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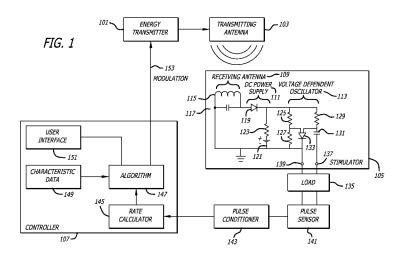
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(54) Title: MONITORING AND CONTROLLING CHARGE RATE AND LEVEL OF BATTERY IN INDUCTIVELY-CHARGED PULSE GENERATING DEVICE



(57) Abstract: A battery charging system for wirelessly charging a battery in an electrical pulse- generating device that generates electrical pulses at a rate that is dependent upon the charge in the battery. The charging system charges the battery at a rate and to a threshold that are both determined based on the rate of the electrical pulses. A calibration system that calibrates the electrical pulse-generating device by computing information indicative of a mathematical relationship between changes in the pulse rate and the voltage applied to the electrical pulse generating device. A pacemaker that includes a resistor in series with its battery and that does not have any circuit that measures or detects the voltage across the resistor. A packaged pacemaker that includes a pacemaker having electrodes and a light emitting diode in detachable electrical contact with the electrodes.





MONITORING AND CONTROLLING CHARGE RATE AND LEVEL OF BATTERY IN INDUCTIVELY-CHARGED PULSE GENERATING DEVICE

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application is based upon and claims priority to U.S. provisional patent application 61/694,671, entitled "System for Monitoring Battery Charge Level and Controlling Recharging Process," filed August 29, 2012. The entire content of this application is incorporated herein by reference.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

[0002] This invention was made with government support under Grant No. UL1TR000130 awarded by the National Institutes of Health. The government has certain rights in the invention.

BACKGROUND

TECHNICAL FIELD

[0003] This disclosure relates to battery-run devices that generate pulses, such as pacemakers, and to devices that wirelessly charge these batteries.

DESCRIPTION OF RELATED ART

[0004] Cardiac pacemakers may have a size and form factor suitable for implantation by minimally invasive surgery. However, they may not have sufficient volume for conventional primary power cells that last for years.

[0005] Secondary power cells can be used and recharged by coupling to externally generated energy fields, such as radio frequency magnetic fields, but can be damaged by overcharging.

[0006] An injectable fetal pacemaker may not have sufficient space for both a battery and control and monitoring circuitry. The battery may need to be recharged repeatedly over the functional life of the implanted pacemaker. An external source of energy may be used, such as a transcutaneous RF magnetic field. The distance and orientation between the implanted pacemaker and the external source of charging energy can be variable and uncertain. Therefore, the

strength of the energy received by the implanted pacemaker can vary. This may require the recharging process to be carefully monitored and controlled to insure that it is proceeding to completion without overcharging or damaging the battery.

[0007] The recharging process may be controlled by voltage and/or current regulator circuits in the implant and/or telemetry circuits in the implant that monitor the implanted battery and transmit information about its status to an external controller. However, such circuits may add size and complexity to the implanted device and be too bulky for an injectable fetal or other type of pacemaker.

[0008] Change in pacing rate with primary battery voltage was used to decide when to replace early cardiac pacemakers. *See, e.g.,* U.S. Patent #3,474,353. More modern pacemakers use sophisticated digital control and telemetry to generate and monitor pacing output and battery condition. However, this ancillary circuitry adds complexity and size and consumes power.

[0009] Inductively rechargeable pacemakers were used in the 1970s and 1980s (see, e.g., U.S. Patents #3,888,260 and #4,014,346) and were a topic of research and development (e.g., US Patent #5,411,537). They incorporated implanted telemetry circuitry that monitored both the voltage and current of the recharging process so as to avoid damage to the battery or other hazardous conditions. Again, however, this circuitry added size, complexity and power drain which can be too large for smaller pacemakers.

SUMMARY

[0010] A battery charging system may charge a battery contained in an electrical pulse-generating device that generates electrical pulses at a rate that is dependent upon the level of charge in the battery. The battery charging system may include a charge-delivery system having a configuration that delivers charge to the battery at a controllable rate; a pulse detector having a configuration that detects the rate of the electrical pulses that are being generated by the electrical pulse-generating device while the battery is being charged; and a controller having a configuration that controls the rate at which the charge-delivery system delivers the charge to the battery based on the rate of the electrical pulses detected by the pulse detector.

[0011] The controller may cause the charge delivery system to deliver charge to the battery at a first rate and at a second rate that is different from the first rate. The second rate may be zero.

- **[0012]** The controller may determine a rate of charge delivery based on the difference between the rate of the electrical pulses at the first and the second rates of charge delivery and information indicative of an internal resistance of the battery or a resistance in series with the battery.
- **[0013]** The controller may include information indicative of a relationship between the rate of the electrical pulses and the level of charge in the battery.
- **[0014]** The controller may, during the delivery of charge to the battery by the charge-delivery system, determine when the rate of the electrical pulses that are detected by the pulse detector have reached a threshold. The controller may, cause the charge-delivery system to cease delivering charge to the battery when the threshold has been determined to have been reached.
- [0015] The controller may control the rate at which the charge-delivery system delivers the charge to the battery in discrete, discontinuous steps.
- **[0016]** The electrical pulse generating device may include an LED that flashes in synchronism with the electrical pulses. The pulse detector may include a light detector having a configuration that detects the LED when flashing.
- **[0017]** The electrical pulse generating device may be a pacemaker. The pulse detector may include electrodes configured to be attached to skin of a patient in which the pacemaker has been implanted.
- **[0018]** The charge-delivery system may include an electromagnetic radiating coil that delivers the charge to the battery without an electrical connection to the battery.
- **[0019]** A battery charging system may charge a battery contained in an electrical pulse-generating device that generates electrical pulses at a rate that is dependent upon the level of charge in the battery. The battery charging system may include a charge-delivery system having a configuration that transmits electrical energy to the battery at controllable rates; a pulse detector having a configuration that detects the rate of the electrical pulses that are being generated by the electrical pulse-generating device while the battery is being charged; and a

controller having a configuration that: determines when the rate of the electrical pulses that are detected by the pulse detector during the delivery of charge to the battery by the charge-delivery system have reach a threshold; and causes the charge-delivery system to cease delivering charge to the battery when the threshold rate has been determined to have been reached.

[0020] A calibration system may calibrate an electrical pulse-generating device that generates electrical pulses at a rate that is dependent upon a supplied voltage. The calibration system may include a controllable voltage source that has a configuration that provides the supplied voltage; a pulse rate detector having a configuration that detects the rate of the electrical pulses that are being generated by the electrical pulse-generating device in response to the supplied voltage; a calibration controller having a configuration that causes the controllable voltage source to supply multiple supplied voltages at different levels and records the pulse rates of the electrical pulse-generating device in response to each; and a data computation system that has a configuration that computes information indicative of a mathematical relationship between changes in the pulse rate and the voltage applied to the electrical pulse generating device.

[0021] The data computation system may cause the computed information to be stored in association with information that identifies the electrical pulse generating device and distinguishes it from other electrical pulse generating devices of the same type that have a different mathematical relationship between changes in their pulse rate and the amount of charge that is being delivered to their battery.

[0022] Each electrical pulse generating device may have a unique serial number or code. The information that identifies each electrical pulse generating device may be its unique serial number or code.

[0023] A pacemaker may generate electrical pulses. The pacemaker may include a battery; a pulse generating circuit having a configuration that generates the electrical pulses at a rate that is dependent upon the level of charge in the battery; an electrical connection between the pulse generating circuit and the battery; and a resistor in series with the electrical connection between the pulse

generating circuit and the battery. The pacemaker may not have any circuit that measures or detects the voltage across the resistor.

[0024] A packaged pacemaker may include a pacemaker having a configuration that generates electrical pulses. The pacemaker may include a battery, a pulse generating circuit that has a configuration that generates the electrical pulses at a rate that is dependent upon the level of charge in the battery, and electrodes that have a configuration that delivers the electrical pulses to neighboring tissue when the pacemaker is placed in contact with the neighboring tissue. The package pacemaker may include a light emitting diode in detachable electrical contact with the electrodes; and a removable sealed housing that houses the pacemaker and light emitting diode, the removable sealed housing including a translucent portion positioned with respect to the light emitting diode so as to allow light that is emitted by the light emitting diode to be seen outside of the removable sealed housing. These, as well as other components, steps, features, objects, benefits, and advantages, will now become clear from a review of the following detailed description of illustrative embodiments, the accompanying drawings, and the claims.

BRIEF DESCRIPTION OF DRAWINGS

[0025] The drawings are of illustrative embodiments. They do not illustrate all embodiments. Other embodiments may be used in addition or instead. Details that may be apparent or unnecessary may be omitted to save space or for more effective illustration. Some embodiments may be practiced with additional components or steps and/or without all of the components or steps that are illustrated. When the same numeral appears in different drawings, it refers to the same or like components or steps.

[0026] Fig. 1 is an example of a battery charging monitor and a recharge control system for a stimulator.

[0027] Fig. 2A is an example of a calibration curve that relates supply voltages to output pulsing rates of a stimulator. Fig. 2B is an example of a monitor and recharge controller in which a pulse generator is calibrated to obtain the calibration curve illustrated in Fig. 2A.

[0028] Fig. 3 is an example process that may provide safe and complete recharging of a battery within a stimulator.

[0029] Fig. 4 is an example of components in an energy transmitter and antenna.

[0030] Fig. 5A is an example of a pacemaker connected to a load and a light emitting diode (LED). Fig. 5B is an example of the pacemaker interfacing with a monitor and recharge controller via the LED that directs light through the exterior of a sterile package.

[0031] Fig. 6 is an example of an implanted pacemaker interfacing with a monitor and recharge controller using ECG skin electrodes.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

[0032] Illustrative embodiments are now described. Other embodiments may be used in addition or instead. Details that may be apparent or unnecessary may be omitted to save space or for a more effective presentation. Some embodiments may be practiced with additional components or steps and/or without all of the components or steps that are described.

[0033] The charge level and recharging rate of a pacemaker battery may be monitored and controlled by measuring the output pulse rate of the pacemaker and by using that information to create a closed loop recharging system. This method may take advantage of a voltage dependent oscillator in the pacemaker, which may exhibit a pulsing rate that varies with the voltage that is supplied to the oscillator by its power supply.

[0034] The oscillator may be a relaxation oscillator which may function by charging a capacitor (C) until it reaches a threshold voltage set by two bias resistors. When the threshold is reached, a breakdown may occur in a programmable unijunction transistor (PUT), causing the capacitor to discharge through an electrode into a heart muscle. The PUT may then revert to an off state, allowing the capacitor to recharge.

[0035] The rate of the pulses may depend primarily on the size of a charging resistor (Rc) and the capacitor (C). The charging of the capacitor and the setting of the threshold voltage may require power, which may be supplied by a battery.

As time goes on and the battery's charge is drained, the battery voltage may decrease. This may result in a small but detectable change in the rate of output pulses as the internal voltage drops in the PUT become a larger fraction of the battery supply voltage to the circuit. The relationship between output pulse rate and supply voltage may be used to monitor the charge level and recharging rate of the battery.

[0036] This relationship can vary somewhat among similarly designed implants, depending on the exact electrical characteristics of each component. So it may be desirable to obtain and record characterization data for each implant under known conditions during manufacturing. The characterization data can be associated with the serial number of the implant and referenced during the recharging process to provide additional accuracy regarding the voltage and recharging current of the battery. The characterization data may be stored in a memory in the charger or be made available over the internet for the charger to download.

[0037] "Battery" is used herein to refer to one or multiple power cells configured in series or parallel to provide operating voltage for the implanted circuitry.

[0038] "Stimulator," "electrical pulse-generating device," and "pacemaker" are used herein to refer to any implanted device that produces a continuous train of electrical stimulation pulses to any type of body tissue.

[0039] Fig. 1 is an example of a battery charging monitor and a recharge control system for a stimulator. Components of the system may include an electrical pulse-generating device, such as a stimulator 105, whose pulse rate may depend on a voltage level supplied by a DC power supply 111, a pulse sensor 141 that enables a controller 107 to infer the voltage level in stimulator 105 from its pulse rate, and an energy transmitter 101 whose level of energy transmission may be adjusted by the controller 107 so as to control the rate and level of recharging of a battery 121 in the stimulator 105. As will be described in greater detail below, various combinations and additions to these main components may be employed in different phases during manufacture, storage, and service of the stimulator 105.

[0040] The stimulator 105 may include a voltage dependent oscillator 113, which may be a relaxation oscillator that alternatively charges and discharges a capacitor (C) 131. The battery 121 may provide a DC voltage that charges up the capacitor (C) 131 through a charging resistor (Rc) 129 until the potential across the capacitor 131 reaches a threshold voltage set by two bias resistors (R1) 125 and (R2) 127. A programmable unijunction transistor (PUT) 133 may have a high internal resistance. However, when the voltage on its anode connection to the capacitor 131 becomes equal to the threshold voltage applied to its gate, a breakdown may occur in which the internal resistance may become very low, discharging the capacitor 131 through an electrode 137 into the load 135. A reference electrode 139 may provide a return path through the DC power supply 111 and the cathode of PUT 133 for current from the load. The PUT 133 may then revert to its off-state, allowing the capacitor 131 to recharge.

[0041] The stimulator 105 may be used as a cardiac pacemaker. In this case, the load 135 may be a heart muscle. The electrical pulse-generating device could instead be applied to other types of loads, such as other biological tissue for therapeutic effect, or to electrical component loads such as resistors and capacitors. The voltage dependent oscillator 113 may use a different circuit from the one illustrated in Fig. 1.

[0042] The capacitor 131 may accumulate charge at a low rate of current flow from the DC power supply 111 and then deliver the charge as a stimulus pulse without loading the DC power supply 111. The capacitor 131 may serve as a DC blocking capacitor. It may insure that equal amounts of charge flow first in one direction through the electrodes 137 and 139 and the load 135 as the capacitor 131 charges up. It may then provide an effective stimulation pulse in the opposite direction as the capacitor 131 discharges through the PUT 133. A net direct current flow through the electrodes in contact with body fluids may thus be avoided to prevent electrolytic damage to the electrodes and body tissue.

[0043] The rate of the output pulses may depend on the size of the charging resistor 129 (Rc) and the capacitor 131 (C). The charging of the capacitor 131 and the setting of the threshold voltage may require power, which may be supplied by the battery 121. As time goes on and the battery's charge is drained, the battery

voltage may decrease. This may result in a small but detectable change in the rate of output pulses as the internal voltage drops in the PUT 133 become a larger fraction of the battery supply voltage to the circuit.

[0044] In addition to the voltage dependent oscillator 113, the battery charging system may have other components in order to effectively monitor and control charging rate. The energy transmitter 101 may generate and transmit energy through a transmitting antenna 103. The energy may radiate through a medium towards a receiving antenna 109 of the stimulator 105. The energy generated and transmitted may be electromagnetic in nature as described below or, in addition or instead, may be other varieties of radiated energy, such as ultrasonic.

[0045] The signal from the receiving antenna 109 may provide power to the DC power supply 111. As shown in FIG. 1, the receiving antenna may be a coil 115 tuned with a capacitor 117 to resonate at a carrier frequency of the energy transmitter 101. The DC power supply 111 may include a diode 119 for half wave rectification. The frequency may be in any amount, such as 6.78MHz -- an Industrial-Scientific-Medical (ISM) band established by the Federal Communications Commission in which unlimited field strength may be radiated.

[0046] From Ohm's law, the total supply voltage powering voltage dependent oscillator 113 may be the sum of the voltage of the battery 121, plus the voltage induced by current flow through a resistance 123 that may be induced by energy received by the receiving antenna 109 and rectified by the diode 119. As described in more detail below, the resistance 123 may be a discrete electronic resistor or merely representative of the effective internal resistance of the battery 121 or a combination of the two.

[0047] Because the output pulse rate of stimulator 105 may depend on the total supply voltage available to it, information about the output pulse rate obtained at various times and under various conditions of operation and recharging can be used by the controller 107 to control the recharging process. The controller 107 may be a microcontroller, microprocessor, general purpose digital computer, logical gate array, or other suitable control technology. To compute the output pulse rate, the period of time between occurrences of electrical pulses may be measured and inverted. The pulse sensor 141 may

detect electrical energy of the pulses in the load 135 and translate it into a form recognizable by the downstream system. Examples of such a pulse sensor 141 are described below.

[0048] After the pulse sensor 141 detects the electrical pulses, the signal from the pulse sensor 141 may be conditioned by the pulse conditioner 143. Conditioning may include amplification, noise filtration, rectification, digitization, and/or other types of signal conditioning. The conditioned signal may be in digital format and fed into the controller 107. A rate calculator 145 in the controller 107 may compute the rate of the electrical pulses. That rate may be used in an algorithm 147 (implemented by computer hardware and optionally software) to infer the supply voltage in the stimulator 105 based on characteristic data 149 that is indicative of a relationship between pulse rate and supply voltage. The characteristic data 149 may be a table of pulse rates vs. voltage and/or a mathematical equation specifying the relationship. When a data table is used, values between data points in the table may be extrapolated.

[0049] Once the supply voltage is determined, the algorithm 147 in the controller 107 may decide whether the system should be in a charging mode or an idle mode and, if in charging mode, a level of modulation 153 to be applied to the energy transmitter 101.

[0050] A user interface 151 may include a display, keyboard, mouse, microphone, loudspeaker, and/or any other type of user interface device. The user interface 151 may allow users to interact with the controller 107, such as to provide information to the user about the state and effectiveness of the recharging process and/or to allow the user to control the process, such as to initiate or terminate the various steps and processes of monitoring and recharging.

[0051] Fig. 2A is an example of a calibration curve that relates supply voltages to output pulsing rates of a stimulator. Fig. 2B is an example of a monitor and recharge controller in which a pulse generator may be calibrated to obtain the calibration curve illustrated in Fig. 2A. Before complete assembly, the voltage dependent oscillator 113 may be connected temporarily to a load 135, such as through electronic probes. The electrical pulses picked up by the electronic probe may be fed into a pulse rate detector 203 and the time between beats and

therefore its inverse - instantaneous rate in beats per minute - can be measured as a function of calibrated supply voltages. A calibration controller 201 may be used to provide a controllable voltage source 205, which may be contained within controller 201 or a separate instrument connected to controller 201, and to record the pulse rate from the pulse rate detector 203 at various known DC voltages that are supplied by the controllable voltage source 205 to construct the characteristic curve illustrated in Fig. 2A. This calibration controller 201 may include a computer programmed to output various test voltages and to record the resulting pulse rates in an automated manner, or conventional instrumentation such as a variable DC power supply and an oscilloscope that may be operated manually.

[0052] Once the voltage-dependent oscillator 113 has been characterized, the measured rate of its output can be used to infer its voltage supply and to maintain its battery 121 within upper and lower limits, such as limits recommended by its manufacturer or known to be associated with its electrochemical processes. The upper limit may be used as a threshold during charging to discontinue the charging when reached. The lower limit may be used when reached as a trigger to begin charging. Typical voltage limits for a rechargeable lithium polymer battery that may be used in a pacemaker may be 3.3V as a minimum below which charging may begin and 4V as a maximum at which charging may be terminated. The recharging current may be at a rate of 1.5mA and may also be determined and maintained based on the detected pulse rate. Other battery chemistries may require different operating voltage and currents to avoid damaging the battery and/or to reduce the number of recharging cycles over which the battery may be operated.

[0053] FIG. 2A also illustrates how the rate of charge into the battery may be monitored. The supply voltage may be assessed when the charging system is active, such as at a data point 207, and again when the charging system is off, such as at a data point 209. The difference between the two supply voltages may occur because of the voltage drop induced in the resistance 123 in series with (or part of) the battery when recharging current is driven through the battery. The battery used in the electrical pulse-generating device may be charged at a 1mA rate and the internal resistance of the battery may be negligible. The resistance 123 in series with the battery may be a discrete resistor which may have a value

of between 100 to 200Ω in order to generate a voltage drop that can be accurately inferred from the change in output pulse rate. In the example illustrated in Fig. 2A, the data point 209 may be when the recharging transmitter is off and may be at a pulse rate of about 100BPM (beats per minute), and a corresponding supply voltage of about 3.2VDC. Data point 207 may point to a measured pulse rate when the recharging transmitter is on and may be at a rate of about 105BPM, and at a supply voltage of about 3.8VDC. If the resistance 123 is 200 ohms, then the voltage difference between the two data points of 0.6VDC implies that the recharging current is 3mA. This may exceed the recommended recharging rate and may indicate that energy transmitter 101 needs to be reduced in the strength of its transmission. Conversely, the charging rate may be unnecessarily too slow in which case the energy transmitter 101 may be increased in strength by the controller.

[0054] Several factors may affect the calibration data. Similarly designed oscillators may exhibit slightly different behavior depending on the exact electrical characteristics of each component. The ratio of the bias resistors (ratio of R1 to R2) may affect the curve in that a smaller ratio may yield a larger gate voltage and a larger proportion of the PUT offset voltage. This particular aspect may be used to benefit the feedback controller. By using a smaller ratio, such as 20% rather than 30% or 50%, the characteristic rate of pacing between different supply voltages may be more different and the calculation of the resulting supply voltage may be more accurate. Other factors that affect calibration data may include ambient light, temperature, and impedance of the load 135. Characterization data may be recorded for each implant during manufacture under known conditions to mitigate this variability. Correction factors can be computed empirically from calibration data or estimated from prior research to account for changes in operating temperature and impedance of the load 135 associated with different conditions of use, such as dry storage in a sterile package versus implantation in the human body.

[0055] Fig. 3 is an example process that may provide safe and complete recharging of a battery within a stimulator. The process may be implemented by an algorithm employed within the controller 107 whereby information about the

voltage and recharging current of the battery may be used to provide closed-loop control of an external source of power for the recharging process.

[0056] If the inferred recharge current is excessive for the ratings of the battery, then the field strength produced by the energy transmitter 101 and the transmitting antenna 103 may be reduced until the pulse rate is consistent with the desired recharging current. If the current is too low and the battery is charging too slowly, the field strength may be increased. If the maximum field strength is reached and the charging rate is still too slow, the controller 107 may prompt the user through the user interface 151 to adjust the position and/or orientation of the transmitting coil with respect to the implant to obtain better inductive coupling.

[0057] In FIG. 3, the algorithm may begin at a start step 301 whenever the controller 107 is turned on. This algorithm can be applied in multiple contexts, such as when the electrical pulse-generating device is fully or partially charged, implanted, in manufacture, or on the shelf in sterile packaging awaiting implantation as described in more detail below.

[0058] The energy carrier may remain off, as reflected by a carrier off step 303. until a pulse detector detects a pulse rate, as reflected by a detect rate step 305, and determines the existence of a pacing signal, as reflected by a "pacing signal?" decision step 307, completing the feedback loop. If pacing is detected, the system may assess whether the battery is fully charged, as reflected by a battery fully charged step 309, by using the relationship between pacing rates and supply voltages, as stored in the characteristic curve collected during a prior calibration process. If the battery is fully charged, the system may continue in an idle mode, which may continue to monitor the device and determine battery charge level from output pulse rate, as reflected by an idle mode and monitor step 311. If the battery is below or drops below a pre-set charge level, the algorithm may go into a charging mode and turn on the energy carrier, as reflected by a turn on carrier step 313. The charging rate may be calculated, as reflected by a calculate charge step 315, from the difference between the voltage supply before and after the carrier is turned on.

[0059] The algorithm may then decide if the rate of charge is within a predetermined amount of the pre-set rate of charge, such as 20%, as reflected by

a charge decision step 317. If so, the charge-delivery system may remain "on" for a set amount of time, here the time required for 120 output pulses, as reflected by a charge and monitor step 327. If at any time during this "on" mode the charging rate exceeds the preset limit, such as by 120%, the system may exit energy transmission mode and begin the algorithm again, as reflected by logic flow 319. In a pacemaker system such as illustrated in Fig. 1, this event may occur if the receiving antenna 109 or transmitting antenna 103 were to suddenly move to a position or orientation where the inductive coupling between them is stronger. Once the charging cycle has completed, the algorithm may proceed again to the start step 301.

[0060] In the event that the charge is not within the predetermined limit (e.g., 20%) during the decision step 317, the algorithm may check to ensure that the charge rate has not reached its maximum, as reflected by a decision step 321. If so, this may indicate that the charging coil is not transmitting energy or is too weakly coupled with the implant to achieve a desired recharging current. In this instance, the carrier may be turned off and the user may be told to adjust the coil, as reflected in a turn off and adjust coil step 325.

[0061] If the transmitting energy can still be elevated, the charge may be increased until it is within the acceptable level, e.g., about around ±20%, as reflected in an increase current charge step 323. Charging and monitoring may commence at this point, as reflected in a charge and monitor step 327, and the algorithm may proceed in the loop until the battery voltage increases beyond the fully charged level.

[0062] Fig. 4 is an example of components in an energy transmitter 101 and antenna 103. The energy transmitter 101 may interface with the controller 107 of the system via the modulation link 153. For a class E oscillator 405, the amount of energy transmitted to the transmitting antenna 103 may be modulated by changing the value of the DC voltage supplied through the modulation signal 153, as described in more detail below.

[0063] The energy transmitter 101 may include a Pierce gate oscillator 401 that may use a 6.78MHz crystal to generate a frequency for the ISM band in which it is desired to operate. The oscillator's signal may be buffered through a buffer

network 403 to generate enough current to drive an N-channel MOSFET 407 in the class E oscillator 405. The class E oscillator 405 may allow energy transmitter 101 to use resonance to further increase the power of the signal. This topology may minimize dissipative losses. The N-channel MOSFET 407 may be rated at 55V and 17A. The MOSFET 407 may be setup as a common source amplifier, and current may be drawn into the drain from the modulation signal 153 through an RF choke 409, which may have a value of 5.6µH. The class E amplifier may include capacitors 415, 411, and 417 and an inductor 413 to generate resonant frequencies and produce the equivalent of a 50 ohm resistive source impedance for efficient connection to the transmitting antenna 103, such as via a coaxial cable. Example values include 940pF, 568pF, 387pF, and 604nH, respectively.

[0064] The transmitting antenna 103 may use an electromagnetic radiating coil. It may include a balun 425 and capacitors 427 through 437 to provide tuning and impedance matching for the coil 439, which may have a center tap 441 to divide the peak voltage across the coil for safety. The coil may be realized by two turns of coaxial cable, thereby providing shielding to reduce radiation of electrostatic fields.

[0065] Fig. 5A is an example of a pacemaker connected to a load and a light emitting diode (LED). Fig. 5B is an example of the pacemaker interfacing with a monitor and recharge controller via the LED that directs light through the exterior of a sterile package.

[0066] The pacemaker may be interfaced with a monitor and recharge controller via an LED that directs light through the exterior of a sterile package. This configuration may be useful for maintaining the stimulator 105 near its fully-charged state while in a sterile pouch and awaiting implantation. As illustrated in Fig. 1, the DC power supply 111 may not be fully turned off, even when load 135 is disconnected from the output electrodes 137 and 139, because current may still flow through the bias resistors 125 and 127.

[0067] The length of time during which the stimulator 105 needs to be stored in a sterile condition prior to implantation may be unpredictable. Thus, it may be desirable to monitor and recharge the battery 121 within the stimulator 105 without penetrating a pouch 520 in which it may be sterilized and stored. The pouch 520

may include at least one translucent or transparent region 521. It may also include one or more non-transparent regions 523, as is common with Tyvek pouches commercially available for this purpose. The stimulator 103 may be housed in a tray 525 so that its electrical contacts 137 and 139 are touching metal contacts 527 that may be mounted on the tray 525, thus completing the circuit illustrated in Fig. 5A. Output current from stimulator 105 may pass through a load resistor 507 and a light emitting diode (LED) 509. During each stimulation pulse from stimulator 105, a pulse of light 529 emitted from the LED 509 may pass through the transparent region 521 of the pouch 520 towards a light detector 511, which may be a photodiode, on the outside of the pouch 520, which may use a power source 513 to generate an electrical signal from the optical signal. The electrical signal may be amplified by an amplifier 515, processed through a Schmitt Trigger 517, and processed by the rate calculator 145 of the controller 107. All of the components now illustrated in Fig. 5B, together with the transmitting antenna 103, may be held in a fixture to assure their physical alignment (not illustrated). The physical alignment may include positioning the light detector 511 so as to pick up light from the LED 529, and positioning the transmitting antenna 103 so as to have adequate coupling with the receiving antenna 109 of the stimulator 105.

[0068] Fig. 6 is an example of an implanted pacemaker interfacing with a monitor and recharge controller using ECG skin electrodes. FIG. 6 may be useful when the stimulator 105 is implanted and in contact with biological bodily tissue 609, which may serve as a load 603. An electric field 611 created by output pulses from the stimulator 105 may radiate towards the surface of the tissue 609 and be picked up by surface skin electrodes 613, such as are commonly used for electrocardiographical (ECG) recordings. The signal from the electrodes 613 may be filtered by a filter 615 to eliminate noise from adjacent equipment, as well as noise generated from the energy transmitter 101 and the transmitting antenna 103.

[0069] The clean signal may be amplified with an instrumentation amplifier 617 and rectified by a rectifier 619. An optical isolator 621 may isolate the patient from downstream electronics and main power. The signal may be processed through a Schmitt trigger 623 to convert it into the digital realm and may enter the rate calculator 145 of the controller 107.

[0070] In this mode, the transmitting antenna 103 may be positioned so as to achieve adequate coupling with the receiving antenna 109 in the implanted stimulator 105. In the case of a fetal cardiac pacemaker, this may require the transmitting antenna 103 to be placed over, along, or around the abdomen of the mother and oriented so that its axis is coaxial with the receiving antenna 109 to the degree feasible. This may maximize the coupling of the system and minimize energy loss to the surrounding environment. A desired orientation could be determined using ultrasonic or other non-invasive imaging of the implanted stimulator 105 or a trial and error method based on the strength of the transmitted energy required to achieve the desired rate of charging in the implanted stimulator 105.

[0071] The computers that have been mentioned are implemented with a computer system configured to perform the functions that have been described herein for the component. Each computer system includes one or more processors, tangible memories (e.g., random access memories (RAMs), read-only memories (ROMs), and/or programmable read only memories (PROMS)), tangible storage devices (e.g., hard disk drives, CD/DVD drives, and/or flash memories), system buses, video processing components, network communication components, input/output ports, and/or user interface devices (e.g., keyboards, pointing devices, displays, microphones, sound reproduction systems, and/or touch screens).

[0072] Each computer system may be a desktop computer or a portable computer, such as a laptop computer, a notebook computer, a tablet computer, a PDA, a smartphone, or part of a larger system.

[0073] Each computer system may include one or more computers at the same or different locations. When at different locations, the computers may be configured to communicate with one another through a wired and/or wireless network communication system.

[0074] Each computer system may include software (e.g., one or more operating systems, device drivers, application programs, and/or communication programs). When software is included, the software includes programming instructions and may include associated data and libraries. When included, the

programming instructions are configured to implement one or more algorithms that implement one or more of the functions of the computer system, as recited herein. The description of each function that is performed by each computer system also constitutes a description of the algorithm(s) that performs that function.

[0075] The software may be stored on or in one or more non-transitory, tangible storage devices, such as one or more hard disk drives, CDs, DVDs, and/or flash memories. The software may be in source code and/or object code format. Associated data may be stored in any type of volatile and/or non-volatile memory. The software may be loaded into a non-transitory memory and executed by one or more processors.

[0076] The components, steps, features, objects, benefits, and advantages that have been discussed are merely illustrative. None of them, nor the discussions relating to them, are intended to limit the scope of protection in any way. Numerous other embodiments are also contemplated. These include embodiments that have fewer, additional, and/or different components, steps, features, objects, benefits, and advantages. These also include embodiments in which the components and/or steps are arranged and/or ordered differently.

[0077] For example, there might be a more complex stimulator whose nominal pacing rate or stimulus amplitude can be turned off or adjusted, while the nominal rate may be at least weakly modulated by the supply voltage, and the stimulus amplitude may generate a detectable pulse for computation of actual stimulus rate.

[0078] Unless otherwise stated, all measurements, values, ratings, positions, magnitudes, sizes, and other specifications that are set forth in this specification, including in the claims that follow, are approximate, not exact. They are intended to have a reasonable range that is consistent with the functions to which they relate and with what is customary in the art to which they pertain.

[0079] All articles, patents, patent applications, and other publications that have been cited in this disclosure are incorporated herein by reference.

[0080] The phrase "means for" when used in a claim is intended to and should be interpreted to embrace the corresponding structures and materials that have been described and their equivalents. Similarly, the phrase "step for" when used in

a claim is intended to and should be interpreted to embrace the corresponding acts that have been described and their equivalents. The absence of these phrases from a claim means that the claim is not intended to and should not be interpreted to be limited to these corresponding structures, materials, or acts, or to their equivalents.

[0081] The scope of protection is limited solely by the claims that now follow. That scope is intended and should be interpreted to be as broad as is consistent with the ordinary meaning of the language that is used in the claims when interpreted in light of this specification and the prosecution history that follows, except where specific meanings have been set forth, and to encompass all structural and functional equivalents.

[0082] Relational terms such as "first" and "second" and the like may be used solely to distinguish one entity or action from another, without necessarily requiring or implying any actual relationship or order between them. The terms "comprises," "comprising," and any other variation thereof when used in connection with a list of elements in the specification or claims are intended to indicate that the list is not exclusive and that other elements may be included. Similarly, an element preceded by an "a" or an "an" does not, without further constraints, preclude the existence of additional elements of the identical type.

[0083] None of the claims are intended to embrace subject matter that fails to satisfy the requirement of Sections 101, 102, or 103 of the Patent Act, nor should they be interpreted in such a way. Any unintended coverage of such subject matter is hereby disclaimed. Except as just stated in this paragraph, nothing that has been stated or illustrated is intended or should be interpreted to cause a dedication of any component, step, feature, object, benefit, advantage, or equivalent to the public, regardless of whether it is or is not recited in the claims.

[0084] The abstract is provided to help the reader quickly ascertain the nature of the technical disclosure. It is submitted with the understanding that it will not be used to interpret or limit the scope or meaning of the claims. In addition, various features in the foregoing detailed description are grouped together in various embodiments to streamline the disclosure. This method of disclosure should not be interpreted as requiring claimed embodiments to require more features than

are expressly recited in each claim. Rather, as the following claims reflect, inventive subject matter lies in less than all features of a single disclosed embodiment. Thus, the following claims are hereby incorporated into the detailed description, with each claim standing on its own as separately claimed subject matter.

CLAIMS

The invention claimed is:

1. A battery charging system for charging a battery contained in an electrical pulse-generating device that generates electrical pulses at a rate that is dependent upon the level of charge in the battery, the battery charging system comprising:

a charge-delivery system having a configuration that delivers charge to the battery at a controllable rate;

a pulse detector having a configuration that detects the rate of the electrical pulses that are being generated by the electrical pulse-generating device while the battery is being charged; and

a controller having a configuration that controls the rate at which the chargedelivery system delivers the charge to the battery based on the rate of the electrical pulses detected by the pulse detector.

- 2. The battery charging system of claim 1 wherein the controller causes the charge delivery system to deliver charge to the battery at a first rate and at a second rate that is different from the first rate.
 - 3. The battery charging system of claim 2 wherein the second rate is zero.
- 4. The battery charging system of claim 2 wherein the controller has a configuration that determines a rate of charge delivery based on the difference between the rate of the electrical pulses at the first and the second rates of charge delivery and information indicative of an internal resistance of the battery or a resistance in series with the battery.
- 5. The battery charging system of claim 2 wherein the controller includes information indicative of a relationship between the rate of the electrical pulses and the level of charge in the battery.
- 6. The battery charging system of claim 1 wherein the controller has a configuration that:

during the delivery of charge to the battery by the charge-delivery system, determines when the rate of the electrical pulses that are detected by the pulse detector have reached a threshold; and

causes the charge-delivery system to cease delivering charge to the battery when the threshold has been determined to have been reached.

- 7. The battery charging system of claim 1 wherein the controller has a configuration that controls the rate at which the charge-delivery system delivers the charge to the battery in discrete, discontinuous steps.
- 8. The battery charging system of claim 1 wherein the electrical pulse generating device includes an LED that flashes in synchronism with the electrical pulses and wherein the pulse detector includes a light detector having a configuration that detects the LED when flashing.
- 9. The battery charging system of claim 1 wherein the electrical pulse generating device is a pacemaker.
- 10. The battery charging system of claim 8 wherein the pulse detector includes electrodes configured to be attached to skin of a patient in which the pacemaker has been implanted.
- 11. The battery charging system of claim 1 wherein the charge-delivery system includes an electromagnetic radiating coil that has a configuration that delivers the charge to the battery without an electrical connection to the battery.
- 12. A battery charging system for charging a battery contained in an electrical pulse-generating device that generates electrical pulses at a rate that is dependent upon the level of charge in the battery, the battery charging system comprising:
 - a charge-delivery system having a configuration that transmits electrical energy to the battery at controllable rates;
 - a pulse detector having a configuration that detects the rate of the electrical pulses that are being generated by the electrical pulse-generating device while the battery is being charged; and
 - a controller having a configuration that:

determines when the rate of the electrical pulses that are detected by the pulse detector during the delivery of charge to the battery by the charge-delivery system have reach a threshold; and

causes the charge-delivery system to cease delivering charge to the battery when the threshold rate has been determined to have been reached.

13. A calibration system for an electrical pulse-generating device that generates electrical pulses at a rate that is dependent upon a supplied voltage, the calibration system comprising:

a controllable voltage source that has a configuration that provides the supplied voltage;

a pulse rate detector having a configuration that detects the rate of the electrical pulses that are being generated by the electrical pulse-generating device in response to the supplied voltage;

a calibration controller having a configuration that causes the controllable voltage source to supply multiple supplied voltages at different levels and records the pulse rates of the electrical pulse-generating device in response to each; and

a data computation system that has a configuration that computes information indicative of a mathematical relationship between changes in the pulse rate and the voltage applied to the electrical pulse generating device.

- 14. The calibration system of claim 13 wherein the data computation system has a configuration that causes the computed information to be stored in association with information that identifies the electrical pulse generating device and distinguishes it from other electrical pulse generating devices of the same type that have a different mathematical relationship between changes in their pulse rate and the amount of charge that is being delivered to their battery.
- 15. The calibration system of claim 14 wherein each electrical pulse generating device has a unique serial number or code and wherein the information that identifies each electrical pulse generating device is its unique serial number or code.

16. A pacemaker for generating electrical pulses comprising:

a battery;

a pulse generating circuit having a configuration that generates the electrical pulses at a rate that is dependent upon the level of charge in the battery; an electrical connection between the pulse generating circuit and the battery; and a resistor in series with the electrical connection between the pulse generating circuit and the battery,

the pacemaker not having any circuit that measures or detects the voltage across the resistor.

17. A packaged pacemaker comprising:

a pacemaker having a configuration that generates electrical pulses, the pacemaker including a battery, a pulse generating circuit that has a configuration that generates the electrical pulses at a rate that is dependent upon the level of charge in the battery, and electrodes that have a configuration that delivers the electrical pulses to neighboring tissue when the pacemaker is placed in contact with the neighboring tissue;

a light emitting diode in detachable electrical contact with the electrodes; and a removable sealed housing that houses the pacemaker and light emitting diode, the removable sealed housing including a translucent portion positioned with respect to the light emitting diode so as to allow light that is emitted by the light emitting diode to be seen outside of the removable sealed housing.

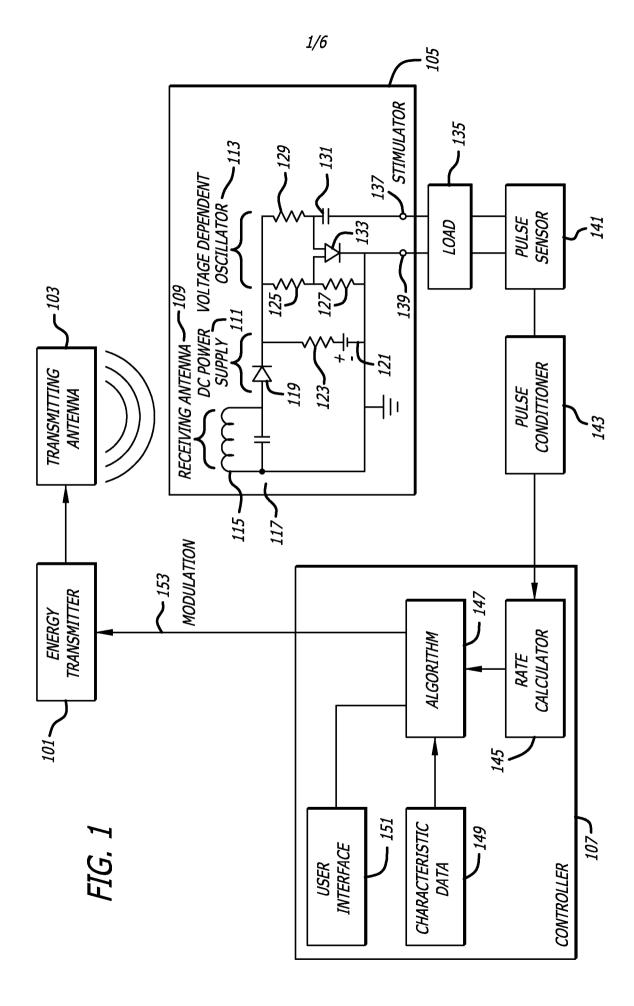


FIG. 2A

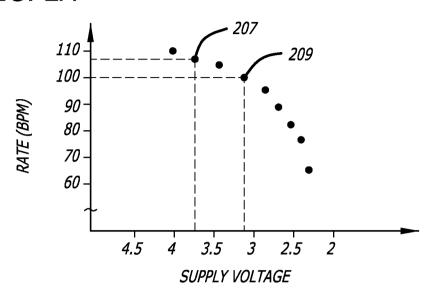
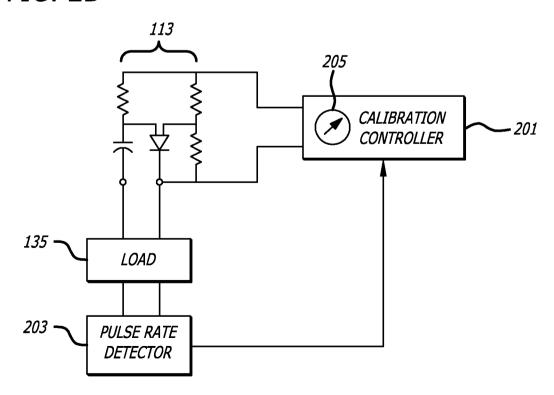


FIG. 2B



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