A method and system for providing electrical pulses to vagal nerve(s) using rechargeable implantable pulse generator for stimulation and/or blocking to provide therapy for neurological and neuropsychiatric disorders comprises implantable and external components. These disorders include (but are not limited to) epilepsy, partial complex epilepsy, generalized epilepsy, and involuntary movement disorders such as Parkinson’s disease, depression, bipolar depression, schizophrenia, anxiety disorders, neurogenic/psychogenic pain, compulsive eating disorders, obesity, obsessive compulsive disorders, dementia including Alzheimer’s disease, sleep disorders, learning difficulties, migraines and cardiac disorders such as atrial fibrillation and congestive heart failure (CHF). The implantable components are a lead and an implantable pulse generator, comprising rechargeable 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. The implanted stimulus-receiver is adapted to work in conjunction with an external stimulator. In another embodiment, the implanted pulse generator is adapted to be rechargeable, utilizing inductive coupling with an external recharger. Existing vagal nerve stimulators may also be adapted to be used with rechargeable power sources as disclosed herein. The implanted system may also use a lead with two or more electrodes, for vagus nerve(s) modulation with selective stimulation and/or blocking.
FIG. 1

- Nerve fibers
- Endoneurium
- Perineurium
- Epineurium
<table>
<thead>
<tr>
<th>Axons from skin</th>
<th>Axons from muscles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aₓ</td>
<td>Aβ</td>
</tr>
<tr>
<td>Group I</td>
<td>II</td>
</tr>
<tr>
<td>Diameter (µm)</td>
<td>13-20</td>
</tr>
<tr>
<td>Speed (m/sec)</td>
<td>80-120</td>
</tr>
<tr>
<td>Sensory receptors</td>
<td>Proprioceptors of skeletal muscle</td>
</tr>
</tbody>
</table>

**FIG. 2**
MEMBRANE PROTEINS
OUTSIDE

LIPID BILAYER

INSIDE

FIG. 3 A

AQUEOUS PORE

CHANNEL SUBUNITS

LIPID BILAYER

FIG. 3 B
FIG 4
FIG. 7
FIG. 8

Myelinated axon

Non-myelinated axon

Active site
Excite state

FIG. 9
HYPOTHALAMUS

FIG. 15B

RIGHT VAGUS NERVE

LEFT VAGUS NERVE

DEEP CARDIAC PLEXUS

LEFT GASTRIC NERVE

FIG. 15 A
Energy density

**FIG. 20A**

Cell voltage

**FIG. 20B**
METHOD AND SYSTEM FOR PROVIDING ELECTRICAL PULSES FOR NEUROMODULATION OF VAGUS NERVE(S), USING RECHARGEABLE IMPLANTED PULSE GENERATOR

[0001] This application is a continuation of application Ser. No. 10/841,995 filed May 8, 2004, entitled "METHOD AND SYSTEM FOR MODULATING THE VAGUS NERVE (10th CRANIAL NERVE) WITH ELECTRICAL PULSES USING IMPLANTED AND EXTERNAL COMPONENTS, PROVIDE THERAPY FOR NEUROLOGICAL AND NEUROPSYCHIATRIC DISORDERS", which is a continuation of application Ser. No. 10/196,533 filed Jul. 16, 2002, which is a continuation of 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] The present invention relates to electrical stimulation with implanted medical device, more specifically to neuromodulation of vagus nerve(s) with rechargeable implantable pulse generator, to provide therapy for neurological, neuropsychiatric, and other medical disorders.

BACKGROUND

[0003] Implantable neuromodulation systems are known in the art. This patent application is directed to novel method and system for increasing the useful service life of nerve stimulators which are used for applications that can be demanding on the power source. The implantable neurostimulation system for modulating vagus nerve(s) is used to provide therapy for neurological, neuropsychiatric, and other medical disorders such as obesity, and certain cardiac disorders such as atrial fibrillation and congestive heart failure (CHF). Vagus nerve neuromodulation systems generally fall into two categories, RF coupled devices and implantable pulse generators (IPG).

[0004] U.S. Pat. No. 6,205,359 (Boveja), U.S. Pat. No. 6,356,788 (Boveja), U.S. Pat. No. 6,208,902 (Boveja), U.S. Pat. No. 6,269,270 (Boveja), U.S. Pat. No. 6,611,715 (Boveja), and U.S. Pat. No. 6,668,191 (Boveja) are generally directed to neuromodulating vagus nerve(s) with an RF coupled device. U.S. Patents, U.S. Pat. No. 4,702,254 (Zabara), U.S. Pat. No. 5,023,807 (Zabara), and U.S. Pat. No. 4,867,164 (Zabara) are generally directed to neuromodulation of vagus nerve, preferably using an implantable pulse generator (IPG).

[0005] The prior art IPG devices are similar to cardiac pacemakers, and have been adapted to deliver pulses at higher frequencies than cardiac pacemakers. In cardiac pacing, pulses are typically delivered at a rate of approximately one Hz (generally 50-70 beats per min.). In contrast, pulses to vagus nerve(s) are typically delivered at frequency of about 20-50 Hz. Electrical pulse neuromodulation of vagus nerve(s) can be very demanding for an implantable power source. It would be desirable to have an implantable pulse generator comprising a rechargeable power source, such as rechargeable Li-ion battery or re-chargeable Li-ion polymer battery.

[0006] This patent application discloses two embodiments of implantable pulse generator comprising rechargeable batteries. Even a rechargeable implanted pulse generator does not have an indefinite life, therefore in order to enhance the service life, in one embodiment the implanted pulse generator may comprise stimulus-receiver means, and a pulse generator means with rechargeable battery. The implanted pulse generator of this embodiment is also adapted to function in conjunction with an external stimulator. In another embodiment, the implanted pulse generator is adapted to be rechargeable, utilizing inductive coupling with an external recharger. Existing vagal nerve stimulators may also be adapted to be used with rechargeable power sources as disclosed herein.

Background of Neuromodulation

[0007] The 10th cranial nerve or the vagus nerve plays a role in mediating afferent information from visceral organs to 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. The vagus nerve provides an easily accessible, peripheral route to modulate central nervous system (CNS) function. Observations on the profound effect of electrical stimulation of the vagus nerve on central nervous system (CNS) activity extends back to the 1930’s.

[0008] The present invention is primarily directed to a method and system for selective electrical stimulation and/or blocking or neuromodulation of vagus nerve, for providing adjunct therapy for neurological and neuropsychiatric disorders comprises at least one of epilepsy, partial complex epilepsy, generalized epilepsy, and involuntary movement disorders such as in Parkinson’s disease, depression, bipolar depression, schizophrenia, anxiety disorders, neurogenic/pyscogenic pain, compulsive eating disorders, obesity, obsessive compulsive disorders, dementia including Alzheimers disease, sleep disorders, learning difficulties, migraines and cardiac disorders such as atrial fibrillation and congestive heart failure(CHF).

[0009] In the human body there are two vagal nerves (VN), the right VN and the left VN. Each vagus nerve is encased in the carotid sheath along with the carotid artery and jugular vein. The innervation of the right and left vagus nerves is different. The innervation of the right vagus nerve is such that stimulating it results in profound bradycardia (slowing of the heart rate). The left vagus nerve has some innervation to the heart, but mostly innervates the visceral organs such as the gastrointestinal tract. It is known that stimulation of the left vagus nerve does not cause substantial slowing of the heart rate or cause any other significant deleterious side effects.

[0010] One of the fundamental features of the nervous system is its ability to generate and conduct electrical impulses. Most nerves in the human body are composed of thousands of fibers of different sizes. This is shown schematically in FIG. 1. 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.

[0011] 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. 2. 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.

[0012] 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.

[0013] Nerve cells have membranes that are composed of lipids and proteins (shown schematically in FIGS. 3A and 3B), 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 (FIG. 3A), 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.

[0014] The lipid component of the membrane is a double sheet of phospholipids, elongated molecules with polar groups at one end and the fatty acid chains at the other. The ions that carry the currents used for neuronal signaling are among these water-soluble substances, so the lipid bilayer is also an insulator, across which membrane potentials develop. In biophysical terms, the lipid bilayer is not permeable to ions. In electrical terms, it functions as a capacitor, able to store charges of opposite sign that are attracted to each other but unable to cross the membrane. Embedded in the lipid bilayer is a large assortment of proteins. These are proteins that regulate the passage of ions into or out of the cell. Certain membrane-spanning proteins allow selected ions to flow down electrical or concentration gradients or by pumping them across.

[0015] These membrane-spanning proteins consist of several subunits surrounding a central aqueous pore (shown in FIG. 3B). Ions whose size and charge “fit” the pore can diffuse through it, allowing these proteins to serve as ion channels. Hence, unlike the lipid bilayer, ion channels have an appreciable permeability (or conductance) to at least some ions. In electrical terms, they function as resistors, allowing a predictable amount of current flow in response to a voltage across them.

[0016] 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. As shown in FIG. 4, stimuli 4 and 5 are subthreshold, and do not induce a response. Stimulus 6 exceeds a threshold value and induces an action potential (AP) which will be propagated. The threshold stimulus intensity is defined as that 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.

[0017] FIG. 5A illustrates a segment of the surface of the membrane of an excitable cell. Metabolic activity maintains ionic gradients across the membrane, resulting in a high concentration of potassium (K⁺) ions inside the cell and a high concentration of sodium (Na⁺) ions in the extracellular environment. The net result of the ionic gradient is a transmembrane potential that is largely dependent on the K⁺ gradient. Typically in nerve cells, the resting membrane potential (RMP) is slightly less than 90 mV, with the outside being positive with respect to inside.

[0018] 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 (TP); Which is shown in FIG. 5B. When the threshold potential (TP) 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).

[0019] For a stimulus to be effective in producing an excitation, it must have an abrupt onset, be intense enough, and last long enough. These facts can be drawn together by considering the delivery of a suddenly rising cathodal constant-current stimulus of duration d to the cell membrane as shown in FIG. 5B.

[0020] Cell membranes can be reasonably well represented by a capacitance C, shunted by a resistance R as shown by a simplified electrical model in diagram 5C, and shown in a more realistic electrical model in FIG. 6, 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).

[0021] When the stimulation pulse is strong enough, an action potential will be generated and propagated. As shown in FIG. 7, 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 impor-
tant 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.

[A0022] A single electrical impulse passing down an axon is shown schematically in FIG. 8. The top portion of the figure (A) shows conduction over myelinated axon (fiber) and the bottom portion (B) shows conduction over nonmyelinated axon (fiber). These electrical signals will travel along the nerve fibers.

[A0023] The information in the nervous system is coded by frequency of firing rather than the size of the action potential. This is shown schematically in FIG. 9. The bottom portion of the figure shows a train of action potentials.

[A0024] 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 wide 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.

[A0025] As shown in FIG. 10A, 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 below.

<table>
<thead>
<tr>
<th>Fiber Type</th>
<th>Conduction Velocity (m/sec)</th>
<th>Fiber Diameter (μm)</th>
<th>Myelination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpha</td>
<td>70–120</td>
<td>12–20</td>
<td>Yes</td>
</tr>
<tr>
<td>Beta</td>
<td>40–70</td>
<td>5–12</td>
<td>Yes</td>
</tr>
<tr>
<td>Gamma</td>
<td>10–50</td>
<td>3–6</td>
<td>Yes</td>
</tr>
<tr>
<td>Delta</td>
<td>6–30</td>
<td>2–5</td>
<td>Yes</td>
</tr>
<tr>
<td>B Fibers</td>
<td>5–15</td>
<td>&lt;2</td>
<td>Yes</td>
</tr>
<tr>
<td>C Fibers</td>
<td>0.5–2.0</td>
<td>0.4–1.2</td>
<td>No</td>
</tr>
</tbody>
</table>

[B0026] FIG. 10B further clarifies the differences in action potential conduction velocities between the Aβ-fibers and the C-fibers. For many of the application of current patent application, it is the slow conduction C-fibers that are stimulated by the pulse generator.

[B0027] The modulation of nerve in the periphery, as done by the body, in response to different types of pain is illustrated schematically in FIGS. 11 and 12. As shown schematically in FIG. 11, the electrical impulses in response to acute pain sensations are transmitted to brain through peripheral nerve and the spinal cord. The first-order peripheral neurons at the point of injury transmit a signal along A-type nerve fibers to the dorsal horns of the spinal cord. Here the second-order neurons take over, transfer the signal to the other side of the spinal cord, and pass it through the spinothalamic tracts to thalamus of the brain. As shown in FIG. 12, duller and more persistent pain travel by another-slower route using unmyelinated C-fibers. This route made up from a chain of interconnected neurons, which run up the spinal cord to connect with the brainstem, the thalamus and finally the cerebral cortex. The autonomic nervous system also senses pain and transmits signals to the brain using a similar route to that for dull pain.

[B0028] Vagus nerve stimulation with or without blocking, as performed by the system and method of the current patent application, is a means of directly affecting central function. FIG. 13 shows cranial nerves having bothafferent 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 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).

[B0029] The vagus nerve is composed of somatic and visceral afferents and efferents. Usually, nerve stimulation activates signals in both directions (bi-directionally). It is possible however, through the use of special electrodes and waveforms, to selectively stimulate a nerve in one direction only (unidirectionally). The vast majority of vagus nerve fibers are C fibers, and a majority are visceral afferents having cell bodies lying in masses or ganglia in the skull.

[B0030] In considering the anatomy, 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 (visceral 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).

[B0031] As shown in FIG. 14, the vagus nerve emerges from the medulla of the brain stem dorsal to the olive as eight to ten rootlets. These rootlets converge into a flat cord that exits the skull through the jugular foramen. Exiting the jugular foramen, the vagus nerve enlarges into a second swelling, the inferior ganglion.

[B0032] In the neck, the vagus lies in a groove between the internal jugular vein and the internal carotid artery. It descends vertically within the carotid sheath, giving off branches to the pharynx, larynx, and constrictor muscles. From the root of the neck downward, the vagus nerve takes a different path on each side of the body to reach the cardiac, pulmonary, and esophageal plexus (consisting of both sym-
pathetic and parasympathetic axons). From the esophageal plexus, right and left gastric nerves arise to supply the abdominal viscera as far caudal as the splenic flexure.

[0033] In the body, the vagus nerve regulates viscera, swallowing, speech, and taste. It has sensory, motor, and parasympathetic components. Table two below outlines the innervation and function of these components.

<table>
<thead>
<tr>
<th>TABLE 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vagus Nerve Components</strong></td>
</tr>
<tr>
<td>Component fibers</td>
</tr>
<tr>
<td>SENSORY</td>
</tr>
<tr>
<td>MOTOR</td>
</tr>
<tr>
<td>PARASYMPATHETIC</td>
</tr>
</tbody>
</table>

[0034] On the Afferent side, visceral sensation is carried in the visceral sensory component of the vagus nerve. As shown in FIGS. 15A and 15B, visceral sensory fibers from plexus around the abdominal viscera converge and join with the right and left gastric nerves of the vagus. These nerves pass upward through the esophageal hiatus (opening) of the diaphragm to merge with the plexus of nerves around the esophagus. Sensory fibers from plexus around the heart and lungs also converge with the esophageal plexus and continue up through the thorax in the right and left vagus nerves. As shown in FIG. 15B, the central process of the nerve cell bodies in the inferior vagal ganglion enter the medulla and descend in the tractus solitarius to enter the caudal part of the nucleus of the tractus solitarius. From the nucleus, bilateral connections important in the reflex control of cardiovascular, respiratory, and gastrointestinal functions are made with several areas of the reticular formation and the hypothalamus.

[0035] The afferent fibers project primarily to the nucleus of the solitary tract (shown schematically in FIGS. 16 and 17) which extends throughout the length of the medulla oblongata. A small number of fibers pass directly to the spinal trigeminal nucleus and the reticular formation. As shown in FIG. 16, the nucleus of the solitary tract has widespread projections to cerebral cortex, basal forebrain, thalamus, hypothalamus, amygdala, hippocampus, dorsal raphe, and cerebellum. Because of the widespread projections of the Nucleus of the Solitary Tract, neuromodulation of the vagal afferent nerve fibers produce alleviation of symptoms of the neurological and neuropsychiatric disorders covered in this patent application, such as epilepsy, depression, involuntary movement disorders including Parkinson’s disease, anxiety disorders, neurogenic pain, psychogenic pain, obsessive compulsive disorders, migraines, obesity, dementia including Alzheimer’s disease, and the like.

PRIOR ART

[0036] U.S. Pat. Nos. 4,702,254, 4,867,164 and 5,025,807 (Zabara) generally disclose animal research and experimentation related to epilepsy and the like. Applicant’s method of neuromodulation is significantly different than that disclosed in Zabara ‘254, ‘164 and ‘807 patents.

[0037] U.S. Pat. No. 5,299,569 (Wernicke et al) is directed to the use of implantable pulse generator technology for treating and controlling neuropsychiatric disorders including schizophrenia, depression, and borderline personality disorder.

[0038] U.S. Pat. No. 6,205,359 B1 (Boveja) and U.S. Pat. No. 6,356,788 B2 (Boveja) are directed to adjunct therapy for neurological and neuropsychiatric disorders using an implanted lead-receiver and an external stimulator.

[0039] U.S. Pat. No. 5,807,397 (Barreras) is directed to an implantable stimulator with replenishable, high value capacitive power source.

[0040] U.S. Pat. No. 5,193,539 (Schulman, et al) is generally directed to an addressable, implantable microstimulator that is of size and shape which is capable of being implanted by expulsion through a hypodermic needle. In the Schulman patent, up to 256 microstimulators may be implanted within a muscle and they can be used to stimulate in any order as each one is addressable, thereby providing therapy for muscle paralysis.

[0041] 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 combining a stimulus-receiver module to an implantable pulse generator (IPG) for use with an external stimulator, for providing modulating pulses to vagal nerve(s), as in the applicant’s disclosure.

[0042] 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.

[0043] U.S. Pat. No. 6,622,041 B2 (Terry, Jr. et al) is directed to treatment of congestive heart failure and autonomic cardiovascular drive disorders using implantable neurostimulator.

SUMMARY OF THE INVENTION

[0044] Method and system of the current invention provides vagal nerve(s) neuromodulation to provide therapy for at least one of epilepsy, partial complex epilepsy, generalized epilepsy, and involuntary movement disorders such as in Parkinson’s disease, depression, bipolar depression, schizophrenia, anxiety disorders, neurogenic/psychogenic pain, compulsive eating disorders, obesity, obsessive compulsive disorders, dementia including Alzheimer’s disease, sleep disorders, learning difficulties, migraines and cardiac disorders such as atrial fibrillation and congestive heart failure (CHF). The method and system comprises both implantable and external components.

[0045] In one aspect of the invention, the method and system for modulating vagal nerve(s) comprises implantable pulse generator with rechargeable battery, and battery charging circuitry. The charging of the implantable battery being performed by an external charger via an inductive link.
In another aspect of the invention, one embodiment of the implanted pulse generator comprises, a stimulus-receiver module that can be used in conjunction with an external stimulator, and an implanted pulse generator module with rechargeable battery.

In another aspect of the invention, the implantable pulse generator with rechargeable battery is connected to an implanted lead with at least two electrodes for providing stimulation and/or blocking pulses to vagal nerve(s).

In another aspect of the invention, the recharge coil is externalized from the titanium case and is wrapped around the titanium case in an epoxy header, thereby eliminating the need for a magnetic shield.

In another aspect of the invention, the recharge coil is also used for bi-directional telemetry.

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

In another aspect of the invention, the lead comprises at least two electrodes which are made of one from a group consisting of platinum, platinum/iridium alloy, platinum/iridium alloy coated with titanium nitride, and carbon.

In another aspect of the invention, the selective stimulation and/or blocking to vagus nerve(s) may be anywhere along the length of the nerve, for example such stimulation may be at the cervical level or at a level near the diaphragm.

In another aspect of the invention, the stimulation and/or blocking may be unilateral or bilateral.

In another aspect of the invention, the implanted lead body may be made of a material selected from the group consisting of polyurethane, silicone, and silicone with polytetrafluoroethylene.

In yet another aspect of the invention, the implanted lead comprises at least two electrodes selected from the group consisting of spiral electrodes, cuff electrodes, steroid eluting electrodes, wrap-around electrodes, and hydrogel electrodes.

Various other features, objects and advantages of the invention will be made apparent from the following description taken together with the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

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.

FIG. 1 is a diagram of the structure of a nerve.

FIG. 2 is a diagram showing different types of nerve fibers.

FIGS. 3A and 3B are schematic illustrations of the biochemical makeup of nerve cell membrane.

FIG. 4 is a figure demonstrating subthreshold and suprathreshold stimuli.

FIGS. 5A, 5B, 5C are schematic illustrations of the electrical properties of nerve cell membrane.

FIG. 6 is a schematic illustration of electrical circuit model of nerve cell membrane.

FIG. 7 is an illustration of propagation of action potential in nerve cell membrane.

FIG. 8 is an illustration showing propagation of action potential along a myelinated axon and non-myelinated axon.

FIG. 9 is an illustration showing a train of action potentials.

FIG. 10A is a diagram showing recordings of compound action potentials.

FIG. 10B is a schematic diagram showing conduction of first pain and second pain.

FIG. 11 is a schematic illustration showing mild stimulation being carried over the large diameter A-fibers.

FIG. 12 is a schematic illustration showing painful stimulation being carried over small diameter C-fibers.

FIG. 13 is a schematic diagram of the peculiarities of afferent and efferent pathways.

FIG. 14 is a schematic diagram showing the vagus nerve at the level of the nucleus of the solitary tract.

FIG. 15A is a schematic diagram showing the thoracic and visceral innervations of the vagal nerves.

FIG. 15B is a schematic diagram of the medullary section of the brain.

FIG. 16 is a simplified block diagram illustrating the connections of solitary tract nucleus to other centers of the brain.

FIG. 17 is a schematic diagram of brain showing the relationship of the solitary tract nucleus to other centers of the brain.

FIG. 18 is a simplified general block diagram of an implantable pulse generator.

FIG. 19A shows the pulse train transmitted to the vagus nerve(s).

FIG. 19B shows the ramp-up and ramp-down characteristic of the pulse train.

FIG. 20A shows energy density of different types of batteries.

FIG. 20B shows discharge curves for different types of batteries.

FIG. 21 shows a block diagram of an implantable stimulator which can be used as a stimulus-receiver or an implanted pulse generator with rechargeable battery.

FIG. 22 is a block diagram highlighting battery charging circuit of the implantable stimulator of FIG. 21.

FIG. 23 is a schematic diagram highlighting stimulus-receiver portion of implanted stimulator of one embodiment.

FIG. 24 depicts externalizing recharge and telemetry coil from the titanium case.
FIG. 25A depicts coil around the titanium case with two feedthroughs for a bipolar configuration.

FIG. 25B depicts coil around the titanium case with one feedthrough for a unipolar configuration.

FIG. 25C depicts two feedthroughs for the external coil which are common with the feedthroughs for the lead terminal.

FIG. 25D depicts one feedthrough for the external coil which is common to the feedthrough for the lead terminal.

FIGS. 26A and 26B depict recharge coil on the titanium case with a magnetic shield in-between.

FIG. 27 shows in block diagram form an implantable rechargeable pulse generator.

FIG. 28 depicts in block diagram form the implanted and external components of an implanted rechargeable system.

FIG. 29 depicts the alignment function of rechargeable implantable pulse generator.

FIG. 30 is a block diagram of the external recharger.

FIG. 31 depicts an implantable system with tri-polar lead for selective unidirectional blocking of vagus nerve(s) stimulation.

FIG. 32 depicts selective efferent blocking in the large diameter A and B fibers.

FIG. 33 depicts unilateral stimulation of vagus nerve at near the diaphragm level.

FIG. 34 depicts bilateral stimulation of vagus nerves with one stimulator.

FIG. 35 is a schematic diagram of the implantable lead with two electrodes.

FIG. 36 is a schematic diagram of the implantable lead with three electrodes.

**DETAILED DESCRIPTION OF THE INVENTION**

The pulses delivered to the nerve tissue for stimulation therapy are shown graphically in FIG. 19A. As shown in FIG. 19B, for patient comfort when the electrical stimulation is turned on, the electrical stimulation may be ramped up and ramped down, instead of abrupt delivery of electrical pulses.

Because of the rapidity of the pulses required for modulating nerve tissue (unlike cardiac pacing), 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. 20A 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. 20B, 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 developments in rechargeable 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.

For the practice of the current invention, two embodiments of implantable pulse generators may be used. Both embodiments comprise rechargeable power sources, such as Lithium-ion polymer battery.

In one embodiment, the implanted device 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 coupled with an implanted stimulus-receiver, or the power source can be from the implanted rechargeable battery. Shown in conjunction with FIG. 21 is a simplified overall block diagram of this embodiment. A coil 48C 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 48C may be externalized at the header portion 79C of the implanted
device, and may be wrapped around the titanium can, eliminating the need for a magnetic shield. In this case, the coil is encased in the same material as the header 79C. Alternatively, the coil may be positioned on the titanium case, with a magnetic shield.

[0107] In this embodiment, as disclosed in FIG. 21, the IPG circuitry within the titanium case is used for all stimulation pulses whether the energy source is the internal 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. An external stimulator and recharger may also be combined within the same enclosure. For programming, the energy is sent as high frequency sine waves with superimposed telemetry wave driving the external coil 46C. 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 48C 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.

[0108] The system of this embodiment 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 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.

[0109] Shown in conjunction with FIG. 22, this embodiment of the invention is practiced with a rechargeable battery. 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.

[0110] The stimulus-receiver portion of the circuitry is shown in conjunction with FIG. 23. Capacitor C1 (729) makes the combination of C1 and L1 sensitive to the resonant frequency and less sensitive to other frequencies, and energy from an external (primary) coil 46C is inductively transferred to the implanted unit via the secondary coil 48C. The AC signal is rectified DC via diode 731, and filtered via capacitor 733. A regulator 735 sets the output voltage and limits it to a value just above the maximum IPG cell voltage. The output capacitor C4 (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 FIG. 23, a capacitor C3 (727) couples signals for forward and back telemetry.

[0111] In another embodiment, existing nerve stimulators and cardiac pacemakers can be modified to incorporate rechargeable batteries. Among the nerve stimulators that can be adopted with rechargeable batteries can for example be the vagus nerve stimulator manufactured by Cyberonics Inc. (Houston, Tex.). U.S. Pat. No. 4,702,254 (Zabara), U.S. Pat. No. 5,023,807 (Zabara), and U.S. Pat. No. 4,867,164 (Zabara) on Neurocybernetic Prostheses, which can be practiced with rechargeable power source as disclosed in the next section. These patents are incorporated herein by reference.

[0112] As shown in conjunction with FIG. 24, in both embodiments, the coil is externalized from the titanium case 57. The RF pulses transmitted via coil 46 and received via subcutaneous coil 48A 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 48C may be externalized at the header portion 79 of the implanted device, and may be wrapped around the titanium can, as shown in FIGS. 25A and 25B. Shown in FIG. 25A is a bipolar configuration which requires two feedthroughs 76,77. Advantageously, as shown in FIG. 25B 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. 25C and 25D, 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.

[0113] In one embodiment, the coil may also be positioned on the titanium case as shown in conjunction with FIGS. 26A and 26B. FIG. 26A shows a diagram of the finished implantable stimulator 391 R of one embodiment. FIG. 26B shows the pulse generator with some of the components used in assembly in an exploded view. These components include a coil cover 7, 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 13 located between the coil assembly and the feed through for positioning the electrical connection. The positioning detail 13 secures the electrical connection.

[0114] A schematic diagram of the implanted pulse generator (IPG 391 R), with re-chargeable battery 694, is shown in conjunction with FIG. 27. 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. Stimulation pulses are provided to the nerve tissue 54 via output circuitry 677 controlled by the microcontroller.

[0115] 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- or lithium-ion polymer battery. Recharging occurs inductively from an external charger to an implanted coil 48B under the skin 60. The rechargeable battery 694 may be recharged repeatedly as needed. Additionally, the IPG 391R is able to monitor and telemeter the status of its rechargeable battery 691 each time a communication link is established with an external programmer 85.

[0116] 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 a titanium and is shaped in a rounded case.
Shown in conjunction with FIG. 28 are the recharging elements of the invention. The re-charging 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 re-charger receives energy from a battery 672 in the re-charger. 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 46B and an implanted coil 48B located subcutaneously with the implanted pulse generator (IPG) 391 R. The AC signal received via implanted coil 48B is rectified 686 to a DC signal which is used for recharging the rechargeable 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 rechargeable 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 rechargeable 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. 28, 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.

A simplified block diagram of charge completion and misalignment detection circuitry is shown in conjunction with FIG. 29. 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 48B (from external coil 46B) passes through the switch rectifier 686 and charging and protection circuitry 698 to the implanted rechargeable 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.

The indicator 706 may similarly be used as a misalignment indicator. In normal operation, when coils 46B (external) and 48B (implanted) are properly aligned, the voltage V<sub>3</sub> sensed by voltage detector 704 is at a minimum level because maximum energy transfer is taking place. If and when the coils 46B and 48B become misaligned, then less than a maximum energy transfer occurs, and the voltage V<sub>3</sub> sensed by detection circuit 704 increases significantly. If the voltage V<sub>3</sub> 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<sub>3</sub> to decrease below the predetermined threshold level, the alignment indicator 706 is turned off.

The elements of the external recharger are shown as a block diagram in conjunction with FIG. 30. In this disclosure, the words charger and recharger are used interchangeably. 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 re-charger is placed in a charger base station 680, the rechargeable battery 672 of the re-charger 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 re-charger 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.

As also shown in FIG. 30, 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.

Since another key concept of this invention is to deliver afferent stimulation, in one aspect efferent stimulation of selected types of fibers may be substantially blocked, utilizing the "greenwave" effect. In such a case, as shown in conjunction with FIGS. 31 and 32, a tripolar lead is utilized. As depicted on the top right portion of FIG. 31, there is a depolarization peak 10 on the vagus nerve bundle corresponding to electrode 61 (cathode) and the two hyper-polarization peaks 8, 12 corresponding to electrodes 62, 63 (anodes). With the microcontroller controlling the tripolar device, the size and timing of the hyper-polarizations 8, 12 can be controlled. As was shown previously in FIGS. 2 and 10, since the speed of conduction is different between the larger diameter A and B fibers and the smaller diameter c-fibers, by appropriately timing the pulses, collision blocks can be created for conduction via the large diameter A and B fibers in the afferent direction. This is depicted schematically in FIG. 32. A number of blocking techniques are known in the art, such as collision blocking, high frequency blocking, and anodal blocking. Any of these well known blocking techniques may be used with the practice of this invention, and are considered within the scope of this invention.

In one aspect of the invention, the pulsed electrical stimulation and/or blocking to the vagus nerve(s) may be provided anywhere along the length of the vagus nerve(s). As was shown earlier in conjunction with FIG. 31, the pulsed electrical stimulation may be at the cervical level. Alternatively, shown in conjunction with FIG. 33, the stimulation to the vagus nerve(s) may be around the diaphragmatic level. Either above the diaphragm or below the diaphragm. Further, the stimulation may be unilateral or bilateral, i.e. stimulation is to one or both vagus nerves. FIG. 34 depicts bilateral vagal nerve stimulation at around the level of the diaphragm. Any combination of vagal nerve(s) stimulation, either unilateral or bilateral, anywhere along the length of the vagus nerve(s) is considered within the scope of this invention.
Referring now to FIG. 35, 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 shows a pair of electrodes 61,62 that are used for providing electrical pulses for stimulation. Alternatively, FIG. 36 depicts a lead with tripolar electrodes 62,61,63 for stimulation and/or blocking. 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 polytetrafluoroethylene (PTFE), or polyurethane. The electrodes 61,62 for stimulating the vagus nerve 54 may either wrap around the nerve once or may be spiral shaped. 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

<table>
<thead>
<tr>
<th>Proximal End Lead Terminal</th>
<th>Lead body-Insulation Materials</th>
<th>Conductor (connecting proximal and distal ends)</th>
<th>Electrode - Material</th>
<th>Distal End Electrode - Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linear bipolar Polyurethane</td>
<td>Antimicrobial coating</td>
<td>Alloy of Nickel-Cobalt</td>
<td>Pure Platinum</td>
<td>Spinal electrode</td>
</tr>
<tr>
<td>Bifurcated Silicone</td>
<td>Anti-Inflammatory coating</td>
<td>Platinum-iridium (Pt/Ir) Alloy</td>
<td>Wrap-around electrode</td>
<td></td>
</tr>
<tr>
<td>Silicone with Polytetrafluoroethylene (PTFE)</td>
<td>Lubricious coating</td>
<td>Pt/Ir coated with Titanium Nitride Carbon</td>
<td>Steroid eluting</td>
<td>Hydrogel electrodes Cuff electrodes</td>
</tr>
</tbody>
</table>

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

We claim:

1. A method of providing electrical pulses with a rechargeable implantable pulse generator for stimulation and/or blocking of vagus nerve(s) and/or its branches or part thereof, for treating or alleviating the symptoms for at least one of neurological, neuropsychiatric disorders, comprising the steps of:

   - providing said implantable rechargeable 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 vagus nerve(s) or its branches or part thereof, 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 neurological, neuropsychiatric disorders comprises at least one of epilepsy, partial complex epilepsy, generalized epilepsy, involuntary movement disorders such as in Parkinson's disease, depression, bipolar depression, schizophrenia, anxiety disorders, neurogenic/pyscogenic pain, compulsive eating disorders, obesity, obsessive compulsive disorders, dementia including Alzheimer's disease, sleep disorders, learning difficulties, migraines and cardiac disorders such as atrial fibrillation and congestive heart failure (CHF).

3. A method of claim 1, wherein said coil is also used for bidirectional telemetry.

4. 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.

5. A method of claim 4, wherein said implantable rechargeable pulse generator does not require magnetic shielding between said coil and said titanium case.

6. A method of claim 1, wherein said rechargeable implanted pulse generator further comprises one or two feedthrough(s) for unipolar or bipolar configurations respectively.

7. A method of claim 1, wherein said implantable rechargeable pulse generator further comprises means stimulus-receiver means such that, said implantable rechargeable pulse generator can function in conjunction with an external stimulator, to provide said stimulation and/or blocking to said vagus nerve(s) and/or its branches.

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

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

10. A method of modulating vagus nerve(s) and/or its branches or part thereof with electrical pulses for treating or alleviating the symptoms of neurological, or neuropsychiatric disorders, comprising at least one of epilepsy, partial...
complex epilepsy, generalized epilepsy, involuntary movement disorders such as in Parkinson’s disease, depression, bipolar depression, schizophrenia, anxiety disorders, neurogenic/psychogenic pain, compulsive eating disorders, obesity, obsessive compulsive disorders, dementia including Alzheimer’s disease, sleep disorders, learning difficulties, migraines and cardiac disorders such as atrial fibrillation and congestive heart failure (CHF), and further 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.

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

11. A method of claim 10, wherein said rechargeable implantable pulse generator can function in conjunction with an external stimulator, to provide said stimulation and/or blocking to said vagus nerve(s) and/or its branches.

12. A method of claim 10, wherein said coil used in recharging said pulse generator is around said implantable rechargeable pulse generator case in a silicone enclosure.

13. A method of claim 10, wherein said implantable rechargeable pulse generator can be recharged using an external recharger or an external stimulator.

14. A method of claim 10, wherein said rechargeable battery comprises at least one of lithium-ion, lithium-ion polymer batteries.

15. A vagus nerve(s) stimulation and/or blocking system for providing electrical pulses to vagus nerve(s) or its branches or part thereof for treating or alleviating the symptoms for at least one of neurological, and neuropsychiatric disorders, 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 vagus nerve(s) or its branches or part thereof 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.

16. A system of claim 15, wherein said at least one of neurological and neuropsychiatric disorders comprises at least one of epilepsy, partial complex epilepsy, generalized epilepsy, and involuntary movement disorders such as in Parkinson’s disease, depression, bipolar depression, schizophrenia, anxiety disorders, neurogenic/psychogenic pain, compulsive eating disorders, obesity, obsessive compulsive disorders, dementia including Alzheimer’s disease, sleep disorders, learning difficulties, migraines and cardiac disorders such as atrial fibrillation and congestive heart failure (CHF).

17. A system of claim 15, wherein said coil is used for bidirectional telemetry, or receiving electrical pulses from said external stimulator.

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

19. A system of claim 15, wherein said rechargeable implantable pulse generator does not require a magnetic shield between said coil and said titanium case.

20. A system of claim 15, wherein said rechargeable implantable rechargeable pulse generator does require a magnetic shield between said coil and said titanium case.

21. A system of claim 15, wherein said rechargeable implanted pulse generator further comprises one or two feedthrough(s) for unipolar or bipolar configurations respectively.

22. A system of claim 15, wherein said implantable rechargeable pulse generator further comprises means such that said implantable rechargeable pulse generator can also function in conjunction with an external stimulator, to provide said stimulation and/or blocking to said vagus nerve(s) and/or its branches.

23. A system of claim 15, wherein said at least two electrodes are 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 15, wherein said rechargeable battery comprises at least one of lithium-ion, lithium-ion polymer batteries.

25. A system for modulating the vagus nerve(s) and/or its branches or part thereof with electrical pulses, for treating or for alleviating the symptoms for at least one of epilepsy, partial complex epilepsy, generalized epilepsy, involuntary movement disorders such as in Parkinson’s disease, depression, bipolar depression, schizophrenia, anxiety disorders, neurogenic/psychogenic pain, compulsive eating disorders, obesity, obsessive compulsive disorders, dementia including Alzheimer’s disease, sleep disorders, learning difficulties, migraines and cardiac disorders such as atrial fibrillation and congestive heart failure (CHF), comprising:

a rechargeable implantable pulse generator, comprising a microprocessor, pulse generation circuitry, rechargeable battery, and stimulus-receiver means;

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;

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

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

26. A system of claim 25, wherein said implantable rechargeable pulse generator can function in conjunction with an external stimulator, to provide said stimulation and/or blocking to said vagus nerve(s) and/or its branches.

26. A system of claim 25, wherein said coil used in recharging said pulse generator is around said implantable rechargeable pulse generator case in a silicone enclosure.

27. A system of claim 25, wherein said rechargeable battery comprises at least one of lithium-ion, lithium-ion polymer batteries.