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(54) MRI-COMPATIBLE PACEMAKER WITH POWER CARRYING PHOTONIC CATHETER AND ISOLATED PULSE GENERATING ELECTRONICS PROVIDING VOO FUNCTIONALITY

(76) Inventors: **Victor Miller**, Clarence, NY (US); **Wilson Greatbatch**, Akron, NY (US); **Patrick Connelly**, Rochester, NY (US); **Michael Weiner**, West Henrietta, NY (US)

Correspondence Address:
Walter W. Duft
Law Office of Walter W. Duft
10255 Main Street, Suite 10
Clarence, NY 14031 (US)

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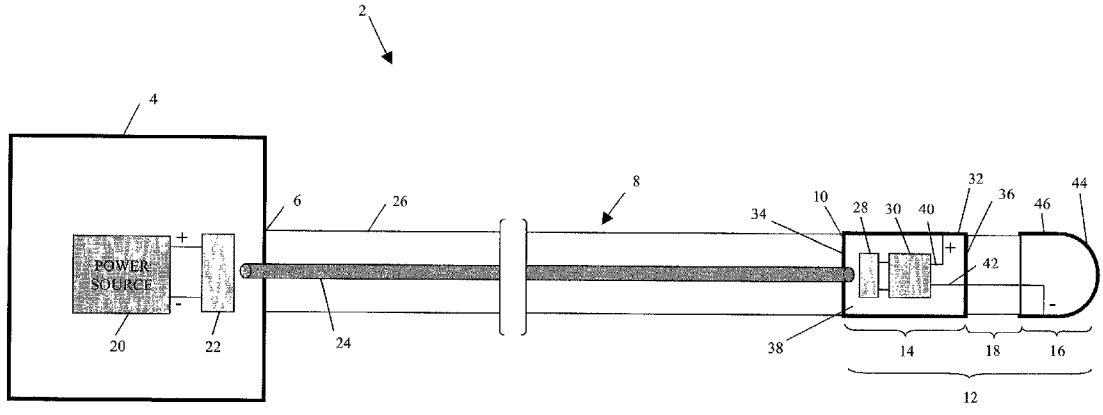
(57) **ABSTRACT**

An MRI-compatible, fixed-rate (VOO) pacemaker includes a self-contained power source housed at the proximal end of a photonic catheter in a first enclosure. Low energy continuous electrical power is delivered from the power source. This electrical power is converted into light energy and directed into the proximal end of the photonic catheter. The photonic catheter includes an optical conduction pathway over which is formed a covering of biocompatible material. Light entering the proximal end of the photonic catheter is transmitted through the optical conduction pathway, where it is collected and converted back to electrical energy at a second enclosure located at the distal end of the photonic catheter. The second enclosure houses a pulse generator that stores electrical energy and periodically releases that energy to deliver electrical pulses to bipolar heart electrodes. One of the electrodes comprises the second enclosure housing the pulse generator and the other electrode is provided by another enclosure that is spaced from the second enclosure. The electrical pulses are delivered to the electrodes at an amplitude of about 3.3 volt and a current of about 3 milliamperes for a total pulse power output of about 10 milliwatts. A 1 millisecond pulse duration and a 1000 millisecond period may be provided for steady state VOO operation. The foregoing arrangement permits the use of photo elements operating in the microwatt region rather than at the milliwatt level as would be required if the output of the electronic pulse generator were delivered directly to the heart itself from the first enclosure in conventional pacemaker fashion.



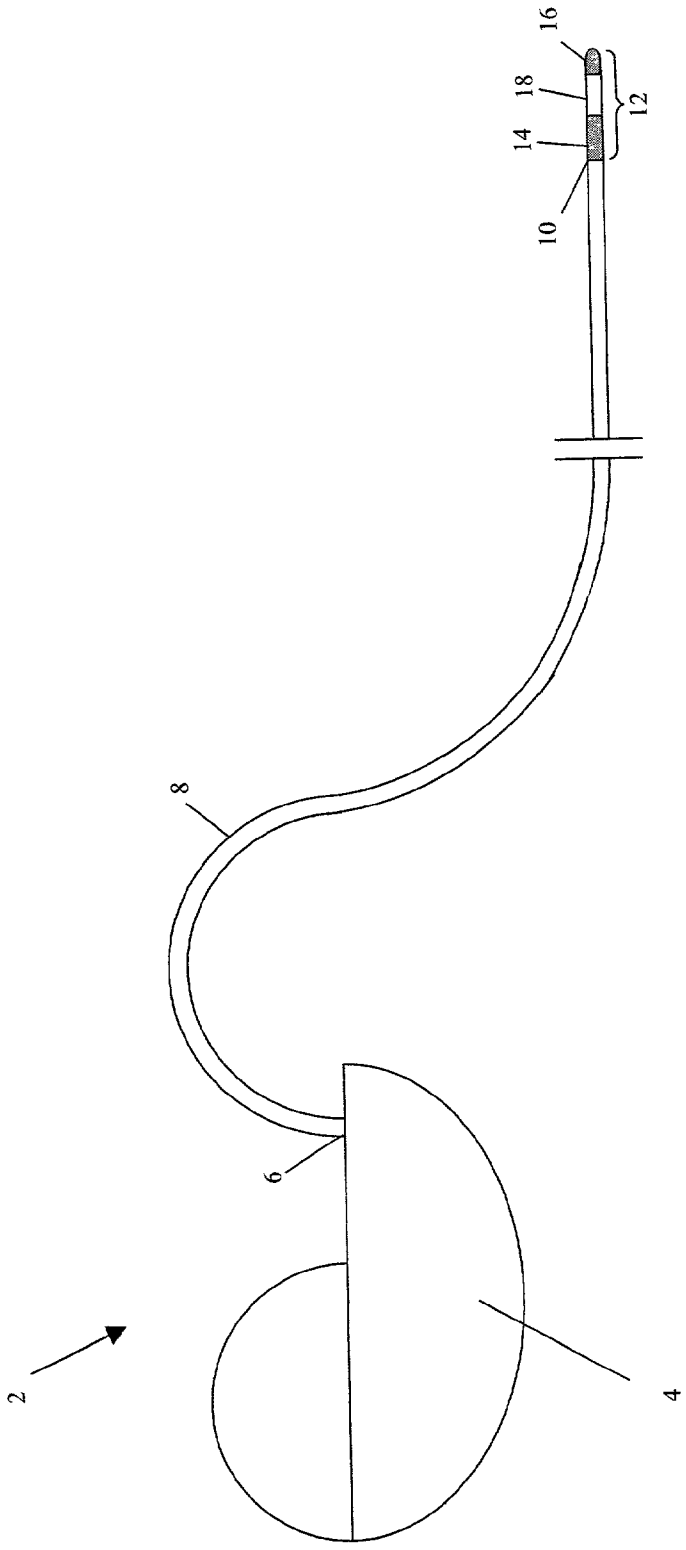
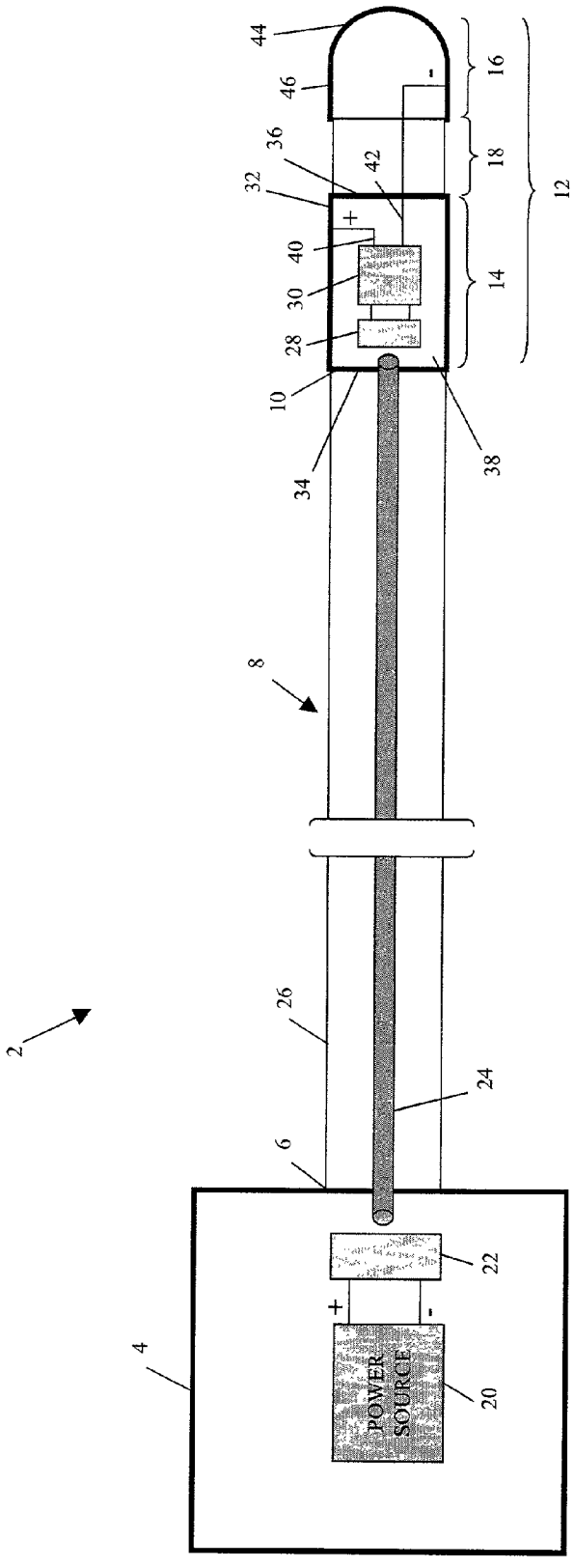


FIG. 1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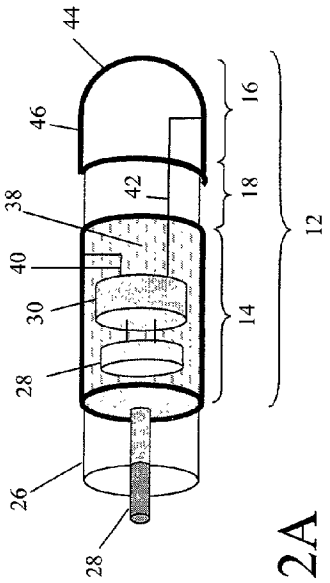
POWER SOURCE
+
-

FIG. 2


12
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38
40
42
44
46

FIG. 2A

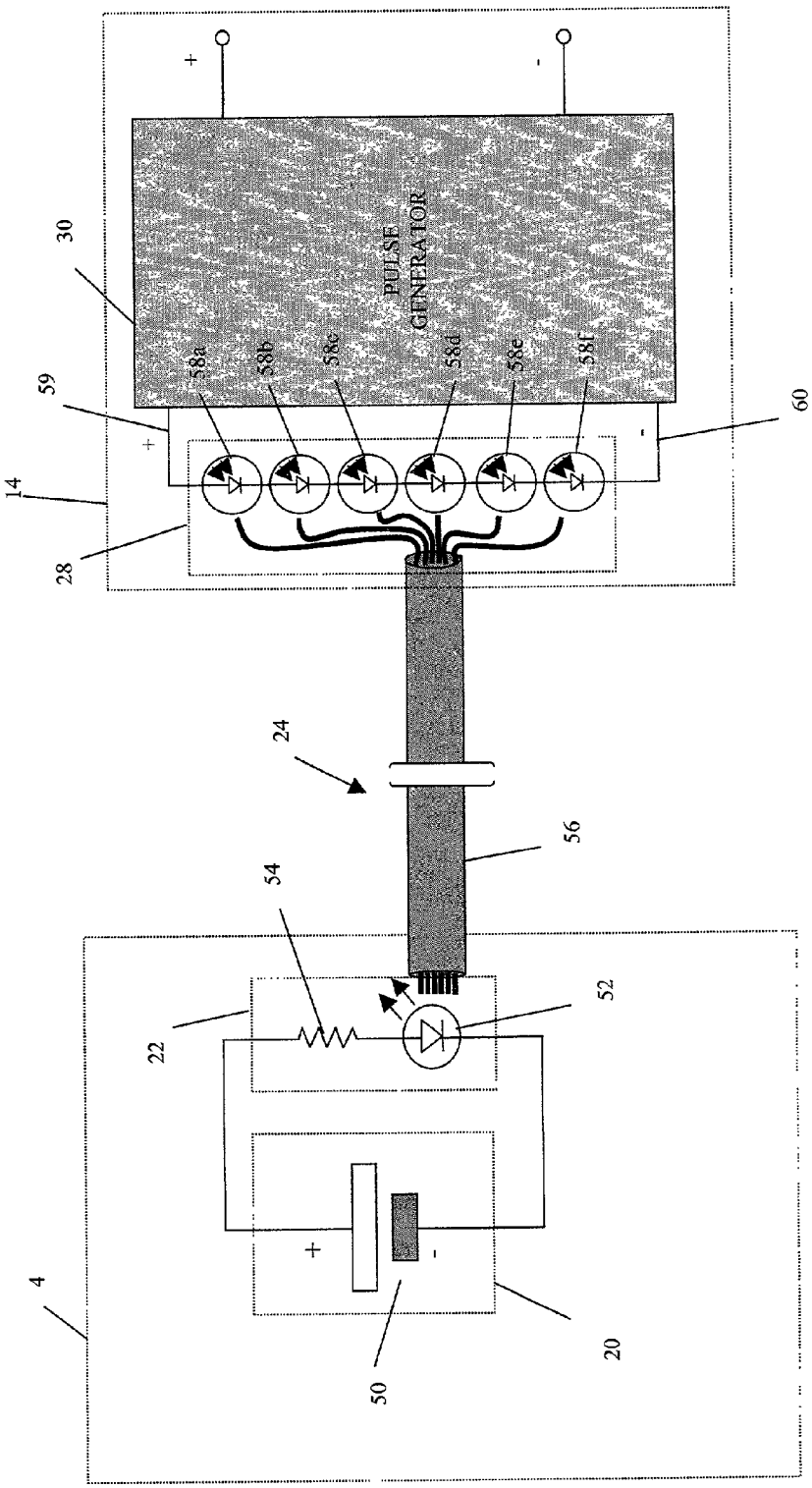
+
-
PULSE GENERATOR
30
58a
58b
58c
58d
58e
58f
59
60
14
28
24
56
54
52
22
4
20
50

FIG. 3

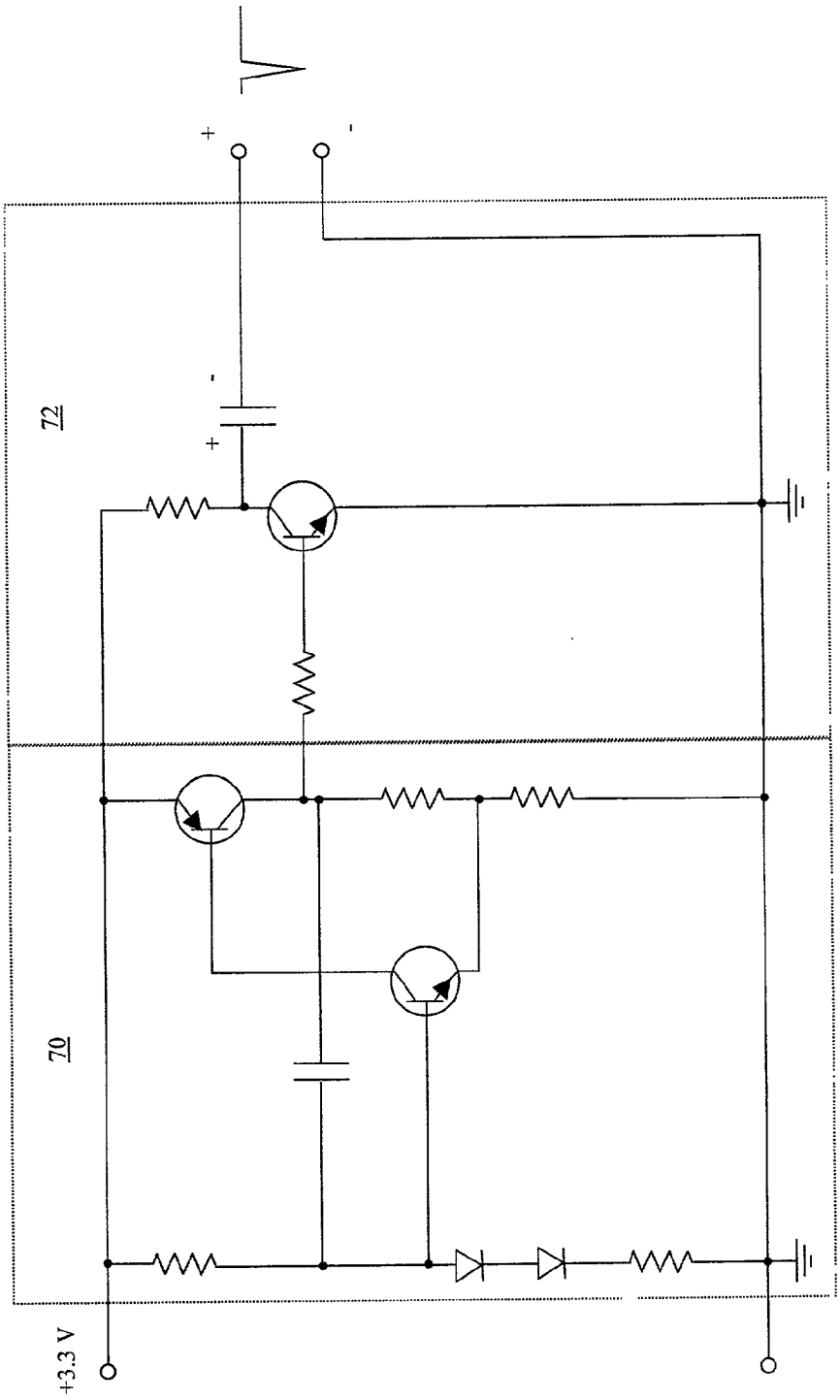

FIG. 4

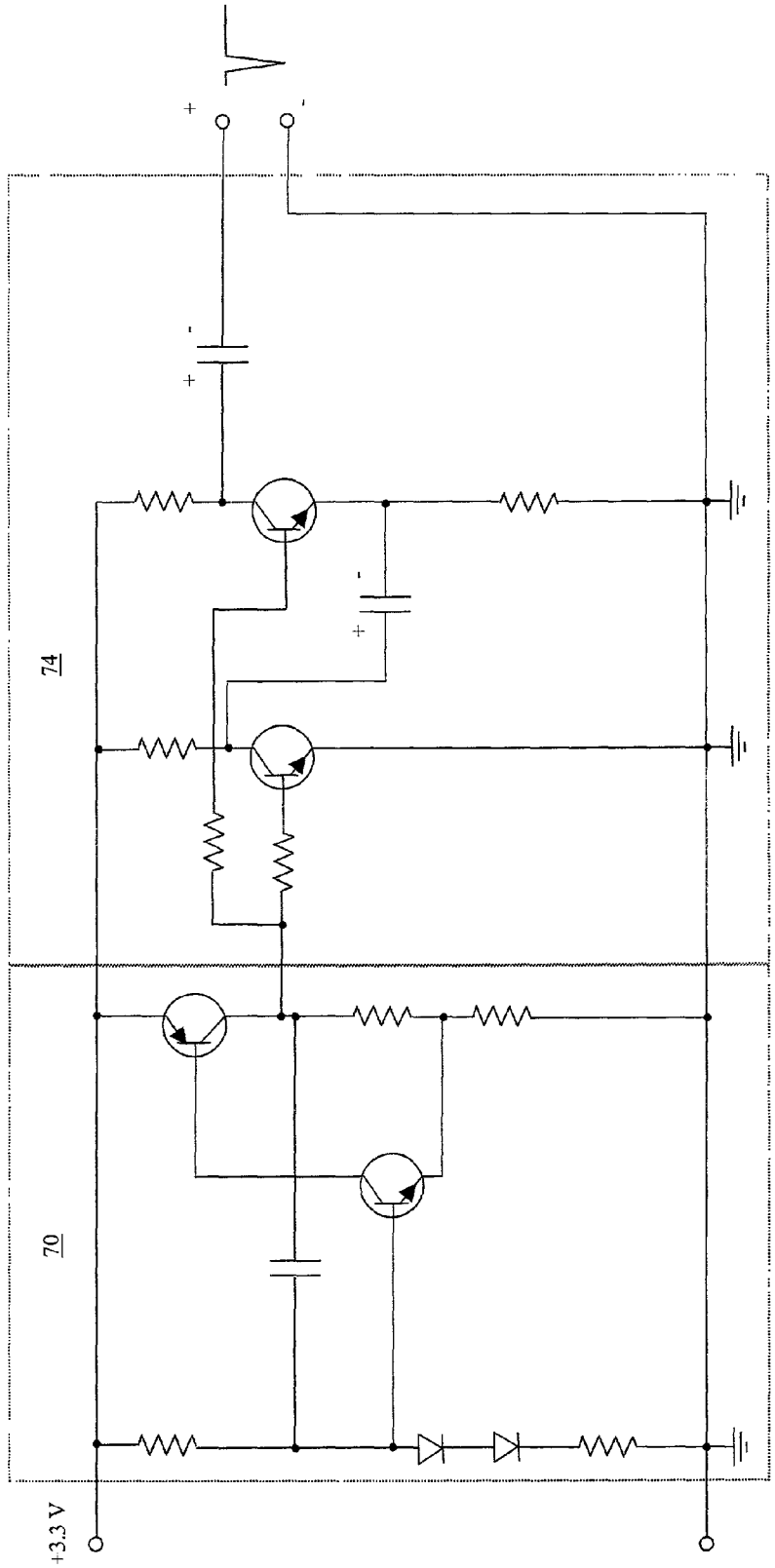

FIG. 5

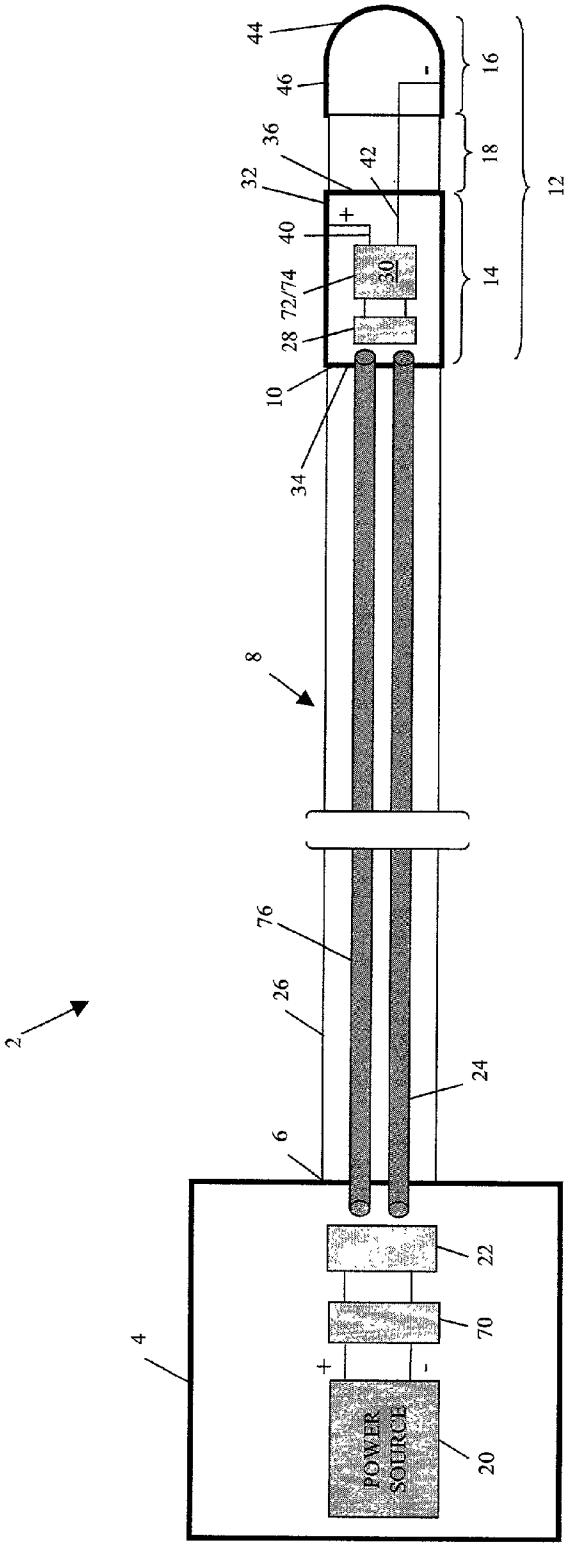
44
46
36
32
42
40
72/74
28
10
34
8
76
26
24
6
2
4
22
70
20
POWER SOURCE
50
16
18
14
12

FIG. 6

MRI-COMPATIBLE PACEMAKER WITH POWER CARRYING PHOTONIC CATHETER AND ISOLATED PULSE GENERATING ELECTRONICS PROVIDING VOO FUNCTIONALITY

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit under 35 U.S.C. 119(e) of U.S. Provisional Patent Application Serial No. 60/269,817, filed on Feb. 20, 2001, entitled "Electromagnetic Interference Immune Cardiac Assist System."

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present invention relates to implantable cardiac pacemakers. More particularly, the invention concerns an implantable cardiac pacemaker that is compatible with Magnetic Resonance Imaging (MRI). Still more particularly, the invention pertains to an MRI resistant implantable cardiac pacemaker with VOO functionality.

[0004] 2. Description of the Prior Art

[0005] By way of background, MRI diagnostic procedures are generally contraindicated for patients wearing implantable pacemakers. A conventional MRI system uses three types of fields that can adversely affect pacemaker operation and cause pacemaker-induced injury to the patient. First, an intense static magnetic field, used to induce nuclear spin polarization changes in the tissue being imaged, is generated at a level of up to 1.5 Tesla (T) in clinical MRI machines and up to 6-8 T in some experimental clinical situations. Second, a time-varying gradient field, usually in the Kilohertz range, is generated for spatial encoding. Third, a Radio Frequency (RF) pulse field in a range of about 6.4-64 MHz is generated to produce an image.

[0006] These fields, acting alone or in combination with each other, can disrupt the function of the pacemaker, or possibly damage its sensitive circuits, or even destroying them. Of particular concern is the effect of induced voltages on the sensitive semiconductors, and magnetic field-induced activation of the reed switch that is used in the pacemaker to temporarily disable pacemaker functions for programming purposes.

[0007] Tsitlik (U.S. Pat. No. 5,217,010) attributes much of the induced voltage problem to the pacemaker electrical leads and electrodes, which together with the tissue between the electrodes, form a winding through which the MRI RF pulse field can generate substantial electromotive force. Tsitlik reports that an MRI system operating at 6.4 MHz can produce voltages of up to 20 volts peak-to-peak in this winding, and that higher frequencies produce even higher voltages. Unipolar electrode systems are said to be worse than bipolar systems. Tsitlik notes that the RF pulses propagating through the pacing leads are delivered directly to the pacemaker case itself, and that once the RF is inside the case, the induced voltage can propagate along the pacemaker circuitry and cause many different types of malfunction, including inhibition or improper pacing.

[0008] A pacemaker's electrical lead system may also cause scarring of patient heart tissue. This scarring is produced by necrosing currents that develop in the electrical leads as a result of large magnetic inductive forces generated by the MRI static magnetic field. If the electrical leads comprise magnetic material, they may also be mechanically displaced by the MRI magnetic field, causing additional physiological damage to the patient. Further physiological damage may result from mechanical displacement of the pacemaker case itself, which is often made of stainless steel and can be torqued or otherwise displaced by a strong magnetic field. That the power of the magnetic field generated by MRI equipment is sufficient to cause pacemaker dislodgment is illustrated by one documented case in which a ferrous brain clip was fatally torn out of the brain tissue in a patient who was only in the proximity of an MRI machine.

[0009] Because of the inherent dangers of subjecting a pacemaker patient to the strong magnetic and electromagnetic fields generated by MRI equipment, a majority of medical practitioners prohibit any type of MRI scan for such patients. Of the minority of medical practitioners who do permit MRI scans for their pacemaker patients, most will only allow scanning under limited conditions with rigid safeguards in place. Those safeguards include disabling the pacemaker while the scan is in progress, performing only emergent scans, avoiding body scans, or requiring the presence of a pacemaker expert during scanning to monitor pacemaker operation.

[0010] It will be appreciated in light of the foregoing that a need exists for a pacemaker that is compatible with MRI scanning procedures. What is required is an improved pacemaker that is capable of withstanding the strong magnetic and electromagnetic fields produced by MRI equipment without operational disruption and without producing physiological injury due to magnetically induced mechanical movement and electrical current. A pacemaker with this capability would allow millions of pacemaker wearers who might otherwise forego potentially life-saving MRI diagnostic evaluation to receive the benefit of this important technology.

SUMMARY OF THE INVENTION

[0011] The foregoing problems are solved and an advance in the art is provided by an MRI-compatible implantable pacemaker that is characterized by a substantial absence of magnetic material and lengthy metallic lead wires, and which uses only a minimal amount of metallic material of any kind. In its most preferred embodiment, the pacemaker includes a photonic catheter, a self-contained electrical power source housed at a proximal end of the photonic catheter, and electrically powered pulsing circuitry housed at a distal end of the photonic catheter. Low energy continuous electrical power is delivered from the power source and converted to light energy at the proximal end of the photonic catheter. The light energy is transmitted to the distal end of the photonic catheter, where it is collected and converted back to electrical energy to power the pulsing circuitry. The pulsing circuitry delivers electrical heart stimulating pulses to a bipolar electrode pair that is also located at the distal end of the photonic catheter.

[0012] The foregoing arrangement permits the use of electro-optical elements operating in the microwatt region rather than at the milliwatt level as would be required if the output of the pulsing circuitry was co-located with the electrical power source in conventional pacemaker fashion.

[0013] The photonic catheter of the invention can be embodied in an optical conduction pathway having a biocompatible covering. Insofar as it must be capable of transvenous insertion, the photonic catheter is preferably very small, having an outside diameter on the order of about 5 millimeters. Advantageously, because the photonic catheter is designed for optical transmission, it cannot develop magnetically-induced and RF-induced electrical currents.

[0014] The housings that respectively contain the electrical power source and the pulsing circuitry may be embodied in a pair of hermetically sealed, non-magnetic metallic, or non-metallic, enclosures. A first enclosure housing the electrical power source is adapted to be implanted remotely from a patient's heart and a second enclosure housing the pulsing circuitry is adapted to be implanted in close proximity to the heart and in electrical contact therewith. The first enclosure, in addition to housing the electrical power source, contains an electro-optical transducer adapted to convert the electrical output of the power source to light energy for delivery to the proximal end of the photonic catheter's optical conduction pathway. The second enclosure, in addition to housing the pulsing circuitry, contains an opto-electrical transducer adapted to receive the light energy at the distal end of the photonic catheter's optical conduction pathway, and convert this light energy to electrical energy to power the pulsing circuitry.

[0015] Whereas the first enclosure may be of a size and shape that is consistent with conventional implantable pacemakers, the second enclosure is preferably a miniaturized housing that is generally cylindrical in shape and substantially co-equal in diameter with the photonic catheter. The second enclosure may also function as one of the pacemaker's bipolar electrodes, namely, the ring electrode. A third enclosure, mounted in closely spaced relationship to the second enclosure, can be used as the pacemaker's tip electrode.

[0016] The third enclosure can be constructed from the same non-magnetic metallic material used to form the first and second enclosures. Because it is adapted to be inserted in a patient's heart as a tip electrode, it is generally bullet shaped. Like the second enclosure, the third enclosure preferably has an outside diameter that substantially matches the diameter of the photonic catheter. Joining the second and third enclosures is a short cylindrical span that can be made from the same material used as the optical conduction pathway's biocompatible covering. Disposed within this cylindrical span is a short length of wire that electrically connects the third enclosure to the output of the pulsing circuitry in the second enclosure.

[0017] In a further embodiment of the invention, the pulsing circuitry can be distributed between the first enclosure and the second enclosure. In particular, a pulse generator oscillator can be housed with the power source in the first enclosure and a pulse generator amplifier can be housed in the second enclosure. The phonic catheter will then carry a steady state optical power signal and a pulse generating trigger signal.

[0018] In the detailed description that follows, embodiments of a VOO (ventricular pacing with no feedback sensing of cardiac function) implantable pacemaker are shown and described. However, it is anticipated that the features of the invention may be used to advantage in non-implantable pacemakers and pacemakers with other electrical configurations, such as VVI (ventricular pacing with ventricular feedback sensing and inhibited response). Similarly, it is expected that the inventive concepts described below will be applicable to other devices used for generating (or sensing) signals of biological significance in a mammalian body.

BRIEF DESCRIPTION OF THE DRAWING

[0019] The foregoing and other features and advantages of the invention will be apparent from the following more particular description of preferred embodiments of the invention, as illustrated in the accompanying Drawing in which:

[0020] **FIG. 1** is a simplified plan view of an MRI-compatible cardiac pacemaker constructed in accordance with a preferred embodiment of the invention, with an intermediate portion of the photonic catheter thereof being removed for illustrative clarity;

[0021] **FIG. 2** is a partially schematic view of the pacemaker of **FIG. 1**, also with an intermediate portion of the photonic catheter thereof removed for illustrative clarity;

[0022] **FIG. 2A** is an enlarged partial perspective view of components located at the distal end of the photonic catheter portion the pacemaker of **FIG. 1**;

[0023] **FIG. 3** is a detailed partially schematic view showing one construction of an electro-optical transducer, an opto-electrical transducer, and the photonic catheter of the **FIG. 1** pacemaker, again with an intermediate portion of the photonic catheter being removed for illustrative clarity;

[0024] **FIG. 4** is a schematic circuit diagram of a first exemplary pulse generator for use in the pacemaker of **FIG. 1**;

[0025] **FIG. 5** is a schematic circuit diagram of a second exemplary pulse generator for use in the pacemaker of **FIG. 1**, with the pulse generator incorporating a voltage doubler; and

[0026] **FIG. 6** is a partially schematic view of an alternative MRI-compatible cardiac pacemaker constructed in accordance with a further embodiment of the invention, with an intermediate portion of the photonic catheter thereof being removed for illustrative clarity.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0027] 1. OVERVIEW

[0028] Applicants have determined that in order to be MRI-compatible, an implantable pacemaker should preferably have no magnetic material, no lengthy metallic lead wires, and a minimum of metallic material of any kind. These limitations have resulted in the development of an improved pacemaker that minimizes the use of electrical pathways carrying electrical signaling information to the heart. Instead, another medium is used. That medium is light. The invention advantageously provides an implantable cardiac pacemaker with VOO functionality that is largely light-driven rather than electrically-driven. As described in detail herein, this challenge is not trivial, but applicants propose solutions herein to achieve the desired goal.

[0029] 2. DESIGN CONSIDERATIONS

[0030] To carry light through a medium such as the human body, an optical conduction pathway is required. A glass conductor, such as glass fiber optic cable, may be used to perform this function. Glass is an excellent conductor of light and appears to offer nearly limitless information bandwidth for signals conducted over it. It transmits light over a wide spectrum of visible frequencies and beyond with very high efficiency. Glass is comprised of silicon dioxide (SiO2), as is sand and silicone rubber. However, whereas silicone rubber is readily accepted by the body, both glass and sand are summarily rejected. The reason for this is that silicone has a negative surface charge, as do blood platelets. Like charges repel and thus there is no reaction between them (assuming the absence of infection). Conversely, glass and sand both have positive surface charges. Opposite charges attract and the blood platelets are attracted to glass or sand, resulting in a foreign body reaction and sand or glass particles are rejected in a "sterile puss." This need not be a problem because the glass fiber light pipe can be encased in a tightly bonding silicone rubber coating, or any other suitable biocompatible material, thus providing mechanical protection and a reaction-free interface in contact with the pacemaker wearer's body.

[0031] As an alternative to glass fiber, an optical conduction pathway may be implemented with plastic optical fiber. Although not as efficient as glass fiber, plastic fiber is ideal for short distance power and signal transmission. In a pacemaker environment, it has an additional advantage in that plastic fiber optic cable is commercially available with a polyethylene outer jacket covering. Polyethylene is a well known biocompatible material.

[0032] Glass and plastic fibers do have one problem that metal leads do not have. Namely, a glass or plastic fiber catheter would not be seen by X-ray imaging while being inserted. Thus, additional marker metallic segments or threads may have to be included in the photonic catheter structure herein disclosed.

[0033] It will be appreciated that a pacemaker pulse generator is an electrical device and that only electrical pulses, not light, will stimulate a heart. As such, a transducer must be used to convert the pacemaker's electrical energy into light energy at the proximal end of the optical conduction pathway, and then another transducer must convert the light signal back into an electrical signal at the distal end of the optical conduction pathway. Light emitting diodes and photo diodes may be used in the transducers. The preferred approach disclosed herein is to transmit light energy at a slow, steady rate down a fiber optic cable, convert the steady-state light energy to electrical energy, and use that to power a conventional electronic pacemaker pulse generator inside a miniaturized, hermetically sealed non-magnetic enclosure.

[0034] Applicants are informed that light emitting diodes, fiber optic light pipes, and photo diodes are all commercially available at the 20 to 50 mw level. A voltage of about 3.3 volts for 1 millisecond at about 3 milliamperes should be adequate to stimulate the heart. This represents a power level of about 10 μW (average) and is easily achievable from presently available light emitting diodes and photo diodes. Moreover, applicants have determined that only low-level light energy needs to be transmitted on an optical catheter to the catheter tip to power the pacemaker pulsing circuitry. This permits the use of microwatt level photonics rather than milliwatt power levels.

[0035] 3. EXEMPLARY PACEMAKER CONSTRUCTIONS

[0036] Turning now to the figures, wherein like reference numerals represent like elements in all of the several views, **FIG. 1** illustrates an MRI-compatible cardiac pacemaker **2** constructed in accordance with a most preferred embodiment of the invention. The pacemaker **2** is implantable and is readily implemented to operate in a fixed-rate (VOO) mode. It includes a first (main) enclosure **4** that is connected to the proximal end **6** of a photonic catheter **8**. A distal end **10** of the photonic catheter **8** mounts a bipolar endocardial (or pericardial) electrode pair **12** that includes a second enclosure **14** and a third enclosure **16** separated by a short insulative spacer **18**.

[0037] With additional reference now to **FIG. 2**, the main enclosure **4** houses a self-contained electrical power source **20** and an electro-optical transducer **22**. The power source **20** serves to deliver low energy continuous electrical power that is converted by the electro-optical transducer **22** into light energy and directed into the proximal end **6** of the photonic catheter **8**. The main enclosure **4** is preferably formed as a hermetically sealed casing made from a non-magnetic metal, such as titanium, platinum, a platinum-containing alloy, or any other suitable material, including non-metals. The casing is of a size and shape that is consistent with conventional implantable pacemakers, and is adapted to be implanted remotely from a patient's heart at the usual location within the patient's right shoulder area.

[0038] The photonic catheter **8** includes an optical conduction pathway **24** surrounded by a protective outer covering **26**. The optical conduction pathway **24** may include one or more fiber optic transmission elements that are conventionally made from glass or plastic fiber material, e.g., a fiber optic bundle, as outlined above. As also noted above, to avoid body fluid incompatibility problems, the protective outer covering **26** should be made from a biocompatible material, such as silicone rubber, polyurethane, polyethylene, or other biocompatible polymer having the required mechanical and physiological properties. The protective outer covering **26** is thus a biocompatible covering and will be referred to as such in the ensuing discussion. Insofar as the photonic catheter **8** must be adapted for transvenous insertion, the biocompatible covering **26** is preferably a very thin-walled elongated sleeve or jacket having an outside diameter on the order of about 5 millimeters. This will render the photonic catheter **8** sufficiently slender to facilitate transvenous insertion thereof through a large vein, such as the external jugular vein.

[0039] The proximal end **6** of the photonic catheter **8** is mounted to the main enclosure **4** using an appropriate sealed connection that prevents patient body fluids from contacting the optical conduction pathway **24** and from entering the enclosure **4**. The optical conduction pathway **24** may extend into the enclosure **4** for a short distance, where it terminates in adjacent relationship with the electro-optical transducer **22** in order to receive light energy therefrom. Light emitted by the electro-optical transducer **22** will thus be directed into the proximal end **6** of the photonic catheter **8**, and will be transmitted through the optical conduction pathway **24** to the

second enclosure **14**. Advantageously, because the photonic catheter **8** is designed for optical transmission, it cannot develop magnetically-induced or RF-induced electrical currents, as is the case with the metallic leads of conventional pacemaker catheters.

[**0040**] The second enclosure **14** houses an opto-electrical transducer **28**, which converts light energy received from the distal end of the photonic catheter **8** into electrical energy, and a pulse generator **30**. The pulse generator **30** stores the electrical energy provided by the opto-electrical transducer **28** in one or more storage capacitors (see below), and periodically releases that energy to deliver electrical pulses to the bipolar electrode pair **12**. Like the main enclosure **4**, the second enclosure **14** is formed as a hermetically sealed casing made from a non-magnetic metal, such as titanium, platinum, a platinum-containing alloy, or any other suitable metal, or a non-metal. Unlike the main enclosure **4**, the second enclosure **4** is adapted to be implanted via transvenous insertion in close proximity to the heart, and in electrical contact therewith. As such, the second enclosure **4** preferably has a miniaturized tubular profile that is substantially co-equal in diameter with the photonic catheter **8**. A diameter of about 5 millimeters will be typical.

[**0041**] As can be seen in **FIGS. 2 and 2**A, the second enclosure **14** includes a cylindrical outer wall **32** and a pair of disk-shaped end walls **34** and **36**. The end wall **34** is mounted to the distal end **10** of the photonic catheter **8** using an appropriate sealed connection that prevents patient body fluids from contacting the optical conduction pathway **24** and from entering the second enclosure **14**. The optical conduction pathway **24** may extend into the enclosure **14** for a short distance, where it terminates in adjacent relationship with the opto-electrical transducer **28** in order to deliver light energy thereto. Light received by the opto-electrical transducer **28** will thus be converted to electrical energy and delivered to the pulse generator **30**. Due to the miniature size of the second enclosure **14**, the opto-electrical transducer **28** and the pulse generator **30** need to be implemented as miniaturized circuit elements. However, such components are conventionally available from commercial electronic component manufacturers. Note that the opto-electrical transducer **28** and the pulse generator **30** also need to be adequately supported within the second enclosure **14**. To that end, the second enclosure **14** can be filled with a support matrix material **38** that may be the same material used to form the photonic catheter's biocompatible covering **26** (e.g., silicone rubber, polyurethane, polyethylene, or any biocompatible polymer with the required mechanical and physiological properties).

[**0042**] As stated above, the second enclosure **14** represents part of an electrode pair **12** that delivers the electrical output of the pacemaker **2** to a patient's heart. In particular, the electrode pair **12** is a tip/ring system and the second enclosure **14** is used as an endocardial (or pericardial) ring electrode thereof. To that end, a positive output lead **40** extending from the pulse generator **30** is electrically connected to the cylindrical wall **32** of the second enclosure **14**, as by soldering or the like. A negative output lead **42** extending from the pulse generator **30** is fed out of the second enclosure **14** and connected to the third enclosure **16**, which functions as an endocardial tip electrode of the electrode pair **12**.

[**0043**] The third enclosure **16** can be constructed from the same non-magnetic metallic material used to form the first enclosure **4** and the second enclosure **14**, such as titanium, platinum, a platinum-containing alloy, or any other suitable material. Because it is adapted to be inserted in a patient's heart as an endocardial tip electrode, the third enclosure **16** has a generally bullet shaped tip **44** extending from a tubular base end **46**. The base end **46** preferably has an outside diameter that substantially matches the diameter of the second enclosure **14** and the photonic catheter **8**. Note that the base end **46** of the third enclosure **16** is open insofar as the third enclosure does not house any critical electrical components. Indeed, it mounts only the negative lead **42**, which is electrically connected to the third enclosure's base end **46**, as by soldering or the like.

[**0044**] As stated above, the second enclosure **14** and the third enclosure **16** are separated by an insulative spacer **18**. The spacer **18** is formed as a short cylindrical span of insulative material that may be the same material used to form the optical conduction pathway's biocompatible covering **26** (e.g., silicone rubber, polyurethane, polyethylene, or any biocompatible polymer with the required mechanical and physiological properties). Its diameter is preferably co-equal to that of the photonic catheter **8**, the second enclosure **14** and the third enclosure **16**. Extending through this material is the negative lead **42** that electrically connects the third enclosure **16** to the negative side of the pulse generator's output. The material used to form the spacer **18** preferably fills the interior of the second enclosure **16** so that there are no voids and so that the negative lead **42** is fully captured therein. Note that the spacer **18** is mounted to the end wall **36** of the second enclosure **14** using an appropriate sealed connection that prevents patient body tissue and fluids from contacting the negative lead **42** and from entering the second enclosure **14**. To connect the spacer **18** to the third enclosure **16**, the latter can be press fit over the spacer, crimped thereto or otherwise secured in non-removable fashion.

[**0045**] It will be appreciated that the electrical and optical components of the pacemaker **2** can be implemented in a variety of ways. By way of example, **FIG. 3** show construction details of the electro-optical transducer **22**, the optical conduction pathway **24** and the opto-electrical transducer **28**. **FIGS. 4 and 5**, described further below, show construction details for the pulse generator **30**.

[**0046**] In **FIG. 3**, the electrical power source **20** is implemented using one or more conventional pacemaker lithium batteries **50** providing a steady state d.c. output of about 3 volts. The electro-optical transducer **22** is implemented with a light emitting diode **52** and a current limiting resistor **54**. The light emitting diode **52** is conventional in nature and thus has a forward voltage drop of about 2 volts and a maximum allowable current rating of about 50 milliamperes. If additional supply voltage is available from the power source **20** (e.g., 4 volts or higher), more than one light emitting diode **52** can be used for additional light energy output. The value of the resistor **54** is selected accordingly. By way of example, if the batteries **50** produce 3 volts and the desired current through the light emitting diode **52** is 0.5 milliamperes, the value of the resistor **54** should be about (3-2)/0.0005 or 2000 ohms. The optical conduction pathway **24** in **FIG. 3** can be implemented as a fiber optic bundle **56**. The opto-electrical transducer **28** is implemented with six

photo-diodes **58***a,* **58***b,* **58***c,* **58***d,* **58***e,* and **58***f* that are wired for photovoltaic operation. The photo diodes **58***a-f* are suitably arranged so that each receives the light output of one or more fibers of the fiber optic bundle **56** and is forward biased into electrical conduction thereby. Each photo diode **58***a-f* is conventional in nature and thus produces a voltage drop of about 0.6 volts. Cumulatively, the photo diodes **58***a-f* develop a voltage drop of about 3.3 volts across the respective positive and negative inputs **59** and **60** of the pulse generator **30**. Note that the photo diodes **58***a-f* could be discrete devices, or they could be or part of an integrated device, such as a solar cell array. As described in more detail below, respective positive and negative outputs **62** and **64** of the pulse generator **30** provide pulse signals of about 3.3-6.6 volts.

[**0047**] **FIGS. 4 and 5** show two alternative circuit configurations that may be used to implement the pulse generator **30**. Both alternatives are conventional in nature and do not constitute part of the present invention per se. They are presented herein as examples of the pulsing circuits that have been shown to function well in an implantable pacemaker environment. In **FIG. 4**, the pulse generator **30** includes an oscillator **70** and an amplifier **72**. The oscillator **70** is a semiconductor pulsing circuit of the type disclosed in U.S. Pat. No. 3,508,167 of Russell, Jr. (the '167 patent). As described in the '167 patent, the contents of which are incorporated herein by this reference, the pulsing circuit forming the oscillator **70** provides a pulse width and pulse period that are relatively independent of load and supply voltage. The semiconductor elements are relegated to switching functions so that timing is substantially independent of transistor gain characteristics. In particular, a shunt circuit including a pair of diodes is connected so that timing capacitor charge and discharge currents flow through circuits that do not include the base-emitter junction of a timing transistor. Further circuit details are available in the '167 patent. The values of the components that make up the oscillator **70** are selected to provide a conventional VOO pacemaker pulse of about 1 milliseconds duration at a period of about 1000 milliseconds.

[**0048**] The amplifier **72** of **FIG. 4** is a circuit that uses a single switching transistor and a storage capacitor to deliver a negative-going pulse of approximately 3.3 volts across the pulse generator outputs when triggered by the oscillator **70**. An example of such a circuit is disclosed in U.S. Pat. No. 4,050,004 of Greatbatch (the '004 patent), which discloses voltage multipliers having multiple stages constructed using the circuit of amplifier **72**. As described in the '004 patent, the contents of which are incorporated herein by this reference, the circuit forming the amplifier **72** uses a 3.3 volt input voltage to charge a capacitor between oscillator pulses. When the oscillator **70** triggers, it drives the amplifier's switching transistor into conduction, which effectively grounds the positive side of the capacitor, causing it to discharge through the pulse generator's outputs. The values of the components which make up the amplifier **72** are selected to produce an output potential of about 3.3 volts and a current of about 3 milliamperes, for a total power level of about 10 milliwatts.

[**0049**] The amplifier **74** of **FIG. 5** is a circuit that uses a pair of the amplifier circuits of **FIG. 4** to provide voltage doubling action. As described in the '004 patent, the capacitors are arranged to charge up in parallel between oscillator pulses. When the oscillator **70** triggers, it drives the amplifier's switching transistors into conduction, causing the capacitors to discharge in series to provide the required voltage doubling action. The values of the components which make up the amplifier **74** are selected to produce an output potential of about 6.6 volts and a current of about 3 milliamperes, for a total power level of about 20 milliwatts.

[**0050**] An advantage of the pacemaker **2** is that it permits the use of electro-optical elements operating in the microwatt region rather than at the milliwatt level, as would be required if the output of the pulsing circuitry was co-located with the electrical power source in conventional pacemaker fashion. In particular, where the optical conduction pathway **24** terminates at the opto-electrical transducer **28**, the steady-state light energy is transduced into a steady-state electric voltage of about 3.3 volts. This drives the pulse generator **30** in the manner described above to produce milliwatt level pulses.

[**0051**] Turning now to **FIG. 6, a** modified version of the pacemaker **2** is shown to illustrate a further embodiment of the invention wherein the pulse generator **30** is distributed between the first enclosure **4** and the second enclosure **14**. In particular, the oscillator **70** is housed in the main enclosure **4** and the amplifier **72** (or **74**) is housed in the second enclosure **14**. Thus, there is distributed pulsing circuitry in both enclosures. The photonic catheter's optical conduction pathway **24** continues to provide steady state optical energy to power the amplifier **72**/**74**. Specifically, this energy is used to charge the amplifier storage capacitor(s) between pulses. In addition, a second optical conduction pathway **76** is provided in the photonic catheter to carry an optical pulse signal representing the pulse output of the oscillator **70**. This pulse signal triggers the amplifier **72**/**74** in the manner described above. It will be appreciated that the electro-optical transducer **22** and the opto-electrical transducer **28** can be readily modified in view of the disclosure herein to accommodate the optical pulse signal.

[**0052**] Accordingly an MRI-compatible demand pacemaker has been disclosed that is largely light-driven rather than electrically-driven, and which is believed to offer a unique solution to the problem of MRI incompatibility found in conventional pacemakers. While various embodiments of the invention have been shown and described, it should be apparent that many variations and alternative embodiments could be implemented in accordance with the invention. For example, although the development of an MRI-compatible cardiac pacemaker is a substantial advance, it is submitted that the use of light transmission to carry signals through the human body, as disclosed herein, will have additional applications beyond the pacemaker field, perhaps as an overall replacement for signal transmission through electrical wires. Indeed, the disclosure herein of device configurations for the conduction of power and signals through a mammalian body by way of light signals and photonic catheters may have significant impact on the manner in which active (self-powered) prosthetic devices are designed for implantable service. It is understood, therefore, that the invention is not to be in any way limited except in accordance with the spirit of the appended claims and their equivalents.

What is claimed is:

1. An MRI-compatible implantable cardiac pacemaker, comprising:

a photonic catheter;

a self-contained electrical power source housed at a proximal end of said photonic catheter;

electrically powered pulsing circuitry housed at a distal end of said photonic catheter;

first power conversion means for converting the output of said electrical power source to optical energy for transmission through said photonic catheter; and

second power conversion means for converting said optical energy transmitted through said photonic catheter to electrical energy for powering said pulsing circuitry.

2. A pacemaker in accordance with claim 1, wherein said electrical power source and said pulsing circuitry are respectively housed in first and second enclosures that are hermetically sealed and made from non-magnetic metallic material.

3. A pacemaker in accordance with claim 2, wherein said material is titanium.

4. A pacemaker in accordance with claim 2, wherein said material is platinum or an alloy containing platinum.

5. A pacemaker in accordance with claim 1, wherein said photonic catheter includes a fiber optic conduction pathway.

6. A pacemaker in accordance with claim 1, wherein said fiber optic conduction pathway is a glass or plastic fiber optic conduction pathway.

7. A pacemaker in accordance with claim 1 wherein said photonic catheter comprises a fiber optic conduction pathway covered by a biocompatible covering.

8. A pacemaker in accordance with claim 7 wherein said biocompatible covering comprises a material from a group that includes silicone rubber, polyurethane and polyethylene.

9. A pacemaker in accordance with claim 1 further including a pacemaker tip electrode spaced from the distal end of said photonic catheter, and wherein said pulsing circuitry is housed in a ring electrode of said pacemaker connected to the distal end of said photonic catheter.

10. A pacemaker in accordance with claim 1 wherein said pulsing circuitry is partially housed at said distal end of said photonic catheter and also partially housed at said proximal end of said photonic catheter.

11. An MRI-compatible implantable cardiac pacemaker, said pacemaker comprising:

a first enclosure adapted to be implanted in a patient's body at a location that is remote from the implanted patient's heart;

a second enclosure unit adapted to be electrically connected to the implanted patient's heart;

an optical conduction pathway disposed between said first and second enclosures;

an optical power source in said first enclosure operatively connected to a first end of said optical conduction pathway;

an optically driven electrical pulse generating system in said second enclosure operatively connected to a second end of said optical conduction pathway; and

said optical power source being adapted to provide a steady state optical power signal through said optical conduction pathway for use by said pulse generating system, and said pulse generating system being adapted to generate periodic electrical signals to stimulate the implanted patient's heart.

12. A pacemaker in accordance with claim 11 wherein said first enclosure houses an electrical power supply and an electro-optical transducer adapted to convert the electrical signal output of said power supply to light energy for placement on said optical conduction pathway.

13. A pacemaker in accordance with claim 11 wherein said second enclosure houses an opto-electrical transducer adapted to receive said light energy from said optical conduction pathway and convert said energy to electrical energy, and a pulse generator powered by the electrical energy output of said opto-electrical transducer.

14. A pacemaker in accordance with claim 11 wherein said first enclosure comprises a hermetically sealed casing made of non-magnetic material.

15. A pacemaker in accordance with claim 14 wherein said non-magnetic material is selected from a group that includes titanium, platinum, and alloys thereof.

16. A pacemaker in accordance with claim 11 wherein said first enclosure houses a battery made from non-magnetic material, and an electro-optical transducer electrically connected to said battery and optically communicating with said first end of said optical conduction pathway.

17. A pacemaker in accordance with claim 16 wherein said electro-optical transducer comprises a light emitting diode.

18. A pacemaker in accordance with claim 11 wherein said optical conduction pathway comprises a fiber optic element.

19. A pacemaker in accordance with claim 18 wherein said optical conduction pathway further comprises a biocompatible covering over said fiber optic element.

20. A pacemaker in accordance with claim 19 wherein said covering comprises a jacket made from a group that includes silicone rubber, polyurethane and polyethylene.

21. A pacemaker in accordance with claim 19 wherein said covering has an outside diameter of about 5 millimeters.

22. A pacemaker in accordance with claim 11 wherein said second enclosure comprises a hermetically sealed casing made of non-magnetic metallic material.

23. A pacemaker in accordance with claim 22 wherein said non-magnetic material is selected from a group that includes titanium, platinum, and alloys thereof.

24. A pacemaker in accordance with claim 11 wherein said second enclosure houses an opto-electrical transducer adapted to optically communicate with said second end of said optical conduction pathway and electrically connected to a pulse generator.

25. A pacemaker in accordance with claim 24 wherein said opto-electrical transducer comprises a photo diode.

26. A pacemaker in accordance with claim 22 wherein said casing is generally cylindrical in shape.

27. A pacemaker in accordance with claim 26 wherein said optical conduction pathway is a fiber optic element having a biocompatible covering with an outside diameter, and wherein said casing has an outside diameter which is substantially co-equal to said covering outside diameter.

28. A pacemaker in accordance with claim 27 wherein the outside diameter of said casing and the outside diameter of said covering are each about 5 millimeters.

29. A pacemaker in accordance with claim 28 wherein said opto-electrical transducer and said pulse generator are carried in a matrix disposed within said casing.

30. A pacemaker in accordance with claim 29 wherein said casing functions as a ring electrode of a tip/ring portion of said pacemaker.

31. A pacemaker in accordance with claim 30 further including a third enclosure adapted to be inserted in the implanted patient's heart and comprising a non-magnetic casing that electrically communicates with said pulse generator and which functions as a tip electrode of said tip/ring portion of said pacemaker.

32. A pacemaker in accordance with claim 31 wherein said optical conduction pathway is a fiber optic element having a biocompatible covering with an outside diameter, said casings of said second and third enclosures have an outside diameter which is substantially the same as said covering outside diameter, and said second and third enclosures are separated by a cylindrical length of the material used to form said biocompatible covering.

33. A pacemaker in accordance with claim 31 wherein said optical conduction pathway, said second enclosure and said third enclosure form a catheter extending from said first enclosure, said second enclosure and said third enclosure being generally cylindrical and being joined by a generally cylindrical length of a biocompatible material to form a catheter tip, and said optical conduction pathway being a fiber optic element having a biocompatible covering with an outside diameter substantially matching that of said second and third enclosures.

34. An MRI-compatible pacemaker, comprising:

a direct current voltage source housed in a first enclosure and adapted to produce a steady state electrical output signal;

a pulse generating circuit housed in a second enclosure and adapted to generate periodic heart-triggering pulses;

a cardiac electrode system adapted to electrically stimulate a heart in accordance with said heart-triggering pulses; and

an optical system adapted to transport optical signals representing said steady state electrical output signal from said first enclosure to said second enclosure.

35. A pacemaker in accordance with claim 34, wherein said voltage source is electrically connected to an electro-optical transducer that is co-located with said voltage source in said first enclosure, said electro-optical transducer being adapted to produce a steady state optical signal that is fed into said optical system at a power level which is in the microwatt region.

36. A pacemaker in accordance with claim 35, wherein said pulse generator includes an opto-electrical transducer that receives said steady state optical signal and produces a steady state electrical signal having a voltage level of about 3.3 volts, said pulse generator further including an oscillator and an amplifier powered by said opto-electrical transducer and being adapted to produce electrical pulses of about 1 millisecond duration at a voltage level of about 3.3 volts and a current level of about 3 milliamperes for a total power output of about 10 milliwatts.

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