United States Patent [19]

Kolenik

[11] **3,926,198**

[45] **Dec. 16, 1975**

[54] **CARDIAC PACER**

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[22] Filed: **May 2, 1975**

[21] Appl. No.: **574,199**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 477,571, June 10, 1974, abandoned.

[52] **U.S. Cl.. 128/419 PG;** 128/419 P; 128/419 PS; 136/156

[51] **Int. Cl.²**..... **A61N 1/36**

[58] **Field of Search**..... 128/419 P, 419 PG, 419 PS, 128/419 R, 421, 422, 423; 136/86 F, 153; 307/304, 313

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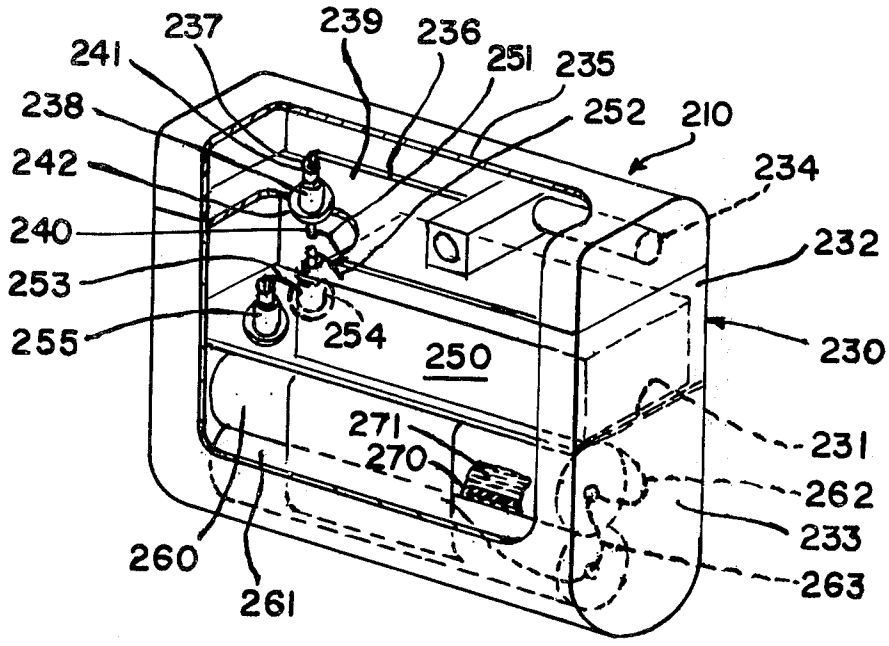
[57] **ABSTRACT**

The forces which are imparted by a cardiac pacer to adjacent tissues are below the threshold of troublesome difficulty when the body is subjected to acceleration or deceleration. Such below-threshold forces are attributed to controlling the weight of the cardiac pacer to be less than 100 grams, and to controlling the specific gravity to be less than 1.7. Such low density and low weight are attainable by reason of the use of a miniaturized oscillator featuring complementary metal oxide semiconductors consuming such a small power that more than 5 years of life are attainable from the thionyl chloride-lithium type of battery having a prolonged stable voltage of at least 3.3 volts. The cardiac pacer is thin enough to avoid troublesome bulging of the skin adjacent the implanting location.

3 Claims, 5 Drawing Figures



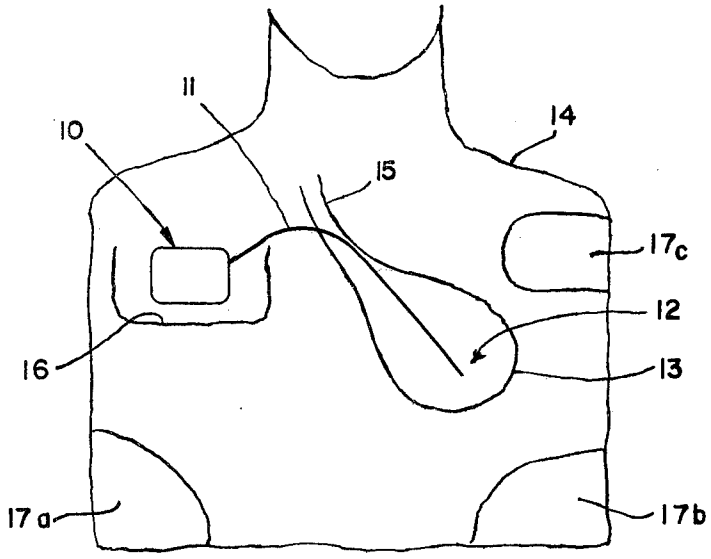


Fig. 1.

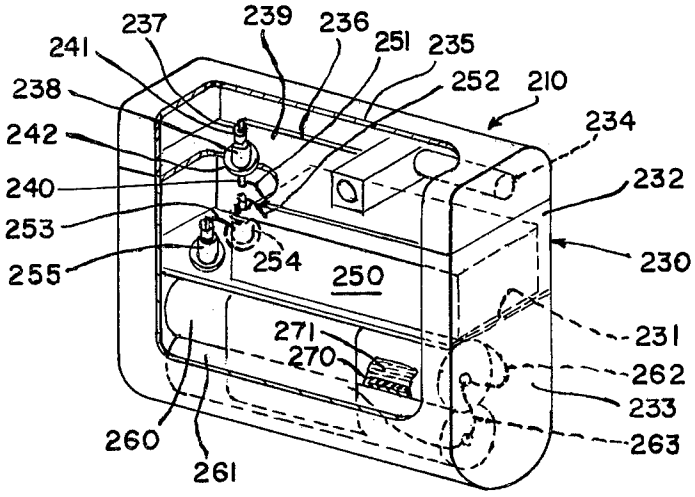


Fig. 2.

Fig. 4.

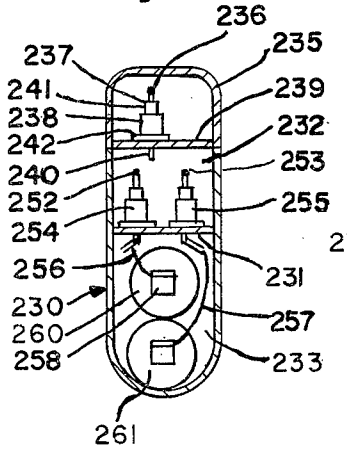


Fig. 3.

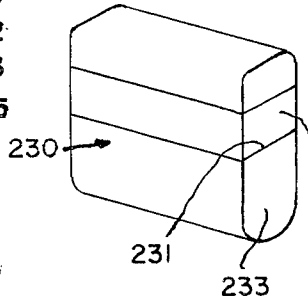
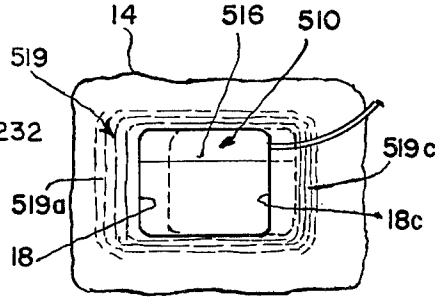


Fig. 5.



CARDIAC PACER

RELATED APPLICATION

This is a continuation-in-part of Ser. No. 477,571, filed June 10, 1974, and now abandoned.

FIELD OF INVENTION

This invention relates to cardiac pacers suitable for implantation and particularly to overcoming the adverse side effects heretofore observed in connection with prior art use of some types of implantable cardiac pacers.

HISTORY OF PRIOR ART

In a hospital in which a patient under intensive care can receive electrical pulse signals from an external oscillator, the size and complexity of the signal generating apparatus is of only minor importance. Any implantable cardiac pacer, however, must be sufficiently miniaturized to permit surgical placement in a cavity within the body. As used herein, the lead (or conduit or catheter) is deemed a supplement to the pacer, although others have designated the combination of the lead and unit generating pulses as a "pacer". An electrical conduit, sometimes called a catheter, transmits the electrical signals from the implanted cardiac pacer to an appropriate signal-receiving zone of the heart. A significant portion of implanted cardiac pacers have employed batteries comprising mercury. Such mercury batteries generate a gas which must be vented from the battery chamber. Such venting has complicated the problem of preventing the eventual penetration of body fluids into undesired portions of the cardiac pacer. The durability of a mercury battery has permitted usage for more than a year but generally less than 4 years. A variety of other types of batteries, including batteries comprising a lithium anode, have been proposed for use with cardiac pacers but the numerous problems related to the long-term reliability has left most of the needs unanswered.

When a heart pacer, which generally weighs from about 200 to 500 grams, is implanted in the body, the bulge in the skin at the zone of implantation is troublesome to the patient. The tissue adjacent the cavity in which the heart pacer is implanted is subjected to severe forces under certain jolting conditions or other rapid acceleration or deceleration conditions in which the inertia of the heart pacer imparts forces to such tissue adjacent the implantation cavity. It is well known that bruising, sense of pain, and/or other biological phenomena are influenced by threshold phenomena. As long as the forces are below the threshold, no biological response is apparent but above the threshold, increasing force involves increasing biological response.

Initially, only older patients were treated with implanted heart pacers. As their usefulness became better known, it was recognized that certain types of cardiac problems in children are best treated with heart pacers. Some children needing implanted heart pacers were too small to permit implantation of the previously available heart pacers, and the continuing reports of deaths of such children has provided a long-standing demand for miniaturized pacers for cardiac patients.

SUMMARY OF THE PRESENT INVENTION

In accordance with the present invention, a cardiac pacer is maintained at a weight less than 100 grams and at a specific gravity less than 1.7, whereby the inertia forces attributable to acceleration and deceleration are below the threshold of significant trouble to the tissue adjacent the cavity of implantation, whereby the patient may wear the implanted cardiac pacer with greater comfort than prior art cardiac pacers. Such small size and low specific gravity for the heart pacer are attributable in part to the utilization of oscillator means featuring the use of complementary metal oxide semiconductor devices which not merely occupy a small volume, but more particularly utilize significantly less power per day, whereby the battery life is significantly prolonged. In accordance with the present invention, the sub-threshold weight, sub-threshold density, and acceptable battery life are achieved in part by the combination of said complementary metal oxide semiconductor devices and a battery featuring the combination of a lithium anode and a thionyl chloride electrolyte. No gas is evolved by the generation of current from the thionyl chloride type battery. One of the most significant and unique characteristics of such thionyl chloride battery is the attainment of a voltage of about 3.3 volts or more over a battery life of more than 5 years. The invention features a metal casing effective in shielding the electric components from electromagnetic interference. At least two lithium thionyl chloride type batteries may desirably be maintained in parallel with circuit means protecting the pacer from interferences attributable to failure of one battery while assuring redundant reliability of parallel batteries.

The smallness of the cardiac pacer permits its implantation in an infant a few weeks old, thus fulfilling a long-standing demand for a pediatric pacer for cardiac patients.

The nature of the present invention is further clarified by reference to descriptions of appropriate embodiments which merely illustrate and do not restrict the invention.

DESCRIPTION OF DRAWINGS

FIG. **1** is a schematic drawing showing a heart pacer implanted in a body so that the electrical conduit can direct stimulating pulse to an appropriate zone of a heart.

FIG. **2** is a schematic drawing of a sub-threshold inertia cardiac pacer of the present invention.

FIG. **3** is a perspective view of the heart pacer.

FIG. **4** is a schematic partially sectional end view of FIG. **3.**

FIG. **5** is a schematic showing of a heart pacer exerting forces upon the tissue of the walls of the cavity in which it is placed. Differential acceleration and/or deceleration attributable to differential inertia of the heart pacer relative to such adjoining tissue during periods when rapid shifts of acceleration and/or deceleration occur, impart such forces upon such tissues.

DESCRIPTION OF INVENTION

As shown in FIG. **1,** a heart pacer **10** is electrically and mechanically connected to an electrical conduit **11** carrying electrical impulses to a signal reception zone **12** of a heart **13** of a mammal **14.** The electrical conduit may be directed through a vein **15** toward the signal reception zone **12.** The heart pacer **10** is implanted

within a cavity 16. Heretofore, surgeons have employed any of several cavities such as 17*a*, 17*b*, and 17*c* as alternative cavities for heart pacer implantation. The small size and weight of the heart pacer of the present invention is so much less than that of prior heart pacers that additional locations might be suitable for implantation.

As shown in FIG. 5, a heart pacer 510 can be positioned within a cavity 516. The walls 18 of cavity 16 transmit mechanical forces arising from shifting of heart pacer 10 and may compress and/or stretch tissue 519 near cavity walls 18.

In FIG. 5, there is a schematic showing of compression of tissue 519*c* and the stretching of tissue 519*a* as a result of inertial shifting of heart pacer 510 toward wall 18*c*. The specific gravity of heart pacer 510 is greater than the specific gravity of tissue 519 so that when mammal 14 is jerked back and forth, the inertia of heart pacer 510 is not identical to the inertia of the tissue 519, thereby causing differential inertial forces.

Using the heavy heart pacers of the prior art, differences in weight and/or density amongst the heart pacers appear to be of little consequence because all heart pacers had a weight and density above the threshold of tissue modification from such differential inertia forces. In accordance with the present invention, however, the weight and density of the heart pacer are below the threshold of tissue modification from conventional differential inertial forces, whereby the heart pacer may be worn with significantly greater comfort and with less likelihood of trauma, infection, inflammation, and/or other adverse developments in the tissue adjacent the walls of the cavity in which the heart pacer is implanted.

In accordance with the present invention, there is greatly decreased likelihood of discomfort for the person having an implanted heart pacer by reason of the control of the density and weight of the heart pacer to be so low as to be below the threshold of significant discomfort from the differential inertial forces arising from the plausible acceleration-deceleration forces to which the wearer might be subjected.

As shown in FIG. 2, a heart pacer 210 comprises a casing 230. Such casing is made of titanium to assure adequate inertness to the biological fluids. In a preferred embodiment, a partition 231 divides the interior of the casing into a circuitry chamber 232 and a battery chamber 233. A socket 234 is adapted to receive a plug portion of electrical conduit 11. The socket 234 is an insert within a molded organic polymeric shield 235 which protects a wire 236 extending from upper portion of an electrical pass-through 238 through the roof 239 of circuitry chamber 232. Any electrical signal directed to the electrical pass-through 238 is transmitted to the upper portion 237 and thence to wire 236 to socket 234, all electrical components being anchored within plastic shield 235. The electrical pass-through 238 comprises a pin 240, an insulating member 241 constructed of pure alumina, and bonded to pin 240 and brazed to the edges of an opening in roof 239 by a brazing connection 242. The electrical pass-through 238 has the important advantage of providing a hermetic sealing between the circuitry chamber 232 and the zone of plastic shield 235.

Within circuitry chamber 232 is a circuitry unit 250 having an output wire 251 directed to said pass-through pin 240. The circuitry unit 250 is energized by the combination of wire means from the negative pole of the battery and positive grounding to the casing 230, as by having a casing of the circuitry unit in electrical contact with casing 230.

The positive pole of batteries are associated electrically with casing 230. Wires 252 and 253 from pass-throughs 254 and 255 are energized respectively by wire 256 from a standard battery and by wire 257 from a supplemental battery. A negative terminal 258 of standard battery 260 supplies current to wire 256 and thence to pass-through 254, and wire 252 and thence to circuitry means, conveniently designated as circuitry unit 250. Similarly, supplemental battery 261 supplies current to wire 257, pass-through 255, wire 253 and thence to circuitry unit 250. Thus, power from parallel batteries 260 and 261 in chamber 233 is supplied to circuitry unit 250 in chamber 232.

Each of the pass-throughs comprises an insulating member, desirably constructed of alumina, sealed to a pin and brazed in an opening in partition 231, thus closely resembling the structure of pass-through 238. Wires 262 and 263 assure the good electrical connection between the positive posts of batteries 260, 261 with casing 230.

It should be noted that in a preferred embodiment, the batteries 260 and 261 are connected electrically in parallel within hermetically sealed battery chamber 233 and that the power of two batteries is transmitted through pass-throughs 254 and 255 independently to the circuitry unit 250. Various materials, such as body fluids from cavity 16 and/or fluids within a battery might adversely affect operation of the circuitry unit 250 if any leakage occurred. However, because in such preferred embodiment circuitry chamber 232 is hermetically sealed, both from cavity 16 and from battery chamber 233, the circuitry unit 250 has appropriate protection against any leakage which might occur. Of particular importance, in all embodiments, casing 30 is hermetically sealed from cavity 16 so that the heart pacer is protected from the effects of liquids and/or gases in cavity 16.

Particular attention is directed to the fact that battery 260 features a lithium anode 270 and an electrolyte consisting predominantly of thionyl chloride 271. Because battery 260 features the combination of lithium anode 270 and thionyl chloride electrolyte 271, its voltage can be as high as 3.64 volts and is assuredly at least 3.3 volts during a lifetime of more than 5 years. Of particular importance, the voltage of such lithium-thionyl chloride type battery remains substantially constant during substantially all of the life expectancy of the battery and diminishes significantly only during a few months of the terminal period of use of the battery. The decreasing voltage and thus alteration of the pulse rate, provides the clue indicative of the appropriateness of a change of batteries. It is especially important that there be a procedure for detection of battery depletion. The combination of lithium anode and thionyl chloride achieves this highly significant desiderata.

In a constant rate heart pacer, the signal pulses to the heart represent only about ⅛ of 1 per cent of the time during which the heart pacer is implanted. Accordingly, the battery life for a heart pacer is significantly influenced by the current drain during the 799/800's fraction of the time when no pulse is sent even though the circuitry unit must be operative. Any demand circuitry sensitive to the normal operation of the heart delivers impulses to the heart during a time fraction less than the delivery time fraction for a fixed rate heart

pacer. Early types of heart pacers were based upon circuitry energized by a voltage supply of about 6 volts. Significant power was consumed by 6 volt circuitry, thereby shortening battery life.

Circuitry unit **250** is characterized by oscillator means employing complementary metal oxide semiconductor devices operable at a low voltage, so that the two lithium batteries can be connected in parallel instead of in series. Moreover, such complementary metal oxide semiconductor devices of the oscillator means permit the circuitry unit to function much of the time at a current drain which is so small that battery life can be based to a significant extent upon the dissipation of power at the signal reception zone **12** of the heart. The power consumption during the quasi-dormant portion of use is particularly significant in connection with demand pacers, in which the combination of thionyl chloride-lithium batteries and complementary metal oxide semiconductor devices are particularly advantageous.

The nature of the cardiac pacer of the present invention can be clarified by noting that the pacer consists essentially of the combination of a metal casing hermetically sealing the interior zones of the cardiac pacer from exposure to body fluids in the cavity in which the cardiac pacer is implanted, said casing being less than 20 mm thick, and each other orthagonal dimension being less than 60 mm, such small dimensions permitting implantation without troublesome bulging of the skin adjacent the cardiac pacer, said metal casing shielding electrical components from electromagnetic interference; at least one battery in said casing, each battery generating no gas, each battery having a lithium anode and an electrolyte consisting predominantly of thionyl chloride, each battery having prolonged low impedance and constant high voltage of at least 3.3 volts during an expected life of more than 5 years, the voltage diminishing significantly only during the terminal period of use of the battery, whereby detection of battery depletion is manageable; in a preferred embodiment there are wires and pass-throughs within the casing associating at least two batteries in parallel and protecting other circuit means from interference attributable to failure of one battery while assuring the redundant reliability of parallel batteries; employing complementary metal oxide semiconductor circuit means for producing pulses adapted to stimulate the heart, said circuit means being electrically energized by current supplied by the combination of wire means from the negative pole of the battery and positive grounding to the casing of the cardiac pacer, said circuit means desirably being within a circuitry chamber within said samll casing; said complementary metal oxide semiconductors and said circuitry means consuming such a small amount of power that the battery life is more than 5 years; electrical socket means adapted to transmit to an electrical conduit said electrical pulses suitable for stimulating the heart; and said combination of casing, batteries, wires, pass-throughs, circuit means, and electrical socket means having a weight less than 100 grams and a specific gravity less than 1.7, whereby changes in acceleration or deceleration of a body having such implanted cardiac pacer impart only forces which are tolerable to tissue adjacent the cavity in which the cardiac pacer is implanted.

Various modifications of the invention are possible without departing from the scope of the appended claims.

It is claimed:

1. A cardiac pacer consisting essentially of the combination of:

a metal casing hermetically sealing the interior zones of the cardiac pacer from exposure to body fluids in the cavity in which the cardiac pacer is implanted, said casing being less than 20 mm thick, and each other orthagonal dimension being less than 60 mm, such small dimensions permitting implantation without troublesome bulging of the skin adjacent the cardiac pacer, said metal casing shielding electrical components from electro-magnetic interference and constituting a grounding electrode for the cardiac pacer;

a hermetically sealed battery chamber and a hermetically sealed circuitry chamber within said casing;

a plurality of batteries in said battery chamber, there being an electrical conductor transmitting battery power from each battery to said circuitry chamber, each battery generating no gas, each battery having a lithium anode and an electrolyte consisting predominantly of thionyl chloride, each battery having prolonged low impedance and constant high voltage of at least 3.3 volts during an expected life of more than 5 years, the voltage diminishing significantly only during the terminal period of use of the battery, whereby detection of battery depletion is manageable, the positive pole of the batteries being grounded to the metal casing;

wires and pass-throughs within the casing associating at least two batteries in parallel and assuring the redundant reliability of parallel batteries;

a circuitry unit employing complementary metal oxide semiconductor circuit means for producing pulses adapted to stimulate the heart, said circuit means being electrically energized by current from said batteries, the casing of the circuit means being grounded to the casing of the heart pacer, said circuit means being within said circuitry chamber, said circuit means including an output wire, said wires and pass-throughs being electrically connected to said circuit means;

said complementary metal oxide semiconductors and said circuit means consuming such a small amount of power that the battery life is more than 5 years;

electrical socket means adapted to transmit to an electrical conduit the output from said circuit means, said electrical conduit being adapted to transmit the output from said circuit means to a signal-receiving zone of a heart, electrical pass-through means connecting said output wire to said socket means; and

said combination of casing, batteries, wires, pass-throughs, circuit means, and electrical socket means having a weight less than 100 grams and a specific gravity less than 1.7, whereby changes in acceleration or deceleration of a body having such implanted cardiac pacer impart only forces which are tolerable to tissue adjacent the cavity in which the cardiac pacer is implanted.

2. The cardiac pacer of claim **1** in which the casing consists of titanium.

3. The cardiac pacer of claim **1** in which the electrical socket means is an insert within a molded organic plastic shield.

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