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(54) METHOD AND SYSTEM FOR VAGAL BLOCKING WITH OR WITHOUT VAGAL STIMULATION TO PROVIDE THERAPY FOR OBESITY AND OTHER GASTROINTESTINAL DISORDERS USING RECHARGEABLE IMPLANTED PULSE GENERATOR

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(21) Appl. No.: **11/047,232**

(22) Filed: **Jan. 31, 2005**

Related U.S. Application Data

(63) Continuation of application No. 11/035,374, filed on Jan. 13, 2005, which is a continuation of application No. 10/841,995, filed on May 8, 2004, which is a continuation of application No. 10/196,533, filed on Jul. 16, 2002, which is a continuation of application No. 10/142,298, filed on May 9, 2002.

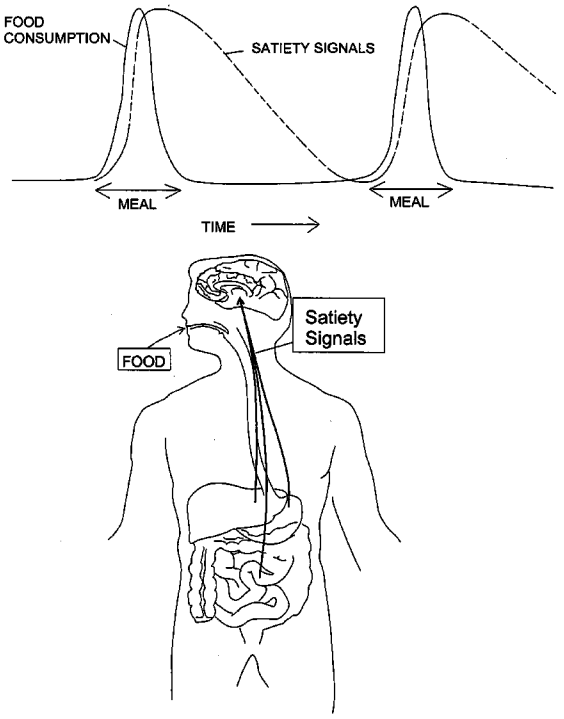
Publication Classification

(51) **Int. Cl.**[7] **A61N 1/18**

(52) **U.S. Cl.** **607/40**; 607/58

(57) **ABSTRACT**

Method and system to provide therapy for obesity and gastrointestinal disorders such as FGIDs, gastroparesis, gastro-esophageal reflex disease (GERD), pancreatitis and ileus comprises vagal blocking and/or vagal stimulation, utilizing implanted and external components. Vagal blocking may be in the afferent or efferent direction, and may be with or without selective stimulation. Blocking may be provided by one of a number of different electrical blocking techniques. The implantable components are a lead and an implantable pulse generator (IPG), comprising re-chargeable lithium-ion or lithium-ion polymer battery. The external components are a programmer and an external recharger. In one embodiment, the implanted pulse generator may also comprise stimulus-receiver means, and a pulse generator means with rechargeable battery. In another embodiment, the implanted pulse generator is adapted to be rechargeable, utilizing inductive coupling with an external recharger. Existing nerve stimulators may also be adapted to be used with rechargeable power sources as disclosed herein. The implanted system comprises a lead with two or more electrodes, for vagus nerve(s) modulation with selective stimulation and/or blocking. In another embodiment, the external stimulator and/or programmer may comprise an optional telemetry unit. The addition of the telemetry unit to the external stimulator and/or programmer provides the ability to remotely interrogate and change stimulation programs over a wide area network, as well as other networking capabilities.



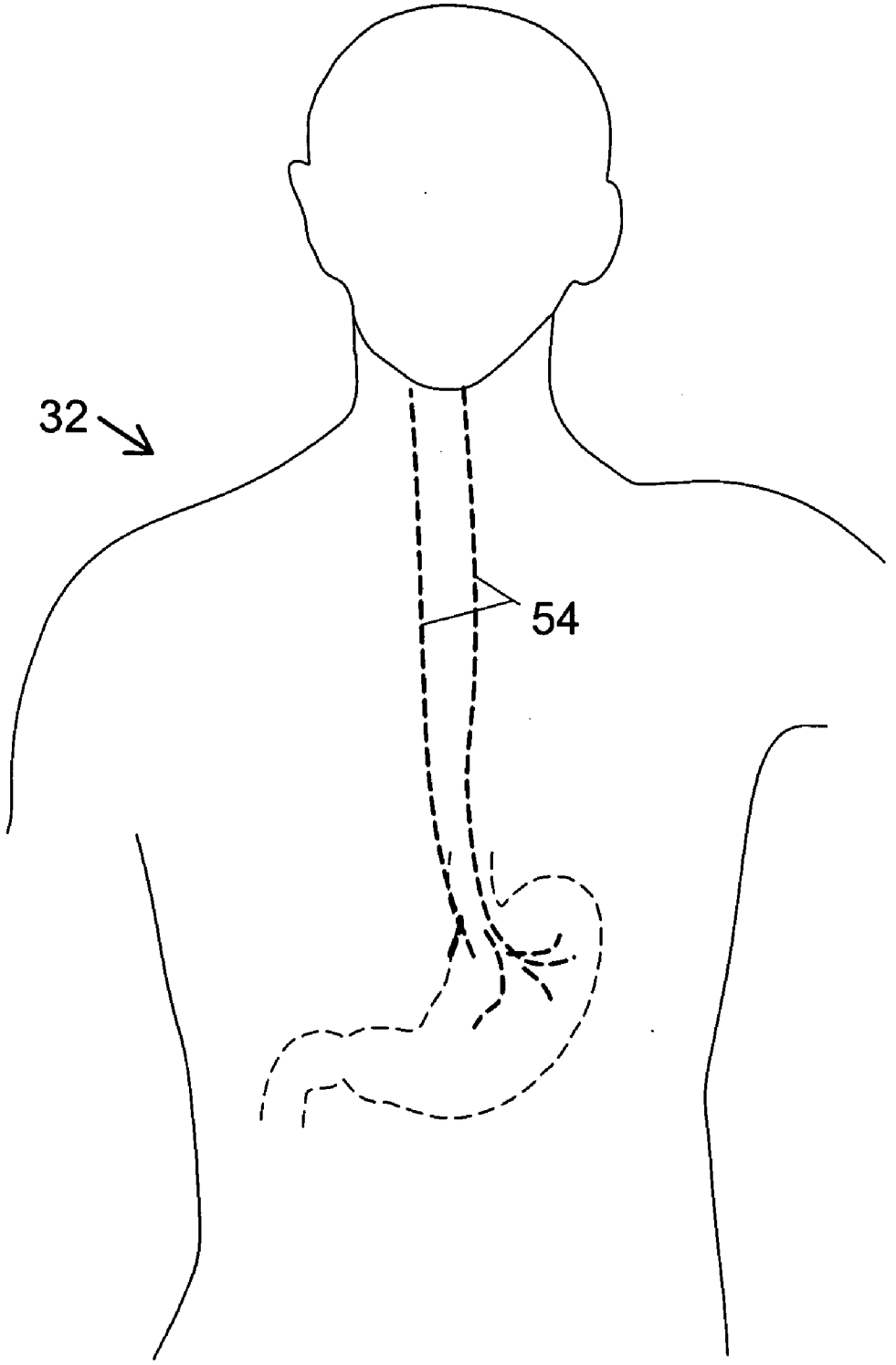


FIG. 1

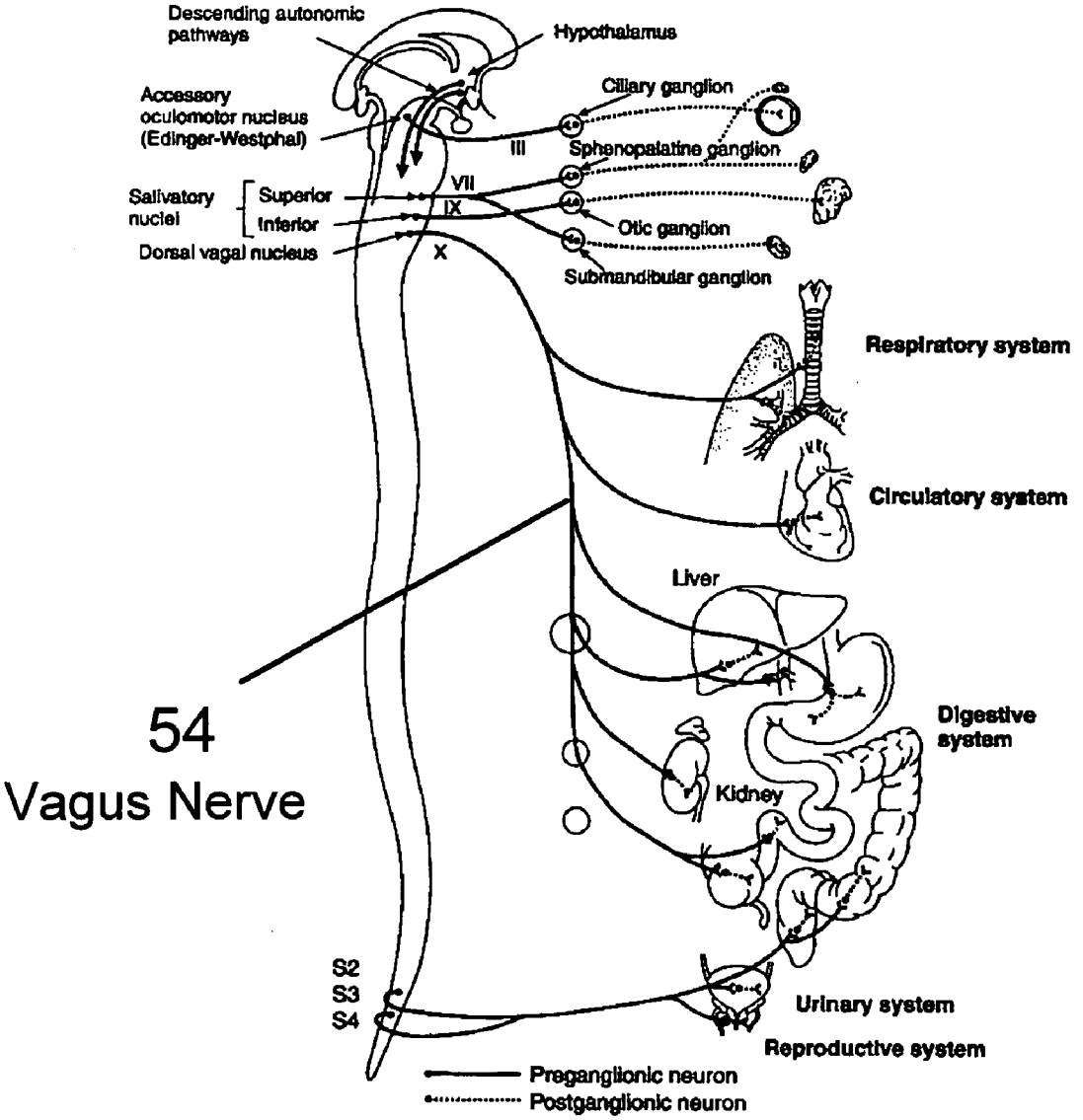
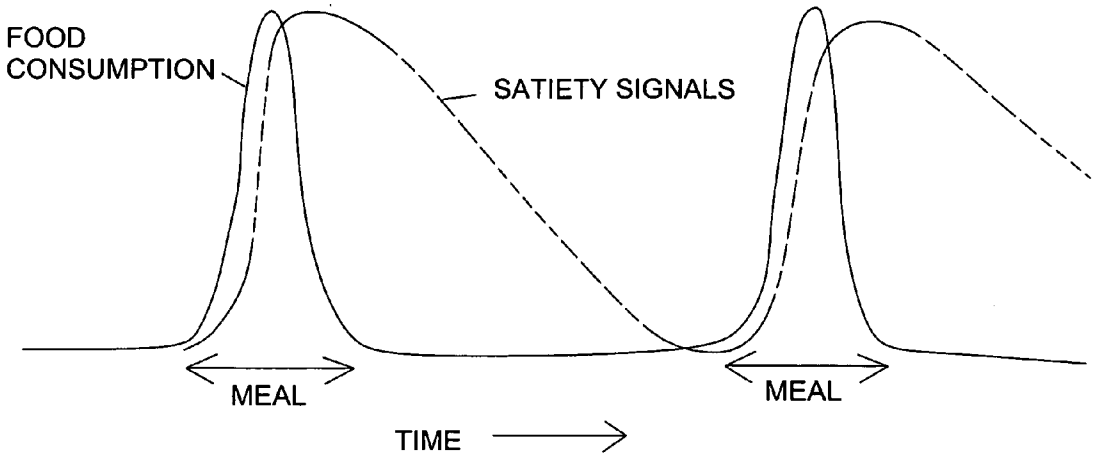

Descending autonomic pathways
Hypothalamus
Accessory oculomotor nucleus (Edinger-Westphal)
Ciliary ganglion
III
Sphenopalatine ganglion
Salivatory nuclei
Superior
Inferior
VII
IX
Otic ganglion
Dorsal vagal nucleus
X
Submandibular ganglion
Respiratory system
Circulatory system
Liver
54
Vagus Nerve
Digestive system
Kidney
S2
S3
S4
Urinary system
Reproductive system
Preganglionic neuron
Postganglionic neuron

FIG 2


FOOD
CONSUMPTION
SATIETY SIGNALS
MEAL
MEAL
TIME

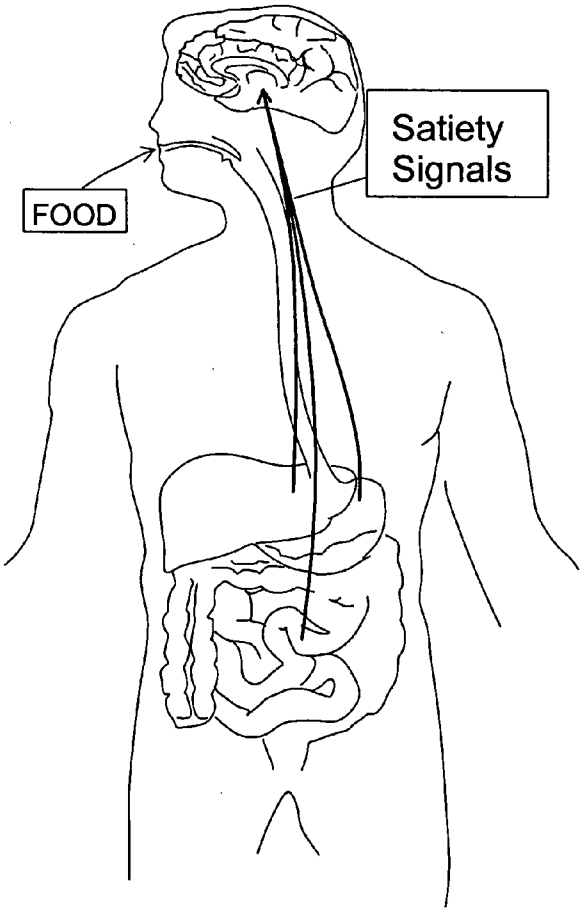

Satiety
Signals
FOOD

FIG. 3

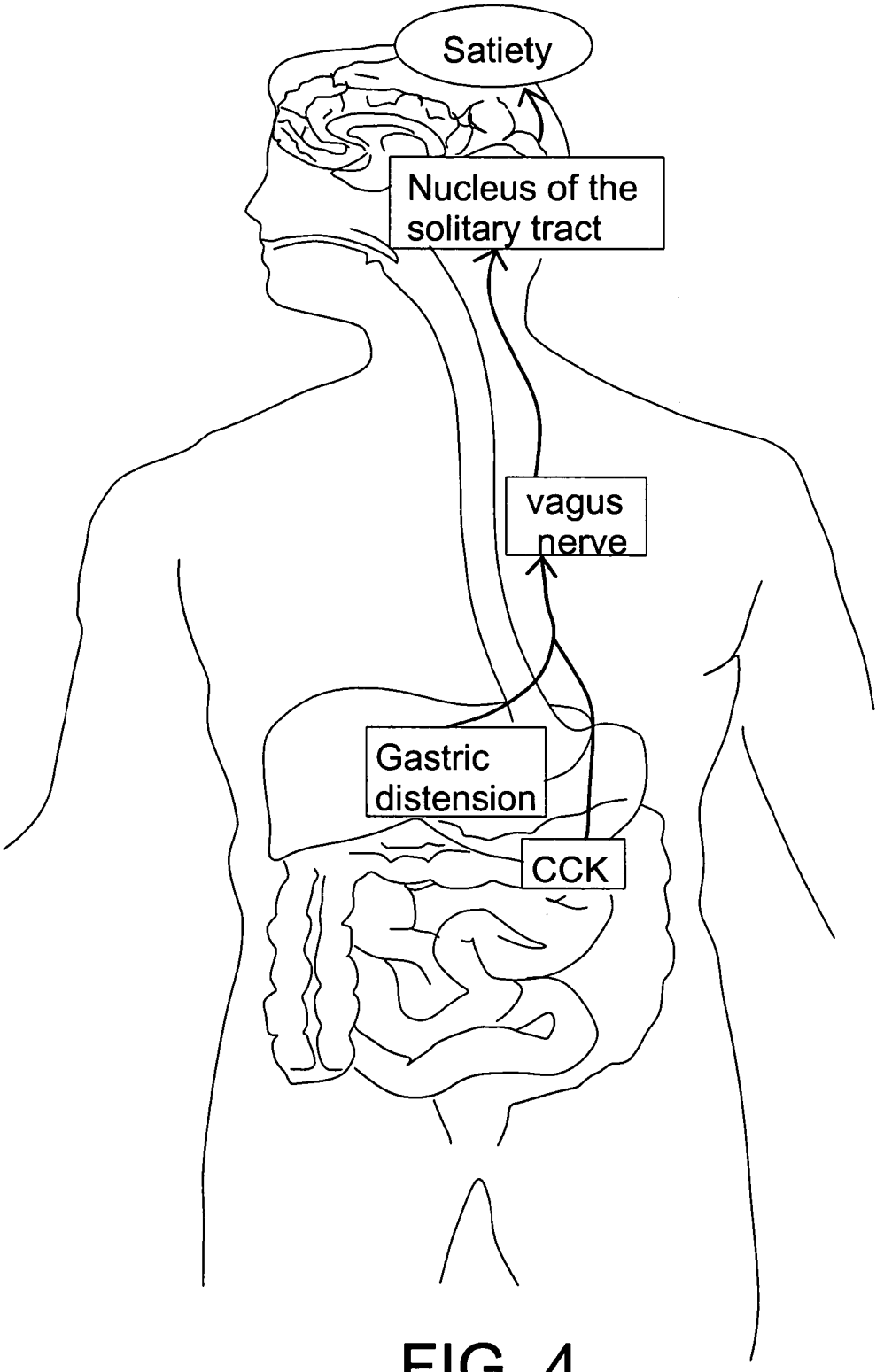

Satiety
Nucleus of the solitary tract
vagus nerve
Gastric distension
CCK

FIG. 4

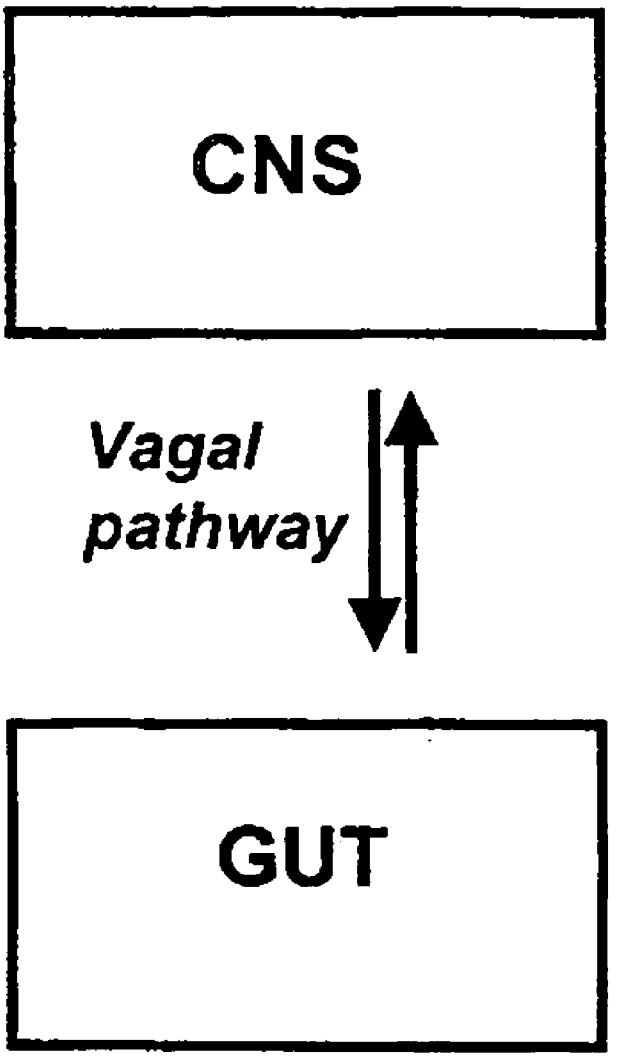


FIG. 5

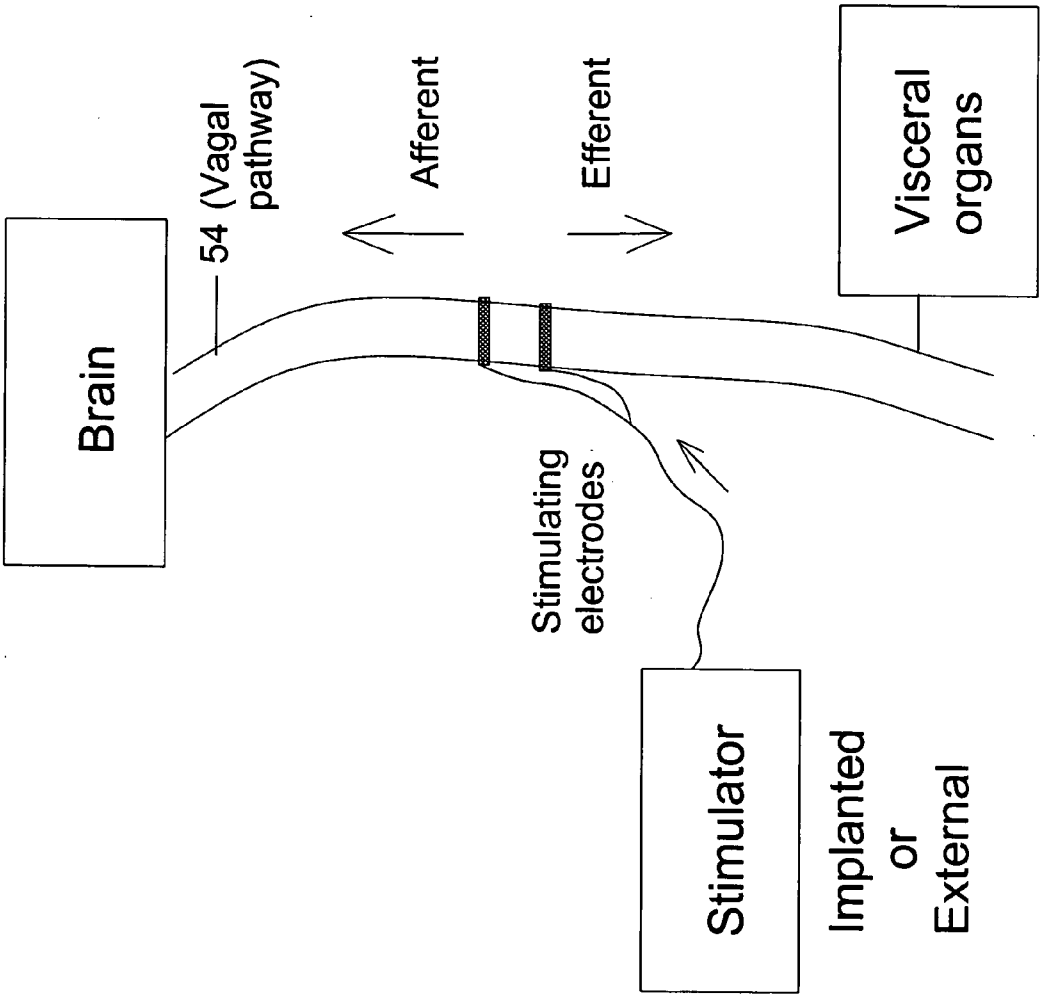

Brain
54 (Vagal pathway)
Afferent
Efferent
Visceral organs
Stimulating electrodes
Stimulator
Implanted or External

FIG. 6

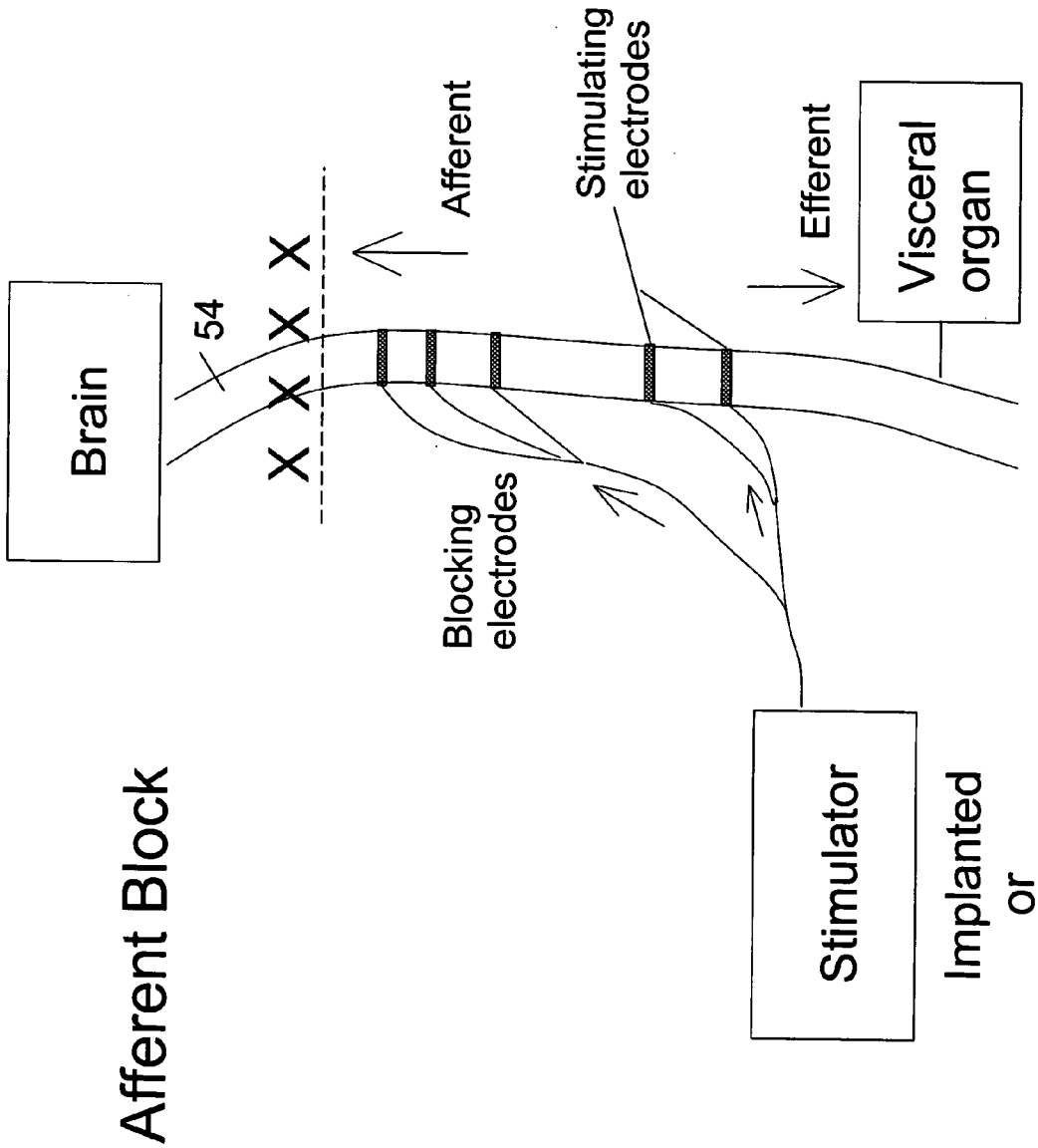

Afferent Block
Brain
54
Afferent
Stimulating electrodes
Efferent
Visceral organ
Blocking electrodes
Stimulator
Implanted or External

FIG. 7

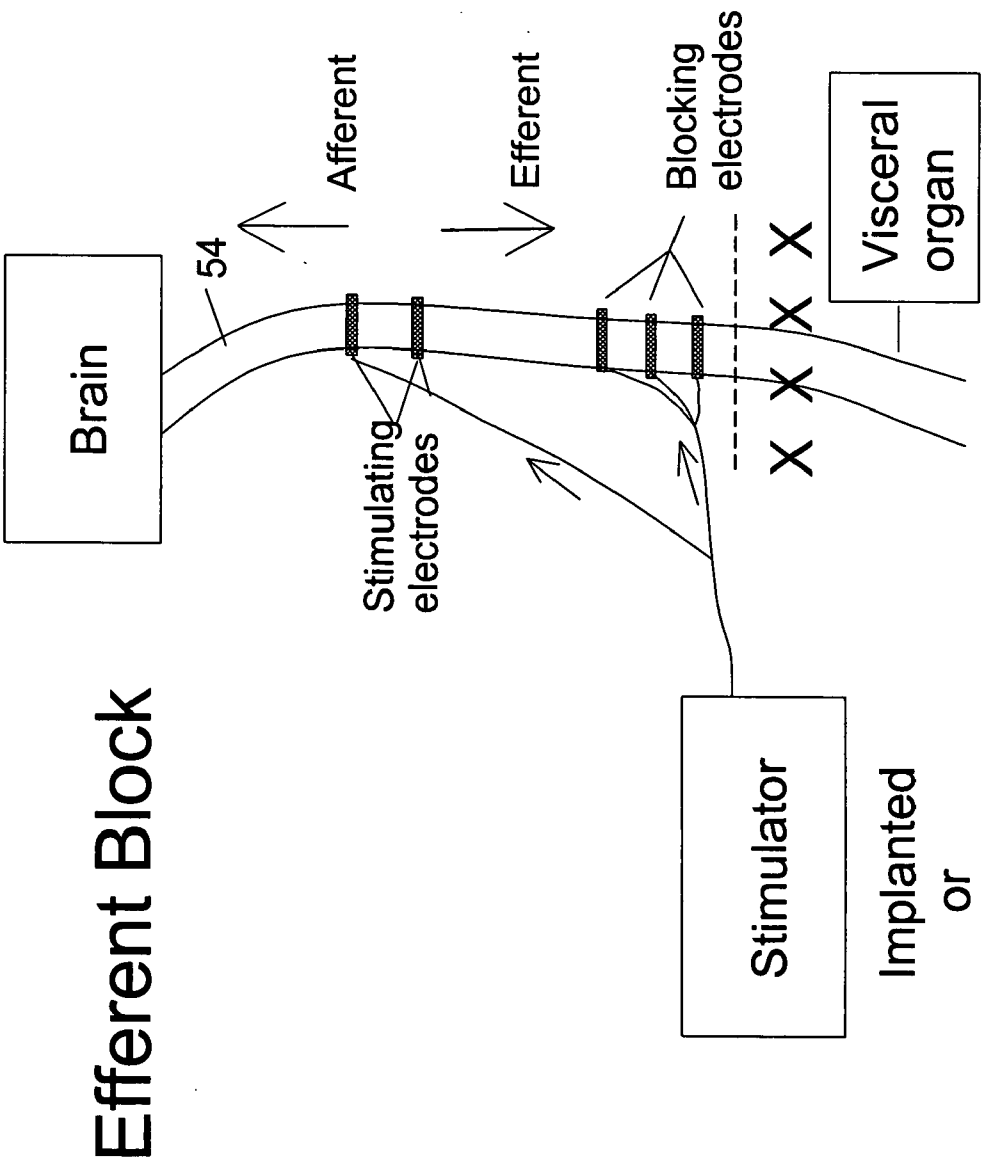

Efferent Block
Brain
54
Afferent
Efferent
Blocking electrodes
Visceral organ
Stimulating electrodes
Stimulator
Implanted or External

FIG. 8

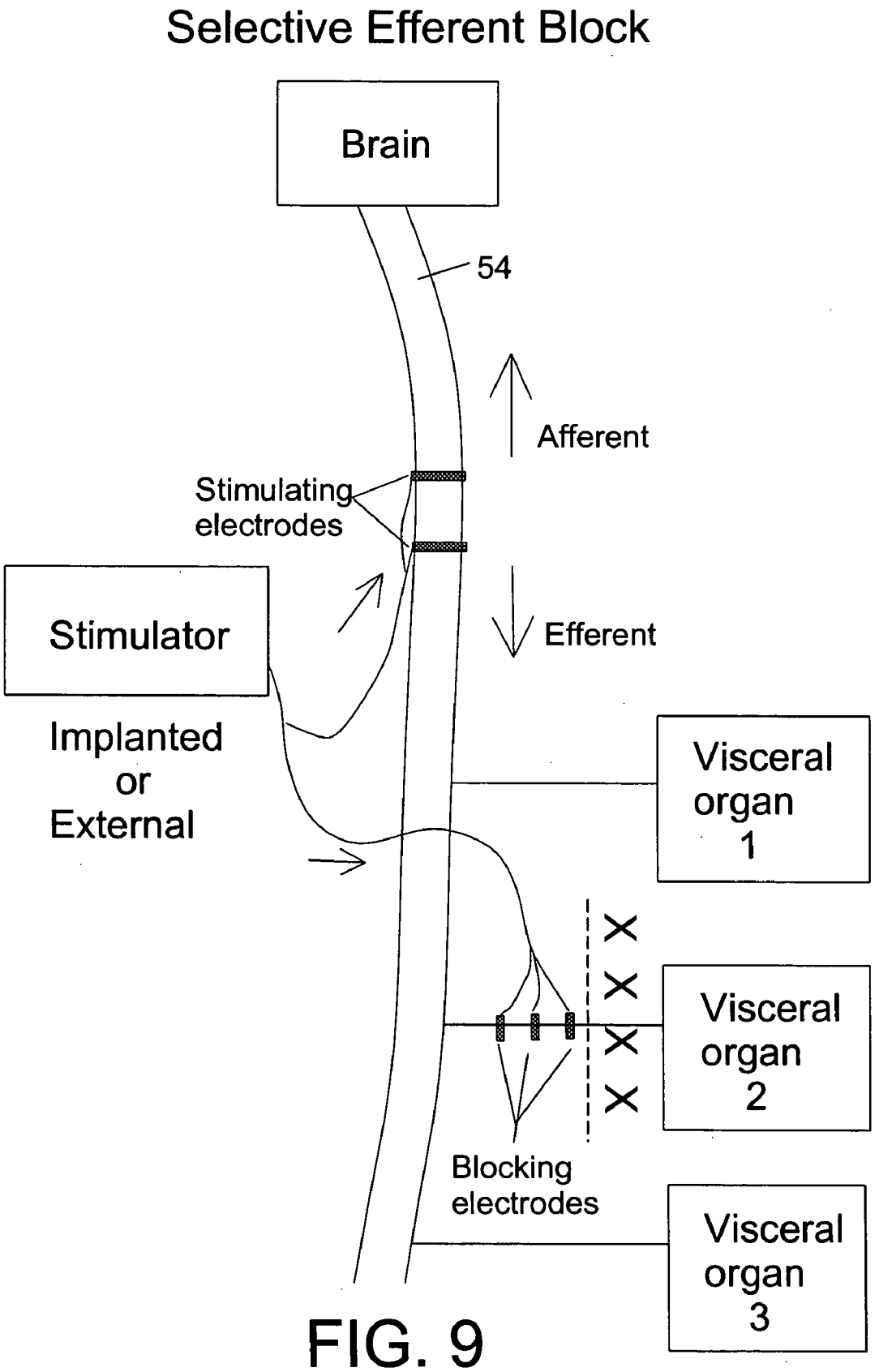

Selective Efferent Block
Brain
54
Afferent
Stimulating electrodes
Stimulator
Efferent
Implanted or External
Visceral organ 1
Visceral organ 2
Blocking electrodes
Visceral organ 3

FIG. 9

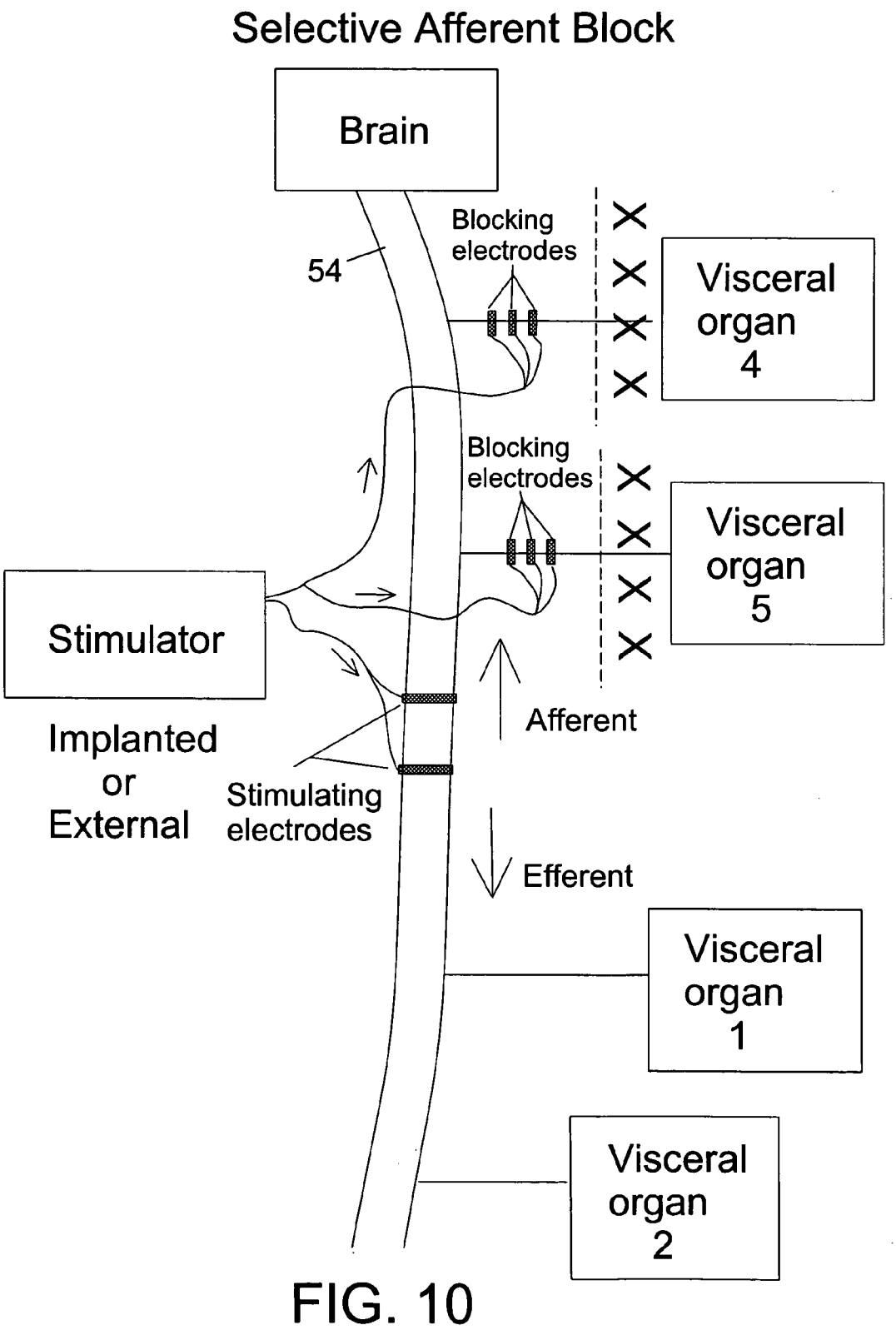

Selective Afferent Block
Brain
54
Blocking electrodes
Visceral organ 4
Blocking electrodes
Visceral organ 5
Stimulator
Implanted or External
Stimulating electrodes
Afferent
Efferent
Visceral organ 1
Visceral organ 2

FIG. 10

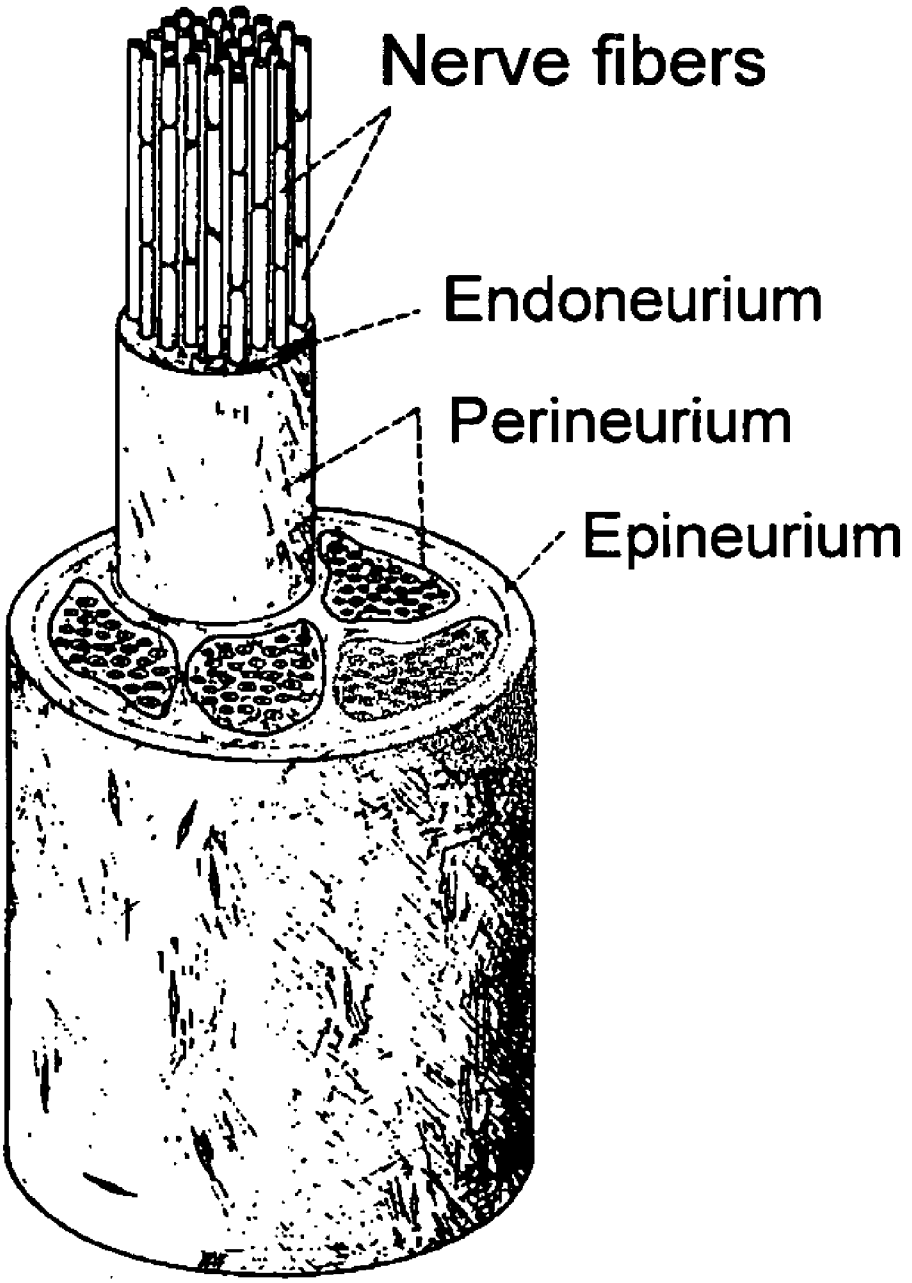


FIG. 11

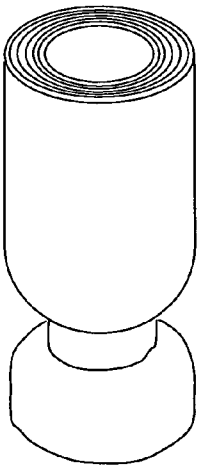
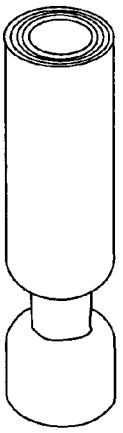
Axons from skin	A α	Aβ	Aδ	C
Axons from muscles	Group I	II	III	IV
				
Diameter (μm)	13- 20	6-12	1-5	0.2-1.5
Speed (m/sec)	80-120	35-75	5-30	0.5-2
Sensory receptors	Proprio-ceptors of skeletal muscle	Mechano-receptors of skin	Pain tempe-rature	Tempe-rature, pain, itch

FIG. 12

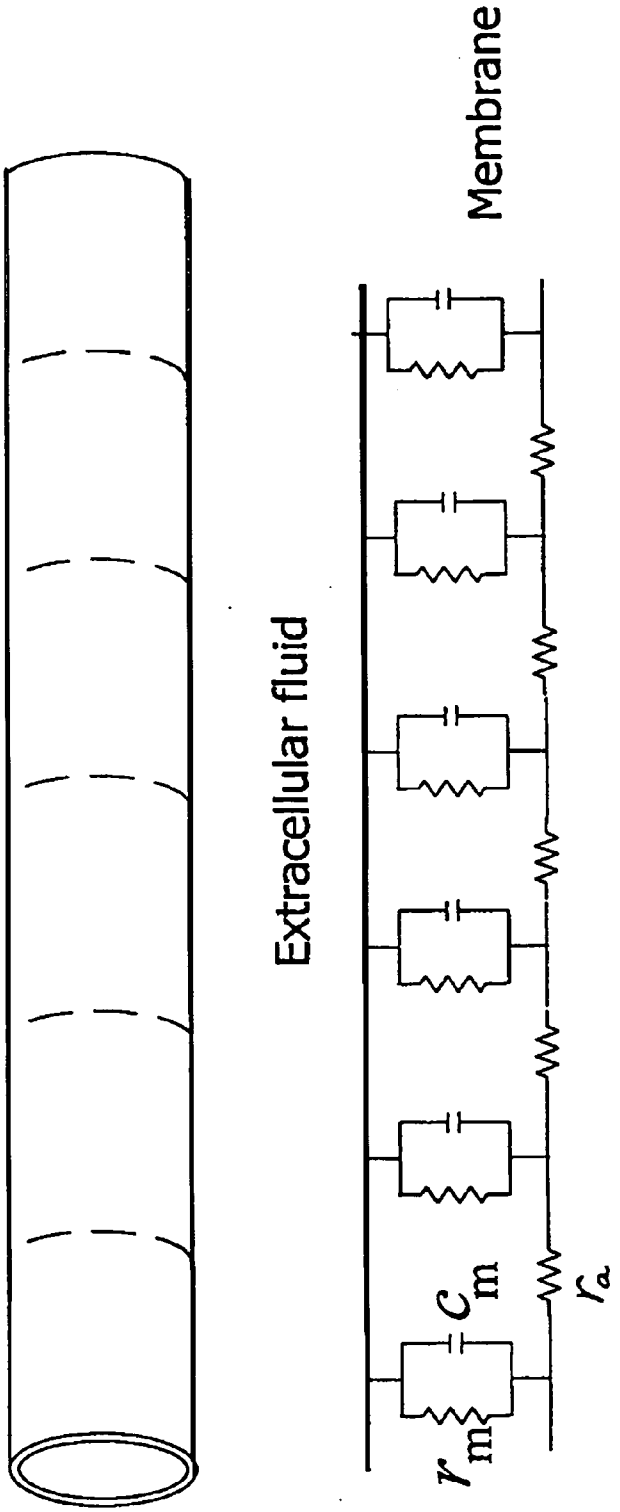


FIG. 13

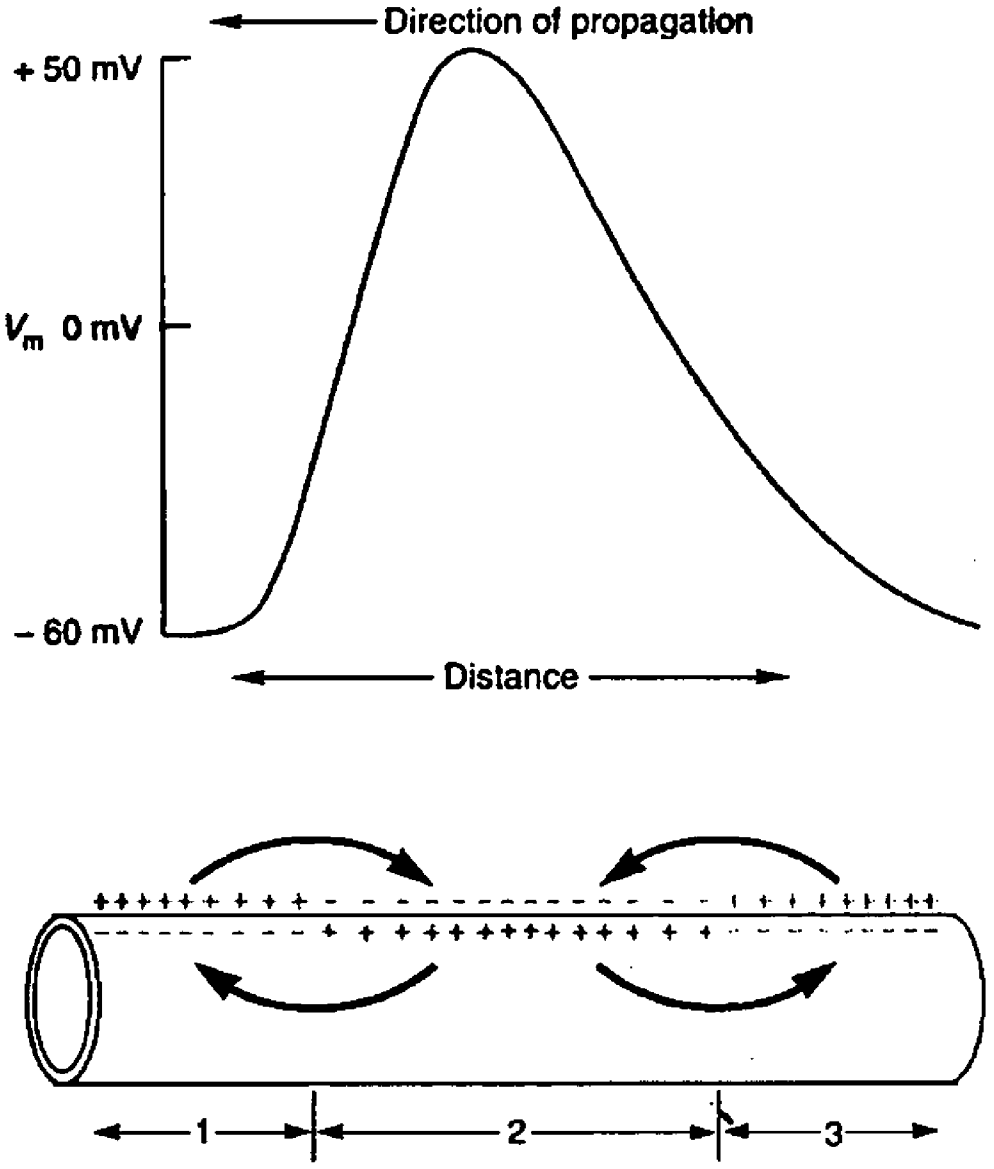


FIG. 14

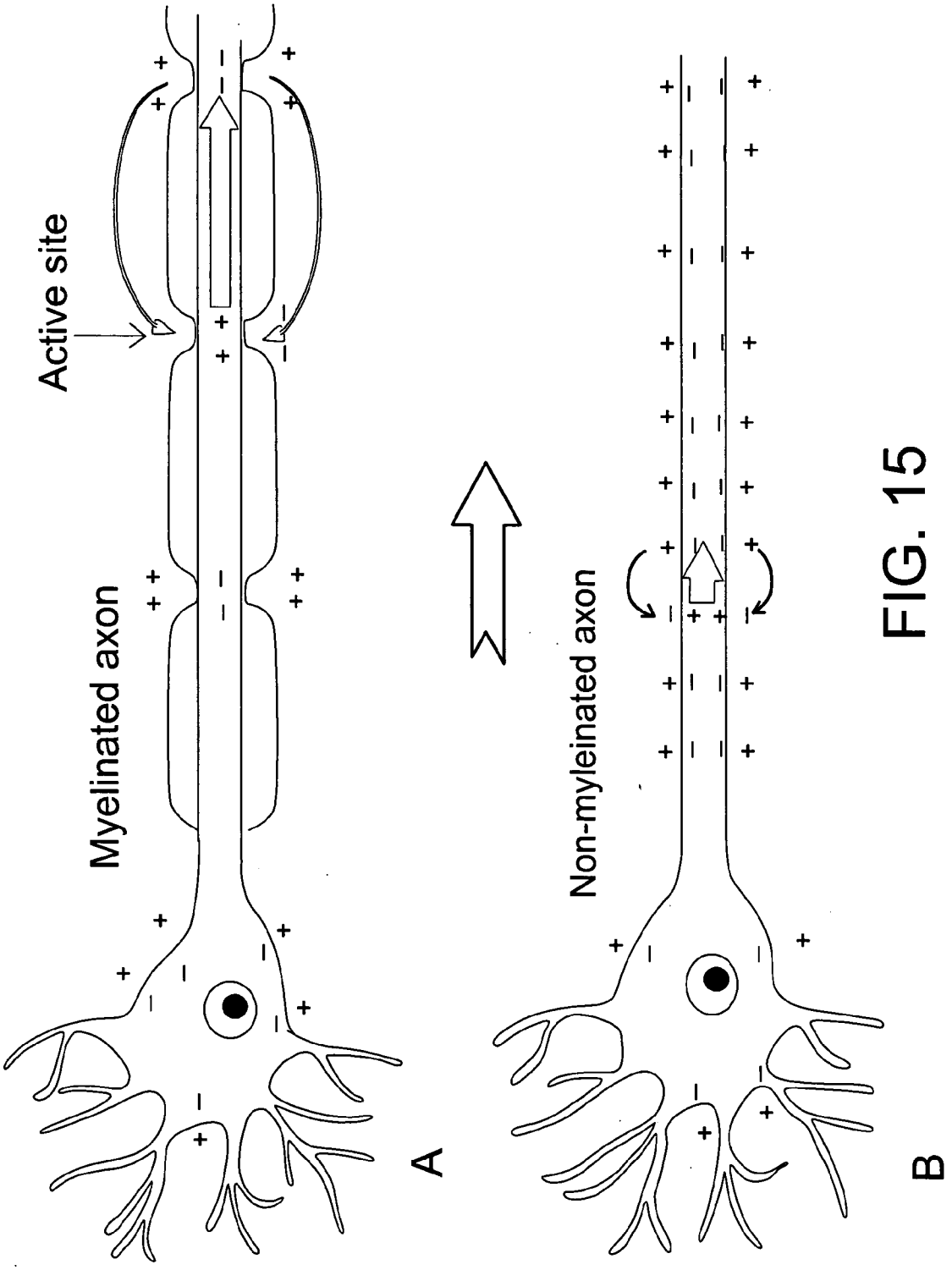


FIG. 15

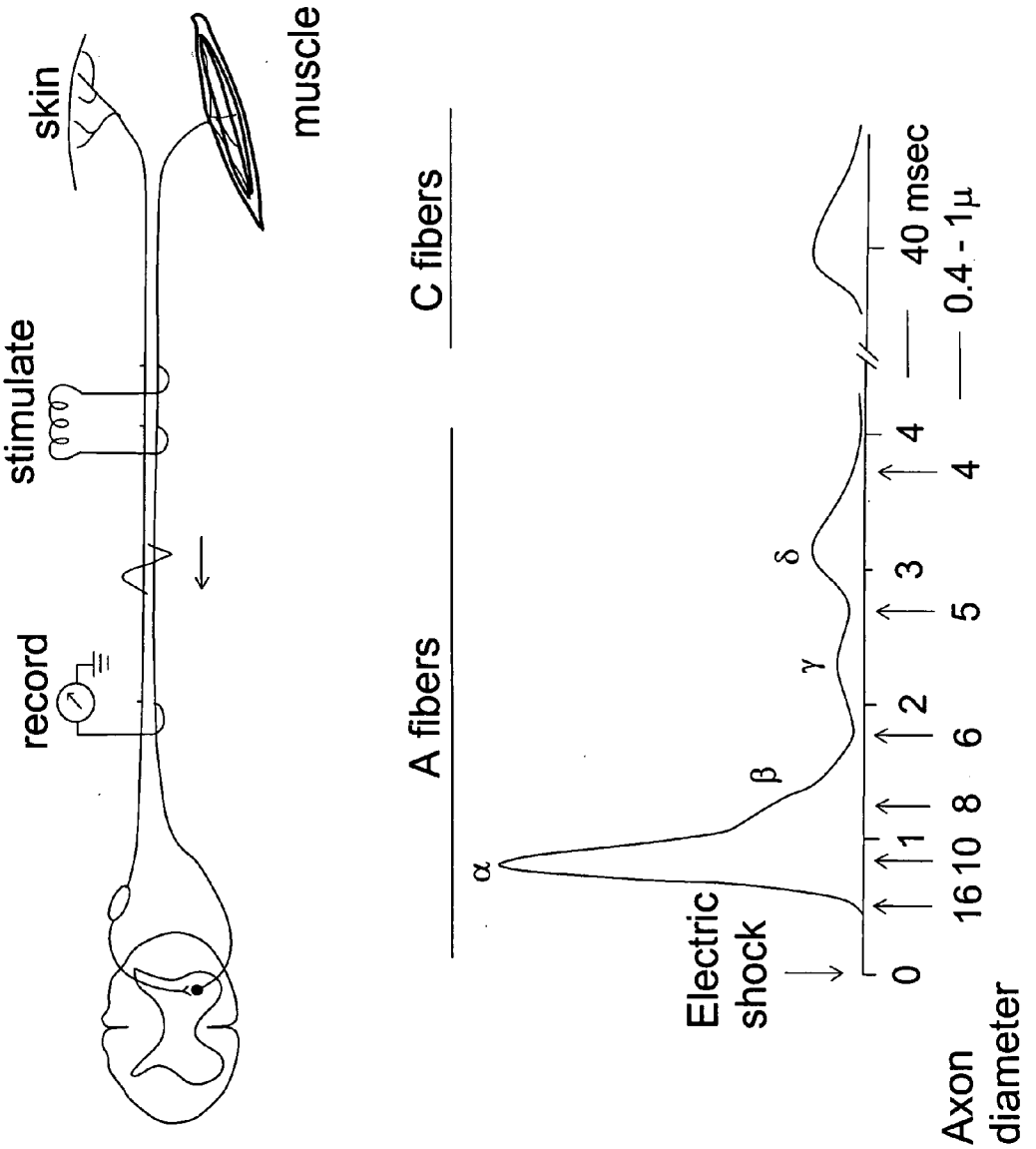

skin
muscle
stimulate
record
A fibers
C fibers
α
β
γ
δ
Electric shock
0
16
10
8
6
2
1
5
3
4
4
40 msec
0.4 - 1μ
Axon diameter

FIG. 16

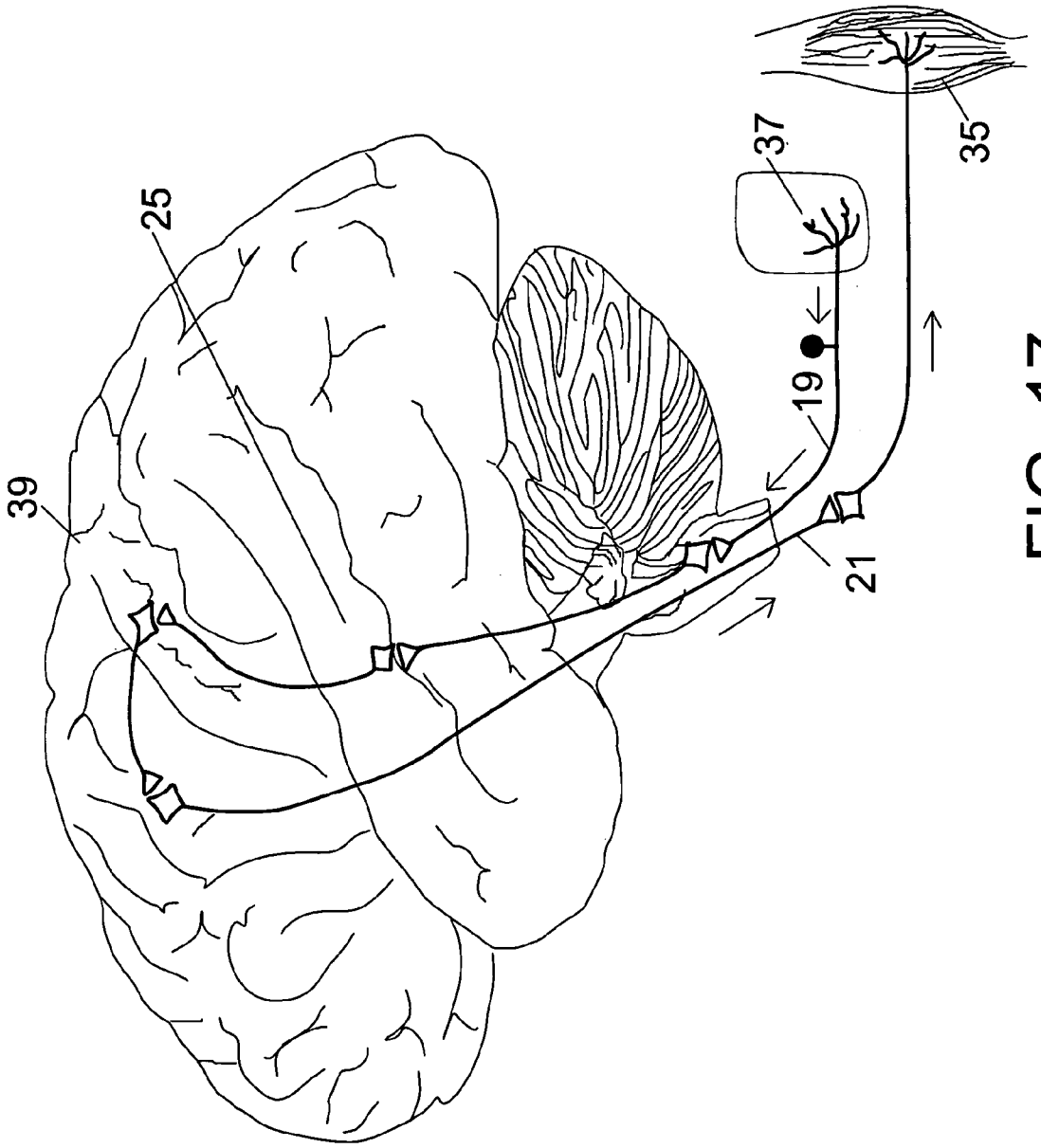


FIG. 17

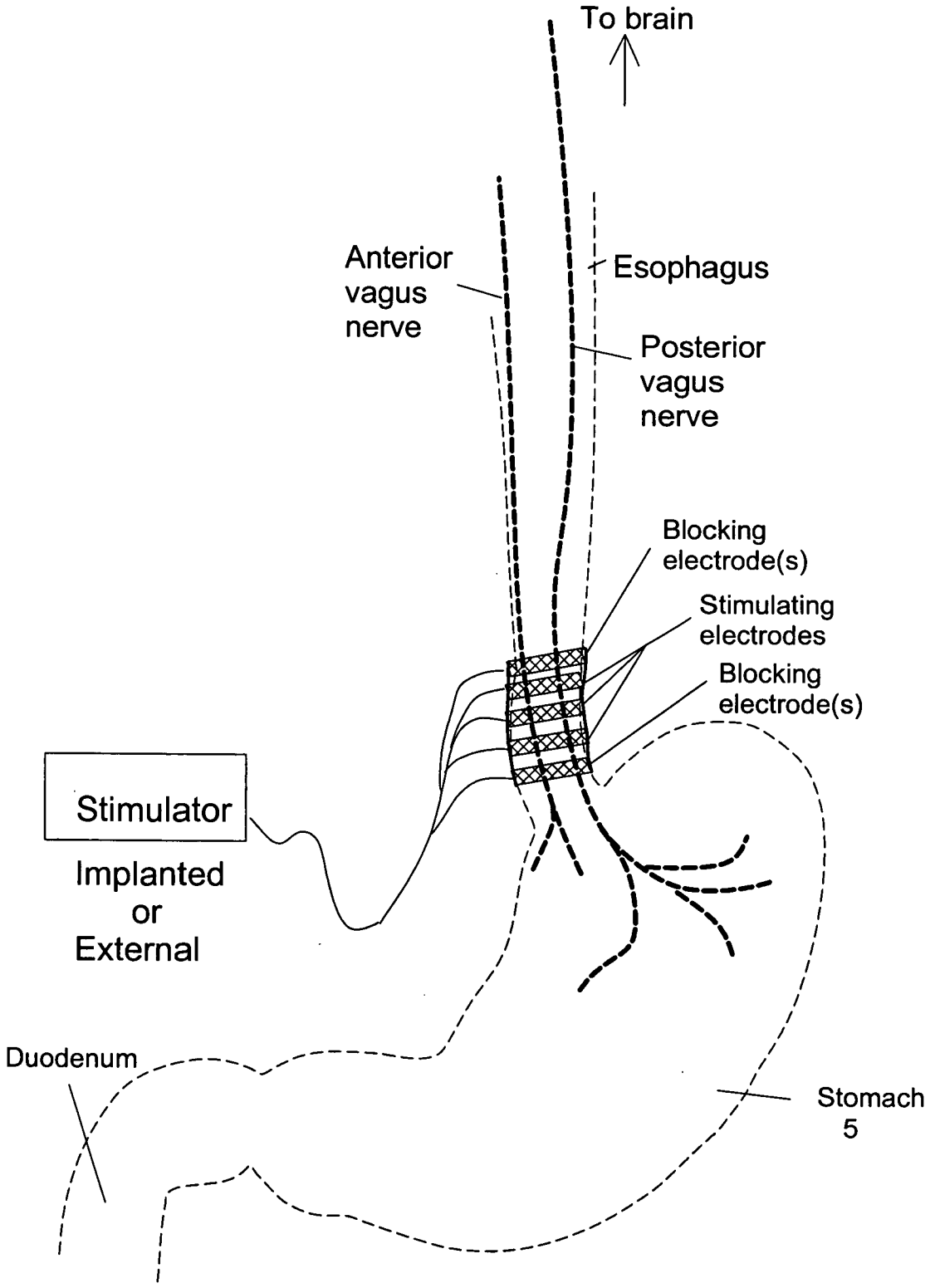

To brain
Anterior vagus nerve
Esophagus
Posterior vagus nerve
Blocking electrode(s)
Stimulating electrodes
Blocking electrode(s)
Stimulator
Implanted or External
Duodenum
Stomach 5

FIG. 18

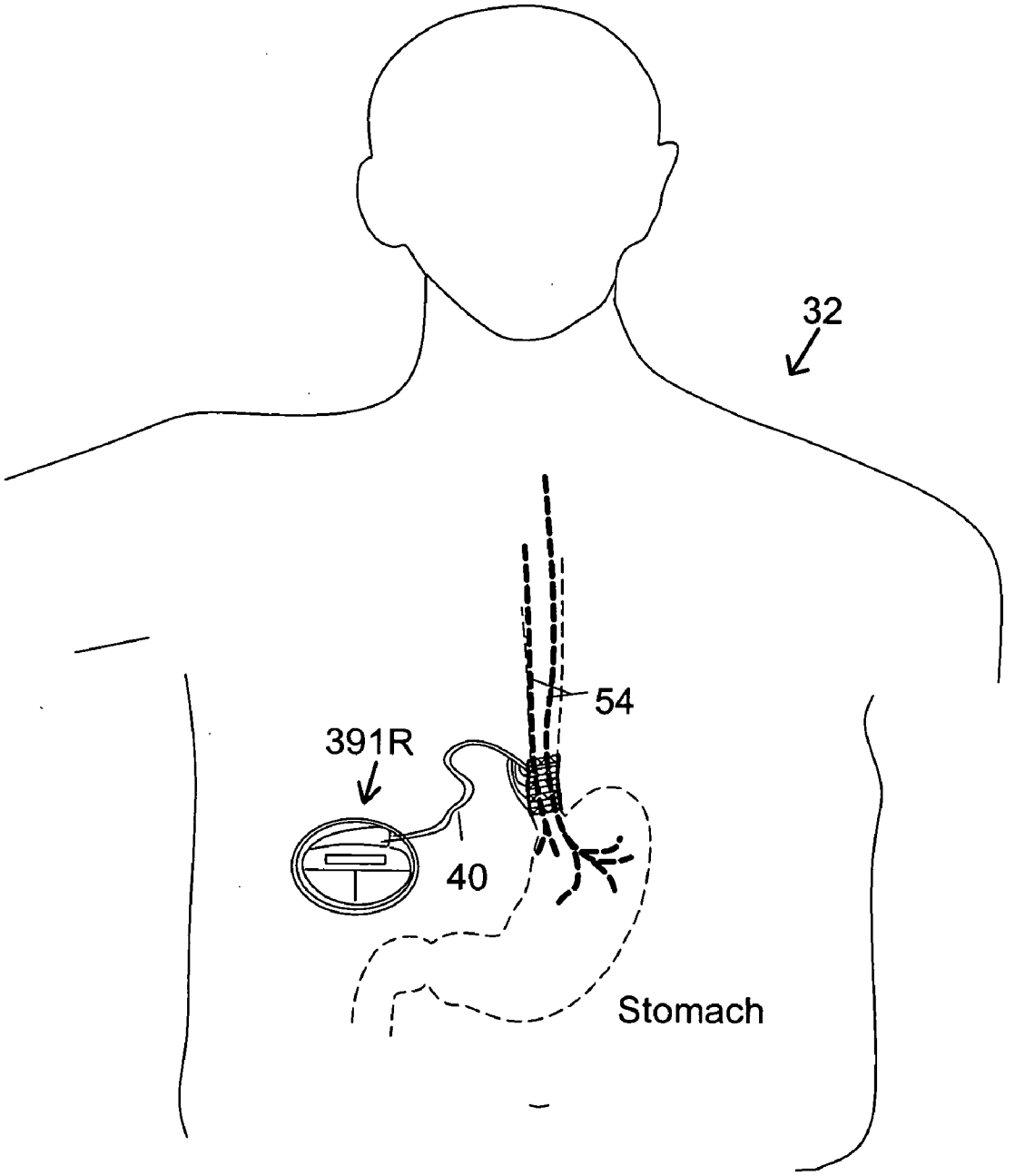


FIG. 19 A

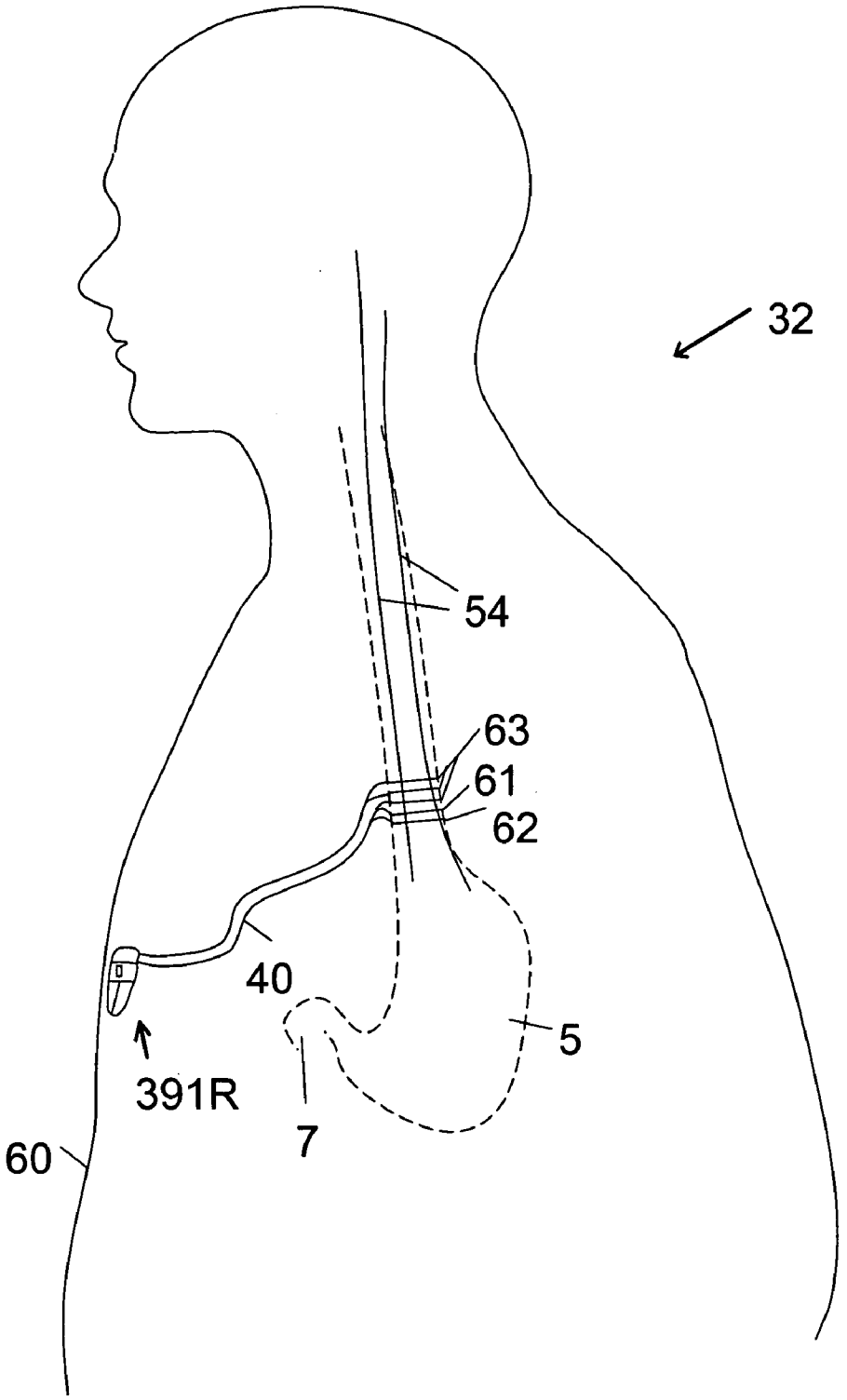


FIG. 19 B

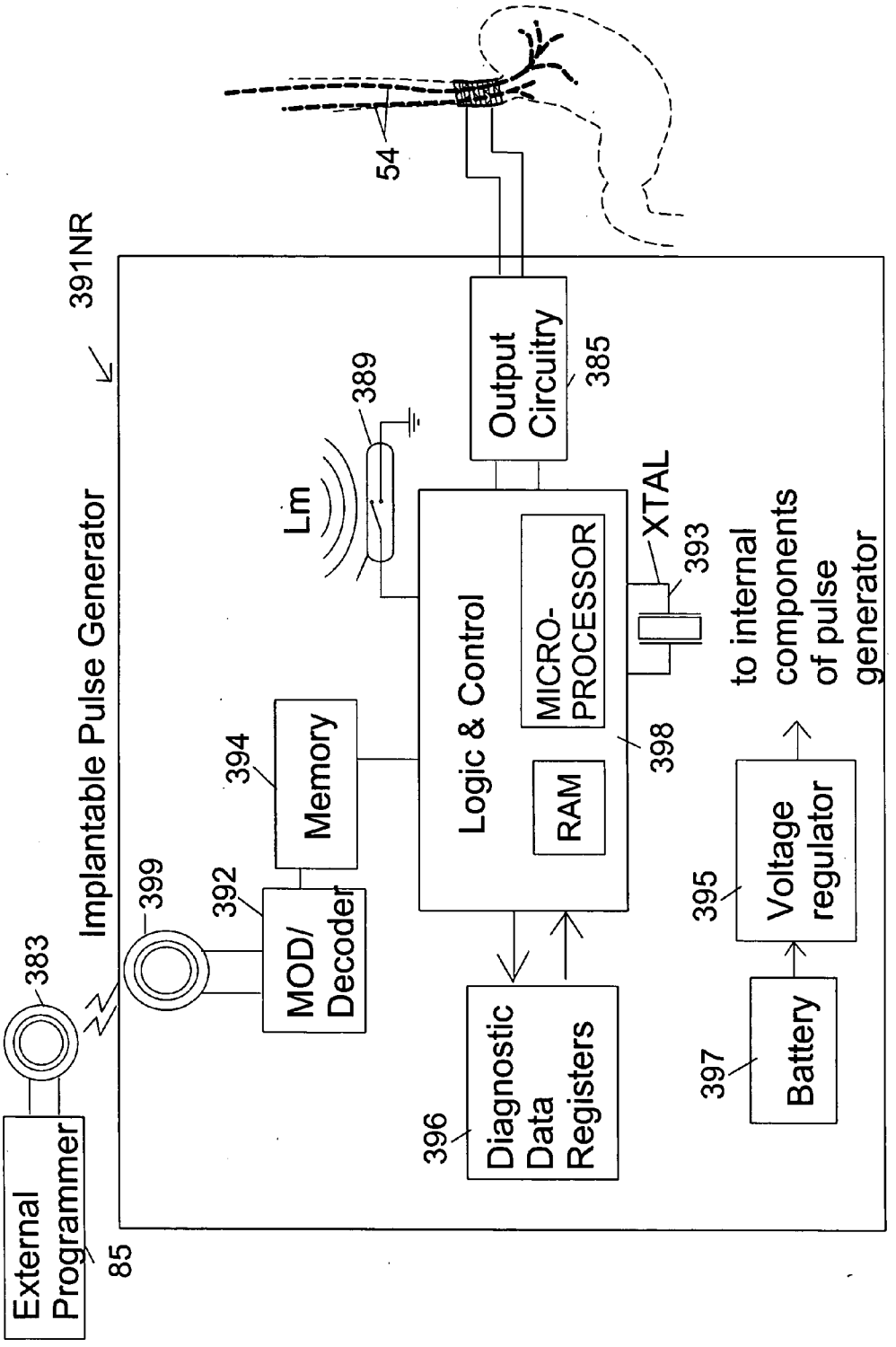

54
391NR
Implantable Pulse Generator
Output Circuitry
385
389
Lm
XTAL
393
MICRO-PROCESSOR
Logic & Control
RAM
398
394
Memory
392
MOD/ Decoder
399
383
External Programmer
85
396
Diagnostic Data Registers
395
Voltage regulator
397
Battery
to internal components of pulse generator

FIG. 20

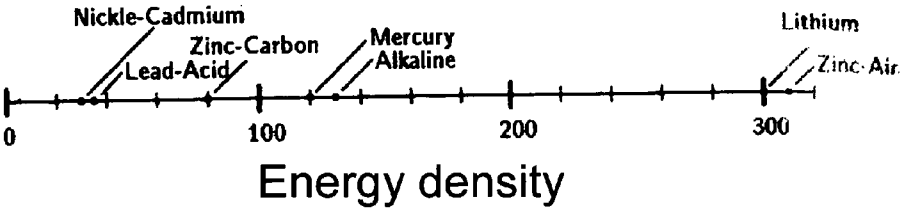


FIG. 21A

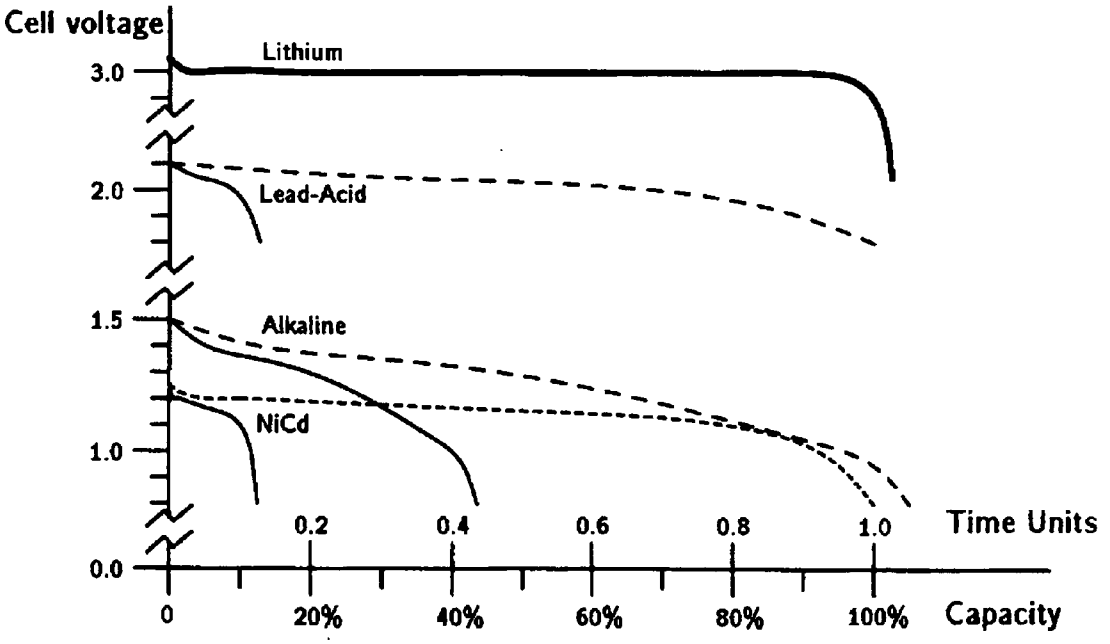


FIG. 21B

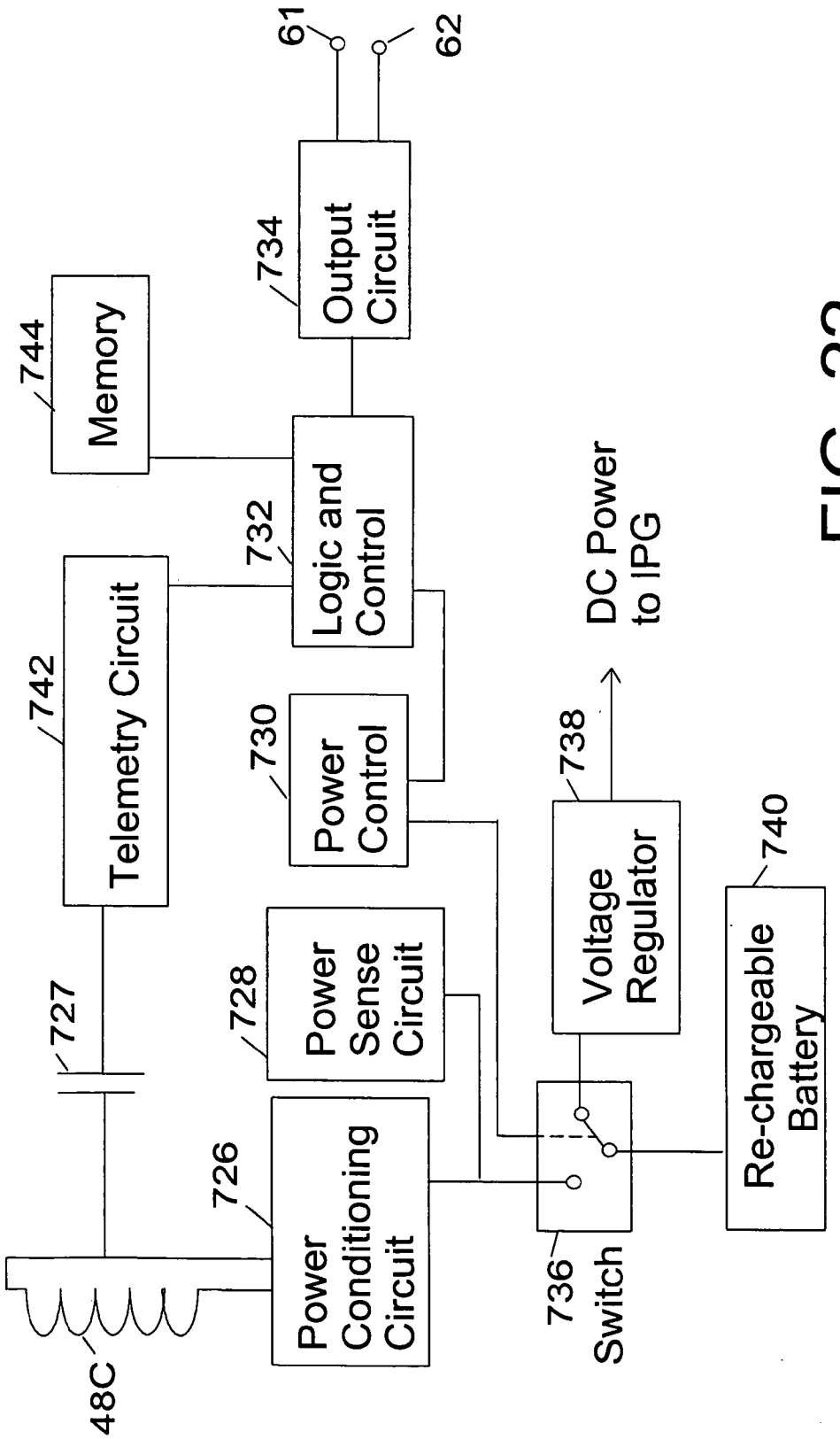

61
62
734
Output Circuit
744
Memory
732
Logic and Control
742
Telemetry Circuit
730
Power Control
738
Voltage Regulator
DC Power to IPG
740
Re-chargeable Battery
727
728
Power Sense Circuit
726
Power Conditioning Circuit
736
Switch
48C

FIG. 22

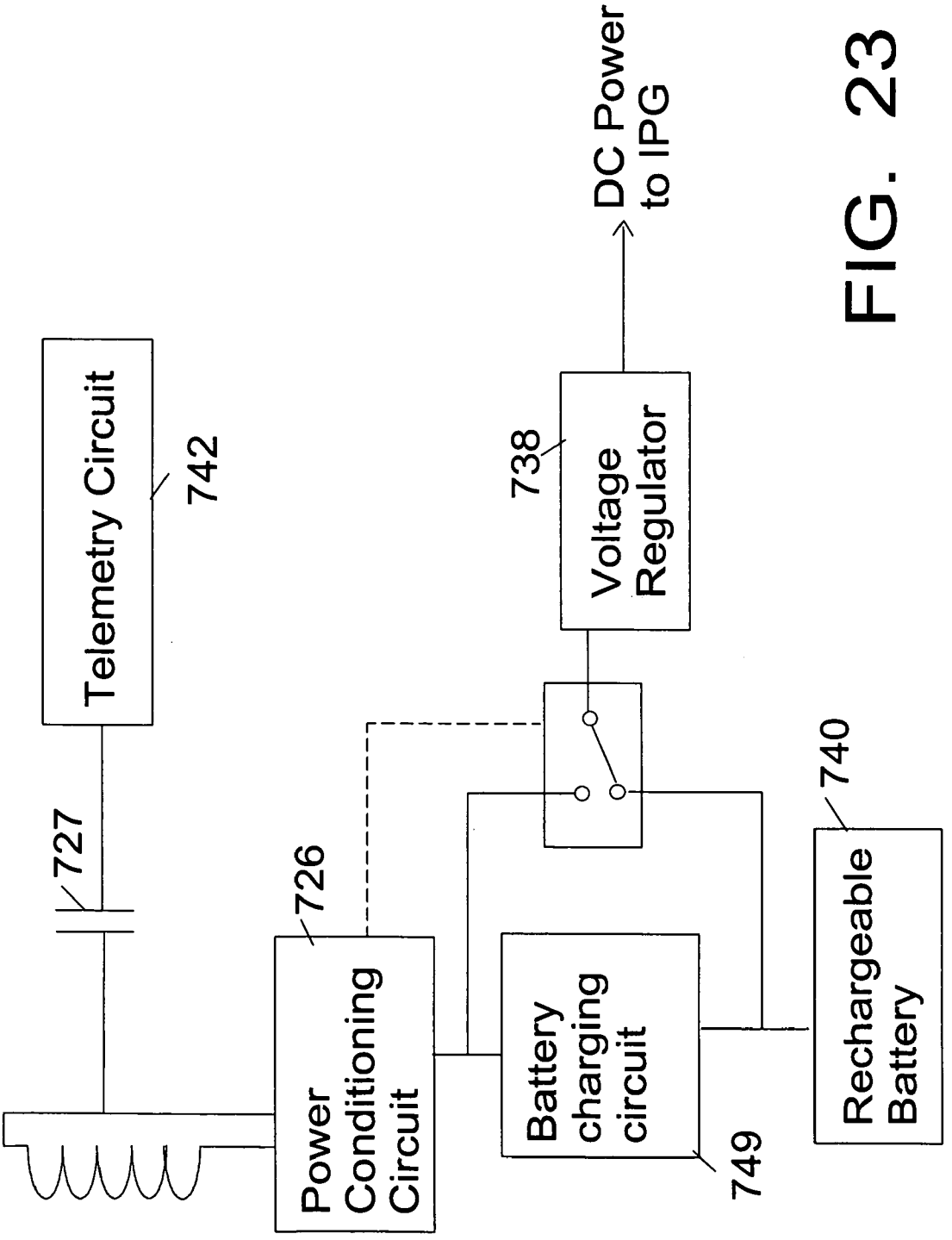

DC Power to IPG
Telemetry Circuit
742
738
Voltage Regulator
727
726
740
Power Conditioning Circuit
Battery charging circuit
749
Rechargeable Battery

FIG. 23

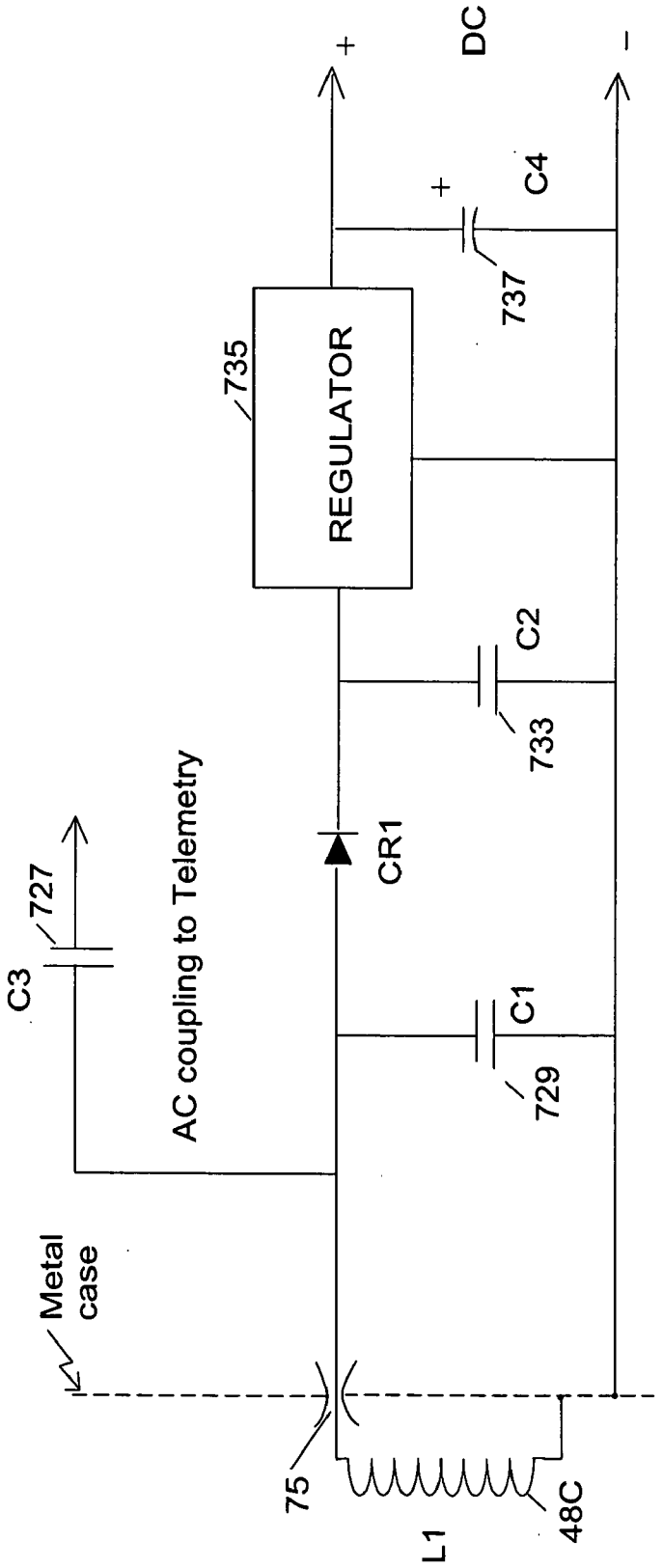

+
DC
-
+
C4
737
735
REGULATOR
C2
733
CR1
727
C3
AC coupling to Telemetry
C1
729
Metal case
75
L1
48C

FIG. 24

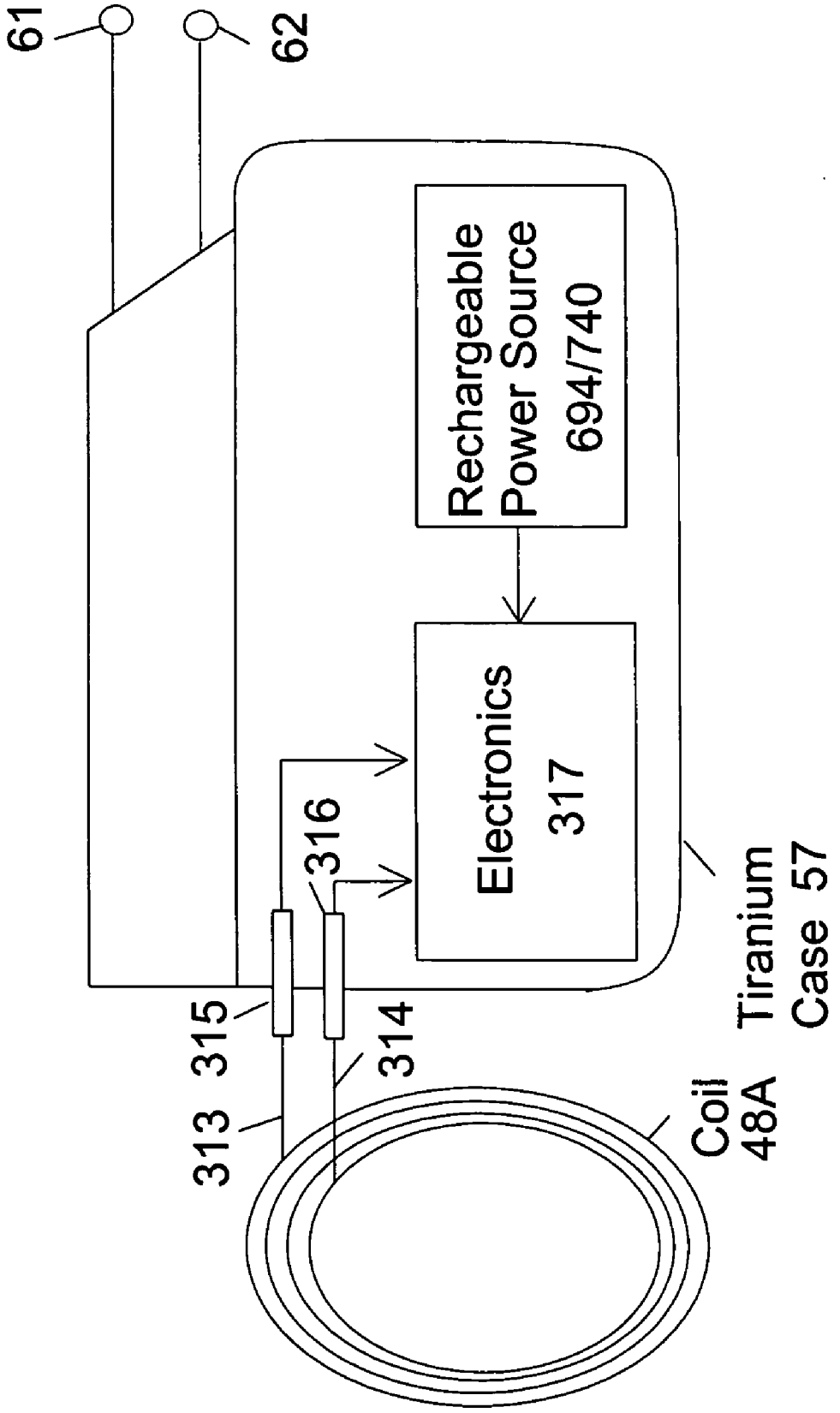

61
62
Rechargeable Power Source 694/740
Electronics 317
316
315
314
313
Coil 48A
Tiranium Case 57

FIG. 25

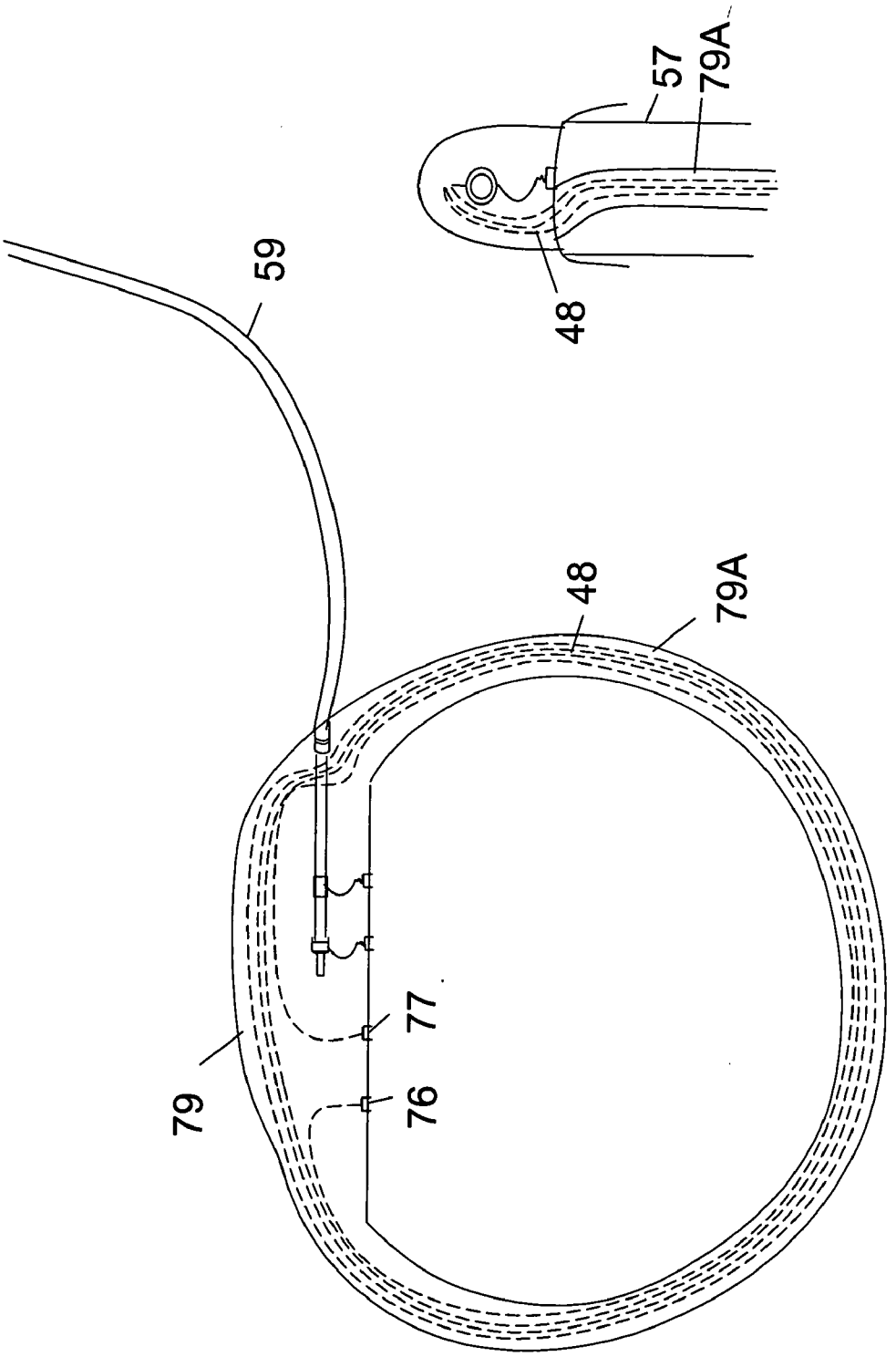


FIG. 26A

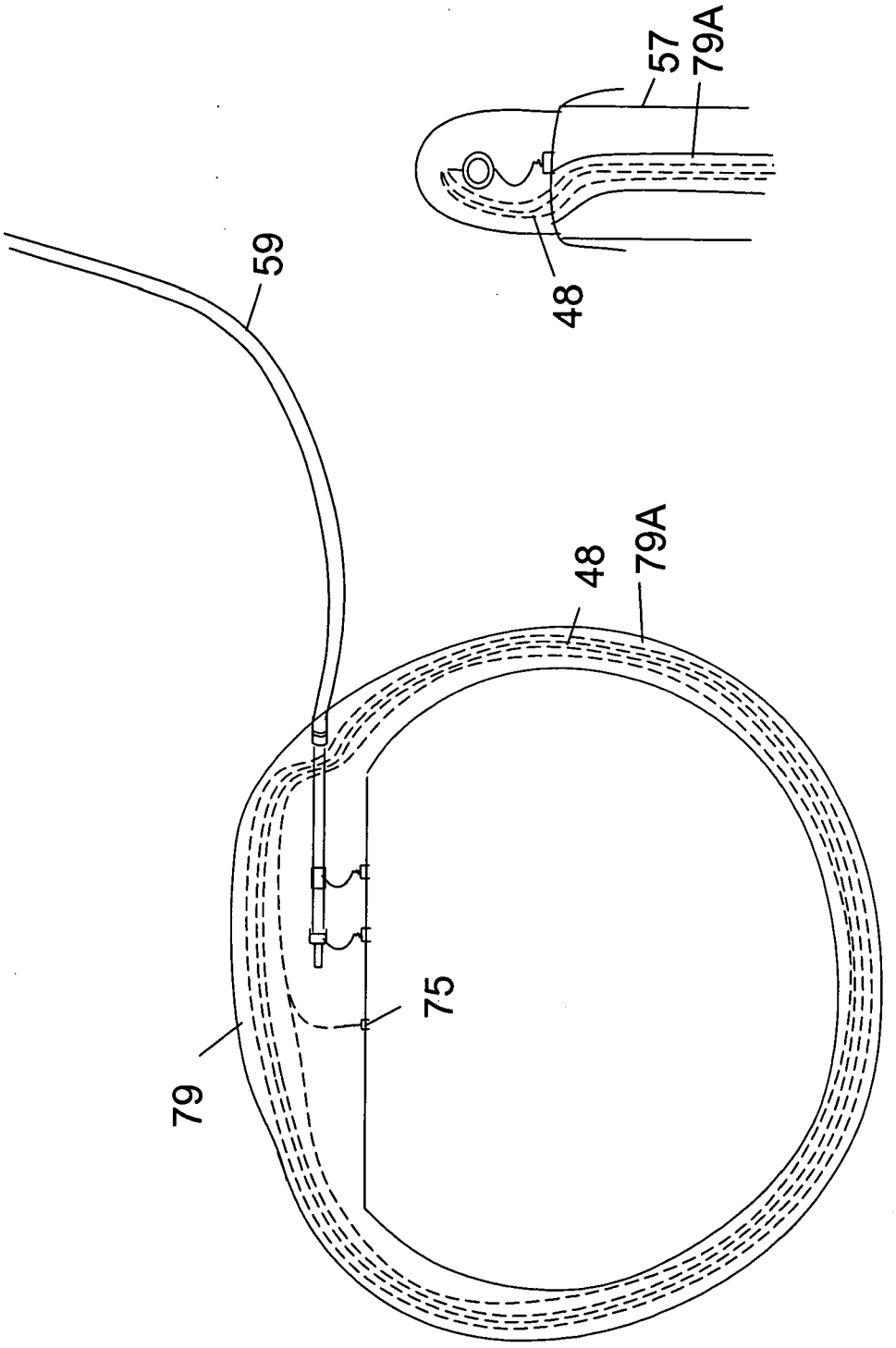


FIG. 26B

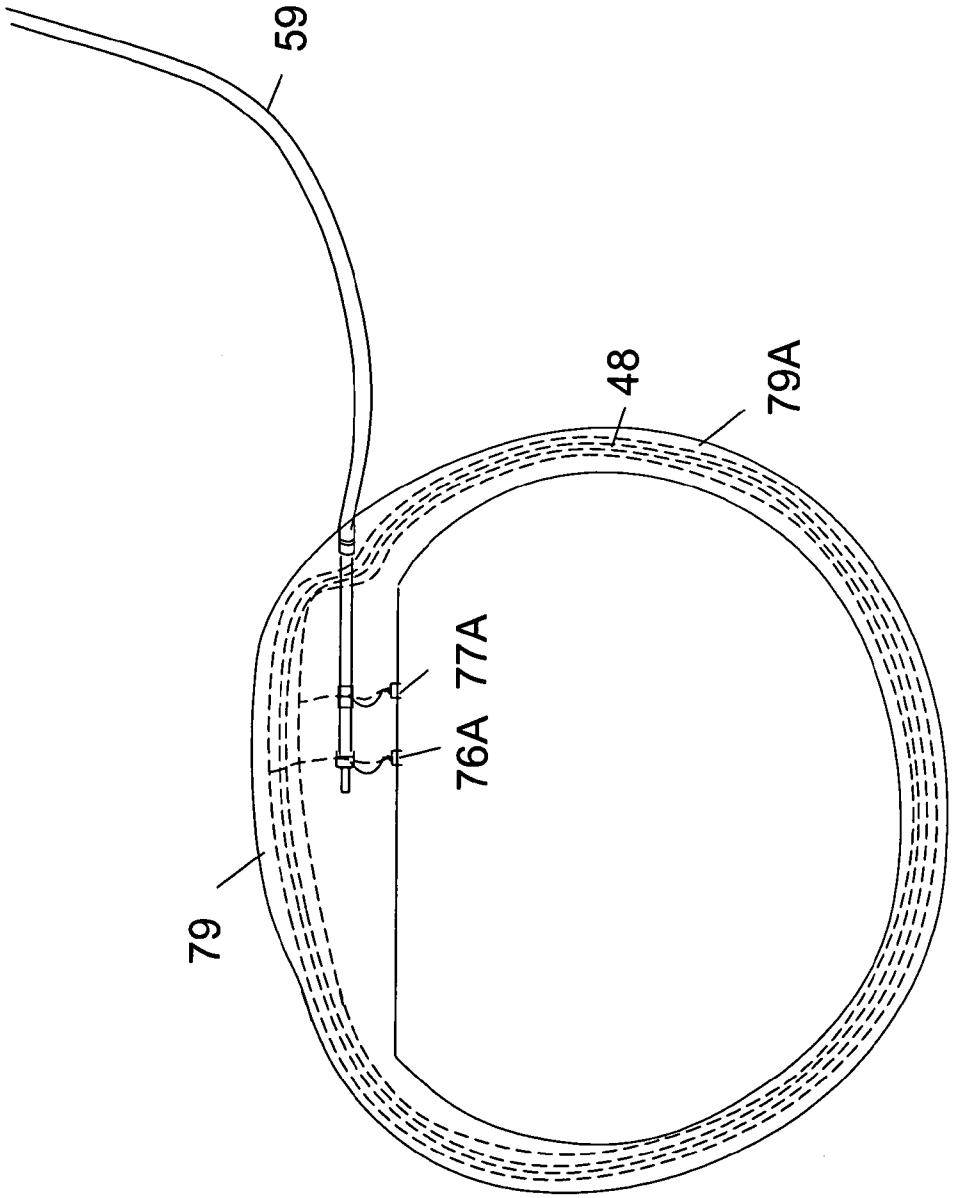


FIG. 26C

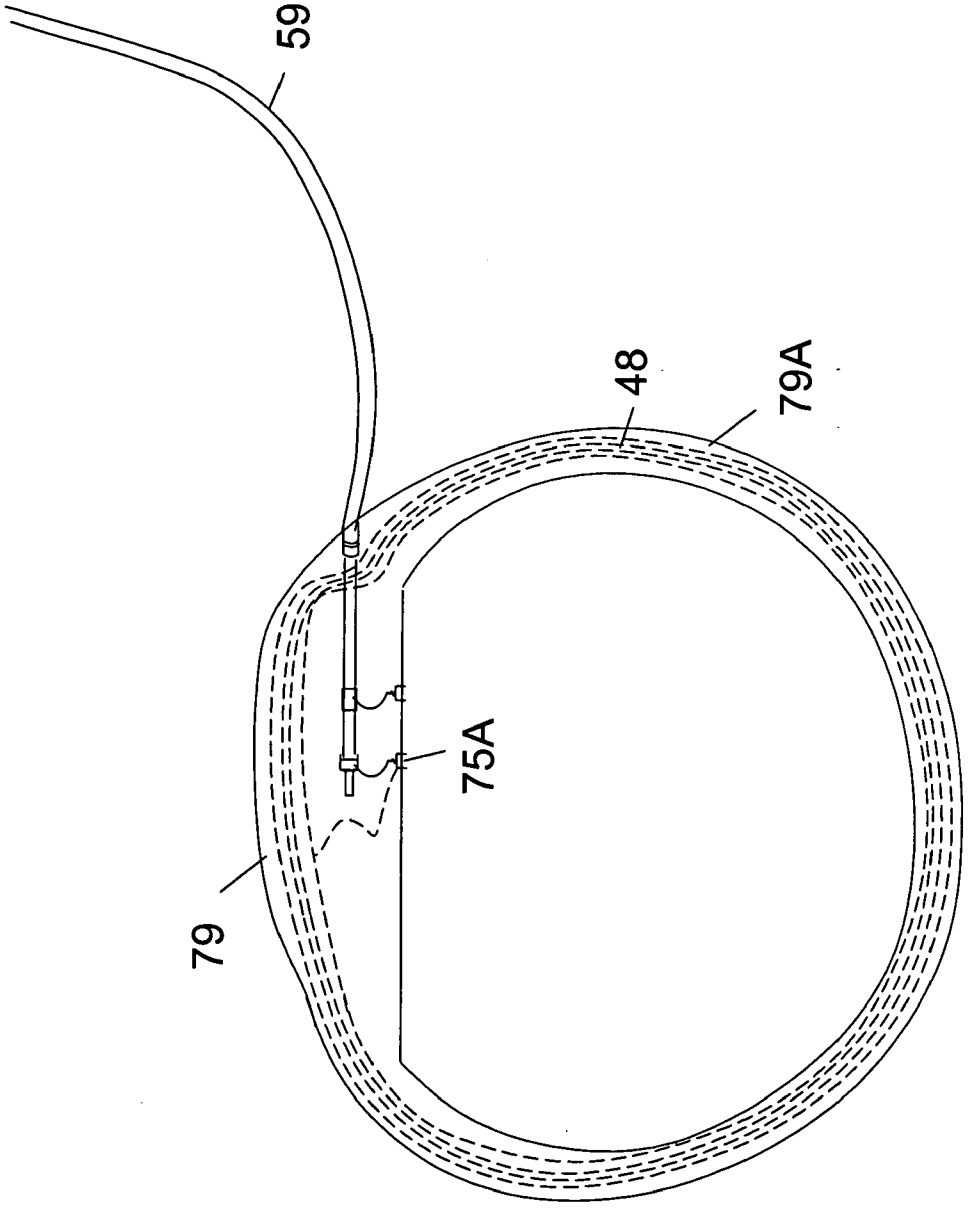


FIG. 26D

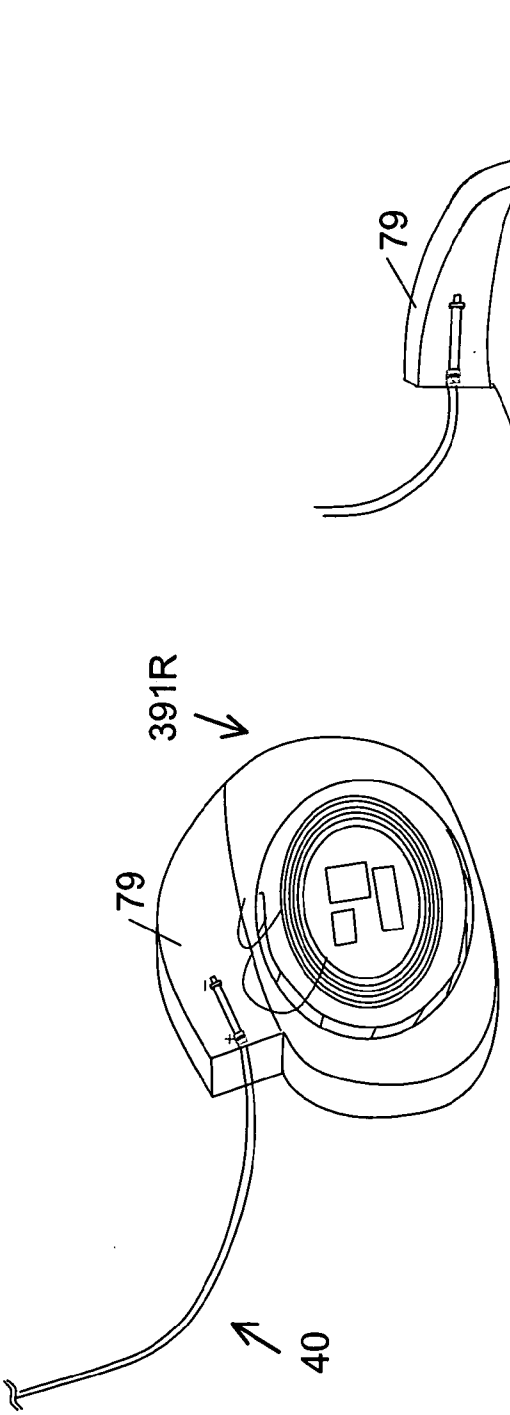


FIG. 27A

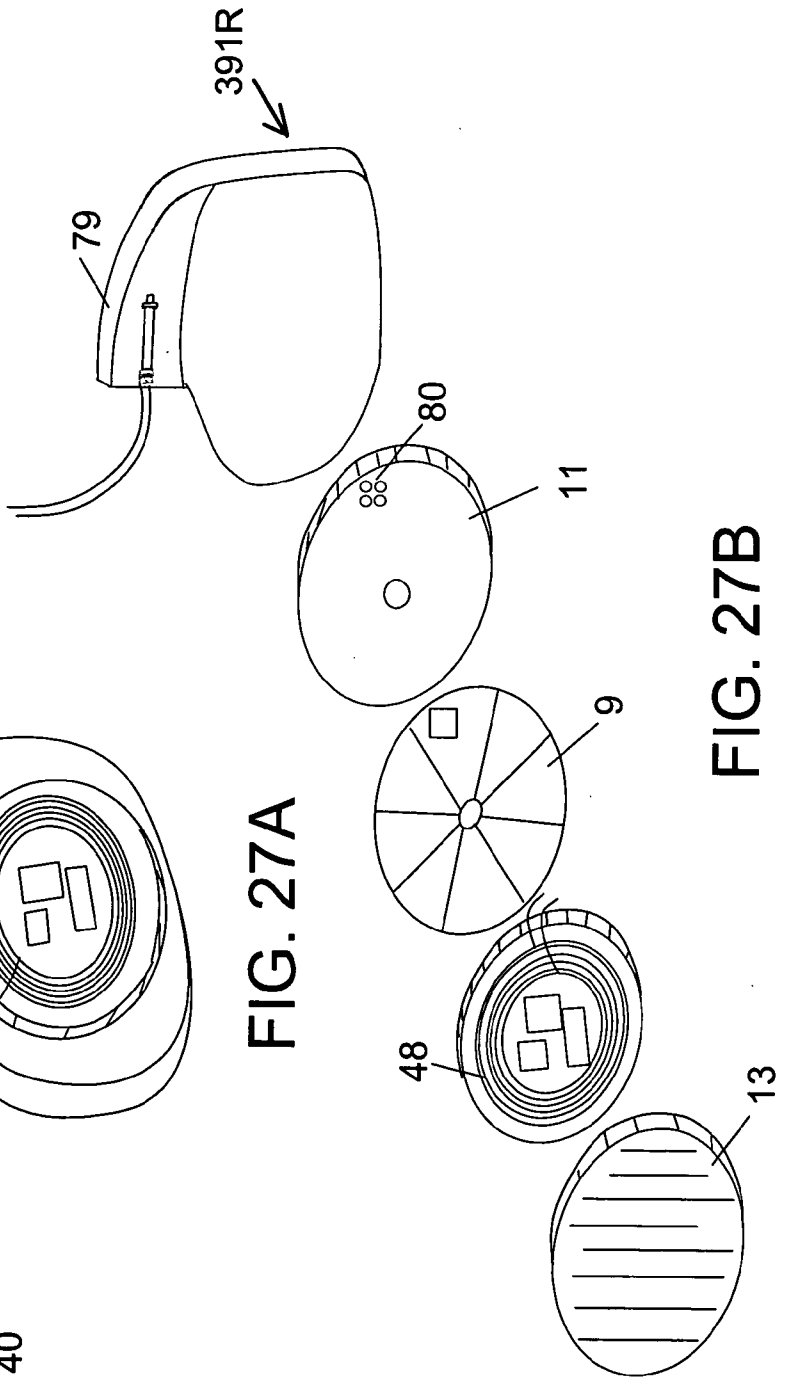


FIG. 27B

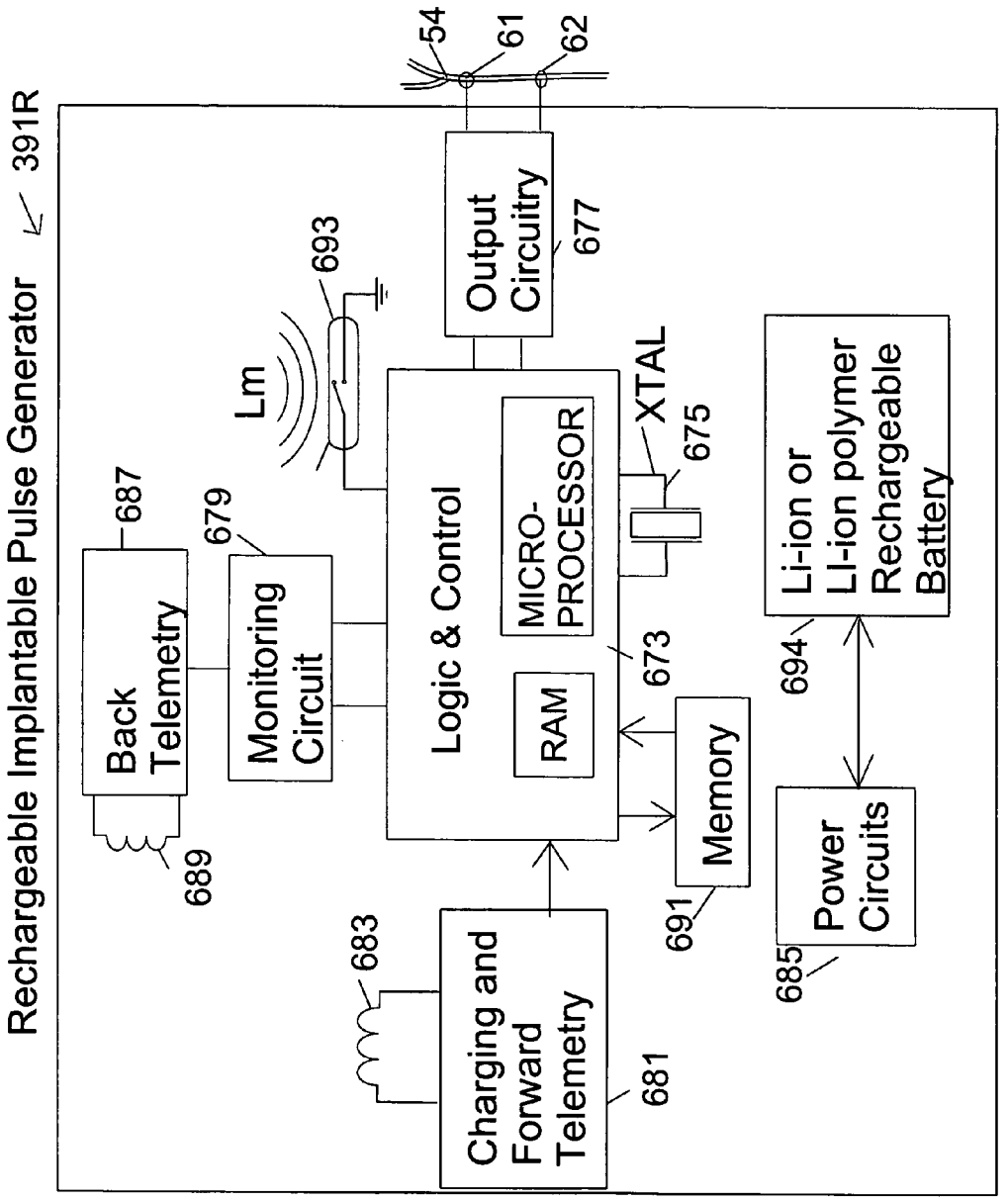

Rechargeable Implantable Pulse Generator
391R
54
61
62
Output Circuitry
677
693
Lm
687
679
Back Telemetry
Monitoring Circuit
Logic & Control
MICRO-PROCESSOR
XTAL
675
RAM
673
Li-ion or LI-ion polymer Rechargeable Battery
694
Memory
691
Power Circuits
685
689
683
Charging and Forward Telemetry
681

FIG. 28

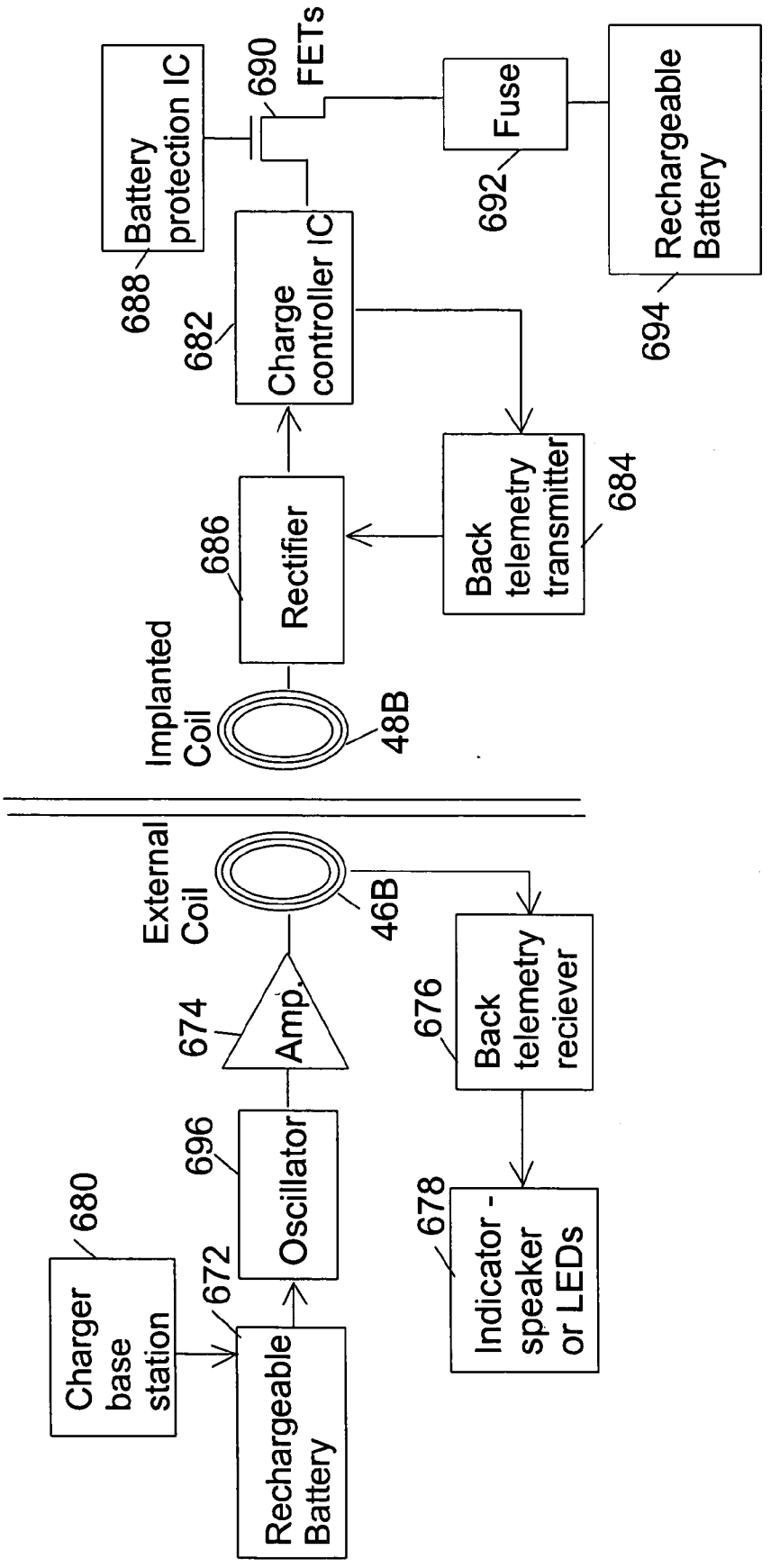

Charger base station
680
672
Rechargeable Battery
Oscillator
696
Amp.
674
External Coil
46B
Implanted Coil
48B
Rectifier
686
Charge controller IC
682
Battery protection IC
688
690
FETs
Fuse
692
Rechargeable Battery
694
Back telemetry transmitter
684
Back telemetry reciever
676
Indicator - speaker or LEDs
678

FIG. 29

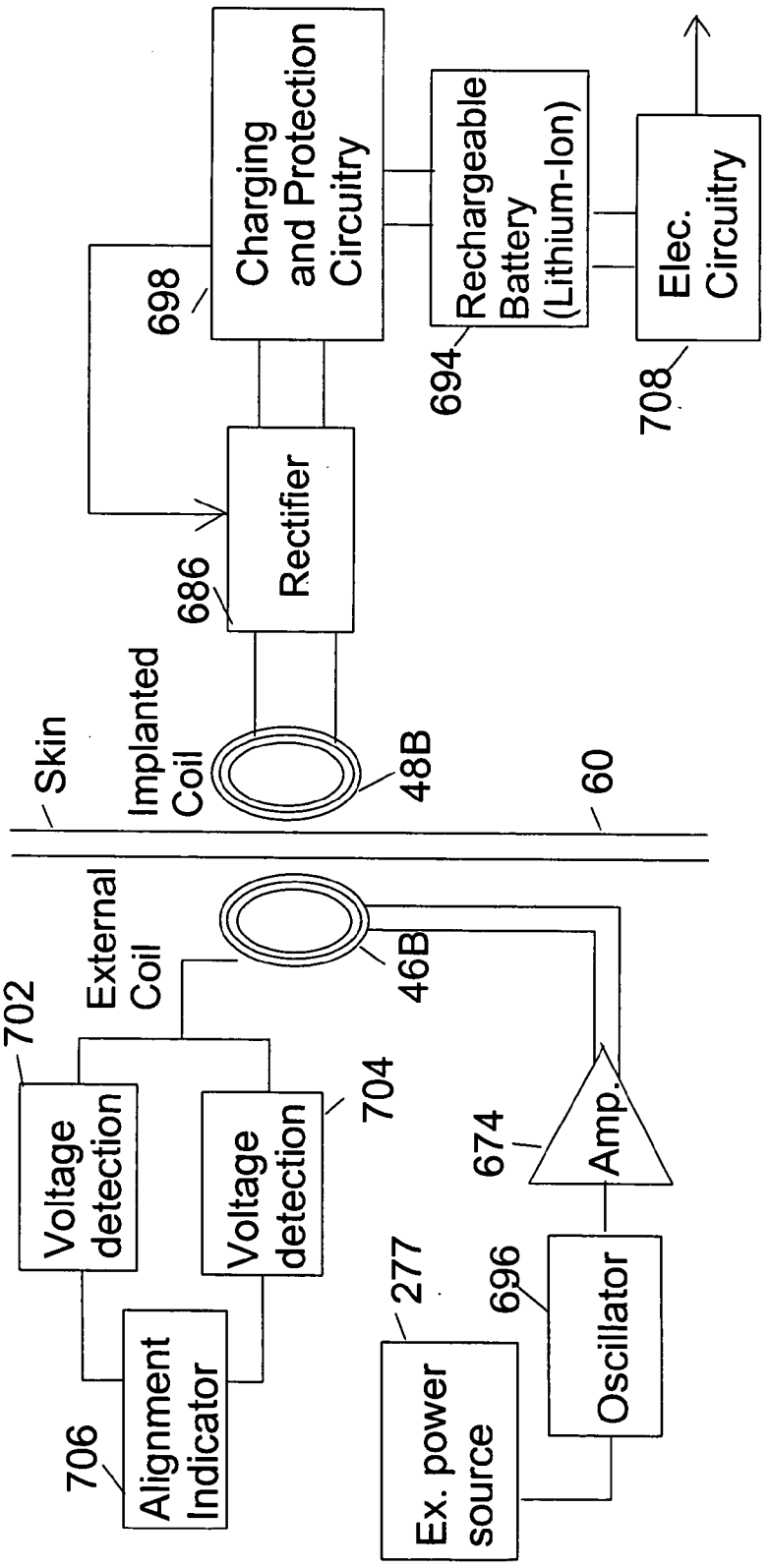

Charging and Protection Circuitry
698
Rechargeable Battery (Lithium-Ion)
694
Elec. Circuitry
708
Rectifier
686
Implanted Coil
48B
Skin
60
External Coil
46B
702
Voltage detection
704
Voltage detection
674
Amp.
277
Ex. power source
696
Oscillator
706
Alignment Indicator

FIG. 30

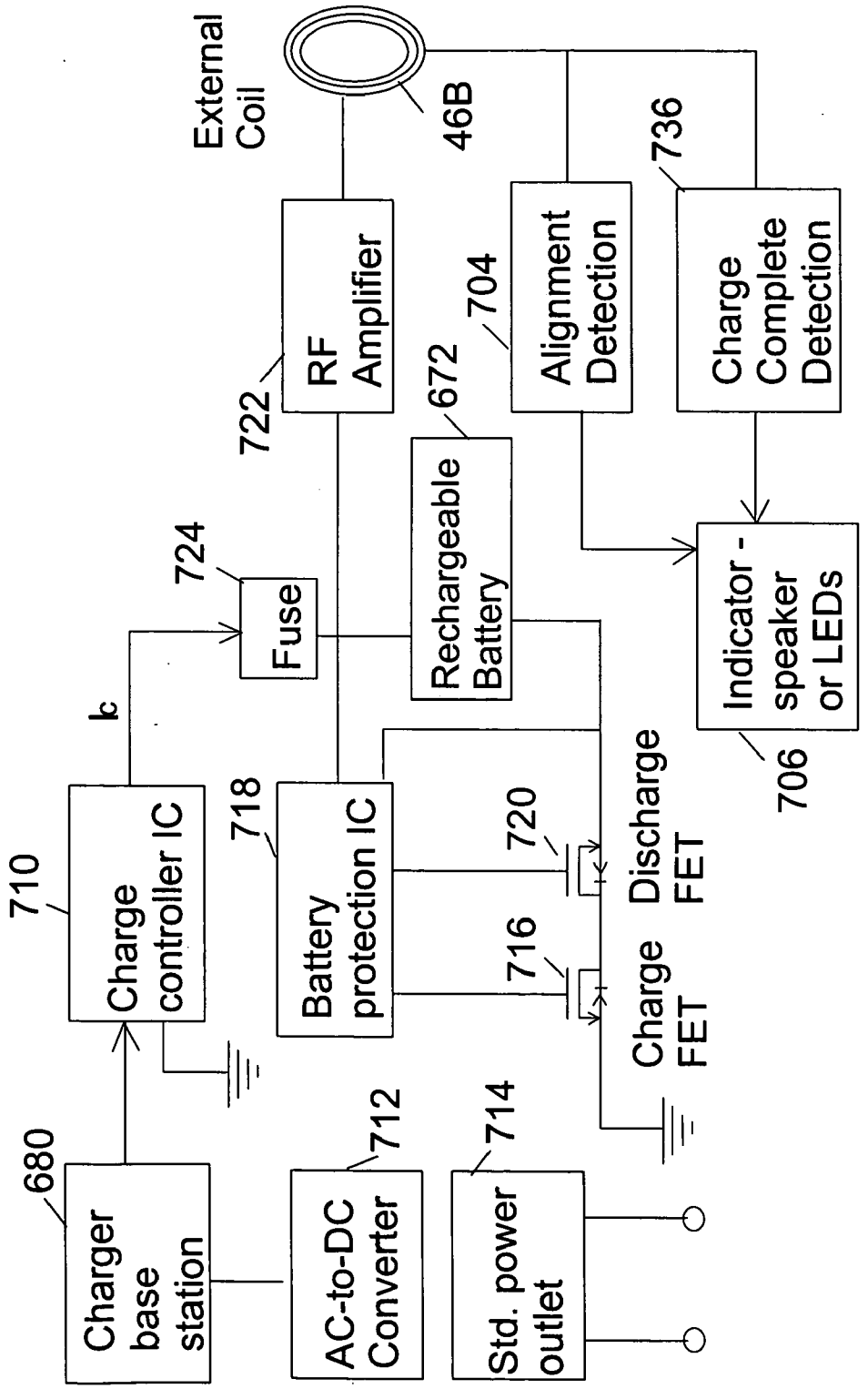

External Coil
46B
736
Charge Complete Detection
704
Alignment Detection
722
RF Amplifier
672
Rechargeable Battery
724
Fuse
Indicator - speaker or LEDs
706
k
718
Battery protection IC
720
Discharge FET
716
Charge FET
710
Charge controller IC
680
Charger base station
712
AC-to-DC Converter
714
Std. power outlet

FIG. 31

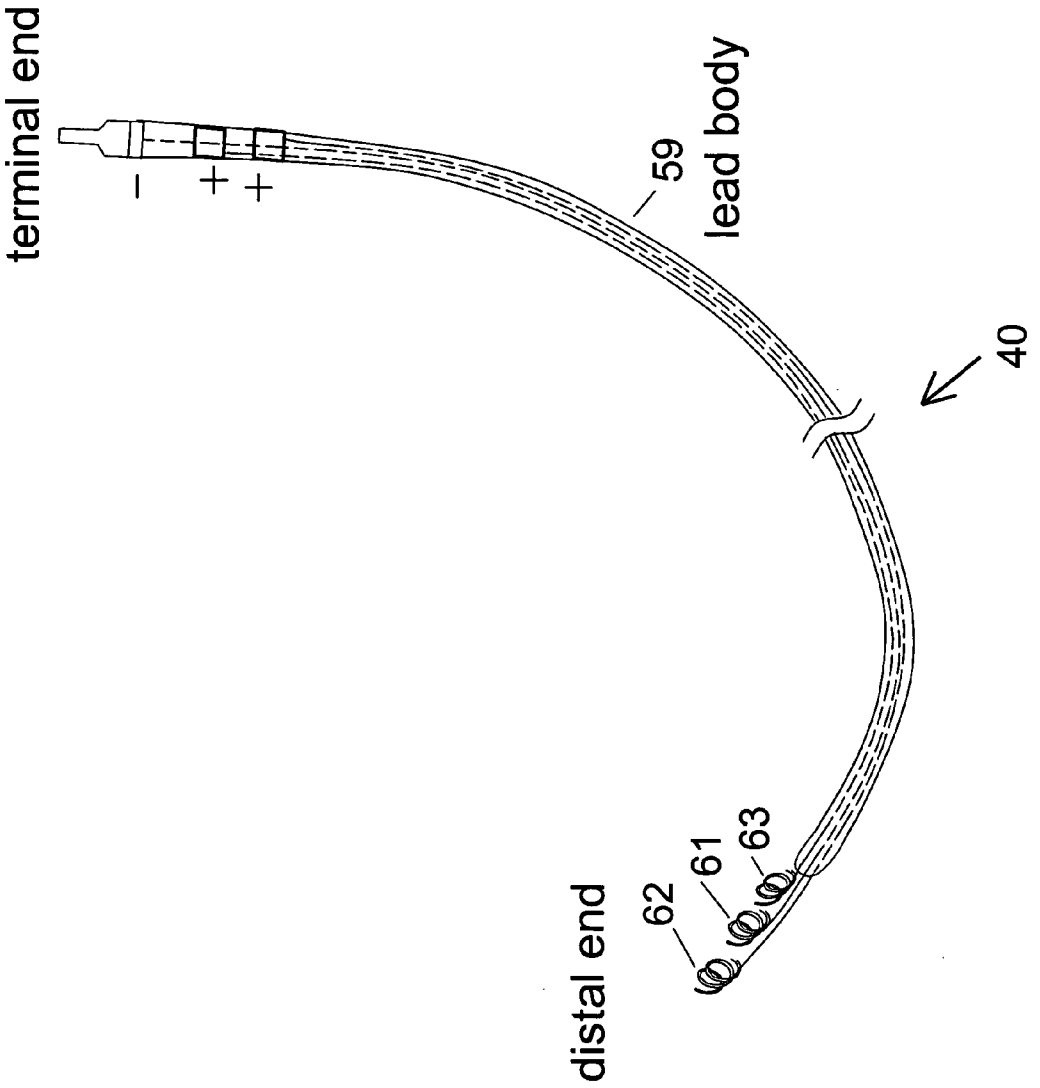


FIG. 32 A

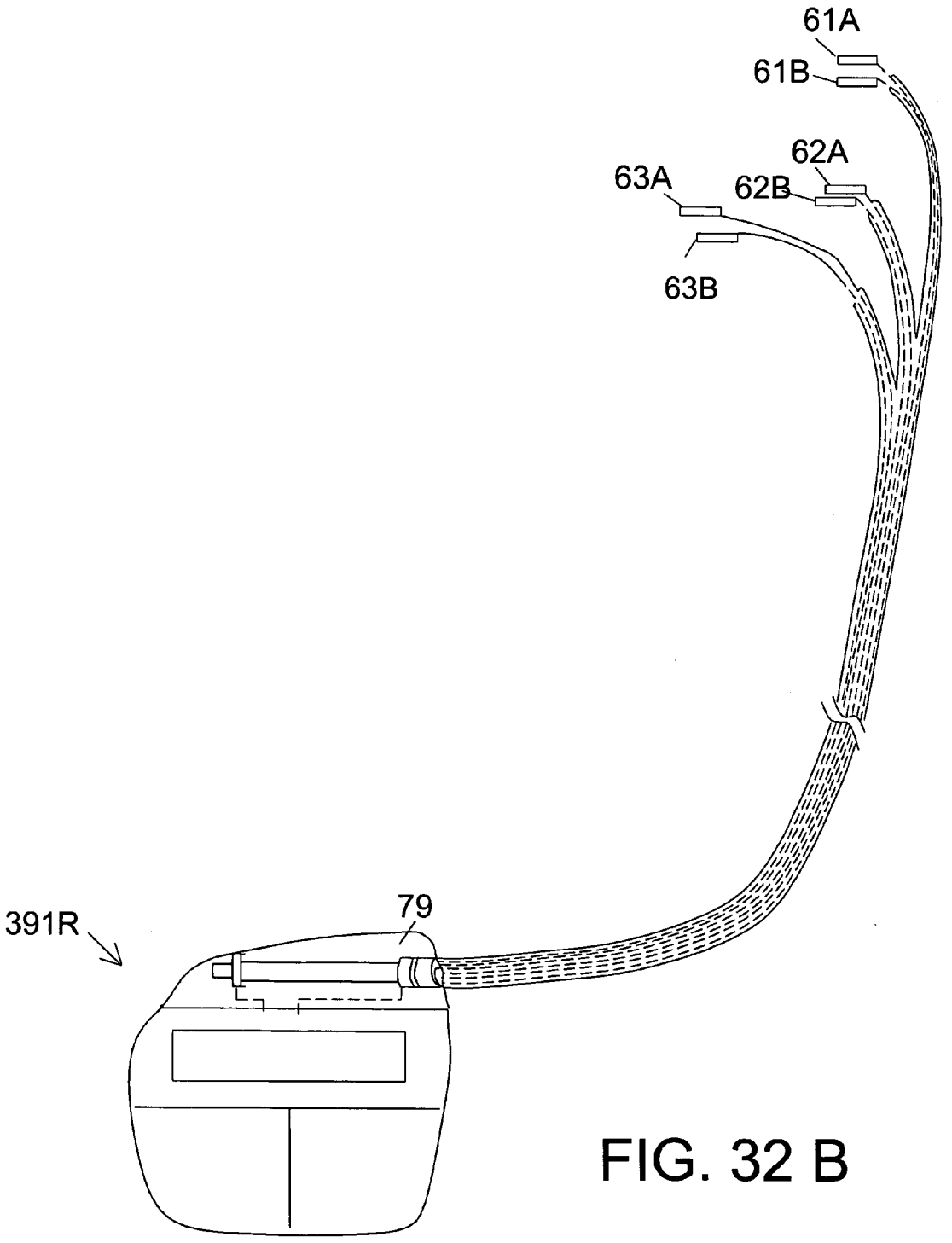


FIG. 32 B

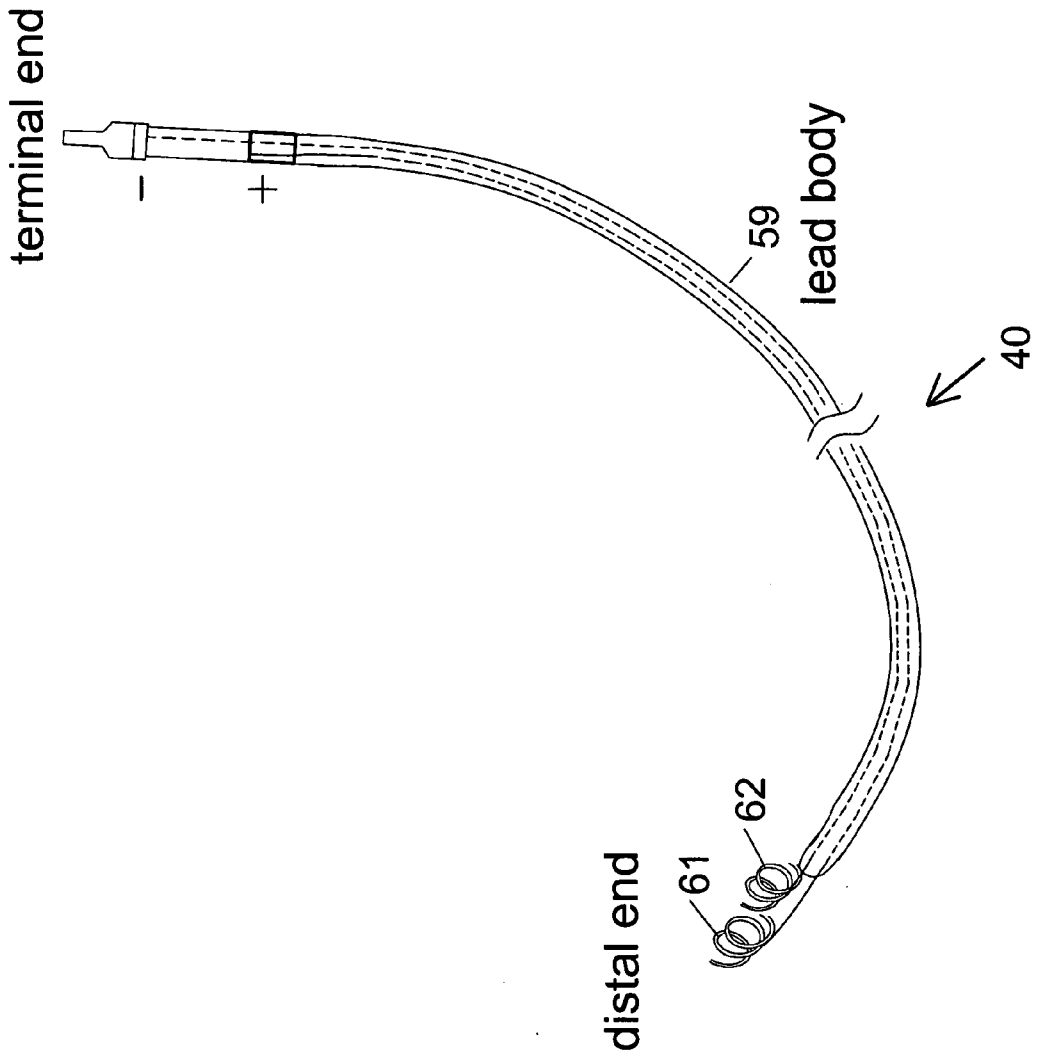
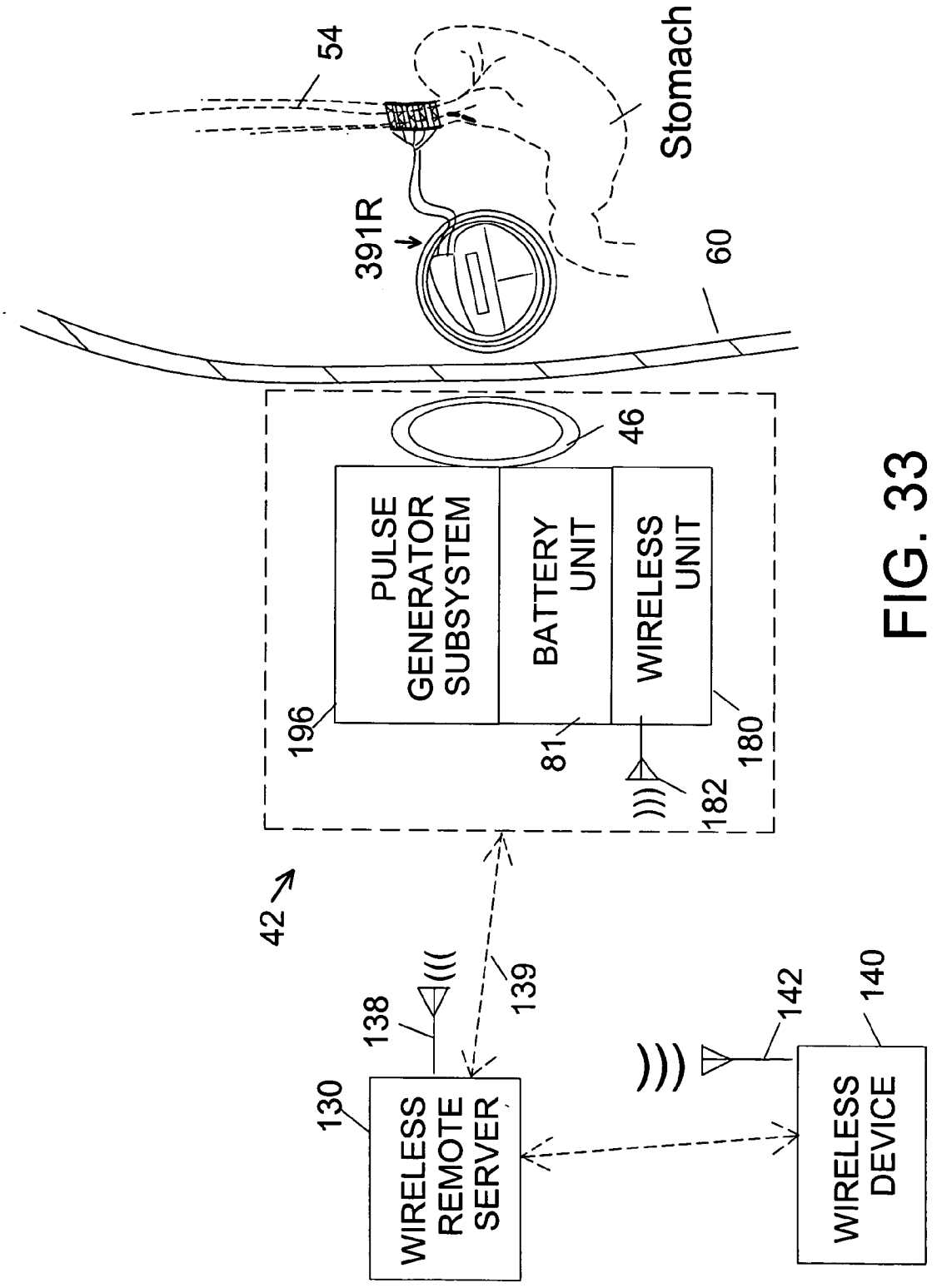


FIG. 32 C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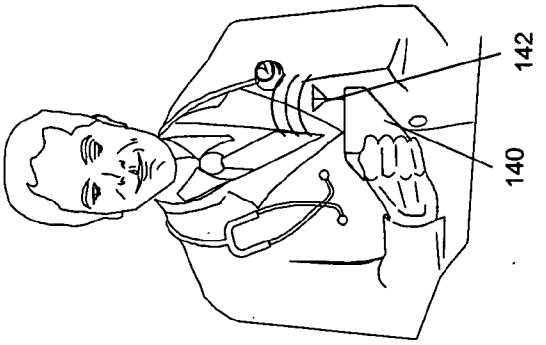
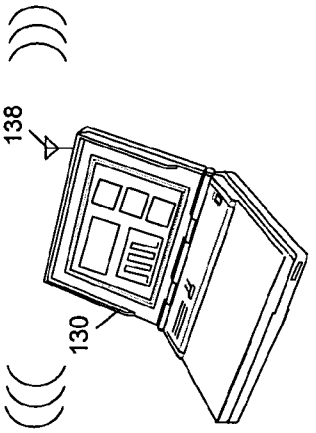
Stomach
391R
60
46
PULSE GENERATOR SUBSYSTEM
BATTERY UNIT
WIRELESS UNIT
196
81
180
182
42
139
138
130
WIRELESS REMOTE SERVER
142
140
WIRELESS DEVICE

FIG. 33





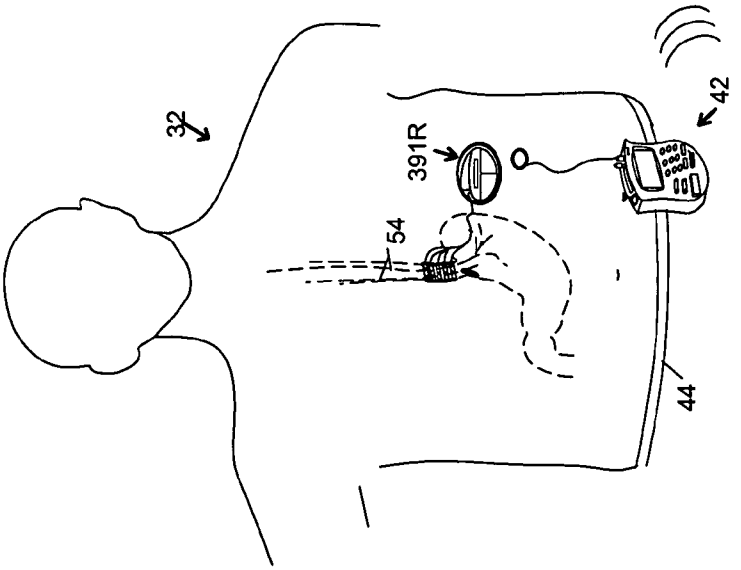
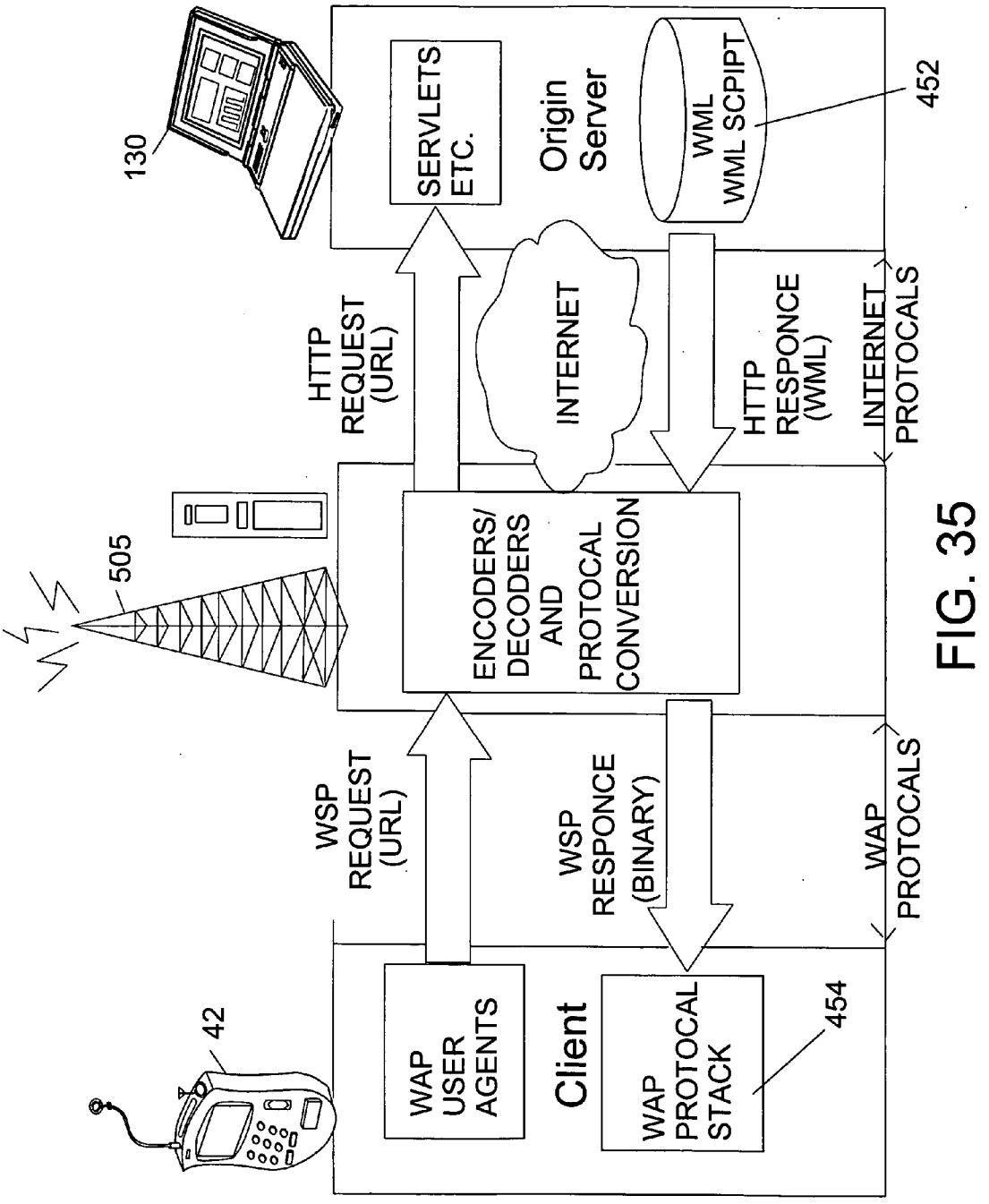


FIG. 34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SERVLETS ETC.
Origin Server
WML WML SCPIPT
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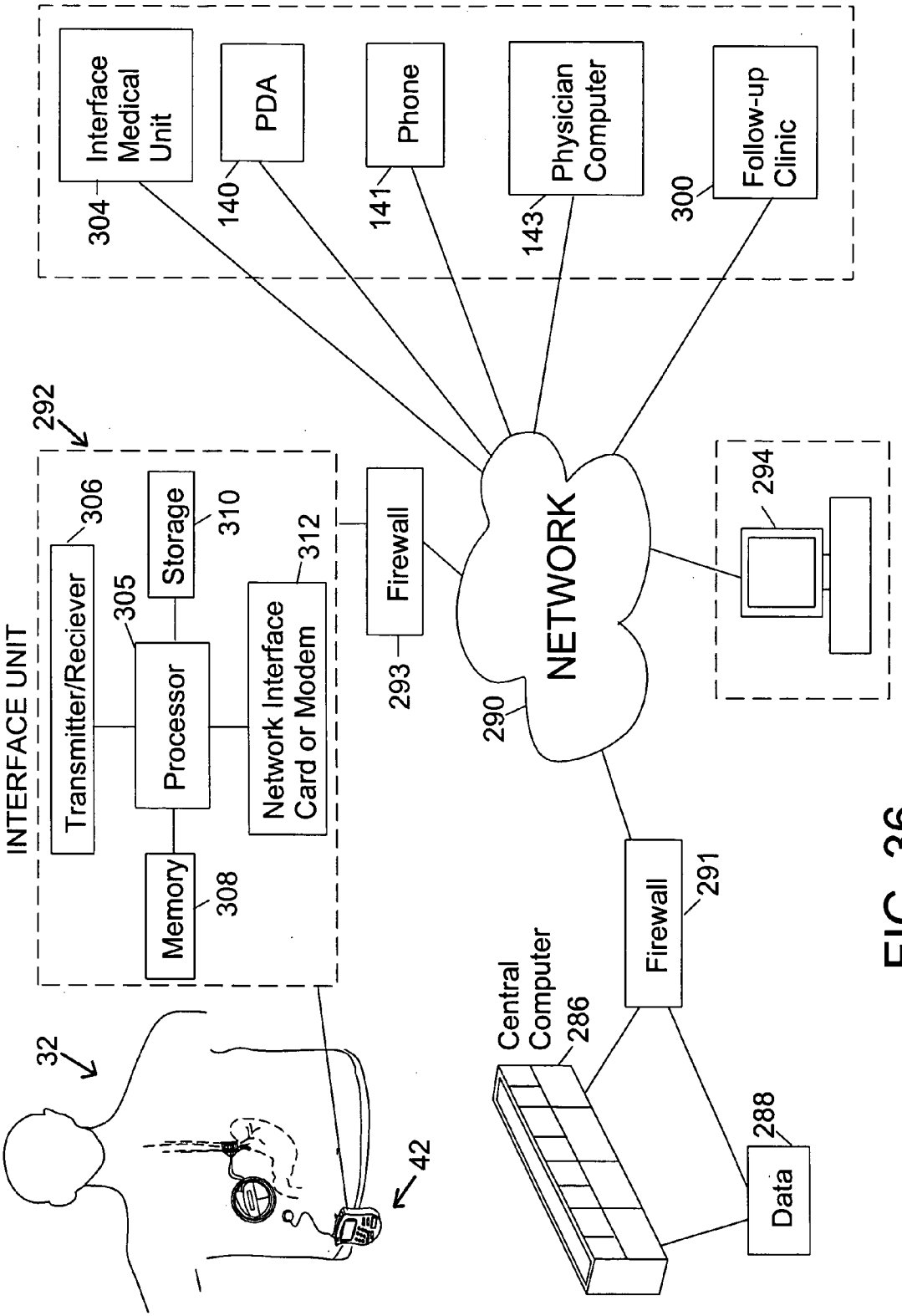
HTTP REQUEST (URL)
INTERNET
HTTP RESPONCE (WML)
INTERNET PROTOCALS
505
ENCODERS/ DECODERS AND PROTOCAL CONVERSION
WSP REQUEST (URL)
WSP RESPONCE (BINARY)
WAP PROTOCALS
42
WAP USER AGENTS
Client
WAP PROTOCAL STACK
454

FIG. 35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Phone
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Physician Computer
143
Follow-up Clinic
300
292
INTERFACE UNIT
Transmitter/Reciever
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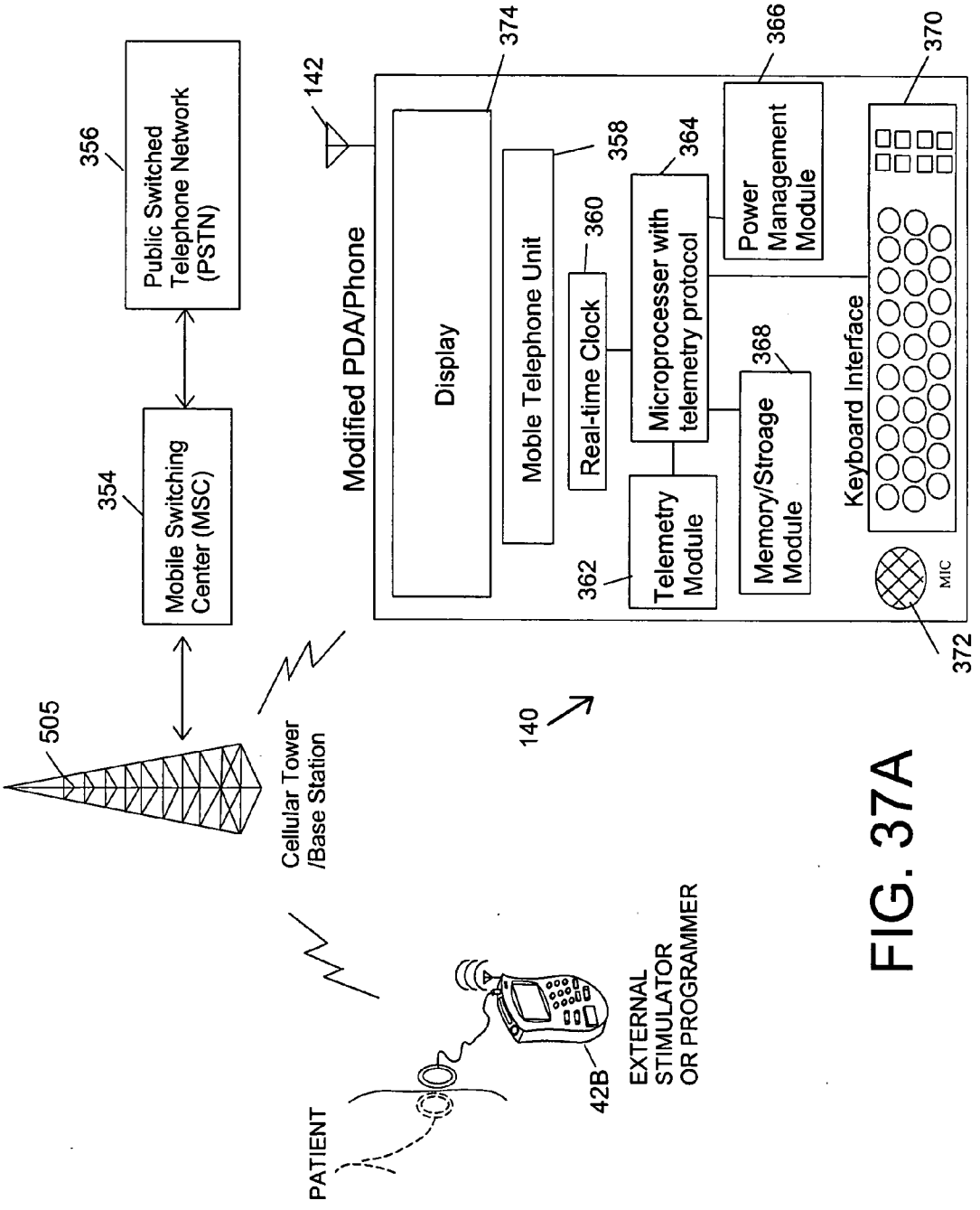
Storage
310
Processor
305
Network Interface Card or Modem
312
Memory
308
Firewall
293
NETWORK
290
294
32
42
Central Computer
286
Firewall
291
Data
288

FIG. 36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Mobile Switching Center (MSC)
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Cellular Tower /Base Station
140
142
Modified PDA/Phone
Display
374
Moble Telephone Unit
358
Real-time Clock
360
Microprocesser with telemetry protocol
364
Power Management Module
366
Keyboard Interface
370
Telemetry Module
362
Memory/Stroage Module
368
MIC
372
PATIENT
42B
EXTERNAL STIMULATOR OR PROGRAMMER

FIG. 37A

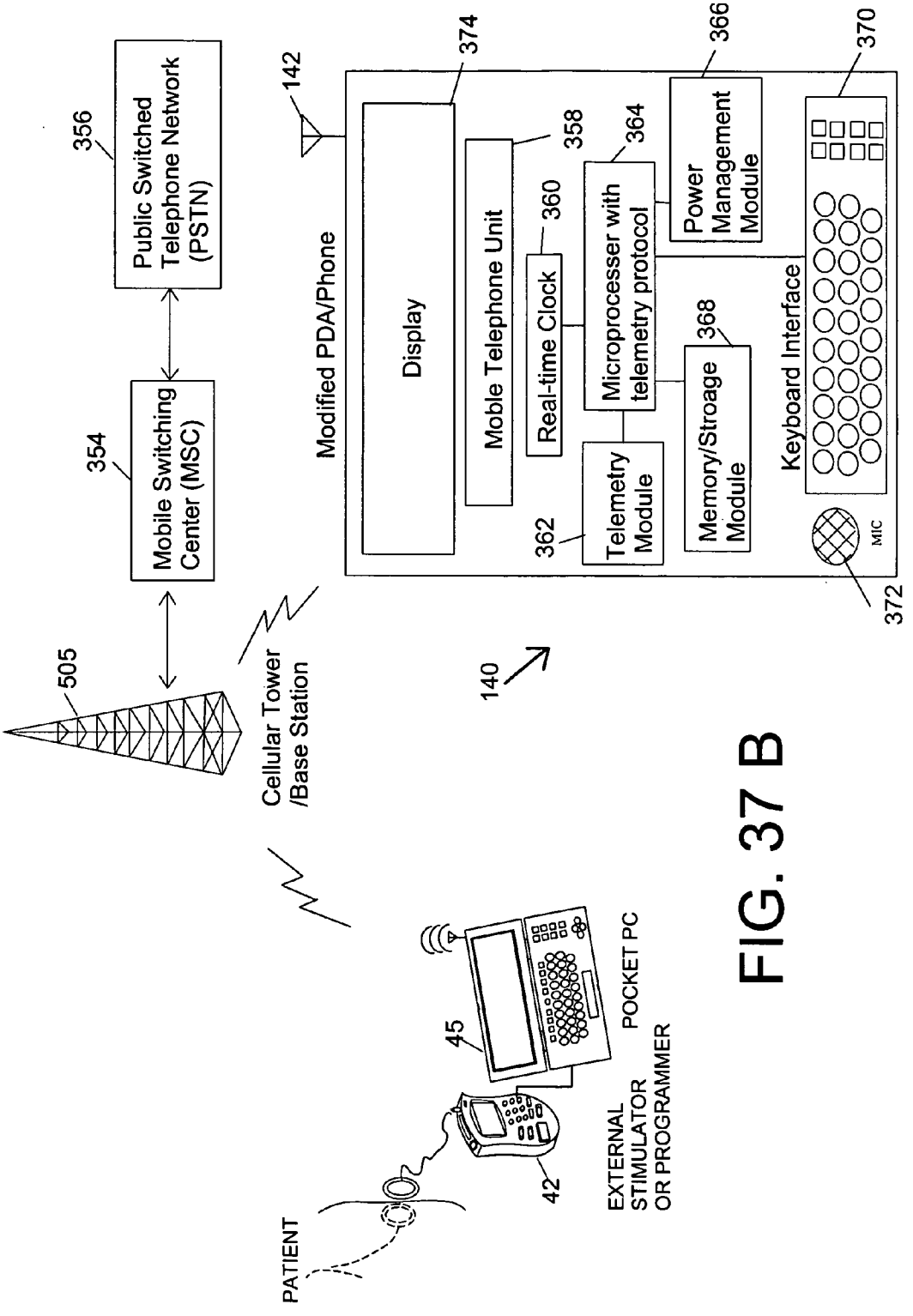
Public Switched Telephone Network (PSTN)
356
Mobile Switching Center (MSC)
354
505
Cellular Tower /Base Station
Modified PDA/Phone
142
374
Display
Moble Telephone Unit
358
Real-time Clock
360
Microprocesser with telemetry protocol
364
Power Management Module
366
Telemetry Module
362
Memory/Stroage Module
368
Keyboard Interface
370
MIC
372
140
45
42
EXTERNAL STIMULATOR OR PROGRAMMER
POCKET PC
PATIENT

FIG. 37 B

METHOD AND SYSTEM FOR VAGAL BLOCKING WITH OR WITHOUT VAGAL STIMULATION TO PROVIDE THERAPY FOR OBESITY AND OTHER GASTROINTESTINAL DISORDERS USING RECHARGEABLE IMPLANTED PULSE GENERATOR

[0001] This application is a continuation of application Ser. No. 11/035,374 filed Jan. 13, 2005, entitled "Method and system for providing electrical pulses for neuromodulation of vagus nerve(s) using rechargeable implanted pulse generator", which is a continuation of application Ser. No. 10/841,995 filed May 8, 2004, which is a continuation of application Ser. No. 10/196,533 filed Jul. 16, 2002, which is a continuation of application Ser. No. 10/142,298 filed on May 9, 2002. The prior applications being incorporated herein in entirety by reference, and priority is claimed from these applications.

FIELD OF INVENTION

[0002] This invention relates generally to providing electrical pulses for blocking/stimulation therapy for medical disorders, more specifically to neuromodulation therapy comprising vagal blocking with or without vagal stimulation, for providing therapy for obesity and other gastrointestinal (GI) disorders, utilizing rechargeable implantable pulse generator.

Background of Obesity and Relation to Vagus Nerve

[0003] Obesity is a significant health problem in the United States and many other developed countries. Obesity results from excessive accumulation of fat in the body. It is caused by ingestion of greater amounts of food than can be used by the body for energy. The excess food, whether fats, carbohydrates, or proteins, is then stored almost entirely as fat in the adipose tissue, to be used later for energy. Obesity is not simply the result of gluttony and a lack of willpower. Rather, each individual inherits a set of genes that control appetite and metabolism, and a genetic tendency to gain weight that may be exacerbated by environmental conditions such as food availability, level of physical activity and individual psychology and culture. Other causes of obesity also include psychogenic, neurogenic, and other metabolic related factors.

[0004] Obesity is defined in terms of body mass index (BMI), which provides an index of the relationship between weight and height. The BMI is calculated as weight (in Kilograms) divided by height (in square meters), or as weight (in pounds) times 703 divided by height (in square inches). The primary classification of overweight and obesity relates to the BMI and the risk of mortality. The prevalence of obesity in adults in the United States without coexisting morbidity increased from 12% in 1991 to 17.9% in 1998, and is still increasing.

[0005] Treatment of obesity depends on decreasing energy input below energy expenditure. Treatment has included among other things various drugs, starvation, and even stapling or surgical resection of a portion of the stomach. Surgery for obesity has included gastroplasty and gastric bypass procedure. Gastroplasty which is also known as stomach stapling, involves constructing a 15- to 30 mL pouch along the lesser curvature of the stomach. A modification of this procedure involves the use of an adjustable band that wraps around the proximal stomach to create a small pouch. Both gastroplasty and gastric bypass procedures have a number of complications.

[0006] The vagus nerve (which is the 10^{th} cranial nerve) plays a role in mediating afferent information from the stomach to the satiety center in the brain. The vagus nerve arises directly from the brain, but unlike the other cranial nerves extends well beyond the head. At its farthest extension it reaches the lower parts of the intestines. This is shown schematically in **FIG. 1**, and in more detail in **FIG. 2**.

[0007] In 1988 it was reported in the *American Journal of Physiology*, that the afferent vagal fibers from the stomach wall increased their firing rate when the stomach was filled. One way to look at this regulatory process is to imagine that the drive to eat, which may vary rather slowly with the rise and fall of hormone Leptin, is inhibited by satiety signals that occur when we eat and begin the digestive process (i.e., the prandial period). As shown schematically in **FIG. 3**, these satiety signals both terminate the meal and inhibit feeding for some time afterward. During this postabsorptive (fasting) period, the satiety signals slowly dissipate until the drive to eat again takes over.

[0008] The regulation of feeding behavior involves the concentrated action of several satiety signals such as gastric distention, the release of the gastrointestinal peptide cholecystokinin (CCK), and the release of the pancreatic hormone insulin. The stomach wall is richly innervated by mechanosensory axons, and most of these ascend to the brain via the vagus nerve(s) **54**. The vagus sensory axons activate neurons in the Nucleus of the Solitary Tract in the medulla of the brain. These signals inhibit feeding behavior. In a related mechanism, the peptide CCK is released in response to stimulation of the intestines by certain types of food, especially fatty ones. CCK reduces frequency of eating and size of meals. As depicted schematically in **FIG. 4**, both gastric distension and CCK act synergistically to inhibit feeding behavior.

Vagal Blocking and/or Stimulation

[0009] In commonly assigned disclosures, application Ser. No. 10/079,21 now U.S. Pat. _____, and U.S. Pat. No. 6,611,715, pulsed electrical neuromodulation therapy for obesity and other medical conditions is obtained by providing electrical pulses to the vagus nerve(s) via an implanted lead comprising plurality of electrodes. In those disclosures, the electrical pulses are provided by at least one electrode on the lead. This patent application is directed to system and method for neuromodulation of vagal activity, wherein vagal block with or without selective vagal stimulation may be used to provide therapy for obesity, weight loss, eating disorders, and other gastrointestinal disorders such as FGIDs, gastroparesis, gastro-esophageal reflex disease (GERD), pancreatitis, ileus and the like. Even though the invention is disclosed in the context of vagal blocking, the nerve blocking methodology can also be used to provide therapy for other ailments, and to provide electric pulses for blocking of other nerves such as sympathetic nerve(s), sacral nerves, or other cranial nerves or their branches or part thereof.

[0010] The gastrointestinal tract and central nervous system (CNS) engage each other in two-way communication.

This has both parasympathetic and sympathetic components. Of particular interest in this disclosure is the parasympathetic component or the vagal pathway, which is shown in conjunction with **FIG. 5**.

[**0011**] In some gastrointestinal (GI) disorders, to provide therapy, stimulation of the vagus nerve(s) is adequate and is the preferred mode of providing therapy. For other GI disorders, to provide therapy, stimulation and selective block is the preferred mode of therapy. For some GI disorders, vagal nerve(s) blocking only is the preferred mode of providing therapy. Advantageously, the method and system disclosed in this patent application can provide vagal blocking with or without vagal stimulation to provide therapy for obesity and other gastrointestinal disorders.

[**0012**] As is shown in conjunction with **FIG. 6** when vagal pathway is stimulated, the stimulation is conducted both in the Afferent (towards the brain) and Efferent (away from the brain) direction. Shown in conjunction with **FIG. 7**, by placing blocking electrodes proximal to the stimulating electrodes, and supplying blocking pulses, the conduction in the Afferent direction (towards the brain) can be blocked or significantly reduced. The blocking pulses may be 500 Hz or other frequency, as described later in this disclosure. This is useful for certain GI disorders, for example ileus and the like.

[**0013**] Shown in conjunction with **FIG. 8**, the blocking electrodes may be placed distal to the stimulating electrodes. If the stimulator provides blocking pulses to the blocking electrode, then the vagus nerve(s) impulses in the Efferent direction are either blocked or are significantly reduced. As the vagus nerves are involved in pancreatitus, the down-regulating of vagal activity can be used to treat pancreatitus and the like.

[**0014**] It will be clear to one of ordinary skill in the art, that by selectively placing the blocking electrode, selective block can be obtained when the stimulator applies blocking pulses to the blocking electrode. Selective Efferent block is depicted in conjunction with **FIG. 9**. As shown in the figure, because of the selective placement of blocking electrode(s), only the impulses to visceral organ **2** are blocked or significantly reduced, and impulses to visceral organ-**1** and visceral organ-**2** continue unimpeded. Selective Afferent block can also be achieved, and is depicted in conjunction with **FIG. 10**. Here the nerve impulses to visceral organ and visceral organ-**5** are selectively blocked. An example would be where Afferent vagal pulses are desired, but impulses to the heart and vocal cords would be blocked. Thus, advantageously providing the desired therapy without the side effects of voice or cardiac complications such as bradycardia. Similarly other side effects can be alleviated or minimized with nerve blocking.

Background of Neuromodulation

[**0015**] Most nerves in the human body are composed of thousands of fibers of different sizes. This is shown schematically in **FIG. 11**. The different sizes of nerve fibers, which carry signals to and from the brain, are designated by groups A, B, and C. The vagus nerve, for example, may have approximately 100,000 fibers of the three different types, each carrying signals. Each axon or fiber of that nerve conducts only in one direction, in normal circumstances. In the vagus nerve sensory fibers outnumber parasympathetic fibers four to one.

[**0016**] In a cross section of peripheral nerve it is seen that the diameter of individual fibers vary substantially, as is also shown schematically in **FIG. 12**. The largest nerve fibers are approximately 20 μm in diameter and are heavily myelinated (i.e., have a myelin sheath, constituting a substance largely composed of fat), whereas the smallest nerve fibers are less than 1 μm in diameter and are unmyelinated.

[**0017**] The diameters of group A and group B fibers include the thickness of the myelin sheaths. Group A is further subdivided into alpha, beta, gamma, and delta fibers in decreasing order of size. There is some overlapping of the diameters of the A, B, and C groups because physiological properties, especially in the form of the action potential, are taken into consideration when defining the groups. The smallest fibers (group C) are unmyelinated and have the slowest conduction rate, whereas the myelinated fibers of group B and group A exhibit rates of conduction that progressively increase with diameter.

[**0018**] Nerve cells have membranes that are composed of lipids and proteins, and have unique properties of excitability such that an adequate disturbance of the cell's resting potential can trigger a sudden change in the membrane conductance. Under resting conditions, the inside of the nerve cell is approximately −90 mV relative to the outside. The electrical signaling capabilities of neurons are based on ionic concentration gradients between the intracellular and extracellular compartments. The cell membrane is a complex of a bilayer of lipid molecules with an assortment of protein molecules embedded in it, separating these two compartments. Electrical balance is provided by concentration gradients which are maintained by a combination of selective permeability characteristics and active pumping mechanism.

[**0019**] A nerve cell can be excited by increasing the electrical charge within the neuron, thus increasing the membrane potential inside the nerve with respect to the surrounding extracellular fluid. The threshold stimulus intensity is the value at which the net inward current (which is largely determined by Sodium ions) is just greater than the net outward current (which is largely carried by Potassium ions), and is typically around −55 mV inside the nerve cell relative to the outside (critical firing threshold). If however, the threshold is not reached, the graded depolarization will not generate an action potential and the signal will not be propagated along the axon. This fundamental feature of the nervous system i.e., its ability to generate and conduct electrical impulses, can take the form of action potentials, which are defined as a single electrical impulse passing down an axon. This action potential (nerve impulse or spike) is an "all or nothing" phenomenon, that is to say once the threshold stimulus intensity is reached, an action potential will be generated.

[**0020**] To stimulate an excitable cell, it is only necessary to reduce the transmembrane potential by a critical amount. When the membrane potential is reduced by an amount ΔV, reaching the critical or threshold potential. When the threshold potential is reached, a regenerative process takes place: sodium ions enter the cell, potassium ions exit the cell, and the transmembrane potential falls to zero (depolarizes), reverses slightly, and then recovers or repolarizes to the resting membrane potential (RMP). For a stimulus to be effective in producing an excitation, it must have an abrupt onset, be intense enough, and last long enough.

[0021] Cell membranes can be reasonably well represented by a capacitance C, shunted by a resistance R as shown by an electrical model in **FIG. 13**, where neuronal process is divided into unit lengths, which is represented in an electrical equivalent circuit. Each unit length of the process is a circuit with its own membrane resistance (r_m), membrane capacitance (c_m), and axonal resistance (r_a).

[0022] When the stimulation pulse is strong enough, an action potential will be generated and propagated. As shown in **FIG. 14**, the action potential is traveling from right to left. Immediately after the spike of the action potential there is a refractory period when the neuron is either unexcitable (absolute refractory period) or only activated to sub-maximal responses by supra-threshold stimuli (relative refractory period). The absolute refractory period occurs at the time of maximal Sodium channel inactivation while the relative refractory period occurs at a later time when most of the Na^+ channels have returned to their resting state by the voltage activated K^+ current. The refractory period has two important implications for action potential generation and conduction. First, action potentials can be conducted only in one direction, away from the site of its generation, and secondly, they can be generated only up to certain limiting frequencies.

[0023] A single electrical impulse passing down an axon is shown schematically in **FIG. 15**. The top portion of the figure (A) shows conduction over mylinated axon (fiber) and the bottom portion (B) shows conduction over nonmylinated axon (fiber). These electrical signals will travel along the nerve fibers.

[0024] The information in the nervous system is coded by frequency of firing rather than the size of the action potential. In terms of electrical conduction, myelinated fibers conduct faster, are typically larger, have very low stimulation thresholds, and exhibit a particular strength-duration curve or respond to a specific pulse width versus amplitude for stimulation, compared to unmyelinated fibers. The A and B fibers can be stimulated with relatively narrow pulse widths, from 50 to 200 microseconds (μs), for example. The A fiber conducts slightly faster than the B fiber and has a slightly lower threshold. The C fibers are very small, conduct electrical signals very slowly, and have high stimulation thresholds typically requiring a wider pulse width (300-1, 000 μs) and a higher amplitude for activation. Because of their very slow conduction, C fibers would not be highly responsive to rapid stimulation. Selective stimulation of only A and B fibers is readily accomplished. The requirement of a larger and wider pulse to stimulate the C fibers, however, makes selective stimulation of only C fibers, to the exclusion of the A and B fibers, virtually unachievable inasmuch as the large signal will tend to activate the A and B fibers to some extent as well.

[0025] As shown in **FIG. 16**, when the distal part of a nerve is electrically stimulated, a compound action potential is recorded by an electrode located more proximally. A compound action potential contains several peaks or waves of activity that represent the summated response of multiple fibers having similar conduction velocities. The waves in a compound action potential represent different types of nerve fibers that are classified into corresponding functional categories as shown in the Table one below,

TABLE 1

Fiber Type	Conduction Velocity (m/sec)	Fiber Diameter (μm)	Myelination
A Fibers			
Alpha	70–120	12–20	Yes
Beta	40–70	5–12	Yes
Gamma	10–50	3–6	Yes
Delta	6–30	2–5	Yes
B Fibers	5–15	<3	Yes
C Fibers	0.5–2.0	0.4–1.2	No

[0026] Vagus nerve blocking and stimulation, performed by the system and method of the current patent application, is a means of directly affecting central function, as well as, peripheral function. **FIG. 17** shows cranial nerves have both afferent pathway **19** (inward conducting nerve fibers which convey impulses toward the brain) and efferent pathway **21** (outward conducting nerve fibers which convey impulses to an effector). Vagus nerve (the 10^{th} cranial nerve) is composed of 80% afferent sensory fibers carrying information to the brain from the head, neck, thorax, and abdomen. The sensory afferent cell bodies of the vagus reside in the nodose ganglion and relay information to the nucleus tractus solitarius (NTS).

[0027] The vagus nerve spans from the brain stem all the way to the splenic flexure of the colon. Not only is the vagus the parasympathetic nerve to the thoracic and abdominal viscera, it also the largest visceral sensory (afferent) nerve. Sensory fibers outnumber parasympathetic fibers four to one. In the medulla, the vagal fibers are connected to the nucleus of the tractus solitarius (viceral sensory), and three other nuclei. The central projections terminate largely in the nucleus of the solitary tract, which sends fibers to various regions of the brain (e.g., the thalamus, hypothalamus and amygdala).

[0028] This application is also related to co-pending applications entitled "METHOD AND SYSTEM FOR PROVIDING ELECTRICAL PULSES TO GASTRIC WALL OF A PATIENT WITH RECHARGEABLE IMPLANTABLE PULSE GENERATOR FOR TREATING OR CONTROLLING OBESITY AND EATING DISORDERS" and "METHOD AND SYSTEM TO PROVIDE THERAPY FOR OBESITY AND OTHER MEDICAL DISORDERS, BY PROVIDING ELECTRICAL PULSES TO SYMPATHETIC NERVES OR VAGAL NERVE(S) WITH RECHARGEABLE IMPLANTED PULSE GENERATOR.

PRIOR ART

[0029] Prior art is generally directed to adapting cardiac pacemaker technology for nerve stimulation, where U.S. Pat. Nos. 5,263,480 (Wernicke et al.) and 5,188,104 (Wernicke et al.) are generally directed to treatment of eating disorders with vagus nerve stimulation using an implantable neurocybernetic prosthesis (NCP), which is a "cardiac pacemaker-like" device. There is no disclosure for vagal blocking.

[0030] U.S. Pat. No. 5,540,730 (Terry et al.) is generally directed to treating motility disorders with vagus nerve stimulation using an implantable neurocybernetic prosthesis (NCP), which is a "cardiac pacemaker-like" device.

[0031] U.S. Pat. No. 6,553,263B1 (Meadows et al.) is generally directed to an implantable pulse generator system for spinal cord stimulation, which includes a rechargeable battery. In the Meadows '263 patent there is no disclosure or suggestion for combing a stimulus-receiver module to an implantable pulse generator (I PG) for use with an external stimulator, for providing modulating pulses to sympathetic nerve(s), as in the applicant's disclosure.

[0032] U.S. Pat. No. 6,505,077 B1 (Kast et al.) is directed to electrical connection for external recharging coil. In the Kast '077 disclosure, a magnetic shield is required between the externalized coil and the pulse generator case. In one embodiment of the applicant's disclosure, the externalized coil is wrapped around the pulse generator case, without requiring a magnetic shield.

[0033] U.S. Pat. No. 6,600,954 B2 (Cohen et al.) is generally directed to selectively blocking propagation of body-generated action potentials particularly useful for pain control.

[0034] U.S. Pat. No. 6,684,105 B2 (Cohen et al.) is generally directed to an apparatus for unidirectional nerve stimulation.

[0035] U.S. Pat. No. 6,611,715 B1 (Boveja) is generally directed to a system and method to provide therapy for obesity and compulsive eating disorders using an implantable lead-receiver and an external stimulator.

SUMMARY OF THE INVENTION

[0036] The method and system of the current invention overcomes many shortcomings of the prior art by providing a system for neuromodulation with extended power source either in the form of rechargeable battery, or by utilizing an external stimulator in conjunction with an implanted pulse generator device, to provide therapy for obesity, motility disorders, eating disorders, inducing weight loss, FGIDs, gastroparesis, gastro-esophageal reflex disease (GERD), pancreatitis, and ileus.

[0037] Accordingly, in one aspect of the invention, electrical pulses are provided utilizing a rechargeable implantable pulse generator for nerve blocking, with or without selective electrical stimulation of vagus nerve(s) or its branches or part thereof for treating obesity and other GI disorders.

[0038] In another aspect of the invention, the electrical pulses are provided for at least one of afferent block, efferent block, or organ block.

[0039] In another aspect of the invention, the nerve blocking comprises at least one from a group consisting of: DC or anodal block, Wedenski block, and Collision block.

[0040] In another aspect of the invention, a coil used in recharging said pulse generator is around the implantable pulse generator case, and in a silicone enclosure.

[0041] In another aspect of the invention, the rechargeable implanted pulse generator comprises two feedthroughs.

[0042] In another aspect of the invention, the rechargeable implanted pulse generator comprises only one feed-through for externalizing the recharge coil.

[0043] In another aspect of the invention, the implantable rechargeable pulse generator comprises stimulus-receiver means such that, the implantable rechargeable pulse generator can function in conjunction with an external stimulator, to provide nerve blocking with or without selective electrical stimulation of vagus nerve(s) or its branches or part thereof.

[0044] In another aspect of the invention, the rechargeable battery comprises at least one of lithium-ion, lithium-ion polymer batteries.

[0045] In another aspect of the invention, the external programmer or the external stimulator comprises networking capabilities for remote communications over a wide area network for remote interrogation and/or remote programming.

[0046] In yet another aspect of the invention, the implanted lead comprises at least two electrode(s) which are made of a material selected from the group consisting of platinum, platinum/iridium alloy, platinum/iridium alloy coated with titanium nitride, and carbon.

[0047] This and other objects are provided by one or more of the embodiments described below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0048] For the purpose of illustrating the invention, there are shown in accompanying drawing forms which are presently preferred, it being understood that the invention is not intended to be limited to the precise arrangement and instrumentalities shown.

[0049] **FIG. 1** is a diagram depicting vagal nerves in a patient.

[0050] **FIG. 2** is a diagram showing vagal nerve innervation to the viceral organs.

[0051] **FIG. 3** is a schematic diagram showing the relationship of meals and satiety signals.

[0052] **FIG. 4** is a schematic diagram showing impulses traveling via the vagus nerve in response to gastric distention and CCK release.

[0053] **FIG. 5** is a diagram depicting two-way communication between the gut and central nervous system (CNS).

[0054] **FIG. 6** is a diagram showing conduction of nerve impulses in both afferent and efferent direction with artificial electrical stimulation.

[0055] **FIG. 7** is a diagram depicting blocking in the afferent direction, but conducting in the efferent direction with electrical stimulation.

[0056] **FIG. 8** is a diagram depicting electrical stimulation with conduction in the afferent direction and blocking in the efferent direction.

[0057] **FIG. 9** is a diagram depicting electrical stimulation with conduction in the afferent direction and selective organ blocking in the efferent direction.

[0058] **FIG. 10** is a diagram depicting electrical stimulation with conduction in the efferent direction and selective organ blocking in the afferent direction.

[0059] **FIG. 11** is a diagram of the structure of a nerve.

[0060] **FIG. 12** is a diagram showing different types of nerve fibers.

[0061] **FIG. 13** is a schematic illustration of electrical circuit model of nerve cell membrane.

[0062] **FIG. 14** is an illustration of propagation of action potential in nerve cell membrane.

[0063] **FIG. 15** is an illustration showing propagation of action potential along a myelinated axon and non-myelinated axon.

[0064] **FIG. 16** is a diagram showing recordings of compound action potentials.

[0065] **FIG. 17** is a schematic diagram of brain showing afferent and efferent pathways.

[0066] **FIG. 18** is a diagram of implanted components of stimulation/blocking system with multiple electrodes around anterior and posterior vagal nerves.

[0067] **FIG. 19A** is a diagram showing the implanted components (rechargeable implantable pulse generator), and an external stimulator coupled to implanted stimulus-receiver.

[0068] **FIG. 19B** is a diagram showing placement of the external (primary) coil in relation of the implanted stimulus-receiver.

[0069] **FIG. 20** is a simplified general block diagram of an implantable pulse generator.

[0070] **FIG. 21A** shows energy density of different types of batteries.

[0071] **FIG. 21B** shows discharge curves for different types of batteries.

[0072] **FIG. 22** shows a block diagram of an implantable stimulator which can be used as a stimulus-receiver or an implanted pulse generator with rechargeable battery.

[0073] **FIG. 23** is a block diagram highlighting battery charging circuit of the implantable stimulator of **FIG. 22**.

[0074] **FIG. 24** is a schematic diagram highlighting stimulus-receiver portion of implanted stimulator of one embodiment.

[0075] **FIG. 25** depicts externalizing recharge and telemetry coil from the titanium case.

[0076] **FIG. 26A** depicts coil around the titanium case with two feedthroughs for a bipolar configuration.

[0077] **FIG. 26B** depicts coil around the titanium case with one feedthrough for a unipolar configuration.

[0078] **FIG. 26C** depicts two feedthroughs for the external coil which are common with the feedthroughs for the lead terminal.

[0079] **FIG. 26D** depicts one feedthrough for the external coil which is common to the feedthrough for the lead terminal.

[0080] **FIGS. 27A and 27B** depict recharge coil on the titanium case with a magnetic shield in-between.

[0081] **FIG. 28** shows a rechargeable implantable pulse generator in block diagram form.

[0082] **FIG. 29** depicts in block diagram form, the implanted and external components of an implanted rechargable system.

[0083] **FIG. 30** depicts the alignment function of rechargable implantable pulse generator.

[0084] **FIG. 31** is a block diagram of the external recharger.

[0085] **FIG. 32A** is a schematic diagram of an implantable lead with three electrodes.

[0086] **FIG. 32B** is a schematic diagram of an implantable lead with multiple electrodes.

[0087] **FIG. 32C** is a schematic diagram of an implantable lead with two electrodes.

[0088] **FIG. 33** is a schematic diagram of the pulse generator and two-way communication through a server.

[0089] **FIG. 34** is a diagram depicting wireless remote interrogation and programming of the external pulse generator.

[0090] **FIG. 35** is a schematic diagram of the wireless protocol.

[0091] **FIG. 36** is a simplified block diagram of the networking interface board.

[0092] **FIGS. 37A and 37B** are simplified diagrams showing communication of modified PDA/phone with an external stimulator via a cellular tower/base station.

DESCRIPTION OF THE INVENTION

[0093] To provide vagal blocking and/or vagal stimulation therapy to a patient, blocking and stimulation electrodes are implanted at the appropriate sites. In one preferred embodiment, without limitation, multiple electrodes comprising both blocking and stimulation electrodes are placed in a band. As shown in conjunction with **FIG. 18**, the band comprising multiple electrodes is wrapped around the esophagus, close to the junction of esophagus and the stomach **5** (just below the diaphragm). Alternatively, the individual electrodes do not have to be in a band, and may be individual electrodes, connected to the body of the lead via insulated conductors (shown in **FIG. 32B**). In such a case, the portion of the electrode contacting the nerve tissue would be exposed and the rest of the electrode being insulated with a non-conductive material such as silicone or polyurethane. Such electrodes are well known in the art.

[0094] The electrodes may be implanted using laproscopic surgery or alternatively a surgical exposure may be made for implantation of the electrodes at the appropriate site to be stimulated and/or blocked. After placing the electrodes, the terminal portion of the lead is tunneled to a subcutaneous site where the electronics package is to be implanted. The terminal end of the lead is connected to the rechargeable implantable pulse generator. The patient is surgically closed in layers, and electrical pulse delivery can begin once the patient has fully recovered from the surgery.

[0095] In the method and system of this invention, stimulation without block may be provided. Additionally, stimulation with selective block may be provided. Furthermore, block alone (without stimulation) may be provided, which would be functionally equivalent to reversible vagotomy.

[0096] Blocking of nerve impulses, unidirectional blocking, and selective blocking of nerve impulses is well known in the scientific literature. Some of the general literature is listed below and is incorporated herein by reference. (a) "Generation of unidirectionally propagating action potentials using a monopolar electrode cuff", *Annals of Biomedical Engineering*, volume 14, pp. 437-450, By Ira J. Ungar et al. (b) "An asymmetric two electrode cuff for generation of unidirectionally propagated action potentials", *IEEE Transactions on Biomedical Engineering*, volume BME-33, No. 6, June 1986, By James D. Sweeney, et al. (c) A spiral nerve cuff electrode for peripheral nerve stimulation, *IEEE Transactions on Biomedical Engineering*, volume 35, No. 11, November 1988, By Gregory G. Naples. et al. (d) "A nerve cuff technique for selective excitation of peripheral nerve trunk regions, *IEEE Transactions on Biomedical Engineering*, volume 37, No. 7, July 1990, By James D. Sweeney, et al. (e) "Generation of unidirectionally propagated action potentials in a peripheral nerve by brief stimuli", *Science*, volume 206 pp. 1311-1312, Dec. 14, 1979, By Van Den Honert et al. (f "A technique for collision block of perpheral nerve: Frequency dependence"*IEEE Transactions on Biomedical Engineering*, MP-12, volume 28, pp. 379-382, 1981, By Van Den Honert et al. (g) "A nerve cuff design for the selective activation and blocking of myelinated nerve fibers"*Ann. Conf. of the IEEE Engineering in Medicine and Biology Soc.*, volume 13, No. 2, p 906, 1991, By D. M Fitzpatrick et al. (h) "Orderly recruitment of motoneurons in an acute rabbit model", "*Ann. Conf. of the IEEE Engineering in Medicine and Biology Soc.*, volume 20, No. 5, page 2564, 1998, By N. J. M. Rijkhof, et al. (i) "Orderly stimulation of skeletal muscle motor units with tripolar nerve cuff electrode", *IEEE Transactions on Biomedical Engineering*, volume 36, No. 8, pp. 836,1989, By R. Bratta. (j) M. Devor, "Pain Networks", Handbook of Brand Theory and Neural Networks, Ed. M. A. Arbib, MIT Press, page 698, 1998.

[0097] Blocking can be generally divided into 3 categories: (a) DC or anodal block, (b) Wedenski Block, and (c) Collision block. In anodal block there is a steady potential which is applied to the nerve causing a reversible and selective block. In Wedenski Block the nerve is stimulated at a high rate causing the rapid depletion of the neurotransmitter. In collision blocking, unidirectional action potentials are generated anti-dromically. The maximal frequency for complete block is the reciprocal of the refractory period plus the transit time, i.e. typically less than a few hundred hertz. The use of any of these blocking techniques can be applied for the practice of this invention, and all are considered within the scope of this invention.

[0098] **FIGS. 19A and 19B** depict the implantable components of the system. A rechargeable implantable pulse generator **391**R is connected to the lead **40** for delivering pulses via multiple electrodes in contact with nerve tissue. The selective blocking and/or stimulation to the vagal nerve tissue **54** can be performed by "pre-determined" programs stored in the memory, or by "customized" programs where the electrical parameters are selectively programmed for specific therapy to the individual patient. The electrical parameters which can be individually programmed, include variables such as pulse amplitude, pulse width, frequency of stimulation, type of pulse (e.g. blocking pulses may be sinusoidal), stimulation on-time, and stimulation off-time. Table two below defines the approximate range of parameters,

TABLE 2

Electrical parameter range delivered to the nerve for stimulation and/or blocking

PARAMER	RANGE
Pulse Amplitude	0.1 Volt–10 Volts
Pulse width	20 μS–5 mSec.
Stim. Frequency	5 Hz–200 Hz
Freq. for blocking	DC to 5,000 Hz
On-time	5 Secs–24 hours
Off-time	5 Secs–24 hours

[0099] The parameters in Table 2 are the electrical signals delivered to the nerve tissue via the two stimulation electrodes **61**,**62** (or blocking electrodes) at the nerve tissue **54**.

[0100] Shown in conjunction with **FIG. 20**, is an overall schematic of a general implantable pulse generator system to deliver electrical pulses for modulating the vagus nerve(s) (selective stimulation and/or blocking) and providing therapy. The implantable pulse generator unit **391** is a microprocessor based device, where the entire circuitry is encased in a hermetically sealed titanium can. As shown in the overall block diagram, the logic & control unit **398** provides the proper timing for the output circuitry **385** to generate electrical pulses that are delivered to a pair of electrodes via a lead **40**. Timing is provided by oscillator **393**. The pair of electrodes to which the stimulation energy is delivered is switchable. Programming of the implantable pulse generator (IPG) **391** is done via an external programmer **85**. Once programmed via an external programmer **85**, the implanted pulse generator **391** provides appropriate electrical blocking and/or stimulation pulses to the vagal nerve(s) **54** via the blocking/stimulating electrodes **61**,**62**,**63**.

[0101] Because of the high energy requirements for the pulses required for blocking and/or selective stimulation of vagal nerve tissue **54**, there is a real need for power sources that will provide an acceptable service life under conditions of continuous delivery of high frequency pulses. **FIG. 21A** shows a graph of the energy density of several commonly used battery technologies. Lithium batteries have by far the highest energy density of commonly available batteries. Also, a lithium battery maintains a nearly constant voltage during discharge. This is shown in conjunction with **FIG. 21B**, which is normalized to the performance of the lithium battery. Lithium-ion batteries also have a long cycle life, and no memory effect. However, Lithium-ion batteries are not as tolerant to overcharging and overdischarging. One of the most recent development in rechargable battery technology is the Lithium-ion polymer battery. Recently the major battery manufacturers (Sony, Panasonic, Sanyo) have announced plans for Lithium-ion polymer battery production.

[0102] For preferred method of the current invention, two embodiments of implantable pulse generators may be used. Both embodiments comprise re-chargeable power sources, such as Lithium-ion polymer battery.

[0103] In one embodiment of this invention, the implanted stimulator comprises a stimulus-receiver module and a pulse generator module. Advantageously, this embodiment provides an ideal power source, since the power source can be an external stimulator in conjunction with an implanted

stimulus-receiver, or the power source can be from the implanted rechargable battery **740**. Shown in conjunction with **FIG. 22** is a simplified overall block diagram of this embodiment. A coil **48**C which is external to the titanium case may be used both as a secondary of a stimulus-receiver, or may also be used as the forward and back telemetry coil. The coil **48**C may be externalized at the header portion **79**C of the implanted device, and may be wrapped around the titanium case, eliminating the need for a magnetic shield. In this case, the coil is encased in the same material as the header **79**C. Alternatively, the coil may be positioned on the titanium case, with a magnetic shield.

[**0104**] In this embodiment, as disclosed in **FIG. 22**, the IPG circuitry within the titanium case is used for all stimulation pulses whether the energy source is the internal rechargeable battery **740** or an external power source. The external device serves as a source of energy, and as a programmer that sends telemetry to the IPG. For programming, the energy is sent as high frequency sine waves with superimposed telemetry wave driving the external coil **46**C. The telemetry is passed through coupling capacitor **727** to the IPG's telemetry circuit **742**. For pulse delivery using external power source, the stimulus-receiver portion will receive the energy coupled to the implanted coil **48**C and, using the power conditioning circuit **726**, rectify it to produce DC, filter and regulate the DC, and couple it to the IPG's voltage regulator **738** section so that the IPG can run from the externally supplied energy rather than the implanted battery **740**.

[**0105**] The system provides a power sense circuit **728** that senses the presence of external power communicated with the power control **730**, when adequate and stable power is available from an external source. The power control circuit controls a switch **736** that selects either implanted rechargeable battery power **740** or conditioned external power from **726**. The logic and control section **732** and memory **744** includes the IPG's microcontroller, pre-programmed instructions, and stored changeable parameters. Using input for the telemetry circuit **742** and power control **730**, this section controls the output circuit **734** that generates the output pulses.

[**0106**] Shown in conjunction with **FIG. 23**, this embodiment of the invention is practiced with a rechargeable battery **740**. This circuit is energized when external power is available. It senses the charge state of the battery and provides appropriate charge current to safely recharge the battery without overcharging. Recharging circuitry is described later.

[**0107**] The stimulus-receiver portion of the circuitry is shown in conjunction with **FIG. 24**. Capacitor C**1** (**729**) makes the combination of C**1** and L**1** sensitive to the resonant frequency and less sensitive to other frequencies, and energy from an external (primary) coil **46**C is inductively transferred to the implanted unit via the secondary coil **48**C. The AC signal is rectified to DC via diode **731**, and filtered via capacitor **733**. A regulator **735** set the output voltage and limits it to a value just above the maximum IPG cell voltage. The output capacitor C**4** (**737**), typically a tantalum capacitor with a value of 100 micro-Farads or greater, stores charge so that the circuit can supply the IPG with high values of current for a short time duration with minimal voltage change during a pulse while the current draw from the external source remains relatively constant. Also shown in conjunction with **FIGS. 23 and 24**, a capacitor C**3** (**727**) couples signals for forward and back telemetry.

[**0108**] In another embodiment, existing implantable pulse generators can be modified to incorporate rechargeable batteries. As shown in conjunction with **FIG. 25**, in both embodiments, the coil is externalized from the titanium case **57**. The RF pulses transmitted via coil **46** and received via subcutaneous coil **48**A are rectified via a diode bridge. These DC pulses are processed and the resulting current applied to recharge the battery **694**/**740** in the implanted pulse generator. In one embodiment the coil **48** may be externalized at the header portion **79**C of the implanted device, and may be wrapped around the titanium case, as shown in **FIGS. 26A and 26B**. Shown in **FIG. 26A** is a bipolar configuration which requires two feedthroughs **76**,**77**. Advantageously, as shown in **FIG. 26B** unipolar configuration may also be used which requires only one feedthrough **75**. The other end is electronically connected to the case. In both cases, the coil is encased in the same material as the header **79**. Advantageously, as shown in conjunction with **FIGS. 26C and 26D**, the feedthrough for the coil can be combined with the feedthrough for the lead terminal. This can be applied both for bipolar and unipolar configurations.

[**0109**] In one embodiment, the coil may be positioned on the titanium case as shown in conjunction with **FIGS. 27A and 27B**. **FIG. 27A** shows a diagram of the finished implantable stimulator **391**R of one embodiment. **FIG. 27B** shows the pulse generator with some of the components used in assembly in an exploded view. These components include a coil cover **13**, the secondary coil **48** and associated components, a magnetic shield **9**, and a coil assembly carrier **11**. The coil assembly carrier **11** has at least one positioning detail **80** located between the coil assembly and the feed through for positioning the electrical connection. The positioning detail **80** secures the electrical connection in this embodiment.

[**0110**] A schematic diagram of the implanted pulse generator (IPG **391**R), with re-chargeable battery **694** of one preferred embodiment of this invention, is shown in conjunction with **FIG. 28**. The IPG **391**R includes logic and control circuitry **673** connected to memory circuitry **691**. The operating program and stimulation parameters are typically stored within the memory **691** via forward telemetry. Blocking/stimulation pulses are provided to the nerve tissue **54** via output circuitry **677** controlled by the microcontroller.

[**0111**] The operating power for the IPG **391**R is derived from a rechargeable power source **694**. The rechargeable power source **694** comprises a rechargeable lithium-ion or lithium-ion polymer battery. Recharging occurs inductively from an external charger to an implanted coil **48**B underneath the skin **60**. The rechargeable battery **694** may be recharged repeatedly as needed. Additionally, the IPG **391**R is able to monitor and telemeter the status of its rechargeable battery **691** each time a communication link is established with the external programmer **85**.

[**0112**] Much of the circuitry included within the IPG **391**R may be realized on a single application specific integrated

circuit (ASIC). This allows the overall size of the IPG **391**R to be quite small, and readily housed within a suitable hermetically-sealed case. The IPG case is preferably made from titanium and is shaped in a rounded case.

[**0113**] Shown in conjunction with **FIG. 29** are the recharging elements of the invention. The recharging system uses a portable external charger to couple energy into the power source of the IPG **391**R. The DC-to-AC conversion circuitry **696** of the recharger receives energy from a battery **672** in the recharger. A charger base station **680** and conventional AC power line may also be used. The AC signals amplified via power amplifier **674** are inductively coupled between an external coil **46**B and an implanted coil **48**B located subcutaneously with the implanted pulse generator (IPG) **391**R. The AC signal received via implanted coil **48**B is rectified **686** to a DC signal which is used for recharging the rechargable battery **694** of the IPG, through a charge controller IC **682**. Additional circuitry within the IPG **391**R includes, battery protection IC **688** which controls a FET switch **690** to make sure that the rechargable battery **694** is charged at the proper rate, and is not overcharged. The battery protection IC **688** can be an off-the-shelf IC available from Motorola (part no. MC 33349N-3R1). This IC monitors the voltage and current of the implanted rechargable battery **694** to ensure safe operation. If the battery voltage rises above a safe maximum voltage, the battery protection IC **688** opens charge enabling FET switches **690**, and prevents further charging. A fuse **692** acts as an additional safeguard, and disconnects the battery **694** if the battery charging current exceeds a safe level. As also shown in **FIG. 29**, charge completion detection is achieved by a back-telemetry transmitter **684**, which modulates the secondary load by changing the full-wave rectifier into a half-wave rectifier/voltage clamp. This modulation is in turn, sensed by the charger as a change in the coil voltage due to the change in the reflected impedance. When detected through a back telemetry receiver **676**, either an audible alarm is generated or a LED is turned on.

[**0114**] A simplified block diagram of charge completion and misalignment detection circuitry is shown in conjunction with **FIG. 30**. As shown, a switch regulator **686** operates as either a full-wave rectifier circuit or a half-wave rectifier circuit as controlled by a control signal (CS) generated by charging and protection circuitry **698**. The energy induced in implanted coil **48**B (from external coil **46**B) passes through the switch rectifier **686** and charging and protection circuitry **698** to the implanted rechargable battery **694**. As the implanted battery **694** continues to be charged, the charging and protection circuitry **698** continuously monitors the charge current and battery voltage. When the charge current and battery voltage reach a predetermined level, the charging and protection circuitry **698** triggers a control signal. This control signal causes the switch rectifier **686** to switch to half-wave rectifier operation. When this change happens, the voltage sensed by voltage detector **702** causes the alignment indicator **706** to be activated. This indicator **706** may be an audible sound or a flashing LED type of indicator.

[**0115**] The indicator **706** may similarly be used as a misalignment indicator. In normal operation, when coils **46**B (external) and **48**B (implanted) are properly aligned, the voltage V_s sensed by voltage detector **704** is at a minimum level because maximum energy transfer is taking place. If and when the coils **46**B and **48**B become misaligned, then less than a maximum energy transfer occurs, and the voltage V_s sensed by detection circuit **704** increases significantly. If the voltage V_s reaches a predetermined level, alignment indicator **706** is activated via an audible speaker and/or LEDs for visual feedback. After adjustment, when an optimum energy transfer condition is established, causing V_s to decrease below the predetermined threshold level, the alignment indicator **706** is turned off.

[**0116**] The elements of the external recharger are shown as a block diagram in conjunction with **FIG. 31**. The charger base station **680** receives its energy from a standard power outlet **714**, which is then converted to 5 volts DC by a AC-to-DC transformer **712**. When the recharger is placed in a charger base station **680**, the rechargable battery **672** of the recharger is fully recharged in a few hours and is able to recharge the battery **694** of the IPG **391**R. If the battery **672** of the external recharger falls below a prescribed limit of 2.5 volt DC, the battery **672** is trickle charged until the voltage is above the prescribed limit, and then at that point resumes a normal charging process.

[**0117**] As also shown in **FIG. 31**, a battery protection circuit **718** monitors the voltage condition, and disconnects the battery **672** through one of the FET switches **716**, **720** if a fault occurs until a normal condition returns. A fuse **724** will disconnect the battery **672** should the charging or discharging current exceed a prescribed amount.

[**0118**] Referring now to **FIG. 32A**, the implanted lead component of the system is similar to cardiac pacemaker leads, except for distal portion (or electrode end) of the lead. This figure depicts a lead with tripolar electrodes **62**,**61**,**63** for stimulation and/or blocking. **FIG. 32B** shows a lead with multiple pairs of electrodes (**63**, **62**, **61**). Different electrodes or electrode pairs are used for blocking or for stimulation, as directed by logic and control unit **673** of rechargeable implantable pulse generator **691**R. An alternative embodiment with a pair of electrodes **61**, **62** is also shown in **FIG. 32C**. The lead terminal preferably is linear bipolar, even though it can be bifurcated, and plug(s) into the cavity of the pulse generator means. The lead body **59** insulation may be constructed of medical grade silicone, silicone reinforced with polytetrafluoro-ethylene (PTFE), or polyurethane. The electrodes **61**,**62**,**63** for stimulating/blocking the vagus nerve **54** may either wrap around the nerve or may be adapted to be in contact with tissue to be blocked/stimulated. These stimulating electrodes may be made of pure platinum, platinum/Iridium alloy or platinum/iridium coated with titanium nitride. The conductor connecting the terminal to the electrodes **61**,**62** is made of an alloy of nickel-cobalt. The implanted lead design variables are also summarized in table four below.

TABLE 4

Lead design variables					
Proximal End					Distal End
Lead Terminal	Lead body-Insulation Materials	Lead-Coating	Conductor (connecting proximal and distal ends)	Electrode - Material	Electrode - Type
Linear bipolar	Polyurethane	Antimicrobial coating	Alloy of Nickel-Cobalt	Pure Platinum	Wrap-around electrodes
Bifurcated	Silicone	Anti-Inflammatory coating		Platinum-Iridium (Pt/Ir) Alloy	Standard Ball and Ring electrodes
	Silicone with Polytetrafluoroethylene (PTFE)	Lubricious coating		Pt/Ir coated with Titanium Nitride Carbon	Steroid eluting

[0119] Once the lead is fabricated, coating such as anti-microbial, anti-inflammatory, or lubricious coating may be applied to the body of the lead.

Telemetry Module

[0120] Shown in conjunction with **FIG. 33**, in one embodiment of the invention the external stimulator **42** and/or programmer **85** may comprise two-way wireless communication capabilities with a remote server, using a communication protocol such as the wireless application protocol (WAP). The purpose of the telemetry module is to enable the physician to remotely, via the wireless medium change the programs, activate, or disengage programs. Additionally, schedules of therapy programs, can be remotely transmitted and verified. Advantageously, the physician is thus able to remotely control the stimulation therapy.

[0121] **FIG. 34** is a simplified schematic showing the communication aspects between the external stimulator **42** and or programmer **85**, and the remote hand-held computer. A desktop or laptop computer can be a server **130** which is situated remotely, perhaps at a health-care provider's facility or a hospital. The data can be viewed at this facility or reviewed remotely by medical personnel on a wireless internet supported hand-held device **140**, which could be a personal data assistant (PDA), for example, a "palm-pilot" from PALM corp. (Santa Clara, Calif.), a "Visor" from Handspring Corp. (Mountain view, CA) or on a personal computer (PC) available from numerous vendors or a cell phone or a handheld device being a combination thereof. The physician or appropriate medical personnel, is able to interrogate the external stimulator **42** device and know what the device is currently programmed to, as well as, get a graphical display of the pulse train. The wireless communication with the remote server **130** and hand-held device (wireless internet supported) **140** can be achieved in all geographical locations within and outside the United States (US) that provides cell phone voice and data communication service. The pulse generation parameter data can also be viewed on the handheld devices **140**.

[0122] The telecommunications component of this invention uses Wireless Application Protocol (WAP). WAP is a set of communication protocols standardizing Internet access for wireless devices. Previously, manufacturers used different technologies to get Internet on hand-held devices. With WAP, devices and services inter-operate. WAP promotes convergence of wireless data and the Internet. The WAP Layers are Wireless Application Environment (WAE), Wireless Session Layer (WSL), Wireless Transport Layer Security (WTLS) and Wireless Transport Layer (WTP).

[0123] The WAP programming model, which is heavily based on the existing Internet programming model, is shown schematically in **FIG. 35**. Introducing a gateway function provides a mechanism for optimizing and extending this model to match the characteristics of the wireless environment. Over-the-air traffic is minimized by binary encoding/decoding of Web pages and readapting the Internet Protocol stack to accommodate the unique characteristics of a wireless medium such as call drops. Such features are facilitated with WAP.

[0124] The key components of the WAP technology, as shown in **FIG. 35**, includes 1) Wireless Mark-up Language (WML) **400** which incorporates the concept of cards and decks, where a card is a single unit of interaction with the user. A service constitutes a number of cards collected in a deck. A card can be displayed on a small screen. WML supported Web pages reside on traditional Web servers. 2) WML Script which is a scripting language, enables application modules or applets to be dynamically transmitted to the client device and allows the user interaction with these applets. 3) Microbrowser, which is a lightweight application resident on the wireless terminal that controls the user interface and interprets the WML/WMLScript content. 4) A lightweight protocol stack **402** which minimizes bandwidth requirements, guaranteeing that a broad range of wireless networks can run WAP applications. The protocol stack of WAP can comprise a set of protocols for the transport (WTP), session (WSP), and security (WTLS) layers. WSP is binary encoded and able to support header caching, thereby economizing on bandwidth requirements. WSP also compensates for high latency by allowing requests and responses to be handles asynchronously, sending before receiving the response to an earlier request. For lost data segments, perhaps due to fading or lack of coverage, WTP only retransmits lost segments using selective retransmission, thereby compensating for a less stable connection in wire-

less. The above mentioned features are industry standards adopted for wireless applications, and well known to those skilled in the art.

[0125] The presently preferred embodiment utilizes WAP, because WAP has the following advantages, 1) WAP protocol uses less than one-half the number of packets that the standard HTTP or TCP/IP Internet stack uses to deliver the same content. 2) Addressing the limited resources of the terminal, the browser, and the lightweight protocol stack are designed to make small claims on CPU and ROM. 3) Binary encoding of WML and SMLScript helps keep the RAM as small as possible. And, 4) Keeping the bearer utilization low takes account of the limited battery power of the terminal.

[0126] In this embodiment two modes of communication are possible. In the first, the server initiates an upload of the actual parameters being applied to the patient, receives these from the stimulator, and stores these in its memory, accessible to the authorized user as a dedicated content driven web page. The web page is managed with adequate security and password protection. The physician or authorized user can make alterations to the actual parameters, as available on the server, and then initiate a communication session with the stimulator device to download these parameters.

[0127] The physician is also able to set up long-term schedules of stimulation therapy for their patient population, through wireless communication with the server. The server in turn communicates these programs to the neurostimulator. Each schedule is securely maintained on the server, and is editable by the physician and can get uploaded to the patient's stimulator device at a scheduled time. Thus, therapy can be customized for each individual patient. Each device issued to a patient has a unique identification key in order to guarantee secure communication between the wireless server **130** and stimulator device **42**.

[0128] In this embodiment, two modes of communication are possible. In the first, the server initiates an upload of the actual parameters being applied to the patient, receives these from the stimulator, and stores these in its memory, accessible to the authorized user as a dedicated content driven web page. The physician or authorized user can make alterations to the actual parameters, as available on the server, and then initiate a communication session with the stimulator device to download these parameters.

[0129] Shown in conjunction with **FIG. 36**, in one embodiment, the external stimulator **42** and/or the programmer **85** may also be networked to a central collaboration computer **286** as well as other devices such as a remote computer **294**, PDA **140**, phone **141**, physician computer **143**. The interface unit **292** in this embodiment communicates with the central collaborative network **290** via landlines such as cable modem or wirelessly via the internet. A central computer **286** which has sufficient computing power and storage capability to collect and process large amounts of data, contains information regarding device history and serial number, and is in communication with the network **290**. Communication over collaboration network **290** may be effected by way of a TCP/IP connection, particularly one using the internet, as well as a PSTN, DSL, cable modem, LAN, WAN or a direct dial-up connection.

[0130] The standard components of interface unit shown in block **292** are processor **305**, storage **310**, memory **308**, transmitter/receiver **306**, and a communication device such as network interface card or modem **312**. In the preferred embodiment these components are embedded in the external stimulator **42** and can also be embedded in the programmer **85**. These can be connected to the network **290** through appropriate security measures (Firewall) **293**.

[0131] Another type of remote unit that may be accessed via central collaborative network **290** is remote computer **294**. This remote computer **294** may be used by an appropriate attending physician to instruct or interact with interface unit **292**, for example, instructing interface unit **292** to send instruction downloaded from central computer **286** to remote implanted unit.

[0132] Shown in conjunction with **FIG. 37A** the physician's remote communication's module is a Modified PDA/Phone **140** in this embodiment. The Modified PDA/Phone **140** is a microprocessor based device as shown in a simplified block diagram in **FIGS. 37A and 37B**. The PDA/Phone **140** is configured to accept PCM/CIA cards specially configured to fulfill the role of communication module **292** of the present invention. The Modified PDA/Phone **140** may operate under any of the useful software including Microsoft Window's based, Linux, Palm OS, Java OS, SYMBIAN, or the like.

[0133] The telemetry module **362** comprises an RF telemetry antenna **142** coupled to a telemetry transceiver and antenna driver circuit board which includes a telemetry transmitter and telemetry receiver. The telemetry transmitter and receiver are coupled to control circuitry and registers, operated under the control of microprocessor **364**. Similarly, within stimulator a telemetry antenna **142** is coupled to a telemetry transceiver comprising RF telemetry transmitter and receiver circuit. This circuit is coupled to control circuitry and registers operated under the control of microcomputer circuit.

[0134] With reference to the telecommunications aspects of the invention, the communication and data exchange between Modified PDA/Phone **140** and external stimulator **42** operates on commercially available frequency bands. The 2.4-to-2.4853 GHz bands or 5.15 and 5.825 GHz, are the two unlicensed areas of the spectrum, and set aside for industrial, scientific, and medical (ISM) uses. Most of the technology today including this invention, use either the 2.4 or 5 GHz radio bands and spread-spectrum technology.

[0135] The telecommunications technology, especially the wireless internet technology, which this invention utilizes in one embodiment, is constantly improving and evolving at a rapid pace, due to advances in RF and chip technology as well as software development. Therefore, one of the intents of this invention is to utilize "state of the art" technology available for data communication between Modified PDA/Phone **140** and external stimulator **42**. The intent of this invention is to use 3G technology for wireless communication and data exchange, even though in some cases 2.5G is being used currently.

[0136] For the system of the current invention, the use of any of the "3G" technologies for communication for the Modified PDA/Phone **140**, is considered within the scope of the invention. Further, it will be evident to one of ordinary skill in the art that as future 4G systems, which will include new technologies such as improved modulation and smart

antennas, can be easily incorporated into the system and method of current invention, and are also considered within the scope of the invention.

What is claimed is:

1. A method of providing electrical pulses with rechargeable implantable pulse generator for nerve blocking with or without selective electrical stimulation of vagus nerve(s) or its branches or part thereof for treating, controlling, or alleviating the symptoms for at least one of obesity, motility disorders, eating disorders, inducing weight loss, FGIDs, gastroparesis, gastro-esophageal reflex disease (GERD), pancreatitis, and ileus, comprising the steps of:

providing said rechargeable implantable pulse generator, comprising a microcontroller, pulse generation circuitry, rechargeable battery, battery recharging circuitry, and a coil;

providing a lead with at least two electrodes adapted to be in contact with said nerve tissue, and in electrical contact with said rechargeable implantable pulse generator;

providing an external power source to charge said rechargeable implantable pulse generator; and

providing an external programmer to program said rechargeable implantable pulse generator.

2. A method of claim 1, wherein said nerve blocking comprises selective blocking of nerve impulses of a vagus nerve(s), its branch(es) or part thereof, at one or more sites with said electrical pulses.

3. A method of claim 1, wherein said electrical pulses are for at least one of afferent block, efferent block, or organ block.

4. A method of claim 1, wherein nerve blocking may also be provided to alleviate the side effects of nerve stimulation therapy.

5. A method of claim 1, wherein said nerve blocking comprises at least one from a group consisting of: DC or anodal block, Wedenski block, and Collision block.

6. A method of claim 1, wherein said rechargeable implantable pulse generator further comprises stimulus-receiver means such that, said implantable rechargeable pulse generator can also function in conjunction with an external stimulator, to provide said electrical pulses for said nerve blocking and/or stimulation.

7. A method of claim 1, wherein said external power source to recharge said rechargeable implantable pulse generator can be an external re-charger or an external stimulator.

8. A method of claim 1, wherein said coil used in recharging said pulse generator is around said implantable rechargeable pulse generator case in a silicone enclosure.

9. A method of claim 1, wherein said rechargeable implanted pulse generator further comprises one or two feed-through(s) for externalizing coils, for unipolar or bipolar configurations respectively.

10. A method of claim 1, wherein said at least two electrodes are made of a material selected from the group consisting of platinum, platinum/iridium alloy, platinum/iridium alloy coated with titanium nitride, and carbon.

11. A method of claim 1, wherein said rechargeable battery comprises at least one of lithium-ion, lithium-ion polymer batteries.

12. A method of claim 1, wherein said rechargeable implanted pulse generator is adapted to be remotely interrogated and/or programmed over a wide area network by an external interface means.

13. A method of providing electrical pulses with rechargeable implantable pulse generator for vagal blocking with or without selective vagal stimulation for treating or alleviating the symptoms for at least one of obesity, eating disorders, inducing weight loss, FGIDs, gastroparesis, gastro-esophageal reflex disease (GERD), pancreatitis, and ileus, comprising the steps of:

providing an implantable rechargeable pulse generator, wherein said implantable rechargeable pulse generator comprises a stimulus-receiver means, and an implantable pulse generator means comprising a microcontroller, pulse generation circuitry, rechargeable battery, and battery recharging circuitry;

providing a lead with at least two electrodes adapted to be in contact with said vagus nerve(s) or its branches or part thereof, and in electrical contact with said implantable rechargeable pulse generator;

providing an external power source to charge rechargeable implantable pulse generator; and

providing an external programmer to program the said rechargeable implantable pulse generator.

14. A method of claim 13, wherein said rechargeable implantable pulse generator can function in conjunction with an external stimulator, to provide said blocking to said vagus nerve(s) and/or its branches with or without said selective stimulation.

15. A method of claim 13, wherein said coil used in recharging said pulse generator is around said rechargeable implantable pulse generator case in a silicone enclosure.

16. A method of claim 13, wherein said rechargeable battery comprises at least one of lithium-ion, lithium-ion polymer batteries.

17. A system for providing electrical pulses with rechargeable implantable pulse generator for nerve blocking with or without selective electrical stimulation of vagus nerve(s) or its branches or part thereof for treating, controlling, or alleviating the symptoms for at least one of obesity, motility disorders, eating disorders, inducing weight loss, FGIDs, gastroparesis, gastro-esophageal reflex disease (GERD), pancreatitis, and ileus, comprising:

a rechargeable implantable pulse generator, comprising, a microprocessor, pulse generation circuitry, rechargeable battery, battery recharging circuitry, and a coil;

a lead with at least two electrodes adapted to be in contact with said nerve tissue and in electrical contact with said implantable rechargeable pulse generator;

an external power source to charge said rechargeable implantable pulse generator; and

an external programmer to program said rechargeable implantable pulse generator.

18. A system of claim 17, wherein said nerve blocking comprises at least one from a group consisting of: DC or anodal block, Wedenski block, and Collision block.

19. A system of claim 17, wherein said coil is used for bidirectional telemetry, or receiving electrical pulses from said external stimulator.

20. A system of claim 17, wherein said coil used in recharging said pulse generator is around said rechargeable implantable pulse generator case in a silicone enclosure.

21. A system of claim 17, wherein said rechargeable implanted pulse generator further comprises one or two feed-through(s) for externalizing coils, for unipolar or bipolar configurations respectively.

22. A system of claim 17, wherein said implantable rechargeable pulse generator further comprises stimulus receiver means such that said implantable rechargeable pulse generator can also function in conjunction with an external stimulator, to provide said blocking with or without stimulation to said vagus nerve(s) and/or its branches.

23. A system of claim 17, wherein said at least two electrodes are made of a material selected from the group consisting of platinum, platinum/iridium alloy, platinum/iridium alloy coated with titanium nitride, and carbon.

24. A system of claim 17, wherein said rechargeable battery comprises at least one of lithium-ion, lithium-ion polymer batteries.

25. A system of claim 17, wherein said rechargeable implanted pulse generator is adapted to be remotely interrogated and/or programmed over a wide area network by an external interface means.

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