contact with the endocardium. Endocardial stimulation has many advantages; major surgery is avoided and the electrodes are not fatigued by the motion of the heart and eventually fractured. In unipolar stimulation the second electrode is an implanted large-area disc. In bipolar stimulation the catheter has a second electrode in the form of a ring located about one centimeter above the tip and insulated from it.

The present invention permits cardiac pacing energy thresholds of one-twentieth the value of those obtained with typical metal electrodes. Electrode polarization is negligible with the new device. The lower thresholds are a result of two interacting factors:

- (1) There is negligible polarization.
- (2) The absence of polarization permits using high current densities but low total current at the electrode tip.

POLARIZATION OF CONVENTIONAL
ELECTRODES

Typical metal myocardial electrodes have a surface area of 0.15 cm.². When a pulse of 1 ms. duration is applied, the typical threshold voltage and current values are 0.50 v. and 1.0 ma., corresponding to a threshold energy of 0.5 microjoule in acute stimulation. The corresponding values for endocardial stimulation are somewhat lower than these. These figures are just "order of magnitude" since there is considerable variation. This energy cannot be substantially reduced by changing the surface area of the electrode or the pulse duration. This is because increasing current density at the tissue decreases pacing thresholds but increases polarization in the ordinary electrodes, and a corresponding increase in corrosion.

The build up of polarization occurs gradually at a rate proportional to the current density. The energy dissipated at the interface is lost as far as stimulation is concerned.

The electrode of the present invention achieves low

electrode polarization by creating a low current density at the electrolyte-metal interface and high current density at the electrolyte-tissue interface. The electrode of the present invention is basically a small container completely enclosed except for a small hole. A piece of platinum foil of large area is placed inside and connected to a pulse generator by a wire which passes through a water-tight seal in the dielectric container and the container is then filled with a saline solution. The hole is placed in contact with the heart and it is the portion of the electrode which does the stimulation. Since all of the current which leaves the platinum foil must pass through the hole, the current density may be made high at the hole and low at the metal. The container soon fills up with body fluids replacing the original saline solution and, since the body fluids are also a conductor, this does not alter the operation of the electrode.

For the purpose of illustrating the invention, there are shown in the drawings forms which are presently preferred; it being understood, however, that this invention is not limited to the precise arrangements and instrumentalities shown.

FIGURE 1 shows typical current and voltage-time curves of proprietary myocardial electrodes for acute stimulation.

FIGURE 2 is a curve of overvoltage as a function of platinum electrode area for a constant current of 2 ma. at 70 p.p.s. in Ringer solution.

FIGURE 3 is a cross-sectional view of an epicardial electrode built in accordance with the principles of the present invention.

FIGURE 4 is a cross-sectional view of an endocardial electrode built in accordance with the principles of the present invention.

FIGURE 5 is a cross-sectional view of a myocardial electrode built in accordance with the principles of the present invention.

FIGURE 6 is a voltage current-time graph similar to FIGURE 1 for the electrode of FIGURE 3.

FIGURE 7 is a graphical analysis utilized for calculating the field produced by the electrodes and the surrounding tissues utilizing the principles of the present invention.

The current and voltage traces for a typical myocardial electrode are shown in FIGURE 1. It will be observed that while the current remains almost constant by design, the voltage increases 30 percent during the pulse from 0.35 volt to 0.5 volt because of the electrode polarization. The voltage increase is called "over voltage." The slight drop in current is caused by the regulation of the Grass stimulator utilized. For the usual electrode, the polarization impedance was so great that the drop in current was considerable. Processes occur at the electrode-tissue interface which are equivalent to a resistance increase of this interface. The amount depends upon, among many factors, the type of metal utilized. The present invention, and the considerations in this application are directed to the use of platinum as an electrode as this has been found to be the preferred metal because of its biological non-toxicity. The nature of this polarization is probably due to the transport of ions to the electrode during the current pulse, and these ions will be removed by passing the same charge in an opposite direction.

FIGURE 2 shows the amount of overvoltage as a function of electrode area for a constant current of 2 ma. It demonstrates how the overvoltage is reduced when the current density is decreased. However, current density alone is not the only factor determining polarization. When area and current were reduced simultaneously in one experiment, while keeping the current density constant, the overvoltage increased 30 percent. However, the practical conclusion from FIGURE 2 is that the polarization can be rendered negligible in a typical stimulation

pulse by using a platinum electrode of at least one square centimeter in area. Since polarization increases with the total charge passed in one direction, it is preferable to use biphasic excitation.

It follows from the foregoing that large area electrodes are needed to avoid wasting energy by polarization. On the other hand, it is known that a potential drop of 20 mv. has to be produced across the cell membranes in the heart to initiate firing. Experience shows that a current density of above 5 ma. per square centimeter is needed. Hence, we have the contradictory requirements that, for minimum energy, a low current density is required at the electrode to avoid polarization, but a high current density is required to produce the potential drop needed for stimulation at the responsive cells.

Obviously, with customary electrodes the current density is the same at the metal surface and in the adjacent tissue so a compromise is necessary with such electrodes. However, the requirements can be met by the use of a current density transformer. The differential current density electrode of the present invention achieves low electrode polarization by creating a low current density at the electrode-electrolyte interface but a high current density at the electrolyte-tissue interface. The use of this electrode provides a higher current density at the tissue to be stimulated, than at the metal portion of the electrode. In the conventional electrode stimulation, the reverse is true.

As shown in FIGURES 3-5, the differential current density electrode of the present invention is basically a small container which is completely enclosed except for a small hole. The container is manufactured of dielectric material such as plastic. A piece of platinum foil (FIG. 5) or platinum iridium wire (FIG. 4) of large area is placed inside and connected to a pulse generator by a wire which passes through a water-tight seal in the container. The foil preferably has a surface area greater than approximately 0.2 cm.² to 1.0 cm.². The container is then filled with a saline solution such as Ringer's solution. The hole in the container is placed in contact with the heart and it is at or near this portion of the electrode where the stimulation takes place. Since all of the current which leaves the platinum foil must pass through the hole, the current density may be made high at the hole and low at the metal. Experience has shown that the container soon fills up with body fluids replacing the original saline solution. Since the body fluids are also a good conductor, this does not alter the operation of the electrode.

In FIGURE 3, there is shown an epicardial electrode built in accordance with the principles of the present invention and generally designated by the numeral 10. The epicardial electrode 10 comprises a generally cylindrical housing or container 12 manufactured of a dielectric material such as plastic. A piece of platinum foil 14 is mounted within the container and connected to a pulse generator (not shown) by a wire 15 extending through the top wall 16 of the container 12. The bottom wall 18 of the container 12 has centrally located a hole 20 therein having a cross-sectional area of 1.0 mm.² with walls at the entrance diverging therefrom. The interior of the container 12 is filled with a saline solution 22.

An endocardial electrode built in accordance with the principles of the present invention and generally designated by the numeral 30 is shown in FIGURE 4. The electrode 30 comprises a housing or container 32 manufactured of a dielectric material such as plastic. A platinum iridium coil 34 extends through the top wall 36 of the container 32. The platinum iridium coil 34 has a small diameter in the upper or small diameter portion of the housing 32 and has an expanded diameter 36' at the lower end in an expanded diameter portion of the housing 32. The bottom wall 38 of the electrode 30 has a suitable aperture or hole 40 which is 1.0 mm.² in area. It is desirable that the electrode 36 shall be disposed in close proximity to the hole 40, preferably less than 3 mm. It will be noted that the electrode has been constructed utilizing a single coil of wire which has an expanding helix diameter

at the bottom end thereof in order to provide the necessary surface area. The one piece construction for the electrode 34 reduces the possibility of fatigue failures and of corrosions which could be produced by welds. The plastic material forming the container 32 is a medical grade silicone rubber.

The inside surface area of the electrode 36' is .5 cm.² for a typical current of 0.25 ma. The top side of the coil 34 is shielded by the housing and it is assumed that all of the current flows from the inside surfaces of the expanded diameter portion 36 of the coil 34. The housing 32 is filled with a saline solution 42. The resistance of the saline solution as determined by the distance between the electrodes and the aperture 40 should be small enough so that the voltage drop between the electrode and the aperture is not more than .25 volt. This is less than 1000 ohms for .25 ma. current. It has been found that the optimal size for the area of the aperture 20 for minimum current is .5 to 1 mm.². A preferred ratio of the cross-sectional area of the metal to the cross-sectional area of the aperture is at least 10:1.

In FIGURE 5, there is shown myocardial electrode generally designated by the numeral 44.

The myocardial electrode 44 comprises a dielectric housing 46 with a platinum foil electrode 48 therein. The foil is preferably corrugated to provide a larger external surface. The electrode 48 is in electrical conducting relation with a pulse generator through a wire 50 extending through the top wall 52 of the housing. The myocardial electrode of FIGURE 5 is similar to the epicardial electrode of FIGURE 3 except that there is a passageway 54 extending through a downwardly extending projection 56 integral with the bottom wall 58 of the container 46. The passageway 54 terminates in an aperture 60 having the same dimensions as apertures 20 and 40. Again, the container 46 is filled with a saline solution 62. It is to be understood that the passageway 54 may assume other directions, and is not critical as long as the cross-sectional area of the entrance is as hereinbefore presented.

The platinum foil 14 and 48 is several centimeters square in area. The epicardial electrode 10 is adapted to be held with the aperture 20 against the heart. A lateral extension of silicone rubber or Dacron cloth (not shown) is used for suturing to the heart.

For myocardial stimulation, the myocardial electrode 44 has its downwardly extending member 56 extending into the myocardium.

For endocardium stimulation, the catheter 30 is used with the aperture 40 at the bottom thereof.

In FIGURE 6, there is shown a typical voltage and current trace for a differential current density epicardial electrode built in accordance with the principles of the present invention. When it is compared with the trace of FIGURE 1, the different scales for the current and voltage should be noted. The load for the electrode in FIGURE 3 is purely resistive and there is virtually no polarization. The traces of FIGURES 1 and 6 were taken at the stimulation threshold of the same dog and at the same time. The parameters, pulse duration, current, and current density were checked experimentally. The strength-duration curves follow the same pattern as conventional electrodes. A pulse width of 1 milli-second was used as a standard. If the hole area is made too small or the plate through which the hole is drilled made too thick, the voltage drop in the hole can become appreciable and the power requirements will go up. The optimum hole needs an area of about .5 mm.² with a maximum of 1 mm.². Not only the current density, but the current itself had to be increased when the hole became too small. Table I, below, compares the stimulus threshold values in the dog of typical myocardial electrodes (similar to electrodyne electrodes) with differential current density unipolar epicardial and catheter platinum electrodes of 1 to 3 centimeters square area with a hole of .5 mm.². At .04 ma. the current density at the hole was 8 ma./cm.². This would cause an overvoltage of about .7 volt on platinum. It should be

noted that the minimum voltage is about 10 times the minimum voltage change across the membrane of a nerve cell needed for firing. Such low stimulation levels were obtained repeatedly in the experiments.

TABLE I.—UNIPOLAR CARDIAC THRESHOLD STIMULATION

Type of Electrode	Pulse Width, ms.	Average Voltage, v.	Current, ma.	Energy Micro-joule
E1-----	1	0.5	0.6	0.3
E1-----	1.5	0.35	0.4	0.21
E1-----	3	0.35	0.4	0.42
DCD-Ep-----	1	0.25	0.04	0.01
DCD-Ep-----	1.5	0.25	0.04	0.015
DEC-Ep-----	3	0.15	0.03	0.013
C-51 End-----	1	0.4	0.8	0.32
DCD-End. minimum-----	1	0.15	0.018	0.003

E1 Electrodyne type, myocardial.
DCD-Ep Differential current density, epicardial.
C-51 USC1 electrode, endocardial.
DCD-End Differential current density, endocardial.

The mathematical treatment of the thresholds of cardiac stimulation of surface electrodes can be derived. The result of the derivation will be a proof of the optimum hole size for the surface electrode set forth above.

The heart for the purposes of this development will be assumed to be a homogeneous, resistive material of finite but large dimensions. In the heart tissue will be sensitive cells. If the potential of the interior of one of these cells changes with respect to the exterior by a certain threshold voltage V_T (of the order of 20 mv. for cardiac cells), that cell will depolarize and the entire heart will contract. In the equations which follow, the cell will be assumed to be lying along the x axis for the sake of convenience. Since the cells are continually changing direction, there will be a cell near an electrode with the proper orientation with very high probability.

The fundamental equation used, from Lale and Katz (Lale, P.G., "Muscular Contraction by Implanted Stimulators," Med. Biol. Eng. and Katz, B., Nerve, Muscle and Synapse, McGraw-Hill, 1966) is

$$(1) \quad (v-V) = \lambda^2 \frac{d^2v}{dx^2}$$

where λ is the characteristic length of the cell (the length such that the radial resistance of that length of membrane equals the longitudinal resistance of the inner core); v is the potential change in the inner core at x , caused by the stimulus; and V is the potential in the external medium at x .

As shown by Lale, a suitable approximation for solving this equation is to replace d^2v/dx^2 (the derivation in the cell) by d^2v/dx^2 (the derivation in the medium external to the cell) because the perturbation of the field caused by the cell is small. Thus, only the field produced by the electrodes and the surrounding tissue must be computed. Note that Equation 1 basically states that the threshold of stimulation is proportional to the gradient of the components of the electric field. FIGURE 7 shows the model used for calculating the fields. A perfectly-conducting electrode is assumed to extend from $-c$ to $+c$ along the x axis, and to have a potential V_0 applied to it. The upper half plane is a resistive tissue medium. The remainder of the x axis is at zero potential. Thus, this implies that the surface of the heart, except for the electrode, is an equipotential surface. The strip is assumed to be infinitely long in the z direction; thus, this derivation basically represents the field for a long thin electrode. It is desired to calculate the potential and the fields in the upper half plane.

The electric potential for the geometry of FIGURE 7 is given by

$$V(x, y) = \frac{1}{\pi} V_0 \left(\tan^{-1} \frac{c-x}{y} + \tan^{-1} \frac{c+x}{y} \right)$$

The electric field is computed by taking the gradient of the potential:

$$E = -\nabla V(x, y)$$

The result of this operation is

$$E = \frac{V_0}{\pi} \left\{ i y \left[\frac{1}{y^2 + (c+x)^2} - \frac{1}{y^2 + (c-x)^2} \right] - j \left[\frac{c-x}{y^2 + (c-x)^2} + \frac{c+x}{y^2 + (c+x)^2} \right] \right\}$$

where i and j are unit vectors in the x and y directions, respectively.

The formula for electric field exhibits the rate of change of potential both with x and y . Examination of these expressions will show that the voltage change between the cell core and the medium is the maximum if the cell lies along the x axis. Assuming the cell lies along the x axis, then

$$\frac{d^2V}{dx^2} = - \left[- \frac{(y^2 + (c-x)^2 + 2(c-x)^2)}{(y^2 + (c-x)^2)^2} + \frac{(y^2 + (c+x)^2) - 2(c+x)^2}{(y^2 + (c+x)^2)^2} \right]$$

It can be shown that this reaches its maximum for $x = \pm C$ (the edges of the electrode). At this point, the value is

$$\frac{d^2V}{dx^2} = - \frac{4cy}{(y^2 + 4c^2)^2}$$

and the threshold is (where V_T is the threshold value of $v - V$, the transmembrane potential)

$$V_T = \frac{V_0 \lambda^2}{\pi} \frac{4cy}{(y^2 + 4c^2)^2} = (v - V) \text{ Threshold}$$

The differential is the same at $+c$ and $-c$ except for a change in sign, so the transmembrane potential will have the proper polarity at only one edge of the electrode. This equation has a maximum value for

$$c = \frac{y}{2\sqrt{3}}$$

This may be interpreted in the following manner: If sensitive cells were in contact (or very near) the electrode (corresponding to $y=0$), then making the electrode very small would lower the electrode threshold (V_0 for a given cell threshold. This would be in agreement with the intuitive notion that increasing the current density would lower the threshold. However, as is well known, the epicardium is electrically insensitive; the closest sensitive cells are in the myocardium corresponding to a minimum value of y . When the differential current density electrode is an epicardial electrode 10, y will have a minimum value equal to the distance between the surface of the epicardium and the nearest sensitive cells. There will be thus an optimum electrode size.

From symmetry, similar considerations apply to circular electrodes, since both fall in the same equations in any cross-sectional plane. In the strip electrode, all planes perpendicular to the Z axis are equivalent, while for the circular case all perpendicular planes passing through the origin are equivalent.

This optimum cannot be verified experimentally for the endocardial electrode because the electrode cannot be repositioned accurately in the same plane.

As scar tissue forms, y will gradually increase. Thus, the size of the electrode cannot be completely optimized in advance.

The present invention may be embodied in other specific forms without departing from the spirit or essential attributes thereof, and accordingly, reference should be made to the appended claims rather than to the foregoing specification as indicating the scope of the invention.

We claim as our invention:

1. A stimulator electrode for applying electrical impulses to living tissue comprising

(a) a dielectric housing for a conductive medium having an aperture therein for establishing electrical contact between a conductive fluid in the housing and the tissue positioned at the aperture,

- (b) an electrode in the housing in spaced relation to the aperture,
- (c) the ratio of the cross-sectional area of the electrode to the cross-sectional area of the aperture being at least 10:1,
- (d) said housing being adapted to be filled with an electrically conductive fluid,
- (e) and means for connecting said electrode to a source of electric power.
2. The stimulator electrode for applying electrical impulses to living tissue of claim 1 wherein said aperture has a cross-sectional area between .5 mm.² and 2 mm.².
3. The stimulator electrode for applying electrical impulses to living tissue of claim 2 wherein said aperture has a cross-sectional area of approximately .5 mm.².
4. The stimulator electrode for applying electrical impulses to living tissue of claim 1 wherein said electrode has a cross-sectional area of between 0.2 and 2 cm.².
5. The stimulator electrode for applying electrical impulses to living tissue of claim 1 wherein said electrode is platinum foil.
6. The stimulator electrode of claim 1 wherein said electrode is a coil of wire extending in said housing the surface area of said coil from which current is adapted to flow to said aperture being greater than 0.2 cm.² and in close proximity thereto to said aperture.
7. The stimulator electrode of claim 6 wherein said coil is platinum, one end of said coil extending through a wall of said housing in seal-tight relation forming said connecting means.
8. The stimulator electrode for applying electrical impulses to living tissue of claim 7 wherein said housing is cylindrical in shape, said aperture being formed in one end wall of said housing and said platinum coil extending through the opposite end wall of said housing.
9. The stimulator electrode of claim 8 wherein said cylindrical housing has a smaller diameter portion and a larger diameter portion along the length thereof, said smaller diameter portion being adjacent said other end wall and said larger diameter portion being adjacent said first mentioned end wall, said coil being coaxial with said cylindrical housing and having a first smaller diameter in said smaller diameter portion of said housing and a sec-

ond expanded diameter in said larger diameter portion of said housing.

10. The stimulator electrode for applying electrical impulses to living tissue of claim 1 wherein said electrode is positioned less than 3 millimeters from said aperture.

11. The method of applying electrical impulses to living tissue lies in the steps of:

- (a) providing an electrode in the form of a dielectric housing filled with a conductive liquid having a single aperture.
- (b) placing the aperture in conductive relation to living tissue to be stimulated,
- (c) providing said electrode with a conductive surface within said housing spaced from said aperture,
- (d) supplying electric energy to said conductive surface,
- (e) providing a voltage of about 20 mv. to said tissue to be stimulated,
- (f) providing a current density of at least 5 ma. per cm.² at said aperture, and
- (g) and limiting the overvoltage at said conductive surface to less than .5 volt.

12. The method of stimulating living tissue with electrical impulses of claim 11 wherein said step of providing an electrode having an aperture includes providing an electrode having an aperture of approximately .5 mm.².

13. The method of stimulating living tissue with electrical impulses of claim 11 wherein said aperture is positioned adjacent the endocardium of the heart.

14. The method of stimulating living tissue by applying electrical impulses of claim 11 wherein said aperture is positioned adjacent the myocardium.

References Cited

UNITED STATES PATENTS

1,363,807	12/1920	Murphy	128—417
3,107,672	10/1963	Hofmann	128—405
3,170,459	2/1965	Phipps et al.	128—2.06
3,253,595	5/1966	Murphy et al.	128—405
3,437,091	4/1969	Jerushalani	128—404

WILLIAM E. KAMM, Primary Examiner