

[54] **IMPLANTABLE HEART PACER OR THE LIKE WITH INTERNAL CELL ELECTRODE**

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[58] Field of Search..... 128/419 B, 419 C, 419 E, 128/419 P, 419 R, 421-423, 2 P, 2 C; 307/110; 136/184, 86 A, 86 F

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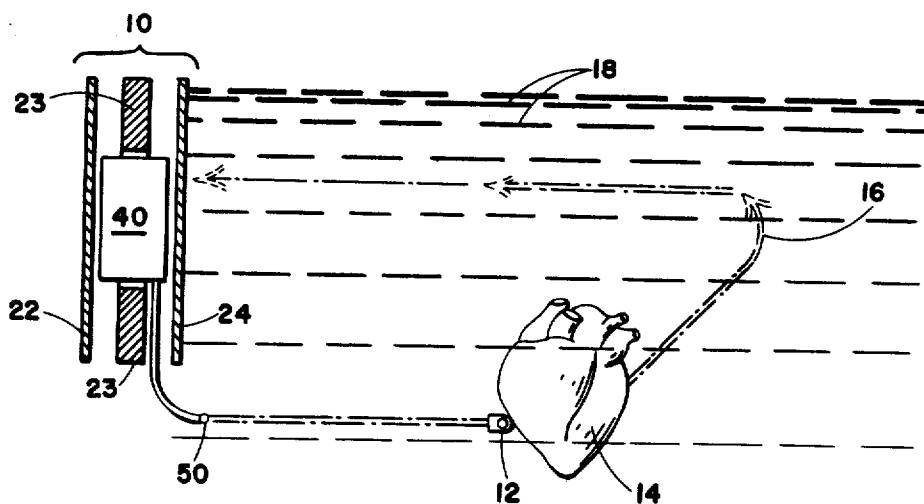
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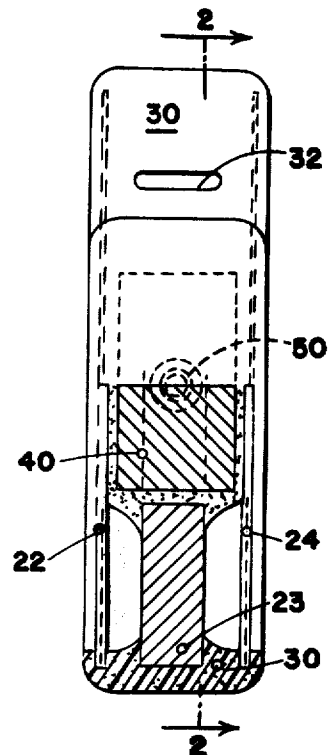
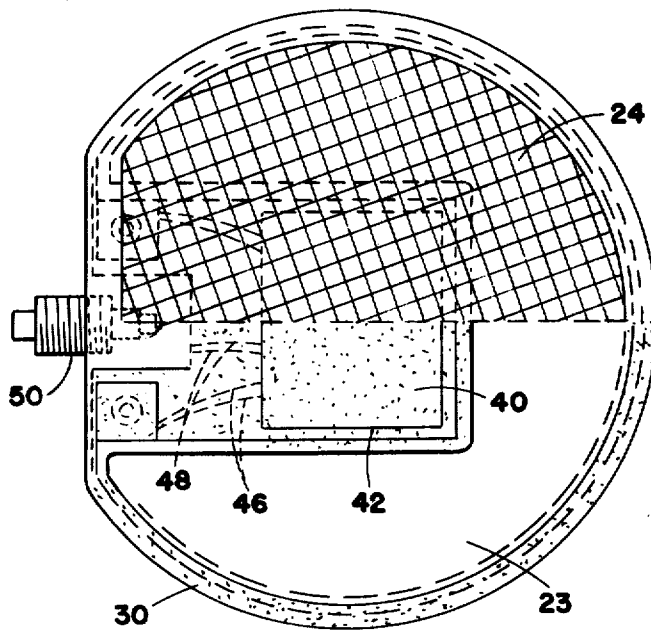
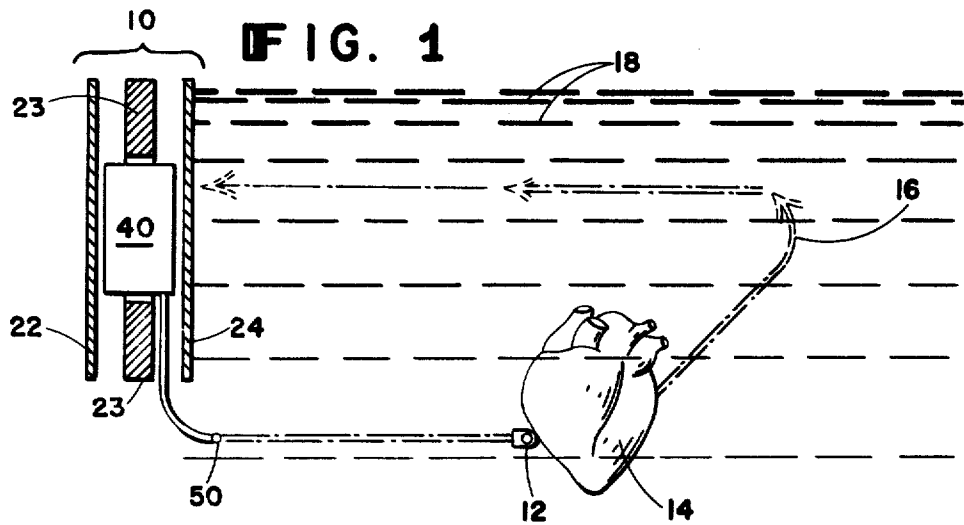
Primary Examiner—William C. Kamm

[57] **ABSTRACT**

An implantable heart pacer comprising electrode means of dissimilar materials spaced from one another to provide an electrolyte-containing space therebetween for cooperating with an electrolyte therein to produce a cell voltage, being in communication with the exterior of said device. One of the electrode means has its surface exposed only to the electrolyte-containing space and is free from exposure on an external surface of said device to prevent direct contact with body tissues. A sealed electronic pulse unit provides an output pulse of higher voltage than said cell voltage, said electrode means providing a power source for said unit and providing an indifferent electrode for return current flow from a remote unipolar heart electrode connected to the output pulse terminal. With an output pulse voltage greater than the cell voltage, there is reverse current flow in the electrode means during the pulse for electrolytically cleaning their surfaces.

6 Claims, 5 Drawing Figures





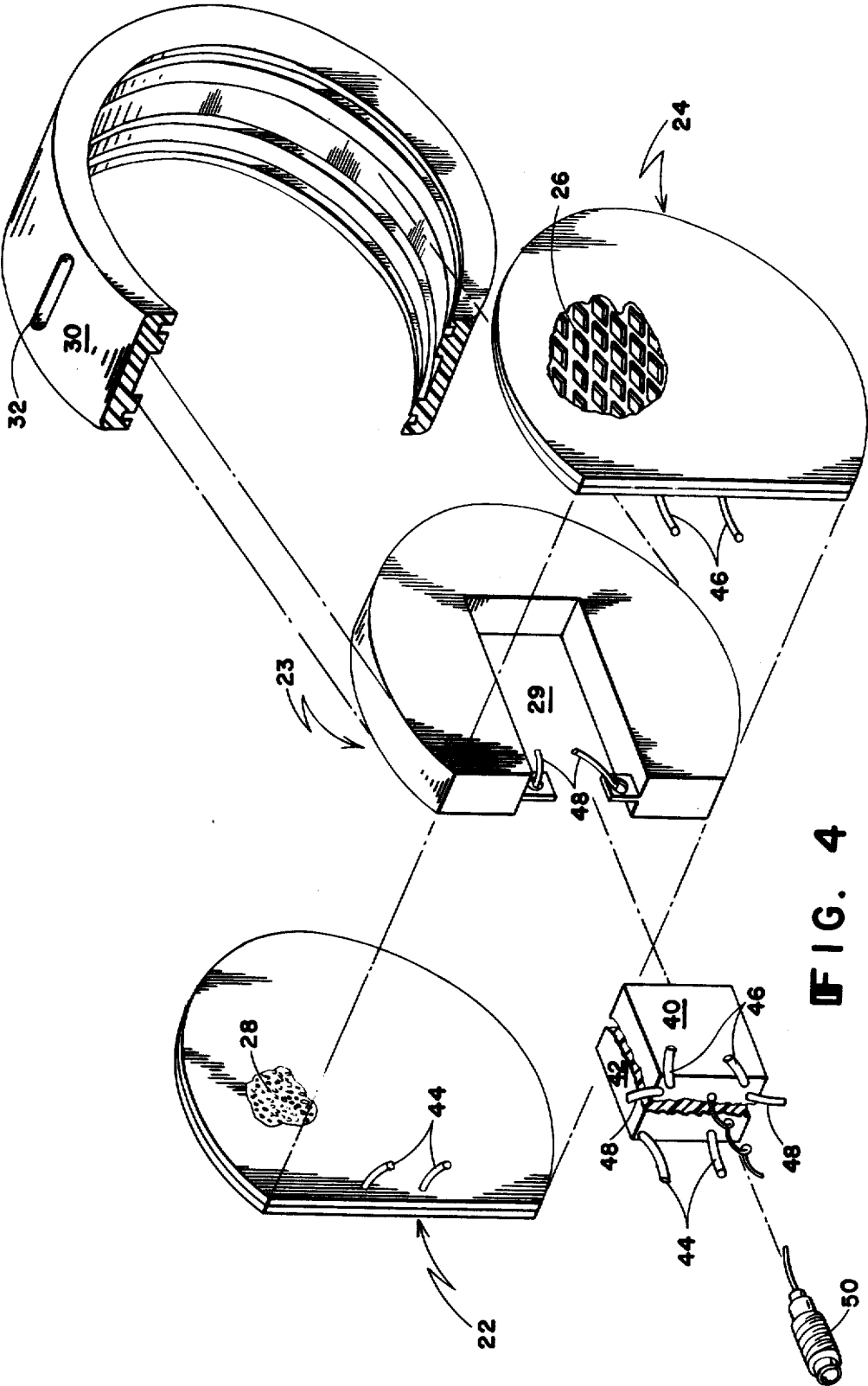


FIG. 4

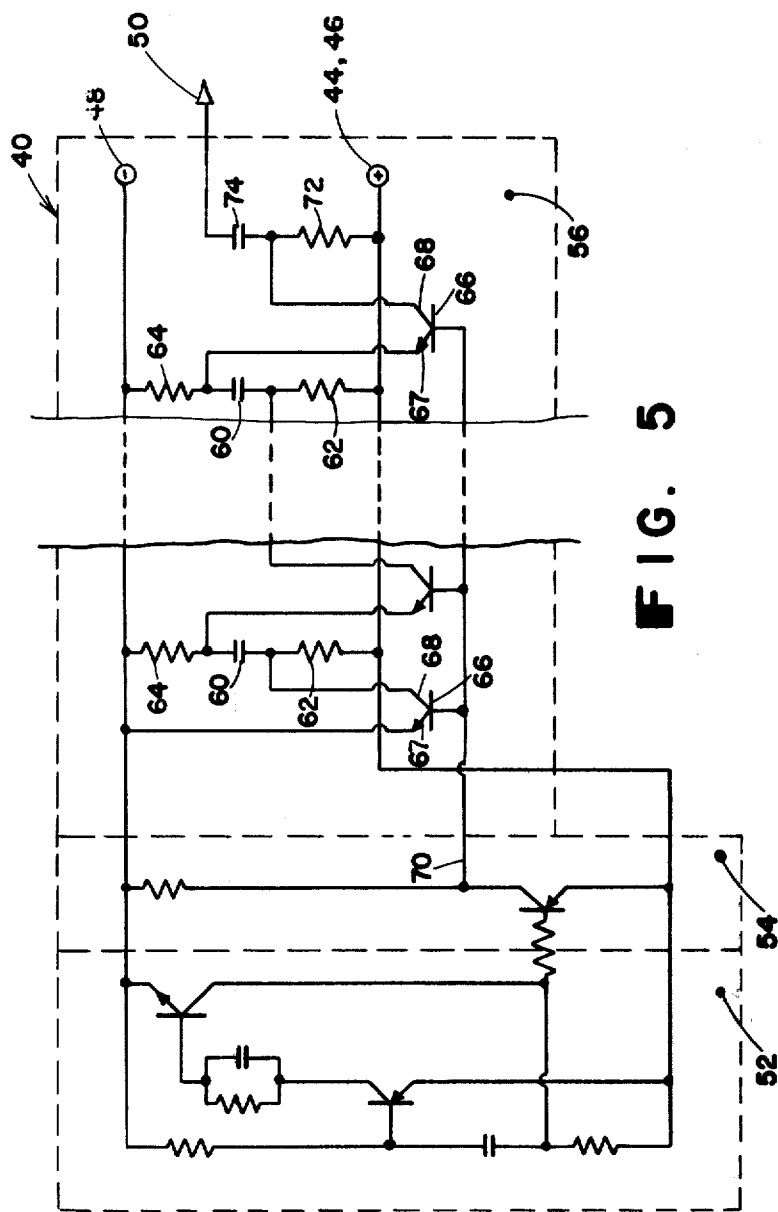


FIG. 5

IMPLANTABLE HEART PACER OR THE LIKE WITH INTERNAL CELL ELECTRODE

This invention relates to implantable electronic pulse devices, such as heart pacers and other stimulators, and, more particularly, to such devices which have electrodes providing both a power source and an indifferent electrode for return of stimulating current flow through the body fluids.

Although heart pacers powered by electrodes using body fluids as an electrolyte have been disclosed, for example in U.S. Pat. No. 3,421,512, they are deficient in a number of respects, which heretofore has made impractical their use in humans as a replacement for conventional battery powered heart pacers. There are a number of reasons for their deficiencies. Among these are problems caused by the reaction of the active metal electrode, the difficulty of keeping the electrode surface active and clean enough to function over long periods of time, and the difficulty of providing in conjunction therewith an indifferent electrode for return current flow through the body fluids from a remote electrode connected to the heart pacer output.

Accordingly, it is an object of the present invention to solve the above problems and provide a novel implantable electronic pulse device, such as a heart pacer or the like, having a greatly extended operating life as compared to conventional battery powered devices.

This is accomplished, according to the present invention, by providing a device having a number of unique features.

In one aspect of the invention, there is provided an implantable electronic pulse device comprising at least two electrode means of dissimilar materials spaced from one another to provide an electrolyte-containing space therebetween for cooperating with an electrolyte therein to produce a cell voltage, said electrolyte-containing space being in communication with the exterior of said device and at least one of said electrode means having its surface exposed only to said electrolyte-containing space and being free from exposure on an external surface of said device to prevent direct contact of said one electrode with body tissues.

In another aspect, the present invention provides an implantable electronic pulse device comprising at least two electrode means of dissimilar materials spaced from one another for cooperating with an electrolyte to produce a cell voltage, and an electronic pulse unit having input terminals connected to said electrode means and an output pulse terminal, said electrodes providing a power source for said unit and providing an indifferent electrode for return current flow from a remote electrode connected to said output pulse terminal. Preferably, said output pulse voltage is higher than said cell voltage, causing reverse current flow in said electrode means for a substantial portion of an output pulse for cleaning said electrodes.

Still other aspects of the present invention include the provision of a sealed electronic pulse unit mounted within the peripheries of the electrodes and electrically insulated therefrom and a pulse voltage multiplying circuit for raising the relatively low cell voltage to a value sufficiently high to provide a heart pacing function.

For the purpose of explaining the above and still further objects, features and aspects of the present invention, reference is now made to the following detailed

description of a preferred embodiment thereof, together with the accompanying drawings wherein:

FIG. 1 is a diagrammatic view of the device of the invention implanted for heart stimulation;

FIG. 2 is a side view, partly in section, of the device of FIG. 1;

FIG. 3 is an end view, partly in section, of the device of FIG. 1;

FIG. 4 is an exploded view of the device of FIG. 1, showing the major elements thereof; and

FIG. 5 is a circuit diagram of the electronic pulse unit of the device of FIG. 1.

Referring to the drawings, in FIG. 1 is shown a heart pacer device, generally designated 10, implanted in a body and having a single remote output pulse, so-called unipolar, heart stimulating electrode suitably attached to a heart 14 to stimulate it, the return current flow, shown as dashed line 16, to the indifferent electrode of pacer device 10, being through the body fluids 18 which also function as an electrolyte for power generation.

According to the present invention, the implantable electronic pulse heart pacer 10 thereof has electrodes of dissimilar materials spaced from one another for cooperating with an electrolyte to produce a predetermined cell voltage for powering device 10 to produce suitable heart stimulating output pulses, as well as providing the indifferent electrode thereof.

More specifically, as best shown in FIGS. 2 through 4, there is provided a pair of spaced, opposing, plate cathode elements 22, 24, of disk shape. Such elements are of body tissue non-reactive and electrolytically non-consumable material, preferably of a platinum black activated carbon material, and form a major external wall portion of device 10. These elements are preferably of a two layer fuel cell platinum catalyst electrode, manufactured by E.S.B., Inc., of Yardley, Pa. Such electrode consists of an apertured tantalum outer plate 26, carrying the platinum black activated carbon, and a porous teflon inner plate 28, the entire electrode being porous for ionic communication there-through.

Positioned between cathode elements 22, 24 is a plate anode element 23 of reactive electrolytically consumable material, preferably zinc or aluminum, for example. Plate anode element 23 is generally C-shaped, with an outer periphery generally of about the same diameter as that of cathode elements 22, 24 and with a rectangular cutout 29 on one side thereof. Anode element 23 is generally parallel to and spaced from said cathode elements to provide an electrolyte-containing space therebetween.

During the electrochemical reaction to generate electrical energy in the cell including the cathode and anode elements 22, 23 and 24 and the electrolyte-containing space therebetween, anode element 23 is gradually dissolved in the electrolyte and is converted into metal ions, metal hydroxide ions and metal oxide ions. To this end, however, it is essential that the electrolyte in the electrolyte-containing space be in communication with the body fluids to provide a source of oxygen to the cell. Although it is preferred that this be accomplished by free body fluid communication with the interior of the cell by utilizing the body fluids as the electrolyte, it may also be accomplished by ionic or even gaseous communication to permit diffusion of oxygen, without direct communication by body fluids.

Under these circumstances, the anode mass loss due to Faraday current and spontaneous metal decay (corrosion) are the only factors which limit the effective life of the power generating cell of the invention, and the anode mass can readily be made large enough to last for upwards of ten years.

A generally cylindrical electrical insulation element 30 extends between the outer peripheries of the electrode elements 22, 23, 24, defining the outer periphery of the electrolyte-containing space on both sides of anode element 23, said electrolyte-containing space being in communication with the exterior of device 10, both through the porous cathode elements 22, 24 and through optional apertures 32 in insulation element 30.

It is a particular feature of the invention that the reactive plate anode element 23, since it has its surfaces exposed only to the electrolyte-containing space within the outer periphery of insulation element 30, is completely free from exposure on an external surface of device 10 to prevent direct contact of the body tissue reactive anode material with body tissue when the device is implanted. Nevertheless, as explained above, anode element 23 is in direct communication with body fluids so that it is able to function in conjunction with cathode elements 22, 24 to provide a large indifferent electrode surface area of about four times the exposed surface area of device 10.

A sealed electronic pulse unit 40 is mounted within the peripheries of the electrode elements 22, 23, 24 and is electrically insulated therefrom and from body fluids by an insulating cover 42, the C-shaped plate anode element 23 surrounding a major portion of said pulse unit which fits within its rectangular cutout 29. The exposed insulated end of electronic pulse unit 40 has input terminals 44, 46, 48 connected, respectively, to cathode and anode elements 22, 24 and 23 and an output pulse terminal 50, said unit providing at said output terminal an output voltage pulse. An external electrode 12 remote from device 10 may be connected to output terminal 50 in the usual manner for providing heart stimulation.

The electrical circuitry of pulse unit 40 is shown in FIG. 5. In general, it includes a pulse timing and generating circuit 52, a pulse shaping circuit 54 and an output pulse voltage multiplying circuit 56. Pulse generating circuit 52 and pulse shaping circuit 54 are well known; for example, similar circuits are shown in U.S. Pat. No. 3,057,356 for generating pulses at a rate of 60-70 per minute for heart simulation. However, since a relatively low cell voltage of about one volt is produced by cathode and anode elements 22, 23, 24 and a higher voltage, preferably of about four to eight volts, is needed for heart stimulation, a voltage multiplier circuit is needed to produce the requisite output pulse voltage.

Although this may be provided by a conventional pulse transformer, it is preferred that the more efficient circuit 56 of FIG. 5 be utilized.

Specifically, the pulse voltage multiplier output circuit of FIG. 5 consists of a plurality of capacitors 60 each connected to cathode terminals 44, 46 through resistor 62 and to anode terminal 48 through resistor 64. A series of N-P-N switching transistors is provided for simultaneously switching capacitors 60 from parallel to series connection, each said transistor having its base 66 connected to the pulse output connection 70 of pulse forming circuit 54 which provides a pulse

source, its emitter 67 connected to the preceding junction of capacitor 60 and resistor 62 (except the first transistor in the series which has its emitter connected to cathode terminals 44, 46) and its collector connected to the succeeding junction of capacitors 60 and resistors 64 (except the last transistor in the series which has its collector connected to anode terminal 48 through resistor 72 and to pulse output terminal 50 through capacitor 74). Preferably, eight such capacitor and transistor circuits are used to produce about an eight volt output pulse from a one volt input pulse on connection 70. In ambient condition, capacitors 60 are each charged through their resistors 62, 64, the transistors being non-conducting under such condition. When a pulse is applied from line 70 to the bases 66 of the transistors, they are switched to conducting condition, such being effective to connect the capacitors 60 in series so that the voltage charges thereon are added together and discharged through output pulse terminal 50.

The output pulses so generated are then delivered through a suitable connecting wire to the unipolar stimulating electrode 12 at the heart 14 or other internal organ. The stimulating current flows in a circuit depicted in FIG. 1. This circuit consists of a source of high current density stimulus, namely the unipolar stimulating electrode 12, the organ under stimulation, herein the heart 14, the electrically conductive body tissue and fluid 18, the indifferent electrode system which is constituted of cathode elements 22, 24 and anode 23 and, finally back to electronic pulse unit 40.

The cathode and anode elements thus provide a power source for unit 10 and also provide an indifferent electrode for return current flow through the body fluid electrolyte from remote output electrode 12 connected to output pulse terminal 50. Since the output pulse voltage is greater than the battery voltage, it causes reverse current flow in the electrodes for a substantial portion of an output pulse for electrolytic cleaning of the electrode surfaces. This is an important aspect of the device of the invention since it continuously cleans these surfaces to permit them to function during the upwards of ten year period during which the device is expected to function.

What is claimed is:

1. For use in combination with a single remote unipolar implantable heart electrode, an implantable electronic pulse heart pacer device comprising
 - a at least two electrode means of dissimilar materials spaced from one another to provide an electrolyte-containing space therebetween for cooperating with electrolyte therein to produce a cell voltage insulation means mounting at least one of said electrode means so that its surface is exposed only to said electrolyte-containing space within the outer periphery thereof and is free from exposure on an external surface of said device to prevent direct contact of said one electrode with body tissues
 - said electrolyte-containing space being in communication with the exterior of said device
 - a sealed electronic pulse unit electrically insulated from said electrodes, said unit having input terminals connected to said electrode means and a single output pulse terminal for connection to said heart electrode
 - said electrode means providing a power source for said unit and providing an indifferent electrode for

return current flow from said single remote implantable heart electrode connected to said output pulse terminal.

2. For use in combination with a single remote unipolar implantable heart electrode, an implantable electronic pulse heart pacer device comprising

a plate cathode element of body tissue non-reactive material having an outer peripheral edge

a plate anode element of reactive material having an outer peripheral edge, said anode element being positioned adjacent said plate cathode element spaced from said cathode element to provide an electrolyte-containing space therebetween for cooperating with an electrolyte therein to produce a cell voltage

said electrolyte-containing space being in communication with the exterior of said device

said plate cathode element forming a major external wall portion of said device and

insulation means mounting said plate anode element so that its surface is exposed only to said fluid electrolyte-containing space and is free from exposure on an external surface of said device to prevent direct contact of said reactive anode material with body tissue

a sealed electronic pulse unit mounted within the outer peripheral edges of said electrodes and electrically insulated therefrom,

said electronic pulse unit having input terminals connected to said cathode and anode elements and a single output pulse terminal for connection to said heart electrode, said unit having circuit means providing at said output terminal an output pulse

said cathode and anode elements providing a power source for said unit and providing an indifferent electrode for return current flow from said single remote implantable heart electrode connected to said output pulse terminal.

3. For use in combination with a single remote unipolar implantable heart electrode, an implantable electronic pulse heart pacer device comprising

a pair of spaced opposing plate cathode elements of body tissue non-reactive material having outer peripheral edges

a generally "C" shaped plate anode element of reactive material having an outer peripheral edge, said anode element being positioned between and spaced from said cathode elements to provide a fluid electrolyte-containing space therebetween for cooperating with an electrolyte therein to provide a cell voltage

electrical insulation means extending between the outer peripheral edges of said elements defining the outer periphery of said electrolyte-containing space

said electrolyte containing space being in communication with the exterior of said device

said plate cathode elements forming a major external wall portion of said device and

insulation means mounting said plate anode element so that its surfaces are exposed only to said electrolyte-containing space and is free from exposure on an external surface of said device to prevent direct contact of said reactive anode material with body tissue

a sealed electronic pulse unit mounted within the outer peripheral edges of said electrodes and elec-

trically insulated therefrom, said C-shaped plate anode element surrounding a major portion of said pulse unit

said electronic pulse unit having input terminals connected to said cathode and anode elements and a single output pulse terminal for connection to said heart electrode, said unit having circuit means providing at said output pulse terminal an output pulse having a voltage greater than that of said cell voltage

said cathode and anode elements providing a power source for said unit and providing an indifferent electrode for return current flow from said single remote implantable heart electrode connected to said output pulse terminal

said output pulse voltage when greater than said cell voltage causing reverse current flow in said cathode and anode elements for a substantial portion of an output pulse for cleaning said electrodes.

4. An implantable electronic pulse heart pacer device as claimed in claim 3, wherein

said electronic pulse unit circuit means includes a pulse source and a pulse voltage multiplying circuit comprising

a plurality of capacitors connected to provide preceding and succeeding capacitors, each connected through resistor means to said electrodes

a plurality of switching transistors having their bases connected to said pulse source, their emitters connected to one terminal of a preceding capacitor and their collectors connected to the other terminal of a succeeding capacitor, said transistor switching means being responsive to an input pulse for simultaneously switching said capacitors from parallel to series connection with each other for the duration of said input pulse

said capacitors when connected to each other in parallel connection being connected across said electrode means to charge said capacitors and when connected to each other in series connection being connected to said output pulse terminal to discharge said capacitors to provide said output pulse voltage greater than said cell voltage.

5. For use in combination with a single remote unipolar implantable heart electrode, an implantable electronic pulse heart pacer device comprising

a plate cathode element of body tissue non-reactive material having an outer peripheral edge

a plate anode element of reactive material having an outer peripheral edge, said anode element being positioned adjacent said plate cathode element spaced from said cathode element to provide an electrolyte-containing space therebetween for cooperating with an electrolyte therein to produce a cell voltage

said electrolyte-containing space being in communication with the exterior of said device

said plate cathode element forming a major external wall portion of said device and

insulation means mounting said plate anode element so that its surface is exposed only to said fluid electrolyte-containing space and is free from exposure on an external surface of said device to prevent direct contact of said reactive anode material with body tissue

an electronic pulse unit having input terminals connected to said cathode and anode elements and a

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single output pulse terminal for connection to said heart electrode, said unit having circuit means providing at said output terminal an output pulse
said cathode and anode elements providing a power source for said unit and providing an indifferent electrode for return current flow from said single remote implantable heart electrode connected to said output pulse terminal.

6. For use in combination with a single remote unipolar implantable heart electrode, an implantable electronic pulse heart pacer device comprising
a plate cathode element of body tissue non-reactive material having an outer peripheral edge
a plate anode element of reactive material having an outer peripheral edge, said anode element being positioned adjacent said plate cathode element spaced from said cathode element to provide an electrolyte-containing space therebetween for co-operating with an electrolyte therein to produce a cell voltage
said electrolyte-containing space being in communication with the exterior of said device
said plate cathode element forming a major external wall portion of said device and
insulation means mounting said plate anode element

so that its surface is exposed only to said fluid electrolyte-containing space and is free from exposure on an external surface of said device to prevent direct contact of said reactive anode material with body tissue

a sealed electronic pulse unit mounted within the outer peripheral edges of said electrodes and electrically insulated therefrom,

said electronic pulse unit having input terminals connected to said cathode and anode elements and a single output pulse terminal for connection to said heart electrode, said unit having circuit means providing at said output terminal an output pulse having a voltage greater than that of said cell voltage
said cathode and anode elements providing a power source for said unit and providing an indifferent electrode for return current flow from said single remote implantable heart electrode connected to said output pulse terminal

said output pulse voltage when greater than said cell voltage causing reverse current flow in said cathode and anode elements for a substantial portion of an output pulse.

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