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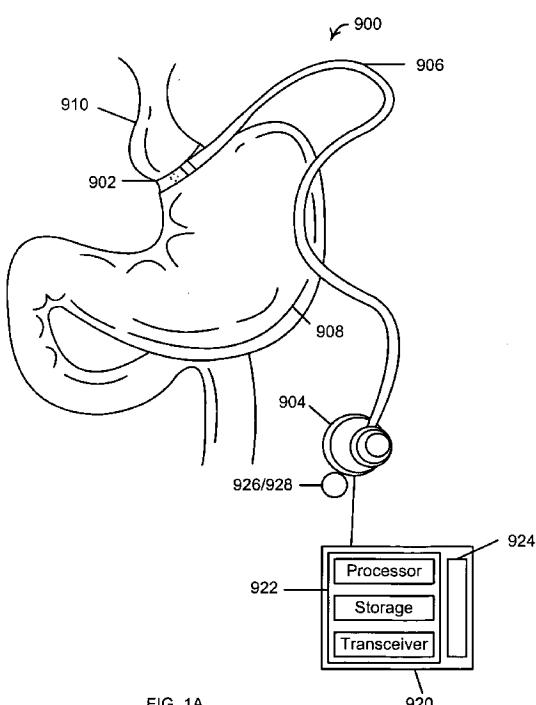
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(54) Title: FEEDBACK SYSTEMS AND METHODS TO ENHANCE OBSTRUCTIVE AND OTHER OBESITY TREATMENTS



(57) Abstract: Feedback systems and methods enhance obstructive and other obesity treatments by presenting feedback regarding patients' actual eating and/or exercise habits. An ingestion restricting implant body can be deployed along the gastrointestinal tract. In some embodiments, ingestion alters the implant body, which, in turn, generates signals. The generated signals can be used to inhibit unhealthy ingestion by the patient. In other embodiments, the implant body can be altered by signals so as to selectable change the restriction imposed on the gastrointestinal tract, optionally in response to ingestion events, an eating schedule, or the like. The implant body may comprise a gastric band or an intragastric balloon. Sensor signals may be processed to identify ingestion and/or characterize ingestion of a solid or a liquid, and the results may be displayed on a screen for a patient or coach to view.



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FEEDBACK SYSTEMS AND METHODS TO ENHANCE OBSTRUCTIVE AND OTHER OBESITY TREATMENTS

CROSS-REFERENCES TO RELATED APPLICATIONS

5 [0001] The present application claims the benefit under 35 USC 119(e) of US
Provisional Application No. 61/166,636 filed April 3, 2009; the full disclosure of which is
incorporated herein by reference in its entirety. The subject matter of the present
application is related to the following applications: US Application No. 12/145,430 filed
June 24, 2008; US Application No. 10/950,345 filed September 23, 2004 (Allowed); US
10 Application No. 61/122,315 filed December 12, 2008; US Application No. 12/637,452 filed
December 14, 2009, and US Application No. _____, filed concurrently herewith
and entitled "Feedback Systems and Methods for Communicating Diagnostic and/or
Treatment Signals to Enhance Obesity Treatments" (Attorney Docket No. 026458-
001210US), the full disclosures of each of which are also incorporated herein by reference
15 in their entirety.

BACKGROUND OF THE INVENTION

[0002] Since the mid-seventies, the prevalence of obesity has increased sharply for both
adults and children. These increasing rates raise concern because of their implications for
20 Americans' health. Being overweight or obese may increase the risk of many diseases and
health conditions, including: hypertension, dyslipidemia (for example, high total
cholesterol or high levels of triglycerides), type 2 diabetes, coronary heart disease, stroke,
gallbladder disease, osteoarthritis, sleep apnea and respiratory problems, and some cancers
(such as endometrial, breast, and colon).

25 [0003] Obesity and its associated health problems have a significant economic impact on
the U.S. health care system. Medical costs associated with excess weight and obesity may
involve direct and indirect costs. Direct medical costs may include preventive, diagnostic,
and treatment services related to obesity. Indirect costs relate to morbidity and mortality
costs. Morbidity costs are defined as the value of income lost from decreased productivity,
30 restricted activity, absenteeism, and bed days. Mortality costs are the value of future
income lost by premature death.

[0004] Many therapies are currently being investigated for treatment of obesity and diseases associated with obesity. To date, the widely used obesity treatments have not been shown to be ideal, particularly for those afflicted with severe obesity. The approaches that have been proposed range from lifestyle coaching to major surgical therapies.

5 [0005] Many severely obese patients have turned to surgical options. These surgical options include highly invasive procedures such as stomach reduction and gastric bypass, while less invasive procedures include the implantation of gastric bands. Another option for the severely obese patients involves the endoscopic placement of an intragastric balloon, a silicon balloon device that is placed in the stomach endoscopically.

10 [0006] Unfortunately, patient compliance and the accuracy with which patients report their own activities can significantly limit the effectiveness of weight loss treatments. One of the problems associated with the surgical procedures of gastric reduction, gastric bypass, gastric banding and intragastric balloons revolves around patient compliance. Even after these surgeries or endoscopic procedures, a number of patients find ways to "cheat;" they
15 avoid the volume limitation imposed by stomach reduction from the above-mentioned procedures simply by ingesting liquids or liquefied solids that easily drain into their small intestines. For weight loss treatment to be successful, the surgical or endoscopical procedures should ideally be combined with lifestyle changes. Patients' self-reporting has very often proven to be inaccurate.

20 [0007] Therefore, it would be desirable to provide devices, systems and methods that can accurately monitor and report a patient's actual daily caloric intake as well as activity related caloric expenditure, to be used in obesity treatment therapy. Ideally, such a system would provide a patient, his or her physician, a lifestyle coach, support group, and/or other caregivers the information collected about the patient's eating and exercise habits for use in
25 monitoring the patient's progress and so as to present actual behavior-based information to the patient for effective behavior modification and greater success in achieving weight loss or health goals.

BRIEF SUMMARY OF THE INVENTION

[0008] The present invention relates to feedback systems and methods to enhance obstructive and other obesity treatments. Although embodiments of the invention make

specific reference to treatment of obesity, the system and methods described herein may be applicable to other treatments seeking patient behavior modification, and particularly disorders in which presenting feedback regarding patients' actual eating and/or exercise habits is desired.

[0009] In first aspect, the invention provides a method for treating a patient having a gastrointestinal tract and an unhealthy ingestion pattern. The method comprises deploying an ingestion restricting implant body along the gastrointestinal tract. Signals are generated correlating to altering of the implant body. Unhealthy ingestion by the patient are inhibited in response to the signals sufficiently to modify the unhealthy ingestion pattern toward a healthier ingestion pattern.

[0010] The signals may comprise sensor signals and/or actuation signals. In some embodiments, ingestion alters the implant body, which, in turn, generates signals in the form of sensor signals. The generated sensor signals can be used to inhibit unhealthy ingestion by the patient by activating a stimulation electrode of the implant, enhancing the restriction, presenting documented ingestion events to the patient or a lifestyle coach, or the like. In other embodiments, the implant body can be altered by actuator signals so as to change the restriction imposed on the gastrointestinal tract, optionally in response to ingestion events, an eating schedule, or the like. The actuator signals may induce changes in the implant a plurality of times a day for a plurality of days, allowing the implant to adjust dynamically so as to facilitate healthy ingestion while inhibiting unhealthy ingestion.

[0011] In many embodiments, the implant body will be deployed using bariatric surgery so as to surgically implant an implant system for weight loss. The implant system may include the implant body and a processor coupled to the implant body. The coupling between the processor and the implant body allows the signals to be transmitted between these two structures, with the signals optionally being electrical signals, optical signals, wireless telemetry signals, mechanical signals, or the like. For example, the implant body of the implant system will often comprise a gastric band that having a channel that receives a patient's gastrointestinal tract therein, and a processor coupled to the gastric band. The signals may include sensor signals transmitted from the gastric band to the processor in response to ingestion, and/or actuation signals transmitted from the processor to the gastric band so as to alter a size or compliance of the channel.

[0012] In many embodiments, the gastric band comprises a fluid pressure bladder disposed between the channel and a support structure of the gastric band. The gastric band is altered a number of times each day, with an associated alteration in an engagement force between the gastrointestinal tract and the fluid-filled pressure bladder of the gastric band. The engagement force may be altered by ingestion-related distension of the gastrointestinal tract within the channel of the gastric band. At least one sensor can generate signals in response to transient changes in fluid pressure within the bladder, often as a result of ingestion events. Unhealthy ingestion can optionally be inhibited by showing a display of sensed eating events to the patient or a lifestyle coach. In some embodiments, ingestion inhibiting therapies may be applied in response to the sensor signals, such as by increasing the pressure within the bladder, and/or by electrically stimulating tissue of the gastrointestinal tract with the implant.

[0013] In many embodiments, the sensors include at least a pressure sensor, a temperature sensor, an optical sensor, an impedance sensor, a pH sensor, or an acoustic sensor. The ingestion event may be ingestion of a solid or ingestion of a drink.

[0014] In some embodiments, the processor of the implant sends pressure commands or actuator signals to the bladder to alter the engagement force by changing the fluid pressure within the bladder. The pressure within the bladder can be decreased each day to allow healthy ingestion and increased each day to inhibit unhealthy ingestion. More generally, the processor may send signals via an actuator to alter the implant by varying the size, compliance, or shape of the channel of the gastric band. The actuator typically comprises a fluid actuator.

[0015] In some embodiments, the actuator is energized with signals so as to activate the gastric band by increasing restriction and decreasing ingestion into the patient. The actuator can also be energized by signals in an opposite direction to deactivate the gastric band by decreasing restriction and allowing increased ingestion into the patient.

[0016] In many embodiments, the implant body includes a gastric balloon, with a processor coupled to an actuator. The processor sends signals to the actuator to vary the size of the gastric balloon such to alter restriction of the ingestion. Altering of the implant body includes changing the fluid pressure within the gastric balloon.

[0017] In many embodiments, deploying the implant system delivers electrical stimulation to an internal organ of the living body.

[0018] In many embodiments, the implant senses a physiological trigger and the processor transmits the signals in response to the physiological trigger. The processor transmits the signals at least in part in response to a non-physiological trigger.

[0019] In many embodiments, a pressure sensor coupled to the implant body identifies pressure changes in the gastrointestinal tract. Signals are used to identify an ingestion event; an unhealthy ingestion is inhibited when an unhealthy ingestion event has been identified

[0020] In many embodiments, the processing of the signals identifies peristaltic waves of the gastrointestinal tract proximate to the ingestion restricting implant body.

[0021] In many embodiments, an ingestion event is characterized as ingestion of a liquid in response to a pressure change that lasts more than 10 seconds but less than 5 minutes. An ingestion event is characterized as ingestion of a solid in response to a pressure change that lasts more than 5 minutes but less than 60 minutes.

[0022] In many embodiments, a temperature sensor may sense a temperature within the gastrointestinal tract and send corresponding signals. A processor uses the signals from the pressure sensor and temperature sensor to characterize the ingestion event, inhibiting of the unhealthy ingestion.

[0023] In many embodiments, an ingestion event that causes sufficiently high pressure change and sufficiently low temperature change is identified as ingestion of a solid. An ingestion event that causes sufficiently high pressure change and sufficiently high temperature change is identified as a combined solid and liquid ingestion. An ingestion event that causes sufficiently low pressure change and sufficiently low temperature change is identified as no ingestion. An ingestion event that causes sufficiently low pressure change and sufficiently high temperature change is identified as a liquid ingestion and possible cheating event.

[0024] In a second aspect, embodiments of the present invention provide a method for treating a patient by deploying an ingestion restricting implant along the gastrointestinal

tract. The implant senses an ingestion into the patient and transmits signals in response to the ingestion. Based on the signals, ingestion information is displayed and/or the patient is treated.

[0025] In many embodiments, deploying the implant includes positioning the implant around the gastrointestinal tract so that a tissue of the gastrointestinal tract extends through a channel of the implant. The size of the channel limits transmission of ingested material along the gastrointestinal tract from upstream of the implant to downstream of the implant.

[0026] In many embodiments, the implant is deployed through a laparoscopic gastric band placement procedure.

[0027] In many embodiments, the implant may include a gastric balloon. Deploying the implant includes positioning the implant inside the stomach; the implant has a sufficient food displacement volume to significantly limit ingestion.

[0028] In a third aspect, embodiments of the present invention provide a method for treating a patient by deploying at least a portion of an implant along the gastrointestinal tract, the implant having a body and a processor; identifying an allowed ingestion and allowing the ingested material to pass though the gastrointestinal tract; and, in response to identifying of an unhealthy ingestion, transmitting signals from the processor to the implant so as to alter a shape or size of the implant to restrict the unhealthy ingestion.

[0029] In many embodiments, deploying the implant includes positioning the implant around a gastrointestinal tract that extends through a channel of the implant. The size of the channel limits transmission of ingested material along the gastrointestinal tract from upstream of the implant to downstream of the implant. Deploying of the implant includes a laparoscopic gastric band placement procedure.

[0030] In some embodiments, the implant includes positioning the implant inside the stomach; the implant has a sufficient food displacement volume to significantly limit ingestion. In this case, the implant includes a gastric balloon.

[0031] In a fourth aspect, embodiments of the present invention provide a method for treating a patient by deploying an implant with a processor and a body; identifying an

unhealthy ingestion; and transmitting signals from the processor to the patient in response to the identification of the unhealthy ingestion so as to inhibit the unhealthy ingestion.

[0032] In a fifth aspect, embodiments of the present invention provide a therapeutic implant system for treating a patient with an unhealthy ingestion pattern. The therapeutic implant system includes an ingestion restricting implant body that can be deployed along the gastrointestinal tract, a signal generator coupled to the implant body to generate signals correlating to altering of the implant body, and a processor coupled to the signal generator such that the processor can be used to inhibit the patient's unhealthy ingestion pattern.

[0033] The signal generator may comprise a sensor that senses ingestion (via changes in fluid pressure, temperature, or the like) and/or an actuator that alters a size, shape, or compliance of the implant body. In many embodiments, the implant body includes a gastric band forming a channel that surrounds the gastrointestinal tract. The gastric band includes a fluid-filled pressure bladder located between the channel and a support structure, such that changes in a fluid pressure within the fluid pressure bladder correspond with changes in an engagement force between the gastrointestinal tract and the gastric band.

[0034] In some embodiments, the signal generator includes at least one sensor coupled to the fluid pressure bladder, the altering of the engagement force induced by ingestion-related distension of the gastrointestinal tract within the channel of the gastric band so that the signals are generated in response to transient changes in fluid pressure within the bladder and the signals indicate an ingestion event.

[0035] In many embodiments, the implant system includes a display coupled to the processor, to show eating events identified in response to the signals and to communicate to the patient or a lifestyle coach, an actuator coupled to the processor to alter the fluid pressure within the bladder in response to the ingestion event; and an electrode coupled to the processor to stimulate tissue of the gastrointestinal tract in response to the ingestion event.

[0027] In many embodiments, the implant system also includes at least one pressure sensor, a temperature sensor, an optical sensor, an impedance sensor, a pH sensor, or an acoustic sensor coupled to the processor.

[0036] In many embodiments, the signal generator transmits fluid pressure signals transmitted to the bladder from the processor. The signal generator includes an actuator that

induces changes in fluid pressure within the bladder in response to the pressure signals. Each day the pressure within the bladder is decreased to allow healthy ingestion and increased to inhibit unhealthy ingestion.

[0037] In some embodiments, the implant system energizing the actuator activates the gastric band so as to increase restriction and decrease ingestion into the patient.

[0038] In some embodiments, the implant system energizing the actuator deactivates the gastric band so as to decrease restriction and allow increased ingestion into the patient.

[0039] In some embodiments, the implant body includes a gastric balloon. Altering the implant body includes altering a fluid pressure within the gastric balloon.

[0040] In some embodiments, the signal generator includes an actuator which, in response to command signals from the processor, causes the size of the gastric balloon to vary, to alter the restriction of ingestion.

[0041] In some embodiments, the implant system includes an electrode coupled to the processor so as to deliver electrical stimulation to an internal organ of the living body.

[0042] In many embodiments, the implant system the signal generator comprises a pressure sensor. The processor in the implant systems processes the signals to identify pressure changes in the gastrointestinal tract. A pressure change that lasts at least 10 seconds but not more than 5 minutes is identified as an ingestion of a liquid. A pressure change that lasts at least 5 minutes but not more than 60 minutes is identified as an ingestion of a solid.

[0043] In many embodiments a temperature sensor coupled to the processor so as to provide a temperature from inside the gastrointestinal tract. The processor processes signals from the pressure sensor and temperature sensor to identify pressure changes and temperatures. The processor identifies high pressure change and low temperature change as a solid ingestion. The processor identifies high pressure change and high temperature change as a combined solid and liquid ingestion. The processor identifies low pressure change and low temperature change as no ingestion. The processor identifies low pressure change and high temperature change as a liquid ingestion and possible cheating event.

[0044] In some embodiments an optical sensor is coupled to the processor.

[0045] In some embodiments a pH sensor is coupled to the processor.

[0046] In a sixth aspect, embodiments of the present invention provide a system for treating a patient, including an ingestion restricting implant body deployable along the gastrointestinal tract, a sensor coupled to the implant body so as to transmit signals in response to ingestion into the patient in use, and a processor, coupled to the sensor, that generates output in response to the signals. This output includes ingestion display signals and/or patient treatment signals.

[0047] In a seventh aspect, embodiments of the present invention provide a system for treating a patient that includes an implant body deployable along the gastrointestinal tract, a processor; and an actuator coupling the processor to the body. The processor identifies, during a day, an allowed ingestion, and allows an associated ingested material to traverse the body of the implant along the gastrointestinal tract. The processor identifies an unhealthy ingestion and transmits signals to the implant body via the actuator to alter a shape or size of the implant body to restrict the unhealthy ingestion.

[0048] In an eighth aspect, embodiments of the present invention provide a therapeutic implant system for treating a patient that includes an ingestion restricting implant body implantable along the gastrointestinal tract and a processor coupleable to the implant body so as to transmit signals. The signals are transmitted in correlation with changes in a size or a shape of the implant body in use.

[0049] In many embodiments, the therapeutic implant has two possible configurations that differ in size and shape; compared to the first configuration, the second configuration exhibits an enhanced inhibition of ingestion.

[0050] In a ninth aspect, embodiments of the present invention provide a therapeutic implant system for treating a patient that includes an ingestion restricting implant body implantable along the gastrointestinal tract, one or more sensors for generating signals that are transmitted in correlation with an ingestion event, and a processor coupled to the one or more sensors and the implant body so as to transmit the signals.

[0051] In a tenth aspect, embodiments of the present invention provide a therapeutic implant system for treating a patient that includes an ingestion restricting implant body implantable along the gastrointestinal tract, one or more sensors for generating signals that

are transmitted in correlation with physical activity event, and a processor coupled to the one or more sensors and the implant body so as to transmit the signals.

[0052] In some embodiments the sensor includes an activity sensor.

[0053] In some embodiments the sensor includes a heart rate sensor.

[0054] In some embodiments the sensor includes a core body temperature sensor.

[0055] In some embodiments the sensor includes a sleep detector.

[0056] In many embodiments of the therapeutic implant, the signals are transmitted by the processor to a data server.

BRIEF DESCRIPTION OF THE DRAWINGS

[0057] Fig. 1 shows an exemplary system 100 suitable for implementation of embodiments of the present invention.

5 [0058] Fig. 1A shows an exemplary gastric band sensor system implant 900 for use in the system of Fig. 1.

[0059] Fig. 1B-D illustrate the electrical stimulation component of the gastric band sensor system implant 900.

[0060] Figs. 2A-2C illustrate alternative embodiments of system 900.

10 [0061] Fig. 2D shows an embodiment of system 900 comprising two pressure sensors 928 coupled to the fluid-filled cuff 903.

[0062] Fig. 2E shows an alternative embodiment of system 900 comprising at least two lap bands, each lap band comprising at least one sensor 926.

[0063] Fig. 3 illustrates ingestion of food or drink into a stomach.

15 [0064] Fig. 3A shows a cross-sectional view of the superior portion of the stomach constricted by a lap band 902 with a fluid filled cuff 903.

[0065] Figs. 4A-4C show the pressure waveforms from pressure sensor signals one might expect with food or drink input. More specifically, Fig. 4A shows the expected pressure waveforms from an ingestion of food 1000. Fig. 4B illustrates an overeating event. Fig. 4C shows the expected pressure waveforms 1200 from a drinking event.

20 [0066] Fig. 5 shows the pressure waveforms 1300 that occur with injection of fluid, e.g. saline, into the port of the lap band.

[0067] Fig. 6 shows pressure waveforms from peristaltic waves 1400.

[0068] Fig. 7 shows an exemplary intragastric balloon-sensor-monitor system 1500.

[0069] Fig. 8 shows a method of treating a patient with an unhealthy ingestion pattern 2000.

[0070] Fig. 8A-E show alternative treatments method comprising the therapeutic implant.

[0071] Fig. 9 schematically shows a system and method for classification of ingestion events

5 based on signals from a plurality of sensors.

DETAILED DESCRIPTION OF THE INVENTION

[0072] The present invention often takes advantage of processors to enhance obesity therapies that rely on restrictive implants disposed along the gastrointestinal tract. Some 10 embodiments of the present invention relate to feedback systems and methods for communicating implanted sensor-based information so as to affect behavior modification for eating disorders. Some embodiments of the present employ systems which alter a restrictive implant in response to signals. Although embodiments of the invention make specific reference to treatment for obesity, the system and methods described herein may be 15 applicable to any treatment in which presenting feedback regarding patients' eating and/or exercise habits is desired.

[0073] Embodiments of the present invention collect information regarding the patient's eating and exercise habits via one or more sensors implanted within the body of the patient. This information can then be reviewed by a clinician during office visits and used in 20 coaching the patient. Coaching may include helping the patient to make healthy lifestyle choices, such as specifically encouraging the patient to decrease his or her caloric intake while increasing his or her caloric expenditure. Compliance with physician advice may be low in obese patients and caloric intake is often under-reported while caloric expenditures are often over-reported. Although eventually weight gain or loss by a patient will indicate 25 the accuracy of the patient's reporting, the objective monitoring systems provided herein will significantly improve many patients' ability to acknowledge their actual behavior, to identify elements of their behavior that can be changed to improve health, and to effect incremental changes toward achieving long term health goals. The implantable sensors will often detect eating events, solid versus liquid intake, and optionally even meal 30 compositions. The various implantable sensors can be implanted at the same time as the surgical procedures so as to minimize the number of surgical or endoscopic interventions in the patients. The systems and methods described herein may identify eating and other behaviors which the patient is not aware of (including night-time eating and the like).

These systems and methods may also improve the correlation between positive patient behavior and beneficial positive reinforcement, and decrease deleterious correlations between negative patient behavior (such as under-reporting of actual ingestion, over-reporting activity levels, and the like) with misguided positive reinforcement. Such 5 improvements may be particularly effective at promoting and/or maintaining healthy activities when ultimate health goals remain distant.

[0074] The sensor and feedback system of the present invention is not subject to the reporting bias of the patient, thus presenting an objective view. In addition, embodiments of the present invention allow data to be collected twenty-four hours per day, seven days per 10 week, which provides an accurate record of the patient's behavior without dependence upon the patient's memory or commitment to the eating and exercise tracking process. Some embodiments may sense and/or restrict caloric intake, such as using a band implanted around the stomach so as to constrict flow along the gastrointestinal tract, a gastric balloon inflated within the stomach, or the like. In still other embodiments, the present invention 15 also provides stimulation of the stomach to reduce caloric intake.

[0075] Embodiments of the invention provide a system that accesses the data collected by the implanted system remotely. The system is then accessible by the patients and/or the patients' health coaches to support the patient in achieving their weight reduction goals. The automated availability of behavior modification feedback, shortened time between 20 "coaching sessions" and increased accuracy of the sensor data will improve outcomes for the patients.

[0076] In some embodiments, the invention may employ aspects of social networking systems, with sensor-based information that has been generated using signals from an implanted sensor often being available to one or more members of a group. The group may, 25 at least in part, be defined by the patient giving permission to particular individuals. Other members of the group (such as the patient and a supervising physician) may be defined when the group is first organized. Many patients having implanted sensors may join a mutual support group of patients, with sensor-based data being shared between the implant recipients. Advantageously, these systems may allow patients to receive feedback within a 30 relatively short time after exhibiting behavior that is sensed by the sensor, preferably within two days of the sensor identifying an eating event or activity level, and ideally within one day of the behavior. Using telemetry-based communication between the implanted device

and a home monitor (or other intermediate device), some embodiments may allow daily uploads, and/or send messages to a smartphone or personal digital assistant (PDA) in near real time. This significant shortening of the time delay between patient behavior and relationship-based feedback to the patient may provide significant advantages over feedback provided through monthly, quarterly, or annual appointments with a dietitian or physician. Nonetheless, communication enhancement described herein may provide efficacy benefits for alternative embodiments that rely on uploading of patient data during such routine appointments.

[0077] To facilitate the relationships employed for implant patient feedback, embodiments of the invention may make use of aspects of Web-2.0 systems such as FaceBook™ social networking systems and methods, MySpace™ social networking systems and methods, Linked In™ social networking systems and methods, or the like. Embodiments may also employ aspects of known weight reduction support group systems and methods, particularly those that are enhanced through electronic telecommunications such as the WeightWatchers.com™ weight management portal, TheDailyPlate.com™ nutrition and weight management system, and the like. The sensor data sharing aspects of many embodiments may employ systems somewhat analogous to (and/or may be modified from) web-enabled athletic training community systems such as those of TrainingPeaks.com™, EnduranceNation.us™. Still further aspects of the invention may be facilitated by systems and methods that have been developed (and are continuing to be developed, and/or will be developed in the future) in support of Health 2.0 concepts. Hence, embodiments of the inventions described herein may leverage or be modified from a variety of known technologies, including by employing Elgg tools and solutions for creation of online communities as available at <http://elgg.org>.

[0078] An example system 100 suitable for implementation of embodiments of the present invention is illustrated in Fig. 1. In the embodiment shown, the system 100 comprises an implanted device 110 that communicates with a home monitor 120 via a wireless transmitter 112, such as an RF telemetry module. The implanted device 110 includes at least one sensor 114 and, optionally, stimulation circuitry 116 for providing therapeutic stimulation to the patient. A server 130 communicates with home monitor 120 via an internet or other telecommunication system so as to allow access to sensor-based data via a portal 150 and/or health coach workstation 160, thereby providing sensor-based

feedback to a patient 140 (through direct presentation of the sensor-based information to the patient, and/or through a health-coach/patient relationship).

[0079] Each of implanted device 110, home monitor 120, server 130, health coach workstation 160, and a portable patient device will typically include associated data processing systems, with the overall feedback system 100 combining their data manipulation and communication capabilities into an overall data architecture. Generally, the data processing systems included in the discreet devices of the invention may include at least one processor. For implantable device 110, this will typically include circuitry implanted in the patient. Other devices of system 100 will include circuitry external of the patient. Such external processor circuitry may include one or more proprietary processor boards, and/or may make use of a general purpose desktop computer, notebook computer, handheld computer, smart phone, or the like. The external processor may communicate with a number of peripheral devices (and/or other processors) and these peripheral devices may include a data and/or programming storage subsystem or memory. The peripheral devices may also include one or more user interface input devices, user interface output devices, and a network interface subsystem to provide an interface with other processing systems and networks such as the Internet, an intranet, an and/or the like. Implanted circuitry of the processor system may have some of the constituent components described above for the external circuitry as well being coupled to an implanted battery or other power source, with the implanted circuitry generally employing processors, data and software storage, and wireless communication capabilities (although hard-wired embodiments or other transcutaneous data transmission techniques could also be employed).

[0080] Both external and implanted memory of the devices of system 100 will often be used to store, in a tangible storage media, machine readable instructions or programming in the form of a computer executable code embodying one or more of the methods described herein. The memory may also similarly store data for implementing one or more of these methods. The memory may, for example, include a random access memory (RAM) for storage of instructions and data during program execution, and/or a read only memory (ROM) in which fixed instructions are stored. Persistent (non-volatile) storage may be provided, and/or the memory may include a hard disk drive, a compact digital read only memory (CD-ROM) drive, an optical drive, DVD, CD-R, CD-RW, fixed or removable flash memory, memory sticks, solid-state removable memory, and/or other fixed or removable

media cartridges or disks. Some or all of the stored programming code may be altered after implantation and/or initial use of the device to alter functionality of the system.

[0081] The functions and methods described herein may be implemented with a wide variety of hardware, software, firmware, and/or the like. In many embodiments, the various 5 functions will be implemented by modules, with each module comprising data processing hardware and associated software configured to perform the desired function. The modules may be largely integrated together so that a single processor board runs a single integrated code for each device, but will often be separated so that, for example, more than one processor board or chip or a series subroutines or codes are used. Similarly, a single 10 functional module may be separated into separate subroutines or be run in part on separate processor chip that is integrated with another module. Hence, a wide variety of centralized or distributed data processing architectures and/or program code architectures may be employed within different embodiments.

[0082] The electronic circuitry of the various devices of system 100 communicates via RF 15 wired or wireless networking, and/or via telecommunications linkages for coordinating the presentation of sensor-based feedback from implanted device 110 to patient 140, as well as to monitor and facilitate the various operations of the devices, including sensing, stimulating, signal transmission, charging and/or using energy from a battery device for powering the various devices, and the like. In some embodiments, the electronic circuitry of 20 one or more of the devices includes an internal clock. The internal clock may also include a real time clock component. The internal clock and/or real time clock may be used to control stimulation, e.g., by stimulating or allowing stimulation at a particular time of the day. The real time clock component may also provide a date/time stamp for detected events that are stored as information in a memory device, including sensor-based events, patient 25 presentation events (such as accessing portal 150, receiving a text message, communicating with a health coach or group member, or the like). Optionally, the memory may be preserved by saving information corresponding to an event of interest which is saved along with the time/date when the event occurred.

[0083] Sensor 114 is coupled to the stomach so as to generate signals responsive to 30 ingestion, with the sensor ideally comprising at least one temperature sensor for sensing temperature information from within the stomach. The sensors may be located on or extend from a housing of implanted device 110 and/or the sensors may be located on or extend

from a lead or other device. Alternatively or additionally, a sensor may be located separately on the stomach wall and/or a sensor may be otherwise positioned elsewhere within, coupled to or in communication with the patient. In some embodiments, data obtained from the sensor may be pre-processed to remove noise or unwanted artifacts before 5 it is analyzed. Additional sensors may be included, including an accelerometer and/or a heart rate sensor to measure patient activity or the like. The housing of implanted device 110 will typically contain a battery and circuitry of the implanted device, and may be similar to other known implantable stimulator housing structures used for heart pacemaker systems and the like. A suitable heart rate sensor may comprise an electrode or other sensor 10 engaging the stomach wall so as to receive far field electric signals from the heart. Optionally, such a heart rate sensor may employ the same electrode as used to stimulate stomach tissue to inhibit ingestion, though separate electrodes may alternatively be used. Heart signals, accelerometer signals, and/or other activity sensor signals may, like 15 temperature or other ingestion sensor signals, be processed and recorded using circuitry 116. Suitable sensors and implantable devices, as well as aspects of the other devices of the devices of system 100, are described in (and/or may be modified from those described in) U.S. Patent Application Ser. No. 12/145,430, filed on June 24, 2008 and U.S. Patent Application Ser. No. 10/950,345, filed on September 23, 2004, both of which have 20 previously been herein incorporated by reference. Processing of sensor signals so as to identify or classify ingestions events and/or patient activity level to be communicated by system 100 (which may occur partially or entirely in implanted device 110, home monitor 120, or server 130) may be more fully understood with reference to Provisional U.S. Patent Application No. 61/122315, filed on December 12, 2008 and U.S. Patent Application No. 12/637452, filed on December 14, 2009 which were also previously incorporated herein by 25 reference.

[0084] The home monitor 120 includes a processor 122, a storage medium 124, and transmitting/receiving circuitry 126 and is capable of interrogating the implanted system 110 (and of receiving sensor-based data in response) when the patient is within a predetermined distance of the monitor. In some embodiments, this distance is 30 approximately twenty to thirty feet. The data interrogation could also be initiated by the patient via an input into home monitor 120 or a mobile device such as an iPhone® smart phone with abiliti Pocket Coach software. The information communicated to the home monitor 120 is encrypted and sent via the internet to a HIPPA compliant server 130. The

information is then accessible directly by the patient 140 or by approved medical personnel serving as the patient's health coaches (optionally via a workstation 160) via a secure web site or other portal 150. While the home monitor will often comprise a desktop computer or other desktop unit powered by a wall plug, alternative systems may employ home monitors 5 with smaller form factors (the home monitor optionally comprising and/or being similar in size to a notebook computer, a smart phone, a personal digital assistant, or the like) powered by batteries or other portable power sources. Where wireless phone capability is not available to a patient (such as for a patient visiting or living in a rural area) the home monitoring system could also comprise a hand held computer and a port that is connected to 10 the internet via a land-based telecommunications link such as via a modem and telephone connection. The implanted device could be interrogated through radiofrequency (RF) communication with the handheld computer. Such a handheld computer could also be used to enter journal information. Placing the hand-held computer in the port would allow uploading of retrieved device data, and journal entries to the internet portal. Some or all of 15 the functionality of the home monitor 120 may instead be implemented using a portable device 170 such as a smart phone, personal digital assistant, or the like. Even when a home monitor 120 is included in the system, such portable devices will allow the patient to benefit from communications to and/or from server 130 when the patient is out of the house.

[0085] The server 130 contains a number of algorithms designed to evaluate the 20 implanted device data logs in comparison with goals established by the patient and his or her health coaches 160. Based upon the results of the analysis, such as whether the goals have been met, coaching messages may be sent to the patient, for example via email, text message or telephone call. The messages are designed to provide encouragement for positive results and positive reminders for negative or neutral results. This coaching feature 25 encourages patients to obtain energy balance in their lives. Specific examples regarding energy expenditure include sending encouraging messages for meeting daily or weekly activity goals or sending patient alerts if extended periods of sedentary activity have occurred. With regard to caloric intake, examples include communicating feedback to the patient as to whether eating patterns show adherence to the eating plan or whether caloric 30 intake is meeting daily, weekly, or monthly goals.

[0086] Information in the data logs from the activity and consumption sensors of the implanted device 110 will also allow cross-checking between the patient's activity and meal diary and device-detected events. If the diaried and the detected events do not match (such

as when the sensed data indicates that food was ingested but a snack or meal was not logged in the diary, or when a meal time or food intake quantity exceeds a logged meal), then reminders may be sent to the patient to enter additional information in the diaries, and/or to a health coach to check in with the patient. Diary entries may be made by a patient via

5 multiple devices (for example, using a home computer when at home, a notebook computer when at the office or traveling, and/or a Smart Phone while at a restaurant, or the like) and in a variety of different formats (including options for text diary entries, voice entries, photo entries taken via a digital camera or telephone, and the like). Although diaries for the purpose of calorie counting have been typically inaccurate due to lack of patient compliance 10 or attention, this feedback system facilitates improved accuracy. In addition, alerts can be set that send performance summary reports to the patient's health coach and/or physician, which allows the health coach or physician to intervene when needed. The intervention could be in the form of extra coaching for the patient, revising of a weight loss/exercise plan, reprogramming of the implanted device stimulation parameters, or the like.

15 [0087] In embodiments of the present invention, the patient may be provided with a hand-held or pocket device capable of receiving reminders and other notices from the server 130, or the reminders may be sent to a general purpose hand-held or pocket device such as a cell phone or e-mailer, optionally using an appropriate local user interface or other software resident on that device. A patient identification and/or password may optionally be entered

20 to the portable device to obtain patient data so as to prevent others from accessing sensor-based data. The notices transmitted to the portable device may include daily inspirational messages; diet and exercise education information; and particularly feedback messages (for example, identifying positive and negative events, reached daily goals, missed goals, skipped meals, excessive meal quantities or times, and/or added meals or snacks). The

25 feedback messages may be generated by algorithms contained on the server 130; and/or cross-checking between device data logs and patient reporting. In some embodiments of the invention, patients may be offered the option to join an online support group of patients with similar body mass indexes (BMI) who have similar attributes and weight loss goals.

This group may meet online using the website 150 to provide support for one another, as

30 well as review each other's results and provide support and encouragement to each other via email or text messaging via their patient-associated portable devices. Hence, the patients may optionally share access to their sensor-based data with one or more other appropriate patients so as to allow the other patients to act as health coaches to the patient in which

device 110 was implanted, and/or so as to allow the implant patient to coach those other patients based on their associated sensor-based data. The patient will also optionally have the ability to invite health coaches into the online community, with the patient typically granting and managing a support group of the patient by granting permission to individuals

5 to whom the patient is willing to allow access to the patient's sensor-based data. The supporter or member of the group may be a spouse, a gym coach, a parent, a friend, or a family member. In some embodiments, the group may include another patient having an implant providing sensor-based data. Hence, the group may comprise a mutual support group.

10 [0088] The patient and/or health coach may obtain updates by accessing a web site or other portal 150. The portal will optionally comprise a secure website into which the patient or other system user enters a patient identifier and/or password, allowing patients to log into the site with confidence that the system is safe and secure. Patients should feel sensitive medical data is sufficiently protected and that highly sensitive medical data is not displayed as appropriate given the value of the portal. Portal 150 may optionally comprise a "support dashboard," includes a comprehensive set of weight loss tools designed to support the individual. In addition, the support dashboard may allow access to the data logged by the implanted device 110 by the patient. The usefulness of the weight loss tools included in portal 150 may be enhanced through the ease by which the patient is provided accurate information on his or her daily activity and consumption. The sensor-based information may optionally be enhanced by patient reporting of specific food quantities, food types, caloric intake, and/or the like. The support dashboard may include features such as: a calorie database, an online calorie counter, a packaged food database, meal preparation support (such as custom meal menus generated for that patient), an activity diary, an exercise guide and planner, a weight tracking log, a body-mass index calculator, activity or exercise reports, meal frequency and duration reports, and/or a message center. Portal 150 may present patient performance based on predetermined activity and caloric goals, optionally including daily kilocalories to be burned, daily calories consumed, and/or a net summary of the patient's energy balance. Portal 150 may also present additional sensor-based data, including sleep or rest data (such as the number of hours slept, a quantified quality of sleep or other rest periods, and the like).

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[0089] Referring still to Fig. 1, portal 150 may have a food calculator to look up calories of food types, to input quantities of their planned or consumed meals, and the like. Food

calories can be input and/or determined in a variety of different ways, with the site optionally employing a food calculator or linking to a commercial calorie identifying website such as CalorieKing.com or the like. Meal logging may optionally include uploading data or photos to the portal directly or by linking to a meal logging web-base 5 service such as that which was offered commercially by myfoodphone.com. Portal 150 may also have commercially available look-up caloric and/or nutritional data from food suppliers, including commercial prepackaged customized foods suppliers, restaurant chains, or the like.

[0090] Portal 150 may facilitate networking with identified friends using known social 10 networking capabilities, giving users the ability to email to friends and health care providers and accepting input from such individuals so as to allow them to make public or private comments and the like. The members may connect into a live chat room sponsored by the health care practitioner support group (if desired). This may allow real time coaching based on individual own performance on eating, exercise and lifestyle opportunities. The portal 15 may also support a group or circle of friends to allow individuals to in chat real time or transmit messages to one another. Portal 150 may optionally accept predetermined or customized user data, allowing the user to store desired health related information on their personal page, and to control the access of others to that information. This data could include blood pressure, glucose and other data indicative of the general health status or 20 goals of the patient. The portal will allow for daily notes from the individual, this will allow users to note overall feelings of wellness or questions they might have about eating and motivations.

[0091] To enhance the efficacy of coaching and overall feedback, portal 150 may allow 25 for feedback from the network based on the individual's goals. The site will allow for messaging to the individuals own page (as well as other portable or connected device, as described above) which the user chooses. This messaging may be configured to prompt the individual based on performance achieved or notes about missed activity events, meal events, etc. The portal may also notify users when a member of their selected member friends has achieved their personal goals and/or accomplishments. Portal 150 may also 30 include goal-setting and behavior/goal comparison tools. Simple goal setting fields may optionally be available for the patient, though more sophisticated systems may allow the patient to enter a long-term goal and may interactively help the patient to determine short term and long term intermediary goals so as to reach their ultimate weight reduction target.

The system may, for example, provide an indication of the quantity of exercise that would be appropriate to achieve an interim or short term weight loss given the patient's sensed ingestion behavior. Alternatively, a reduction in ingestion may be determined based on maintaining the patient's sensed activity level may be identified by the system. Expected 5 results from changes in ingestion and activity may be identified by the system. As significant weight loss may not be measured until a patient has maintained compliance for a relatively extended period, more immediate short-term goals may also be identified by the system, including reduction in a size of the patient (such as a reduction in dress or pants size, a reduction in waist size, a reduction in neck, arm, or leg circumference, an increase in 10 walking endurance or speed (or other quantifiable exercise parameters), or the like may also be identified). Portal 150 may allow the patient to revise the short term and long term goals throughout the course of treatment, and may generate comparisons between the patients measured and sensed performance with their goals. The system may also be capable of tracking performance against team goals, with a team comprising weight-loss patients of a 15 group. Team goals may be generated by the team, a healthcare provider of the team, or both. As an example, a physician could create a team of patients, each patient of the team having an implanted device. The physician could then work with the team to set a team's goals. This will allow the spirit of competition to be added into the mix for changing the behavior of the individual members of the team.

20 [0092] Portal 150 may include or be linked to one or more reference websites. The portal will preferably have a number of selected reference sites for members to choose from. These sites will allow users to select from a number of tools which the users may prioritize or the site may keep a current list of most frequently used sites. This allows users to refer to a particular reference site based on changing priorities and behaviors. Suitable reference 25 sites may include information on nutrition (food selection and net calorie), food preparation, activity guidelines (walking and other exercises), Kcal Expenditure charts (including activities of daily living), and/or the like. Portal 150 will allow the user to communicate their health status to others, such as by providing the ability to send permission to view the patient's page to an MD, nutritionists, or a selected friend or group member. The patient's 30 page on the portal will typically store a history of the patient, including their weight, wireless or other uploads by or regarding the patient, and the like. Educational links may facilitate access to nutritional information, exercise information, stress management techniques, and lifestyle coaching guides.

[0093] As indicated above, a number of additional devices may communicate with the components of system 100 shown in Fig. 1. Along with portable or handheld devices 170 (such as a BlackBerry™ wireless e-mailer, an iPod™ or other mobile music player, an iPhone™ or other mobile phone, and the like), home monitor 120 or server 130 may 5 communicate with scales (for measuring a weight of the patient or food), pedometers, and the like. In exemplary embodiments, home monitor 120 receives wireless telemetry from a scale, glucose monitor, blood pressure cuff, and/or the like.

[0094] Fig. 1A shows an exemplary gastric band sensor system implant 900. This embodiment includes a gastric band, laparoscopically implanted, also known as a lap band 10 902 having a fluid-filled cuff 903 coupled to an implanted port 904 via a fluid conduit 906. The gastric band may comprise any such lap band currently marketed or available in clinical trials, as for example, the Realize® Adjustable Gastric Band from Ethicon Endo-Surgery, Inc., the Lap-Band® from Allergan, Inc., the Midband™ from Médical Innovation Développment, and Heliogast® Band from Helioscopie, MiniMizer Extra from Bariatric 15 Solutions. The gastrointestinal constriction provided by lap band 902 can be varied by injecting or removing fluid from port 904 using a syringe. Along with mechanically constricting gastrointestinal flow, system 900 includes a housing 920 with circuitry comprising a processor 922 and a battery 924 to wirelessly transmit signals generated in response to signals from one or more sensors 928 to a data collection center. The data 20 collection center comprises the web portal 150 shown in Fig. 1 or a data server. Note that the housing 920 may optionally be incorporated into port 904.

[0095] System 900 will sense ingestion using signals from at least one sensor 926. Sensor 926 comprises at least one of a pressure 928 (e.g. a MEMS-type, strain-gage, etc.), 25 temperature, pH, acoustic, or optical sensor to detect food or drink intake. Sensor 926 may also comprise an activity sensor, such as an accelerometer, heart rate sensor, temperature-based ingestion sensor and/or a core body temperature sensor. The at least one sensor may be wired to the housing 920, or communicate wirelessly with the processor in the housing.

[0096] Figure 1B illustrates the electrical stimulation component of the gastric band sensor system implant 900. The stimulator 20 comprises a housing 21 implanted 30 subcutaneously within a patient. The stimulator further comprises leads 22a, 23a extending from the housing 21 through the abdomen and to the stomach 100 where electrodes 22, 23 at the end of the leads 22a, 23a are implanted into the stomach muscle layer from the

outside of the stomach 100. A method of implanting the stimulator housing 21 and laparoscopically implanting the electrodes 22, 23 in the stomach 100 is generally known to those of ordinary skill in the art.

[0097] The housing 21 further comprises a sensor 24a located on the housing 21 and/or a sensor 24b located elsewhere in the patient and coupled to the electronic circuitry 29, (Figure 1B) in the housing 21 by lead 24c. The sensor 24a or 24b may, for example, include an accelerometer that is configured to sense motion of the patient. The stimulator also includes sensors 25, 26, that are implanted on and in the stomach 100, respectively, with leads 25a, 26a extending from the sensors 25, 26 to the housing 21. Sensor 26 is exposed to the inside of the stomach 100 while sensor 25 is attached to the outside of the stomach. Leads 22a, 23a and 24c, 25a, 26a are electrically coupled to the electronic circuitry 29 located in the housing 21. When the sensors 25, 26 are implanted in the stomach, they may sense presence of material in the stomach, composition of such material and temperature, pH or pressure within the stomach, and/or patient motion corresponding to respiration or gross movement. Sensors positioned on the stomach may also sense various parameters that indicate the actions of the stomach, e.g., movement, contractions. The sensors positioned on the stomach may also utilize various imaging techniques, e.g., ultrasound, and light, to identify presence or composition of food or material in the stomach.

[0098] In use, once the stimulator 20 is deployed, electrical stimulation is provided through electronic circuitry 29. The electronic circuitry 29 is capable of producing various types of programmable waveforms that provide stimulation to the smooth muscle lining of the intestinal tract. It is well known to those of ordinary skill in the art, there are many different types of electrical stimulation programs and strategies which can be utilized for providing electrical stimulation parameters through the circuitry 29, the principal focus being providing electrically stimulating parameters for the stomach. In one embodiment the focus of the electrical stimulation is to cause gastric retention of food to produce a sensation of satiety. Another focus of the electrical stimulation may be to interfere with the innate peristalsis of the stomach, which is intended herein to mean to movement of the stomach that typically also acts to break down food and/or moves material towards the antrum or out of the stomach. Another focus is to cause a sensation of satiety by stimulating the stomach. Another focus is to control the secretions relating to the stomach or hunger by stimulating the stomach.

[0099] An embodiment of the electronic circuitry 29 is illustrated in Figure 1C. The electronic circuitry 29 of the stimulator is located in the housing 21. The electronic circuitry 29 may be in a form of a standardized chip that may be used with one or a variety of sensors, including but not limited to those described herein. The electronic circuitry 29 or similar electronic circuitry may also be included with separately implanted sensors or components of the system. Thus the various components may be configured to communicate with the other components through telemetry or similar signaling.

[0100] The circuitry 29 comprises, a microprocessor or controller 40 for controlling the operations of the electronic circuitry 29, an internal clock 41, and battery device 44 such as a pair of lithium iodine batteries for powering the various components of the circuit 29. As such, the controller 40 and battery device 44 are coupled to each of the major components of the circuit as would be apparent to one of ordinary skill in the art. The battery 44 has its output supplied to a DC-to-DC converter 44a to provide a higher voltage, which is utilized for electrical stimulation pulses. The DC-to-DC converter 44a is conventional and provides an output voltage desired for stimulation. The internal clock 41 may also include a real time clock component that communicates with the controller/microprocessor 40. The real time clock component may be used to control stimulation, e.g. by stimulating or allowing stimulation only at a particular time of the day. The real time clock component may also provide a date/time stamp for detected events that are stored as information in a memory device. The memory may be preserved by only saving information corresponding to an event of interest which is saved along with the time/date when the event occurred.

[0101] The controller 40 is coupled to stimulation driver 42, which is coupled to stimulating electrodes (e.g., 22, 23) that are used to provide electrical stimulation in accordance with programmed parameters, including in response to sensing conditions relating to the patient or the patient's intake of food as described herein.

[0102] The controller 40 is coupled to ROM 43, which contains the program instructions for the controller 40 and any other permanently stored information that allows the microprocessor/controller 40 to operate. The controller 40 addresses memory in ROM 43 through address bus 43a and the ROM 43 provides the stored program instruction to the controller 40 via data bus 43b. The controller/processor 40 controls the telemetry coil 45, which communicates with an external control or programming device 60 (Figure 1D), e.g., via a modulated RF signal. Controller/processor 40 is coupled to a buffered oscillator 51

that provides an RF signal to be emitted from the telemetry coil 45. The RF signal is preferably at about 100kHz-5Mhz so that the signal is efficiently transmitted through tissue. The controller 40 controls the oscillator 51 and provides data to be modulated with the RF signal. For example, various sensed data such as motion, transmitted or reflected light 5 parameters, pressure, pH, temperature, local muscle contraction, strain, impedance, electrical activity (EMG) etc., may be delivered via a modulated signal through the telemetry coil 45. When the telemetry coil 45 is receiving an external telemetry signal, the buffered oscillator 51 is disabled. Telemetry signals received on the telemetry coil 45 are detected in a detector circuit 51a and communicated to controller 40. The detector circuit 10 may be selected based on the modulation used for the telemetry signals.

[0103] The circuit 29 may also be coupled through A/D converters (with amplifiers) 46a, 46b, 46c, 46d to one or more sensors 25, 26, 24a, 24 respectively. The A/D converters convert a representative analog electrical signal from the sensors into a digital signal communicated to the controller 40. Suitable types of these sensors may include but are not 15 limited to the types of sensor described herein. Such sensors at various locations are coupled to the electronic circuit by way of lead wires or through alternative means of communication such as telemetry, wireless communication or indirectly through a separate controller e.g., controller 70 shown in Fig. 1D.

[0104] Controller 40 is coupled to RAM 50 via an address bus 50a for addressing a 20 location in RAM 50 and a bi-directional data bus 50b for delivering information to and from RAM memory 50. The RAM memory 50 includes event memory 48 that temporarily stores data recorded by sensors 24a, 24, 25, 26, or electrodes 22 23. RAM memory 50 also includes a programmable memory 49 which may be programmed, for example, by an external programmer 60. The data stored in the programmable memory may include 25 specifications for the electrical stimulation operating modes (e.g., waveform, type of stimulations: for pacing, inducing, interfering with or reversing contraction, for interfering with innate activity, for controlling biochemistry or secretions relating to the stomach, or other types of stimulation) and various procedures or responsive parameters (e.g., for turning on or off various sensing or stimulation functions, parameter modification, protocols 30 or procedures for recognizing various conditions of the patient of the patient's gastrointestinal tract and protocols or procedures for responding to such recognition). These data and procedure/protocol elements, including responsive elements that respond to sensed data, may also be located in whole or in part in other controller devices that may be located

independently from electronic circuitry 29. The programming may be done in response to sensed information or, it may be done automatically by an external controller or as desired by a treating physician, etc. Sensed data acquired from the sensors or electrodes, provided to the controller 40 may be stored in event memory 48 in the RAM 50. The data stored in 5 the event memory 48 may be sent intermittently as data bursts via the telemetry coil 45, as opposed to continuously, in order to save battery power. The clock may also mark or date/time stamp the data stored in event memory. The processor also may select events based on predetermined thresholds or characteristics that are to be stored as a significant event, while other events are filtered out and not stored.

10 [0105] The electrodes 22, 23 are coupled through A/D converters 46e and 46f to the microprocessor 40. A/D converter 46e converts the electrical EMG signal sensed by the electrodes 22, 23 into a digital signal representative of the EMG electrical activity, which is delivered to the microprocessor/controller 40 and stored in the event memory 48 in the RAM 50. Also, the A/D converter 46f converts the electrical signal sensed by the 15 electrodes 22, 23 and provided through the impedance circuit 53 described below, into a digital signal representative of tissue impedance, which is delivered to the microprocessor and stored in the event memory 48 in the RAM 50.

20 [0106] The electrode 22, 23 outputs are used to provide electrical stimulation delivered through the stimulation driver 42 to electrodes. The stimulation modes and parameters can either be set using the external programmer 60, or they may be set in response to sensory feedback. The same electrode outputs may be used to sense impedance of the stomach tissue or of the contents of the stomach depending upon the location of the electrodes. Impedance circuit 53 is used to sense impedance and EMG or other electrical activity 25 information is provided to the processor 40 through A/D converter 46e. The electrodes 22, 23 are coupled through coupling capacitors 55a and 55b respectively, to output of electrical stimulation driver 42 and input of A/D converters 46e, 46f.

30 [0107] The impedance circuit 53 comprises a constant current source oscillator 54 that oscillates at a frequency of 50-100kHz, and A/D converter 46f with an output coupled to the controller 40. The oscillator 54 provides a constant current source through electrodes 22, 23 resulting in a voltage across the electrodes 22, 23 that is representative of impedance, in view of the constant current. The voltage is provided through and is converted by A/D converter 46f to a digital signal representative of impedance. A/D converter 46f has a

bandwidth that includes the 50kHz frequency signal while filtering out the electrical stimulation signal that is delivered to the electrodes 22, 23 through electrical stimulation driver 42, and the EMG signal that is sensed by the electrodes 22, 23. Both of the outputs are filtered out by A/D converter 46f. A/D converter 46e has a bandwidth that filters out the 5 50-100kHz signal. Further, when a stimulation signal is being delivered, the controller 40 does not receive signals from A/D converters 46e and 46f. Thus the EMG and impedance sensing functions and the stimulation deliver functions may be separated through the electronic circuitry 29, though using the same electrodes.

[0108] An additional circuit 58 may be provided in the electronic circuitry 29 comprised 10 of similar components configured like impedance circuit 53. The circuit 58 delivers an interrogating electrical pulse to the electrodes 16, 17 and senses impedance of material between the electrodes. The electrodes 16, 17 are positioned to be in electrical contact with contents of materials that may be in the stomach

[0109] Additional stimulating sensing electrodes and corresponding signal processing 15 circuits may also be provided.

[0110] Figure 1C illustrates the electronic circuitry 63 for external programmer 60. The electronic circuitry 63 comprises: a microprocessor or controller 70 for controlling the operations of the electronic circuitry, an internal clock 71, and a power source 74 such as battery device for powering the various components of the circuit 63. As such, the 20 controller 70 and battery device 74 are coupled to each of the major components of the circuit as would be apparent to one of ordinary skill in the art. The controller 70 is coupled to a speaker 67 that provides audible alerts and a display 66 such as a CRT to display data such as recorded data, sensed parameters, treatment parameters and status of device (e.g. position or battery charge status). The controller 70 is coupled through a buffer 64 to 25 external input device 65 that is used to provide program parameter input, e.g. from a user, for a user to request data displayed in a desired format through display 66 or speaker 67, or to turn device on and off. The external programmer 60 is also provided with an external data port 68 to interface with a computer and provide a means for bi-directional communication of data or commands. The computer may provide programming or data to 30 the controller/microprocessor 70. A user may also interface with the computer to provide treatment protocols or changes in protocols, etc. Also, a user may control the turning on and off of the stimulation program.

[0111] The controller 70 is coupled to ROM 73, which contains the program instructions for the controller 70 and any other permanently stored information that allows the microprocessor/controller to operate. The controller 70 addresses memory in ROM 73 through address bus 73a and the ROM 73 provides the stored program instruction to the controller 70 via data bus 73b.

[0112] The transceiver comprises a telemetry coil 74, an oscillator 72 and an A/D converter 76. The controller 70 controls the telemetry coil 75, which communicates with stimulator electronics 29 (Figure 1B) through its telemetry coil 45. Controller 70 is coupled to an oscillator 72 that provides an RF signal, preferably having a characteristic frequency of 500kHz or higher, to be emitted from the telemetry coil 75. The controller 70 controls the oscillator 72 and provides data to be modulated with the RF signal, for example, programming information, stimulation parameters, etc. The telemetry coil 75 also receives information transmitted via RF signal from telemetry coil 45 on the stimulator 10 such as various sensed data, e.g., temperature, pressure, pH, impedance of the stomach or of its contents, optical characteristics of stomach contents, motion data, electrical activity (EMG), etc. The received RF signal is passed through A/D converter 76 and is transmitted to the controller 70.

[0113] The data is delivered to the event memory 78 in RAM 77 by way of data bus 77b for temporary storage. The data may be retrieved from RAM 77 by addressing the storage location via the address bus 77a.

[0114] Event memory 78 temporarily stores data sensed by sensors 24a, 24, 25, 26, or electrodes 22, 23; recorded through controller 40; and delivered via telemetry to the external programmer 60. The data may then be downloaded onto a computer using the external data port 68. The RAM 77 also includes a programmable memory 79 which may be programmed, for example, to specify operating modes such as waveform, frequency, pulse width, amplitude, repetition rate, etc. which programming is then telemetrically communicated to the stimulation device 20. The modes and parameters can either be set using an external programmer 60 and/or set in response to sensory feedback according to programs.

[0115] The stimulator 20 may be programmed to deliver electrical stimulation in response to sensed parameters. The sensors 24a, 24, 25, 26, or electrodes 22, 23, depending upon their specific location, may comprise (but are not limited to): a temperature sensor that may

sense a change in temperature or a rate of change in temperature that indicates ingestion of food or liquid; a pH sensor that may be used to determine when food has been ingested; an optical emitter/sensor that may be used to determine the presence and/or composition of food; a pressure sensors that may be used to sense motility patterns, e.g. presence, strength 5 or frequency of contractions; a contractions sensor that may provide information on stomach contractions and local responses to stimulation; an impedance sensor that may provide information on the content of the stomach and/or an impedance sensor that may determine when a characteristic EMG pattern exists to determine wakefulness of a subject; a motion sensor that determines an activity level or wakefulness of a subject; a biochemical 10 sensor that provide information on biochemical compositions relating to the stomach such as secretions.

[0116] The responsive devices may comprise at least one sensor and at least one responsive element. From sensed information, the responsive element determines the existence of a condition, e.g., presence of food; ingestion of food; type of food ingested; 15 activity level of a subject; wakefulness of a subject; time of a daily cycle or schedule; contractions of the stomach, etc.

[0117] The responsive element may combine a number of sensed parameters to determine the existence of a condition or circumstance or a probability of the existence of a condition or circumstance. The responsive element may thereupon determine a course of treatment, 20 including protocols, stimulation parameters and whether or not to stimulate. In one variation responsive element may respond by stimulating to interfere with the stomach contractions; to slow, stop or reverse the innate peristaltic contractions that tend to move food through the stomach.

[0118] For example, the combined determination of temperature changes indicating 25 likelihood of food ingestion, and an accelerometer indicating that a subject is not sleeping or is not highly active may trigger a responsive element to stimulate the stomach to retain food for a predetermined period of time. The accelerometer can determine a low level of activity indicating likelihood of a sleep state, but may be overridden by a temperature sensor sensing that food has been ingested and thus requiring stimulation. PH may be used in a similar 30 manner as temperature to indicate a likelihood of food ingestion. A timer may also confirm the likelihood that food is being eaten given the time of day, or may refrain from stimulating

in spite of food being ingested if it is a certain time of day, e.g., when the stomach is naturally cleaning out the stomach as it typically does during the night.

[0119] The responsive element may receive input from one or more sensors and, in response, the responsive element may interrogate another sensor for information to determine a course of action. This may be used to save battery or power consumption. This may also be used to confirm the existence of a condition or circumstance using more than one sensor. For example, one or more sensors may provide information that food has been ingested. Upon making this determination, another sensor may be triggered to determine what type of food has been ingested. For example, an impedance sensor may determine characteristics of the content of the stomach by measuring the impedance of the contents of the stomach. An optical emitter/sensor may sense the light reflectance/transmission characteristics of contents of the stomach. This information may be recorded in a memory device and downloaded. Also the information may elicit a simulation response controlled by the responsive element when a certain type of food is detected. In addition foods may be provided as part of an eating regimen that have markers for different types of food. Gastric retention of some foods may be created while permitting movement of others out of the stomach.

[0120] As shown in Fig. 1A, the sensor 928 may be mounted in fluid communication with port 904. Figs. 2A-2C illustrate alternative embodiments of system 900. Fig. 2A shows sensor 928 coupled to the fluid-filled cuff 903, the housing 920, circuitry 922, and battery 924 are also attached to the lap band 902. Fig. 2B shows sensor 928 coupled to the fluid filled cuff 903, while housing 920, circuitry 922 and battery 924 are located outside the lap band 902, optionally attached to the implanted port 904.

[0121] Fig. 2C shows an embodiment of system 900 comprising at least two sensors 926. Pressure sensor 928 may be coupled to the fluid-filled cuff 903. The second sensor 926 may comprise a temperature sensor 927 penetrating the stomach wall, coupled to the housing 920 or to the fluid filled cuff 903 and pressure sensor 928 (not shown). This embodiment is particularly suitable when the sensor 928 must collect data from inside the stomach. In an alternative embodiment the second sensor 926 may comprise a sensor attached to the outside of the stomach 925, coupled to the housing 920 or to the fluid filled cuff 903 and pressure sensor 928 (not shown). In yet another alternative embodiment,

system 900 comprises a combination of at least three sensors 928, 927, and 925, as described above.

[0122] Fig. 2D shows an embodiment of system 900 comprising two pressure sensors 928 coupled to the fluid-filled cuff 903. One pressure sensor 928 may be located above the fluid filled cuff, to measure the pressure above the lap band, and the other may be located below the lap band to measure the pressure in the stomach, below the level of the lap band.

[0123] Fig. 2E shows an alternative embodiment of system 900 comprising at least two lap bands, each lap band comprising at least one sensor 926. The lap bands may comprise different elasticities and each lap band's elasticity may be changed dynamically. The 10 superiorly-located lap band may be used to reduce food intake and sense ingestion events with the at least one sensor. The inferiorly-placed lap band may be used primarily for sensing purposes with the at least one sensor. Since the inferiorly-placed lap band may not be inflated, it may need to be fixed in its desired location with seromuscular sutures such as the MiniMizer Extra from Bariatric Solutions, or other means known in the art. If the 15 superiorly-placed band is not fully inflated, it may also need to be fixated using seromuscular sutures, or other means known in the art. The dual lap band set-up may also comprise other sensors, such as for example a combination of optical sensors that can measure ingestion velocities in the lower esophagus and upper portion of the stomach.

Food and Drink Intake Detection

[0124] Fig. 3 illustrates ingestion of food or drink into a stomach. As food intake occurs 20 pressure increases within the lap band, in the upper portion of the stomach and in the lower esophagus. The lower esophagus and upper portion of the stomach will expand to accommodate the incoming food as shown by dashed lines in Fig. 3. Fig. 3A shows a cross-sectional view of the superior portion of the stomach constricted by a lap band 902 with a 25 fluid filled cuff 903. The lap band restricts the perimeter of the stomach, thus slowing down the passage of the food through the stomach. Following ingestion, food moves down the esophagus to the superior portion of the stomach, accumulating above the lap band placing an increasing amount of pressure on the lap band, as well as the upper portion of the 30 stomach (gastric pouch), and lower portion of the esophagus. This accumulation of food and the accompanying increase in pressure on the lap band will occur up to a certain point, then peristaltic action will push the food through the band, thereby causing a drop in pressure.

[0125] Figs. 4A-4C show the pressure waveforms from pressure sensor signals one might expect with food or drink input. Fig. 4A shows the expected pressure waveforms from an ingestion of food 1000. With each swallow of solid food the pressure on the band increases (1020). As the food fills up the gastric pouch, the lower esophagus peristaltic waves are initiated in the esophagus and stomach to push food through the narrow opening created by the band. If the food is solid and dry, the digestion and peristaltic action on the food will not be enough to push the food out as fast it is entering the stomach. At this point the patient will feel severe discomfort and be forced to stop eating, or a vomiting reflex may occur, and maximum pressure is seen at the band (1000). After a delay, the peristaltic waves eventually empty the gastric pouch and baseline pressure will be again detected at the band (1040).

[0126] Fig. 4B illustrates an overeating event; as food is ingested the pressure increases moderately 1060 until a plateau is reached 1070. However, when overeating occurs, the increased food intake beyond the volume of a normal ingestion event increases the pressure at the band and proximal portion of the stomach to a much higher level 1080. This high pressure sets off the vomiting reflex 1090; after vomiting and the pressure rapidly decreases 1100 with the emptying of the proximal portion of the stomach.

[0127] Fig. 4C shows the expected pressure waveforms 1200 from a drinking event. Compared to the expected pressure wave forms from ingestion of a solid, upon ingestion of a drink 1210, there will be less buildup of pressure because liquid passes through the band with little resistance. However, there will be transient pressure increases 1220 with each swallow of liquid, as the increase in volume will temporarily expand the small upper portion of the stomach. Furthermore, since the liquid can exit the proximal portion of the stomach rapidly, it is unlikely that drink intake will be so fast as to cause the pressure to increase to such an extent that a vomiting reflex would occur.

[0128] The differences in pressure waveforms between a normal eating event and a drinking event can be distinguished by the processor. Drinking events will look like multiple positive pressure transients with a return to baseline pressure very quickly after each transient (nominally less than 30 sec). While an intake of any significant volume of solid food (>20 ml) will lead to an increase in pressure that lasts multiple minutes (5-30 min). In addition because of the pressure put on the gastric pouch and lower esophagus during the intake of solid foods, peristaltic waves will cause large pressure transients at the band, on the order of 10's of mm Hg. An increased pressure that lasts at least 5 minutes, but not more than 60 minutes will very likely be interpreted as an ingestion of a solid; whereas, an increased pressure that lasts at on the order of 10 sec to 2 minutes will very

likely be interpreted as an ingestion of a liquid. These results of the food intake diagnostics can be provided to the patient or physician in order to show compliance or lack of compliance with dietary instructions.

[0129] Fig. 5 shows the pressure waveforms 1300 that occur with injection of fluid, e.g.

5 saline, into the port of the lap band. The baseline pressure 1210 increases as fluid is injected into the port. The increase in fluid (saline) volume expands the elastic portion of the port so that it creates a smaller diameter for food to pass through, which leads to an increase in pressure 1320 upon ingestion of food. The pressure changes caused by eating events with eating events 1320 or drinking events 1330 will manifest themselves on top of 10 the baseline pressure. However, this baseline pressure change may be transient as the volume of the lap band may adjust to accommodate the saline. The occurrence of pressure transients due to peristaltic waves following drink intake, may indicate that the band is too tight. These peristaltic waves may be detected at the band and lead to automated adjustment of the band to reduce pressure.

15 [0130] Fig. 6 shows pressure waveforms from peristaltic waves 1400. Slow waves or peristaltic action in the stomach that is always present, is seen as low amplitude pressure waves at a frequency of about 3 per minute 1410. After food intake occurs, the baseline pressure increases and pressure transients due to swallowing and peristaltic action are seen riding on the baseline change. As food intake continues, the pressure at the band and gastric 20 pouch increases and the pressure transients due to peristalsis increase in amplitude and frequency. As the bolus moves forward, the pressure decreases behind it. Fig. 6 shows the initial small transient pressure increases due to peristaltic activity. The peristaltic waves that occur without the presence of food cause little or no pressure change. However, beginning at the cephalic phase, and when food or liquid enters the stomach the peristaltic waves 25 would cause pressure waves of amplitude and duration that is proportional to the amplitude and duration of the peristaltic wave 1430. The peristaltic activity at the end of the meal is higher in order to push the food out of the stomach towards the small intestine, pressure undulations 1440 caused by these peristaltic waves will occur as the pressure recovers to the former baseline.

30 [0131] Pressure waves due to peristaltic activity need to be differentiated from pressure waves due to food intake. In the case of a pressure sensor on the lap band these pressure waves can be differentiated because of their higher frequency and the amplitude of the

pressure transients is significantly higher than the overall increased pressure waves due to food intake.

[0132] Optionally, temperature, optical, impedance, pH, or acoustic sensors signals may also contribute data to be used in food and drink intake detection. In one embodiment,

5 temperature sensors can detect rapid changes in homeostatic temperature within the stomach cavity. The rapid changes in homeostatic temperature can be used to detect ingestion events, and in particular, ingestions of liquids. In another embodiment, impedance spectrometers could determine water content, acidity or other through the measure of impedance of materials; optical spectrometers may determine the composition of ingested 10 matter (i.e. sugar, carbohydrate, and fat content); pH sensors may determine the ingestion of water and other food through changes in acidity from baseline, and acoustic sensors may detect sound waves as each swallow occurs, and as a food bolus passes through the lap band, etc.

Remote Communication:

15 [0133] Remote communication with the system 900 will allow the use of an automated patient support system that would allow coaching type feedback with regards to their activity and food intake, US Patent Application Ser. No. 61/166636.

[0134] In some embodiments, an electrical conduit extends from a temperature sensor within the stomach, through a transgastric port, and to circuitry 922. This electrical conduit 20 or lead could, but need not have any stimulating electrodes. Suitable trans-gastric temperature sensing probes and ingestion analysis may be described in (or may be modified from those described in) US Provisional Patent Application No. 61/122,315, filed on December 12, 2008, the full disclosure of which is incorporated herein by reference, and US Patent Application No. 12/637,452 filed on December 14, 2009.

25 Food or Drink Classification:

[0135] The pressure waveforms from food 1000 and drink ingestion 1200 can provide input to a food and drink selection algorithm. The detection may be based on slope, maximum deviation from baseline, or other signal characteristics of the pressure waveform regarding event classification. When food intake occurs, diagnostics are stored based on the 30 timing and duration of the intake. The diagnostics may be used in monitoring patient's weight loss therapy.

[0136] As shown in Fig. 2D and 2E, pressure sensors may collect pressure readings above and below the restriction created by the inflated lap band. The two pressure readings may be used to classify the ingestion event: for example if the pressure reading above the restriction is higher than the one below, the ingestion will be classified as a solid; if the 5 pressure reading above the restriction is lower than the one below, the ingestion will be classified as a liquid or an attempt to cheat the lap band by blending solid food with a liquid to bypass the restriction of the lap band.

[0137] As shown in Fig. 9, signals from a combination of pressure sensor and a temperature sensor may be used to improve the accuracy of the food detection algorithm. 10 Thus, a high temperature change combined with a low pressure change over a certain time interval will lead to a classification of the ingestion event as a liquid. A low temperature change, combined with a high pressure change will lead to a classification of the ingestion event as a solid. A high temperature change, combined with a high pressure change, will lead to a classification of the ingestion event as a combined solid and liquid.

15 Caloric Determination:

[0138] The detection of these peristaltic waves by the pressure sensor in the lap band sensor system may aid in the determination of caloric or fat content of a meal. Fat and protein chemodetectors in the small intestine provide feedback information through a vagal pathway that controls the amplitude and duration of the peristaltic activity in the stomach 20 and increases the duration of time the food spends in the stomach. The main contractions occur in the antral portion of the stomach, so they may be detected easier with an intragastric balloon, but as the stomach empties the strong peristaltic activity rises higher towards the body of the stomach and these changes could be sensed by a pressure sensor located in the lap band.

25 Lap Band Adjustment:

[0139] Individual ingestion events or ingestion patterns will trigger various therapeutic approaches. In alternative embodiments, the food and drink intake data may be used to trigger automatic tightening of the lap band upon detection of an ingestion event.

[0140] In other embodiments, the implanted device may be capable of electrical 30 stimulation for therapy delivery to an appropriate portion of the stomach wall. For example, electrodes may be placed inside the lap band, to provide electrical stimulation to the portion

of the stomach in contact with the lap band. In this case, the pressure waveforms will trigger therapy, with the therapy type dependent on the classification of event.

[0141] In another embodiment, the lap band may be only partially inflated, to minimize the side effects such as nausea and vomiting; the partial inflation of the lap band will 5 physically restrict the food intake to a certain extent, while the electrical stimulation to further curb the patient's appetite. A patient will be able to achieve substantial weight loss with minimal side effects.

[0142] In one embodiment the lap band sensor system is capable of automatically 10 adjusting the lap band. The pressure signal could be used to automatically determine when a band adjustment is needed. The adjustment may be based on the baseline pressure level, so that the band could be adjusted to stay at a target level. In a further embodiment, the lap band sensor system may comprise an algorithm to relieve pressure on the lap band for certain periods during the day, between meals and/or at night, to avoid erosion and pressure 15 damage to the stomach tissue under the band. The pressure signal may be useful for detecting pre-vomiting and optimizing lap band adjustment.

Activity Sensors:

[0143] System 900 would optionally include a 3D accelerometer and/or a heart rate 20 sensor. This sensor would provide feedback to the patients as to whether they are meeting their activity and exercise goals. Further, these sensors would provide estimates as to the number of calories burned in during exercise and/or total daily energy expenditure, as disclosed in US Provisional Patent Application No. 61/241,154 which is hereby 25 incorporated by reference. The activity sensor(s) may allow therapy adjustment, such as loosening of the gastric band and lessening the intensity or stopping electrical stimulation, during exercise sessions and for a short period, up to thirty minutes after exercising, to encourage healthy eating patterns.

[0144] The accelerometer data may also reduce the tightness of the lap band when sleep is detected. This may reduce the side effects that have been associated with lap banding, such as acid reflux.

Intragastric Balloon Sensor System:

30 [0145] An alternative embodiment includes a intragastric balloon system 1500 having sensors and telemetry circuitry suitable for implantation in the stomach cavity,

endoscopically deployed stimulation systems having sensors and telemetry circuitry suitable for implantation in the stomach cavity, and the like. The intragastric balloon may comprise any such balloon currently marketed or available in clinical trials, as for example, the BioEnterics® Intragastric Balloon (BIB®) System of the dual intragastric balloon 5 developed by ReShape Medical™ Inc.

[0146] Fig. 7 shows an exemplary intragastric balloon-sensor-monitor system 1500. The sensor-monitor device 1520 may be used in conjunction with an intragastric balloon 1510. In this case the sensor-monitor device 1520 could be inserted within the balloon so that when the balloon is filled with saline inside the stomach, the device would be enclosed 10 within the balloon. The sensor-monitor device will comprise a sensor 1530; the sensor may comprise a pressure sensor that would pick up pressure changes within the balloon.

[0147] Pressure changes that occur outside the walls of the balloon will change the internal pressure of the balloon since the material of the balloon is compliant. In an alternative embodiment, the intragastric balloon-sensor-monitoring system 1500 comprises 15 a monitoring device placed outside the balloon, where a pressure sensor 1520 is attached to the surface of the monitoring device.

[0148] Other sensors, such as pressure sensors (e.g. a MEMS-type, strain-gage, etc.), temperature, pH, acoustic, optical sensor to detect food or drink intake and/or activity sensor, such as an accelerometer, heart rate sensor, and/or a core body temperature sensor. 20 The at least one sensor may be wired to the sensor-monitor device 1520, or communicate wirelessly with the processor in the housing.

Sensors Used with Other Type of Stomach Reduction/Bypass Surgeries:

[0149] In the case of gastric bypass and stomach reduction surgeries, the monitoring device could be implanted at the time of surgery, potentially at one of the incisions used as a 25 port for the laparoscopic tools.

[0150] The sensors and monitoring device may also be used in conjunction with a cardiac device or insulin pump who have cardiac problems or diabetes as a co-morbidity with obesity.

Method of Treatment:

[0151] Fig. 8 shows a method of treating a patient with an unhealthy ingestion pattern 2000. A therapeutic implant comprising a gastric band sensor system or an intragastric balloon sensor system 2010 is implanted into a patient. The sensor(s) in the system will sense ingestion by the patient and generate signals correlating to the ingestion 2020.

5 Ingestion deemed unhealthy will be inhibited 2030. For example, patients are given behavioral guidelines to maximize solid food ingestion, and not to drink high calorie liquids or purees. If the device detects a high proportion of liquid intake, then actions will be taken to inhibit the next liquid intake. Another example of unhealthy ingestion would be when the patient has consumed too many calories over a certain period of time based on food
10 content detection.

[0152] In some cases, as shown in Fig. 8A, a therapeutic implant comprising a gastric band sensor system or an intragastric balloon sensor system 2010 is implanted into a patient. The sensor(s) in the system will sense ingestion by the patient and generate signals correlating to the ingestion 2020. Ingestion deemed unhealthy will be inhibited 2040 by
15 either showing a display to a lifestyle coach and/or patient 2050, an increased pressure within the bladder of the lap band or within the intragastric balloon 2060, or electrical stimulation of the gastrointestinal tract tissue with the implant 2070.

20 [0153] In some cases, as shown by Fig. 8B, a therapeutic implant comprising a gastric band sensor system or an intragastric balloon sensor system 2010 is implanted into a patient. The sensor(s) in the system will sense ingestion by the patient 2080 and signals will be transmitted in response to the sensing 2090, and ingestion information will be displayed to the patient 2100 and/or the patient will be treated 2110.

25 [0154] In some cases, as shown by Fig. 8C, a therapeutic implant comprising a gastric band sensor system or an intragastric balloon sensor system 2010 is implanted into a patient. The sensor(s) in the system will sense physical activity by the patient 2120 and signals will be transmitted in response to the sensing 2130, and physical activity information will be displayed to the patient 2140 and/or the patient will be treated 2150. In an alternative embodiment, the patient will receive both ingestion and activity information, in terms of energy balance; thus the patient will be able to easily visualize whether the
30 calorie intake has been larger than the calorie output, or vice versa.

[0155] In some cases, as shown in Fig. 8D, a therapeutic implant comprising a gastric band sensor system or an intragastric balloon sensor system 2010 is implanted into a

patient. Upon identification of unhealthy ingestion 2160, signals will be transmitted to the patient to stop the unhealthy ingestion 2170.

[0156] Fig.8E shows another alternative treatment method where a therapeutic implant comprising a gastric band sensor system or an intragastric balloon sensor system 2010 is implanted into a patient. Allowed ingestions are identified 2180 and the ingested material is allowed to pass through the implant system 2190. Unhealthy ingestions are identified 2200 and signals are transmitted to the implant to restrict unhealthy ingestion 2210.

[0157] While exemplary embodiments have been described in some detail for clarity of understanding and by way of example, a variety of adaptations, modifications, and changes will be obvious to those of skill in the art. Hence, the scope of the present invention is limited solely by the appended claims.

What is claimed is:

1. A method for treating a patient, the patient having a gastrointestinal tract and an unhealthy ingestion pattern, the method comprising:

deploying an ingestion restricting implant body along the gastrointestinal tract;

generating signals correlating to altering of the implant body; and

inhibiting unhealthy ingestion by the patient in response to the signals sufficiently to modify the unhealthy ingestion pattern toward a healthier ingestion pattern.

2. The method of claim 1, wherein deploying the implant body comprises bariatric surgery so as to surgically implant an implant system for weight loss, the implant system comprising the implant body and a processor coupled to the implant body so as to transmit the signals therebetween.

3. The method of claim 2, wherein the implant body comprises a gastric band defining a channel therethrough, wherein deploying the implant body comprises positioning the band so that the gastrointestinal tract extends through the channel of the implant body.

4. The method of claim 3, wherein the altering of the implant body is performed a plurality of times each day for a plurality of days by altering an engagement force between the gastrointestinal tract and a fluid-filled pressure bladder of the gastric band, the fluid pressure bladder disposed between the channel and a support structure of the gastric band.

5. The method of claim 4, wherein the altering of the engagement force is induced each day by ingestion-related distension of the gastrointestinal tract within the channel of the gastric band, wherein the signals are generated by at least one sensor in response to transient changes in fluid pressure within the bladder, the signals indicating an ingestion event, and wherein the inhibiting of unhealthy ingestion comprises at least one member selected from the group consisting of:

showing a display to the patient or a lifestyle coach, the display corresponding to eating events during the plurality of days;

increasing the pressure within the bladder; and/or

electrically stimulating tissue of the gastrointestinal tract with the implant.

6. The method of claim 5, wherein the at least one sensor comprises one of a pressure sensor, a temperature sensor, an optical sensor, an impedance sensor, a pH sensor, or an acoustic sensor.

7. The method of claim 6, wherein the ingestion event comprises ingestion of a solid.

8. The method of claim 6, wherein the ingestion event comprises ingestion of a drink.

9. The method of claim 4, wherein the signals comprise pressure command signals transmitted to the bladder from the processor of the implant, and wherein the altering of the engagement force is induced by changes in fluid pressure within the bladder in response to the pressure command signals so that the pressure within the bladder is decreased each day to allow healthy ingestion and increased each day to inhibit unhealthy ingestion.

10. The method of claim 3, wherein the processor is coupled to an actuator of the gastric band, and wherein altering the implant comprises varying a size or shape of the channel of the gastric band with the actuator in response to signals from the processor such that restriction of ingestion is altered.

11. The method of claim 10, wherein the actuator comprises a fluid actuator.

12. The method of claim 10, further comprising energizing the actuator with the signals so as to activate the gastric band and increase restriction and decrease ingestion into the patient.

13. The method of claim 10, further comprising energizing the actuator with the signals so as to deactivate the gastric band and decrease restriction and allow increased ingestion into the patient.

14. The method of claim 2, wherein the implant body comprises a gastric balloon, and wherein the processor is coupled to an actuator, and wherein altering the implant comprises varying a size of the gastric balloon with the actuator in response to the signals from the processor such that restriction of ingestion is altered.

15. The method of claim 2, wherein the implant body comprises a gastric balloon, wherein the altering of the implant body comprises altering a fluid pressure within the gastric balloon.

16. The method of claim 2, further comprising delivering electrical stimulation to an internal organ of the living body from the implant.

17. The method of claim 2, further comprising sensing a physiological trigger with the implant, wherein the processor transmits the signals in response to the physiological trigger.

18. The method of claim 11, wherein the processor transmits the signals at least in part in response to a non-physiological trigger.

19. The method of claim 1, wherein generating of the signals correlating to altering of the implant body is performed by a pressure sensor coupled to the implant body such that the signals identify pressure changes in the gastrointestinal tract, and further comprising processing the signals so as to identify an ingestion event, the inhibiting of the unhealthy ingestion being performed in response to the identification of the unhealthy ingestion event.

20. The method of claim 19, wherein the processing of the signals is performed so as to identify peristaltic waves of the gastrointestinal tract proximate to the ingestion restricting implant body.

21. The method of claim 19, further comprising characterizing the ingestion event as ingestion of a liquid in response to a pressure change that lasts more than 10 seconds but less than 5 minutes.

22. The method of claim 19, further comprising characterizing the ingestion event as ingestion of a solid in response to a pressure change that lasts more than 5 minutes but less than 60 minutes.

23. The method of claim 19, further comprising sensing a temperature signal proximate the gastrointestinal tract with a temperature sensor, wherein the processing of the signals comprises processing of the signals from the pressure sensor and temperature signals from the temperature sensor by a processor so as to characterize the ingestion event,

the inhibiting of the unhealthy ingestion being performed in response to the characterizing of the ingestion event.

24. The method of claim 24, wherein the characterizing the ingestion event comprises identifying ingestion of a solid in response to a sufficiently high pressure change and sufficiently low temperature change.

25. The method of claim 24, wherein the characterizing the ingestion event comprises identifying combined solid and liquid ingestion in response to a sufficiently high pressure change and sufficiently high temperature change.

26. The method of claim 24, wherein sufficiently low pressure change and sufficiently low temperature change are identified as no ingestion.

27. The method of claim 24, wherein the characterizing the ingestion event comprises identification of a liquid ingestion and possible cheating event in response to sufficiently low pressure change and sufficiently high temperature change.

28. A method for treating a patient, the patient having a gastrointestinal tract, the method comprising:

deploying an ingestion restricting implant along the gastrointestinal tract;
sensing, with the implant, an ingestion into the patient;
transmitting, from the implant, signals in response to the ingestion; and
at least one member selected from the group consisting of:
displaying ingestion information and
treating the patient
per the signals.

29. The method of claim 28, wherein the deploying of the implant comprising positioning the implant so that a tissue of the gastrointestinal tract extends through a channel of the implant such that a size of the channel limits transmission of ingested material along the gastrointestinal tract from upstream of the implant to downstream of the implant.

30. The method of claim 29, wherein the deploying of the implant comprises a laparoscopic gastric band placement procedure.

31. The method of claim 28, wherein deploying the implant comprises positioning the implant within an interior of the stomach, the implant having a sufficient food displacement volume to significantly limit ingestion.

32. The method of claim 32, wherein the implant comprises a gastric balloon.

33. A method for treating a patient, the patient having a gastrointestinal tract, the method comprising:

deploying at least a portion of an implant along the gastrointestinal tract, the implant having a body and a processor;

identifying, during a day, an allowed ingestion, and allowing associated ingested material to traverse the body of the implant along the gastrointestinal tract;

identifying, during the day, an unhealthy ingestion; and

transmitting signals from the processor to the body so as to alter a shape, compliance, and/or size of the body such that the body restricts the unhealthy ingestion.

34. The method of claim 33, wherein the deploying of the implant comprising positioning the implant so that a tissue of the gastrointestinal tract extends through a channel of the implant such that a size of the channel limits transmission of ingested material along the gastrointestinal tract from upstream of the implant to downstream of the implant.

35. The method of claim 34, wherein the deploying of the implant comprises a laparoscopic gastric band placement procedure.

36. The method of claim 33, wherein deploying the implant comprises positioning the implant within an interior of the stomach, the implant having a sufficient food displacement volume to significantly limit ingestion.

37. The method of claim 36, wherein the implant comprises a gastric balloon.

38. A method for treating a patient, the patient having a gastrointestinal tract, the method comprising:

deploying an implant along the gastrointestinal tract, the implant having a processor and a body;

identifying, during a day, an unhealthy ingestion; and

transmitting signals from the processor to the patient in response to the identification of the unhealthy ingestion so as to inhibit the unhealthy ingestion.

39. A therapeutic implant system for treating a patient, the patient having a gastrointestinal tract and an unhealthy ingestion pattern, the therapeutic implant system comprising:

an ingestion restricting implant body deployable along the gastrointestinal tract;

a signal generator coupled to the implant body so as to generate signals correlating to altering of the implant body; and

a processor coupled to the signal generator such that, in response to the signals, the unhealthy ingestion pattern by the patient is inhibited in use sufficiently to modify the unhealthy ingestion pattern toward a healthier ingestion pattern.

40. The system of claim 39, wherein the implant body comprises a gastric band defining a channel therethrough, the gastrointestinal tract extendable through the channel of the implant body, wherein the gastric band comprises a fluid-filled pressure bladder disposed between the channel and a support structure such that changes in a fluid pressure within the fluid pressure bladder correspond with changes in an engagement force between the gastrointestinal tract and the gastric band.

41. The system of claim 40, wherein the signal generator comprises at least one sensor coupled to the fluid pressure bladder, the altering of the engagement force induced by ingestion-related distension of the gastrointestinal tract within the channel of the gastric band so that the signals are generated in response to transient changes in fluid pressure within the bladder and the signals indicate an ingestion event.

42. The system of claim 41, further comprising at least one of:
a display coupled to the processor, the display showing eating events identified in response to the signals during a plurality of days and configured for communicating to the patient or a lifestyle coach;

an actuator coupled to the processor so as to alter the fluid pressure within the bladder in response to the ingestion event; and

an electrode coupled to the processor so as to stimulate tissue of the gastrointestinal tract in response to the ingestion event.

43. The system of claim 42, further comprising at least one of a pressure sensor, a temperature sensor, an optical sensor, an impedance sensor, a pH sensor, or an acoustic sensor coupled to the processor.

44. The system of claim 40, wherein the signal generator comprises an actuator, the signals comprising fluid pressure signals transmitted to the bladder from the processor, and wherein the altering of the engagement force is induced by changes in fluid pressure within the bladder in response to the pressure signals so that the pressure within the bladder is decreased each day to allow healthy ingestion and increased each day to inhibit unhealthy ingestion.

45. The system of claim 44, wherein energizing the actuator activates the gastric band so as to increase restriction and decrease ingestion into the patient.

46. The system of claim 44, wherein energizing the actuator deactivates the gastric band so as to decrease restriction and allow increased ingestion into the patient.

47. The system of claim 39, wherein the implant body comprises a gastric balloon, wherein the altering of the implant body comprises altering a fluid pressure within the gastric balloon.

48. The system of claim 47, wherein the signal generator comprises an actuator, and wherein altering the implant comprises varying a size of the gastric balloon with the actuator in response to command signals from the processor such that restriction of ingestion is altered.

49. The system of claim 39, further comprising an electrode coupled to the processor so as to deliver electrical stimulation to an internal organ of the living body.

50. The system of claim 49, wherein the signal generator comprises a pressure sensor, and wherein the processor is configured to process the signals to as to identify pressure changes in the gastrointestinal tract.

51. The system of claim 50, wherein the processor is configured so that a pressure change that lasts at least 10 seconds but not more than 5 minutes is identified as an ingestion of a liquid.

52. The system of claim 50, wherein the processor is configured so that a pressure change that lasts at least 5 minutes but not more than 60 minutes is identified as an ingestion of a solid.

53. The system of claim 39, further comprising a temperature sensor coupled to the processor so as to provide a temperature from proximate the gastrointestinal tract thereto.

54. The system of claim 53, wherein the processor is configured so that signals from the pressure sensor and temperature sensor are processed to identify pressure changes and temperatures.

55. The system of claim 54, wherein the processor is configured so that high pressure change and low temperature change is identified as a solid ingestion.

56. The system of claim 54, wherein the processor is configured so that high pressure change and high temperature change is identified as a combined solid and liquid ingestion.

57. The system of claim 54, wherein the processor is configured so that low pressure change and low temperature change is identified as no ingestion.

58. The system of claim 54, wherein the processor is configured so that low pressure change and low temperature change is identified as a liquid ingestion and possible cheating event.

59. The system of claim 39, further comprising a sensor coupled to the processor, wherein the sensor comprises an optical sensor.

60. A system for treating a patient, the patient having a gastrointestinal tract, the system comprising:

an ingestion restricting implant body deployable along the gastrointestinal tract;

a sensor coupled to the implant body so as to transmit signals in response to ingestion into the patient in use; and

a processor coupled to the sensor, the processor, in response to the signals, generating output comprising at least one member selected from the group consisting of:

ingestion display signals, and
patient treatment signals.

61. A system for treating a patient, the patient having a gastrointestinal tract, the system comprising:

an implant body deployable along the gastrointestinal tract;

a processor; and

an actuator coupling the processor to the body;

the processor configured so as to identify, during a day, an allowed ingestion, and for allowing associated ingested material to traverse the body of the implant along the gastrointestinal tract;

the processor configured so as to identify, during the day, an unhealthy ingestion and to transmit signals to the body via the actuator so as to alter a shape or size of the body such that the body restricts the unhealthy ingestion.

62. A therapeutic implant system for treating a patient, the patient having a gastrointestinal tract and an unhealthy ingestion pattern, the therapeutic implant system comprising:

an ingestion restricting implant body implantable along the gastrointestinal tract; and

a processor coupleable to the implant body so as to transmit signals therebetween, wherein the signals are transmitted in correlation with changes in a size or a shape of the implant body in use.

63. The therapeutic implant of claim 62, wherein the implant body has a first configuration and a second configuration, the size, compliance, or shape of the implant body in the second configuration being different than the size, compliance, or shape of the implant body in the first configuration such that the implant body has an enhanced inhibition of ingestion in the second configuration.

64. A therapeutic implant for treating a patient, the patient having a gastrointestinal tract and an unhealthy ingestion pattern, the therapeutic implant comprising:
an ingestion restricting implant body implantable along the gastrointestinal tract;
at least one sensor for generating signals; and
a processor coupled to the at least one sensor and the implant body so as to transmit the signals therebetween, wherein the signals are transmitted in correlation with an ingestion event.

65. A therapeutic implant for treating a patient, the patient having a gastrointestinal tract and an unhealthy ingestion pattern, the therapeutic implant comprising:
an ingestion restricting implant body implantable along the gastrointestinal tract;
at least one sensor for generating signals; and
a processor coupleable to the at least one sensor and the implant body so as to transmit the signals therebetween, wherein the signals are transmitted in correlation with a physical activity event.

66. The therapeutic implant of claim 65, wherein the sensor comprises an activity sensor.

67. The therapeutic implant of claim 65, wherein the sensor comprises a heart rate sensor.

68. The therapeutic implant of claim 65, wherein the sensor comprises a core body temperature sensor.

69. The therapeutic implant of claim 65, wherein the sensor comprises a sleep detector.

70. The therapeutic implant of claim 65, wherein the signals are transmitted by the processor to a data server.

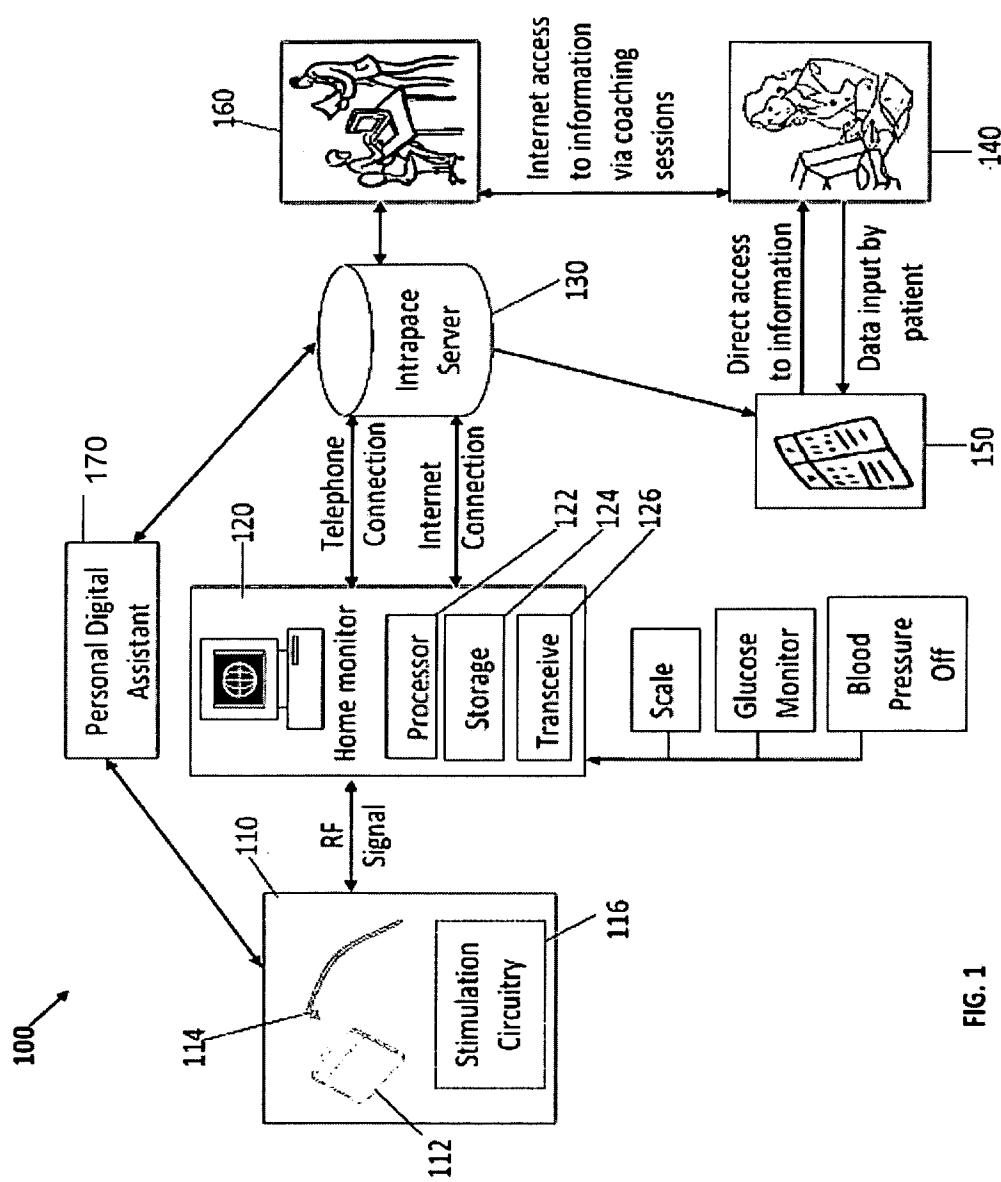


FIG. 1

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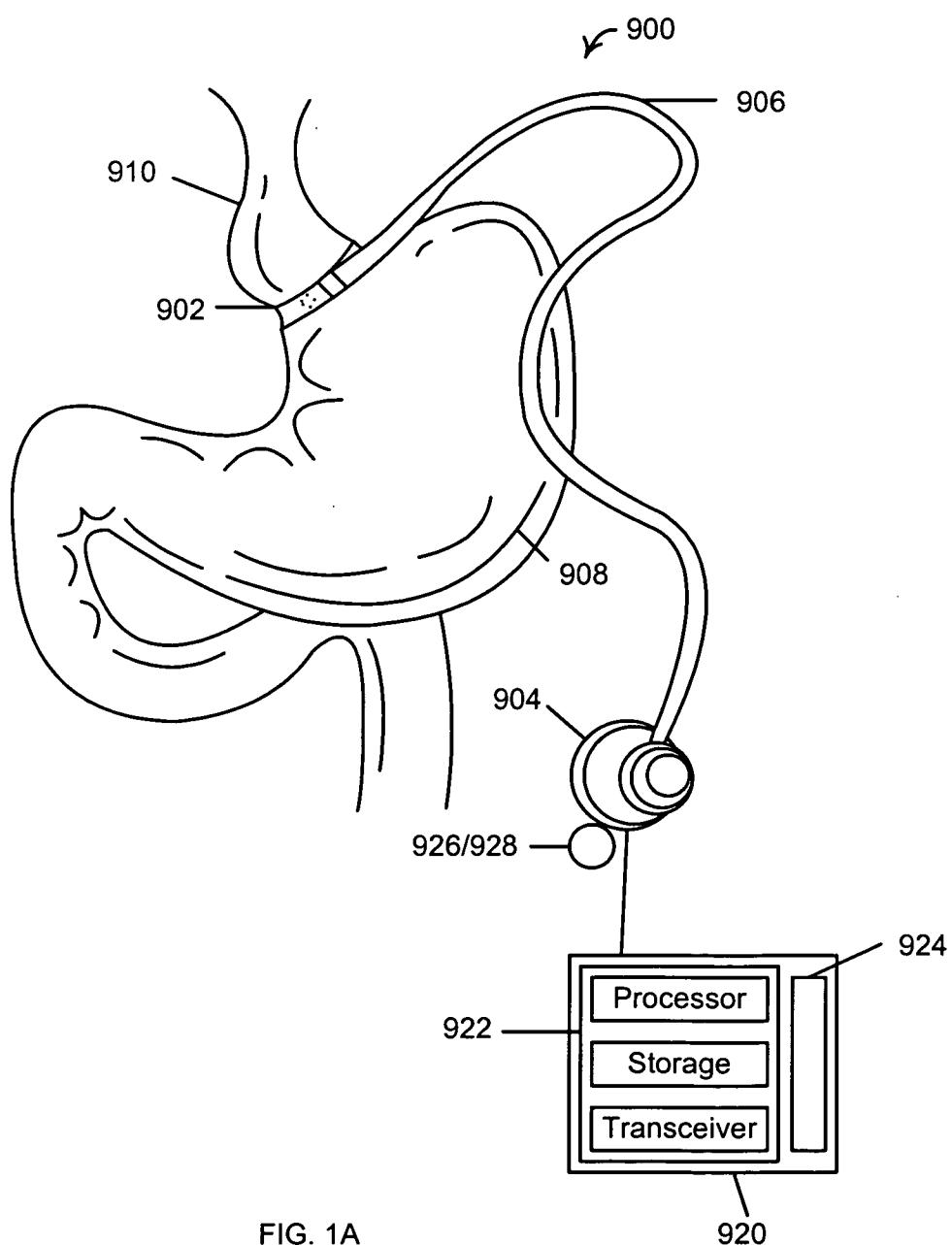


FIG. 1A

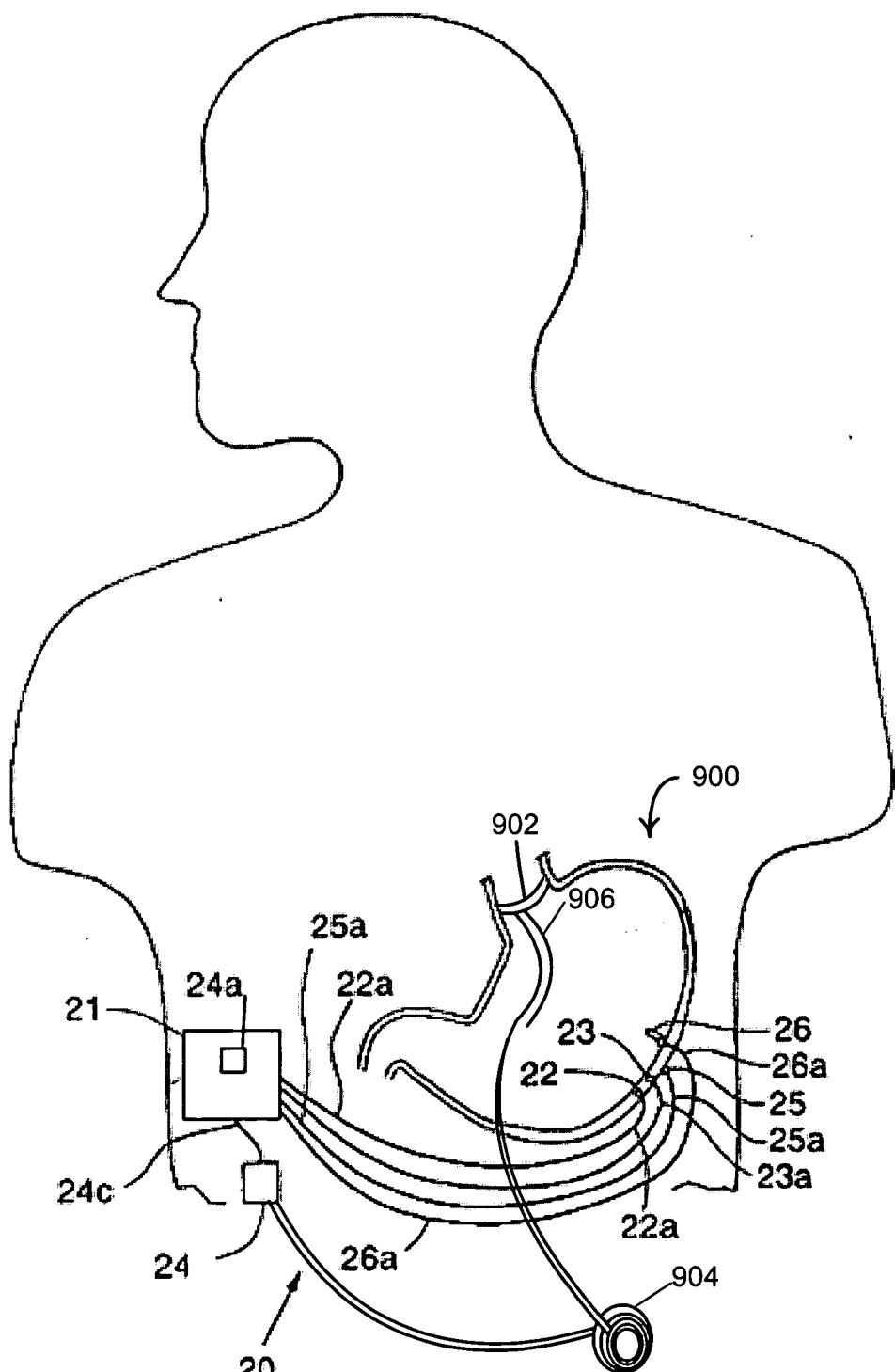


FIG. 1B

FIG. 1C

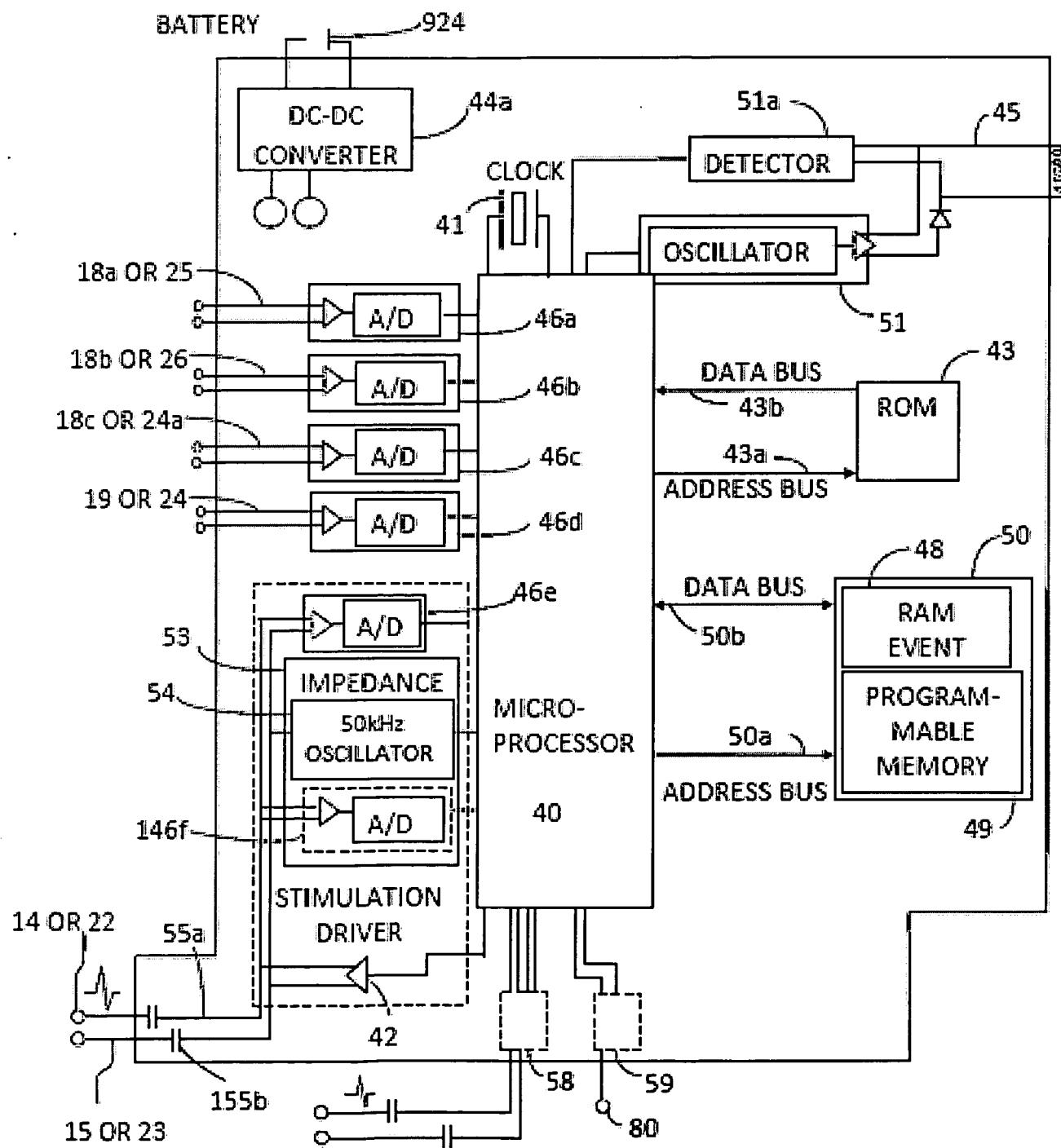
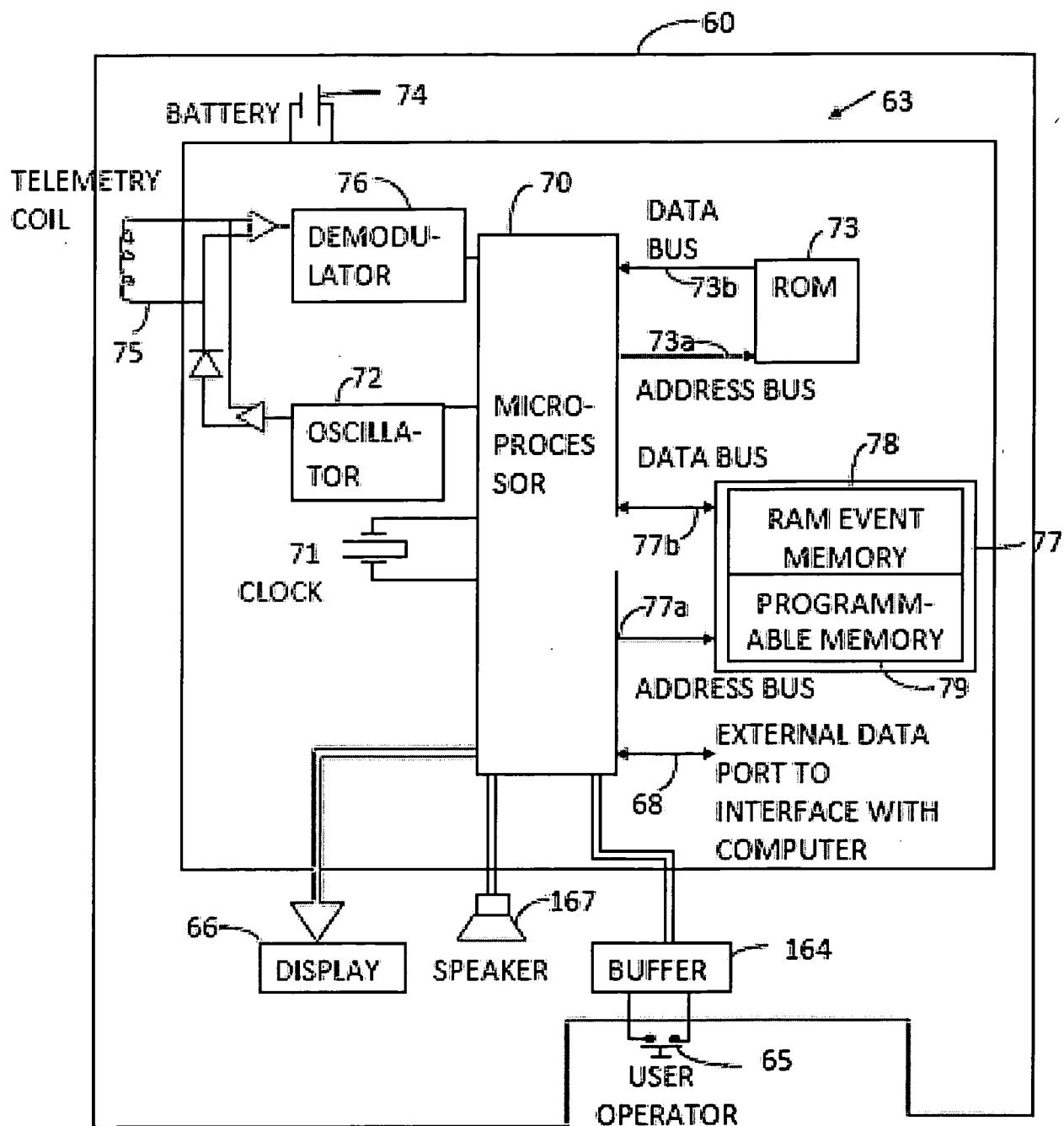


FIG. 1D



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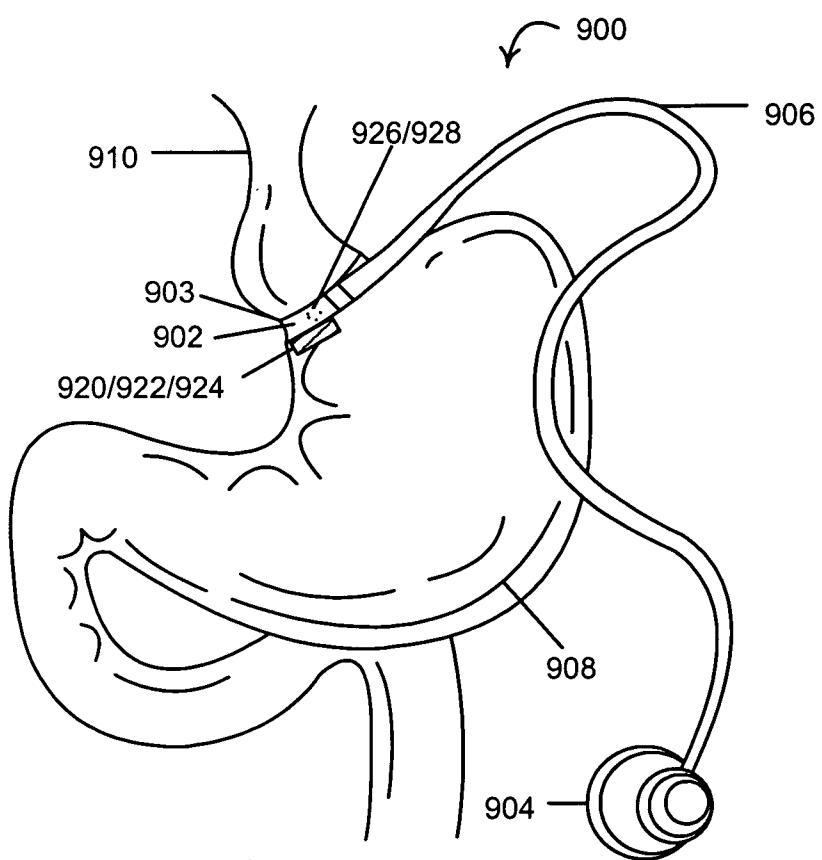
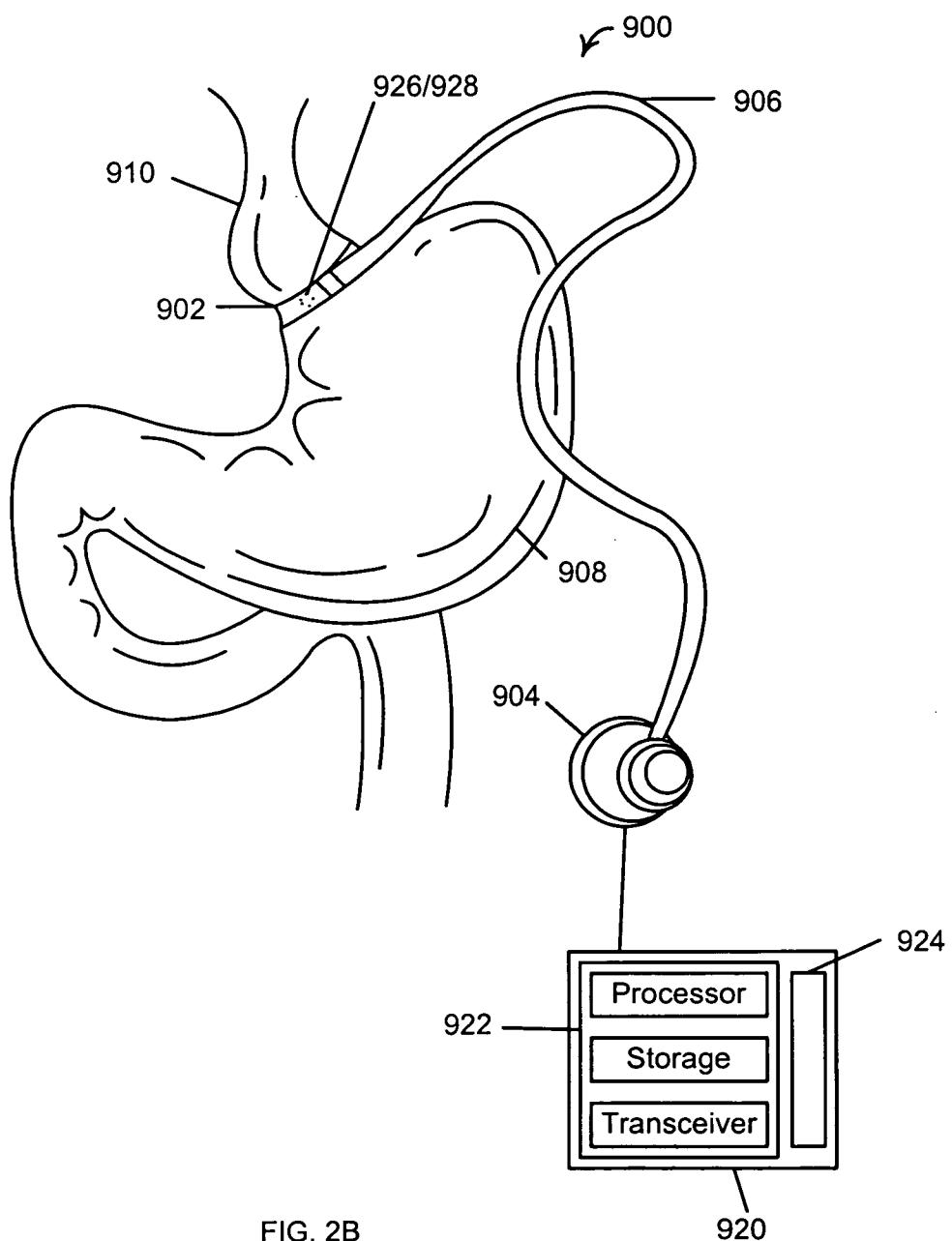


FIG. 2A

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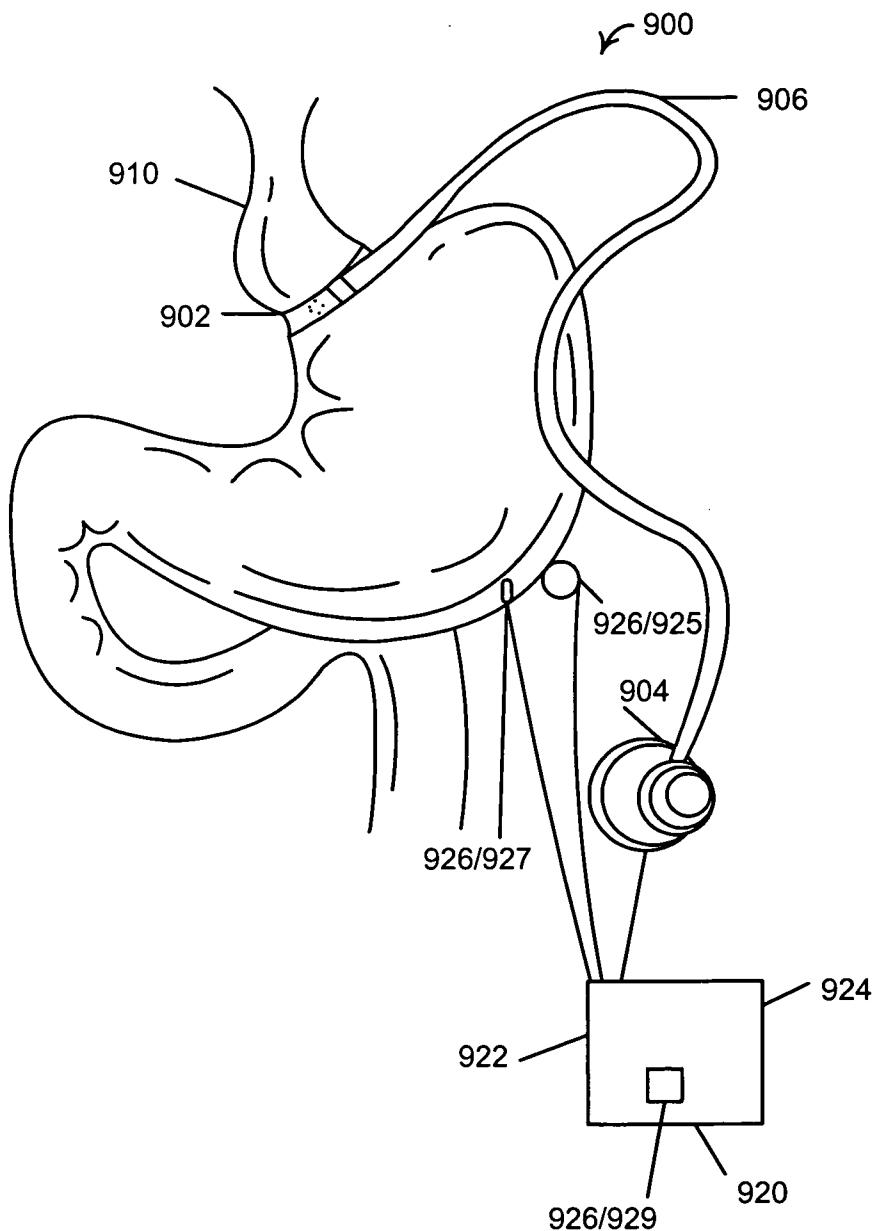


FIG. 2C

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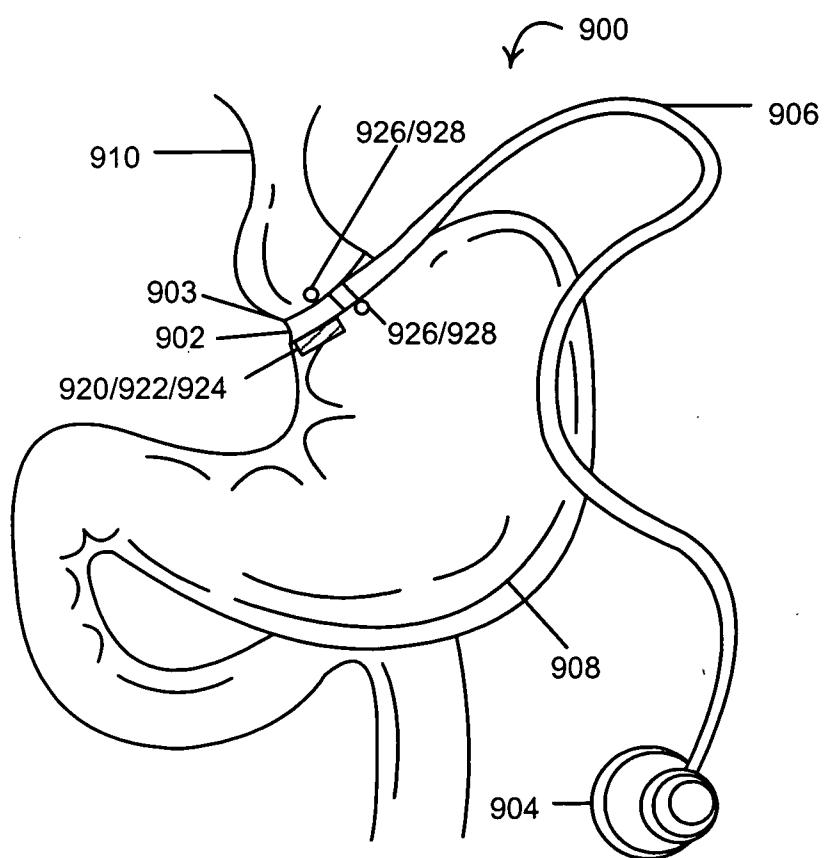


FIG. 2D

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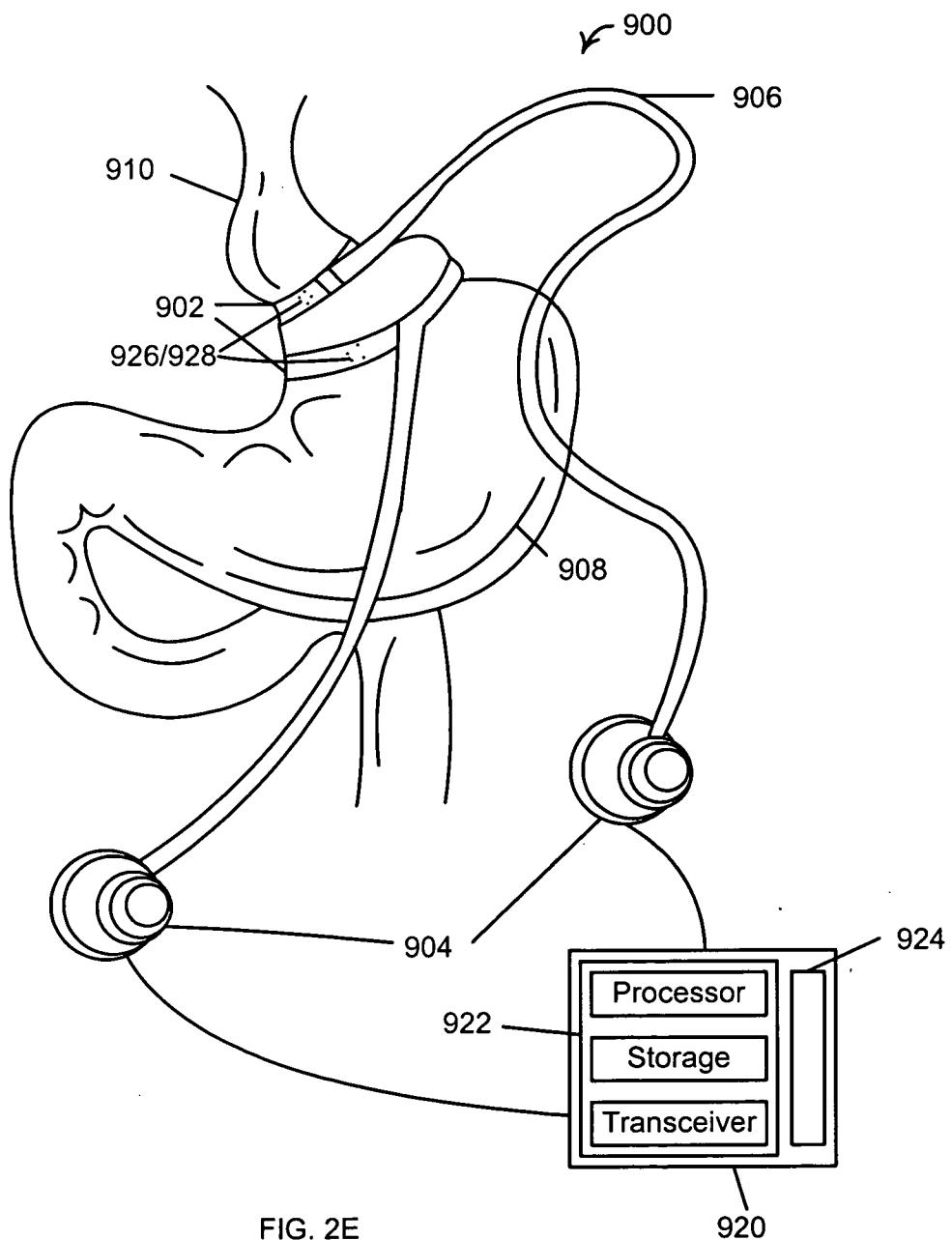


FIG. 2E

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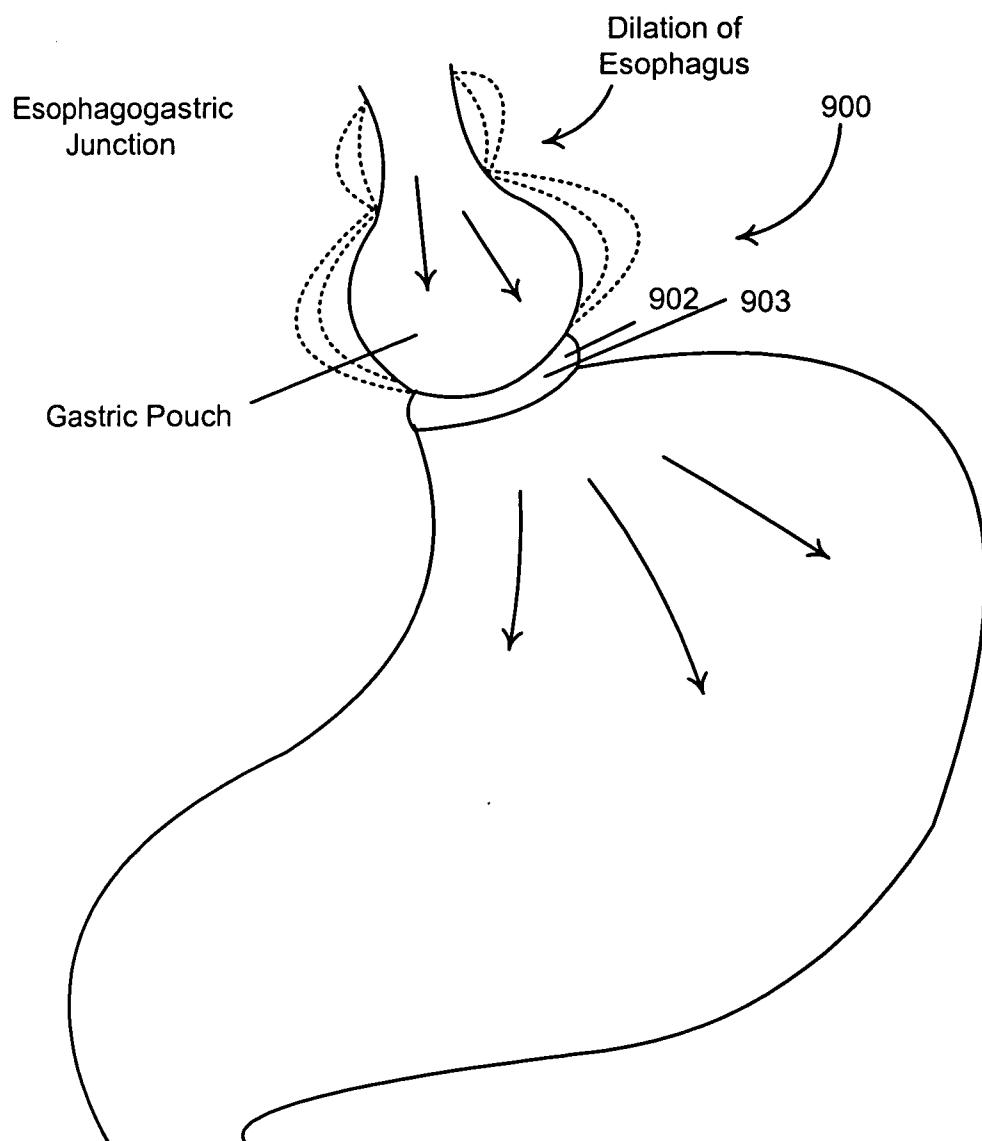


FIG. 3

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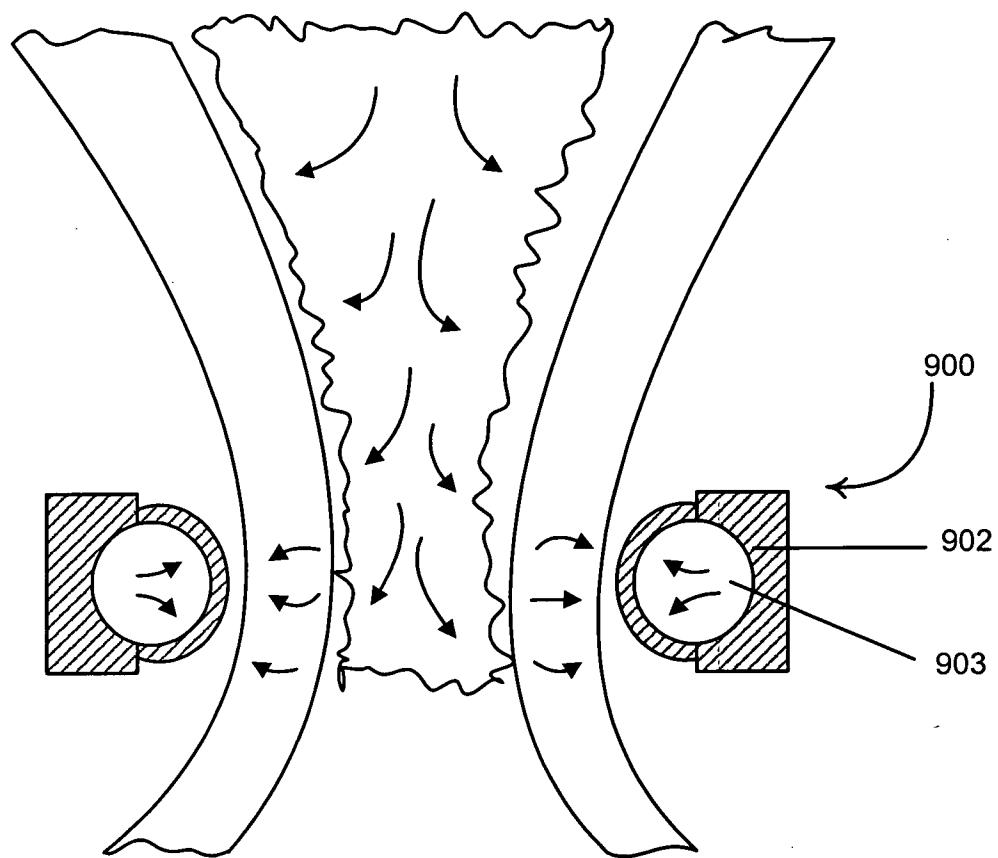
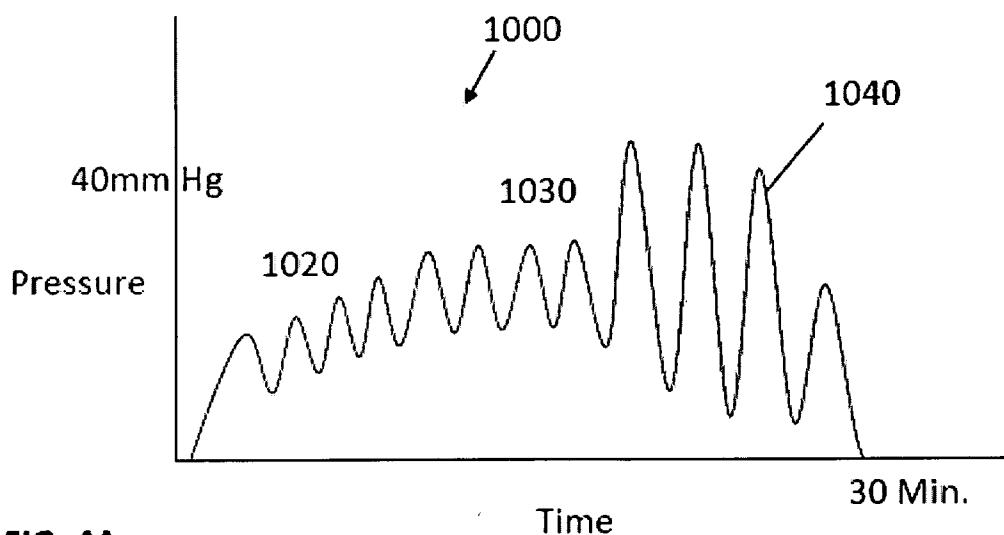
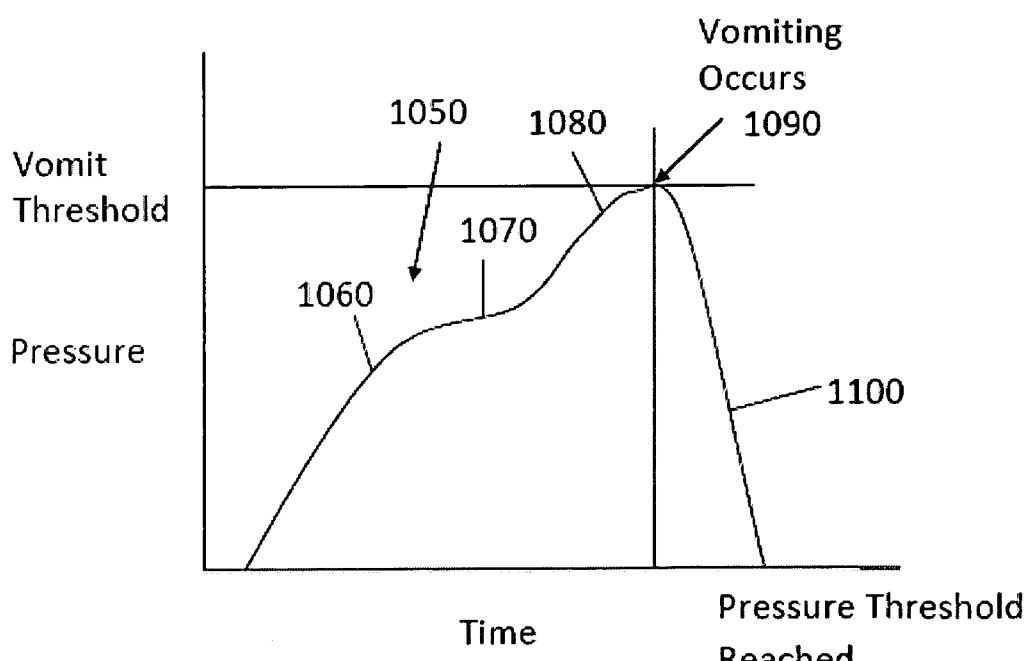


FIG. 3A

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**FIG. 4A****FIG. 4B**

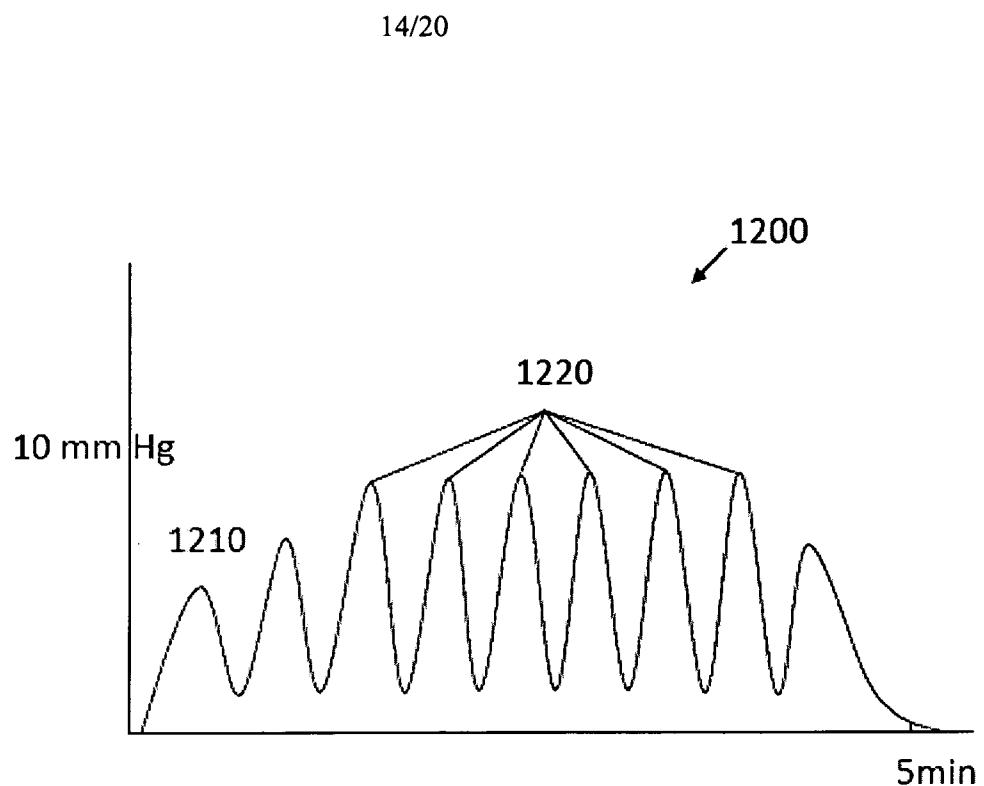


FIG. 4C

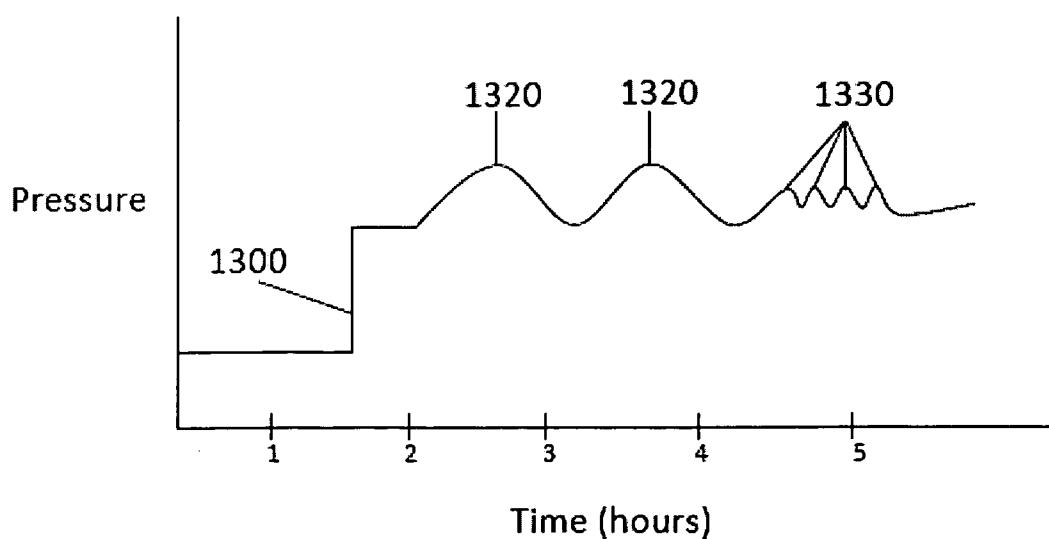
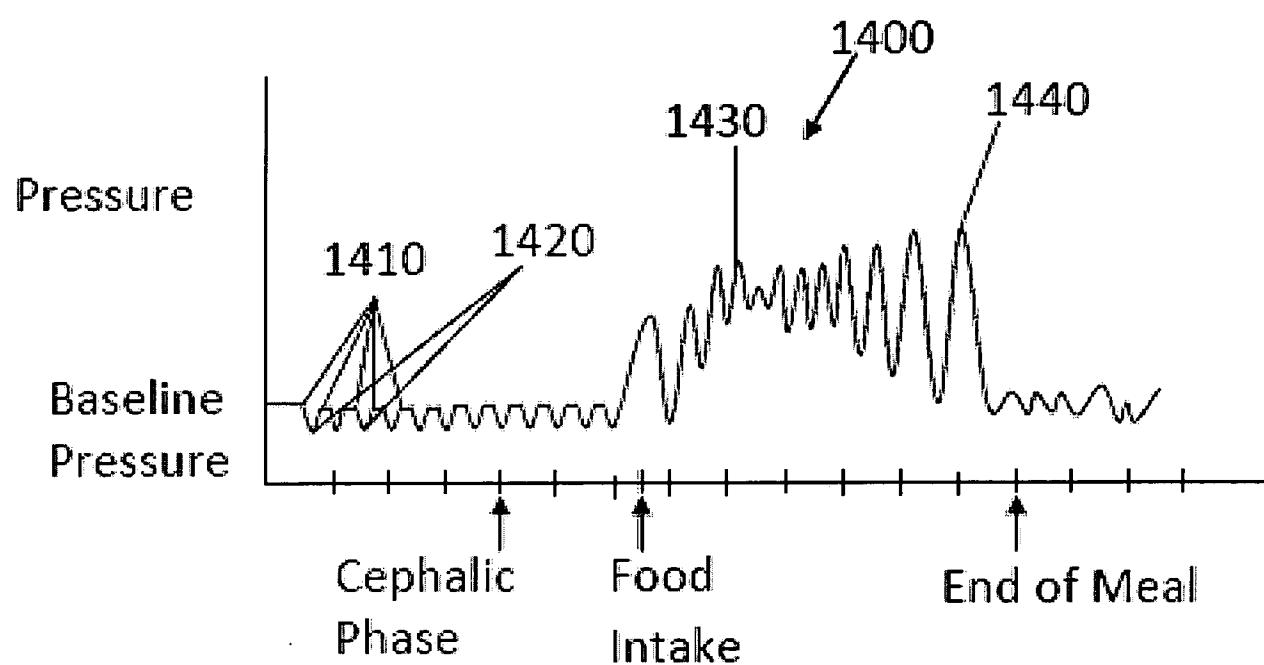


FIG. 5

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**FIG. 6**

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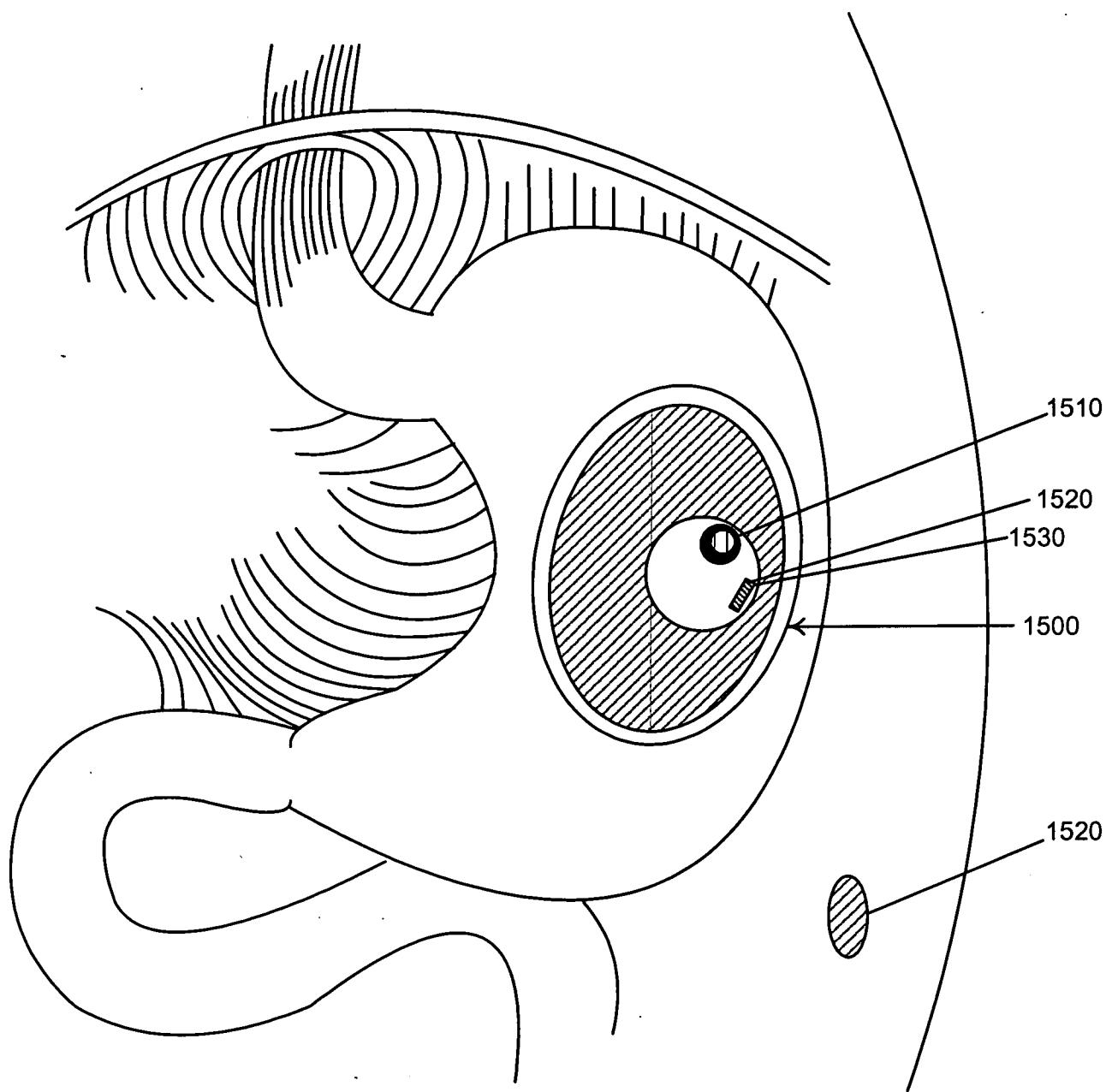


FIG. 7

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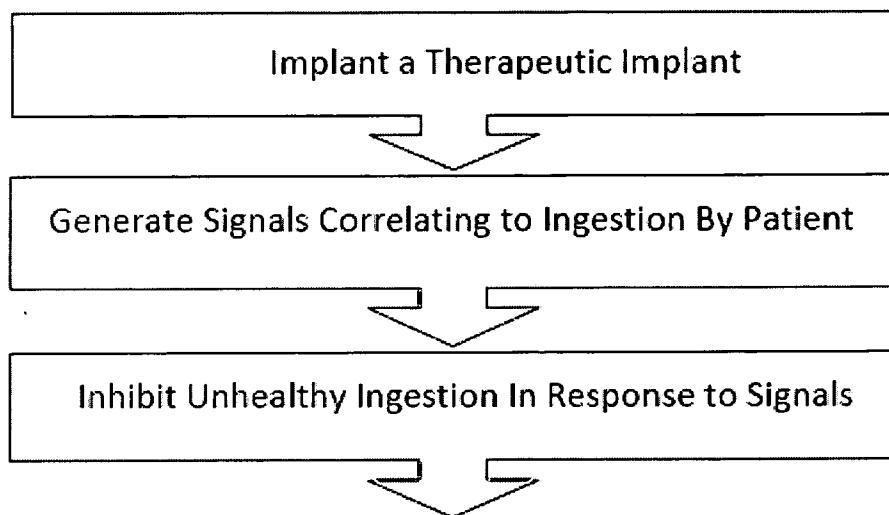


FIG. 8

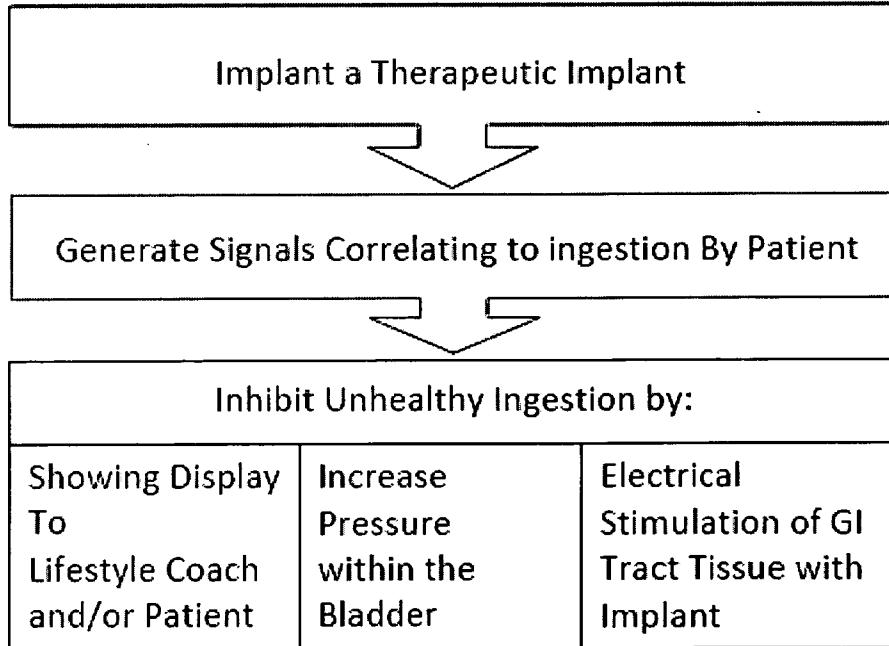
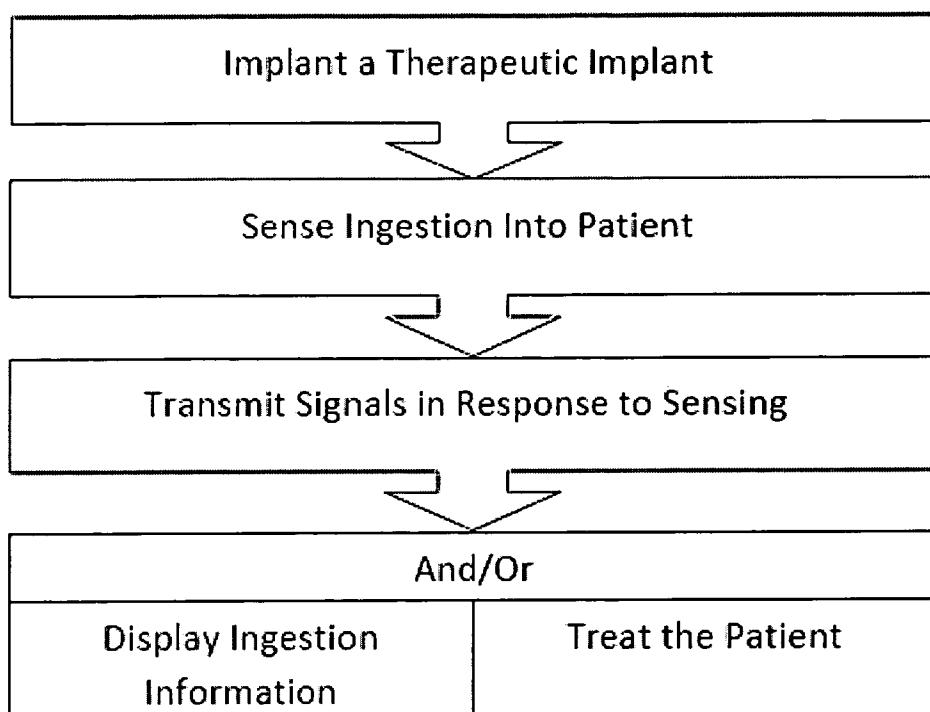
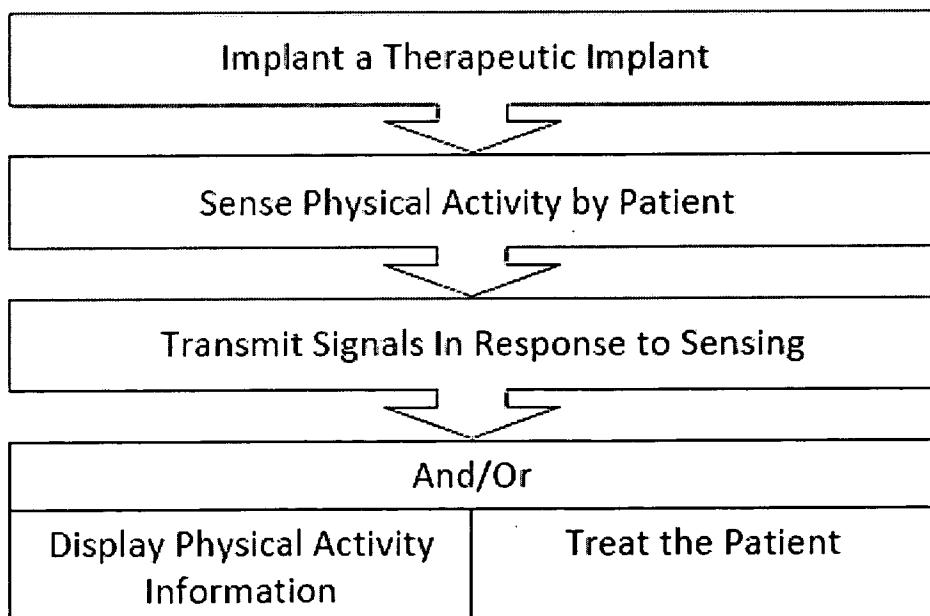


FIG. 8A

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**FIG. 8B****FIG. 8C**

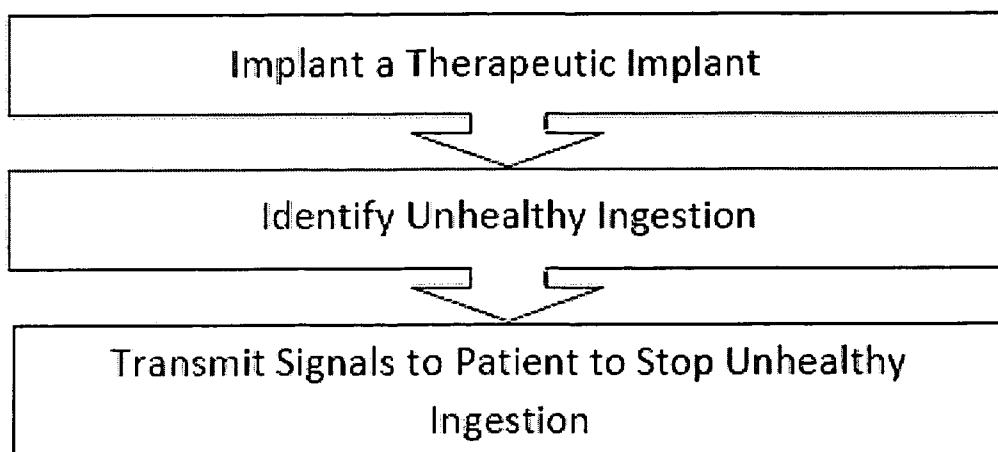


FIG. 8D

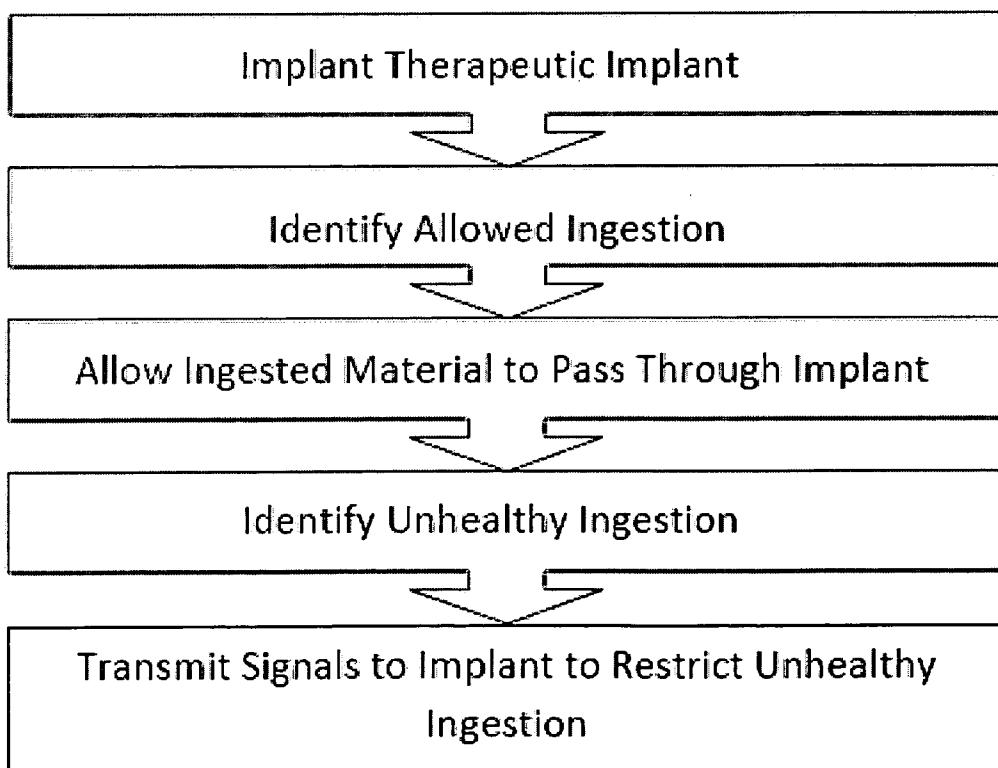
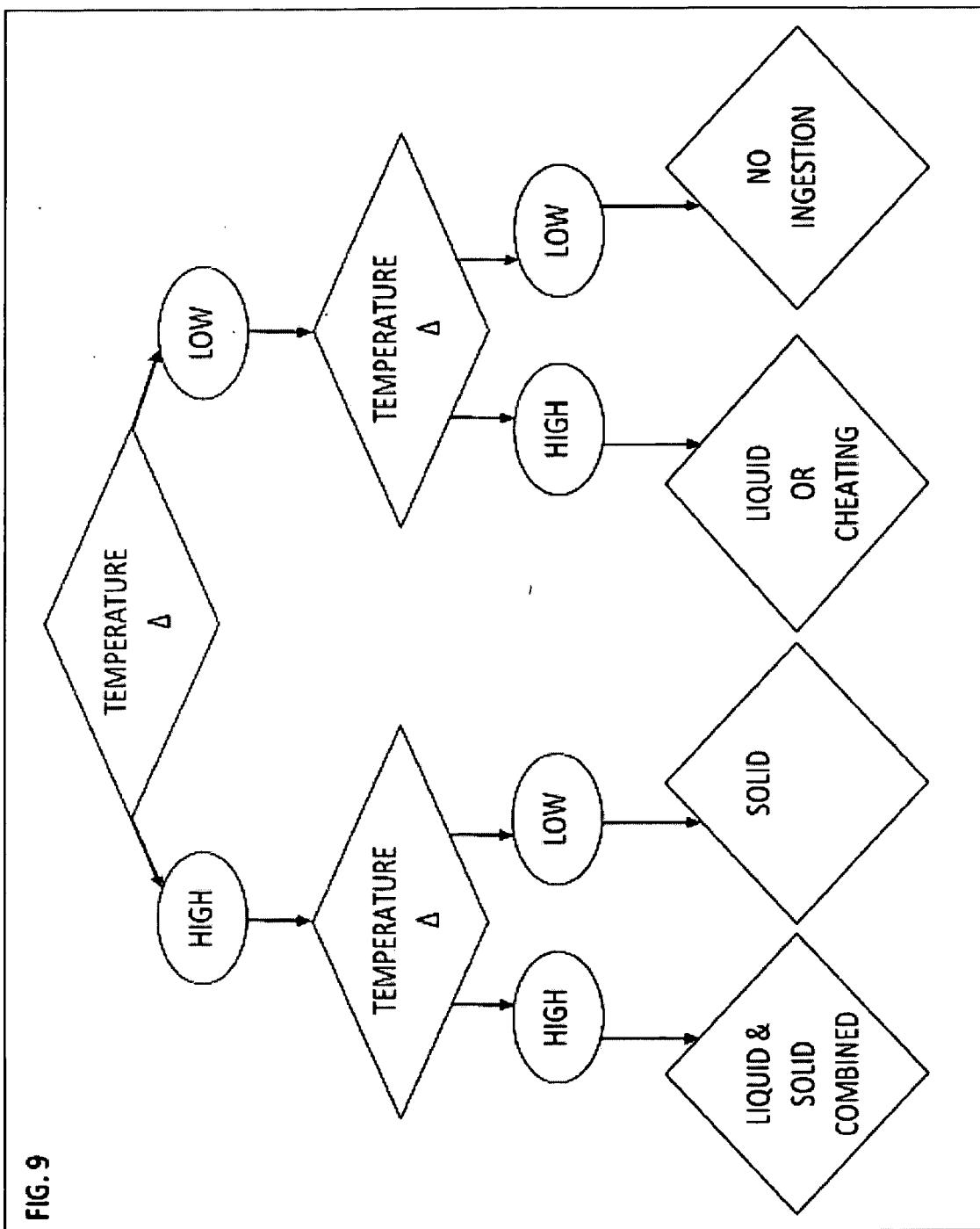


FIG. 8E



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2010/029987

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 5/00 (2010.01)

USPC - 600/309

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61B 5/00, 5/04, 5/05, 5/103; A61F 2/00, 5/00, 13/00 (2010.01)

USPC - 128/903; 600/37, 309, 365, 546, 547, 549, 587

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PatBase, Google Patents

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2006/0173238 A1 (STARKEBAUM) 03 August 2006 (03.08.2006) entire document	28-37, 60-66, 68, 70
Y		1-27, 38-59, 67, 69
Y	US 2005/0096514 A1 (STARKEBAUM) 05 May 2005 (05.05.2005) entire document	1-27, 38-59
Y	US 5,938,669 A (KLAIBER et al) 17 August 1999 (17.08.1999) entire document	4-9, 19-27, 40-46, 50-52, 54-58
Y	US 7,044,942 B2 (JOLLY et al) 16 May 2006 (16.05.2006) entire document	16, 49-52
Y	US 2006/0293609 A1 (STAHHMANN et al) 28 December 2006 (28.12.2006) entire document	67, 69

Further documents are listed in the continuation of Box C.

* Special categories of cited documents:

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- “O” document referring to an oral disclosure, use, exhibition or other means
- “P” document published prior to the international filing date but later than the priority date claimed

- “T” later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- “X” document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- “Y” document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- “&” document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
13 May 2010	01 JUN 2010
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

专利名称(译)	用于增强阻塞性和其他肥胖症治疗的反馈系统和方法		
公开(公告)号	EP2413785A1	公开(公告)日	2012-02-08
申请号	EP2010759546	申请日	2010-04-05
[标]申请(专利权)人(译)	内测公司		
申请(专利权)人(译)	INTRAPACE INC.		
当前申请(专利权)人(译)	INTRAPACE INC.		
[标]发明人	BRYNELSEN CHARLES R IMRAN MIR PROVINCE ROSE		
发明人	BRYNELSEN, CHARLES, R. IMRAN, MIR PROVINCE, ROSE		
IPC分类号	A61B5/00 A61B5/0205 A61B5/07 A61B5/11 A61F5/00 A61N1/36 A61N1/372		
CPC分类号	G09B19/0092 A61B5/0022 A61B5/02055 A61B5/076 A61B5/1118 A61B5/411 A61B5/4205 A61B5/486 A61B5/6846 A61B5/6871 A61F5/0053 A61N1/36007 A61N1/37247 G06F19/34 G06F19/3418 G06F19 /3475 G06F19/3481 G16H10/60		
优先权	61/166636 2009-04-03 US		
其他公开文献	EP2413785A4		
外部链接	Espacenet		

摘要(译)

反馈系统和方法通过呈现关于患者的实际进食和/或运动习惯的反馈来增强阻塞性和其他肥胖症治疗。可以沿胃肠道部署摄取限制植入物本体。在一些实施例中，摄取改变植入物本体，植入物本体又产生信号。产生的信号可用于抑制患者的不健康摄取。在其他实施例中，植入物本体可以通过信号改变，以便可选择地改变施加在胃肠道上的限制，任选地响应于摄取事件，进食计划等。植入物本体可包括胃束带或胃内气囊。可以处理传感器信号以识别摄取和/或表征固体或液体的摄取，并且可以将结果显示在屏幕上以供患者或教练查看。