

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
5 February 2009 (05.02.2009)

PCT

(10) International Publication Number
WO 2009/018535 A1

(51) International Patent Classification:
A61N 1/39 (2006.01) A61N 1/378 (2006.01)

(21) International Application Number:
PCT/US2008/071976

(22) International Filing Date: 1 August 2008 (01.08.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
11/833,163 2 August 2007 (02.08.2007) US

(71) Applicant (for all designated States except US):
CAMERON HEALTH, INC. [US/US]; 905 Calle
Amanecer, Suite 300, San Clemente, CA 92673 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **SIGNOFF, David, M.** [US/US]; 120 Cristianitos Road, No. 13203, San Clemente, CA 92673 (US). **JULIAN, Marcus, F.** [US/US]; 34011 Amber Lantern, Unit A, Dana Point, CA 92629 (US).

(74) Agent: **PRAMUDJI, Ari**; Pramudji, Wendt, and Tran,
1800 Bering Drive, Suite 540, Houston, TX 77057 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:

— as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))

[Continued on next page]

(54) Title: MULTIPLE BATTERY CONFIGURATIONS IN AN IMPLANTABLE MEDICAL DEVICE

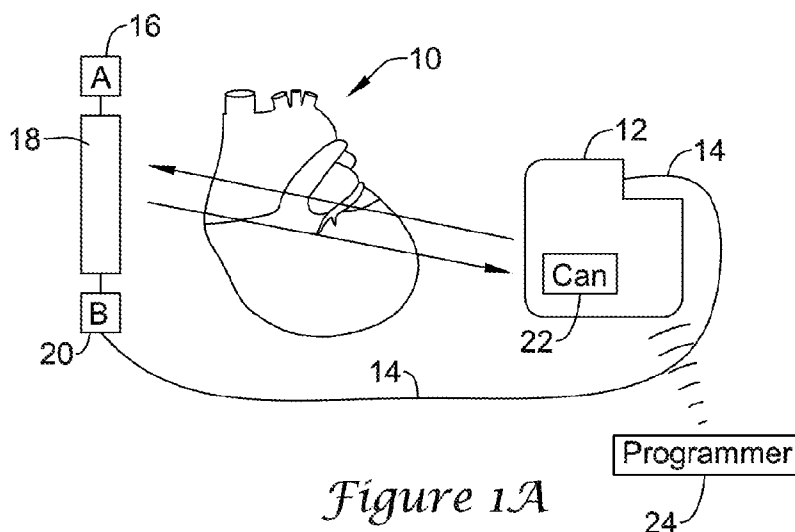


Figure 1A

(57) Abstract: Implantable medical device power circuits are disclosed. Multiple batteries may be provided, along with a number of switches, enabling a plurality of battery and power circuit configurations to be defined. Configurations of the power circuit may be changed in response to changes in battery status as the batteries are used and/or near end-of-life. Configurations of the power circuit may also be performed in response to changes in device operation. Methods associated with operating such circuits and implantable medical devices are also disclosed.

WO 2009/018535 A1



Published:

- *with international search report*
- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

Multiple Battery Configurations in an Implantable Medical Device**Field**

[0001] The present invention is related to the field of implantable medical devices. More particularly, the present invention relates to electric power supply systems in implantable medical devices.

Background

[0002] Some implantable medical device operations require both low-power and high-power functions. An example is an implantable cardioverter-defibrillator (ICD). An ICD monitors cardiac function in a patient using implanted electrodes that capture electrical signals generated by the heart. This monitoring function requires the operation of low power control and analysis circuitry which may include, for example, amplifiers, filters, analog-to-digital converting hardware and/or a microcontroller. The low power circuitry will use currents in the range of microamps at voltages that have been decreasing with improvements in digital and analog circuitry.

[0003] In an ICD, monitoring is performed in part to determine whether a malignant arrhythmia is occurring in a patient's heart. If a malignant arrhythmia is identified, high power circuitry is used to build up and then release a large amplitude stimulus to the patient. Such a stimulus may have a voltage of hundreds or even thousands of volts, with total power ranging from less than a Joule up to 80 or more Joules.

[0004] A challenge in designing an implantable medical device (IMD) is to find power supply circuitry which can meet the low and high power needs of the device. The simplest approach is to use a single battery. However, challenges arise because available batteries often come in one of two forms: batteries capable of delivering large currents (i.e., high power outputs) but lacking optimal energy density, and batteries having high energy density but which encounter large internal impedances at high currents. One approach could be to provide separate low and high power sources using separate batteries, one having high current output capacity and one having high energy density. However, using separate batteries would cause the device to be disabled as soon as one of the batteries reaches its end-of-life. Alternative solutions are desired.

Summary

[0005] The present invention, in an illustrative embodiment, includes an implantable medical device comprising at least first and second batteries and switching circuitry associated with the first and second batteries. In an illustrative example, a plurality of configurations are provided by the switching circuitry such that, in a first configuration, the batteries operate in parallel with anodes and cathodes coupled together, equalizing voltage output; in a second configuration, the batteries operate in series with the anode of one battery coupled to the cathode of the other battery such that low and high power outputs may be taken from the nodes at each of the anodes; in a third

configuration, the batteries are isolated from one another. More than two batteries may be used. Some embodiments include configurations in which one or more batteries may be entirely excluded from operation, if so desired, for example, after it is determined that a battery is near its effective end-of-life. Additional illustrative embodiments include methods associated with such devices. In another embodiment, the configuration of a power circuit in an implantable medical device is selected in response to changes in device state or operation.

Brief Description of the Drawings

[0006] FIGS. 1A-1B show respective subcutaneous and transvenous implantable cardiac stimulus systems;

[0007] FIG. 2 is a functional block diagram for an illustrative implantable medical device;

[0008] FIG. 3 is a schematic for an illustrative embodiment;

[0009] FIGS. 4A-4C show the illustrative embodiment of FIG. 3 in three configurations;

[0010] FIG. 5 is an illustrative embodiment having three batteries;

[0011] FIG. 6 is an illustrative embodiment having four batteries;

[0012] FIGS. 7A-7C show the illustrative embodiment of FIG. 6 in three configurations; and

[0013] FIG. 7D shows an alternative construction and configuration for the embodiment of FIG. 6; and

[0014] FIG. 8 is a process flow diagram showing an illustrative method.

Detailed Description

[0015] The following detailed description should be read with reference to the drawings. The drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention.

[0016] FIGS. 1A-1B, respectively, show subcutaneous and transvenous implanted cardiac stimulus systems relative to a patient's heart. Referring to FIG. 1A, the heart 10 is shown in relation to an implanted, subcutaneous cardiac stimulus system including a canister 12. A lead 14 is secured to canister 12 and includes sensing electrode A 16, a coil electrode 18, and sensing electrode B 20. A can electrode 22 is shown on the canister 12. Other electrode configurations may be used. An alternative subcutaneous system uses a flexible unitary housing rather than a can 12, with or without

a lead. Illustrative subcutaneous systems are shown in US Patent Numbers 6,647,292 and 6,721,597, and the disclosures of these patents are incorporated herein by reference.

[0017] A vector for delivering cardiac stimulus is defined between the can electrode 22 and the coil electrode 18. Other vectors for stimulus delivery may be defined depending upon the internal circuitry of the device, different lead designs, and/or the size and shape of electrodes A and B 16, 20, which may also be used for stimulus delivery if so suited. The stimulus vector is illustrated as having two polarities. In addition, although not shown, a number of sensing vectors are defined, for example, using combinations of electrode A 16, electrode B 20, can electrode 22, and/or, if desired, coil electrode 18.

[0018] Referring now to FIG. 1B, a transvenous system is shown relative to a patient's heart 30. The transvenous cardiac stimulus system includes a canister 32 connected to a lead 34. The lead 34 resides partly within the patient's vasculature, enters the patient's heart, and includes sensing electrodes A 36 and B 38. Stimulus electrodes are shown at 50, 52. The lead 34 may be anchored into the patient's myocardium. Again, a can electrode 40 is shown on the canister 32. With this system, plural sensing and stimulus delivery vectors may be defined. The embodiment shown includes two stimulus delivery vectors each having two polarities, that is, stimulus vectors between electrodes 50 and 52 and between electrodes 40 and 50. A third stimulus vector may also be defined between electrodes 40 and 52, although this is not shown in the illustration. Other lead and electrode configurations may also be used.

[0019] Each of the devices 12, 32 may further include such components as would be appropriate for communication (such as RF communication, inductive telemetry or other suitable communication linkage) with an external device such as a programmer. To this end, programmers 24 (FIG. 1A) and 42 (FIG. 1B) are also shown. For example, during an implantation procedure, once the implantable device 12, 32 and leads (if included) are placed, the programmer 24, 42 may be used to activate the implanted device 12, 32, and/or direct/observe diagnostic or operational tests. After implantation, the programmer 24, 42 may be used to non-invasively determine the status and history of the implanted device. The programmers 24, 42 in combination with the implanted devices 12, 32 may also allow annunciation of statistics, errors, history and potential problems to the user/medical practitioner, and may also allow for updating of programming in the implanted devices 12, 32.

[0020] The systems shown in FIGS. 1A-1B are merely illustrative. The present invention may be embodied in virtually any implantable system. For example, it may be embodied in transvenous or subcutaneous systems such as those shown in FIGS. 1A-1B, as well as hybrid systems combining features of both. Additionally, the present invention may also be embodied in fully intravascular systems modeled on those shown in US Patent Application Publication Number 2006/0224225A1 to Ransbury et al. Although explained in the context of a cardiac stimulus system, the present invention

may also be embodied in other implantable medical systems directed toward other portions of the anatomy.

[0021] FIG. 2 is a functional block diagram for an illustrative implantable cardiac stimulus device. In the illustrative example, operational circuitry for an implantable cardiac stimulus device is shown at 100, a patient is shown both at 102a and 102b. It should be understood that this is the same patient in both instances 102a, 102b, but the coupling electrodes may be different for each. For example, shock delivery electrodes may be separate or different from sensing electrodes, although this need not always be the case.

[0022] The operational circuitry includes a control block 104, which may take any suitable or conventional form. Microcontrollers are one class of device that may be used in control block 104, although in addition to or as a replacement for a microcontroller, there may be various logic and other devices or subcircuits. The control block 104 may access a memory 108, which may take various forms including RAM, ROM, Flash memory, or any other suitable form (optical, electrical, magnetic, etc.) for temporarily or permanently storing information and/or instruction sets. The control block 104 is configured and connected to other circuitry within the device such that it can direct operations associated with methods of practicing some illustrative embodiments of the present invention. A battery block 106 is also shown. The battery block 106 is more fully explained below.

[0023] The operational circuitry 100 may also include telemetry 110, which may include such drivers, mixers, antenna(s), amplifiers and the like as are known for use in communications circuitry. The telemetry 110 is used to communicate with a programmer, such as programmers 24, 42 shown in FIGS. 1A-1B.

[0024] Signal capture block 112 includes amplifying and filtering circuitry which may take any form suitable for use in an implantable cardiac stimulus device for observing cardiac function. Signal capture block 112 may also include sampling and analog-to-digital devices, as well as local registers, memory or the like for temporarily storing captured information.

[0025] Generally speaking, the control block 104 uses the signal capture block 112 to capture data from the patient 102a. In response to instructions from telemetry 110 and/or instructions or data stored in memory 108, the control block 104 may analyze data from the signal capture block 112 to determine whether the patient 102a/b is in need of stimulus. If so, the control block 104 calls on the charger 114 to charge energy storage 116, which may include one or more capacitors in any suitable configuration. As is known to those of skill in the art, the charger 114 is used to step up the voltage from the battery 106 (typically less than 10 volts) to a higher level (up to several hundred or even several thousand volts) for use in cardioversion or defibrillation. In order to achieve sufficient energy

storage, the charger 114 typically draws significantly larger currents than other portions of the operational circuitry 100.

[0026] The control block 104 and/or the charger 114 may monitor the voltage level on the energy storage 116 during charging to determine whether and when sufficient stimulus energy has been stored. Once enough energy is stored at energy storage 116 for stimulus delivery, the control block 104 manipulates output circuitry 118, which may include, for example, a plurality of switches and/or an H-bridge configuration, in order to deliver the stored energy to the patient 102b. An H-bridge is shown, for example, in US Patent Numbers 6,865,417 and 6,952,608. In other medical devices, there may be output circuitry, such as transducers (such as sonic drivers for phoresis delivery of a drug), pumps, etc., that take the place of the illustrative subcircuits shown at 114, 116 and 118 in FIG. 2.

[0027] In the illustration, the battery block 106 is shown as providing a Low Power portion 106A, which powers the control block 104, telemetry 110, and signal capture block 112. For illustrative purposes, not all connections are shown. The battery block 106 also includes a High Power portion 106B, which is used to power a charger 114.

[0028] In an illustrative example, the control block 104 can manipulate the duration and format of the applied stimulus by controlling the output circuitry 118, for example, controlling whether the applied waveform is monophasic or biphasic, and also controlling the amplitude and polarity. It is typical for the amplitude of the applied voltage to drop during its application as the energy storage 116 (typically a bank of capacitors) discharges energy. The change in output amplitude during an applied pulse is sometimes referred to as "tilt," a ratio of the final voltage to the initial voltage. Constant current stimuli may also be applied.

[0029] FIG. 3 is a schematic for an illustrative embodiment of a power system. The illustrative embodiment includes a high output battery Bh, shown at 200, and a low output battery Bl, shown at 202. The batteries 200, 202 are coupled to high and low outputs shown, respectively, at P_High and P_Low, which are taken with respect to a common ground, as shown. Three switches 210, 212, and 214 selectively couple the batteries 200, 202 to the outputs, ground, and each other. An optional attenuating resistor is shown at 220.

[0030] The switches 210, 212, 214 may take any suitable form, including for example, MOSFET, JFET and/or BJT electrical devices. Other devices, such as relays and/or silicon controlled rectifiers, may also be used. It should be understood that control wires for these switches 210, 212, 214 have been omitted from the Figures for simplicity.

[0031] As shown, switch 212 selectively couples the positive terminal + of the low output battery BI 202 to the negative terminal – of the high output battery Bh 200. Switch 214 selectively couples the negative terminal of the high output battery Bh 200 to ground. The positive terminal of the high output battery Bh 200 is directly coupled to a P_High output of the battery subcircuit, while the positive terminal of the low output battery BI 202 is directly coupled to a P_Low output of the battery subcircuit. The operation of the switches to provide multiple configurations is further illustrated below by reference to FIGS. 4A-4C.

[0032] In an illustrative example, P_High is used to power high current portions of the implantable device circuitry, and P_Low is used to power low current portions of the implantable device circuitry. For example, in an ICD, P_High is used to power charging circuitry that quickly stores up energy on power capacitors for delivering as a defibrillation pulse, while P_Low can power the control circuitry. In another illustrative example, P_High is element 106B in FIG. 2, while P_Low is element 106A in FIG. 2.

[0033] In an illustrative example, the batteries 200 and 202 may differ in chemistry and/or structure such that each has distinct characteristics. For example, the low output battery 202 may be a battery having relatively higher internal impedance than the high output battery 200, but higher energy density, making the low output battery 202 well suited to providing power for long-term operation of control and monitoring circuitry, while the high output battery 200, with the lower internal impedance, would be better suited to powering high current applications such as charging a high power capacitor for use in delivering large stimulus. In an alternative embodiment, the batteries 200, 202 may be of the same construction as one another.

[0034] FIGS. 4A-4C show the illustrative embodiment of FIG. 3 in three configurations. In FIG. 4A, switch 212 is closed, while switches 210 and 214 are open. This couples the positive terminal + of the low output battery 202 to the negative terminal – of the high output battery 200, placing the batteries 200, 202 in series. The output of the series is at P_High, and an output is taken between the batteries 200, 202, as P_Low. The illustration to the right of the drawing shows this simplified circuit. The voltage at P_High will be the sum of the voltages across the batteries 200, 202, which in turn reduces the equivalent current draw at P_High during high power output, since less current is drawn to produce the same power output at this summed voltage.

[0035] In FIG. 4B, switch 212 is left open, while switches 214 and 210 are closed. As shown to the right, this configuration places P_High and P_Low in parallel connection with one another across the optional resistor 220, which may be omitted if desired. This configuration allows either battery 200, 202 to make up for a deficiency of the other battery. The optional resistor 220 can be used to prevent shorting of one battery 200/202 to the other 202/200, for example, if the batteries 200, 202

have different output voltages. Alternatively, the optional resistor 220 may be omitted to prevent attenuation of energy within the circuit.

[0036] In an alternative configuration, an additional switch may be placed between the negative terminal of the low output battery 202 and ground. This switch may be opened to remove the low output battery 202 from the circuit entirely, which may be desired if the low output battery 202 reaches or nears its end-of-life. Then all circuitry would be powered from the other battery. Conversely, the configuration of FIG. 4B may be modified to open switch 214, removing the high output battery 200 from the circuit entirely, since the negative terminal of the high output battery 200 would then be left floating. This would allow the low output battery 202 to power the entire device in the event that the high output battery 200 reaches or nears its end-of-life. In some embodiments, each battery may be individually tested to determine whether either is at or near its end-of-life, for example, by monitoring changes in internal impedance, loaded voltage, or open circuit voltage.

[0037] In some illustrative examples, battery status may be measured by one or more of the following methods. An illustrative method may include coupling a battery output to a high impedance input to an analog-to-digital converter to check open circuit voltage. Another illustrative method may include measuring a voltage across a resistor, to check loaded voltage of the battery. If both such measurements are taken, yielding V_{Open} and V_{Loaded} , and the resistor size is known, the internal impedance of a battery may be identified by noting that the resistor and the internal resistance of the battery form a voltage divider, with:

$$V_{Open} = V_{Loaded} \times \frac{R_{Load} + R_{Internal}}{R_{Load}}$$

Solving for the internal resistance:

$$R_{Internal} = R_{Load} \times \left(\frac{V_{Open}}{V_{Loaded}} - 1 \right)$$

Another method of measuring battery status is disclosed in copending US Patent Application Number 11/487,103, entitled END OF LIFE BATTERY TESTING IN AN IMPLANTABLE MEDICAL DEVICE, filed on July 14, 2006, the disclosure of which is incorporated herein by reference. Any of these methods and metrics (open circuit voltage, loaded voltage, and internal impedance or resistance) may be used to determine battery status and estimate the end-of-life (EOL) for a battery. Additional methods, devices and sub-circuits for testing any of these metrics, or other metrics indicating battery status, are known in the art as well. Battery status may be annunciated to an associated programmer when queried or whenever a battery nears EOL. If EOL approaches or occurs, the device may notify an implantee, as is known in the art.

[0038] In yet another embodiment, a switch is supplied between the positive terminal of the low output battery 202 and the P_Low output, with the configuration of FIG. 4A being used. In this

manner, the two batteries 200, 202 can be used in series to supply power for both the P_High and P_Low outputs; this may be desired when either or both batteries are near end of life. While it is likely best that a patient seek medical attention, likely including explant and replacement of the device, when end of life for either or both batteries is near, the device itself, as implanted, can be configured to maximize the available battery power even if the patient delays in obtaining medical attention.

[0039] FIG. 4C demonstrates yet another configuration. Here, switches 210 and 212 are left open, isolating the batteries from one another. The result is that the P_High output is provided exclusively by the high output battery 200, and the P_Low output is provided exclusively by the low output battery 202.

[0040] Usage of these configurations may be programmed into a device. The configuration of FIG. 4C may be used, in this example, as a default or standard configuration during ordinary operation of an implantable medical device (IMD) such as an ICD. If the ICD is also equipped to provide a pacing output, the configuration of FIG. 4C may be used during pacing, with P_High and hence only the high output battery 200 used to provide pacing output energy, while P_Low and hence only the low output battery 202 used to power associated control circuitry. If a defibrillation or cardioversion stimulus is used, either the configuration of FIG. 4C or the configuration of FIG. 4A may be used. In one example, the power supply switches are adjusted to the configuration of FIG. 4A in the event that a high voltage pulse charge fails to build on associated capacitors within a predetermined period of time. In another example, the configuration of FIG. 4A is used when multiple large amplitude stimuli are needed within a short period of time. In yet another example, an ICD is configured to provide defibrillation pulses having increasing amplitudes (i.e., 5 Joules, 10 Joules, 15 Joules, etc.), and the configuration of FIG. 4C is used for lesser amplitudes, while the configuration of FIG. 4A is used for greater amplitudes. The configuration of FIG. 4B may be used near the end of life of the low output battery 202.

[0041] FIG. 5 is an illustrative embodiment of a power system 250 having three batteries. In the illustrative embodiment, batteries R, S, and T are shown coupled together with a plurality of switches 252, 254, 256, 258, 260, 262. It can be seen, when compared to FIG. 3, that the embodiment of FIG. 5 is similar except that a module of battery R and switches 258, 260, 262 has been added.

[0042] The following chart is illustrative of operation:

Configuration	252	254	256	258	260	262	P_High	P_Low
1	O	X	O	O	X	O	R+S+T	T
2	X	O	X	X	O	X	R=S=T	R=S=T
3	X	O	O	X	O	X	R+T	T
4	O	X	O	X	O	O	S+T	T
5	O	O	X	O	X	O	R+S	T

Additional configurations can be added as well. Configuration 1 allows all three batteries to contribute during a high power output time period. Configuration 2 allows each battery to contribute to high and low power output, for example, to compensate for one of the batteries being at or near its end-of-life. Configuration 3 allows a battery, in this case, battery S, to be isolated, while configuration 4 allows a different battery, in this case, battery R, to be isolated. Configuration 5 separates the functions of the batteries completely such that two batteries are dedicated to only high power output P_High while the third battery is dedicated to only the low power output P_Low.

[0043] Those of skill in the art will recognize that the pattern and configuration in FIG. 5 can be expanded using $3(N-1)$ switches to couple N batteries together. Those of skill in the art will also recognize that an additional switch may be provided at one of locations 270, 272 to allow isolation of battery T in a manner analogous to configurations 3 and 4 shown above. An example includes another switch at location 272: switches 256 and 260 would be closed such that $P_High = S + R$, and switch 252 is closed such that $P_Low = S$, while switches 254, 258, 262 and 272 are opened, with switches 254 and 272 isolating battery T, and switches 258 and 262 being opened to allow series operation of batteries S and R for output P_High.

[0044] FIG. 6 is an illustrative embodiment of a power system having four batteries. The embodiment in FIG. 6 includes yet another "module" comprising battery W and switches 314, 316, 318, as compared to FIG. 5. Batteries W, X, Y and Z are shown and coupled together. Switches 304, 310 and 316 selectively couple battery pairs in series with positive terminals coupled to negative terminals for battery pairs Z/Y, Y/X, and X/W, respectively. Switches 306, 312, 318 selectively couple the negative terminals of batteries Y, X and W, respectively, to ground. Switches 302, 308 and 314 selectively couple positive terminals of pairs of batteries together, with switch 302 between batteries Z/Y, switch 308 between batteries Y/X, and switch 314 between batteries X/W. Again, an optional resistor is shown at 320. The interconnections of the batteries W, X, Y, Z and switches 302, 304, 306, 308, 310, 312, 314, 316 and 318 form a power system.

[0045] FIGS. 7A-7C show the illustrative embodiment of FIG. 6 in three configurations. In FIG. 7A, all of the batteries are connected in parallel with one another by having switches 302, 306, 308, 312, 314 and 318 closed. In FIG. 7B, P_Low is taken from battery Z only by opening switch 302, and the P_High is taken from the series combination of batteries W, X, Y, and Z by closing switches 304, 310 and 316, while leaving other switches open, as shown. FIG. 7C shows a configuration in which one battery (battery X) is excluded from the circuit as indicated at 330, which may be necessary if one of the batteries becomes depleted faster than other batteries; alternatively, this may simply be a configuration deliberately chosen for other design purposes. Battery X is excluded by closing switches 304, 308 and 316 and opening switches 310, 312, thereby routing current around the excluded battery X.

[0046] FIG. 7D shows an alternative construction and configuration for the embodiment of Figure 6. This construction includes an additional switch 340 in series with battery Z and located between the negative terminal of battery Z and ground, and the otherwise optional resistor is omitted as indicated at 350. In this configuration, opening switch 340 allows battery Z to be excluded from the circuit. In the configuration shown, P_Low is powered by battery Y alone, while P_High is powered by batteries W and X in series with one another by closing switches 312 and 316, while the other switches remain open. The additional switch may be included in other configurations shown herein such that the number of switches in each would then be $3N-2$ for N batteries.

[0047] In an illustrative example, battery Z may be a battery used by default to power P_Low (for example, battery Z may be of different chemistry or construction than batteries W, X and Y). In this example, battery Z may near or reach end-of-life well before the other batteries if the device is implanted for prophylactic purposes in a patient who rarely needs high power therapy, as may happen if a high risk patient eliminates risk factors by changes to habits, diet, exercise and/or medication and sees substantial improvement. In this scenario, the remaining batteries may be reconfigured as shown to provide a low power output P_Low without continued reliance on the end-of-life battery. As an alternative to that shown in FIG. 7D, switch 310 may be closed while switch 312 is opened, allowing the P_High output to be generated by the series combination of all three of batteries W, X and Y.

[0048] In an illustrative example, at least one of the batteries is coupled to the P_Low node in series with a switching device that is "closed" when no voltage is applied. For example, switch 340 may be a depletion-type MOSFET, which turns off when a voltage is applied to its control terminal. This may simplify device turn-on, since at least one battery is coupled between P_Low and ground without any voltage output from a control terminal to the depletion-type MOSFET.

[0049] FIG. 8 is a process flow diagram showing an illustrative method. The method 400 may begin from a start block 402, which will in some embodiments be initiated at intervals, for example,

daily, weekly or at lesser or greater intervals. The method 400 may also be initiated in response to a query during a session in which communication is established between an implanted device and a programmer.

[0050] First, battery status is checked, as indicated at 404. In some embodiments, all batteries in the system may be checked during step 404. Alternatively, only batteries which are known to have produced currents during operation may be tested, for example, in an ICD, it is possible for monitoring of cardiac activity, which is a relatively low power function of the device, to occur for a great period of time without any stimuli being delivered to an implant recipient. In this instance, the method may perform a battery status check on only the battery(ies) that are powering the low power functions. In yet another embodiment, all batteries are checked to monitor for conditions that indicate device or battery malfunction. Although not shown, in response to step 404, a flag or other stored value may be set by the implanted device to indicate the battery status and/or if one or more batteries are at or near end-of-life. If and when communication is established with an external programmer, such flags or values may be annunciated.

[0051] From step 404, the device continues to step 406, in which a battery configuration is selected. Next, the selected battery configuration is effected, as shown at 408, by opening and/or closing appropriate switches in the power supply circuit. The method then ends, as shown at 410. In an illustrative example, an indicator of the configuration in use can be stored and this indicator is annunciated during communication with an external programmer.

[0052] In addition to periodic starting at 402, in some embodiments, a change in device operation 412 may cause initiation of method 400. This may occur, for example, when it is determined that a high power output is needed from the power supply circuit, for example, when a malignant arrhythmia is detected by an ICD and stimulus is needed, or when a bradyarrhythmia is detected by a pacemaker and pacing is indicated, or when stimulus of another portion of patient anatomy, such as parts of the nervous system, is needed. In one example of an ICD, the change in device operation may also occur during operation if multiple stimuli are delivered at increasing amplitudes. The change in device operation 412 may occur if a time-out occurs during charging of a high power capacitor in an ICD as may happen if the previously selected configuration fails to provide adequate current/power to charge the high power capacitor quickly. In another example, the implanted medical device may be a drug delivery device having output circuitry for delivering a drug to a patient, or having a pump that requires operation, and the decision to deliver the drug represents a change in device operation. Similarly, block 412 may be an indication that use of the high power output has ended, such that a different configuration adapted for delivery of only low power output may be adopted.

[0053] Initiation of method 402 from block 412 may go to either block 404 or block 406. For example, if the method is embodied in an ICD and a high power stimulus is to be delivered to prevent sudden cardiac death, a new configuration 406 may be selected without re-checking battery status, in order to reduce delay between the decision to deliver stimulus and actual stimulus delivery. Alternatively, in a device such as an insulin pump, a delay of a few seconds to allow battery status to be checked in step 404 may be acceptable.

[0054] In the example of an ICD, if the change in device operation occurs due to a time-out occurring during high power capacitor charging, a check of battery status 404 may be performed to determine why the time-out occurred – and, if one or more batteries is at or near end-of-life, to remove the offending battery from the high power output circuit. For example, a battery at or near its end-of-life may undergo an increase in internal impedance, which may introduce a time constant into the charging circuitry that prevents fast charging. If such a battery is placed in series with the high power output, one “dead” battery in series with one or more non-depleted batteries can prevent the other batteries from successful charging.

[0055] In an illustrative embodiment, the select configuration step 406 may include determining whether a change in battery configuration is appropriate. For example, the previous/current battery configuration may be checked in light of a change in device operation, and if the configuration is appropriate for the change of device operation which has or is occurring, then the previous/current battery configuration may be left in place. Otherwise, a different configuration is selected.

[0056] Those skilled in the art will understand that reference to “ground” or a “ground node” indicates a reference node for the system and does not imply or require an actual connection to an earth ground or other external environment reference.

[0057] Those skilled in the art will recognize that the present invention may be manifested in a variety of forms other than the specific embodiments described and contemplated herein. Accordingly, departures in form and detail may be made without departing from the scope and spirit of the present invention as described in the appended claims.

What is claimed is:

1. An implantable medical device (IMD) comprising:
 - a housing configured for implantation in the body of a patient;
 - operational circuitry having low power monitoring sub-circuitry elements and high power stimulus generating sub-circuitry elements;
 - a power supply circuit coupled to the operational circuitry, the power supply circuit including at least first and second batteries and a plurality of switches, the power supply circuit configured to allow selective opening and closing of the switches such that the following output configurations are available:
 - a first configuration in which the first and second batteries are coupled in series to provide a low power output from only one battery and a high power output from more than one battery; and
 - a second configuration in which the two batteries are isolated from one another to provide a first output taking power from one of the batteries and a second output taking power from the other of the batteries.
2. The IMD of claim 1, wherein the power supply circuit is further configured such that a third configuration is available, wherein in the third configuration, the first and second batteries are coupled in parallel to one another to provide an output from both batteries.
3. An IMD as in either of claims 1-2, wherein the power supply circuit comprises a third battery and the first configuration provides the high power output from the first, second and third batteries in series.
4. An IMD as in either of claims 1-2, wherein the power supply circuit comprises a third battery and the second configuration uses the first battery alone to provide the low power output, and the second and third batteries in series to provide the high power output.
5. An IMD as in either of claims 3-4, wherein the power supply circuit comprises switches configured to omit one of the first, second or third batteries from use in supplying power.
6. An IMD as in either of claims 1-2, wherein the power supply circuit comprises switches configured to omit one of the first or second batteries from use in supplying power.
7. An IMD as in any of claims 1-6, wherein the operational circuitry is configured to perform the following steps:
 - test at least one of the batteries to determine a status of the at least one battery;
 - select a configuration for the power supply circuit in light of the battery status; and
 - effect the configuration in the power supply circuit.

8. A method of supplying power in an implantable medical device (IMD) comprising:
providing a first battery having a positive terminal and a negative terminal;
providing a second battery having a positive terminal and a negative terminal;
providing a plurality of switches and connections between the first and second batteries, a ground node, and a high power output and a low power output to form a power system; and
manipulating control of the switches to provide power in each of the following configurations during different times of operation of the IMD:
(a) providing the high and low power outputs from the first and second batteries connected together in parallel; and
(b) providing the high power output from the first and second batteries in series, and the low power output from the second battery alone.
9. The method of claim 8, wherein the step of manipulating control of the switches further includes providing power in the following additional configuration:
providing the high power output from the first battery alone and providing the low power output from the second battery alone.
10. A method as in either of claims 8-9, wherein the step of providing a plurality of switches and connections between the first and second batteries, a ground node, and a high power output and a low power output to form a power system is performed such that the power circuit includes:
a first switch coupling a positive terminal of the first battery to a negative terminal of the second battery;
a second switch coupling the negative terminal of the second battery to the ground node; and
a third switch coupling the positive terminal of the first battery to a positive terminal of the second battery; and further wherein:
the low power output is taken from the positive terminal of the first battery; and the high power output is taken from the positive terminal of the second battery.
11. The method of claim 10, wherein a fourth switch couples a negative terminal of the first battery to the ground node and the method further includes determining if either the first battery or the second battery is near or at its end of life and, if so, isolating the battery that is near or at its end of life from the rest of the circuitry.
12. The method of claim 8, further comprising providing a third battery having a positive terminal and a negative terminal, wherein:
the step of providing a plurality of switches and connections includes coupling the third battery to the other parts of the power system; and
the step of manipulating control of the switches is performed such that:

in configuration (a), the third battery is also connected in parallel to the first and second batteries; and

in configuration (b), the high power output is provided from the first, second and third batteries all in series.

13. The method of claim 12, wherein the step of manipulating control of the switches is performed such that another configuration is used during a time of operation of the IMD this configuration being one in which at least one of the first, second and third batteries is excluded from the power circuit.

14. The method of claim 12, wherein the step of providing a plurality of switches and connections between the first and second batteries, a ground node, and a high power output and a low power output to form a power system, which also includes coupling the third battery to other parts of the power system, is performed such that the power circuit includes:

- a first switch coupling a positive terminal of the first battery to a negative terminal of the second battery;

- a second switch coupling the negative terminal of the second battery to the ground node;

- a third switch coupling a positive terminal of the second battery to the positive terminal of the first battery;

- a fourth switch coupling the positive terminal of the second battery to the negative terminal of the third battery;

- a fifth switch coupling the negative terminal of the third battery to the ground node; and

- a sixth switch coupling the positive terminal of the third battery to the positive terminal of the second node; and further wherein:

- the low power output is taken from the positive terminal of the first battery and the high power output is coupled to the positive terminal of the third battery.

15. The method of claim 8, further comprising:

- observing the status of at least one of the batteries; and

- selecting a configuration for the power system given the battery status;

- wherein the step of manipulating control of the switches is performed to effect the selected configuration.

16. An implantable medical device (IMD) comprising a housing containing operational circuitry configured to operate the IMD, the operational circuitry comprising:

- control circuitry for controlling operation of the IMD, the control circuitry operating using a low power circuit for power supply;

- stimulus circuitry for providing an output stimulus to a patient during operation of the IMD, the stimulus circuitry operating, at least in part, by the use of a high power circuit for power supply; and

a battery system comprising at least a first battery, a second battery, and a plurality of switches coupling the first and second battery to a low power output and a high power output, the low power output coupled to the low power circuit for power supply and the high power output being coupled to the high power circuit for power supply, wherein the battery system and switches are coupled to the control circuitry such that the control circuitry can operate the switches in at least the following configurations:

(a) a configuration in which the low power circuit receives power from only the first battery and the high power circuit receives power from the first battery connected in series with the second battery; and

(b) a configuration in which the low power circuit and the high power circuit each receive power from the first battery and second battery connected in parallel such that the low power circuit and the high power circuit are receive similar voltages.

17. The IMD of claim 16, wherein:

the battery system further comprises at least a third battery, and the plurality of switches also couples the third battery with the first and second batteries such that the control circuitry can also operate the switches in:

(c) a configuration in which at least one of the first, second and third batteries is excluded from use;

the control circuitry includes means for testing battery status of one or more of the batteries; and

the control circuitry is configured to perform a power configuration method comprising the following steps:

testing battery status of at least one of the batteries;

selecting a battery configuration; and

effecting the selected battery configuration.

18. The IMD of claim 17, wherein the control circuitry is further configured to perform the power configuration method at intervals.

19. An IMD as in either of claims 17 or 18, wherein the control circuitry is further configured to perform the power configuration in response to a change in device operation.

20. An IMD as in claim 19, wherein the change in device operation is a determination by the control circuitry that cardiac stimulus is indicated.

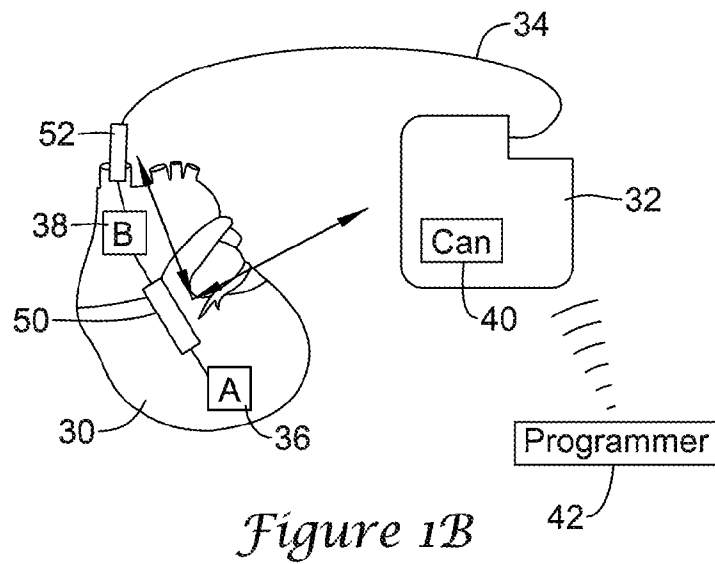
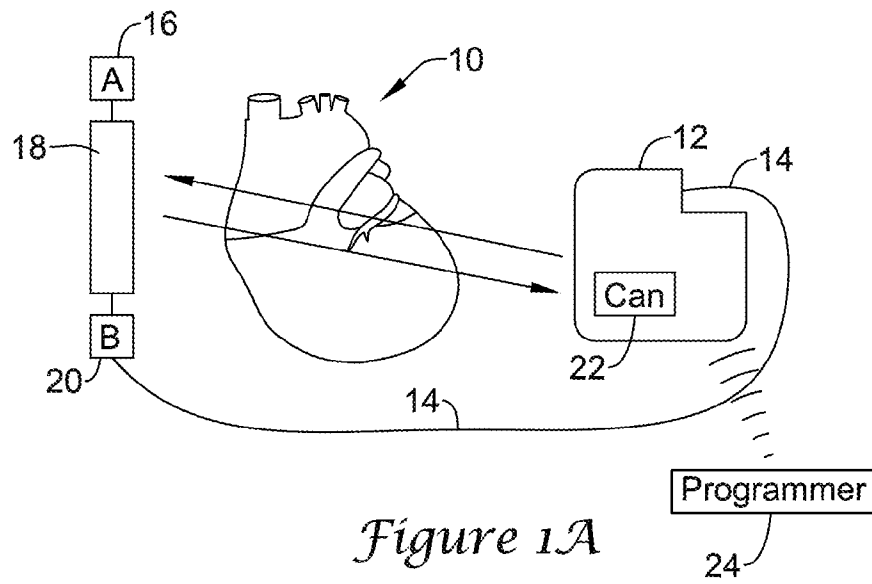
21. An IMD as in claim 19, wherein the change in device operation is a time-out occurring during preparation of the stimulus circuitry to provide a stimulus.

22. A method of operating an implantable medical device (IMD), the IMD comprising power circuitry including a plurality of batteries and switches allowing for multiple configurations of the batteries to provide output power to other sub-circuits of the IMD, the method comprising:

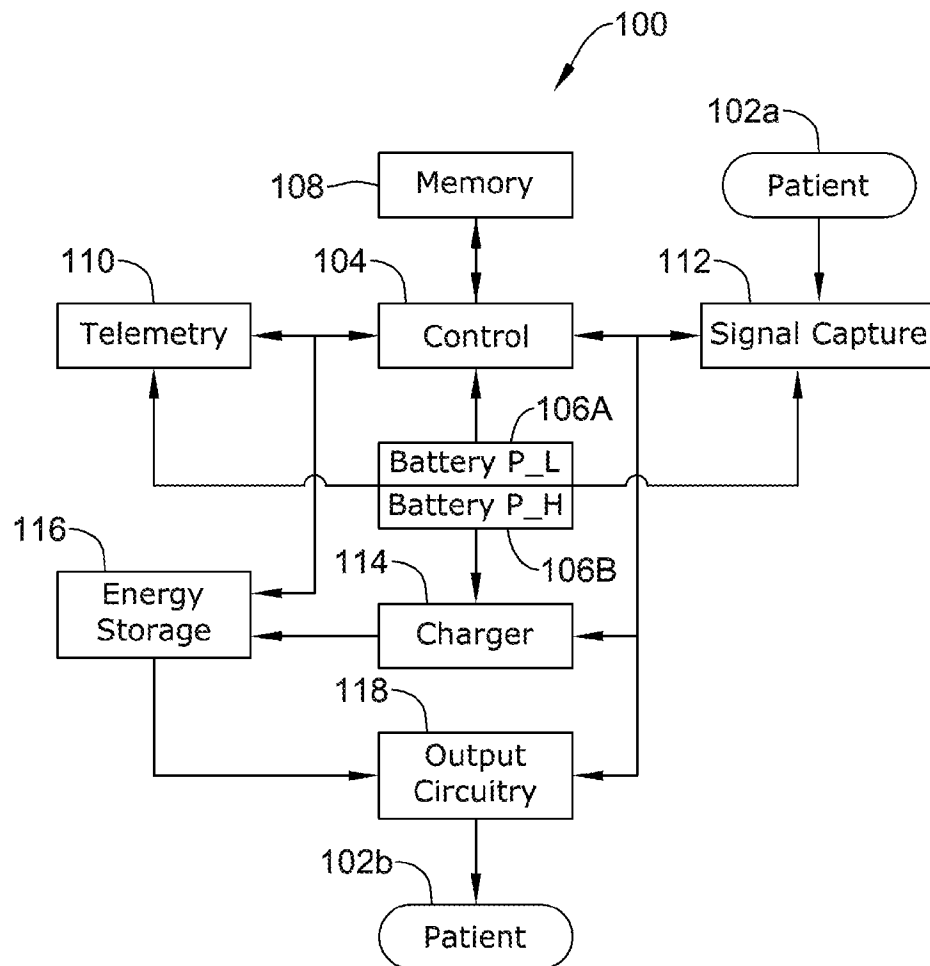
determining that a change in device operation is occurring;
determining whether a change in battery configuration is appropriate; and, if so,
effecting the change in battery configuration in the power circuitry.

23. The method of claim 22, further comprising checking a status of one or more of the batteries.

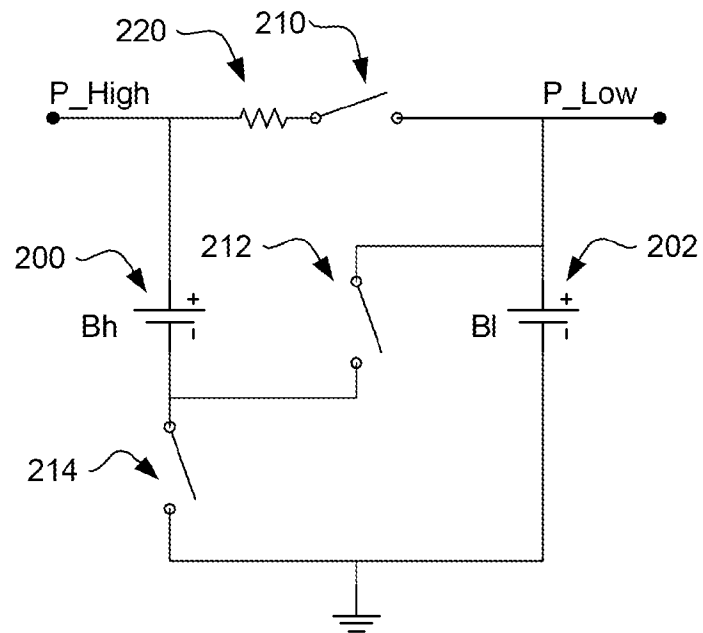
1/13



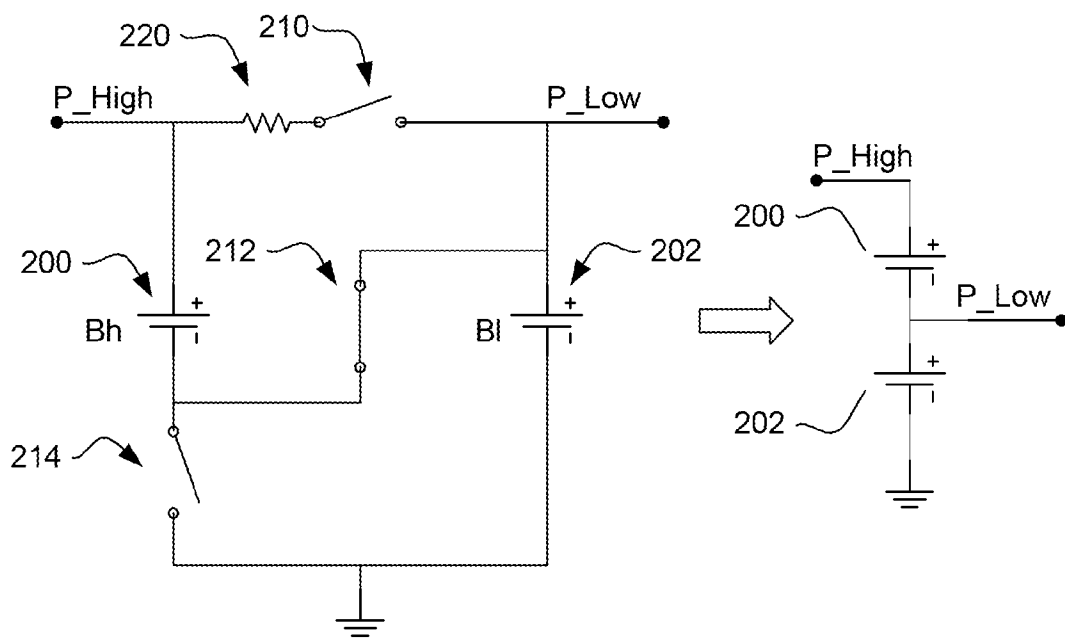
2/13

*Figure 2*

3/13

*Figure 3*

4/13

*Figure 4A*

5/13

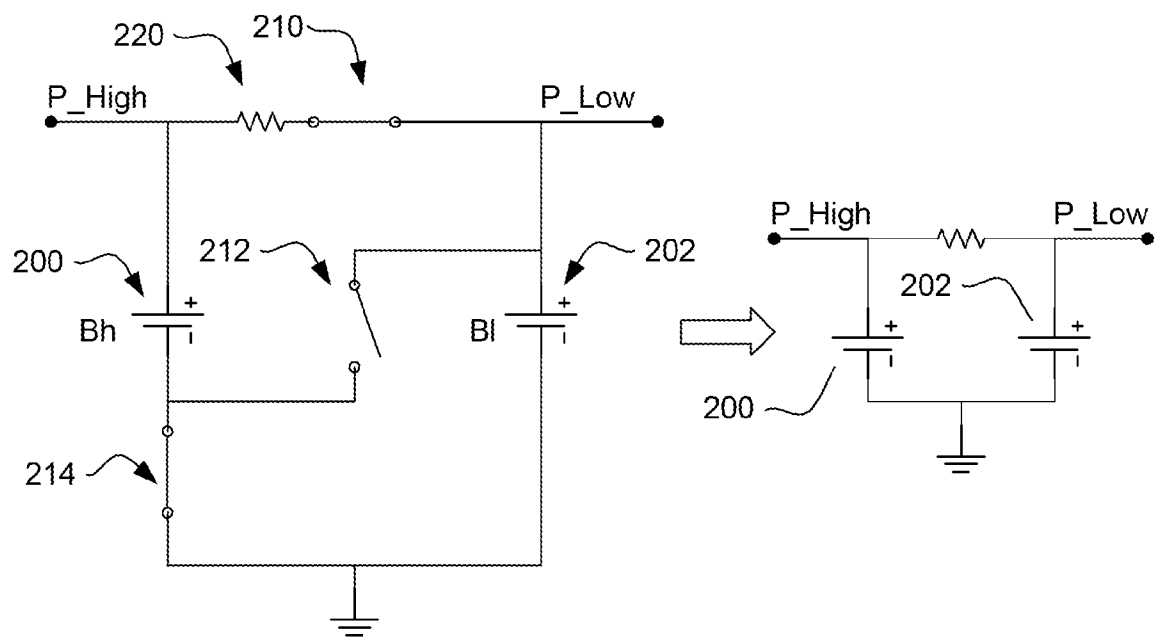


Figure 4B

6/13

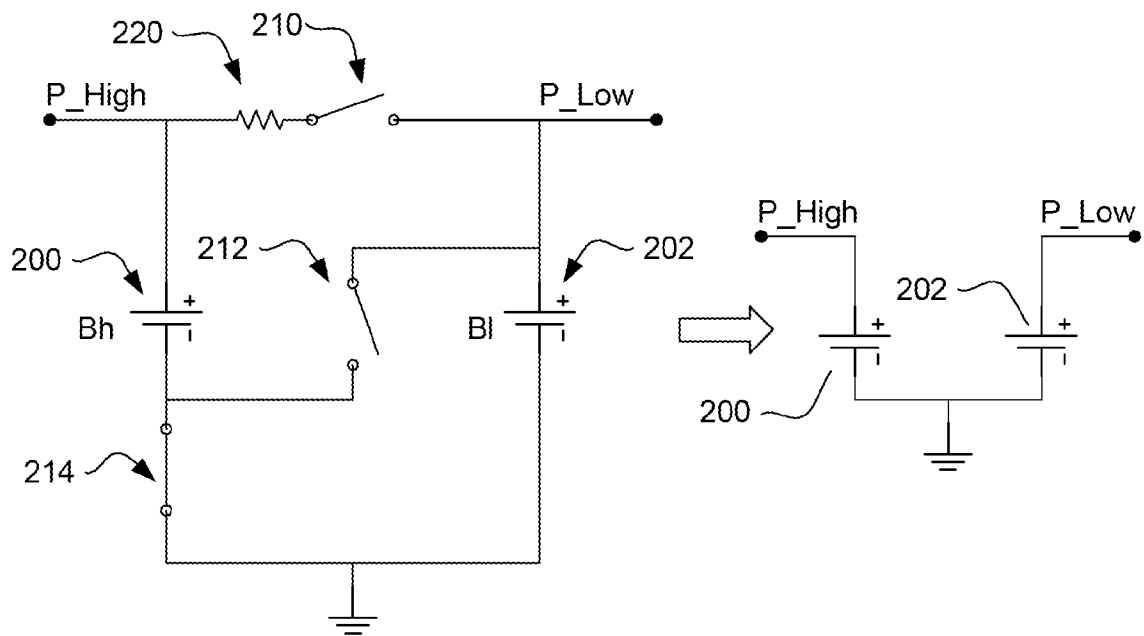


Figure 4C

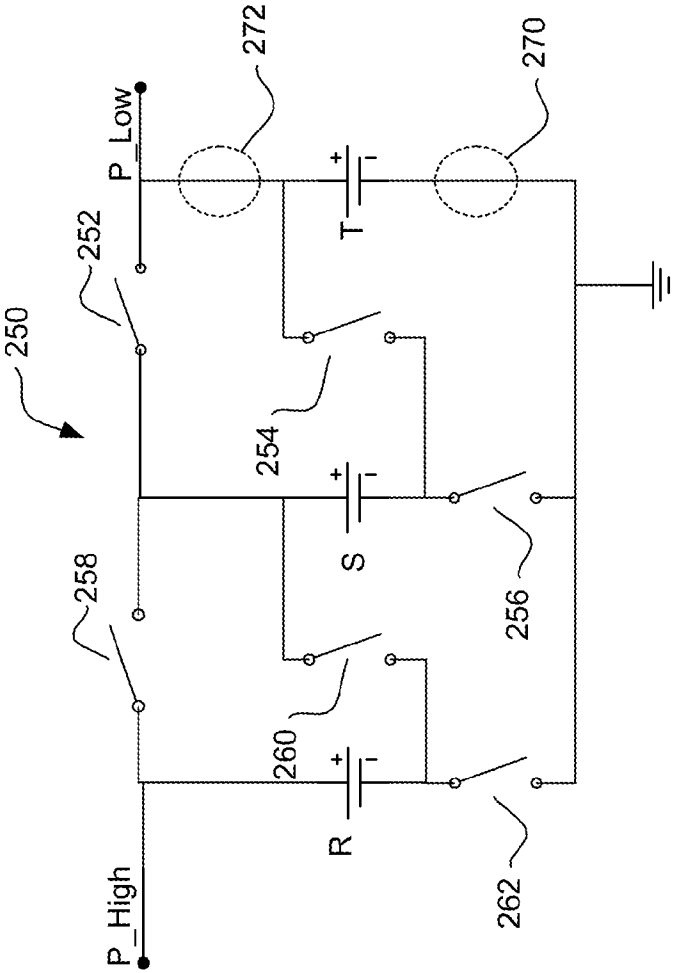
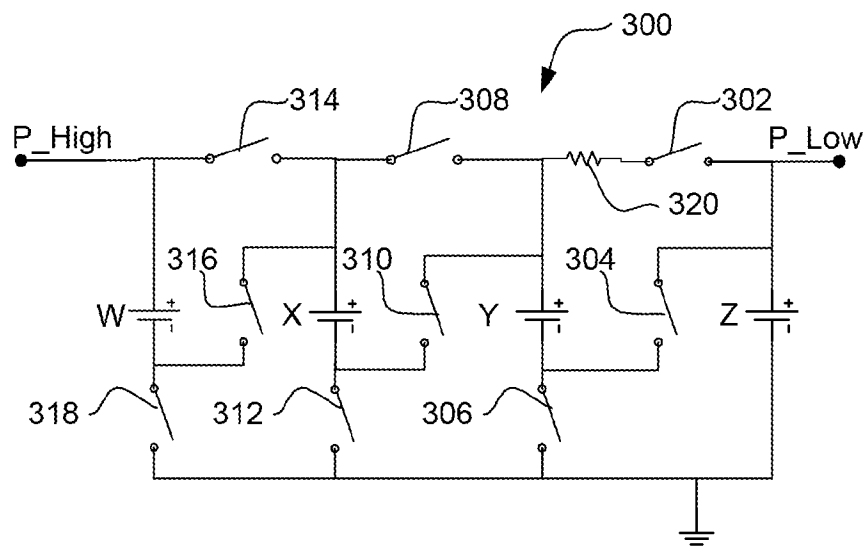
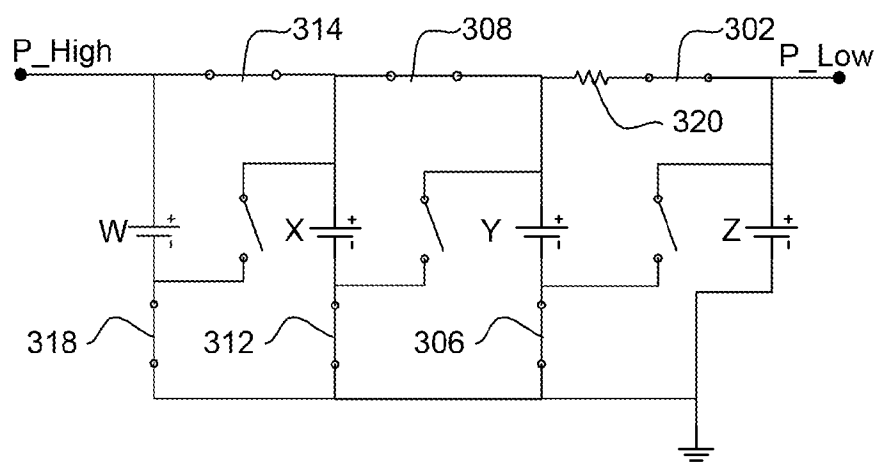


Figure 5

8/13

*Figure 6*

9/13

*Figure 7A*

10/13

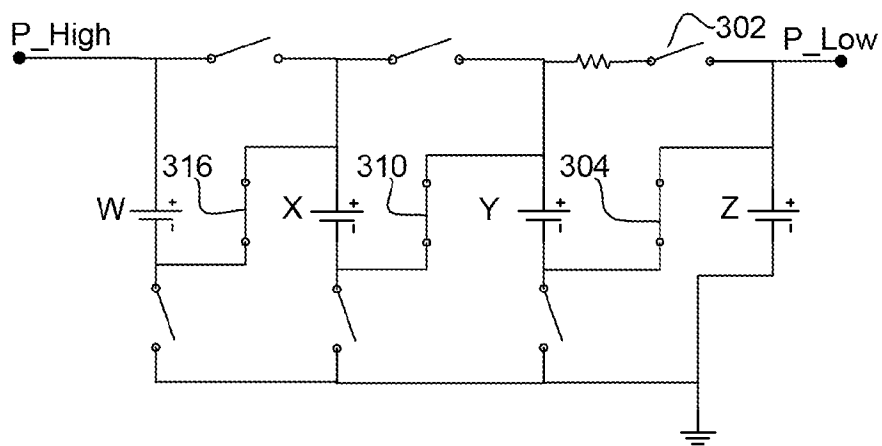


Figure 7B

11/13

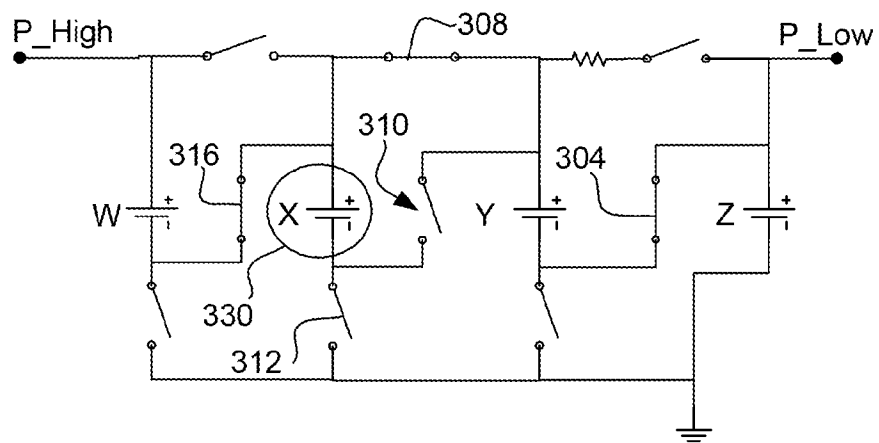


Figure 7C

12/13

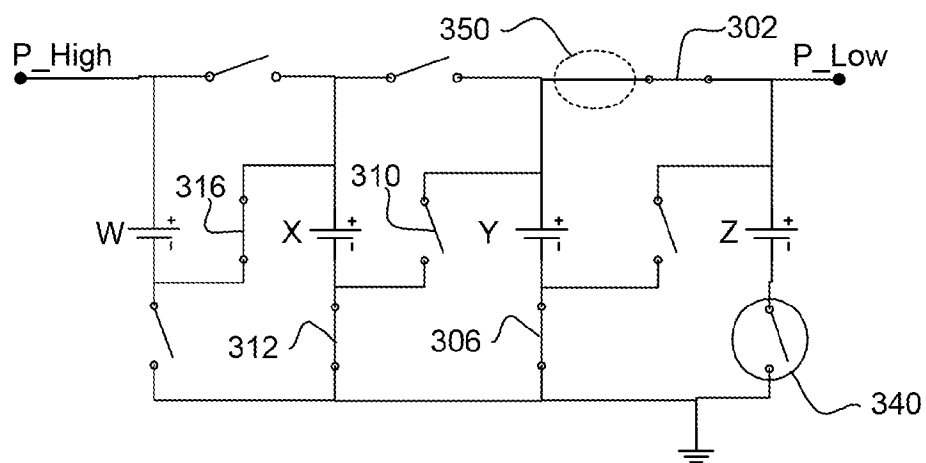
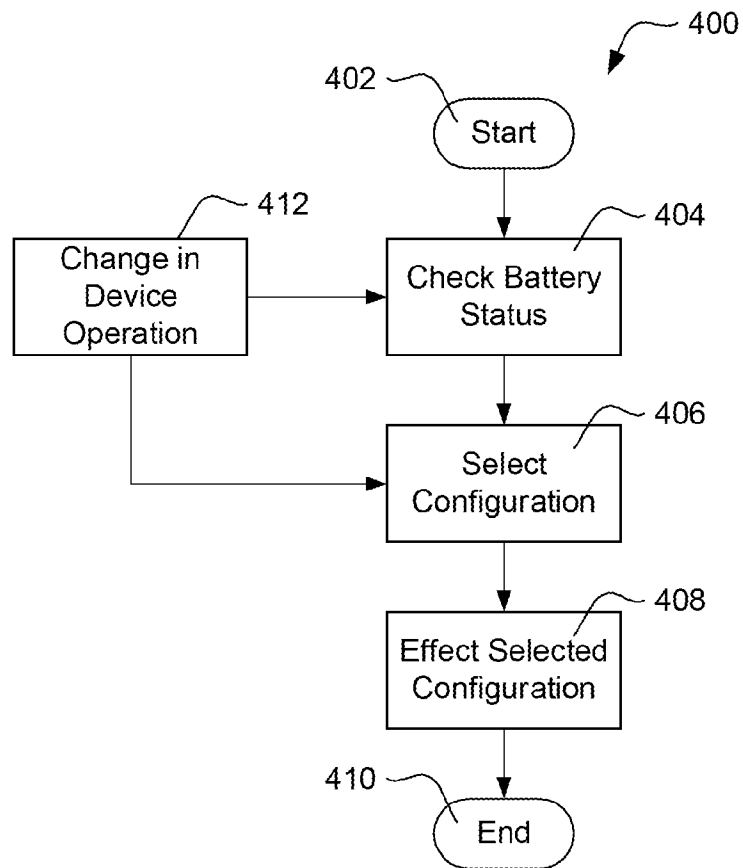


Figure 7D

13/13

*Figure 8*

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/071976

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/39 A61N1/378

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61N H02J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 369 351 A (ADAMS THEODORE P [US]) 29 November 1994 (1994-11-29) abstract; figures 3-6 column 3, lines 8-11 column 4, lines 39-68	1-3,5-7, 22,23
Y		4,8-21
Y	US 6 038 473 A (OLSON KENNETH F [US] ET AL) 14 March 2000 (2000-03-14) abstract; figure 4	4,8-21
Y	US 5 439 482 A (ADAMS THEODORE P [US] ET AL) 8 August 1995 (1995-08-08) abstract; figure 8	9
A	US 4 412 137 A (HANSEN JAMES E [US] ET AL) 25 October 1983 (1983-10-25) the whole document	1-21
	-/-	

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

28 November 2008

Date of mailing of the international search report

05/12/2008

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040
Fax: (+31-70) 340-3016

Authorized officer

Pfeiffer, Uwe

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2008/071976

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/193227 A1 (SCHMIDT CRAIG L [US]) 30 September 2004 (2004-09-30) abstract; figure 4 paragraph [0037]	22, 23
A	-----	1-21
A	WO 2006/058028 A (GENTCORP LTD [US]; GREATBATCH W [US]; DEAL JEFFREY [US]; THOMAS GLENN) 1 June 2006 (2006-06-01) the whole document	1-23
A	----- WO 2006/061725 A (KONINKL PHILIPS ELECTRONICS NV [NL]; BRINK GREGORY D [US]; POWERS DANI) 15 June 2006 (2006-06-15) the whole document -----	1-23

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2008/071976

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5369351	A	29-11-1994	NONE	
US 6038473	A	14-03-2000	NONE	
US 5439482	A	08-08-1995	NONE	
US 4412137	A	25-10-1983	NONE	
US 2004193227	A1	30-09-2004	CA 2520780 A1 DE 602004005975 T2 EP 1611630 A1 EP 1995806 A1 JP 2006523134 T WO 2004091021 A1	21-10-2004 17-01-2008 04-01-2006 26-11-2008 12-10-2006 21-10-2004
WO 2006058028	A	01-06-2006	US 2006129192 A1	15-06-2006
WO 2006061725	A	15-06-2006	EP 1871474 A2 US 2008208272 A1	02-01-2008 28-08-2008