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(54) **IMPLANTABLE PULSE GENERATOR FOR PROVIDING FUNCTIONAL AND/OR THERAPEUTIC STIMULATION OF MUSCLES AND/OR NERVES AND/OR CENTRAL NERVOUS SYSTEM TISSUE**

(75) Inventors: **Robert B. Strother**, Willoughby Hills, OH (US); **Joseph J. Mrva**, Euclid, OH (US); **Geoffrey B. Thrope**, Shaker Heights, OH (US)

(73) Assignee: **Medtronic, Inc.**, Minneapolis, MN (US)

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See application file for complete search history.

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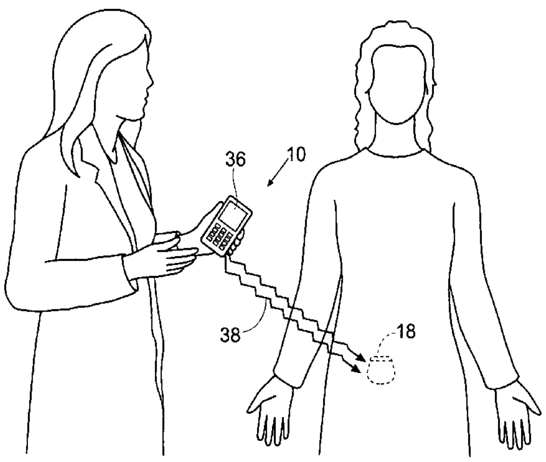
Primary Examiner—Carl H Layno
Assistant Examiner—Jessica Sarcione
(74) *Attorney, Agent, or Firm*—Shumaker & Sieffert, P.A.

(57) **ABSTRACT**

An implantable pulse generator for prosthetic or therapeutic stimulation of muscles, nerves, or central nervous system tissue, or any combination is sized and configured to be implanted in subcutaneous tissue. The implantable pulse generator includes an electrically conductive laser welded titanium case. Control circuitry is located within the case, and includes a primary cell or rechargeable power source, a receive coil for receiving an RF magnetic field to recharge the rechargeable power source, non-inductive wireless telemetry circuitry, and a microcontroller for control of the implantable pulse generator. A stimulation system for prosthetic or therapeutic stimulation of muscles, nerves, or central nervous system tissue, or any combination comprises at least one electrically conductive surface, a lead connected to the electrically conductive surface, and an implantable pulse generator electrically connected to the lead.

35 Claims, 13 Drawing Sheets



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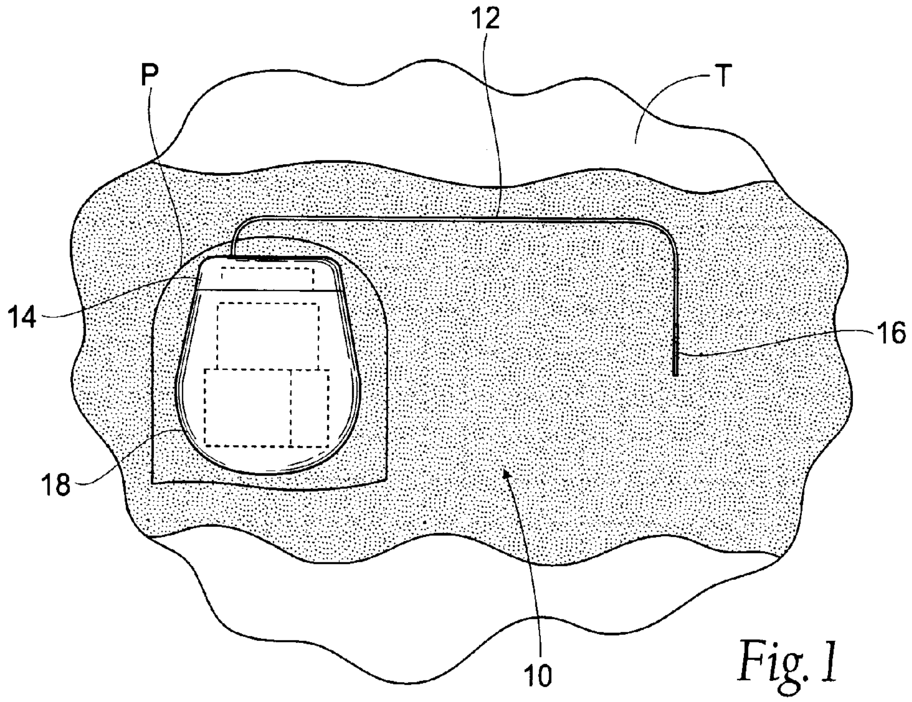


Fig. 1

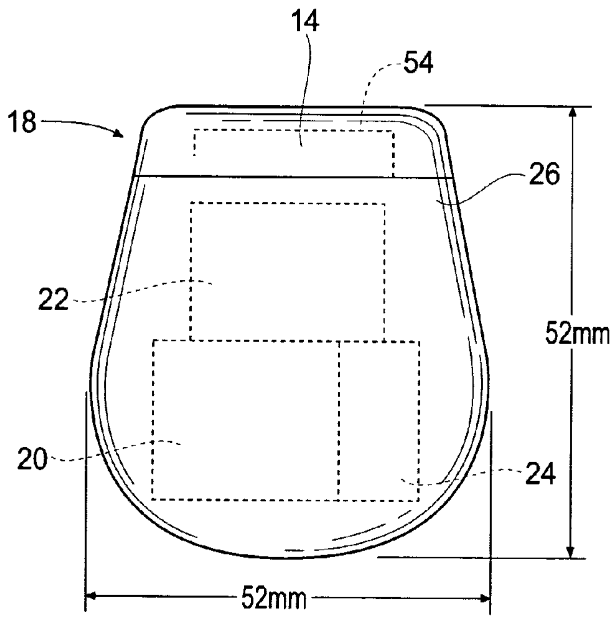


Fig. 2A

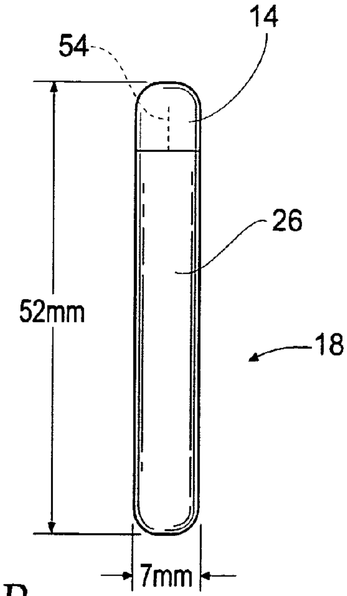


Fig. 2B

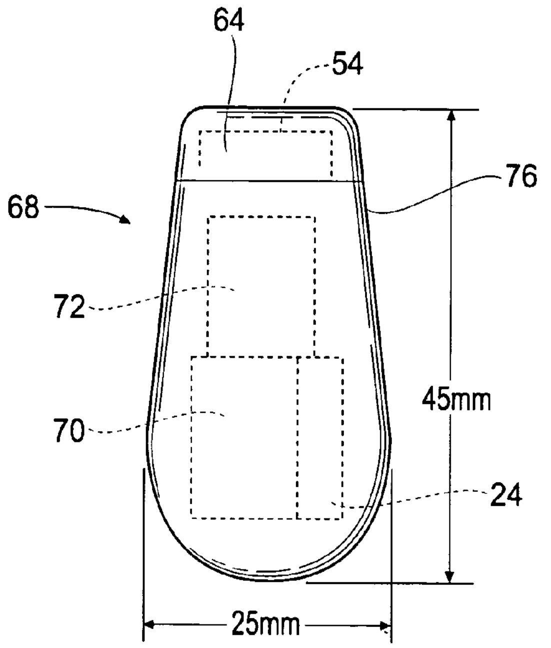


Fig. 2C

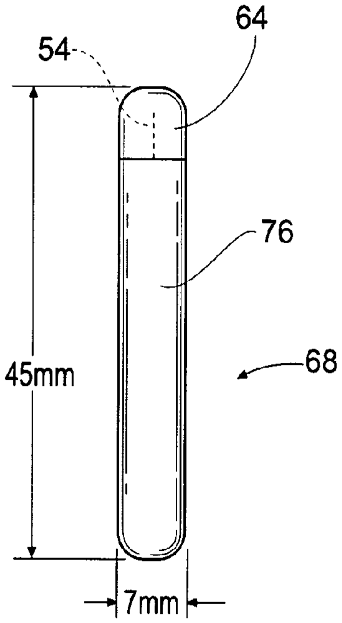


Fig. 2D

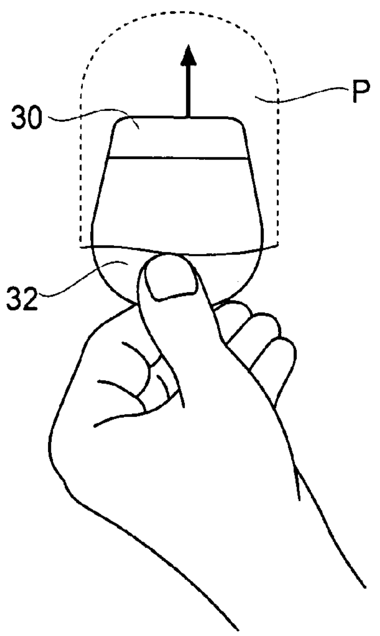


Fig. 3

Fig. 4A

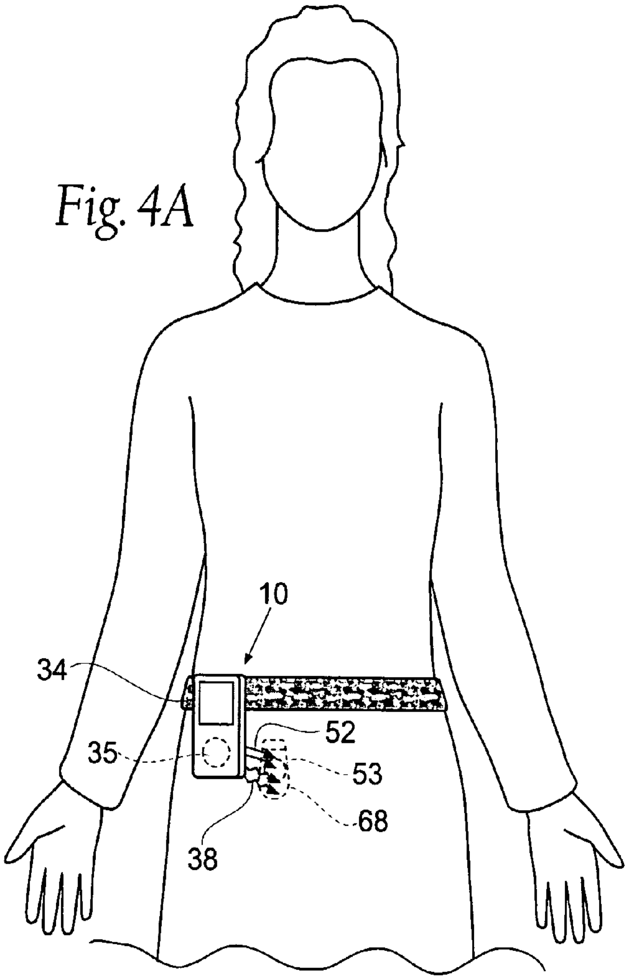
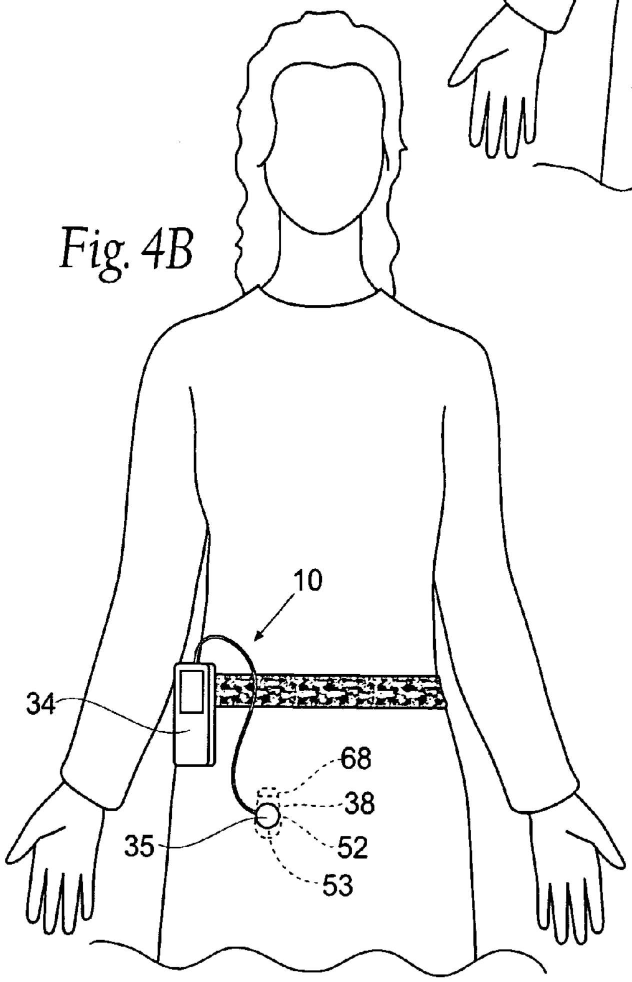


Fig. 4B



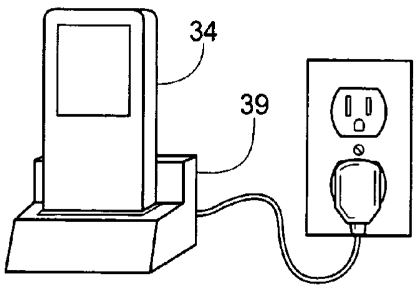


Fig. 4C

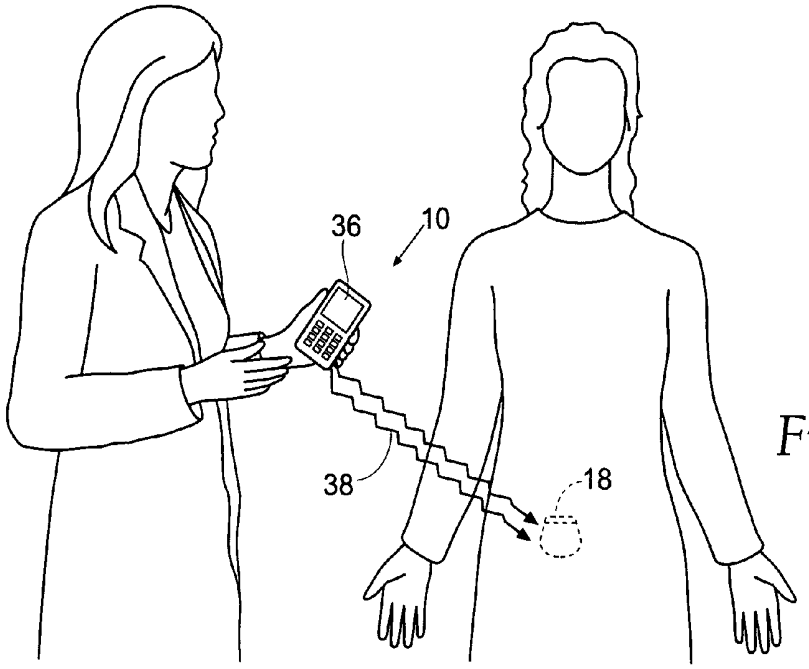


Fig. 5A

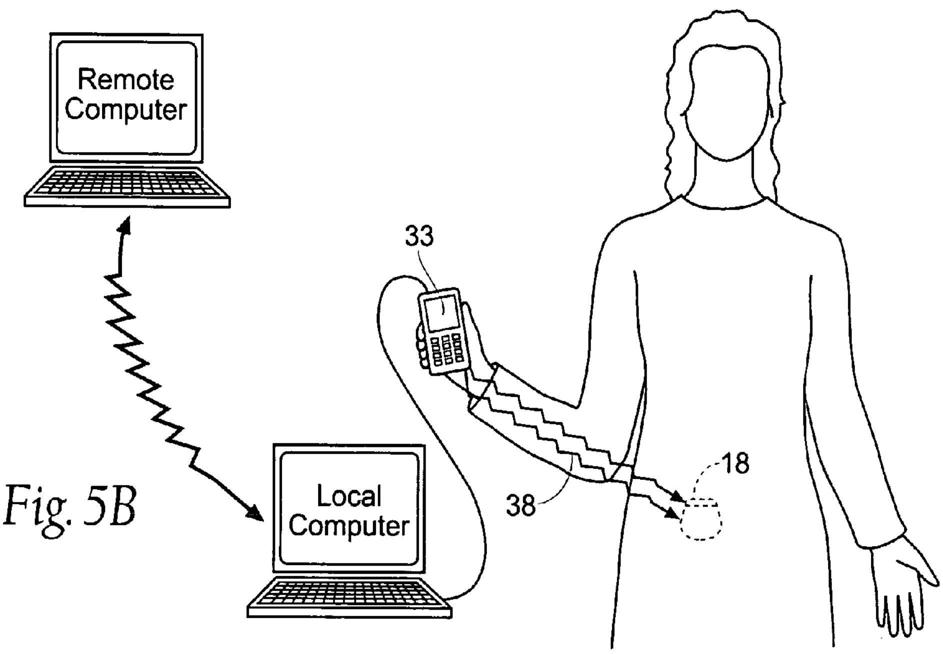


Fig. 5B

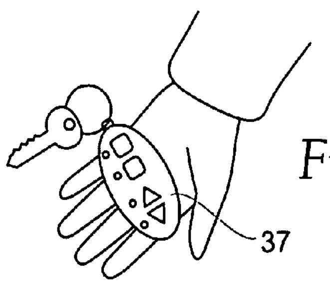
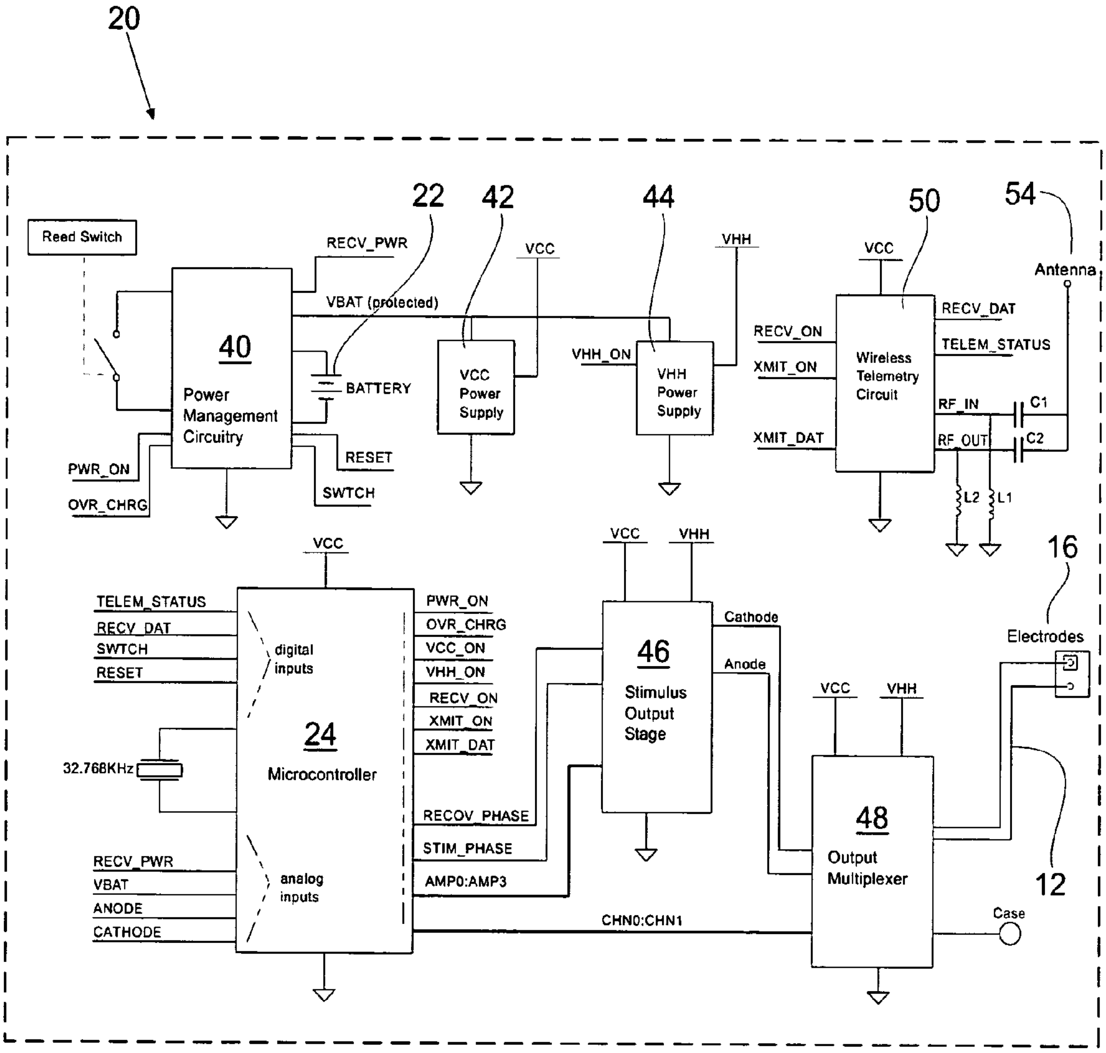


Fig. 5C



20
22
42
44
50
54
Reed Switch
RECV_PWR
VBAT (protected)
40
Power
Management
Circuitry
BATTERY
PWR_ON
OVR_CHRG
RESET
SWTCH
VCC
VCC
Power
Supply
VHH
VHH_ON
VHH
Power
Supply
Wireless
Telemetry
Circuit
RECV_ON
XMIT_ON
XMIT_DAT
RECV_DAT
TELEM_STATUS
RF_IN
RF_OUT
C1
C2
L1
L2
Antenna
16
Electrodes
TELEM_STATUS
RECV_DAT
SWTCH
RESET
digital
inputs
24
Microcontroller
32.768KHz
RECV_PWR
VBAT
ANODE
CATHODE
analog
inputs
PWR_ON
OVR_CHRG
VCC_ON
VHH_ON
RECV_ON
XMIT_ON
XMIT_DAT
RECOV_PHASE
STIM_PHASE
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CHN0:CHN1
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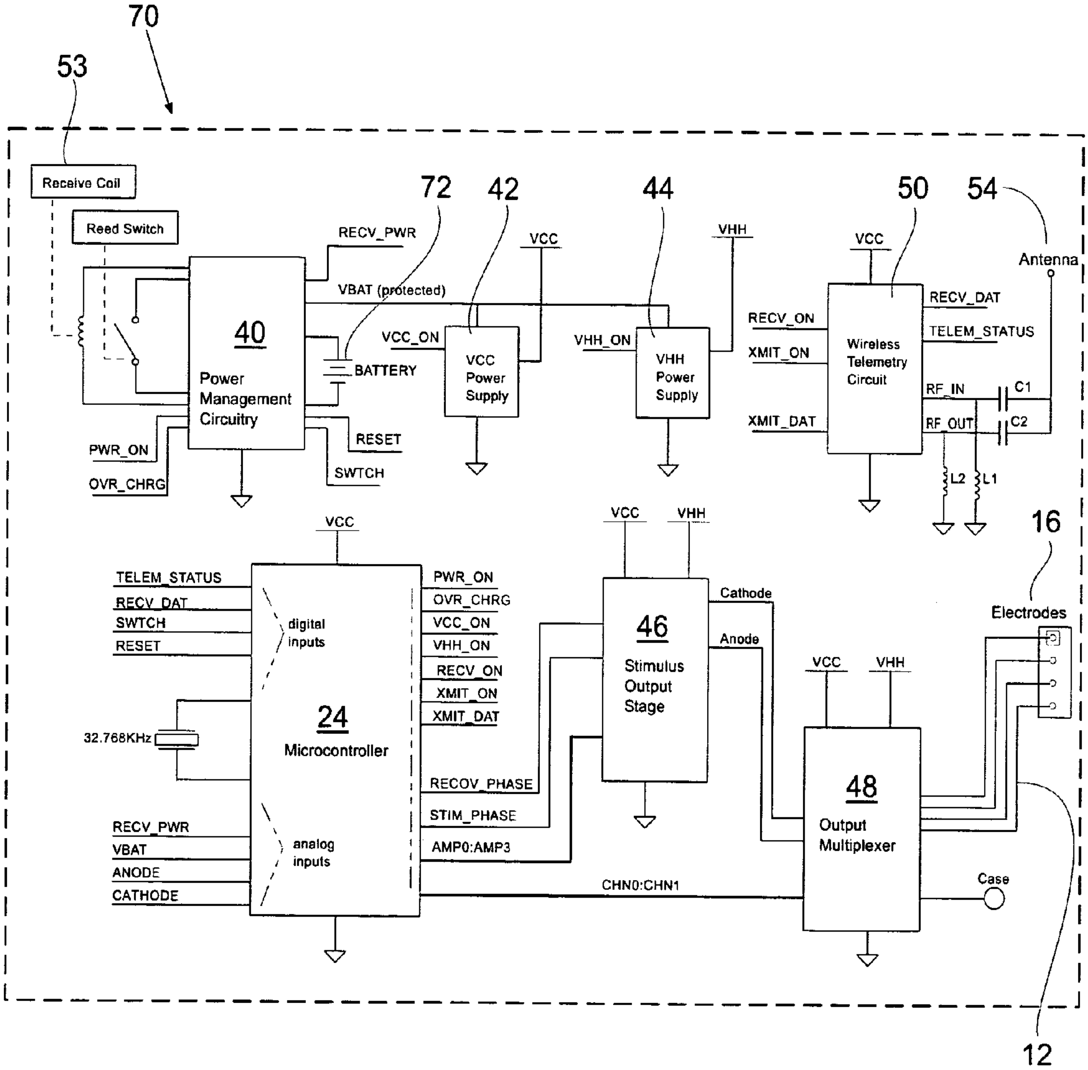
Stimulus
Output
Stage
Cathode
Anode
48
Output
Multiplexer
12
Case

Fig. 6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RECV_PWR
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VCC
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VBAT (protected)
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Power
Management
Circuitry
BATTERY
VCC_ON
VCC
Power
Supply
VHH_ON
VHH
Power
Supply
RECV_ON
XMIT_ON
XMIT_DAT
Wireless
Telemetry
Circuit
RECV_DAT
TELEM_STATUS
RF_IN
RF_OUT
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C2
L2
L1
PWR_ON
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VCC
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16
TELEM_STATUS
RECV_DAT
SWTCH
RESET
digital
inputs
32.768KHz
24
Microcontroller
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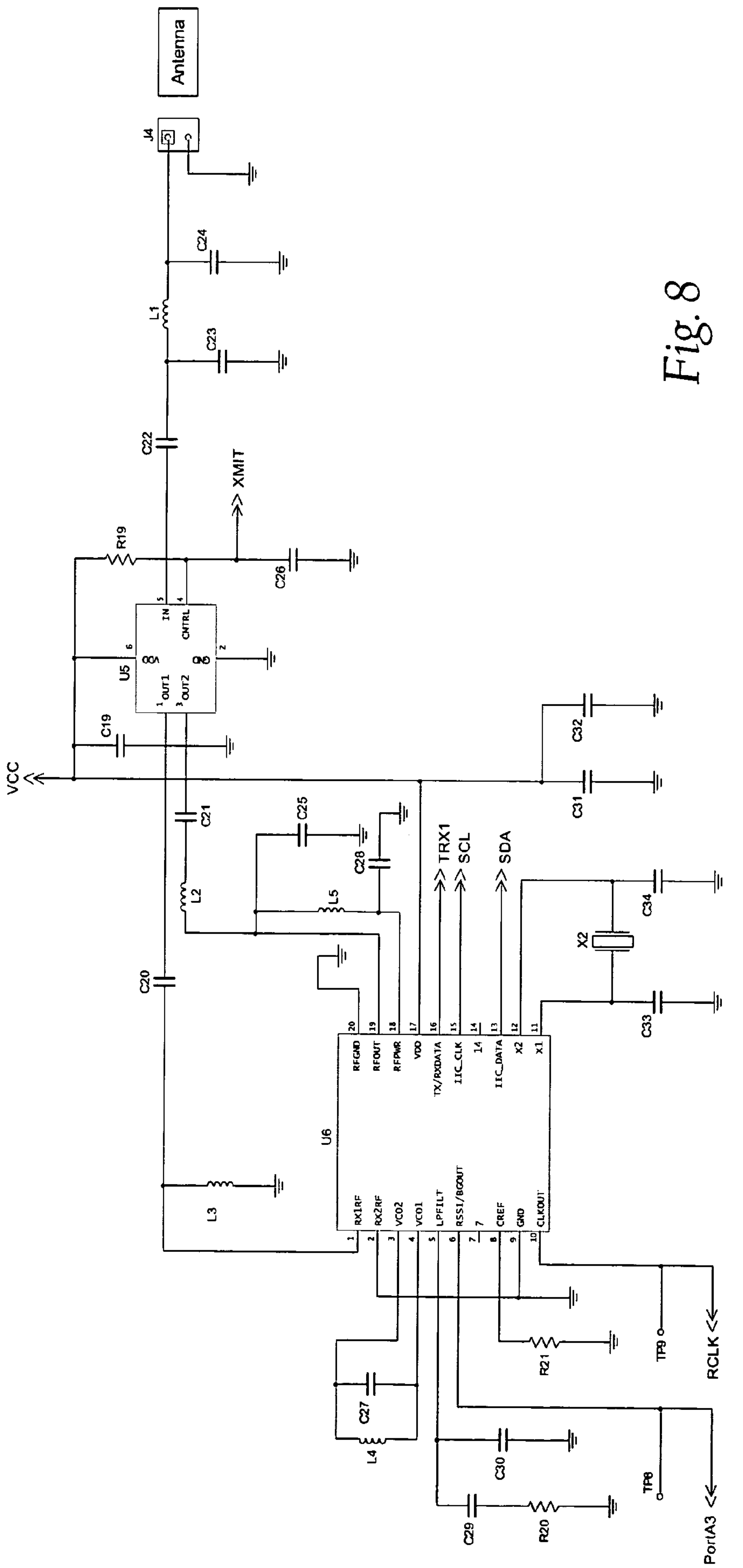
VBAT
ANODE
CATHODE
analog
inputs
PWR_ON
OVR_CHRG
VCC_ON
VHH_ON
RECV_ON
XMIT_ON
XMIT_DAT
RECOV_PHASE
STIM_PHASE
AMP0:AMP3
CHN0:CHN1
46
Stimulus
Output
Stage
Cathode
Anode
Electrodes
VCC
VHH
48
Output
Multiplexer
Case
12

Fig. 7



Antenna
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C24
L1
C23
C22
XMIT
R19
C26
U5
IN
CNTRL
VCC
GND
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OUT2
C19
C32
C31
C21
C25
C28
TRX1
SCL
SDA
L2
L5
C34
X2
C20
C33
RFGND
RFOUT
RFPWR
VDD
TX/RXDATA
IIC_CLK
IIC_DATA
X2
X1
U6
RX1RF
RX2RF
VCO2
VCO1
LPFILT
RSSI/BGOUT
CREF
GND
CLKOUT
L3
R21
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RCLK
C27
L4
C30
TP8
C29
R20
PortA3

Fig. 8

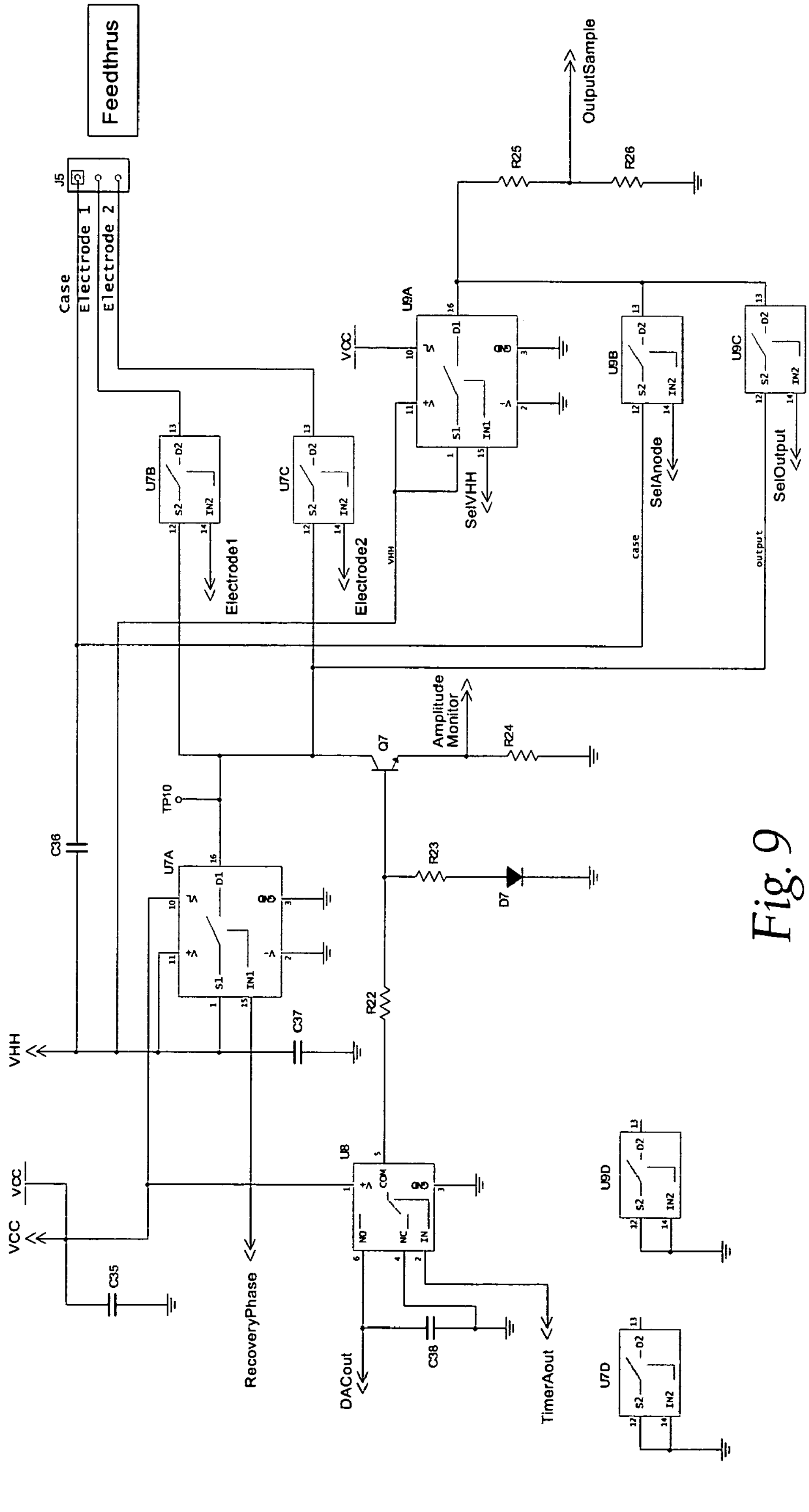

Feedthrus
J5
Case
Electrode 1
Electrode 2
OutputSample
R25
R26
U9A
VCC
SelVHH
U9B
SelAnode
U9C
SelOutput
case
output
U7B
Electrode1
U7C
Electrode2
VHH
Amplitude Monitor
Q7
R24
TP10
C36
U7A
R23
D7
R22
C37
VHH
VCC
VCC
C35
U8
RecoveryPhase
DACout
C38
TimerAout
U9D
U7D

Fig. 9

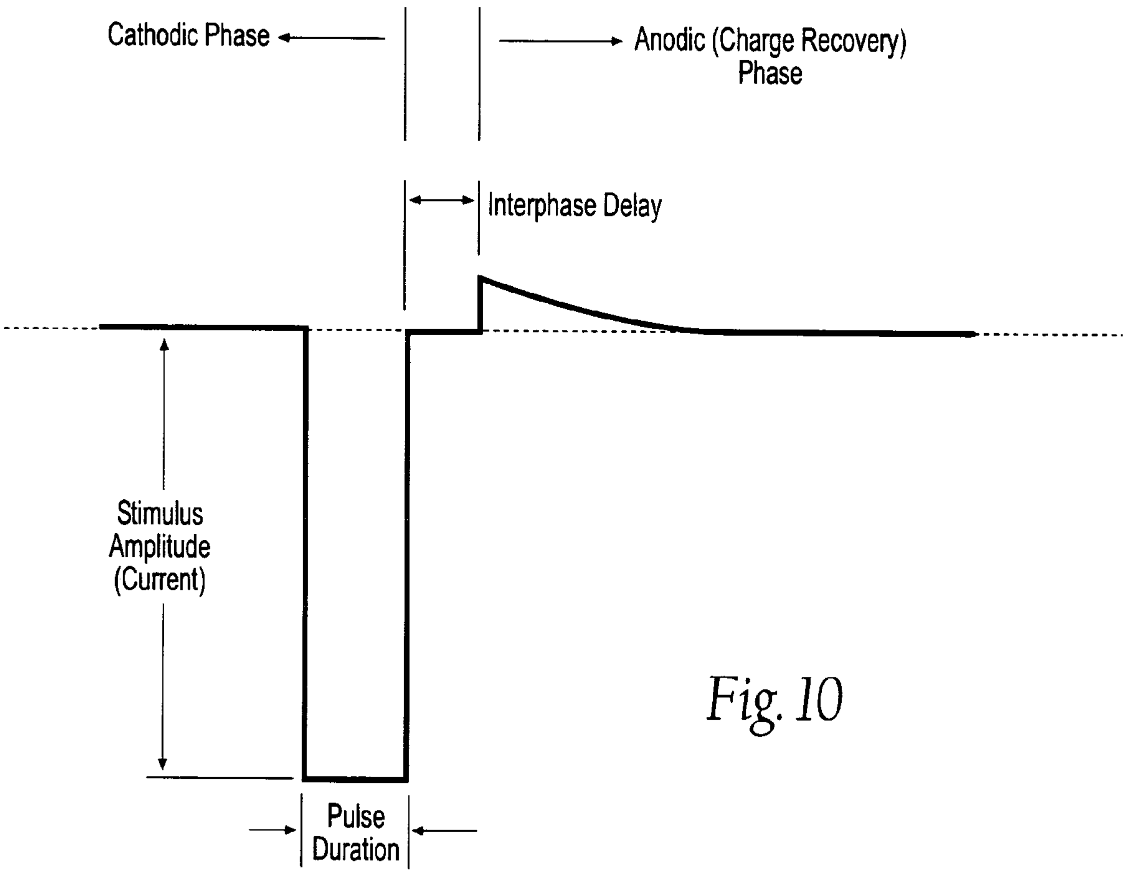
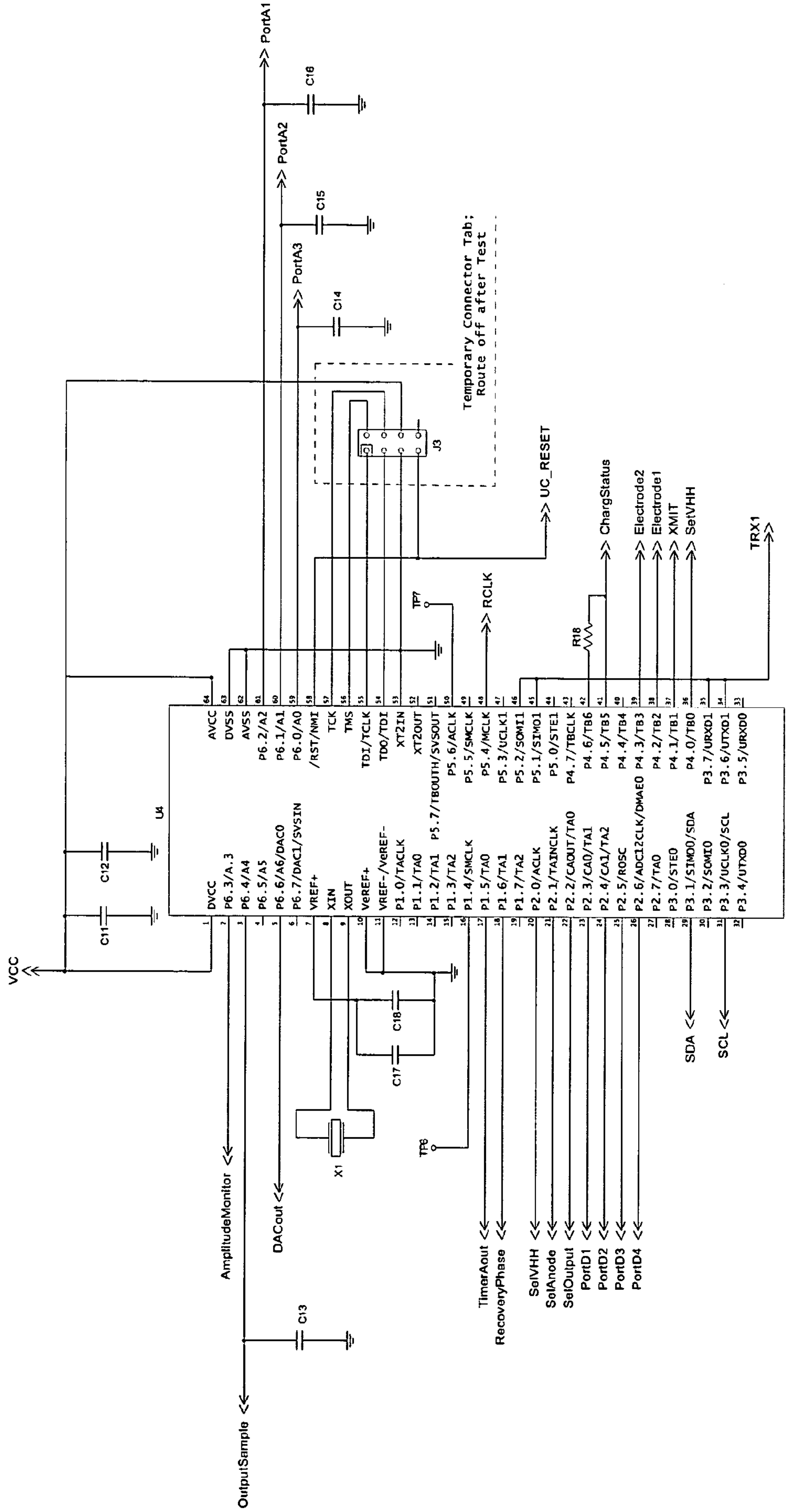

Cathodic Phase
Anodic (Charge Recovery) Phase
Interphase Delay
Stimulus Amplitude (Current)
Pulse Duration

Fig. 10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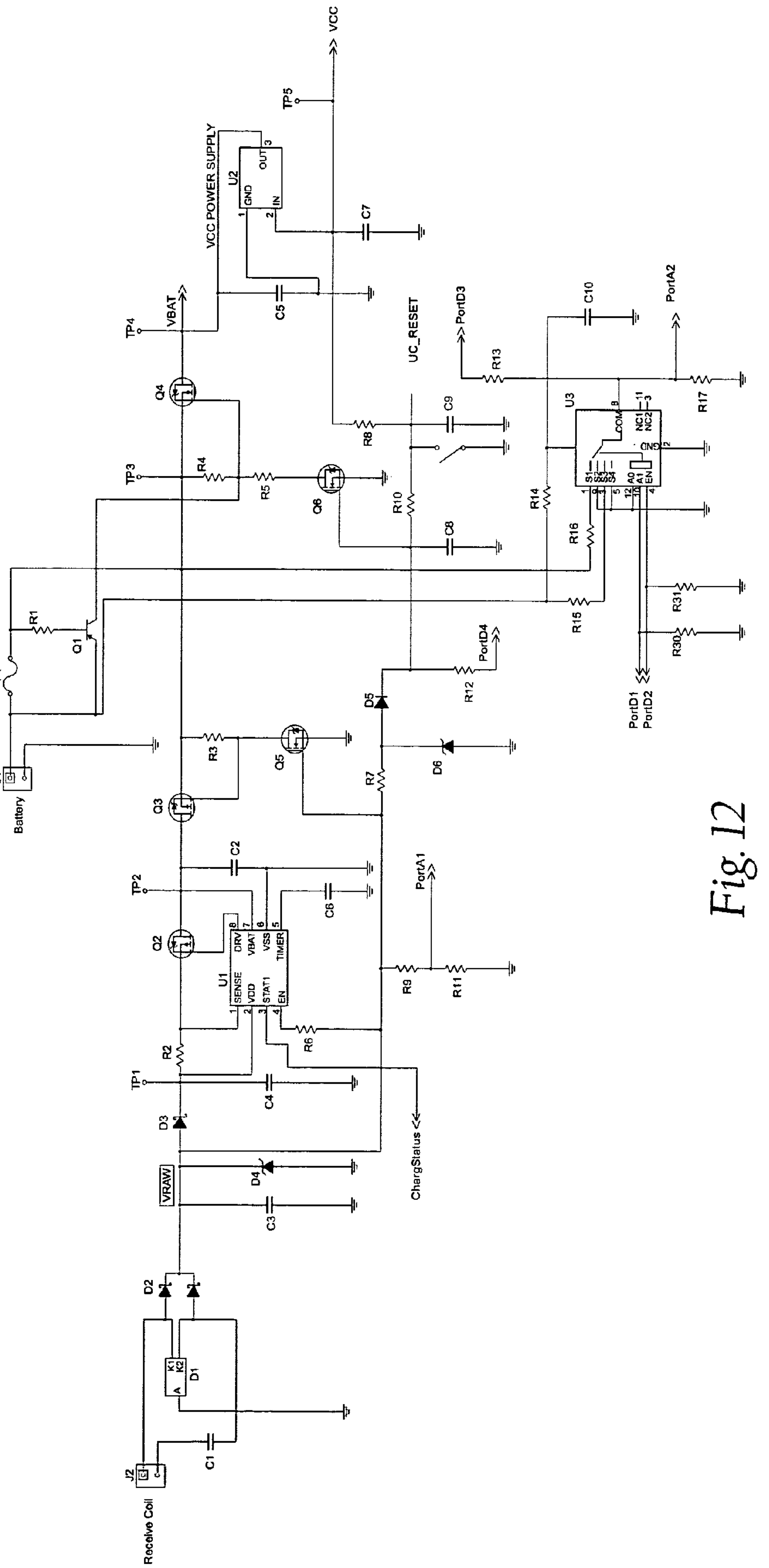
C16
PortA2
C15
PortA3
C14
Temporary Connector Tab;
Route off after Test
J3
UC_RESET
ChargStatus
Electrode2
Electrode1
XMIT
SetVHH
TRX1
TP7
RCLK
R18
U4
C11
C12
VCC
C18
C17
X1
TP6
AmplitudeMonitor
DACout
TimerAout
RecoveryPhase
SelVHH
SelAnode
SelOutput
PortD1
PortD2
PortD3
PortD4
SDA
SCL
C13
OutputSample

Fig. 11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TP5
VCC POWER SUPPLY
U2
GND
OUT
IN
C7
TP4
VBAT
C5
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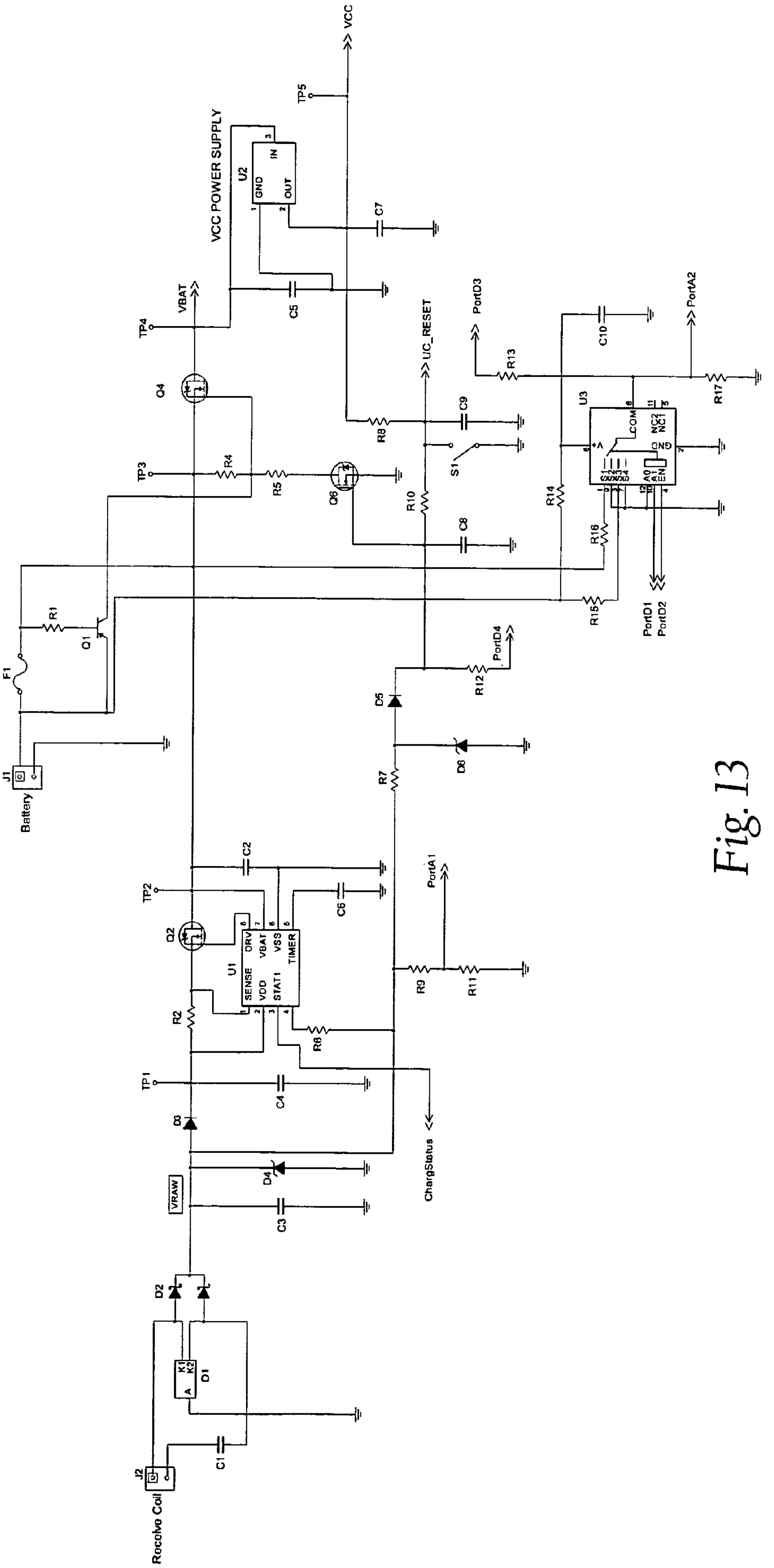
PortD3
C10
PortA2
R13
R17
U3
COM
NC1
NC2
GND
EN
R8
C9
TP3
R4
R5
Q6
Q4
R10
R14
C8
R16
R1
Q1
F1
R15
R31
PortD4
R30
R12
D5
PortD1
PortD2
J1
Battery
R3
Q5
D6
Q3
R7
C2
TP2
C6
PortA1
Q2
U1
SENSE
VDD
STAT1
EN
DRV
VBAT
VSS
TIMER
R9
R11
R2
R6
TP1
C4
D3
ChargStatus
VRAW
D4
C3
D2
K1
K2
D1
J2
Receive Coil
C1

Fig. 12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C5
Q4
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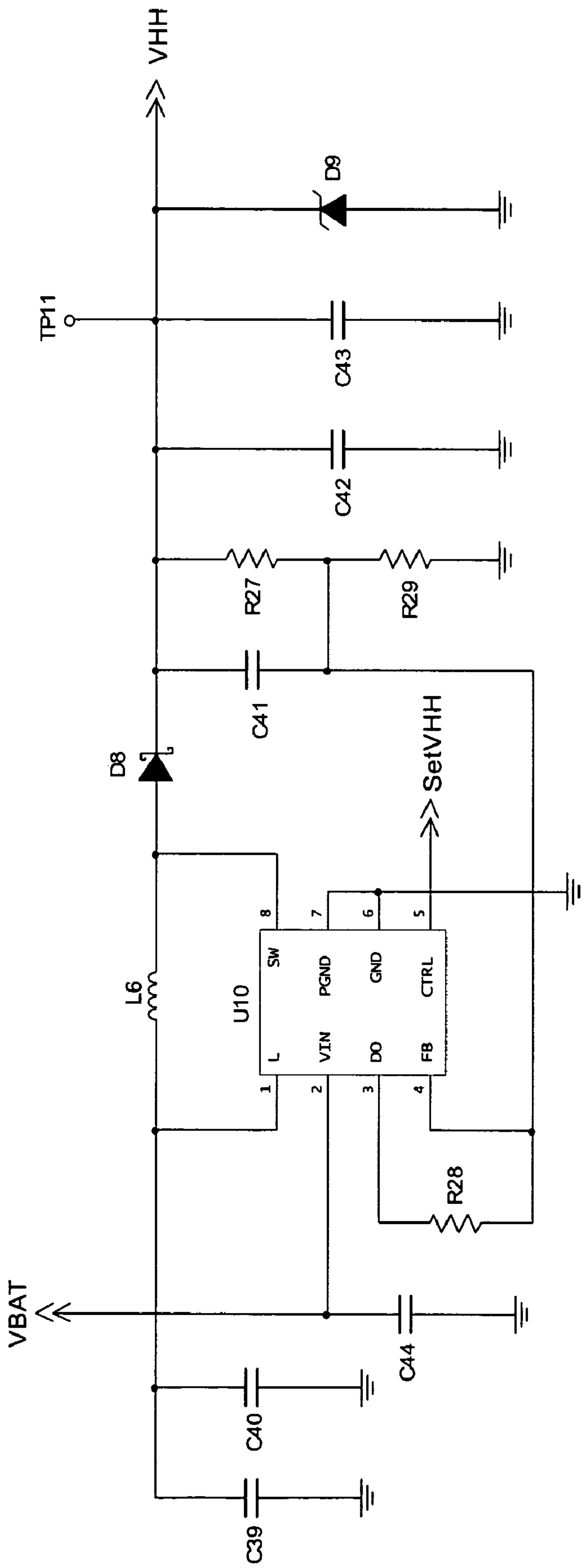
PortD3
PortA2
C10
R13
R17
U3
COM
NC2
NC1
GND
C9
R8
TP3
R4
R5
Q6
S1
R10
C8
R14
R16
R15
PortD1
PortD2
F1
R1
Q1
PortD4
R12
D5
D6
R7
J1
Battery
C2
TP2
C6
PortA1
Q2
U1
SENSE
VDD
STAT1
DRV
VBAT
VSS
TIMER
R9
R11
R2
R8
TP1
C4
D3
ChargStatus
D4
VRAW
C3
D2
D1
J2
Receive Coil
C1

Fig. 13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D9
TP11
C43
C42
R27
R29
C41
SetVHH
D8
L6
U10
SW
PGND
GND
CTRL
L
VIN
DO
FB
1
2
3
4
5
6
7
8
R28
VBAT
C44
C40
C39

Fig. 14

IMPLANTABLE PULSE GENERATOR FOR PROVIDING FUNCTIONAL AND/OR THERAPEUTIC STIMULATION OF MUSCLES AND/OR NERVES AND/OR CENTRAL NERVOUS SYSTEM TISSUE

RELATED APPLICATION

This application claims the benefit of U.S. Provisional Patent Application Ser. No. 60/578,742, filed Jun. 10, 2004, and entitled "Systems and Methods for Bilateral Stimulation of Left and Right Branches of the Dorsal Genital Nerves to Treat Dysfunctions, Such as Urinary Incontinence," and U.S. Provisional Patent Application Ser. No. 60/599,193, filed Aug. 5, 2004, and entitled "Implantable Pulse Generator for Providing Functional and/or Therapeutic Stimulation of Muscles and/or Nerves," and U.S. Provisional Patent Application Ser. No. 60/680,598, filed May 13, 2005, and entitled "Implantable Pulse Generator for Providing Functional and/or Therapeutic Stimulation of Muscles and/or Nerves and/or Central Nervous System Tissue," which are incorporated herein by reference.

FIELD OF INVENTION

This invention relates to systems and methods for providing stimulation of central nervous system tissue, muscles, or nerves, or combinations thereof.

BACKGROUND OF THE INVENTION

Neuromuscular stimulation (the electrical excitation of nerves and/or muscle to directly elicit the contraction of muscles) and neuromodulation stimulation (the electrical excitation of nerves, often afferent nerves, to indirectly affect the stability or performance of a physiological system) and brain stimulation (the stimulation of cerebral or other central nervous system tissue) can provide functional and/or therapeutic outcomes. While existing systems and methods can provide remarkable benefits to individuals requiring neuromuscular or neuromodulation stimulation, many limitations and issues still remain. For example, existing systems often can perform only a single, dedicated stimulation function.

A variety of products and treatment methods are available for neuromuscular stimulation and neuromodulation stimulation. As an example, neuromodulation stimulation has been used for the treatment of erectile dysfunction. Erectile dysfunction (ED) is often referred to as "impotency." When a man has impotency, he cannot get a firm erection or keep his penis erect during intercourse. There are some common diseases such as diabetes, Peyronie's disease, heart disease, and prostate cancer that are associated with impotency or have treatments that may cause impotency. And in some cases the cause may be psychological.

A wide range of options exist for the treatment of erectile dysfunction. Treatments include everything from medications, simple mechanical devices, psychological counseling, and surgery for both external and implantable devices.

Both external and implantable devices are available for the purpose of neuromodulation stimulation for the treatment of erectile dysfunction. The operation of these devices typically includes the use of an electrode placed either on the external surface of the skin, an anal electrode, or a surgically implanted electrode. Although these modalities have shown the ability to provide a neuromodulation stimulation with positive effects, they have received limited acceptance by patients because of their limitations of portability, limitations of treatment regimes, and limitations of ease of use and user control.

Implantable devices have provided an improvement in the portability of neuromodulation stimulation devices, but there remains the need for continued improvement. Implantable stimulators described in the art have additional limitations in that they are challenging to surgically implant because they are relatively large; they require direct skin contact for programming and for turning on and off. In addition, current implantable stimulators are expensive; owing in part to their limited scope of usage.

These implantable devices are also limited in their ability to provide sufficient power which limits their use in a wide range of neuromuscular stimulation, and limits their acceptance by patients because of the need to surgically replace the device when batteries fail, or the need to frequently recharge a rechargeable power supply.

More recently, small, implantable microstimulators have been introduced that can be injected into soft tissues through a cannula or needle. Although these small implantable stimulation devices have a reduced physical size, their application to a wide range of neuromuscular stimulation application is limited. Their micro size extremely limits their ability to maintain adequate stimulation strength for an extended period without the need for frequent replacement, or for recharging of an internal rechargeable power supply (battery). Additionally, their very small size limits the tissue volumes through which stimulus currents can flow at a charge density adequate to elicit neural excitation. This, in turn, limits or excludes many applications.

It is time that systems and methods for providing neuromuscular stimulation address not only specific prosthetic or therapeutic objections, but also address the quality of life of the individual requiring neuromuscular and neuromodulation stimulation.

SUMMARY OF THE INVENTION

The invention provides improved assemblies, systems, and methods for providing prosthetic or therapeutic stimulation of central nervous system tissue, muscles, or nerves, or muscles and nerves.

One aspect of the invention provides a stimulation assembly sized and configured to provide prosthetic or therapeutic stimulation of central nervous system tissue, muscles, or nerves, or muscles and nerves. The stimulation assembly includes an implantable pulse generator (IPG) attached to at least one lead and one electrode. The implantable pulse generator is implanted subcutaneously in tissue, preferably in a subcutaneous pocket located remote from the electrode. The electrode is implanted in electrical conductive contact (i.e., the electrode proximity to the excitable tissue allows current flow from the electrode to excite the tissue/nerve) with at least one functional grouping of neural tissue, muscle, or at least one nerve, or at least one muscle and nerve. The lead is tunneled subcutaneously in order to electrically connect the implantable pulse generator to the electrode.

Another aspect of the invention provides improved assemblies, systems, and methods for providing a universal device which can be used for many specific clinical indications requiring the application of pulse trains to muscle and/or nervous tissue for therapeutic (treatment) or functional restoration purposes.

Most of the components of the implantable pulse generator are desirably sized and configured so that they can accommodate several different indications, with no or only minor change or modification.

Technical features of the implantable pulse generator device may include one or more of the following: a primary power source and/or a rechargeable secondary power source for improved service life, wireless telemetry for programming and interrogation, a single or limited number of stimulus output stage(s) for pulse generation that are directed to one or more output channels, a lead connection header to provide reliable and easy connection and replacement of the lead/electrode, a programmable microcontroller for timing and control of the implantable pulse generator device functions, and power management circuitry for efficient recharging of the secondary power source, and the distribution of appropriate voltages and currents to other circuitry, all of which are incorporated within a small composite case for improved quality of life and ease of implantation.

In one embodiment, the power management circuitry (through the use of logic and algorithms implemented by the microcontroller) communicates with an external controller outside the body through the wireless telemetry communications link. The power management may include operating modes configured to operate the implantable pulse generator at its most efficient power consumption throughout the storage and operation of the implantable pulse generator. These modes selectively disable or shut down circuit functions that are not needed. The modes may include, but are not limited to IPG Active, IPG Dormant, and IPG Active and Charging.

In one embodiment, the power management circuitry may also be generally responsible for recovery of power from a radio-frequency (RF) magnetic field applied externally over the implantable pulse generator, for charging and monitoring the optional rechargeable battery. The efficient recharging of the secondary power source (rechargeable battery) is accomplished by adjusting the strength of the RF magnetic field generated by the externally mounted implantable pulse generator charger in response to the magnitude of the voltage recovered by the implantable pulse generator and the power demands of the implantable pulse generator's battery.

In one embodiment, the wireless telemetry may allowss the implantable pulse generator to wirelessly interact with a clinician programmer, a clinician programmer derivative, a patient controller, and in an alternative embodiment, an implantable pulse generator charger, for example. The wireless telemetry allows a clinician to transmit stimulus parameters, regimes, and other setting to the implantable pulse generator before or after it has been implanted. The wireless telemetry also allows the clinician to retrieve information stored in the implantable pulse generator about the patient's usage of the implantable pulse generator and information about any modifications to the settings of the implantable pulse generator made by the patient. The wireless telemetry also allows the patient controller operated by the user to control the implantable pulse generator, both stimulus parameters and settings in the context of a therapeutic application, or the real-time stimulus commands in the case of a neural prosthetic application. In addition, the wireless telemetry allows the operating program of the implantable pulse generator, i.e., the embedded executable code which incorporates the algorithms and logic for the operation of the implantable pulse generator, to be installed or revised after the implantable pulse generator has been assembled, tested, sterilized, and perhaps implanted. This feature could be used to provide flexibility to the manufacturer in the factory and perhaps to a representative of the manufacturer in the clinical setting. In one embodiment, the wireless telemetry allows the implantable pulse generator to communicate with the recharger (implantable pulse generator charger) during a battery recharge in order to adjust the recharging parameters if necessary, which provides for an efficient and effective recharge.

In one embodiment, the assemblies, systems and methods may provide a clinician programmer incorporating technology based on industry-standard hand-held computing platforms. The clinician programmer allows the clinician or physician to set parameters in the implantable pulse generator (IPG) relating to the treatment of the approved indication. The clinician programmer uses the wireless telemetry feature of the implantable pulse generator to bi-directionally communicate to the implantable pulse generator. In addition, additional features are contemplated based on the ability of the clinician programmer to interact with industry standard software and networks to provide a level of care that improves the quality of life of the patient and would otherwise be unavailable. Such features, using subsets of the clinician programmer software, might include the ability of the clinician or physician to remotely monitor and adjust parameters using the Internet or other known or future developed networking schemes. A clinician programmer derivative (or perhaps a feature included in the IPG charger) would connect to the patient's computer in their home through an industry standard network such as the Universal Serial Bus (USB), where in turn an applet downloaded from the clinician's server would contain the necessary code to establish a reliable transport level connection between the implantable pulse generator and the clinician's client software, using the clinician programmer derivative as a bridge. Such a connection may also be established through separately installed software. The clinician or physician could then view relevant diagnostic information, such as the health of the unit or its current efficacy, and then direct the patient to take the appropriate action. Such a feature would save the clinician, the patient and the health care system substantial time and money by reducing the number of office visits during the life of the implant.

Other features of the clinician programmer, based on an industry standard platform, might include the ability to connect to the clinician's computer system in his or hers office. Such features may take advantage of the Conduit connection employed by Palm OS based devices. Such a connection then would transfer relevant patient data to the host computer or server for electronic processing and archiving. With a feature as described here, the clinician programmer then becomes an integral link in an electronic chain that provides better patient service by reducing the amount of paperwork that the physician's office needs to process on each office visit. It also improves the reliability of the service since it reduces the chance of mis-entered or mis-placed information, such as the record of the parameter setting adjusted during the visit.

Other features and advantages of the inventions are set forth in the following specification and attached drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a view of a stimulation assembly that provides electrical stimulation to central nervous system tissue, muscles and/or nerves inside the body using a general purpose implantable pulse generator.

FIGS. **2**A and **2**B are front and side views of the general purpose implantable pulse generator shown in FIG. **1**, which is powered by a primary battery.

FIGS. **2**C and **2**D are front and side views of an alternative embodiment of a general purpose implantable pulse generator shown in FIG. **1**, which is powered using a rechargeable battery.

FIG. **3** is a view showing how the geometry of the implantable pulse generator shown in FIGS. **2**A and **2**B aids in its implantation in a tissue pocket.

FIG. **4**A is a view showing an alternative embodiment of the implantable pulse generator shown in FIGS. **2**C and **2**D, the alternative embodiment having a rechargeable battery and shown in association with a transcutaneous implantable pulse generator charger (battery recharger) including an integral charging coil which generates the RF magnetic field, and also showing the implantable pulse generator charger using wireless telemetry to communicate with the implantable pulse generator.

FIG. **4**B is an anatomic view showing the transcutaneous implantable pulse generator charger (battery recharger) as shown in FIG. **4**A, including a separate, cable coupled charging coil which generates the RF magnetic field, and also showing the implantable pulse generator charger using wireless telemetry to communicate with the implantable pulse generator.

FIG. **4**C is a perspective view of the implantable pulse generator charger of the type shown in FIGS. **4**A and **4**B, with the charger shown docked on a recharge base with the charging base connected to the power mains.

FIG. **5**A is an anatomic view showing the implantable pulse generator shown in FIGS. **2**A and **2**B in association with an external programmer that relies upon wireless telemetry, and showing the programmer's capability of communicating with the implantable pulse generator up to an arm's length away from the implantable pulse generator.

FIG. **5**B is a system view of an implantable pulse generator system incorporating a clinician programmer derivative and showing the system's capability of communicating and transferring data over a network, including a remote network.

FIG. **5**C is a perspective graphical view of one possible type of patient controller that may be used with the implantable pulse generator shown in FIGS. **2**A and **2**B.

FIG. **6** is a block diagram of a circuit that the implantable pulse generator shown in FIGS. **2**A and **2**B can incorporate.

FIG. **7** is an alternative embodiment of the block diagram shown in FIG. **6**, and shows an alternative block circuit diagram that an implantable pulse generator having a rechargeable battery may utilize.

FIG. **8** is a circuit diagram showing a possible circuit for the wireless telemetry feature used with the implantable pulse generator shown in FIGS. **2**A and **2**B.

FIG. **9** is a circuit diagram showing a possible circuit for the stimulus output stage and output multiplexing features used with the implantable pulse generator shown in FIGS. **2**A and **2**B.

FIG. **10** is a graphical view of a desirable biphasic stimulus pulse output of the implantable pulse generator for use with the system shown in FIG. **1**.

FIG. **11** is a circuit diagram showing a possible circuit for the microcontroller used with the implantable pulse generator shown in FIGS. **2**A and **2**B.

FIG. **12** is a circuit diagram showing one possible option for a power management sub-circuit where the sub-circuit includes MOSFET isolation between the battery and charger circuit, the power management sub-circuit being a part of the implantable pulse generator circuit shown in FIG. **7**.

FIG. **13** is a circuit diagram showing a second possible option for a power management sub-circuit where the sub-circuit does not include MOSFET isolation between the battery and charger circuit, the power management sub-circuit being a part of the implantable pulse generator circuit shown in FIG. **7**.

FIG. **14** is a circuit diagram showing a possible circuit for the VHH power supply feature used with the implantable pulse generator shown in FIGS. **2**A and **2**B.

The invention may be embodied in several forms without departing from its spirit or essential characteristics. The scope of the invention is defined in the appended claims, rather than in the specific description preceding them. All embodiments that fall within the meaning and range of equivalency of the claims are therefore intended to be embraced by the claims.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The various aspects of the invention will be described in connection with providing stimulation of central nervous system tissue, muscles, or nerves, or muscles and nerves for prosthetic or therapeutic purposes. That is because the features and advantages that arise due to the invention are well suited to this purpose. Still, it should be appreciated that the various aspects of the invention can be applied to achieve other objectives as well.

I. Stimulation Assembly

A. System Overview

FIG. **1** shows an assembly **10** for stimulating a central nervous system tissue, nerve, or a muscle, or a nerve and a muscle for therapeutic (treatment) or functional restoration purposes. The assembly includes an implantable lead **12** coupled to an implantable pulse generator or IPG **18**. The lead **12** and the implantable pulse generator **18** are shown implanted within a tissue region T of a human or animal body.

The distal end of the lead **12** includes at least one electrically conductive surface, which will in shorthand be called an electrode **16**. The electrode **16** is implanted in electrical conductive contact with at least one functional grouping of neural tissue, muscle, or at least one nerve, or at least one muscle and nerve. The implantable pulse generator **18** includes a connection header **14** that desirably carries a plug-in receptacle for the lead **12**. In this way, the lead **12** electrically connects the electrode **16** to the implantable pulse generator **18**.

The implantable pulse generator **18** is sized and configured to be implanted subcutaneously in tissue, desirably in a subcutaneous pocket P, which can be remote from the electrode **16**, as FIG. **1** shows. Desirably, the implantable pulse generator **18** is sized and configured to be implanted using a minimally invasive surgical procedure.

The surgical procedure may be completed in a number of steps. For example, once a local anesthesia is established, the electrode **16** is positioned at the target site. Next, a subcutaneous pocket P is made and sized to accept the implantable pulse generator **18**. The pocket P is formed remote from the electrode **16**. Having developed the subcutaneous pocket P for the implantable pulse generator **18**, a subcutaneous tunnel is formed for connecting the lead **12** and electrode **16** to the implantable pulse generator **18**. The lead **12** is routed through the subcutaneous tunnel to the pocket site P where the implantable pulse generator **18** is to be implanted. The lead **12** is then coupled to the implantable pulse generator **18**, and both the lead **12** and implantable pulse generator **18** are placed into the subcutaneous pocket, which is sutured closed.

As FIGS. **2**A and **2**B shows, the implantable pulse generator **18** includes a circuit **20** that generates electrical stimulation waveforms. An on-board, primary battery **22** desirably provides the power. In an alternative embodiment, the battery may be a rechargeable battery. The implantable pulse generator **18** also desirably includes an on-board, programmable microcontroller **24**, which carries embedded code. The code expresses pre-programmed rules or algorithms under which the desired electrical stimulation waveforms are generated by the circuit **20**. The implantable pulse generator **18** desirably includes an electrically conductive case **26**, which can also serve as the return electrode for the stimulus current introduced by the lead/electrode when operated in a monopolar configuration.

According to its programmed rules, when switched on, the implantable pulse generator **18** generates prescribed stimulation waveforms through the lead **12** and to the electrode **16**. These stimulation waveforms stimulate the central nervous system tissue, muscle, nerve, or both nerve and muscle tissue that lay in electrical conductive contact (i.e., within close proximity to the electrode surface where the current densities are high) with the electrode **16**, in a manner that achieves the desired therapeutic (treatment) or functional restoration result. As previously discussed, erectile restoration is just one example of a functional restoration result. Additional examples of desirable therapeutic (treatment) or functional restoration indications will be described in greater detail in section II.

The assembly **10** may also include additional operative components, such as but not limited to, a clinician programmer, a clinician programmer derivative, a patient controller, and an implantable pulse generator charger, each of which will be discussed later.

B. The Implantable Pulse Generator

Desirably, the size and configuration of the implantable pulse generator **18** makes possible its use as a general purpose or universal device (i.e., creating a platform technology), which can be used for many specific clinical indications requiring the application of pulse trains to central nervous system tissue, muscle and/or nervous tissue for therapeutic (treatment) or functional restoration purposes. Most of the components of the implantable pulse generator **18** are desirably sized and configured so that they can accommodate several different indications, without major change or modification. Examples of components that desirably remain unchanged for different indications include the case **26**, the battery **22**, the power management circuitry **40**, the microcontroller **24**, much of the software (firmware) of the embedded code, and the stimulus power supply. Thus, a new indication may require only changes to the programming of the microcontroller **24**. Most desirably, the particular code is remotely embedded in the microcontroller **24** after final assembly, packaging, and sterilization of the implantable pulse generator **18**.

Certain components of the implantable pulse generator **18** may be expected to change as the indication changes; for example, due to differences in leads and electrodes, the connection header **14** and associated receptacle(s) for the lead may be configured differently for different indications. Other aspects of the circuit **20** may also be modified to accommodate a different indication; for example, the stimulator output stage(s), sensor(s) and/or sensor interface circuitry.

In this way, the implantable pulse generator **18** is well suited for use for diverse indications. The implantable pulse generator **18** thereby accommodates coupling to a lead **12** and an electrode **16** implanted in diverse tissue regions, which are targeted depending upon the therapeutic (treatment) or functional restoration results desired. The implantable pulse generator **18** also accommodates coupling to a lead **12** and an electrode **16** having diverse forms and configurations, again depending upon the therapeutic or functional effects desired. For this reason, the implantable pulse generator can be considered to be general purpose or "universal."

1. Desirable Technical Features

The implantable pulse generator **18** can incorporate various technical features to enhance its universality.

a. Small, Composite Case

According to one desirable technical feature, the implantable pulse generator **18** can be sized small enough to be implanted (or replaced) with only local anesthesia. As FIGS. **2**A and **2**B show, the functional elements of the implantable pulse generator **18** (e.g., circuit **20**, the microcontroller **24**, the battery **22**, and the connection header **14**) are integrated into a small, composite case **26**. As can be seen in FIG. **2**A and **2**B, the implantable pulse generator **18** may comprise a case **26** having a small cross section, e.g., 5 mm to 10 mm thick×(45 mm to 60 mm wide)×(45 mm to 60 mm long). The overall weight of the implantable pulse generator **18** may be approximately twenty to thirty grams. These dimensions make possible implantation of the case **26** with a small incision; i.e., suitable for minimally invasive implantation. Additionally, a larger, but similarly shaped IPG might be required for applications with more stimulus channels (thus requiring a large connection header) and or a larger internal battery.

FIGS. **2**C and **2**D illustrate an alternative embodiment of an implantable pulse generator **68** utilizing a rechargeable battery **72**. The rechargeable implantable pulse generator **68** shares many features of the primary cell implantable pulse generator **18**. Like structural elements are therefore assigned like numerals. As can be seen, the case **76** defines a small cross section; e.g., (5 mm to 10 mm thick)×(15 mm to 25 mm wide)×(40 mm to 50 mm long). These dimensions make possible implantation of the case **76** with a small incision; i.e., suitable for minimally invasive implantation.

The case **26** of the implantable pulse generator **18** is desirably shaped with a smaller end **30** and a larger end **32**. As FIG. **3** shows, this geometry allows the smaller end **30** of the case **26** to be placed into the skin pocket P first, with the larger end **32** being pushed in last.

Desirably, the case **26** for the implantable pulse generator **18** comprises a laser welded titanium material. This construction offers high reliability with a low manufacturing cost. The clam shell construction has two stamped or successively drawn titanium case halves that are laser welded around the circuit assembly and battery **22** with feed-thrus. Typically, a molded plastic spacing nest is used to hold the battery **22**, the circuit **20**, and perhaps a power recovery (receive) coil together and secure them within the titanium case.

The implantable pulse generator **18** shown in FIGS. **2**A and **2**B includes a clam-shell case **26** having a thickness that is selected to provide adequate mechanical strength The implantable pulse generator **18** may be implanted at a target implant depth of not less than five millimeters beneath the skin, and not more than fifteen millimeters beneath the skin, although this implant depth may change due to the particular application, or the implant depth may change over time based on physical conditions of the patient.

In an alternative embodiment utilizing a rechargeable battery, the thickness of the titanium for the case is selected to provide adequate mechanical strength while balancing the greater power absorption and shielding effects to the low to medium frequency magnetic field **54** used to transcutaneously recharge the implantable rechargeable battery **72** with thicker case material (the competing factors are poor transformer action at low frequencies—due to the very low transfer impedances at low frequencies—and the high shielding losses at high frequencies). The selection of the thickness ensures that the titanium case allows adequate power coupling to recharge the secondary power source (described below) of the rechargeable pulse generator **68** at the target implant depth using a low frequency radio frequency (RF) magnetic field **52** from an implantable pulse generator charger **34** mounted on the skin (see FIGS. **4**A and **4**B).

b. Primary Power Source

According to one desirable technical feature, the implantable pulse generator **18** desirably possesses an internal battery capacity sufficient to allow a service life of greater than three years with the stimulus being a high duty cycle, e.g., virtually continuous, low frequency, low current stimulus pulses, or alternatively, the stimulus being higher frequency and amplitude stimulus pulses that are used only intermittently, e.g., a very low duty cycle.

To achieve this feature, the primary battery **22** of the implantable pulse generator **18** desirably comprises a primary power source; most desirably a Lithium Ion battery **22**. Given the average quiescent operating current (estimated at 8 μA plus 35 μA for a wireless telemetry receiver pulsing on twice every second) and a seventy percent efficiency of the stimulus power supply, a 1.0 Amp-hr primary cell battery can provide a service life of less than two years, which is too short to be clinically or commercially viable for this indication. Therefore, the implantable pulse generator **18** desirably incorporates a primary battery, e.g., a Lithium Ion battery. Given representative desirable stimulation parameters (which will be described later), a Lithium Ion battery with a capacity of at least 30 mA-hr will operate for over three years. Lithium Ion implant grade batteries are available from a domestic supplier. A representative battery provides 35 mA-hr in a package configuration that is of appropriate size and shape to fit within the implantable pulse generator **18**.

The implantable pulse generator **18** desirably incorporates circuitry and/or programming to assure that the implantable pulse generator **18** will suspend stimulation, and perhaps fall-back to only very low rate telemetry, and eventually suspends all operations when the primary battery **22** has discharged the majority of its capacity (i.e., only a safety margin charge remains). Once in this dormant mode, the implantable pulse generator may provide limited communications and is in condition for replacement.

In an alternative embodiment, the rechargeable implantable pulse generator **68** desirably possesses a rechargeable battery capacity sufficient to allow operation with recharging not more frequently than once per week for many or most clinical applications. The battery **72** of the rechargeable implantable pulse generator **68** desirably can be recharged in less than approximately six hours with a recharging mechanism that allows the patient to sleep in bed or carry on most normal daily activities while recharging the battery **72** of the rechargeable implantable pulse generator **68**.

The power for recharging the battery **72** of the rechargeable implantable pulse generator **68** is provided through the application of a low frequency (e.g., 30 KHz to 300 KHz) RF magnetic field **52** applied by a skin or clothing mounted recharger **34** placed over the implantable pulse generator (see FIGS. **4**A and **4**B). In one possible application, it is anticipated that the user would wear the recharger **34**, including an internal magnetic coupling coil (charging coil) **35**, over the rechargeable implantable pulse generator **68** to recharge the rechargeable implantable pulse generator **68** (see FIG. **4**A). Alternatively, the recharger **34** might use a separate magnetic coupling coil (charging coil) **35** which is placed and/or secured on the skin or clothing over the rechargeable implantable pulse generator **68** and connected by cable to the recharger **34** (circuitry and battery in a housing) that is worn on a belt or clipped to the clothing (see FIG. **4**B).

The charging coil **35** preferably includes a predetermined construction, e.g., 200 turns of six strands of #36 enameled magnetic wire, or the like. Additionally, the charging coil mean diameter is preferably about 50 millimeters, although the diameter may vary. The thickness of the charging coil **35** as measured perpendicular to the mounting plane is to be significantly less than the diameter, e.g., two to five millimeters, so as to allow the coil to be embedded or laminated in a sheet to facilitate placement on or near the skin. Such a construction will allow for efficient power transfer and will allow the charging coil **35** to maintain a temperature below 41 degrees Celsius.

The recharger **34** preferably includes its own internal batteries which may be recharged from the power mains, for example. A charging base **39** may be included to provide for convenient docking and recharging of the system's operative components, including the recharger and the recharger's internal batteries (see FIG. **4**C). The implantable pulse generator recharger **34** does not need to be plugged into the power mains while in use to recharge the rechargeable implantable pulse generator **68**.

Desirably, the rechargeable implantable pulse generator **68** may be recharged while it is operating and will not increase in temperature by more than two degrees Celsius above the surrounding tissue during the recharging. It is desirable that the recharging of the battery **72** requires not more than six hours, and a recharging would be required between once per month to once per week depending upon the power requirements of the stimulus regime used.

c. Wireless Telemetry

According to one desirable technical feature, the system or assembly **10** includes an implantable pulse generator **18**, which desirably incorporates wireless telemetry (rather that an inductively coupled telemetry) for a variety of functions to be performed within arm's reach of the patient, the functions including receipt of programming and clinical parameters and settings from the clinician programmer **36**, communicating usage history to the clinician programmer, providing user control of the implantable pulse generator **18**, and alternatively for controlling the RF magnetic field **52** generated by the rechargeable implantable pulse generator charger **34**. Each implantable pulse generator may also have a unique signature that limits communication to only the dedicated controllers (e.g., the matched Patient Controller, implantable pulse generator Charger, or a clinician programmer configured for the implantable pulse generator in question).

The implantable pulse generator **18** desirably incorporates wireless telemetry as an element of the implantable pulse generator circuit **20** shown in FIG. **6**. A circuit diagram showing a desired configuration for the wireless telemetry feature is shown in FIG. **8**. It is to be appreciated that modifications to this circuit diagram configuration which produce the same or similar functions as described are within the scope of the invention.

As shown in FIG. **5**A, the assembly **10** desirably includes a clinician programmer **36** that, through a wireless telemetry **38**, transfers commands, data, and programs into the implantable pulse generator **18** and retrieves data out of the implantable pulse generator **18**. In some configurations, the clinician programmer may communicate with more than one implantable pulse generator implanted in the same user.

The clinician programmer **36** may incorporate a custom programmed general purpose digital device, e.g., a custom program, industry standard handheld computing platform or other personal digital assistant (PDA). The clinician programmer **36** can include an on-board microcontroller powered by a rechargeable battery. The rechargeable battery of the clinician programmer **36** may be recharged in the same or similar manner as described and shown for the recharger **34**, i.e., docked on a charging base **39** (see FIG. **4**C); or the custom electronics of the clinician programmer may receive power from the connected PDA. The microcontroller carries embedded code which may include pre-programmed rules or algorithms that allow a clinician to remotely download program stimulus parameters and stimulus sequences parameters into the implantable pulse generator **18**. The microcontroller of the clinician programmer **36** is also desirably able to interrogate the implantable pulse generator and upload usage data from the implantable pulse generator. FIG. **5**A shows one possible application where the clinician is using the programmer **36** to interrogate the implantable pulse generator. FIG. **5**B shows an alternative application where the clinician programmer, or a clinician programmer derivative **33** intended for remote programming applications and having the same or similar functionality as the clinician programmer, is used to interrogate the implantable pulse generator. As can be seen, the clinician programmer derivative **33** is connected to a local computer, allowing for remote interrogation via a local area network, wide area network, or Internet connection, for example.

Using subsets of the clinician programmer software, features of the clinician programmer **36** or clinician programmer derivative **33** might include the ability of the clinician or physician to remotely monitor and adjust parameters using the Internet or other known or future developed networking schemes. A clinician programmer derivative **33** (perhaps a feature included in the implantable pulse generator charger) would desirably connect to the patient's computer in their home through an industry standard network such as the Universal Serial Bus (USB), where in turn an applet downloaded from the clinician's server would contain the necessary code to establish a reliable transport level connection between the implantable pulse generator **18** and the clinician's client software, using the clinician programmer derivative **33** as a bridge. Such a connection may also be established through separately installed software. The clinician or physician could then view relevant diagnostic information, such as the health of the unit or its current settings, and then modify the stimulus settings in the IPG or direct the patient to take the appropriate action. Such a feature would save the clinician, the patient and the health care system substantial time and money by reducing the number of office visits during the life of the implant.

Other features of the clinician programmer, based on an industry standard platform, might include the ability to connect to the clinician's computer system in his or hers office. Such features may take advantage of the Conduit connection employed by Palm OS based devices. Such a connection then would transfer relevant patient data to the host computer or server for electronic processing and archiving. With a feature as described here, the clinician programmer then becomes an integral link in an electronic chain that provides better patient service by reducing the amount of paperwork that the physician's office needs to process on each office visit. It also improves the reliability of the service since it reduces the chance of mis-entered or mis-placed information, such as the record of the parameter setting adjusted during the visit.

With the use of a patient controller **37** (see FIG. **5**C), the wireless link **38** allows a patient to control certain parameters of the implantable pulse generator within a predefined limited range. The parameters may include the operating modes/states, increasing/decreasing or optimizing stimulus patterns, or providing open or closed loop feedback from an external sensor or control source. The wireless telemetry **38** also desirably allows the user to interrogate the implantable pulse generator **18** as to the status of its internal battery **22**. The full ranges within these parameters may be controlled, adjusted, and limited by a clinician, so the user may not be allowed the full range of possible adjustments.

In one embodiment, the patient controller **37** is sized and configured to couple to a key chain, as seen in FIG. **5**C. It is to be appreciated that the patient controller **37** may take on any convenient shape, such as a ring on a finger, or a watch on a wrist, or an attachment to a belt, for example. It may also be desirable to combine both the functions of the implantable pulse generator charger and the patient controller into a single external device.

The wireless telemetry may incorporate a suitable, low power wireless telemetry transceiver (radio) chip set that can operate in the MICS (Medical Implant Communications Service) band (402 MHz to 405 MHz) or other VHF/UHF low power, unlicensed bands. A wireless telemetry link not only makes the task of communicating with the implantable pulse generator **18** easier, but it also makes the link suitable for use in motor control applications where the user issues a command to the implantable pulse generator to produce muscle contractions to achieve a functional goal (e.g., to stimulate ankle flexion to aid in the gait of an individual after a stroke) without requiring a coil or other component taped or placed on the skin over the implanted implantable pulse generator.

Appropriate use of power management techniques is important to the effective use of wireless telemetry. Desirably, the implantable pulse generator is exclusively the communications slave, with all communications initiated by the external controller (the communications master). The receiver chip of the implantable pulse generator is OFF more than 99 % of the time and is pulsed on periodically to search for a command from an external controller, including but not limited to the clinician programmer **36**, the patient controller **37**, and alternatively the implantable pulse generator charger **34**. Communications protocols include appropriate check and message acknowledgment handshaking to assure the necessary accuracy and completeness of every message. Some operations (such as reprogramming or changing stimulus parameters) require rigorous message accuracy testing and acknowledgement. Other operations, such as a single user command value in a string of many consecutive values, might require less rigorous checking and a more loosely coupled acknowledgement.

The timing with which the implantable pulse generator enables its transceiver to search for RF telemetry from an external controller is precisely controlled (using a time base established by a quartz crystal) at a relatively low rate, e.g., the implantable pulse generator may look for commands from the external controller at a rate of less than one (1) Hz. This equates to a monitoring interval of several seconds. It is to be appreciated that the monitoring rate may vary faster or slower depending on the application, (e.g., twice per second; i.e., every 500 milliseconds). This allows the external controller to time when the implantable pulse generator responds to a command and then to synchronize its commands with when the implantable pulse generator will be listening for commands. This, in turn, allows commands issued within a short time (seconds to minutes) of the last command to be captured and acted upon without having to 'broadcast' an idle or pause signal for 500 milliseconds before actually issuing the command in order to know that the implantable pulse generator will have enabled its receiver and received the command. Similarly, the communications sequence is configured to have the external controller issue commands in synchronization with when the implantable pulse generator will be listening for a command. Similarly, the command set implemented is selected to minimize the number of messages necessary and the length of each message consistent with the appropriate level of error detection and message integrity monitoring. It is to be appreciated that the monitoring rate may vary faster or slower depending on the application; and may vary over time within a given application.

A suitable radio chip is used for the half duplex wireless communications, e.g., the AMIS-52100 (AMI Semiconductor; Pocatello, Id.). This transceiver chip is designed specifically for the MICS and its European counter-part the ULP-AMI (Ultra Low Power-Active Medical Implant) band. This chip set is optimized by micro-power operation with rapid start-up, and RF 'sniffing' circuitry.

In an alternative embodiment having a rechargeable battery, the recharger **34** shown in FIGS. **4**A and **4**B may also use wireless telemetry to communicate with the rechargeable implantable pulse generator **68**, so as to adjust the magnitude of the magnetic field **52** to allow optimal recharging of the rechargeable implantable pulse generator battery **72** while minimizing unnecessary power consumption by the recharger and power dissipation in the rechargeable implantable pulse generator **68** (through circuit losses and/or through absorption by the rechargeable implantable pulse generator case **76** and construction).

d. Stimulus Output Stage

According to one desirable technical feature, the implantable pulse generator **18** desirably uses a single stimulus output stage (generator) that is directed to one or more output channels (electrode surfaces) by analog switch(es) or analog multiplexer(s). Desirably, the implantable pulse generator **18** will deliver at least one channel of stimulation via a lead/electrode. For applications requiring more stimulus channels, several channels (perhaps up to four) can be generated by a single output stage. In turn, two or more output stages could be used, each with separate multiplexing to multiple channels, to allow an implantable pulse generator with eight or more stimulus channels. The stimulation desirably has a biphasic waveform (net DC current less than 10 μA), amplitude of at least 8 mA, for neuromodulation applications, or 16 mA to 20 mA for muscle stimulation applications, and pulse durations up to 500 microseconds. The stimulus current (amplitude) and pulse duration being programmable on a channel to channel basis and adjustable over time based on a clinically programmed sequence or regime or based on user (patient) commands received via the wireless communications link.

A circuit diagram showing a desired configuration for the stimulus output stage feature is shown in FIG. **9**. It is to be appreciated that modifications to this circuit diagram configuration which produce the same or similar functions as described are within the scope of the invention.

For neuromodulation/central nervous system applications, the implantable pulse generator **18** may have the capability of applying stimulation twenty-four hours per day. A typical stimulus regime for such applications might have a constant stimulus phase, a no stimulus phase, and ramping of stimulus levels between these phases.

Desirably, the implantable pulse generator **18** includes a single stimulus generator (with its associated DC current blocking output capacitor) which is multiplexed to a number of output channels; or a small number of such stimulus generators each being multiplexed to a number of output channels. This circuit architecture allows multiple output channels with very little additional circuitry. A typical, biphasic stimulus pulse is shown in FIG. **10**. Note that the stimulus output stage circuitry **46** may incorporate a mechanism to limit the recovery phase current to a small value (perhaps 0.5 mA). Also note that the stimulus generator (and the associated timing of control signals generated by the microcontroller) may provide a delay (typically of the order of 100 microseconds) between the cathodic phase and the recovery phase to limit the recovery phase diminution of the cathodic phase effective at eliciting a neural excitation. The charge recovery phase for any electrode (cathode) must be long enough to assure that all of the charge delivered in the cathodic phase has been returned in the recovery phase; i.e., greater than or equal to five time constants are allowed for the recovery phase. This will allow the stimulus stage to be used for the next electrode while assuring there is no net DC current transfer to any electrode. Thus, the single stimulus generator having this characteristic would be limited to four channels (electrodes), each with a maximum frequency of 30 Hz to 50 Hz. This operating frequency exceeds the needs of many indications for which the implantable pulse generator is well suited. For applications requiring more channels (or higher composite operating frequencies), two or more separate output stages might each be multiplexed to multiple (e.g., four) electrodes.

e. The Lead Connection Header

According to one desirable technical feature, the implantable pulse generator **18** desirably includes a lead connection header **14** for connecting the lead(s) **12** that will enable reliable and easy replacement of the lead/electrode (see FIGS. **2**A and **2**B), and includes a small antenna **54** for use with the wireless telemetry feature.

The implantable pulse generator desirably incorporates a connection header (top header) **14** that is easy to use, reliable, and robust enough to allow multiple replacements of the implantable pulse generator after many years (e.g., more than ten years) of use. The surgical complexity of replacing an implantable pulse generator is usually low compared to the surgical complexity of correctly placing the implantable lead **12**/electrode **16** in proximity to the target nerve/tissue and routing the lead **12** to the implantable pulse generator. Accordingly, the lead **12** and electrode **16** desirably has a service life of at least ten years with a probable service life of fifteen years or more. Based on the clinical application, the implantable pulse generator may not have this long a service life. The implantable pulse generator service life is largely determined by the power capacity of the Lithium Ion battery **22**, and is likely to be three to ten years, based on the usage of the device. Desirably, the implantable pulse generator **18** has a service life of at least three years.

As described above, the implantable pulse generator preferably will use a laser welded titanium case. As with other active implantable medical devices using this construction, the implantable lead(s) **12** connect to the implantable pulse generator through a molded or cast polymeric connection header **14** (top header). Metal-ceramic or metal-glass feed-thrus maintain the hermetic seal of the titanium capsule while providing electrical contact to the electrical contacts of the lead **12**/electrode **16**.

The standard implantable connectors may be similar in design and construction to the low-profile IS-1 connector system (per ISO 5841-3). The IS-1 connectors have been in use since the late 1980s and have been shown to be reliable and provide easy release and re-connection over several implantable pulse generator replacements during the service life of a single pacing lead. Full compatibility with the IS-1 standard, and mating with pacemaker leads, is not a requirement for the implantable pulse generator.

The implantable pulse generator connection system may include a modification of the IS-1 connector system, which shrinks the axial length dimensions while keeping the format and radial dimensions of the IS-1. For application with more than two electrode conductors, the top header **14** may incorporate one or more connection receptacles each of which accommodate leads with typically four conductors. When two or more leads are accommodated by the header, these lead may exit the connection header in opposite directions (i.e., from opposite sides of the header).

These connectors can be similar to the banded axial connectors used by other multi-polar implantable pulse generators or may follow the guidance of the draft IS-4 implantable connector standard. The design of the implantable pulse generator housing and header **14** preferably includes provisions for adding the additional feed-thrus and larger headers for such indications.

The inclusion of the UHF antenna **54** for the wireless telemetry inside the connection header (top header) **14** is necessary as the shielding offered by the titanium case will severely limit (effectively eliminate) radio wave propagation through the case. The antenna **54** connection will be made through a feed-thru similar to that used for the electrode connections. Alternatively, the wireless telemetry signal may be coupled inside the implantable pulse generator onto a stimulus output channel and coupled to the antenna **54** with passive filtering/coupling elements/methods in the connection header **14**.

f. The Microcontroller

According to one desirable technical feature, the implantable pulse generator **18** desirably uses a standard, commercially available micro-power, flash programmable microcontroller **24** or processor core in an application specific integrated circuit (ASIC). This device (or possibly more than one such device for a computationally complex application with sensor input processing) and other large semiconductor components may have custom packaging such as chip-on-board, solder flip chip, or adhesive flip chip to reduce circuit board real estate needs.

A circuit diagram showing a desired configuration for the microcontroller **24** is shown in FIG. **11**. It is to be appreciated that modifications to this circuit diagram configuration which produce the same or similar functions as described are within the scope of the invention.

g. Power Management Circuitry

According to one desirable technical feature, the implantable pulse generator **18** desirably includes efficient power management circuitry as an element of the implantable pulse generator circuitry **20** shown in FIG. **6**. The power management circuitry is generally responsible for the efficient distribution of power and monitoring the battery **22**, and alternatively for the recovery of power from the RF magnetic field **52** and for charging and monitoring the rechargeable battery **72**. In addition, the operation of the implantable pulse generator **18** can be described in terms of having operating modes as relating to the function of the power management circuitry. These modes may include, but are not limited to IPG Active, IPG Dormant, and alternatively, IPG Active and Charging. These modes will be described below in terms of the principles of operation of the power management circuitry using possible circuit diagrams shown in FIGS. **12** and **13**. FIG. **12** shows one possible power management sub-circuit having MOSFET isolation between the battery **22** and the charger circuit. FIG. **13** shows another possible power management sub-circuit diagram without having MOSFET isolation between the battery **22** and the charger circuit. In the circuit without the isolation MOSFET (see FIG. **13**), the leakage current of the disabled charge control integrated circuit chip (U1) must be very low to prevent this leakage current from discharging the battery **22** in all modes (including the Dormant Mode). Except as noted, the description of these modes applies to both circuits.

i. IPG Active Mode

The IPG Active mode occurs when the implantable pulse generator **18** is operating normally. In this mode, the implantable pulse generator may be generating stimulus outputs or it may be waiting for the next request to generate stimulus in response to a timed neuromodulation sequence or a telemetry command from an external controller. In this mode, the implantable pulse generator is active (microcontroller **24** is powered and coordinating wireless communications and may be timing & controlling the generation and delivery of stimulus pulses).

i(a) Principles of Operation, IPG Active Mode

In the IPG Active mode, as can be seen in FIG. **12**, the lack of DC current from VRAW means that Q5 is held off. This, in turn, holds Q3 off and a portion of the power management circuitry is isolated from the battery **22**. In FIG. **13**, the lack of DC current from VRAW means that U**1** is disabled. This, in turn, keeps the current drain from the battery **22** to an acceptably low level, typically less than 1 μA.

ii. IPG Dormant Mode

The IPG Dormant mode occurs when the implantable pulse generator **18** is completely disabled (powered down). In this mode, power is not being supplied to the microcontroller **24** or other enabled circuitry. This is the mode for the long-term storage of the implantable pulse generator before or after implantation. The dormant mode may only be exited by placing a pacemaker magnet (or comparable device) over the implantable pulse generator **18** for a predetermined amount of time, e.g., five seconds.

In an alternative embodiment, the dormant mode may be exited by placing the rechargeable implantable pulse generator **68** into the Active and Charging mode by placing the implantable pulse generator charging coil **35** of a functional implantable pulse generator charger **34** in close proximity to the rechargeable implantable pulse generator **68**.

ii(a) Principles of Operation, IPG Dormant Mode

In the IPG Dormant mode, VBAT is not delivered to the remainder of the implantable pulse generator circuitry because Q**4** is turned off. The Dormant mode is stable because the lack of VBAT means that VCC is also not present, and thus Q**6** is not held on through R**8** and R**10**. Thus the battery **22** is completely isolated from all load circuitry (the VCC power supply and the VHH power supply).

The Dormant mode is entered through the application of a long magnet placement over S**1** (magnetic reed switch) or through the reception of a command by the wireless telemetry. In the case of the telemetry command, the PortD**4**, which is normally configured as a microcontroller input, is configured as a logic output with a logic low (0) value. This, in turn, discharges C**8** through R**12** and turns off Q**6**; which, in turn, turns off Q**4** and forces the implantable pulse generator into the Dormant mode. Note that R**12** is much smaller in value than R**10**, thus the microcontroller **24** can force C**8** to discharge even though VCC is still present.

In FIG. **12**, the lack of DC current from VRAW means that Q**5** is held off. This, in turn, holds Q**3** off and a portion of the power management circuitry is isolated from the battery **22**. Also, Q**4** was turned off. In FIG. **13**, the lack of DC current from VRAW means that U**1** is disabled. This, in turn, keeps the current drain from the battery **22** to an acceptably low level, typically less than 1 μA.

iii. IPG Active and Charging Mode

In an alternative embodiment having a rechargeable battery, the IPG Active and Charging mode occurs when the rechargeable implantable pulse generator **68** is being charged. In this mode, the rechargeable implantable pulse generator **68** is active, i.e., the microcontroller **24** is powered and coordinating wireless communications and may be timing and controlling the generation and delivery of stimulus pulses. The rechargeable implantable pulse generator **68** may be communicating with the implantable pulse generator charger **34** concerning the magnitude of the battery voltage and the DC voltage recovered from the RF magnetic field **52**. The charger **34** uses this data for two purposes: to provide feedback to the user about the proximity of the charging coil **35** to the implanted pulse generator, and to increase or decrease the strength of the RF magnetic field **52**. This, in turn, minimizes the power losses and undesirable heating of the implantable pulse generator.

While in the IPG Active and Charging mode, the power management circuitry **40** serves the following primary functions:

(1) provides battery power to the rest of the rechargeable implantable pulse generator circuitry **70**,

(2) recovers power from the RF magnetic field **52** generated by the implantable pulse generator charger **34**,

(3) provides controlled charging current (from the recovered power) to the rechargeable battery **72**, and

(4) communicates with the implantable pulse generator charger **34** via the wireless telemetry link **38** to provide feedback to the user positioning the charging coil **35** over the rechargeable implantable pulse generator **68**, and to cause the implantable pulse generator charger **34** to increase or decrease the strength of its RF magnetic field **52** for optimal charging of the rechargeable implantable pulse generator battery **72** (Lithium Ion battery).

iii(a)Principles of Operation, IPG Active and Charging Mode

iii(a) (1) RF voltage is induced in the Receive Coil by the RF magnetic field **52** of the implantable pulse generator charger **34**

iii(a) (2) Capacitor C**1** is in series with the Receive Coil and is selected to introduce a capacitive reactance that compensates (subtracts) the inductive reactance of the Receive Coil

iii(a) (3) D**1**-D**2** form a full wave rectifier that converts the AC voltage recovered by the Receive Coil into a pulsating DC current flow

iii(a) (4) This pulsating DC current is smoothed (filtered) by C**3** (this filtered DC voltage is labeled VRAW)

iii(a) (5) D**4** is a zener diode that acts as a voltage limiting device (in normal operation, D**4** is not conducting significant current)

iii(a) (6) D**3** prevents the flow of current from the rechargeable battery **72** from preventing the correct operation of the Charge Management Circuitry once the voltage recovered from the RF magnetic field is removed. Specifically, current flow from the battery [through Q**3** (turned ON), in the case for the circuit of FIG. **11**] through the body diode of Q**2** would hold ON the charge controller IC (U**1**). This additional current drain would be present in all modes, including dormant, and would seriously limit battery operating life. Additionally, this battery current pathway would keep Q**6** turned ON even if the magnetic reed switch (S**1**) were closed; thus preventing the isolation of the IPG circuitry from the battery in the dormant mode.

iii(a) (7) U**1**, Q**2**, R**2**, C**4**, C**6**, and C**2** form the battery charger sub-circuit

U**1** is a micropower, Lithium Ion Charge Management Controller chip implementing a constant current phase and constant voltage phase charge regime. This chip desirably incorporates an internal voltage reference of high accuracy (+/− 0.5%) to establish the constant voltage charge level. U**1** performs the following functions:

monitors the voltage drop across a series resistor R**2** (effectively the current charging the rechargeable battery **72**) to control the current delivered to the battery through the external pass transistor Q**2**. U**1** uses this voltage across R**2** to establish the current of the constant current phase (typically the battery capacity divided by five hours) and

decreases the current charging the battery as required to limit the battery voltage and effectively transition from constant current phase to constant voltage phase as the battery voltage approaches the terminal voltage,

iii(a) (8) U**1** also includes provisions for timing the duration of the constant current and constant voltage phases and suspends the application of current to the rechargeable battery **72** if too much time is spent in the phase. These fault timing features of U**1** are not used in normal operation.

iii (a) (9) In this circuit, the constant voltage phase of the battery charging sequence is timed by the microcontroller **24** and not by U**1**. The microcontroller monitors the battery voltage and terminates the charging sequence (i.e., tells the implantable pulse generator charger **34** that the rechargeable implantable pulse generator battery **72** is fully charged) after the battery voltage has been in the constant voltage region for greater than a fixed time period (e.g., 15 to 20 minutes).

iii(a) (10) In FIG. **12**, Q**3** and Q**5** are turned ON only when the charging power is present. This effectively isolates the charging circuit from the rechargeable battery **72** when the externally supplied RF magnetic field **52** is not present and providing power to charge the rechargeable battery.

iii(a) (11) In FIG. **13**, U**1** is always connected to the rechargeable battery **72**, and the disabled current of this chip is a load on the rechargeable battery **72** in all modes (including the dormant mode). This, in turn, is a more demanding requirement on the current consumed by U**1** while disabled.

iii(a) (12) F**1** is a fuse that protects against long-duration, high current component failures. In all anticipated transient high current failures, (i.e., soft failures that cause the circuitry to consume high current levels and thus dissipate high power levels; but the failure initiating the high current flow is not permanent and the circuit will resume normal function if the circuit is removed from the power source before damage from overheating occurs), the VBAT circuitry will disconnect the rechargeable battery **72** from the temporary high load without blowing the fuse. The specific sequence is:

High current flows into a component(s) powered by VBAT (most likely the VHH power supply or an element powered by the VCC power supply).

The voltage drop across the fuse will (prior to the fuse blowing) turn ON Q**1** (based on the current flow through the fuse causing a 0.5V to 0.6V drop across the resistance of F**1**).

The collector current from Q**1** will turn off Q**4**.

VBAT drops very quickly and, as a direct result, VCC falls. In turn, the voltage on the PortD**4** IO pin from the microcontroller voltage falls as VCC falls, through the parasitic diodes in the microcontroller **24**. This then pulls down the voltage across C**6** as it is discharged through R**12**.

The rechargeable implantable pulse generator **68** is now stable in the Dormant Mode, i.e., VBAT is disconnected from the rechargeable battery **72** by a turned OFF Q**4**. The only load remaining on the battery is presented by the charging circuit and by the analog multiplexer (switches) U**3** that are used to direct an analog voltage to the microcontroller **24** for monitoring the battery voltage and (by subtracting the voltage after the resistance of F**1**) an estimate of the current consumption of the entire circuit. A failure of these voltage monitoring circuits is not protected by the fuse, but resistance values limit the current flow to safe levels even in the event of component failures. A possible source of a transient high-current circuit failure is the SCR latchup or supply-to-ground short failure of a semiconductor device directly connected to VBAT or VCC.

iii(a) (13) R**9** & R**11** form a voltage divider to convert VRAW (0V to 8V) into the voltage range of the microcontroller's A-D inputs (used for closed loop control of the RF magnetic field strength),

iii(a) (14) R**8** and C**9** form the usual R-C reset input circuit for the microcontroller **24**; this circuit causes a hardware reset when the magnetic reed switch (S**1**) is closed by the application of a suitable static magnetic field for a short duration,

iii(a) (15) R**10** and C**8** form a much slower time constant that allows the closure of the reed switch by the application of the static magnetic field for a long duration to force the rechargeable implantable pulse generator **68** into the Dormant mode by turning OFF Q**6** and thus turning OFF Q**4**. The use of the magnetic reed switch for resetting the microcontroller **24** or forcing a total implantable pulse generator shutdown (Dormant mode) may be a desirable safety feature.

2. Representative Implantable Pulse Generator Circuitry

FIG. **6** shows an embodiment of a block diagram circuit **20** for the primary cell implantable pulse generator **18** that takes into account the desirable technical features discussed above. FIG. **7** shows an embodiment of a block diagram circuit **70** for the rechargeable implantable pulse generator **68** that also takes into account the desirable technical features discussed above.

Both the circuit **20** and the circuit **70** can be grouped into functional blocks, which generally correspond to the association and interconnection of the electronic components. FIGS. **6** and **7** show alternative embodiments of a block diagram that provides an overview of a representative desirable implantable pulse generator design. As can be seen, there may be re-use of the circuit **20**, or alternatively, portions of the circuit **20** of the primary cell implantable pulse generator **18**, with minimal modifications, e.g., a predetermined selection of components may be included or may be exchanged for other components, and minimal changes to the operating firmware. Re-use of a majority of the circuitry from the primary cell implantable pulse generator **18** and much of the firmware from the primary cell implantable pulse generator **18** allows for a low development cost for the rechargeable implantable pulse generator **68** having a secondary cell **72**.

In FIGS. **6** and **7**, seven functional blocks are shown: (1) The Microprocessor or Microcontroller **24**; (2) the Power Management Circuit **40**; (3) the VCC Power Supply **42**; (4) the VHH Power Supply **44**; (5) the Stimulus Output Stage(s) **46**; (6) the Output Multiplexer(s) **48**; and (7) the Wireless Telemetry Circuit **50**.

For each of these blocks, the associated functions, possible key components, and circuit description are now described.

a. The Microcontroller

The Microcontroller **24** is responsible for the following functions:

(1) The timing and sequencing of the stimulator stage and the VHH power supply used by the stimulator stage,

(2) The sequencing and timing of power management functions,

(3) The monitoring of the battery voltage, the stimulator voltages produced during the generation of stimulus pulses, and the total circuit current consumption, VHH, and VCC,

(4) The timing, control, and interpretation of commands to and from the wireless telemetry circuit,

(5) The logging (recording) of patient usage data as well as clinician programmed stimulus parameters and configuration data, and

(6) The processing of commands (data) received from the user (patient) via the wireless link to modify the characteristics of the stimulus being delivered.

The use of a microcontroller incorporating flash programmable memory allows the operating program of the implantable pulse generator as well as the stimulus parameters and settings to be stored in non-volatile memory (data remains safely stored even if the battery **22** becomes fully discharged; or if the implantable pulse generator is placed in the Dormant Mode). Yet, the data (operating program, stimulus parameters, usage history log, etc.) can be erased and reprogrammed thousands of times during the life of the implantable pulse generator. The software (firmware) of the implantable pulse generator must be segmented to support the operation of the wireless telemetry routines while the flash memory of the microcontroller **24** is being erased and reprogrammed. Similarly, the VCC power supply **42** must support the power requirements of the microcontroller **24** during the flash memory erase and program operations.

Although the microcontroller **24** may be a single component, the firmware is developed as a number of separate modules that deal with specific needs and hardware peripherals. The functions and routines of these software modules are executed sequentially; but the execution of these modules are timed and coordinated so as to effectively function simultaneously. The microcontroller operations that are associated directly with a given hardware functional block are described with that block.

The Components of the Microcontroller Circuit may include:

(1) A single chip microcontroller **24**. This component may be a member of the Texas Instruments MSP430 family of flash programmable, micro-power, highly integrated mixed signal microcontroller. Likely family members to be used include the MSP430F1610, MSP430F1611, MSP430F1612, MSP430F168, and the MSP430F169. Each of these parts has numerous internal peripherals, and a micropower internal organization that allows unused peripherals to be configured by minimal power dissipation, and an instruction set that supports bursts of operation separated by intervals of sleep where the microcontroller suspends most functions.

(2) A miniature, quartz crystal (X**1**) for establishing precise timing of the microcontroller. This may be a 32.768 KHz quartz crystal.

(3) Miscellaneous power decoupling and analog signal filtering capacitors.

b. Power Management Circuit

The Power Management Circuit **40** (including associated microcontroller actions) is responsible for the following functions:

(1) monitor the battery voltage,

(2) suspend stimulation when the battery voltage becomes very low, and/or suspend all operation (go into the Dormant Mode) when the battery voltage becomes critically low,

(3) communicate (through the wireless telemetry link **38**) with the external equipment the charge status of the battery **22**,

(4) prevent (with single fault tolerance) the delivery of excessive current from the battery **22**,

(5) provide battery power to the rest of the circuitry of the implantable pulse generator, i.e., VCC and VHH power supplies,

(6) provide isolation of the Lithium Ion battery **22** from other circuitry while in the Dormant Mode,

(7) provide a hard microprocessor reset and force entry into the Dormant Mode in the presence of a pacemaker magnet (or comparable device), and

(8) provide the microcontroller **24** with analog voltages with which to measure the magnitude of the battery voltage and the appropriate battery current flow (drain and charge).

Alternative responsibilities for the Power Management Circuitry may include:

(1) recover power from the Receive Coil,

(2) control delivery of the Receive Coil power to recharge the Lithium Ion secondary battery **72**,

(3) monitor the battery voltage during charge and discharge conditions,

(4) communicate (through the wireless telemetry link **38**) with the externally mounted implantable pulse generator charger **34** to increase or decrease the strength of the RF magnetic field **52** for optimal charging of the rechargeable battery **72**,

(5) disable (with single fault tolerance) the delivery of charging current to the rechargeable battery **72** in overcharge conditions, and

(6) provide the microcontroller **24** with analog voltages with which to measure the magnitude of the recovered power from the RF magnetic field **52**.

The Components of the Power Management Circuit may include:

(1) Low on resistance, low threshold P channel MOSFETs with very low off state leakage current (Q**2**, Q**3**, and Q**4**).

(2) Analog switches (or an analog multiplexer) U3.

(3) Logic translation N-channel MOSFETs (Q**5** & Q**6**) with very low off state leakage current.

Alternative components of the Power Management Circuit may include:

(1) The Receive Coil, which desirably is a multi-turn, fine copper wire coil near the inside perimeter of the rechargeable implantable pulse generator **68**. Preferably, the receive coil includes a predetermined construction, e.g., **300** turns of four strands of #40 enameled magnetic wire, or the like. The maximizing of the coil's diameter and reduction of its effective RF resistance allows necessary power transfer at and beyond the typical implant depth of about one centimeter.

(2) A micropower Lithium Ion battery charge management controller IC (integrated circuit); such as the MicroChip MCP73843-41, or the like.

c. The VCC Power Supply

The VCC Power Supply **42** is generally responsible for the following functions:

(1) Some of the time, the VCC power supply passes the battery voltage to the circuitry powered by VCC, such as the microcontroller **24**, stimulator output stage **46**, wireless telemetry circuitry **50**, etc.

(2) At other times, the VCC power supply fractionally steps up the voltage to about 3.3V; (other useable voltages include 3.0V, 2.7V, etc.) despite changes in the Lithium Ion battery **22** voltage. This higher voltage is required for some operations such as programming or erasing the flash memory in the microcontroller **24**, (i.e., in circuit programming).

The voltage converter/switch part at the center of the VCC power supply may be a charge pump DC to DC converter. Typical choices for this part may include the Maxim MAX1759, the Texas Instruments TPS60204, or the Texas Instruments REG710, among others. In an alternative embodiment having a rechargeable battery **72**, the VCC power supply may include a micropower, low drop out, linear voltage regulator; e.g., Microchip NCP1700T-3302, Maxim Semiconductor MAX1725, or Texas Instruments TPS79730.

The characteristics of the VCC Power Supply might include:

(1) high efficiency and low quiescent current, i.e., the current wasted by the power supply in its normal operation. This value should be less than a few microamperes; and

(2) drop-out voltage, i.e., the minimal difference between the VBAT supplied to the VCC power supply and its output voltage. This voltage may be less than about 100 mV even at the current loads presented by the transmitter of the wireless telemetry circuitry **50**.

(3) The VCC power supply **42** may allows in-circuit reprogramming of the implantable pulse generator firmware, or optionally, the implantable pulse generator **18** may not use a VCC power supply, which may not allow in-circuit reprogramming of the implantable pulse generator firmware.

d. VHH Power Supply

A circuit diagram showing a desired configuration for the VHH power supply **44** is shown in FIG. **14**. It is to be appreciated that modifications to this circuit diagram configuration which produce the same or similar functions as described are within the scope of the invention.

The VHH Power Supply **44** is generally responsible for the following functions:

(1) Provide the Stimulus Output Stage **46** and the Output Multiplexer **48** with a programmable DC voltage between the battery voltage and a voltage high enough to drive the required cathodic phase current through the electrode circuit plus the voltage drops across the stimulator stage, the output multiplexer stage, and the output coupling capacitor. VHH is typically 12 VDC or less for neuromodulation applications; and 25V or less for muscle stimulation applications.

The Components of the VHH Power Supply might include:

(1) Micropower, inductor based (fly-back topology) switch mode power supply (U**10**); e.g., Texas Instruments TPS61045, Texas Instruments TPS61041, or Linear Technology LT3464 with external voltage adjustment components.

(2) L**6** is the flyback energy storage inductor.

(3) C**42** & C**43** form the output capacitor.

(4) R**27**, R**28**, and R**29** establish the operating voltage range for VHH given the internal DAC which is programmed via the SETVHH logic command from the microcontroller **24**.

(5) Diode D**9** serves no purpose in normal operation and is added to offer protection from over-voltage in the event of a VHH circuit failure.

(6) The microcontroller **24** monitors VHH for detection of a VHH power supply failure, system failures, and optimizing VHH for the exhibited electrode circuit impedance.

e. Stimulus Output Stage

The Stimulus Output Stage(s) **46** is responsible for the following functions:

(1) Generate the identified biphasic stimulus current with programmable (dynamically adjustable during use) cathodic phase amplitude, pulse width, and frequency. The recovery phase may incorporate a maximum current limit; and there may be a delay time (most likely a fixed delay) between the cathodic phase and the recovery phase (see FIG. **10**). Typical currents (cathodic phase) for neuromodulation applications are 1 mA to 10 mA; and 2 mA to 20 mA for muscle stimulation applications. For applications using nerve cuff electrodes or other electrodes that are in very close proximity to the excitable neural tissue, stimulus amplitudes of less than 1 mA might be necessary. Electrode circuit impedances can vary with the electrode and the application, but are likely to be less than 2,000 ohms and greater than 100 ohms across a range of electrode types.

The Components of the Stimulus Output Stage may include:

(1) The cathodic phase current through the electrode circuit is established by a high gain (HFE) NPN transistor (Q**7**) with emitter degeneration. In this configuration, the collector current of the transistor (Q**7**) is defined by the base drive voltage and the value of the emitter resistor (R**24**).

Two separate configurations are possible: In the first configuration (as shown in FIG. **9**), the base drive voltage is provided by a DAC peripheral inside the microcontroller **24** and is switched on and off by a timer peripheral inside the microcontroller. This switching function is performed by an analog switch (U**8**). In this configuration, the emitter resistor (R**24**) is fixed in value and fixed to ground.

In a second alternative configuration, the base drive voltage is a fixed voltage pulse (e.g., a logic level pulse) and the emitter resistor is manipulated under microcontroller control. Typical options may include resistor(s) terminated by microcontroller IO port pins that are held or pulsed low, high, or floating; or an external MOSFET that pulls one or more resistors from the emitter to ground under program control. Note that the pulse timing need only be applied to the base drive logic; the timing of the emitter resistor manipulation is not critical.

The transistor (Q**7**) desirably is suitable for operation with VHH on the collector. The cathodic phase current through the electrode circuit is established by the voltage drop across the emitter resistor. Diode D**7**, if used, provides a degree of temperature compensation to this circuit.

(2) The microcontroller **24** (preferably including a programmable counter/timer peripheral) generates stimulus pulse timing to generate the cathodic and recovery phases and the interphase delay. The microcontroller **24** also monitors the cathode voltage to confirm the correct operation of the output coupling capacitor, to detect system failures, and to optimize VHH for the exhibited electrode circuit impedance; i.e., to measure the electrode circuit impedance. Additionally, the microcontroller **24** can also monitor the pulsing voltage on the emitter resistor; this allows the fine adjustment of low stimulus currents (cathodic phase amplitude) through changes to the DAC value.

f. The Output Multiplexer

The Output Multiplexer **48** is responsible for the following functions:

(1) Route the Anode and Cathode connections of the Stimulus Output Stage **46** to the appropriate electrode based on addressing data provided by the microcontroller **24**.

(2) Allow recharge (recovery phase) current to flow from the output coupling capacitor back through the electrode circuit with a programmable delay between the end of the cathodic phase and the beginning of the recovery phase (the interphase delay).

The circuit shown in FIG. **9** may be configured to provide monopolar stimulation (using the case **26** as the return electrode) to Electrode **1**, to Electrode **2**, or to both through time multiplexing. This circuit could also be configured as a single bipolar output channel by changing the hardwire connection between the circuit board and the electrode; i.e., by routing the CASE connection to Electrode **1** or Electrode **2**. The use of four or more channels per multiplexer stage (i.e., per output coupling capacitor) is possible.

The Components of the Output Multiplexer might include:

(1) An output coupling capacitor in series with the electrode circuit. This capacitor is desirably located such that there is no DC across the capacitor in steady state. This capacitor is typically charged by the current flow during the cathodic phase to a voltage range of about ¼h to 1/10th of the voltage across the electrode circuit during the cathodic phase. Similarly, this capacitor is desirably located in the circuit such that the analog switches do not experience voltages beyond their ground of power supply (VHH).

(2) The analog switches (U**7**) must have a suitably high operating voltage, low ON resistance, and very low quiescent current consumption while being driven from the specified logic levels. Suitable analog switches include the Vishay/Siliconix DG412HS, for example.

(3) Microcontroller **24** selects the electrode connections to carry the stimulus current (and time the interphase delay) via address lines.

(4) Other analog switches (U**9**) may be used to sample the voltage of VHH, the CASE, and the selected Electrode. The switched voltage, after the voltage divider formed by R**25** and R**26**, is monitored by the microcontroller **24**.

g. Wireless Telemetry Circuit

The Wireless Telemetry circuit **50** is responsible for the following functions:

(1) Provide reliable, bidirectional communications (half duplex) with an external controller, programmer, or an optional charger **34**, for example, via a VHF-UHF RF link (likely in the 403 MHZ to 406 MHz MICS band per FCC 47 CFR Part 95 and the Ultra Low Power-Active Medical Implant (AMI) regulations of the European Union). This circuit will look for RF commands at precisely timed intervals (e.g., twice a second), and this function must consume very little power. Much less frequently this circuit will transmit to the external controller. This function should also be as low power as possible; but will represent a lower total energy demand than the receiver in most of the anticipated applications. The RF carrier is amplitude modulated (on-off keyed) with the digital data. Serial data is generated by the microcontroller **24** already formatted and timed. The wireless telemetry circuit **50** converts the serial data stream into a pulsing carrier signal during the transit process; and it converts a varying RF signal strength into a serial data stream during the receive process.

The Components of the Wireless Telemetry Circuit might include:

(1) a crystal controlled, micropower transceiver chip such as the AMI Semiconductor AMIS-52100 (U**6**). This chip is responsible for generating the RF carrier during transmissions and for amplifying, receiving, and detecting (converting to a logic level) the received RF signals. The transceiver chip must also be capable of quickly starting and stopping operation to minimize power consumption by keeping the chip disabled (and consuming very little power) the majority of the

time; and powering up for only as long as required for the transmitting or receiving purpose.

(2) The transceiver chip has separate transmit and receive ports that must be switched to a single antenna/feedthru. This function is performed by the transmit/receive switch (U**5**) under microcontroller control via the logic line XMIT. The microcontroller **24** controls the operation of the transceiver chip via an I^2C serial communications link. The serial data to and from the transceiver chip may be handled by a UART or a SPI peripheral of the microcontroller. The message encoding/decoding and error detection may be performed by a separate, dedicated microcontroller; else this processing will be time shared with the other tasks of the only microcontroller.

The various inductor and capacitor components (U**6**) surrounding the transceiver chip and the transmit/receive switch (U**5**) are impedance matching components and harmonic filtering components, except as follows:

(1) X**2**, C**33** and C**34** are used to generate the crystal controlled carrier, desirably tuned to the carrier frequency divided by thirty-two,

(2) L**4** and C**27** form the tuned elements of a VCO (voltage controlled oscillator) operating at twice the carrier frequency, and

(3) R**20**, C**29**, and C**30** are filter components of the PLL (phase locked loop) filter.

II. Representative Indications

Due to their technical features, the implantable pulse generator **18** and the alternative embodiment rechargeable implantable pulse generator **68** as described in section I can be used to provide beneficial results in diverse therapeutic and functional restorations indications.

For example, in the field of urology, possible indications for use of the implantable pulse generators **18** and **68** include the treatment of (i) urinary and fecal incontinence; (ii) micturition/retention; (iii) restoration of sexual function; (iv) defecation/constipation; (v) pelvic floor muscle activity; and/or (vi) pelvic pain.

The implantable pulse generators **18** and **68** can be used for deep brain stimulation in the treatment of (i) Parkinson's disease; (ii) multiple sclerosis; (iii) essential tremor; (iv) depression; (v) eating disorders; (vi) epilepsy; and/or (vii) minimally conscious state.

The implantable pulse generators **18** and **68** can be used for pain management by interfering with or blocking pain signals from reaching the brain, in the treatment of, e.g., (i) peripheral neuropathy; and/or (ii) cancer.

The implantable pulse generators **18** and **68** can be used for vagal nerve stimulation for control of epilepsy, depression, or other mood/psychiatric disorders.

The implantable pulse generators **18** and **68** can be used for the treatment of obstructive sleep apnea.

The implantable pulse generators **18** and **68** can be used for gastric stimulation to prevent reflux or to reduce appetite or food consumption.

The implantable pulse generators **18** and **68** can be used in functional restorations indications such as the restoration of motor control, to restore (i) impaired gait after stroke or spinal cord injury (SCI); (ii) impaired hand and arm function after stroke or SCI; (iii) respiratory disorders; (iv) swallowing disorders; (v) sleep apnea; and/or (vi) neurotherapeutics, allowing individuals with neurological deficits, such as stroke survivors or those with multiple sclerosis, to recover functionally.

The foregoing is considered as illustrative only of the principles of the invention. Furthermore, since numerous modifications and changes will readily occur to those skilled in the art, it is not desired to limit the invention to the exact construction and operation shown and described. While the preferred embodiment has been described, the details may be changed without departing from the invention, which is defined by the claims.

We claim:

1. A neuromuscular stimulation system comprising:

at least one electrically conductive surface sized and configured for implantation in a targeted neural or muscular tissue region;

a lead electrically coupled to the electrically conductive surface, the lead sized and configured to be positioned in subcutaneous tissue; and

an implantable pulse generator including a rechargeable battery, wherein the implantable pulse generator is sized and configured to be coupled to the lead and positioned in subcutaneous tissue remote from the at least one electrically conductive surface,

the implantable pulse generator comprising a non-inductive wireless telemetry circuitry using VHF/UHF signals, and inductive wireless telemetry circuitry using a radio frequency magnetic field, the non-inductive wireless telemetry circuitry being functional at a distance as far as arm's reach away from a patient, and being adapted to receive and transmit VHF/UHF signals for programming and interrogation of the implantable pulse generator, the inductive wireless telemetry circuitry including a coil adapted to receive the magnetic field from an external controller to recharge the rechargeable battery,

the implantable pulse generator adapted to communicate with the external controller using the non-inductive wireless telemetry to instruct the external controller to increase or decrease the strength of the magnetic field during recharging for optimal battery charging, while at the same time, the implantable pulse generator adapted to receive the magnetic field to recharge the rechargeable battery, and

the non-inductive wireless telemetry circuitry including a transceiver to listen for commands from the external controller at a predetermined rate and to respond to the commands in synchronization with when the external controller is configured to listen for the response.

2. A system according to claim **1**, wherein the implantable pulse generator includes an antenna for transmission and reception of the non-inductive wireless telemetry signals.

3. A system according to claim **1**, further including the external controller, wherein the external controller is adapted to download program stimulus parameters and stimulus sequence parameters into the implantable pulse generator, and to upload operational data from the implantable pulse generator, the external controller acting as a master and utilizing the non-inductive wireless telemetry for all communications with the implantable pulse generator.

4. A system according to claim **1**,

wherein the implantable pulse generator includes a lead connection header for electrically coupling the lead to the implantable pulse generator, the lead connection header enabling reliable replacement of the implantable pulse generator.

5. A system according to claim **1**,

wherein the implantable pulse generator is sized and configured for implanting in subcutaneous tissue at an implant depth of between about 0.5 cm and about 1.5 cm.

6. A system according to claim **1**,

wherein the implantable pulse generator includes at least one power management operating mode.

7. A system according to claim **1**,

wherein the implantable pulse generator includes at least three power management operating modes including an active mode, an idle mode, and a dormant mode.

8. A system according to claim **1**,

wherein the implantable pulse generator outputs a pulse having a biphasic waveform, the biphasic waveform including a net DC current of less than about 10 μA, an interphase delay, an amplitude of up to about 15 mA, and a pulse duration up to about 500 μsec.

9. A system according to claim **1**,

wherein the implantable pulse generator provides stimulus pulses for the treatment of indications selected from the group consisting of urinary incontinence, fecal incontinence, micturition/retention, defecation/constipation, restoration of sexual function, pelvic floor muscle activity, pelvic pain, deep brain stimulation, obstructive sleep apnea, gastric function, and restoration of motor control.

10. A system according to claim **1**, wherein the implantable pulse generator comprises a case having a size between about 5 mm and about 10 mm thick, between about 15 mm and about 25 mm wide, and between about 40 mm and about 50 mm long.

11. A system according to claim **1**, wherein the implantable pulse generator further comprises a housing having a metallic portion and a non-metallic portion, and an antenna located at least partially inside the non-metallic portion, the antenna for transmission and reception of the non-inductive wireless telemetry signals.

12. A system according to claim **11**, wherein the non-metallic portion comprises a non-metallic lead connection header.

13. A method of using a neuromuscular stimulation system comprising:

providing at least one electrically conductive surface sized and configured for implantation in a targeted neural or muscular tissue region, the at least one electrically conductive surface including a lead electrically coupled to the electrically conductive surface, the lead sized and configured to be positioned in subcutaneous tissue;

providing an implantable pulse generator including a rechargeable battery, wherein the implantable pulse generator is sized and configured to be positioned in subcutaneous tissue remote from the at least one electrically conductive surface, the implantable pulse generator comprising non-inductive wireless telemetry circuitry using VHF/UHF signals, and inductive wireless telemetry circuitry using a radio frequency magnetic field, the non-inductive wireless telemetry circuitry being functional at a distance as far as arm's reach away from a patient, and being adapted to receive and transmit VHF/UHF signals for programming and interrogation of the implantable pulse generator, the non-inductive wireless telemetry circuitry including a transceiver to listen for commands from an external controller at a predetermined rate and to respond to the commands in synchronization with when the external controller is configured to listen for the response, the inductive wireless telemetry circuitry including a coil for receiving the magnetic field from an external controller for recharging the rechargeable battery;

implanting the at least one electrically conductive surface in a targeted neural or muscular tissue region;

implanting the lead in subcutaneous tissue;

implanting the pulse generator in a region remote from the at least one electrically conductive surface;

coupling the pulse generator to the lead implanted in subcutaneous tissue;

operating the pulse generator to use the non-inductive wireless telemetry to be listening for commands from the external controller at the predetermined rate and to be responding to the commands in synchronization with when the external controller is listening for the response; and

operating the implantable pulse generator to be responding to the external controller using the non-inductive wireless telemetry and instructing the external controller to increase or decrease the strength of the magnetic field during recharging, while at the same time, the implantable pulse generator receiving the magnetic field and recharging the rechargeable battery.

14. A method according to claim **13**,

wherein the predetermined rate ranges from listening more than once per second to listening once every other second.

15. A method according to claim **13**,

wherein the timing of the synchronization is controlled by a time base established by a crystal.

16. A method according to claim **13**, further including:

providing an external controller comprising a non-inductive wireless telemetry using VHF/UHF signals, and an inductive wireless telemetry circuitry using a radio frequency magnetic field, and

wherein the external controller is configured to time when the implantable pulse generator responds to a command such that the external controller synchronizes its commands with when the implantable pulse generator will be listening for commands, while at the same time, the external controller is configured to provide the magnetic field to the implantable pulse generator to recharge the rechargeable battery.

17. A method according to claim **13**, wherein the implantable pulse generator comprises a case having a size between about 5 mm and about 10 mm thick, between about 15 mm and about 25 mm wide, and between about 40 mm and about 50 mm long.

18. A method according to claim **13**, wherein the implantable pulse generator further comprises a housing having a metallic portion and a non-metallic portion, and an antenna located at least partially inside the non-metallic portion, the antenna being configured for transmission and reception of the non-inductive wireless telemetry signals.

19. A method according to claim **18**, wherein the non-metallic portion comprises a non-metallic lead connection header.

20. A neuromuscular stimulation system comprising:

at least one electrically conductive surface sized and configured for implantation in a targeted neural or muscular tissue region;

a lead electrically coupled to the electrically conductive surface, the lead sized and configured to be positioned in subcutaneous tissue; and

an implantable pulse generator including a rechargeable battery, wherein the implantable pulse generator is sized and configured to be coupled to the lead and positioned in subcutaneous tissue remote from the at least one electrically conductive surface,

the implantable pulse generator comprising non-inductive wireless telemetry circuitry using VHF/UHF signals, and inductive wireless telemetry circuitry using a radio frequency magnetic field, the non-inductive wireless telemetry circuitry being functional at a distance as far as arm's reach away from a patient, and being adapted to receive and transmit VHF/UHF signals for programming and interrogation of the implantable pulse generator, the inductive wireless telemetry circuitry including a coil adapted to receive the magnetic field from an external controller to recharge the rechargeable battery,

the non-inductive wireless telemetry circuitry including a transceiver to listen for commands from the external controller at a predetermined rate,

the non-inductive wireless telemetry circuitry including a transceiver to listen for commands and not respond to commands from the external controller at a predetermined rate and to respond to the commands in synchronization with when the external controller is configured to listen for the response, and

the implantable pulse generator adapted to communicate with the external controller using the non-inductive wireless telemetry to instruct the external controller to increase or decrease the strength of the magnetic field during recharging for optimal battery charging, while at the same time, the implantable pulse generator adapted to receive the magnetic field to recharge the rechargeable battery.

21. A system according to claim **20**, wherein the implantable pulse generator comprises a case having a size between about 5 mm and about 10 mm thick, between about 15 mm and about 25 mm wide, and between about 40 mm and about 50 mm long.

22. A system according to claim **20**, wherein the implantable pulse generator further comprises a housing having a metallic portion and a non-metallic portion, and an antenna located at least partially inside the non-metallic portion, the antenna being configured for transmission and reception of the non-inductive wireless telemetry signals.

23. A system according to claim **22**, wherein the non-metallic portion comprises a non-metallic lead connection header.

24. A neuromuscular stimulation system comprising:

at least one electrically conductive surface sized and configured for implantation in a targeted neural or muscular tissue region;

a lead electrically coupled to the electrically conductive surface, the lead sized and configured to be positioned in subcutaneous tissue; and

an implantable pulse generator including a rechargeable battery, wherein the implantable pulse generator is sized and configured to be coupled to the lead and positioned in subcutaneous tissue remote from the at least one electrically conductive surface,

the implantable pulse generator comprising non-inductive wireless telemetry circuitry using VHF/UHF signals, and inductive wireless telemetry circuitry using a radio frequency magnetic field, the non-inductive wireless telemetry circuitry being functional at a distance as far as arm's reach away from a patient, and being adapted to receive and transmit VHF/UHF signals for programming and interrogation of the implantable pulse generator, the inductive wireless telemetry circuitry including a coil adapted to receive the magnetic field from an external controller to recharge the rechargeable battery,

the non-inductive wireless telemetry circuitry including a transceiver to listen for commands from the external controller at a predetermined rate and to respond to the commands in synchronization with when the external controller is configured to listen for the response,

the non-inductive wireless telemetry circuitry configured to have commands issued from the external controller within a predetermined time of a last command to be received by the implantable pulse generator without having the external controller broadcast an idle or pause signal for the predetermined rate before issuing the command in order to know that the implantable pulse generator will have enabled its transceiver and received the command, and

the implantable pulse generator adapted to communicate with the external controller using the non-inductive wireless telemetry to instruct the external controller to increase or decrease the strength of the magnetic field during recharging for optimal battery charging, while at the same time, the implantable pulse generator adapted to receive the magnetic field to recharge the rechargeable battery.

25. A system according to claim **24**,

wherein the predetermined time ranges from one command issued per second to one command issued per five minutes.

26. A system according to claim **1** or **20** or **24**,

wherein the predetermined rate ranges from more than one listen per second to one listen every other second.

27. A system according to claim **1** or **20** or **24**,

wherein the timing of the synchronization is controlled by a time base established by a crystal.

28. A system according to claim **1** or **20** or **24**, further including the external controller, wherein the

external controller comprises non-inductive wireless telemetry using VHF/UHF signals, and inductive wireless telemetry circuitry using a radio frequency magnetic field, the external controller adapted to time when the implantable pulse generator responds to a command and then to synchronize its commands with when the implantable pulse generator will be listening for commands, while at the same time, the external controller adapted to provide the magnetic field to the implantable pulse generator to recharge the rechargeable battery.

29. A system according to claim **24**, wherein the implantable pulse generator comprises a case having a size between about 5 mm and about 10 mm thick, between about 15 mm and about 25 mm wide, and between about 40 mm and about 50 mm long.

30. A system according to claim **24**, wherein the implantable pulse generator further comprises a housing having a metallic portion and a non-metallic portion, and an antenna located at least partially inside the non-metallic portion, the antenna being configured for transmission and reception of the non-inductive wireless telemetry signals.

31. A system according to claim **30**, wherein the non-metallic portion comprises a non-metallic lead connection header.

32. A method of using a neuromuscular stimulation system comprising:

providing at least one electrically conductive surface sized and configured for implantation in a targeted neural or muscular tissue region, the at least one electrically conductive surface including a lead electrically coupled to the electrically conductive surface, the lead sized and configured to be positioned in subcutaneous tissue;

providing an implantable pulse generator including a rechargeable battery, wherein the implantable pulse generator is sized and configured to be positioned in subcutaneous tissue remote from the at least one electrically conductive surface, the implantable pulse generator comprising non-inductive wireless telemetry circuitry using VHF/UHF signals, and inductive wireless telemetry circuitry using a radio frequency magnetic field, the non-inductive wireless telemetry circuitry being functional at a distance as far as arm's reach away from a patient, and being adapted to receive and transmit VHF/UHF signals for programming and interrogation of the implantable pulse generator, the inductive wireless telemetry circuitry including a coil for receiving the magnetic field from an external controller for recharging the rechargeable battery;

implanting the at least one electrically conductive surface in a targeted neural or muscular tissue region;

implanting the lead in subcutaneous tissue;

implanting the pulse generator in a region remote from the at least one electrically conductive surface;

coupling the pulse generator to the lead implanted in subcutaneous tissue; and

operating the implantable pulse generator to be responding to the external controller using the non-inductive wireless telemetry and instructing the external controller to increase or decrease the strength of the magnetic field during recharging, while simultaneously, the implantable pulse generator receiving the magnetic field and recharging the rechargeable battery.

33. A method according to claim **32**, wherein the implantable pulse generator comprises a case having a size between about 5 mm and about 10 mm thick, between about 15 mm and about 25 mm wide, and between about 40 mm and about 50 mm long.

34. A method according to claim **32**, wherein the implantable pulse generator further comprises a housing having a metallic portion and a non-metallic portion, and an antenna located at least partially inside the non-metallic portion, the antenna being configured for transmission and reception of the non-inductive wireless telemetry signals.

35. A method according to claim **34**, wherein the non-metallic portion comprises a non-metallic lead connection header.

* * * * *

专利名称(译)	可植入脉冲发生器，用于提供肌肉和/或神经和/或中枢神经系统组织的功能和/或治疗刺激		
公开(公告)号	US7813809	公开(公告)日	2010-10-12
申请号	US11/150535	申请日	2005-06-10
[标]申请(专利权)人(译)	斯特罗瑟ROBERT乙 MRVA JOSEPHĴ THROPE GEOFFREY乙		
申请(专利权)人(译)	斯特罗瑟ROBERT乙 MRVA JOSEPHĴ THROPE GEOFFREY乙		
当前申请(专利权)人(译)	美敦力公司泌尿SOLUTIONS，INC.		
[标]发明人	STROTHER ROBERT B MRVA JOSEPH J THROPE GEOFFREY B		
发明人	STROTHER, ROBERT B. MRVA, JOSEPH J. THROPE, GEOFFREY B.		
IPC分类号	A61N1/08 A61B19/00 A61B5/00 A61B5/04 A61B5/0488 A61N1/18 A61N1/36		
CPC分类号	A61B5/0031 A61B5/0488 A61N1/37247 A61N1/37235 A61B2560/0209 A61N1/36003 Y10S128/904 A61B5/7232 Y10S128/903		
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摘要(译)

用于对肌肉，神经或中枢神经系统组织或任何组合进行假体或治疗性刺激的可植入脉冲发生器的尺寸和构造设计成植入皮下组织中。可植入脉冲发生器包括导电激光焊接钛壳。控制电路位于壳体内，并包括主电池或可充电电源，用于接收RF磁场以对可再充电电源再充电的接收线圈，无感无线遥测电路，以及用于控制可植入脉冲的微控制器发电机。用于肌肉，神经或中枢神经系统组织或任何组合的假体或治疗性刺激的刺激系统包括至少一个导电表面，连接到导电表面的引线，以及电连接到引线的可植入脉冲发生器。