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(54) SYSTEM OF IMPLANTABLE DEVICES FOR MONITORING AND/OR AFFECTING BODY PARAMETERS

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(60) Provisional application No. 60/042,447, filed on Mar. 27, 1997. Provisional application No. 60/039,164, filed on Feb. 26, 1997.

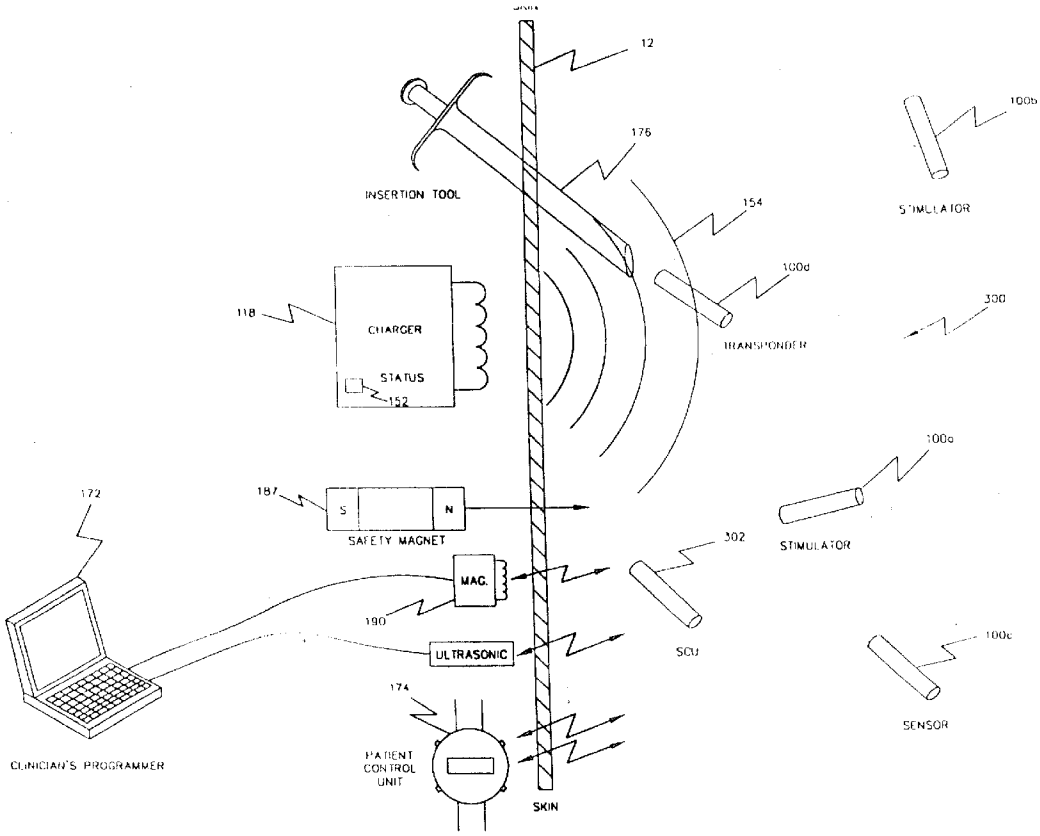
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(57) **ABSTRACT**

A system for monitoring and/or affecting parameters of a patient's body and more particularly to such a system comprised of a system control unit (SCU) and one or more other devices, preferably battery-powered, implanted in the patient's body, i.e., within the envelope defined by the patient's skin. Each such implanted device is configured to be monitored and/or controlled by the SCU via a wireless communication channel. In accordance with the invention, the SCU comprises a programmable unit capable of (1) transmitting commands to at least some of a plurality of implanted devices and (2) receiving data signal from at least some of those implanted devices. In accordance with a preferred embodiment, the system operates in closed loop fashion whereby the commands transmitted by the SCU are dependent, in part, on the content of the data signals received by the SCU. In accordance with the invention, a preferred SCU is similarly implemented as a device capable of being implanted beneath a patient's skin, preferably having an axial dimension of less than 60 mm and a lateral dimension of less than 6 mm. Wireless communication between the SCU and the implanted devices is preferably implemented via a modulated sound signal, AC magnetic field, RF signal, or electric conduction.



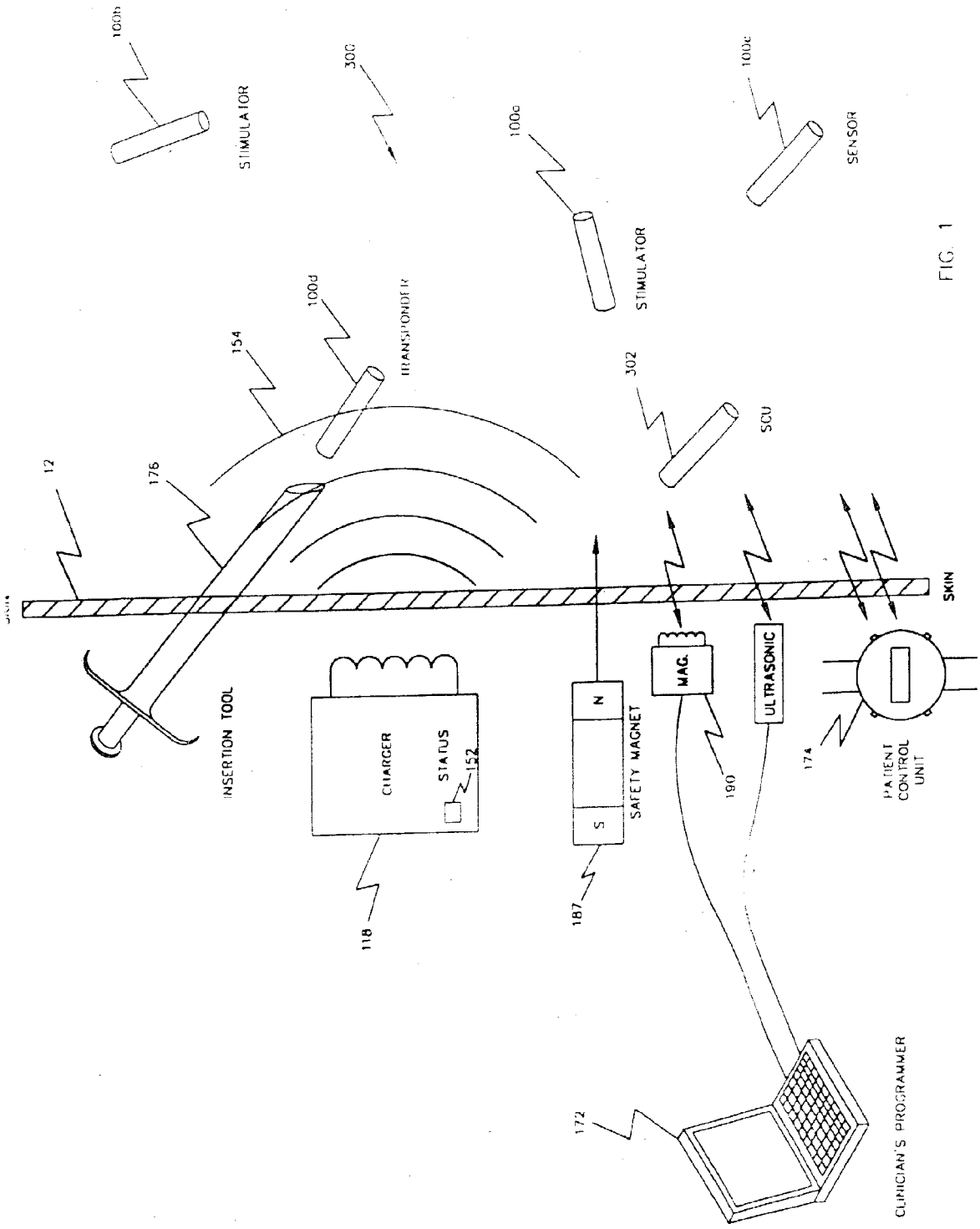

100b
STIMULATOR
300
100a
STIMULATOR
100c
SENSOR
100d
TRANSPONDER
154
302
SCU
12
176
SKIN
INSERTION TOOL
CHARGER
STATUS
152
118
N
S
SAFETY MAGNET
187
MAG.
190
ULTRASONIC
174
PATIENT CONTROL UNIT
172
CLINICIAN'S PROGRAMMER

FIG. 1

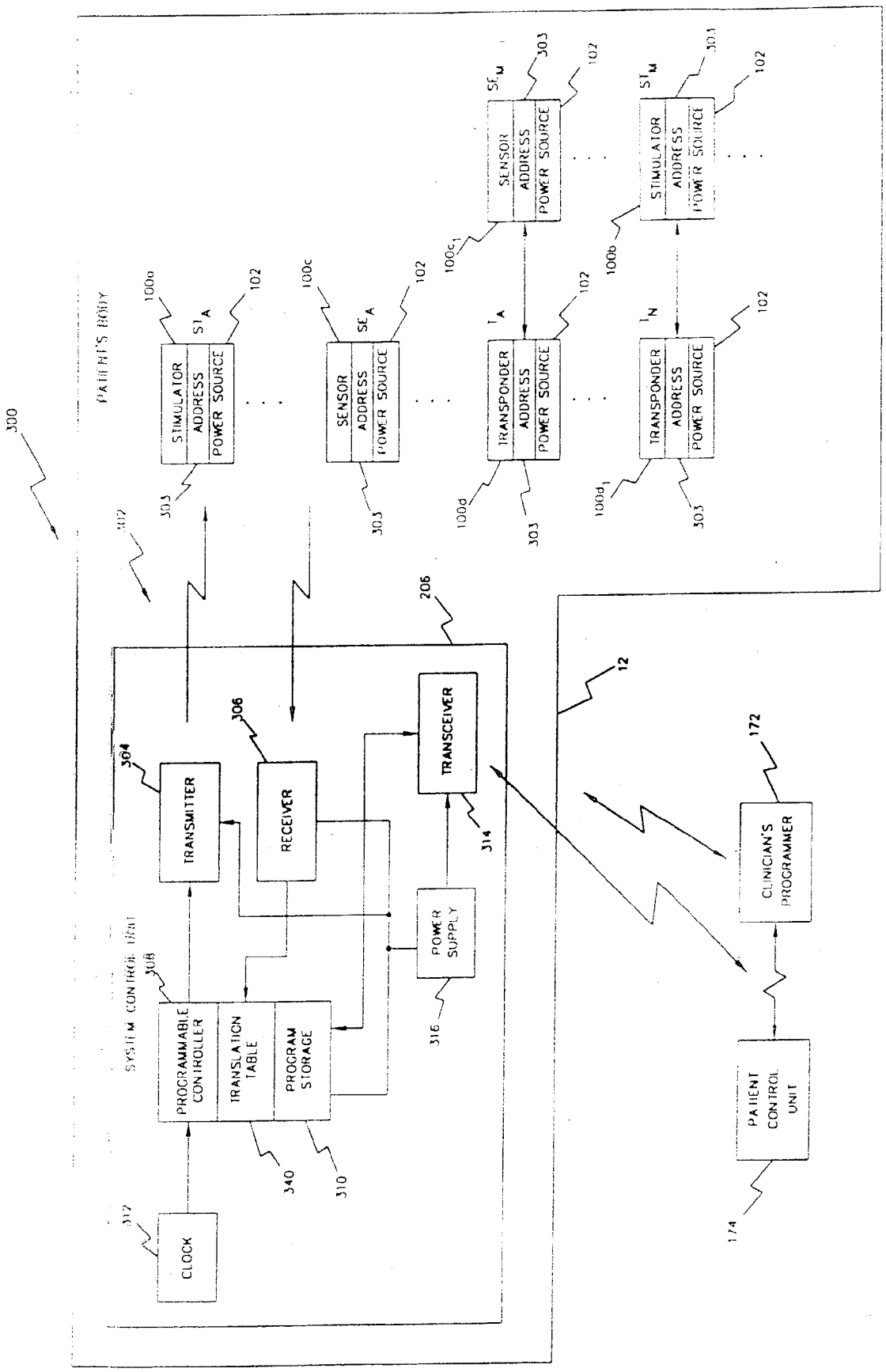

300
PATIENT'S BODY
STIMULATOR
ADDRESS
POWER SOURCE
SENSOR
ADDRESS
POWER SOURCE
TRANSPONDER
ADDRESS
POWER SOURCE
100a
100c
100d
102
303
206
12
TRANSMITTER
RECEIVER
TRANSCEIVER
304
306
314
SYSTEM CONTROLLER
PROGRAMMABLE CONTROLLER
TRANSLATION TABLE
PROGRAM STORAGE
308
340
310
POWER SUPPLY
316
CLOCK
312
CLINICIAN'S PROGRAMMER
172
PATIENT CONTROL UNIT
174

FIG. 2

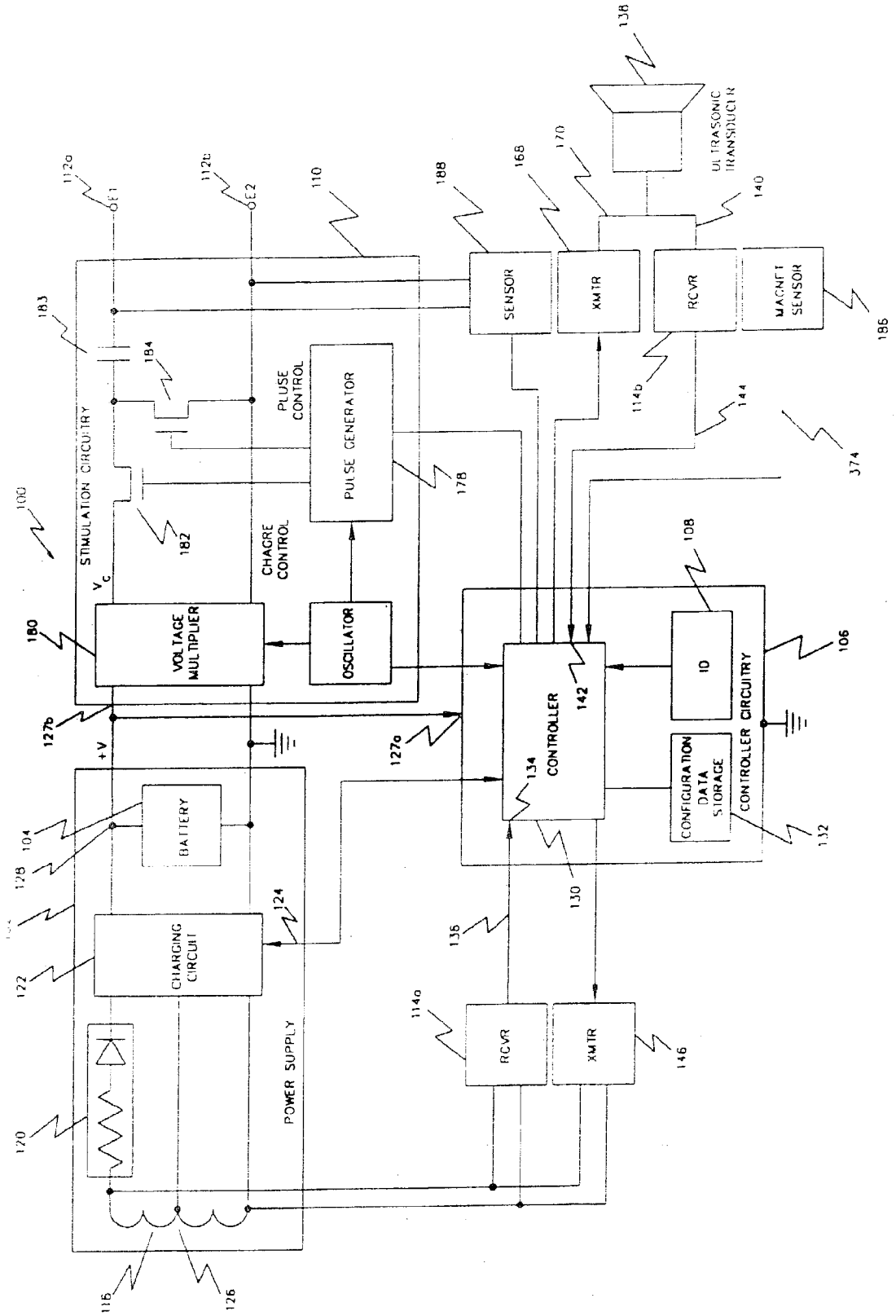

138
ULTRASONIC TRANSDUCER
140
112a
E1
112b
E2
110
188
168
170
SENSOR
XMTR
RCVR
MAGNET SENSOR
186
183
184
PULSE CONTROL
PULSE GENERATOR
178
114b
144
374
100
STIMULATION CIRCUITRY
182
CHARGE CONTROL
108
V_c
180
VOLTAGE MULTIPLIER
OSCILLATOR
ID
106
127b
127a
142
CONTROLLER
134
CONFIGURATION DATA STORAGE
CONTROLLER CIRCUITRY
132
+V
104
BATTERY
128
130
124
136
122
CHARGING CIRCUIT
114a
RCVR
XMTR
146
120
POWER SUPPLY
116
126

FIG. 3A

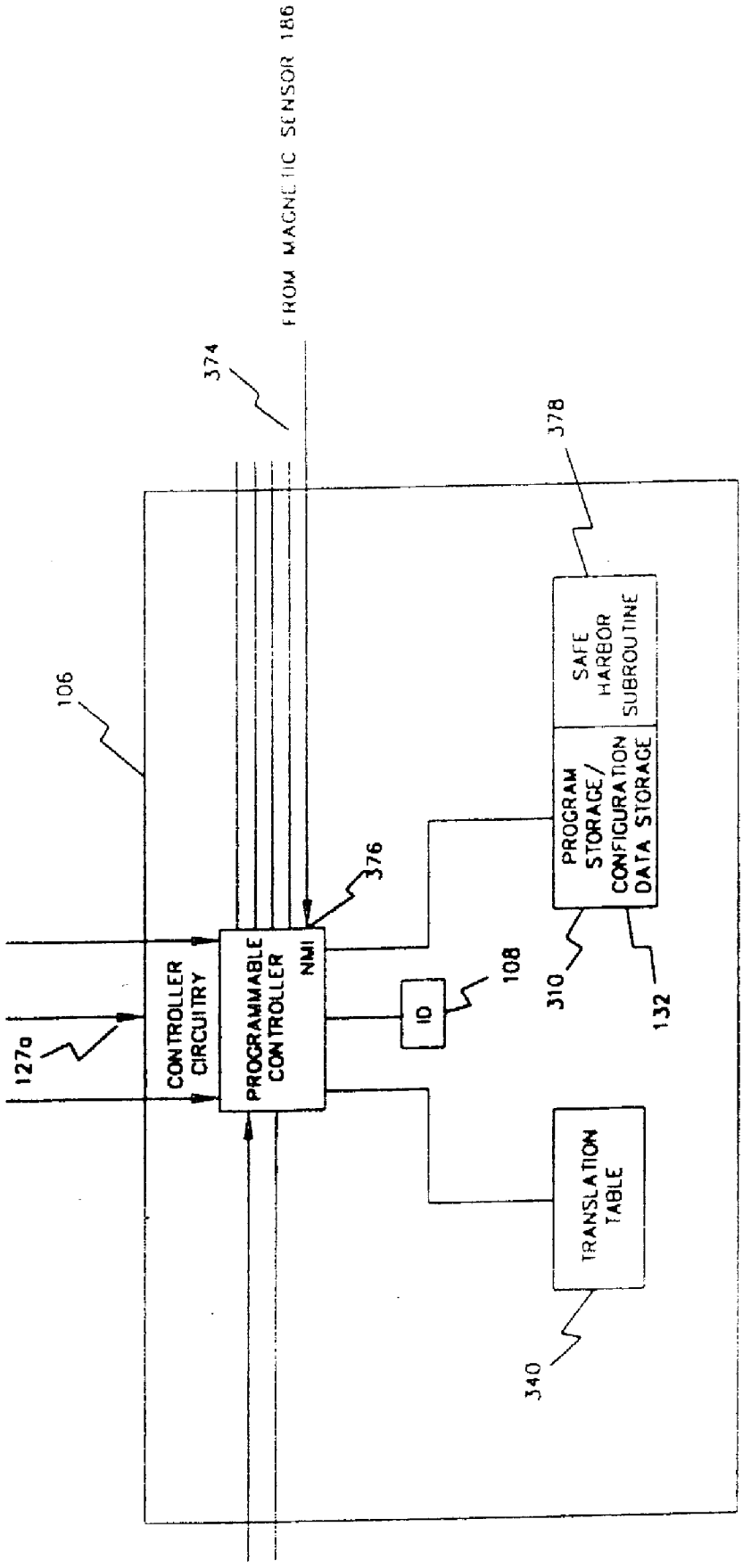

FROM MAGNETIC SENSOR 186
374
378
106
SAFE HARBOR SUBROUTINE
PROGRAM STORAGE/ CONFIGURATION DATA STORAGE
376
CONTROLLER CIRCUITRY
PROGRAMMABLE CONTROLLER
NMI
ID
108
310
132
127a
TRANSLATION TABLE
340

FIG. 3B

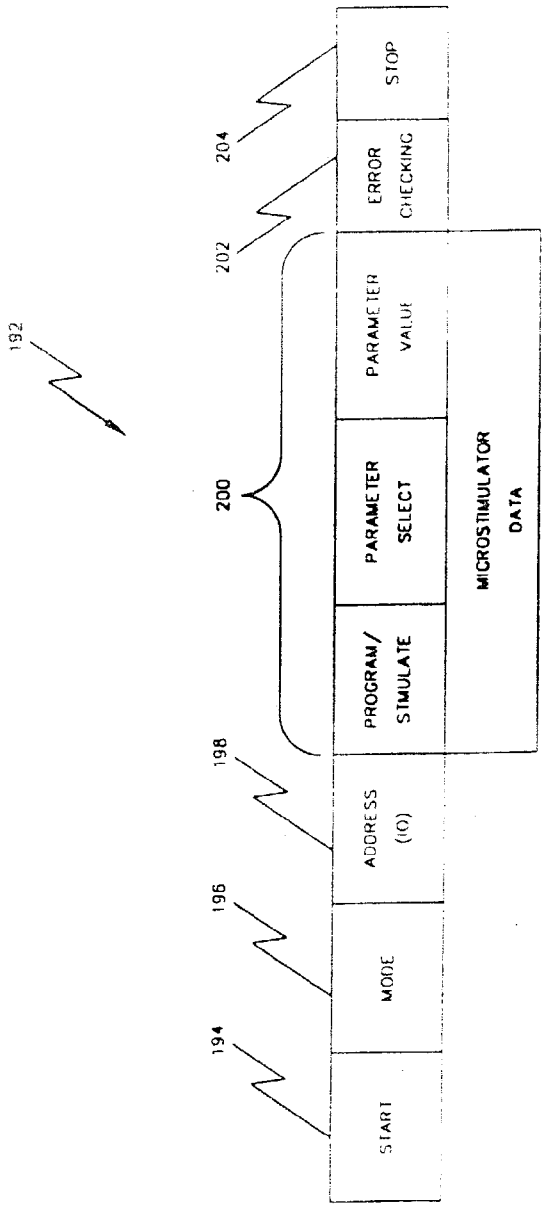

192
194
START
196
MODE
198
ADDRESS (IO)
200
PROGRAM/ STIMULATE
PARAMETER SELECT
PARAMETER VALUE
MICROSTIMULATOR DATA
202
204
ERROR CHECKING
STOP

FIG. 4

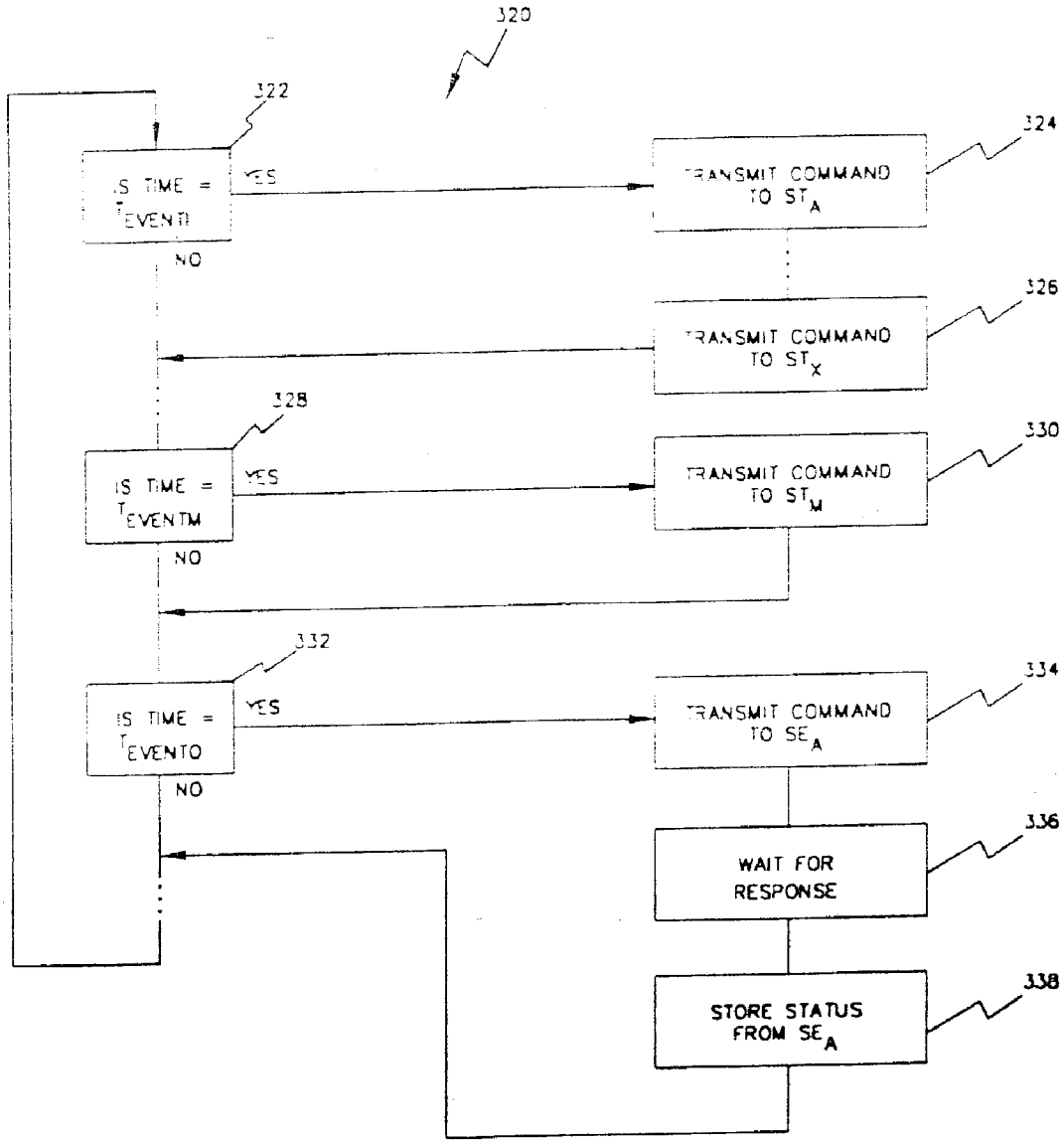
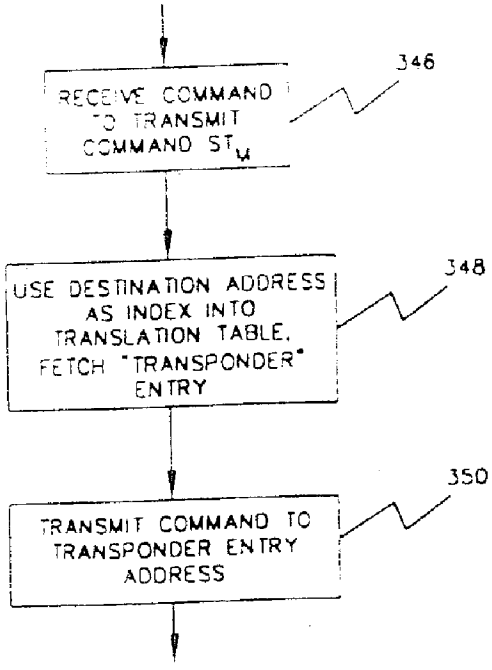
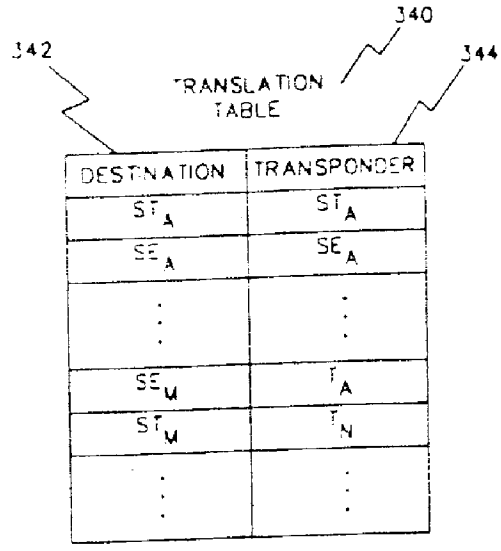

320
322
IS TIME = T EVENTI
YES
NO
TRANSMIT COMMAND TO ST A
324
TRANSMIT COMMAND TO ST X
326
328
IS TIME = T EVENTM
YES
NO
TRANSMIT COMMAND TO ST M
330
332
IS TIME = T EVENTO
YES
NO
TRANSMIT COMMAND TO SE A
334
WAIT FOR RESPONSE
336
STORE STATUS FROM SE A
338
OPEN LOOP CONTROL/MONITOR

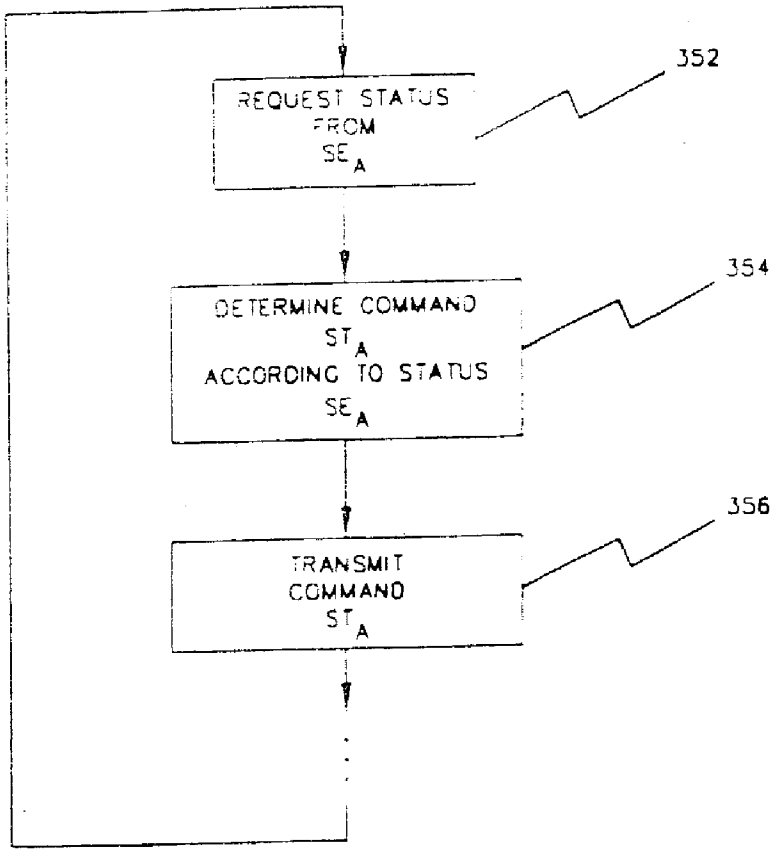
FIG. 5





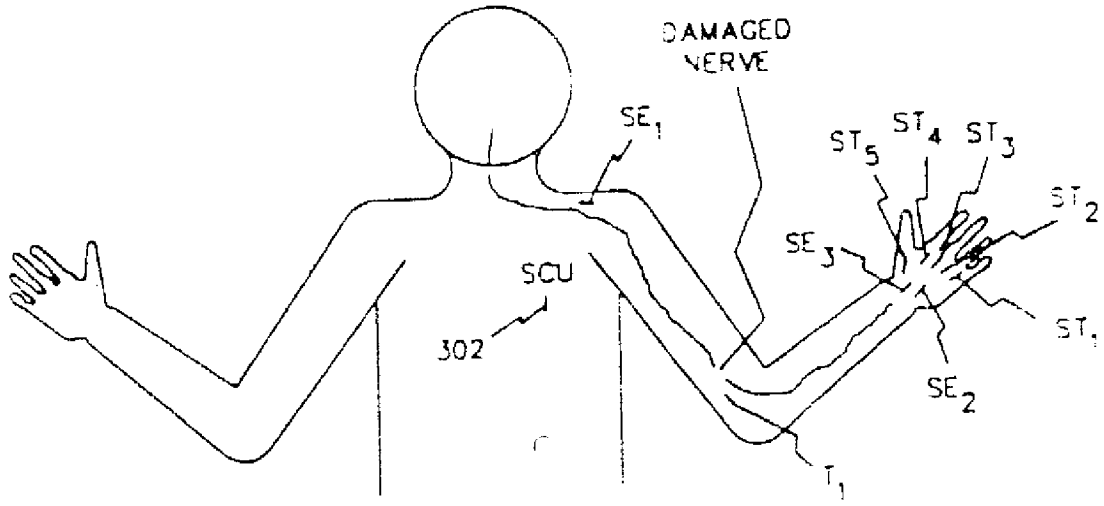
OPTIONAL USE OF TRANSLATION TABLE

FIG. 6



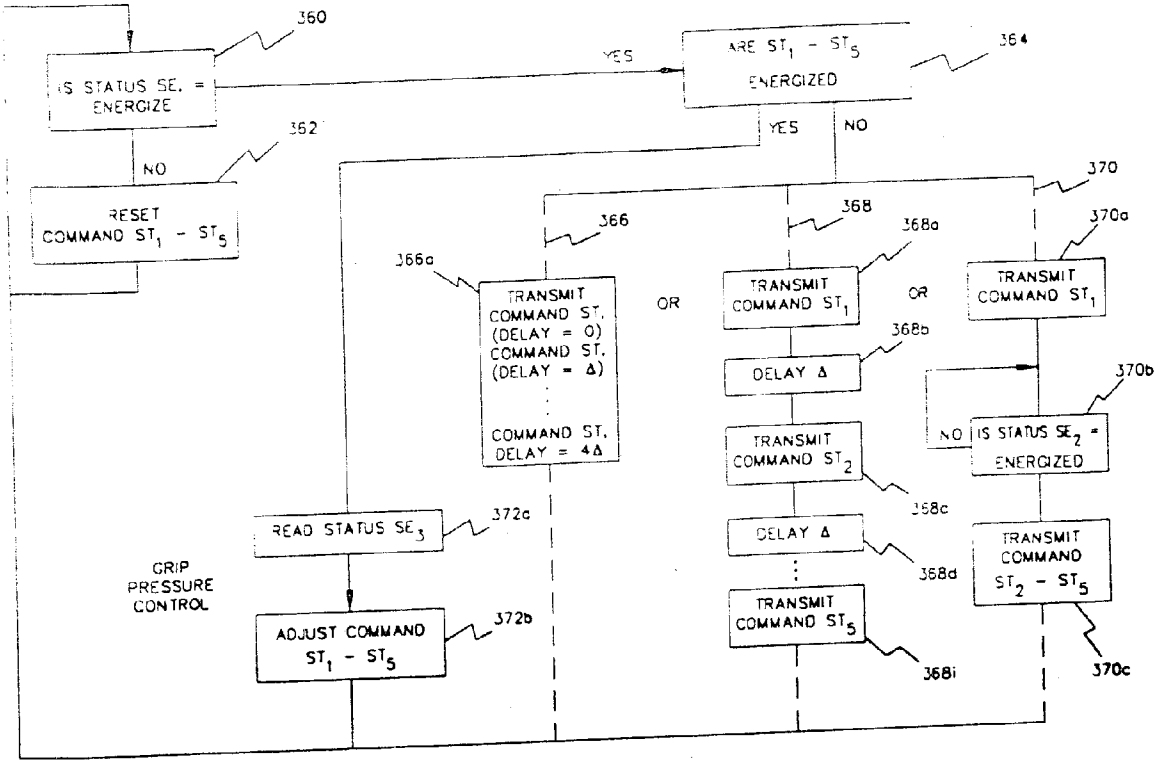
CLOSED LOOP CONTROL

FIG. 7



EXEMPLARY INJURY

FIG. 8



COORDINATED CLOSED LOOP HAND CONTROL

FIG. 9

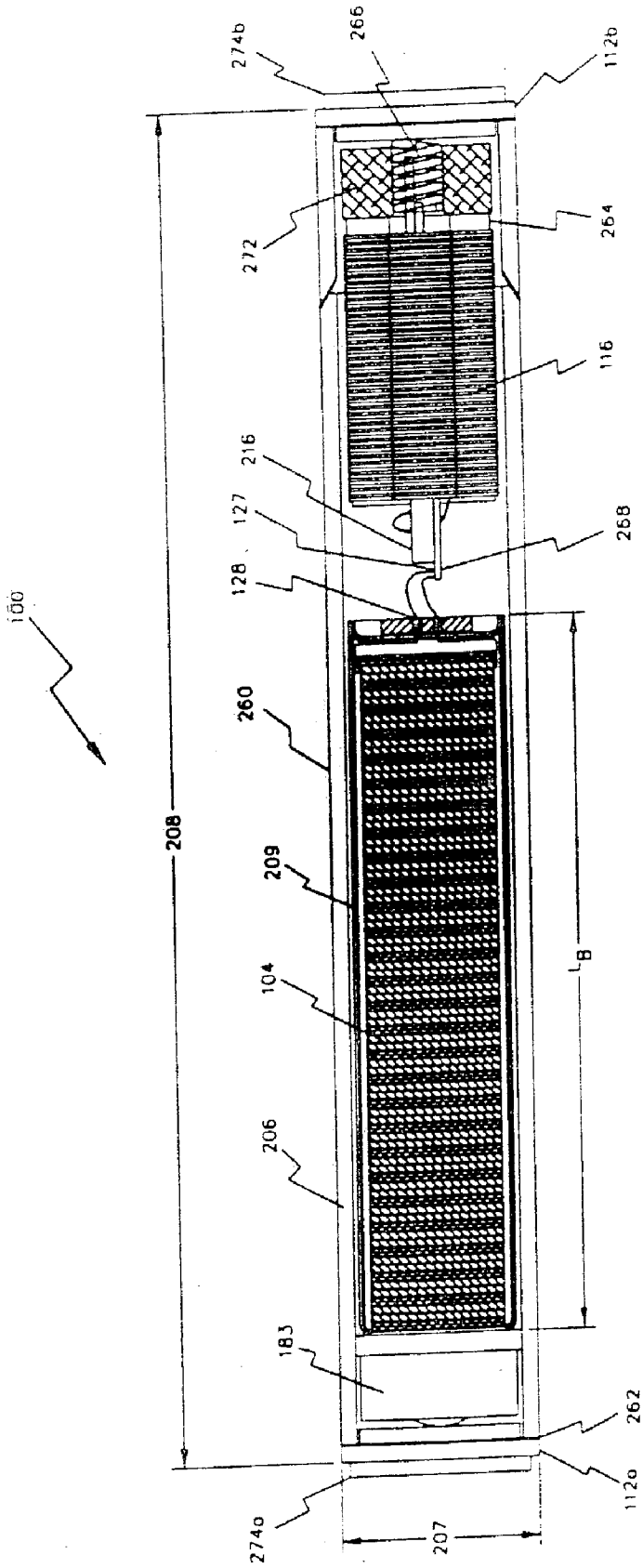

160
274b
266
112b
272
264
116
216
127
268
128
260
208
209
104
206
183
262
112a
274a
207
L_B

FIG. 10A

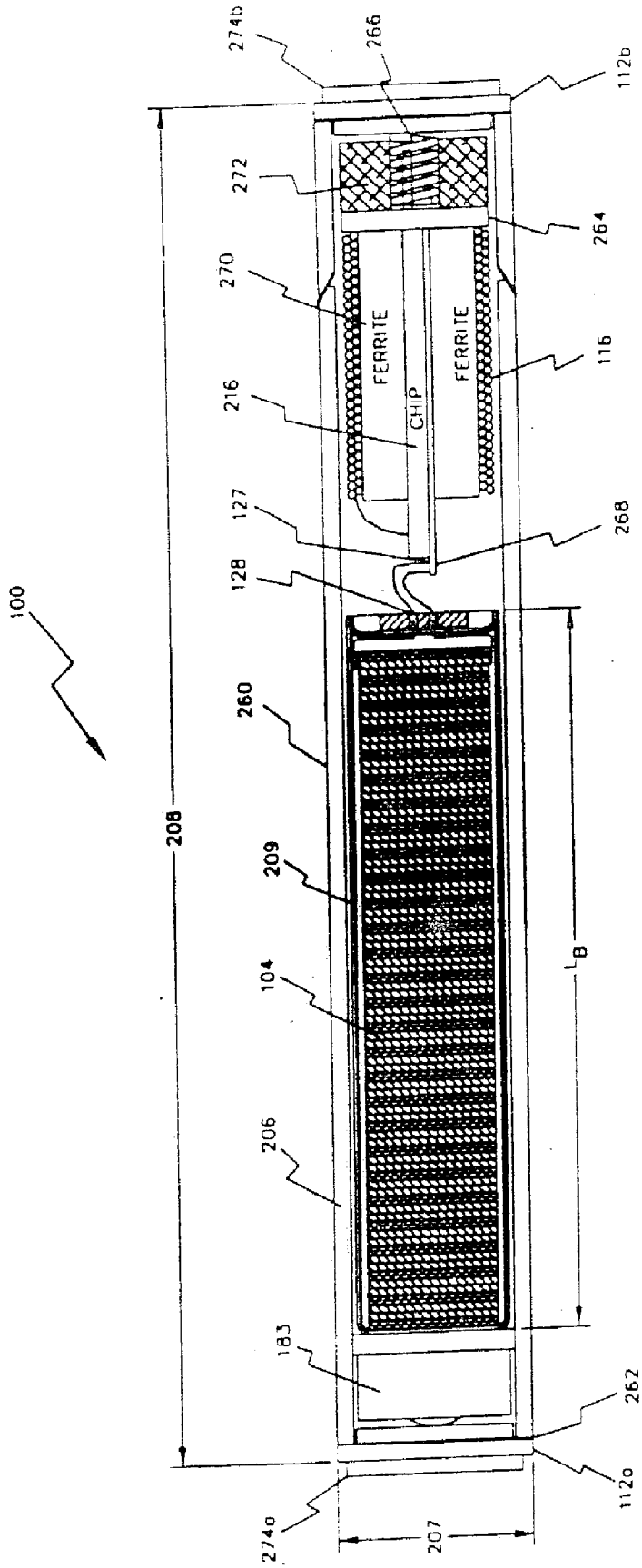
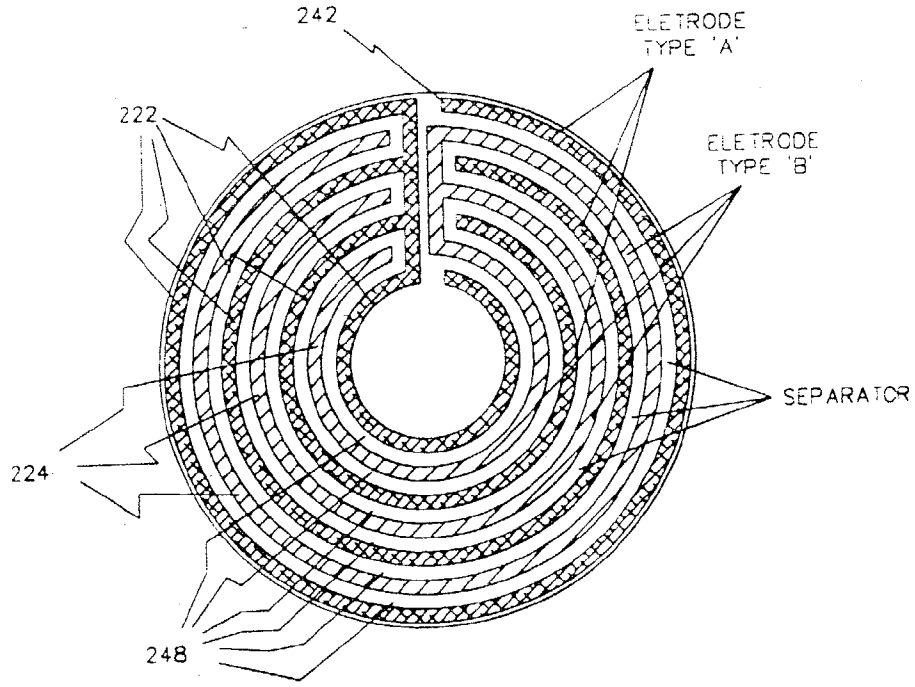

100
208
274b
266
112b
272
264
270
FERRITE
CHIP
FERRITE
116
216
127
268
128
260
209
104
206
183
262
112a
274a
207
L_B

FIG. 10B


242
ELETRODE TYPE 'A'
222
ELETRODE TYPE 'B'
SEPARATOR
224
248

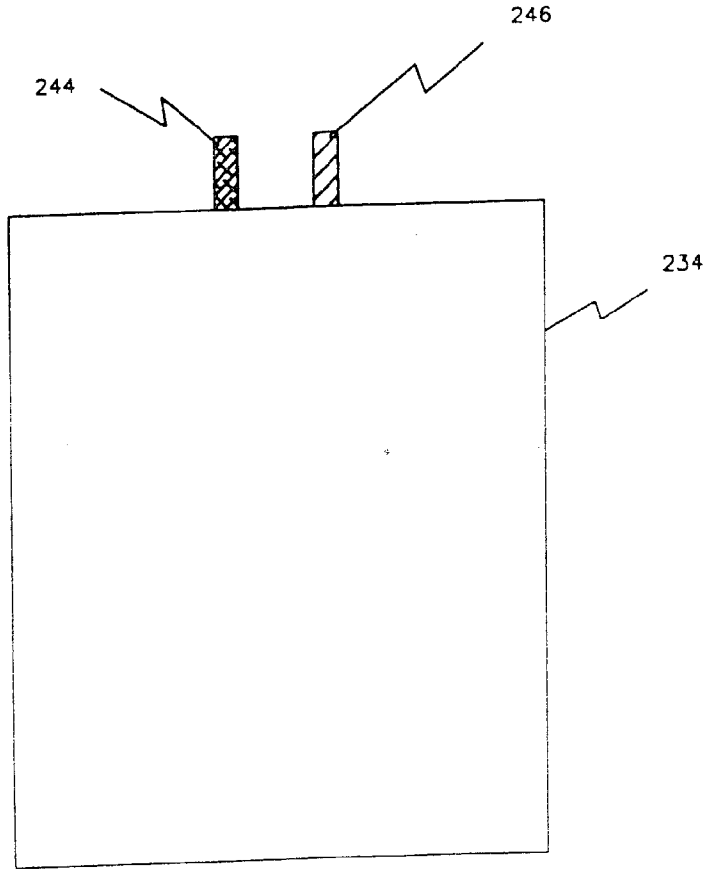

246
244
234

FIG. 11

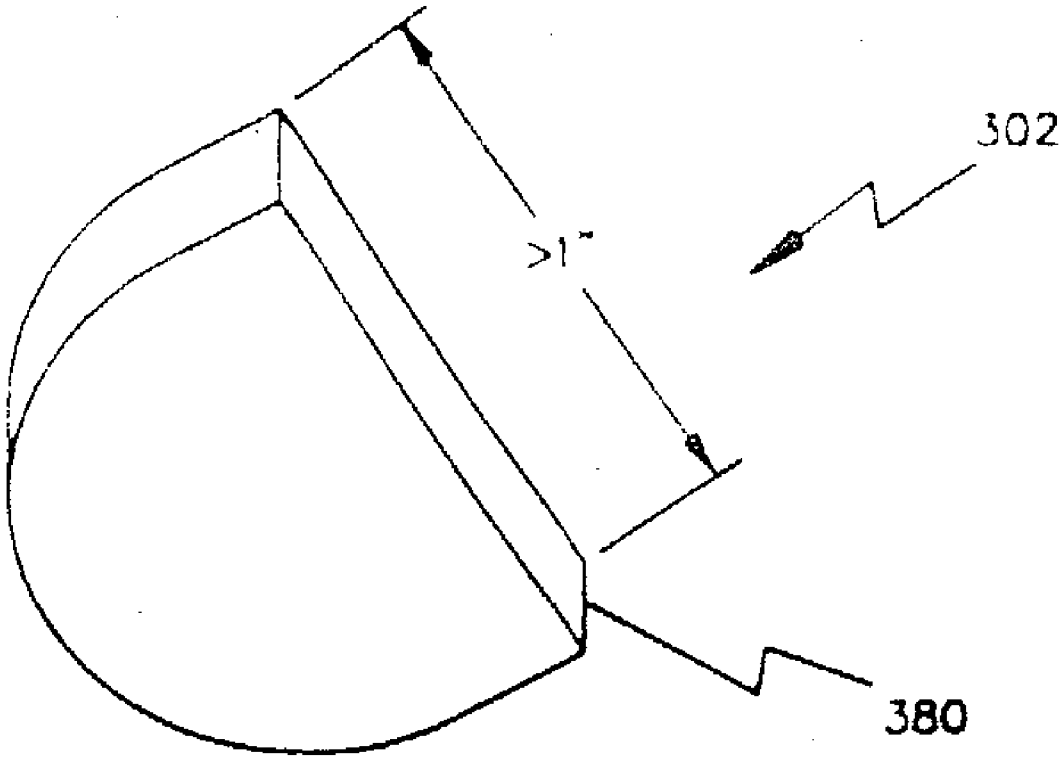


FIG. 12

SYSTEM OF IMPLANTABLE DEVICES FOR MONITORING AND/OR AFFECTING BODY PARAMETERS

[0001] This application claims the benefit of U.S. Provisional Application No. 60/042,447 filed Mar. 27, 1997 and U.S. patent application Ser. No. _____, filed Feb. 25, 1998 entitled "Battery-Powered Patient Implantable Device" which in turn claims the benefit of U.S. Provisional Application No. 60/039,164 filed Feb. 26, 1997.

BACKGROUND OF THE INVENTION

[0002] The present invention relates to systems for monitoring and/or affecting parameters of a patient's body for the purpose of medical diagnosis and/or treatment. More particularly, systems in accordance with the invention are characterized by a plurality of devices, preferably battery-powered, configured for implanting within a patient's body, each device being configured to sense a body parameter, e.g., temperature, O_2 content, physical position, etc., and/or to affect a parameter, e.g., via nerve stimulation.

[0003] Applicants' parent application Ser. No. _____, entitled "Battery Powered Patient Implantable Device", incorporated herein by reference, describes devices configured for implantation within a patient's body, i.e., beneath a patient's skin, for performing various functions including: (1) stimulation of body tissue, (2) sensing of body parameters, and (3) communicating between implanted devices and devices external to a patient's body.

SUMMARY OF THE INVENTION

[0004] The present invention is directed to a system for monitoring and/or affecting parameters of a patient's body and more particularly to such a system comprised of a system control unit (SCU) and one or more devices implanted in the patient's body, i.e., within the envelope defined by the patient's skin. Each said implanted device is configured to be monitored and/or controlled by the SCU via a wireless communication channel.

[0005] In accordance with the invention, the SCU comprises a programmable unit capable of (1) transmitting commands to at least some of a plurality of implanted devices and (2) receiving data signals from at least some of those implanted devices. In accordance with a preferred embodiment, the system operates in closed loop fashion whereby the commands transmitted by the SCU are dependent, in part, on the content of the data signals received by the SCU.

[0006] In accordance with a preferred embodiment, each implanted device is configured similarly to the devices described in Applicants' parent application Ser. No. _____, and typically comprises a sealed housing suitable for injection into the patient's body. Each housing preferably contains a power source having a capacity of at least 1 microwatt-hour, preferably a rechargeable battery, and power consuming circuitry preferably including a data signal transmitter and receiver and sensor/stimulator circuitry for driving an input/output transducer.

[0007] In accordance with a significant aspect of the preferred embodiment, a preferred SCU is also implemented as a device capable of being injected into one patient's body. Wireless communication between the SCU and the other implanted devices can be implemented in various ways, e.g., via a modulated sound signal, AC magnetic field, RF signal, or electrical conduction.

[0008] In accordance with a further aspect of the invention, the SCU is remotely programmable, e.g., via wireless means, to interact with the implanted devices according to a treatment regimen. In accordance with a preferred embodiment, the SCU is preferably powered via an internal power source, e.g., a rechargeable battery. Accordingly, an SCU combined with one or more battery-powered implantable devices, such as those described in the parent application, form a self-sufficient system for treating a patient.

[0009] In accordance with a preferred embodiment, the SCU and other implanted devices are implemented substantially identically, being comprised of a sealed housing configured to be injected into the patient's body. Each housing contains sensor/stimulator circuitry for driving an input/output transducer, e.g., an electrode, to enable it to additionally operate as a sensor and/or stimulator.

[0010] Alternatively, the SCU could be implemented as an implantable but non-injectable housing which would permit it to be physically larger enabling it to accommodate larger, higher capacity components, e.g., battery, microcontroller, etc. As a further alternative, the SCU could be implemented in a housing configured for carrying on the patient's body outside of the skin defined envelope, e.g., in a wrist band.

[0011] In accordance with the invention, the commands transmitted by the SCU can be used to remotely configure the operation of the other implanted devices and/or to interrogate the status of those devices. For example, various operating parameters, e.g., the pulse frequency, pulse width, trigger delays, etc., of each implanted device can be controlled or specified in one or more commands addressably transmitted to the device. Similarly, the sensitivity of the sensor circuitry and/or the interrogation of a sensed parameter, e.g., battery status, can be remotely specified by the SCU.

[0012] In accordance with a significant feature of the preferred embodiment, the SCU and/or each implantable device includes a programmable memory for storing a set of default parameters. In the event of power loss, SCU failure, or any other catastrophic occurrence, all devices default to the safe harbor default parameters. The default parameters can be programmed differently depending upon the condition being treated. In accordance with a further feature, the system includes a switch preferably actuatable by an external DC magnetic field, for resetting the system to its default parameters.

[0013] In an exemplary use of a system in accordance with the present invention, a patient with nerve damage can have a damaged nerve "replaced" by an implanted SCU and one or more implanted sensors and stimulators, each of which contains its own internal power source. In this exemplary system, the SCU would monitor a first implanted sensor for a signal originating from the patient's brain and responsively transmit command signals to one or more stimulators implanted past the point of nerve damage. Furthermore, the SCU could monitor additional sensors to determine variations in body parameters and, in a closed loop manner, react to control the command signals to achieve the desired treatment regimen.

[0014] The novel features of the invention are set forth with particularity in the appended claims. The invention will be best understood from the following description when read in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] **FIG. 1** is a simplified block diagram of the system of the present invention comprised of implanted devices, e.g., microstimulators, microsensors and microtransponders, under control of an implanted system control unit (SCU);

[0016] **FIG. 2** comprises a block diagram of the system of **FIG. 1** showing the functional elements that form the system control unit and implanted microstimulators, microsensors and microtransponders;

[0017] **FIG. 3A** comprises a block diagram of an exemplary implanted device, as shown in the parent application, including a battery for powering the device for a period of time in excess of one hour in response to a command from the system control unit;

[0018] **FIG. 3B** comprises a simplified block diagram of controller circuitry that can be substituted for the controller circuitry of **FIG. 3**A, thus permitting a single device to be configured as a system control unit and/or a microstimulator and/or a microsensor and/or a microtransponder;

[0019] **FIG. 4** is a simplified diagram showing the basic format of data messages for commanding/interrogating the implanted microstimulators, microsensors and microtransponders which form a portion of the present invention;

[0020] **FIG. 5** shows an exemplary flow chart of the use of the present system in an open loop mode for controlling/monitoring a plurality of implanted devices, e.g., microstimulators, microsensors;

[0021] **FIG. 6** shows a flow chart of the optional use of a translation table for communicating with microstimulators and/or microsensors via microtransponders;

[0022] **FIG. 7** shows a simplified flow chart of the use of closed loop control of a microstimulator by altering commands from the system control unit in response to status data received from a microsensor;

[0023] **FIG. 8** shows an exemplary injury, i.e., a damaged nerve, and the placement of a plurality of implanted devices, i.e., microstimulators, microsensors and a microtransponder under control of the system control unit for "replacing" the damaged nerve;

[0024] **FIG. 9** shows a simplified flow chart of the control of the implanted devices of **FIG. 8** by the system control unit;

[0025] FIGS. **10**A and **10**BD show two side cutaway views of the presently preferred embodiment of an implantable ceramic tube suitable for the housing the system control unit and/or microstimulators and/or microsensors and/or microtransponders;

[0026] **FIG. 11** illustrates an exemplary battery suitable for powering the implantable devices which comprise the components of the present invention; and

[0027] **FIG. 12** shows an exemplary housing suitable for an implantable SCU having a battery enclosed within that has a capacity of at least 1 watt-hour.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0028] The present invention is directed to a system for monitoring and/or affecting parameters of a patient's body and more particularly to such a system comprised of a system control unit (SCU) and one or more devices implanted in a patient's body, i.e., within the envelope defined by the patient's skin. Each such implantable device is configured to be monitored and/or controlled by the SCU via a wireless communication channel.

[0029] In accordance with the invention, the SCU comprises a programmable unit capable of (1) transmitting commands to at least some of a plurality of implanted devices and (2) receiving data signals from at least some of those implanted devices. In accordance with a preferred embodiment, the system operates in closed loop fashion whereby the commands transmitted by the SCU are dependent, in part, on the content of the data signals received by the SCU.

[0030] In accordance with a preferred embodiment, each implanted device is configured similarly to the devices described in Applicants' parent application Ser. No. _____ and typically comprises a sealed housing suitable for injection into the patient's body. Each housing preferably contains a power source having a capacity of at least 1 microwatt-hour, preferably a rechargeable battery, and power consuming circuitry preferably including a data signal transmitter and receiver and sensor/stimulator circuitry for driving an input/output transducer.

[0031] **FIG. 1** (essentially corresponding to **FIG. 2** of the parent application) and **FIG. 2** show an exemplary system **300** made of implanted devices **100**, preferably battery powered, under control of a system control unit (SCU) **302**, preferably also implanted beneath a patient's skin **12**. As described in the parent application, potential implanted devices **100** (see also the block diagram shown in **FIG. 3A**) include stimulators , e.g., **100***a*, sensors e.g., **100***c*, and transponders, e.g., **100***d*. The stimulators, e.g., **100***a*, can be remotely programmed to output a sequence of drive pulses to body tissue proximate to its implanted location via attached electrodes. The sensors, e.g., **100***c*, can be remotely programmed to sense one or more physiological or biological parameters in the implanted environment of the device, e.g., temperature, glucose level, O_2 content, etc. Transponders, e.g., **100***d*, are devices which can be used to extend the interbody communication range between stimulators and sensors and other devices, e.g., a clinician's programmer **172** and the patient control unit **174**. Preferably, these stimulators, sensors and transponders are contained in sealed elongate housing having an axial dimension of less than 60 mm and lateral dimension of less than 6 mm. Accordingly, such stimulators, sensors and transponders are respectively referred to as microstimulators, microsensors, and microtransponders. Such microstimulators and microsensors can thus be positioned beneath the skin within a patient's body using a hypodermic type insertion tool **176**.

[0032] As described in the parent application, microstimulators and microsensors are remotely programmed and interrogated via a wireless communication channel, e.g., modulated AC magnetic, sound (i.e., ultrasonic), RF or electric fields, typically originating from control devices external to the patient's body, e.g., a clinicians's programmer **172** or

patient control unit **174**. Typically, the clinician's programmer **172** is used to program a single continuous or one time pulse sequence into each microstimulator and/or measure a biological parameter from one or more microsensors. Similarly, the patient control unit **174** typically communicates with the implanted devices **100**, e.g., microsensors **100***c*, to monitor biological parameters. In order to distinguish each implanted device over the communication channel, each implanted device is manufactured with an identification code (ID) **303** specified in address storage circuitry **108** (see **FIG. 3A**) as described in the parent application.

[**0033**] By using one or more such implantable devices in conjunction with the SCU **302** of the present invention, the capabilities of such implanted devices can be further expanded. For example, in an open loop mode (described below in reference to **FIG. 5**), the SCU **302** can be programmed to periodically initiate tasks, e.g., perform real time tasking, such as transmitting commands to microstimulators according to a prescribed treatment regimen or periodically monitor biological parameters to determine a patient's status or the effectiveness of a treatment regimen. Alternatively, in a closed loop mode (described below in reference to FIGS. **7-9**), the SCU **302** periodically interrogates one or more microsensors and accordingly adjust the commands transmitted to one or more microstimulators.

[**0034**] **FIG. 2** shows the system **300** of the present invention comprised of (1) one or more implantable devices **100** operable to sense and/or stimulate a patient's body parameter in accordance with one or more controllable operating parameters and (2) the SCU, **302**. The SCU **302** is primarily comprised of (1) a housing **206**, preferably sealed and configured for implantation beneath the skin of the patient's body as described in the parent application in reference to the implanted devices **100**, (2) a signal transmitter **304** in the housing **206** for transmitting command signals, (3) a signal receiver **306** in the housing **206** for receiving status signals, and (4) a programmable controller **308**, e.g., a microcontroller or state machine, in the housing **206** responsive to received status signals for producing command signals for transmission by the signal transmitter **304** to other implantable devices **100**. The sequence of operations of the programmable controller **308** is determined by an instruction list, i.e., a program, stored in program storage **310**, coupled to the programmable controller **308**. While the program storage **310** can be a nonvolatile memory device, e.g., ROM, manufactured with a program corresponding to a prescribed treatment regimen, it is preferably that at least a portion of the program storage **310** be an alterable form of memory, e.g., RAM, EEPROM, etc., whose contents can be remotely altered as described further below. However, it is additionally preferable that a portion of the program storage **310** be nonvolatile so that a default program is always present. The rate at which the program contained within the program storage **310** is executed is determined by clock **312**, preferably a real time clock that permits tasks to be scheduled at specified times of day.

[**0035**] The signal transmitter **304** and signal receiver **306** preferably communicate with implanted devices **100** using sound means, i.e., mechanical vibrations, using a transducer having a carrier frequency modulated by a command data signal. In a preferred embodiment, a carrier frequency of 100 KHz is used which corresponds to a frequency that freely passes through a typical body's fluids and tissues. However, such sound means that operate at any frequency, e.g., greater than 1 Hz, are also considered to be within the scope of the present invention. Alternatively, the signal transmitter **304** and signal receiver **306** can communicate using modulated AC magnetic, RF, or electric fields.

[**0036**] The clinician's programmer **172** and/or the patient control unit **174** and/or other external control devices can also communicate with the implanted devices **100**, as described in the parent application, preferably using a modulated AC magnetic field. Alternatively, such external devices can communicate with the SCU **302** via a transceiver **314** coupled to the programmable controller **308**. Since, in a preferred operating mode, the signal transmitter **304** and signal receiver **306** operate using sound means, a separate transceiver **314** which operates using magnetic means is used far communication with external devices. However, a single transmitter **304**/receiver **306** can be used in place of transceiver **314** if a common communication means is used.

[**0037**] **FIG. 3A** comprises a block diagram of an exemplary implanted device **100** (as shown in **FIG. 2** of the parent application) which includes a battery **104**, preferably rechargeable, for powering the device for a period of time in excess of one hour and responsive to command signals from a remote device, e.g., the SCU **302**. As described in the parent application, the implantable device **100** is preferably configurable to alternatively operate as a microstimulator and/or microsensor and/or microtransponder due to the commonality of most of the circuitry contained within. Such circuitry can be further expanded to permit a common block of circuitry to also perform the functions required for the SCU **302**. Accordingly, **FIG. 3B** shows an alternative implementation of the controller circuitry **106** of **FIG. 3A** that is suitable for implementing a microstimulator and/or a microsensor and/or a microtransponder and/or the SCU **302**. In this implementation the configuration data storage **132** can be alternatively used as the program storage **310** when the implantable device **100** is used as the SCU **302**. In this implementation, XMTR **168** corresponds to the signal transmitter **304** and the RCVR **114***b* corresponds to the signal receiver **306** (preferably operable using sound means via transducer **138**) and the RCVR **114***a* and XMTR **146** correspond to the transceiver **314** (preferably operable using magnetic means via coil **116**).

[**0038**] In a preferred embodiment, the contents of the program storage **310**, i.e., the software that controls the operation of the programmable controller **308**, can be remotely downloaded, e.g., from the clinician's programmer **172** using data modulated onto an AC magnetic field. In this embodiment, it is preferable that the contents of the program storage **310** for each SCU **302** be protected from an inadvertent change. Accordingly, the contents of the address storage circuitry **108**, i.e., the ID **303**, is preferably used as a security code to confirm that the new program storage contents are destined for the SCU **302** receiving the data. This feature is significant if multiple patient's could be physically located, e.g., in adjoining beds, within the communication range of the clinician's programmer **172**.

[**0039**] In a further aspect of the present invention, it is preferable that the SCU **302** be operable for an extended period of time, e.g., in excess of one hour, from an internal power supply **316**. While a primary battery, i.e., a nonrechargeable battery, is suitable for this function, it is prefer-

able that the power supply **316** include a rechargeable battery, e.g., battery **104** as described in the parent application, that can be recharged via an AC magnetic field produced external to the patient's body. Accordingly, the power supply **102** of **FIG. 3A** (described in detail in the parent application) is the preferred power supply **316** for the SCU **302** as well.

[**0040**] The battery-powered devices **100** of the parent invention are preferably configurable to operate in a plurality of operation modes, e.g., via a communicated command signal. In a first operation mode, device **100** is remotely configured to be a microstimulator, e.g., **100***a* and **100***b*. In this embodiment, controller **130** commands stimulation circuitry **110** to generate a sequence of drive pulses through electrodes **112** to stimulate tissue, e.g., a nerve, proximate to the implanted location of the microstimulator, e.g., **100***a* or **100***b*. In operation, a programmable pulse generator **178** and voltage multiplier **180** are configured with parameters (see Table I) corresponding to a desired pulse sequence and specifying now much to multiply the battery voltage (e.g., by summing charged capacitors or similarly charged battery portions) to generate a desired compliance voltage V_c. A first FET **182** is periodically energized to store charge into capacitor **183** (in a first direction at a low current flow rate through the body tissue) and a second FET **184** is periodically energized to discharge capacitor **183** in an opposing direction at a higher current flow rate which stimulates a nearby nerve. Alternatively, electrodes can be selected that will form an equivalent capacitor within the body tissue.

TABLE I

Stimulation Parameters	
Current:	continuous current charging of storage capacitor
Charging currents:	1, 3, 10, 30, 100, 250, 500 μa
Current Range:	0.8 to 40 ma in nominally 3.2% steps
Compliance Voltage:	selectable, 3–24 volts in 3 volt steps
Pulse Frequency (PPS):	1 to 5000 PPS in nominally 30% steps
Pulse Width:	5 to 2000 μs in nominally 10% steps
Burst On Time (BON):	1 ms to 24 hours in nominally 20% steps
Burst Off Time (BOF):	1 ms to 24 hours in nominally 20% steps
Triggered Delay to BON:	either selected BOF or pulse width
Burst Repeat Interval:	1 ms to 24 hours in nominally 20% steps
Ramp On Time:	0.1 to 100 seconds (1, 2, 5, 10 steps)
Ramp Off Time:	0.1 to 100 seconds (1, 2, 5, 10 steps)

[**0041**] In a next operation mode, the battery-powered implantable device **100** can be configured to operate as a microsensor, e.g., **100***c*, that can sense one or more physiological or biological parameters in the implanted environment of the device. In accordance with a preferred mode of operation, the system control unit **302** periodically requests the sensed data from each microsensor **100***c* using its ID stored in address storage **108**, and responsively sends command signals to microstimulators, e.g., **100***a* and **100***b*, adjusted accordingly to the sensed data. For example, sensor circuitry **188** can coupled to the electrodes **112** to sense or otherwise used to measure a biological parameter, e.g., temperature, glucose level, or O_2 content and provided the sensed data to the controller circuitry **106**. Preferably, the sensor circuitry includes a programmable bandpass filter and an analog to digital (A/D) converter that can sense and accordingly convert the voltage levels across the electrodes **112** into a digital quantity. Alternatively, the sensor circuitry can include one or more sense amplifiers to determine if the measured voltage exceeds a threshold voltage value or is within a specified voltage range. Furthermore, the sensor circuitry **188** can be configurable to include integration circuitry to further process the sensed voltage. The operation modes of the sensor circuitry **188** is remotely programable via the devices communication interface as shown below in Table II.

TABLE II

Sensing Parameters	
Input voltage range:	5 μv to 1 V
Bandpass filter rolloff:	24 dB
Low frequency cutoff choices:	3, 10, 30, 100, 300, 1000 Hz
High frequency cutoff choices:	3, 10, 30, 100, 300, 1000 Hz
Integrator frequency choices:	1 PPS to 100 PPS
Amplitude threshold for detection choices:	4 bits of resolution

[**0042**] Additionally, the sensing capabilities of a microsensor include the capability to monitor the battery status via path **124** from the charging circuit **122** and can additionally include using the ultrasonic transducer **138** or the coil **116** to respectively measure the magnetic or ultrasonic signal magnitudes (or transit durations) of signals transmitted between a pair of implanted devices and thus determine the relative locations of these devices. This information can be used to determine the amount of body movement, e.g., the amount that an elbow or finger is bent, and thus form a portion of a closed loop motion control system.

[**0043**] In another operation mode, the battery-powered implantable device **100** can be configured to operate as a microtransponder, e.g., **100***d*. In this operation mode, the microtransponder receives (via the aforementioned receiver means, e.g., AC magnetic, sonic, RF or electric) a first command signal from the SCU **302** and retransmits this signal (preferably after reformatting) to other implanted devices (e.g., microstimulators, microsensors, and/or microtransponders) using the aforementioned transmitter means (e.g., magnetic, sonic, RF or electric). While a microtransponder may receive one mode of command signal, e.g., it may retransmit the signal in another mode, e.g., ultrasonic. For example, clinician's programmer **172** may emit a modulated magnetic signal using a magnetic emitter **190** to program/command the implanted devices **100**. However, the magnitude of the emitted signal may not be sufficient to be successfully received by all of the implanted devices **100**. As such, a microtransponder **100***d* may receive the modulated magnetic signal and retransmit it (preferably after reformatting) as a modulated ultrasonic signal which can pass through the body with fewer restrictions. In another exemplary use, the patient control unit **174** may need to monitor a microsensor **100***c* in a patient's foot. Despite the efficiency of ultrasonic communication in a patient's body, an ultrasonic signal could still be insufficient to pass from a patient's foot to a patient's wrist (the typical location of the

patient control unit **174**). As such, a microtransponder **100***d* could be implanted in the patient's torso to improve the communication link.

[**0044**] **FIG. 4** shows the basic format of an exemplary message **192** for communicating with the aforementioned battery-powered devices **100**, all of which are preconfigured with an address (ID), preferably unique to that device, in their identification storage **108** to operate in one or more of the following modes (1) for nerve stimulation, i.e., as a microstimulator, (2) for biological parameter monitoring, i.e., as a microsensor, and/or (3) for retransmitting received signals after reformatting to other implanted devices, i.e., as a microtransponder. The command message **192** is primarily comprised of a (1) start portion **194** (one or more bits to signify the start of the message and to synchronize the bit timing between transmitters and receivers, (2) a mode portion **196** (designating the operating mode, e.g., microstimulator, microsensor, microtransponder, or group mode), (3) an address (ID) portion **198** (corresponding to either the identification address **108** or a programmed group ID), (4) a data field portion **200** (containing command data for the prescribed operation), (5) an error checking portion **202** (for ensuring the validity of the message **192**, e.g., by use of a parity bit), and (6) a stop portion **204** (for designating the end of the message **192**). The basic definition of these fields are shown below in Table III. Using these definitions, each device can be separately configured, controlled and/or sensed as part of a system or controlling one or more neural pathways within a patient's body.

TABLE III

Message Data Fields	
MODE	ADDRESS (ID)
00 = Stimulator	8 bit identification address
01 = Sensor	8 bit identification address
02 = Transponder	4 bit identification address
03 = Group	4 bit group identification address
Data Field Portion	
Program/Stimulate = Parameter/ Preconfiguration	select operating mode
Select =	select programmable parameter in program mode or preconfigured stimulation or sensing parameter in other modes
Parameter Value =	program value

[**0045**] Additionally, each device **100** can be programmed with a group ID (e.g., a 4 bit value) which is stored in its configuration data storage **132**. When a device **100**, e.g., a microstimulator, receives a group ID message that matches its stored group ID, it responds as if the message was directed to its identification address **108**. Accordingly, a plurality of microstimulators, e.g., **100***a* and **100***b*, can be commanded with a single message. This mode is of particular use when precise timing is desired among the stimulation of a group of nerves.

[**0046**] The following describes exemplary commands, corresponding to the command message **192** of **FIG. 4**, which demonstrate some of the remote control/sensing capabilities of the system of devices which comprise the present invention:

[**0047**] Write Command—Set a microstimulator/microsensor specified in the address field **198** to the designated parameter value.

[**0048**] Group Write Command—Set the microstimulators/microsensors within the group specified in the address field **198** to the designated parameter value.

[**0049**] Stimulate Command—Enable a sequence of drive pulses from the microstimulator specified in the address field **198** according to previously programmed and/or default values.

[**0050**] Group Stimulate Command—Enable a sequence of drive pulses from the microstimulators within the group specified in the address field **198** according to previously programmed and/or default values.

[**0051**] Unit Off Command—Disable the output of the microstimulator specified in the address field **198**.

[**0052**] Group Stimulate Command—Disable the output of the microstimulators within the group specified in the address field **198**.

[**0053**] Read Command—Cause the microsensor designated in the address field **198** to read the previously programmed and/or default sensor value according to previously programmed and/or default values.

[**0054**] Read Battery Status Command—Cause the microsensor designated in the address field **198** to return its battery status.

[**0055**] Define Group Command—Cause the microstimulator/microsensor designated in the address field **198** to be assigned to the group defined in the microstimulator data field **200**.

[**0056**] Set Telemetry Mode Command—Configure the microtransponder designated in the address field **198** as to its input mode (e.g., AC magnetic, sonic, etc.), output mode (e.g., AC magnetic, sonic, etc.), message length, etc.

[**0057**] Status Reply Command—Return the requested status/sensor data to the requesting unit, e.g., the SCU.

[**0058**] Download Program Command—Download program/safe harbor routines to the device, e.g., SCU, microstimulator, etc., specified in the address field **198**.

[**0059**] **FIG. 5** shows a block diagram of an exemplary open loop control program, i.e., a task scheduler **320**, for controlling/monitoring a body function/parameter. In this process, the programmable controller **308** is responsive to the clock **312** (preferably crystal controlled to thus permit real time scheduling) in determining when to perform any of a plurality of tasks. In this exemplary flow chart, the programmable controller **308** first determines in block **322** if is now at a time designated as T_{EVENT1} (or at least within a sampling error of that time), e.g., at 1:00 AM. If so, the programmable controller **308** transmits a designated com-

mand to microstimulator A (ST_A) in block **324**. In this example, the control program continues where commands are sent to a plurality of stimulators and concludes in block **326** where a designated command is sent to microstimulator X (ST_X). Such a subprocess, e.g., a subroutine, is typically used when multiple portions of body tissue require stimulation, e.g, stimulating a plurality of muscle groups in a paralyzed limb to avoid atrophy. The task scheduler **320** continues through multiple time event detection blocks until in block **328** it determines whether the time T_{EVENTM} has arrived. If so, the process continues at block **330** where, in this case, a single command is sent to microstimulator M (ST_M). Similarly, in block **332** the task scheduler **320** determines when it is the scheduled time, i.e., T_{EVENTO}, to execute a status request from microsensor A (SE_A). Is so, a subprocess, e.g., a subroutine, commences at block **334** where a command is sent to microsensor A (SE_A) to request sensor data and/or specify sensing criteria. Microsensor A (SE_A) does not instantaneously respond. Accordingly, the programmable controller **308** waits for a response in block **336**. In block **338**, the returned sensor status data from microsensor A (SE_A) is stored in a portion of the memory, e.g., a volatile portion of the program storage **310**, of the programmable controller **308**. The task scheduler **320** can be a programmed sequence, i.e., defined in software stored in the program storage **310**, or, alternatively, a predefined function controlled by a table of parameters similarly stored in the program storage **310**. A similar process can be used where the SCU **302** periodically interrogates each implantable device **100** to determine its battery status.

[**0060**] **FIG. 6** shows an exemplary use of an optional translation table **340** for communicating between the SCU **302** and microstimulators, e.g., **100***a*, and/or microsensors, e.g., **100***c*, via microtransponders, e.g., **100***d*. A microtransponder, e.g., **100***d*, is used when the communication range of the SCU **302** is insufficient to reliably communicate with other implanted devices **100**. In this case, the SCU **302** instead directs a data message, i.e., a data packet, to an intermediary microtransponder, e.g., **100***d*, which retransmits the data packet to a destination device **100**. In an exemplary implementation, the translation table **340** contains pairs of corresponding entries, i.e., first entries **342** corresponding to destination addresses and second entries **344** corresponding to the intermediary microtransponder addresses. When the SCU **302** determines, e.g., according to a timed event designated in the program storage **310**, that a command is to be sent to a designated destination device (see block **346**), the SCU **302** searches the first entries **342** of the translation table **340**, for the destination device address, e.g., ST_M. The SCU **302** then fetches the corresponding second table entry **344** in block **348** and transmits the command to that address. When the second table entry **344** is identical to its corresponding first table entry **342**, the SCU **302** transmits commands directly to the implanted device **100**. However, when the second table entry **344**, e.g., T_N, is different from the first table entry **342**, e.g., ST_M, the SCU **302** transmits commands via an intermediary microtransponder, e.g., **100***d*. The use of the translation table **340** is optional since the intermediary addresses can, instead, be programmed directly into a control program contained in the program storage **310**. However, it is preferable to use such a translation table **340** in that communications can be redirected on the fly by just reprogramming the translation table **340** to take advantage of implanted transponders as required, e.g., if communications should degrade and become unreliable. The translation table **340** is preferably contained in programmable memory, e.g., RAM or EPROM, and can be a portion of the program storage **310**. While the translation table **340** can be remotely programmed, e.g., via a modulated signal from the clinician's programmer **172**, it is also envisioned that the SCU **302** can reprogram the translation table **340** if the communications degrade.

[**0061**] **FIG. 7** is an exemplary block diagram showing the use of the system of the present invention to perform closed loop control of a body function. In block **352**, the SCU **302** requests status from microsensor A (SE_A). The SCU **302**, in block **354**, then determines whether a current command given to a microstimulator is satisfactory and, if necessary, determines a new command and transmits the new command to the microstimulator A in block **356**. For example, if microsensor A (SE_A) is reading a voltage corresponding to a pressure generated by the stimulation of a muscle, the SCU **302** could transmit a command to microstimulator A (ST_A) to adjust the sequence of drive pulses, e.g., in magnitude, duty cycle, etc., and accordingly change the voltage sensed by microsensor A (SE_A). Accordingly, closed loop, i.e., feedback, control is accomplished. The characteristics of the feedback (position, integral, derivative (PID)) control are preferably program controlled by the SCU **302** according to the control program contained in program storage **310**.

[**0062**] **FIG. 8** shows an exemplary injury treatable by embodiments of the present system **300**. In this exemplary injury, the neural pathway has been damaged, e.g, severed, just above the a patient's left elbow. The goal of this exemplary system is to bypass the damaged neural pathway to permit the patient to regain control of the left hand. An SCU **302** is implanted within the patient's torso to control plurality of stimulators, ST_1-ST_3, implanted proximate to the muscles respectively controlling the patient's thumb and fingers. Additionally, microsensor **1** (SE_1) is implanted proximate to an undamaged nerve portion where it can sense a signal generated from the patient's brain when the patient wants hand closure. Optional microsensor **2** (SE_2) is implanted in a portion of the patient's hand where it can sense a signal corresponding to stimulation/motion of the patient's pinky finger and microsensor **3** (SE_3) is implanted and configured to measure a signal corresponding to grip pressure generated when the fingers of the patient's hand are closed. Additionally, an optional microtransponder (T_1) is shown which can be used to improve the communication between the SCU **302** and the implanted devices.

[**0063**] **FIG. 9** shows an exemplary flow chart for the operation of the SCU **302** in association with the implanted devices in the exemplary system of **FIG. 8**. In block **360**, the SCU **302** interrogates microsensor **1** (SE_1) to determine if the patient is requesting actuation of his fingers. If not, a command is transmitted in block **362** to all of the stimulators (ST_1-ST_3) to open the patient's hand, i.e., to de-energize the muscles which close the patient's fingers. If microsensor **1** (SE_1) senses a signal to actuate the patient's fingers, the SCU **302** determines in block **364** whether the stimulators ST_1-ST_3 are currently energized, i.e., generating a sequence of drive pulses. If not, the SCU **302** executes instructions to energize the simulators. In a first optional path **366**, each of the stimulators are simultaneously (subject to formatting and transmission delays) commanded to energize in block **366***a*. However, the command signal given to each one specifies a

different start delay time (using the BON parameter). Accordingly, there is a stagger between the actuation/closing of each finger.

[0064] In a second optional path **368**, the microstimulators are consecutively energized by a delay Δ. Thus, microstimulator **1** (ST_1) is energized in block **368***a*, a delay is executed within the SCU **302** in block **368***b*, and so on for all of the microstimulators. Accordingly, paths **366** and **368** perform essentially the same function. However, in path **366** the interdevice timing is performed by the clocks within each implanted device **100** while in math **368**, the SCU **302** is responsible for providing the interdevice timing.

[0065] In path **370**, the SCU **302** actuates a first microstimulator (ST_1) in block **370***a* and waits in block **370***b* for its corresponding muscle to be actuated, as determined by microsensor **2** (SE_2), before actuating the remaining stimulators (ST_2-ST_3) in block **370***c*. This implementation could provide more coordinated movement in some situations.

[0066] Once the stimulators have been energized, as determined in block **364**, closed loop grip pressure control is performed in blocks **372***a* and **372***b* by periodically reading the status of microsensor **3** (SE_3) and adjusting the commands given to the stimulators (ST_1-ST_3) accordingly. Consequently, this exemplary system has enabled the patient to regain control of his hand including coordinated motion and grip pressure control of the patient's fingers.

[0067] Referring again to **FIG. 3A, a** magnetic sensor **186** is shown. In the parent application, it was shown that such a sensor **186** could be used to disable the operation of an implanted device **100**, e.g., to stop the operation of such devices in an emergency situation, in response to a DC magnetic field, preferably from an externally positioned safety magnet **187**. A further implementation is disclosed herein. The magnetic sensor **186** can be implemented using various devices. Exemplary of such devices are devices manufactured by Nonvolatile Electronics, Inc. (e.g., their AA, AB, AC, AD, or AG series), Hall effect sensors, and subminiature reed switches. Such miniature devices are configurable to be placed within the housing of the disclosed SCU **302** and implantable devices **100**. While essentially passive magnetic sensors, e.g., reed switches, are possible, the remaining devices include active circuitry that consumes power during detection of the DC magnetic field. Accordingly, it is preferred that controller circuitry **302** periodically, e.g., once a second, provide power the magnetic sensor **186** and sample the sensor's output signal **374** during that sampling period.

[0068] In a preferred implementation of the SCU **302**, the programmable controller **308** is a microcontroller operating under software control wherein the software is located within the program storage **310**. The SCU **302** preferably includes an input **376**, e.g., a non maskable interrupt (NMI), which causes a safe harbor subroutine **378**, preferably located within the program storage **310**, to be executed. Additionally, failure or potential failure modes, e.g., low voltage or over temperature conditions, can be used to cause the safe harbor subroutine **378** to be executed. Typically, such a subroutine could cause a sequence of commands to be transmitted to set each microstimulator into a safe condition for the particular patient configuration, typically disabling each microstimulator. Alternatively, the safe harbor condition could be to set certain stimulators to generate a prescribed sequence of drive pulses. Preferably, the safe harbor subroutine **378** can be downloaded from an external device, e.g., the clinician's programmer **172**, into the program storage **310**, a nonvolatile storage device. Additionally, it is preferable that, should the programmable contents of the program storage be lost, e.g., from a power failure, a default safe harbor subroutine be used instead. This default subroutine preferably stored in nonvolatile storage that is not user programmable, e.g., ROM, that is otherwise a portion of the program storage **310**. This default subroutine is preferably general purpose and typically is limited to commands that turn off all potential stimulators.

[0069] Alternatively, such programmable safe harbor subroutines **378** can exist in the implanted stimulators **100**. Accordingly, a safe harbor subroutine could be individually programmed into each microstimulator that is customized for the environments of that microstimulator and a safe harbor subroutine for the SCU **302** could then be designated that disables the SCU **302**, i.e. causes the SCU **302** to not issue subsequent commands to other implanted devices **100**.

[0070] FIGS. **10**A and **10**BD show two side cutaway views of the presently preferred construction of the sealed housing **206**, the battery **104** and the circuitry (implemented on one or more IC chips **216** to implement electronic portions or the SCU **302**) contained within. In this presently preferred construction, the housing **206** is comprised of an insulating ceramic tube **260** brazed onto a first end cap forming electrode **112***a* via a braze **262**. At the other end of the ceramic tube **260** is a metal ring **264** that is also brazed onto the ceramic tube **260**. The circuitry within, i.e., a capacitor **183** (used when in a microstimulator mode), battery **104**, IC chips **216**, and a spring **266** is attached to an opposing second end cap forming electrode **112***b*. A drop of conductive epoxy is used to glue the capacitor **183** to the end cap **112***a* and is held in position by spring **266** as the glue takes hold. Preferably, the IC chips **216** are mounted on a circuit board **268** over which half circular longitudinal ferrite slates **270** are attached. The coil **116** is wrapped around the ferrite plates **270** and attached to IC chips **216**. A getter **272**, mounted surrounding the spring **266**, is preferably used to increase the hermeticity of the SCU **302** by absorbing water introduced therein. An exemplary getter **272** absorbs 70 times its volume in water. While holding the circuitry and the end cap **112***b* together, one can laser weld the end cap **112***b* to the ring **264**. Additionally, a platinum, iridium, or platinum-iridium disk or plate **274** is preferably welded to the end caps of the SCU **302** to minimize the impedance of the connection to the body tissue.

[0071] An exemplary battery **104** is described more fully below in connection with the description of **FIG. 11**. Preferably, the battery **104** is made from appropriate materials so as to provide a power capacity of at least 1 microwatt-hour, preferably constructed from a battery having an energy density of about 240 mW-Hr/cm^3. A Li—I battery advantageously provides such an energy density. Alternatively, an Li—I—Sn battery provides an energy density up to 360 mW-Hr/cm^3. Any of these batteries, or other batteries providing a power capacity of at least 1 microwatt-hour may be used with implanted devices of the present invention.

[0072] The battery voltage V of an exemplary battery is nominally 3.6 volts, which is more than adequate for operating the CMOS circuits preferably used to implement the

IC chip(s) **216**, and/or other electronic circuitry, within the SCU **302**. The battery voltage V, in general, is preferably not allowed to discharge below about 2.55 volts, or permanent damage may result. Similarly, the battery **104** should preferably not be charged to a level above about 4.2 volts, or else permanent damage may result. Hence, a charging circuit **122** (discussed in the parent application) is used to avoid any potentially damaging discharge or overcharge.

[**0073**] The battery **104** may take many forms, any of which may be used so long as the battery can be made to fit within the small volume available. As previously discussed, the battery **104** may be either a primary battery or a rechargeable battery. A primary battery offers the advantage of a longer life for a given energy output but presents the disadvantage of not being rechargeable (which means once its energy has been used up, the implanted device no longer functions). However, for many applications, such as one-time-only muscle rehabilitation regimens applied to damaged or weakened muscle tissue, the SCU **302** and/or devices **100** need only be used for a short time (after which they can be explanted and discarded, or simply left implanted as benign medical devices). For other applications, a rechargeable battery is clearly the preferred type of energy choice, as the tissue stimulation provided by the microstimulator is of a recurring nature.

[**0074**] The considerations relating to using a rechargeable battery as the battery **104** of the implantable device **100** are presented, inter alia, in the book, *Rechargeable Batteries, Applications Handbook, EDN* Series for Design Engineers, Technical Marketing Staff of Gates Energy Products, Inc. (Butterworth-Heinemann 1992). The basic considerations for any rechargeable battery relate to high energy density and long cycle life. Lithium based batteries, while historically used primarily as a nonrechargeable battery, have in recent years appeared commercially as rechargeable batteries. Lithium-based batteries typically offer an energy density of from 240 mW-Hr/cm^3 to 360 mW-Hr/cm^3. In general, the higher the energy density the better, but any battery construction exhibiting an energy density resulting in a power capacity greater than 1 microwatt-hour is suitable for the present invention.

[**0075**] One of the more difficult hurdles facing the use of a battery **104** within the SCU **302** relates to the relatively small size or volume inside the housing **206** within which the battery must be inserted. A typical SCU **302** made in accordance with the present invention is no larger than about 60 mm long and 8 mm in diameter, preferably no larger than 60 mm long and 6 mm in diameter, and includes even smaller embodiments, e.g., 15 mm long with an O.D. of 2.2 mm (resulting in an I.D. of about 2 mm). When one considers that only about ¼ to ½ of the available volume within the device housing **206** is available for the battery, one begins to appreciate more fully how little volume, and thus how little battery storage capacity, is available for the SCU **302**.

[**0076**] **FIG. 11** shows an exemplary battery **104** typical of those disclosed in the parent application. Specifically, a parallel-connected cylindrical electrode embodiment is shown where each cylindrical electrode includes a gap or slit **242**; with the cylindrical electrodes **222** and **224** on each side of the gap **242** forming a common connection point for tabs **244** and **246** which serve as the electrical terminals for the battery. The electrodes **222** and **224** are separated by a suitable separator **248**. The gap **242** minimizes the flow of eddy currents in the electrodes. For this embodiment, there are four concentric cylindrical electrodes **222**, the outer one (largest diameter) of which may function as the battery case **234**, and three concentric electrodes **224** interleaved between the electrodes **222**, with six concentric cylindrical separator layers **248** separating each electrode **222** or **224** from the adjacent electrodes.

[**0077**] Accordingly, a preferred embodiment of the present invention is comprised of an implanted SCU **302** and a plurality of implanted devices **100**, each of which contains its own rechargeable battery **104**. As such, a patient is essentially independent of any external apparatus between battery chargings (which generally occur no more often than once an hour). However, for some treatment regimen, it may be adequate to use a power supply analogous to that described in U.S. Pat. No. 5,324,316 that only provides power while an external AC magnetic field is being provided, e.g., from charger **118**. Additionally, it may be desired, e.g., from a cost standpoint, to implement the SCU **302** as an external device, e.g., within a watch-shaped housing that can be attached to a patient's wrist in a similar manner to the patient control unit **174**.

[**0078**] The power consumption of the SCU **302** is primarily dependent upon the circuitry implementation, preferably CMOS, the circuitry complexity and the clock speed. For a simple system, a CMOS implemented state machine will be sufficient to provide the required capabilities of the programmable controller **308**. However, for more complex systems, e.g., a system where an SCU **302** controls a large number of implanted devices **100** in a closed loop manner, a microcontroller may be required. As the complexity of such microcontrollers increases (along with its transistor count), so does its power consumption. Accordingly, a larger battery having a capacity of 1 watt-hour is preferred. While a primary battery is possible, it is preferable that a rechargeable battery be used. Such larger batteries will require a larger volume and accordingly, cannot be placed in the injectable housing described above. However, a surgically implantable device within a larger sealed housing, e.g., having at least one dimension in excess of 1 inch, will serve this purpose when used in place of the previously discussed injectable housing **206**. **FIG. 12** shows an exemplary implantable housing **380** suitable for such a device.

[**0079**] While the invention herein disclosed has been described by means of specific embodiments and applications thereof, numerous modifications and variations could be made thereto by those skilled in the art without departing from the scope of the invention set forth in the claims. For example, a system including multiple SCUs, e.g., one external and one internal, is considered to be within the scope of the present invention. Additionally, while the use of a single communication channel for communication between one or more SCUs and the other implanted devices has been described, a system implemented using multiple communication channels, e.g., a first sonic channel at a first carrier frequency and a second sonic channel at a second carrier frequency, is also considered to be within the scope of the present invention.

We claim:

1. A system for monitoring and/or affecting at least one parameter of a patient's body, said system comprising:

at least one implantable device operable to sense and/or stimulate a patient's body parameter in accordance with one or more controllable operating parameters; and

a system control unit for controlling said controllable operating parameters, said system control unit comprising:

a sealed elongate housing configured for implantation in a patient's body;

a signal transmitter in said housing for transmitting command signals;

a signal receiver in said housing for receiving status signals; and

a programmable controller in said housing responsive to received status signals for producing command signals for transmission by said signal transmitter to said implantable devices.

2. The system of claim 1 wherein said sealed housing has an axial dimension of less than 60 mm and a lateral dimension of less than 6 mm suitable for injection into the patient's body.

3. The system of claim **A1** comprising at least one said implantable device operable as a sensor and at least one said implantable operable as a stimulator and wherein said controller is responsive to status data signals received from said sensor for generating said addressable command data signals to said stimulator to perform closed loop control of the operation of said stimulator.

4. The system of claim 1 wherein said system control unit additionally comprises a power source contained within said sealed housing for providing operating power to said data signal transmitter, said data signal receiver, and said programmable controller.

5. The system of claim 1 wherein said signal receiver includes a coil responsive to status signals defined by a modulated magnetic field.

6. The system of claim 1 wherein said signal receiver includes a transducer responsible to status signals defined by a modulated ultrasonic signal.

7. The system of claim 1 wherein said signal transmitter includes means for transmitting command signals in the form of a modulated magnetic field.

8. The system of claim 1 wherein said signal transmitter includes means for transmitting command signals in the form of a modulated ultrasonic signal.

9. The system of claim 1 wherein said system control unit additionally includes:

at least one electrode;

sensor/stimulator circuitry; and wherein

said sensor stimulator circuitry is configurable to generate a data signal representative of an electrical signal conducted by said electrode and/or supply a sequence of drive pulses to said electrode.

10. The system of claim 1 wherein each of said implantable devices includes a power source having a capacity of at least 1 microwatt-hour.

11. The system of claim 10 wherein each said implantable device includes means for monitoring status of its power source and said system control unit is configured to transmit command signals to each said implantable device and to responsively receive status signals corresponding to said power source status.

12. The system of claim 1 further including:

program storage means in said housing for specifying the operation of said programmable controller; and

means to modify said program storage means in response to signals received by said signal receiver.

13. The system or claim 12 wherein said program storage means includes means to cause said system control unit to transmit a programmable list of command signals to said implantable devices.

14. The system of claim 13 wherein said means to cause said system control unit to transmit a programmable list of command signals includes:

a magnetic sensor for generating a signal responsive to a DC magnetic field; and wherein

said programmable list of command signals is transmitted in response to said magnetic sensor signal.

15. A system control unit configured for implantation in a patient's body for controlling/monitoring the operation of one or more other implantable addressable devices, said system control unit comprising:

a sealed elongate housing;

a data signal transmitter for wireless transmission of command data signals;

a data signal receiver for wireless reception of status data signals;

a controller capable of accepting status data signals from said data signal receiver and sending addressable command data signals to said data signal transmitter in response thereto to control and/or monitor the operation of one or more other implantable devices in accordance with one or more controllable operating parameters;

program storage means for specifying the operation of said controller; and wherein

said data signal transmitter, data signal receiver, said controller, and said program storage means are disposed within said sealed housing.

16. The system control unit of claim 15 wherein said sealed housing has an axial dimension of less than 60 mm and a lateral dimension of less than 6 mm suitable for injection into the patient's body.

17. The system control unit of claim 15 additionally comprising a power source contained within said sealed housing for providing operating power to said data signal transmitter, said data signal receiver, said controller, and said program storage means.

18. The system control unit of claim 15 wherein said data signal receiver includes a coil responsive to a status data signal defined by a modulated magnetic field.

19. The system control unit of claim 15 wherein said data signal receiver includes a transducer responsive to a status data signal defined by a modulated ultrasonic signal.

20. The system control unit of claim 15 wherein said transmitter includes means for transmitting a command data signal in the form of a modulated magnetic field.

21. The system control unit of claim 15 wherein said transmitter includes means for transmitting a command data signal in the form of a modulated ultrasonic signal.

22. The system control unit of claim 15 further including means to modify said program storage means in response to signals received by said data signal receiver.

23. The system control unit of claim 15 additionally including:

at least one electrode;

sensor/stimulator circuitry; and wherein

said sensor stimulator circuitry is configurable to generate a data signal representative of an electrical signal conducted by said electrode and/or supply a sequence of drive pulses to said electrode.

24. A system for monitoring and/or affecting at least one parameter of a patient's body, said system comprising:

a system control unit positioned outside of the patient's body comprising:

means for providing wireless transmission of command data signals;

means for providing wireless reception of status data signals; and

means capable of accepting status data signals from said data signal receiver and sending addressable command data signals to said data signal transmitter in response thereto to control and/or monitor the operation of one or more implantable devices; and

at least one addressable device configured for implantation in a patient's body responsive to said command data signals, said implantable devices selected from one or more of the following groups:

stimulators having at least one electrode configured to produce an electrical current for stimulating body tissue to affect a parameter of the patient's body; and

sensors having at least one electrode configured to produce a data signal corresponding to an electrical signal conducted by said electrode and representative of a parameter of the patient's body; and wherein

each of said implantable devices includes a power source having a power capacity of at least 1 microwatt-hour.

25. The system of claim 24 wherein said implantable devices include:

at least one stimulator and at least one sensor; and wherein

said system control unit is responsive to status data signals received from said sensor for generating said addressable command data signals to said stimulator to perform closed loop control of the operation of said stimulator.

26. The system of claim 24 wherein said groups of implantable devices further include transponders for transmitting a data signal related to a command signal received by said transponder.

27. The system of claim 24 wherein said implantable devices include:

at least one stimulator, at least one sensor and at least one transponder; and wherein

said system control unit is responsive to status data signals received from said sensor for generating said addressable command data signals to said stimulator to perform closed loop control of the operation of said stimulator.

28. The system of claim 27 wherein said status data signal received from said sensor is received via said transponder.

29. The system of claim 27 wherein said stimulator is responsive to said command data signals received via said transponder.

30. The system of claim 24 wherein said wireless reception means includes a coil responsive to a status data signal defined by a modulated magnetic field.

31. The system of claim 24 wherein said wireless reception means includes a transducer responsive to a status data signal defined by a modulated ultrasonic signal.

32. The system of claim 24 wherein said wireless transmission means includes means for transmitting a command data signal in the form of a modulated magnetic field.

33. The system of claim 24 wherein said wireless transmission means includes means for transmitting a command data signal in the form of a modulated ultrasonic signal.

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