INGESTIBLE THERAPY ACTIVATOR SYSTEM AND METHOD

RELATED APPLICATION AND CROSS REFERENCE

[001] This application claims the benefit of US Provisional Application Serial number 61/114,442 filed on November 13, 2008, the entire disclosure of which is incorporated herein by reference.

FIELD OF THE INVENTION

[002] The present invention relates generally to medical therapy systems, devices, and methods. More specifically, the invention relates to systems, devices, and methods for activation and/or modulation of various medical therapies using an ingestible electronic device.

BACKGROUND

[003] Multiple therapies exist for various health-related conditions, events, and defects. Such therapies may be implemented as implanted devices, e.g., cardiac rhythm management devices, neural stimulation / neuromodulation devices, intrathecal drug delivery pumps, and functional neuromodulation prostheses such as cochlear implants, retinal implants, and artificial joints, limbs and organs. Once implanted, however, such devices may not provide the functionality to facilitate controlled activation or modification.

[004] In one example, a neural stimulation device may deliver pain-control therapies to the spinal column, yet the neural stimulation device may not be activated on demand. Stated differently, the neural stimulation device is always activated after implantation. As a result, the patient may be subjected to neural stimulation, as well as its associated unwanted side effects, at times when such therapy is not needed.

[005] In another example, a neural modulation device such as a spinal cord stimulator may provide therapeutic benefit for pain, yet the rate of stimulation may not be adjustable to align stimulation to the patient's lifestyle, e.g., a higher

intensity during high activity periods and a lower intensity during low activity periods. As a result, the patient may need to restrict activities which do not conform to the stimulation intensity to receive optimal therapy results or suffer diminished therapy results when engaged in non-conforming activities.

[006] Therefore, it would be desirable to have systems, devices, and methods for controlling therapies, for optimizing therapy results, and for enhancing patient treatment without having limitations placed on the patient.

SUMMARY

[007] The present disclosure includes a system for providing instructions to a therapeutic device. The therapeutic device can be any type of device, such as a cardiac therapeutic device, a neural stimulation device, an intrathecal drug delivery pump, a gastrointestinal device; and a neural stimulation prosthesis. The system includes an ingestible unit and a responder module. The ingestible unit includes an output or effector module that provides an effector instruction to the responder module. The responder module receives and processes the effector instruction and communicates the effector instruction to the therapeutic device to alter the operation of the therapeutic device.

BRIEF DESCRIPTION OF THE FIGURES

[008] **FIG. 1** illustrates an ingestible activator environment including an ingestible therapy activator.

[009] **FIG. 2** illustrates the ingestible therapy activator of **FIG. 1** in greater detail.

[010] **FIG. 3** illustrates an ingestible device of the therapy activator of **FIG. 2** in greater detail.

[011] **FIG. 4** illustrates an effector module of the ingestible device of **FIG. 3** in greater detail.

[012] **FIG. 5** illustrates an effector instruction of the ingestible therapy activator of **FIG. 2** in greater detail.

[013] **FIG. 6** illustrates a responder module of the ingestible therapy activator of **FIG. 2** in greater detail.

[014] FIG. 7 illustrates a therapeutic device of the ingestible activator environment of **FIG. 1.**

[015] FIG. 8 illustrates ingestion and activation of a therapeutic device via an ingestible therapy activator.

DETAILED DESCRIPTION

[016] Generally, the invention may provide for controlled activation and/or modulation of an implanted medical device or related therapy. More particularly, the invention includes use of an ingestible device to effect activation and/or modulation of devices / therapies related to implantable medical devices. Typically, the patient controls ingestion of the ingestible device. Ingestion of the ingestible device results in activation and/or modulation of the patient's medical device and/or therapy. Alternatively, ingestion of the ingestible device may inactivate or discontinue a device / therapy. Thus, as a novel and beneficial result of the invention, the patient and/or other party may control at will various outcomes associated with various implanted medical devices and related therapies based on the provision of ingestible devices and a healthcare provider or other party may control a supply, e.g., by prescription, of the ingestible devices.

[017] Use of an ingestible device to activate and/or modulate therapy may have broad potential application for any implanted device or therapy, to include cardiac rhythm management; neural stimulation and/or neuromodulation (sometimes collectively referred to herein as "neural stimulation"); intrathecal drug delivery pumps and therapies; and functional neuromodulation prostheses such as cochlear implants, retinal implants, and artificial joints, limbs and organs.

[018] Activation of therapy includes, for example, activation of a device to induce and event or condition. For example, activation of a gastric banding device having neural stimulation electrodes may induce increased satiety and/or induce an improvement in the rate of stomach motility. Further, the ingestible device may activate the band portion of the gastric banding device, e.g., constricting the band. If the ingestible device is taken prior to ingestion of a meal, the patient

may control appetite, satiety, caloric intake, and ultimately influence weight management results, etc.

[019] Certain aspects may be directed to in-body therapies and may include, for example, implantable medical devices. The term "implantable medical device", as used herein, refers to a device configured to be positioned at least partially on a living body, at least partially in a living body, or a combination thereof.

[020] For example, the implantable medical device may include a lead having various electrode configurations communicably associated with controller circuitry, a power source, etc. More particularly and illustratively, the implantable medical device may comprise one or more leads with multiple in-line segmented electrode satellites, wherein each electrode is independently controllable and power / data wire(s) for multiplexing the multiple segmented electrode satellites. Various configurations of devices which may be used in conjunction with this invention may be described / disclosed in the PCT application no. PCT/US2003/039524 published as WO 2004/052182; PCT application no. PCT/US2005/031559 published as WO 2006/029090; PCT application no. PCT/US2005/046811 published as WO 2006/069322; PCT application no. PCT/US2005/046815 published as WO 2006/069323; PCT application no. PCT US2006/048944 published as WO 2007/075974; United States application serial no. 11/939,524 published as US 2008-0114230 A1.

[021] Various configurations of devices which may be used in conjunction with this invention may be described / disclosed in PCT application serial nos. PCT/US2008/052845 published as WO/2008/095183 and PCT/US2006/016370 published as WO/2006/116718. Each of the aforementioned applications is herein incorporated by reference in its entirety. The aforementioned configurations are for illustrative purposes only and that various other components and configurations are possible.

[022] **FIG. 1** illustrates an ingestible therapy activator environment 100 including an ingestible therapy activator 102. In various aspects, the ingestible therapy activator environment may be a living being, such as a mammalian being, including a human being. In various aspects, the ingestible therapy activator 102 may communicably interoperate with one or more therapeutic devices 108, e.g., in-body devices such as implanted devices or other devices. The communicable interaction may result in activation and/or modulation of the therapeutic device,

108, e.g., immediate activation of the therapeutic device 108, delayed activation of the therapeutic device 108, immediate modulation of the therapeutic device 108, delayed modulation of an activity associated with the therapeutic device 108, etc. In this manner, a patient may control a therapeutic outcome via ingestion of the ingestible therapy activator 102.

[023] **FIG. 2** illustrates the ingestible therapy activator 102 of **FIG. 1** in greater detail. In various aspects, the ingestible therapy activator 102 includes an ingestible device 200 having an effector module 202, an effector instruction 204, and, optionally, a responder module 206. Upon ingestion of the ingestible device 200, the effector module 202 may send, e.g., transmit, the effector instruction 204. The effector instruction 204 may be received, e.g., via the responder module 206, and may cause activation and/or modulation of a therapeutic device 108 and/or a therapy associated with the therapeutic device 108. Further, multiple ingestible devices 200 may be ingested simultaneously or in close temporal proximity, and each of the multiple ingested ingestible devices 200 may interact with one or more therapeutic devices 108.

[024] The ingestible device 200 includes any device, component, hardware, and/or software, and combinations thereof, capable of ingestion by a living being and further capable of mechanical, electronic, and/or in communicable interoperation with the effector module 202, described hereinafter.

[025] To illustrate, the ingestible device 200 may include, comprise, be integrated into, etc., a placebo structure. The placebo structure may comprise, for example, a capsule, a pill, etc. To further illustrate, the ingestible device 200 may include, comprise, be integrated into, etc. an ingestible medication. The ingestible medication may comprise, for example, a capsule, a pill, liquid, etc., and may be prescribed, over-the-counter, etc.

[026] Various ingestible devices 200 may comprise, include, be integrated with, etc., devices such as those described in the PCT/US2008/052845 published as WO/2008/095183 and PCT/US2006/016370 published as WO/2006/116718, the entire disclosure of which is incorporated herein by reference. Additionally, all references cited herein are hereby incorporated by reference in their entirety.

[027] A pharma-informatics system described in PCT / US2006 / 016370, filed April 28, 2006, which includes compositions, includes systems and methods that

allow for the detection of the actual physical delivery of a pharmaceutical agent to a body.

[028] An Ionic Emission Module or Ingestible Event Marker (IEM) system described in PCT / US2008 / 52845, filed February 1, 2008, and US Patent Application Serial Number 12/564,017, filed September 21, 2009 (both of which are incorporated herein by reference) include an IEM and a personal signal receiver. Aspects of the IEM include an identifier, which may or may not be present in a physiologically acceptable carrier. The identifier is characterized by being activated upon contact with a target internal physiological site of a body, such as digestive tract internal target site. The personal signal receiver is configured to be associated with a physiological location, e.g., inside of or on the body, and to receive a signal of the IEM. During use, the IEM broadcasts a signal which is received by the personal signal receiver.

[029] The IEM also includes two dissimilar materials deposited on two sides of the IEM to form electrochemical potentials and act as the cathode and the anode to form a power source. The dissimilar materials may be separated by a non-conducting material or skirt that amplifies the signal through increasing the current path. More specifically, the dissimilar materials can be made of any two materials appropriate for the environment in which the IEM will be operating. For example, when used with the ingestible device the dissimilar materials may be any pair of materials with different electrochemical potentials that are ingestible. An illustrative example includes the instance when the IEM is in contact with an ionic solution such as stomach acids, as shown in FIG. 8 below. Suitable materials are not restricted to metals, and in certain aspects the paired materials are chosen from metals and non-metals, e.g., a pair made up of a metal (such as Mg) and a salt (such as CuCl or CuI). With respect to the active electrode materials, any pairing of substances – metals, salts, or intercalation compounds - with suitably different electrochemical potentials (voltage) and low interfacial resistance are suitable. Additionally, a control module (not shown) is electrically coupled to each of the two dissimilar materials in order to receive power and become activated as well control the conductance and hence the current path between the two dissimilar material. The control module alters conductance between the dissimilar materials in a unique manner. By altering the conductance path between the dissimilar materials, the control module is capable

of controlling the magnitude of the current through the conducting fluid/liquid that surrounds the IEM or ingestible device 200. This produces a unique current signature that carries or encodes the effector instruction and can be detected and measured by a receiver, such as the responder module 206, which can be positioned internal or external to the body.

[030] A controlled activation ingestible identifier described in PCT / US07 / 82563, filed October 17, 2007, includes ingestible compositions such as pharma-informatics enabled compositions. The controlled activation ingestible identifiers include a controlled activation element that provides for activation of the identifier in response to the presence of a predetermined stimulus at a target site of interest.

[031] **FIG. 3** illustrates the ingestible device 200 of the therapy activator of **FIG. 2** in greater detail. More particularly, the ingestible device 200 may be associated with various vehicles 300, e.g., placebo, medication, capsules, etc., as heretofore discussed. In various aspects, multiple ingestible devices 200 may be associated with a single vehicle 300, e.g., two ingestible devices 200 may be included in a single capsule; three or more ingestible devices 200 may be affixed on/manufactured within a pill, etc. In addition to the effector module 202, the ingestible device may comprise, be wholly or partially integrated with, integral to, etc., various other components 302. Examples of various other components 302 include modules for detection of physiological parameters of the subject. The effector module 202 comprises any device, component, hardware, and/or software, and combinations thereof, capable of receiving, processing, storing, generating, and/or communicating the effector instruction 204 of FIG. 2. In various aspects, for example, the effector module 202 may comprise an integrated circuit (IC), microcircuit, microchip, silicon chip, miniaturized electronic circuit, etc., having the processing capability to receive, generate, store, etc., and a means to forward, e.g., via a transmitter, etc., the effector instruction 204.

[032] **FIG. 4** illustrates the effector module 202 of the ingestible device of **FIG. 3** in greater detail. The effector module 202 may comprise a microchip 400, a power source 402, and a transmitter 404. The microchip 400 may be included and /or be associated with various components, e.g., software, storage devices, memory, processing instructions, etc., necessary to receive, generate, perform signal processing, and/or store the effector instruction 204.

[033] The power source 402 may be variously configured, e.g., wet battery, etc. In one aspect, the power source 402 may be an incomplete power source, which may be activated upon contact with a targeted physiological site. Thus, the power source 402 gets activated, thereby powering the microchip 400. Stated differently, the power source 402 may exploit electrochemical reaction in an ionic solution such as gastric fluid, blood, or other bodily fluids and some tissues.

[034] Depending on the configuration of the ingestible device 200, the target physiological site or location may vary, where representative target physiological sites of interest include, but are not limited to: a location in the gastrointestinal tract, such as the mouth, esophagus, stomach, small intestine, large intestine, etc. In certain aspects, the identifier is configured to be activated upon contact with fluid at the target site, e.g., stomach fluid, regardless of the particular composition of the target site. In some aspects, the identifier is configured to be activated by interrogation, following contact of the composition with a target physiological site. In some aspects, the identifier is configured to be activated at a target site, wherein the target site is reached after a specified period of time.

[035] The microchip 400, in turn, forwards a signal incorporating the effector instruction 204 via the transmitter 404 to a destination, e.g., directly to the therapeutic device 108, to the therapeutic device 108 via the responder module 206, etc.

[036] In various aspects, various modes of communication, channels of communication, and combinations thereof may be used. In one example, the effector instruction 204 may be communicated via a radio-frequency (RF) signal. In another example, the effector instruction 204 may be communicated via conduction, e.g., using in-body electrical signals as a communication vehicle. In still another example, the effector instruction 204 may be communicated via conduction to a receiver affixed externally to the patient, e.g., the responder module, which in turn, communicates the effector instruction to one or more therapeutic devices 108, e.g., implanted therapeutic devices via various modes of communication. Thus, as can be seen, various combinations of intra-body and extra-body channels and various modes of communication may be used.

[037] The effector instruction 204 comprises any means capable of carrying the functionality as heretofore described, e.g., instigating an activation and/or

modulation resulting in activation / modulation of a therapeutic device and/or therapy associated with the therapeutic device.

[038] **FIG. 5** illustrates an effector instruction of the ingestible therapy activator of **FIG. 2** in greater detail. In various aspects, the effector instruction 204 comprises any one or a combination of software instruction(s) 500, a signal 502, data 504, etc. Further, any or all of the foregoing may be variously embodied and may be communicated via various modes and channels, as heretofore discussed.

[039] FIG. 6 illustrates the responder module 206, which comprises any device, component, hardware, and/or software, and combinations thereof, capable of receiving, processing, storing, generating, and/or communicating the effector instruction 204. In various aspects the responder module 206 may be directly associated with a therapeutic device 108, e.g., in mechanical communication with the therapeutic device 108. Examples of such a responder module 204 include an instruction receipt and/or processing unit physically configured as a component of a cardiac device, a gastro-intestinal device, a lead device, an electrode device, etc.

[040] In various aspects, the responder module 206 may be indirectly associated with the therapeutic device 108, e.g., may be in electrical communication with the therapeutic device 108 but not in mechanical communication therewith. Examples of such a responder module 204 include an instruction receipt and/or processing unit physically configured with / as a receiver, e.g., a wearable receiver such as a patch receiver, discussed in PCT / US2008 / 52845, *supra*.

[041] **FIG. 6** illustrates a responder module of the ingestible therapy activator of FIG. 2 in greater detail. In various aspects, the responder module 206 may comprise a receiver 600 to receive the effector instruction 204, a microchip 400 to process and/or store, etc., the effector instruction 204, and, optionally, a transmitter 404 to forward the effector instruction onward.

[042] The receiver 600, for example, may be dedicated, i.e., receive only the effector instruction or may be universal, i.e., may receive signals, data, etc., in addition to the effector instruction. In the case of the universal receiver, such reception of multiple types of communications may provide for comprehensive

device functionality, e.g., a cardiac pacing device which receives a pacing signal and the effector instruction.

[043] Referring now to **FIG. 4**, the microchip 400, for example, may perform various processing activities with respect to the effector instruction. One example includes aggregating multiple effector instructions from one or more ingestible devices. Another example includes aggregating data from other sources, e.g., other devices, with the effector instruction. Another example includes modifying the effector instruction based on other data. To illustrate, the responder module 206 may receive and store data related to cardiac pacing from a cardiac device. For example, an effector instruction to slow the rate of the cardiac pacing from 70 beats per minute to 60 beats per minute. When the effector instruction is received, the microchip may analyze the data and, based on the result of the analysis, modify the effector instruction to slow the rate to 65 beats per minute. (After analysis of the data, this rate may be found preferable to the 65 beats per minute, as initially contemplated.) In this manner, the responder module 206 and the effector module 202 may co-operatively affect optimal therapies.

[044] The transmitter 404, for example, may transmit the effector instruction(s) 204, data, or a combination thereof, to a destination device, e.g., the therapeutic device 108. The communication modes and channels may be of various types and combinations thereof, as heretofore discussed.

[045] The therapeutic device 108 may be any device capable of providing or facilitating at least one medical therapy to a living being. Particularly, the therapeutic device 108 includes implantable devices.

[046] **FIG. 7** illustrates a therapeutic device of the ingestible activator environment of FIG. 1. The therapeutic device includes for example, cardiac devices, lead devices, electrode devices, migraine devices, urinary devices, gastrointestinal devices, etc.

[047] The therapeutic devices may be activated and/or modulated in various ways, e.g., mechanical actuation, electrical activation, combinations thereof, etc. In one example of mechanical actuation, the effector instruction received by a gastro-intestinal device such as a gastric banding device (GBD) causes the GBD to signal controller circuitry associated with a clamping device of the GBD. The controller circuitry, in turn, generates the controls necessary to inflate the

clamping device, thus constricting the esophagus which results in greater satiety, reduced ability to ingest food, improved gastric motility, etc.

[048] In one example of an electrical activation, the effector instruction received by an electrode device such as a neural stimulation device (NSD) causes the NSD to signal controller circuitry associated therewith. The controller circuitry, in turn, generates the instructions necessary to provide electrical stimulation via the electrodes, thus masking pain, stimulating a cardiac contraction, etc.

[049] **FIG. 8** illustrates ingestion and activation of a therapeutic device via an ingestible therapy activator. As illustrated, ingestion of an ingestible therapy activator 200 by a human 800 results in activation of the ingestible therapy activator 200 by stomach fluids. Once activated, the ingestible therapy activator 200 transmits the effector instruction 204 to controller circuitry 808 associated with a cardiac pacing device 804. Upon receipt and processing of the effector instruction 204 by the controller circuitry 808, instructions are sent to the cardiac pacing device 804 that result in a change in the rate of pacing of the heart via the cardiac pacing device 804. In this manner, the patient can control, and ultimately optimize, certain features, aspects, and parameters of the patient's cardiac therapy.

[050] Continuing with further illustrations of the foregoing, effectuation of a neural stimulation device directed to migraine management, e.g., electrical stimulation of neural regions associated with migraine pain, may result in pain avoidance or abatement. If the ingestible device is taken at the onset of migraine aura, i.e., a sensory disturbance that often precedes a migraine headache, the patient may completely avoid the migraine headache and the severe pain associated therewith.

[051] Effectuation of a urinary therapeutic device having electrodes to stimulate a voidance activity, which may assist in regulation of incontinence urges and issues.

[052] Effectuation of an electrode device associated with penile erection may result in successful treatment of various impotence-related disorders, including erectile dysfunction.

[053] Effectuation of various cardiac devices to activate / modulate cardiac therapies may result in any one or more of improved cardiac therapy, optimized

cardiac therapy, diminished habituation, eliminated habituation, and avoidance of habituation.

[054] Effectuation of an NSD associated with spinal cord stimulation prior to various physical activities may result in any one or more of improved pain-control therapy, optimized pain-control therapy, diminished habituation, eliminated habituation, and avoidance of habituation.

[055] As a skilled artisan will note, various aspects facilitate at least some measure of control by the patient of the therapy.

[056] The foregoing illustrate a few simple examples of the beneficial results associated the invention. The applications of the invention, as well as the resultant beneficial results, are too numerous to exhaustively list herein.

[057] Various aspects include steps for ingesting an ingestible device having an effector module; sending an effector instruction via the effector module; and receiving and processing, via a responder module associated with a therapeutic device, the effector instruction, resulting in a response by the therapeutic device.

[058] Various aspects include an ingestible therapy activator comprising an ingestible device having an effector module and an effector instruction.

[059] Various aspects include a kit comprising an ingestible therapy activator and a therapeutic device. Further, kits may also include a responder module associated with at least one of the ingestible therapy activator and the therapeutic device.

[060] One or more aspects of the subject invention may be in the form of computer readable media having programming stored thereon for implementing the various methods, or various steps thereof. The computer readable media may be, for example, in the form of a computer disk or CD, a floppy disc, a magnetic "hard card", a server, or any other computer readable media capable of containing data or the like, stored electronically, magnetically, optically or by other means. Accordingly, stored programming embodying steps for carrying-out the subject methods may be transferred or communicated to a processor, e.g., by using a computer network, server, or other interface connection, e.g., the Internet, or other relay means.

[061] It is to be understood that this invention is not limited to particular aspects described, and, as such, may vary. It is also to be understood that the terminology used herein is for the purpose of describing particular aspects only,

and is not intended to be limiting, since the scope of the present invention will be limited only by the appended claims.

[062] Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limit of that range and any other stated or intervening value in that stated range, is encompassed within the invention. The upper and lower limits of these smaller ranges may independently be included in the smaller ranges and are also encompassed within the invention, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the invention.

[063] Certain ranges are presented herein with numerical values being preceded by the term "about." The term "about" is used herein to provide literal support for the exact number that it precedes, as well as a number that is near to or approximately the number that the term precedes. In determining whether a number is near to or approximately a specifically recited number, the near or approximating unrecited number may be a number which, in the context in which it is presented, provides the substantial equivalent of the specifically recited number.

[064] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although any methods and materials similar or equivalent to those described herein can also be used in the practice or testing of the present invention, representative illustrative methods and materials are now described.

[065] All publications and patents cited in this specification are herein incorporated by reference in their entirety as if each individual publication or patent were specifically and individually indicated to be incorporated by reference and are incorporated herein by reference to disclose and describe the methods and/or materials in connection with which the publications are cited. The citation of any publication is for its disclosure prior to the filing date and should not be construed as an admission that the present invention is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication

provided may be different from the actual publication dates which may need to be independently confirmed.

[066] It is noted that, as used herein and in the appended claims, the singular forms "a", "an", and "the" include plural referents unless the context clearly dictates otherwise. It is further noted that the claims may be drafted to exclude any optional element. As such, this statement is intended to serve as antecedent basis for use of such exclusive terminology as "solely," "only" and the like in connection with the recitation of claim elements, or use of a "negative" limitation.

[067] As will be apparent to those of skill in the art upon reading this disclosure, each of the individual aspects described and illustrated herein has discrete components and features which may be readily separated from or combined with the features of any of the other several aspects without departing from the scope or spirit of the present invention. Any recited method can be carried out in the order of events recited or in any other order which is logically possible.

[068] Although the foregoing invention has been described in some detail by way of illustration and example for purposes of clarity of understanding, it is readily apparent to those of ordinary skill in the art in light of the teachings of this invention that certain changes and modifications may be made thereto without departing from the spirit or scope of the appended claims.

[069] Accordingly, the preceding merely illustrates the principles of the invention. It will be appreciated that those skilled in the art will be able to devise various arrangements which, although not explicitly described or shown herein, embody the principles of the invention and are included within its spirit and scope. Furthermore, all examples and conditional language recited herein are principally intended to aid the reader in understanding the principles of the invention and the concepts contributed by the inventors to furthering the art and are to be construed as being without limitation to such specifically recited examples and conditions. Moreover, all statements herein reciting principles, aspects, and aspects of the invention as well as specific examples thereof, are intended to encompass both structural and functional equivalents thereof. Additionally, it is intended that such equivalents include both currently known equivalents and equivalents developed in the future, i.e., any elements developed that perform the same function, regardless of structure. The scope of the present invention, therefore, is not intended to be limited to the exemplary aspects shown and

described herein. Rather, the scope and spirit of present invention is embodied by the appended claims.

WHAT IS CLAIMED IS:

1. A system for providing instructions to a therapeutic device, the system comprising:
   an ingestible unit comprising:
      a housing; and
      an output module secured within the housing for providing an effector instruction,
      wherein the ingestible unit provides the effector instruction to the output module upon activation in response to occurrence of a desired event; and
   a responder module in communication with the therapeutic device for receiving and processing the effector instruction, wherein the effector instruction alters at least an operation of the therapeutic device.
2. The system of claim 1 wherein the housing is hermetically sealed and wherein the ingestible unit further comprises a power source secured within the housing and electrically coupled to the output module for powering the output module.
3. The system of claim 1 wherein the housing dissolves upon contact with the surrounding fluid of a desired target site to release the output module and wherein the output module comprises:
      a support structure including two dissimilar materials deposited thereon wherein the dissimilar materials represent a voltage potential difference and provide power for the ingestible unit upon contact with the fluid;
      a hermetically sealed conductance control module electrically coupled to each of the dissimilar materials for controlling the conductance between the dissimilar materials to generate a unique current signature that presents the effector instruction.
4. The system of claim 3, wherein the current signature is produced through controlled ionic emission.
5. The system of claim 1, wherein the ingestible unit further comprises an oral medication.

6. The system of claim 1, wherein the ingestible unit further comprises a second output module secured within the housing to provide a second effector instruction.
7. The system of claim 1, wherein the responder module comprises at least one of a hardware component and a software component.
8. A method for providing instructions to a therapy unit using an ingestible device, the method comprising the steps of:
   programming an effector module of the ingestible device;
   ingesting the ingestible device;
   activating the ingestible device upon reaching a target site, wherein the target site is characterized by the presence of conducting fluid;
   sending an effector instruction via the effector module; and
   receiving and processing, via a responder module associated with the therapeutic device, the effector instruction, resulting in a response by the therapeutic device.
9. A system for controlling therapy delivery, the system comprising:
   a capsule;
   an ionic emission unit positioned within the capsule for producing a current flow through ionic emission, wherein the ionic emission module includes a pair of materials that produce a voltage potential when exposed to a conducting fluid;
   a conductance control module positioned between the pair of materials and electrically coupled thereto for controlling conductance to produce a unique current signature that carries an effector instruction.
10. The system of claim 9 further comprising a responder module in communication with a therapeutic device, wherein the responder module receives and processes the effector instruction.
11. The system of claim 10 wherein the effector instruction alters at least an operation of the therapeutic device.
12. The system of claim 10 wherein the pair of materials are separated by a non-conducting material that increases the path of the current flow.