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

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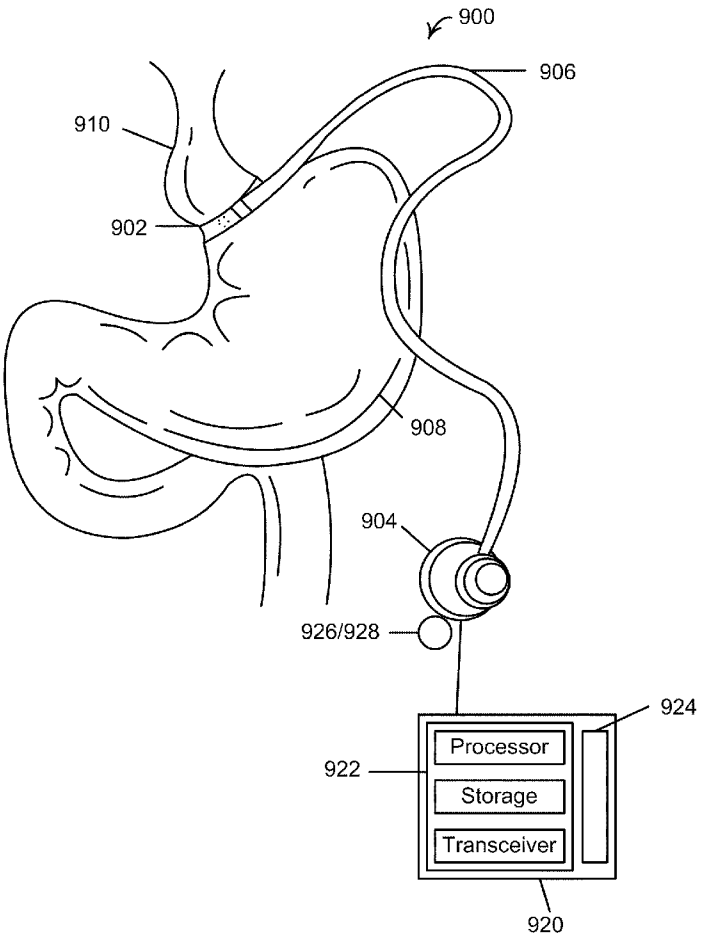
(57) **ABSTRACT**

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.



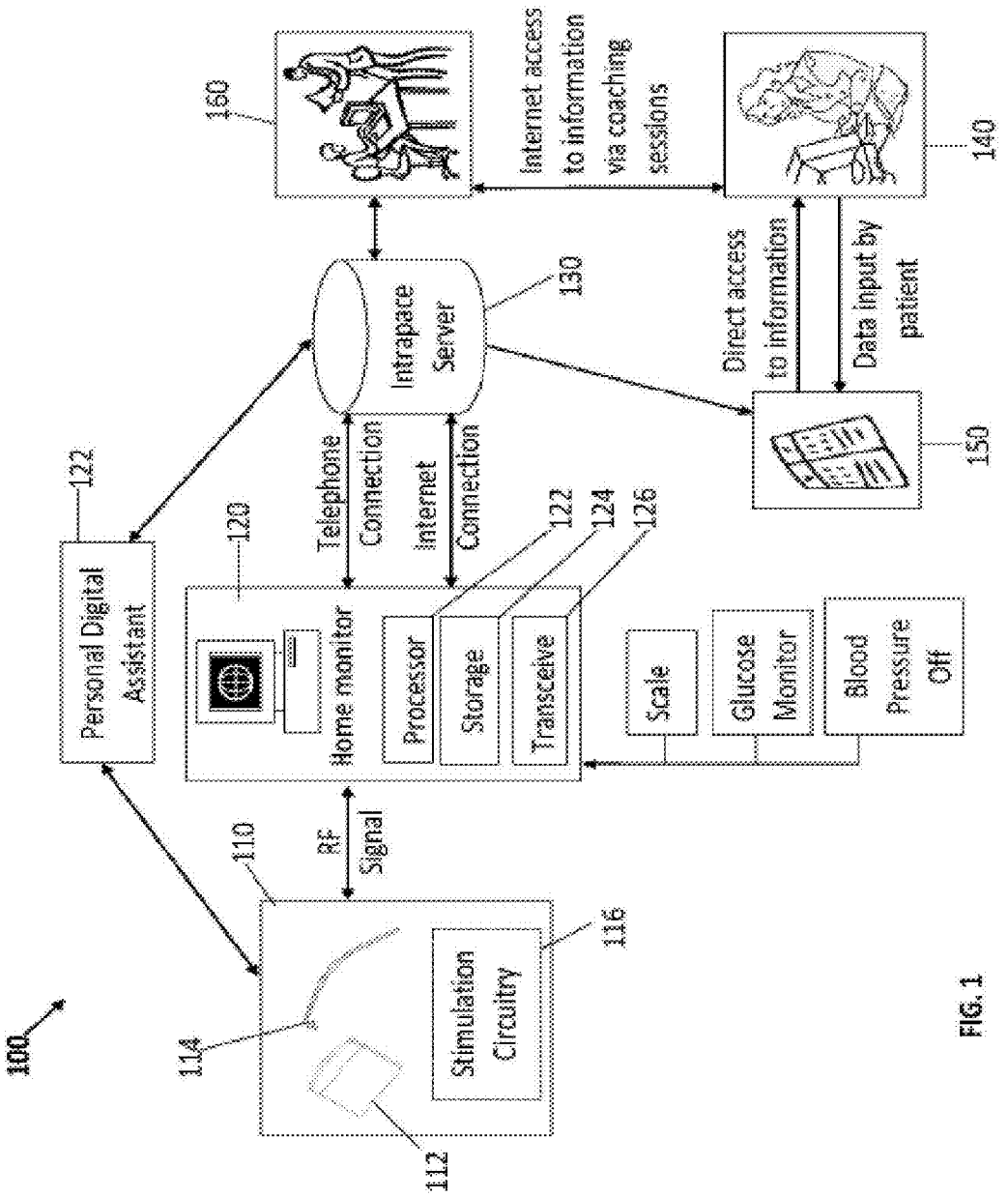

100
110
112
114
116
120
122
124
126
130
140
150
160
Stimulation Circuitry
RF Signal
Personal Digital Assistant
Home monitor
Processor
Storage
Transceive
Scale
Glucose Monitor
Blood Pressure Off
Telephone Connection
Internet Connection
Intrapace Server
Internet access to information via coaching sessions
Direct access to information
Data input by patient

FIG. 1

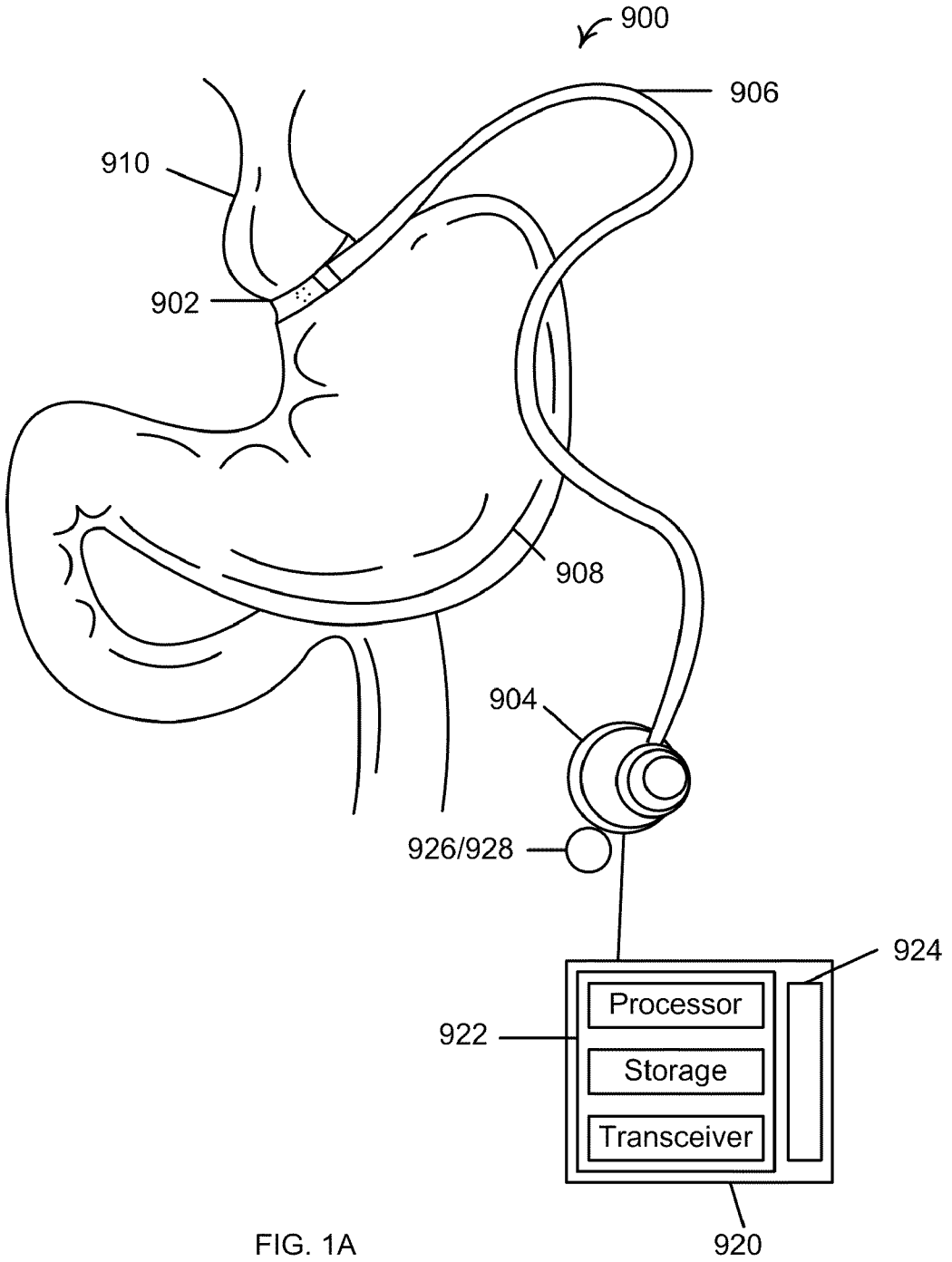

900
906
910
902
908
904
926/928
924
Processor
922
Storage
Transceiver
920

FIG. 1A

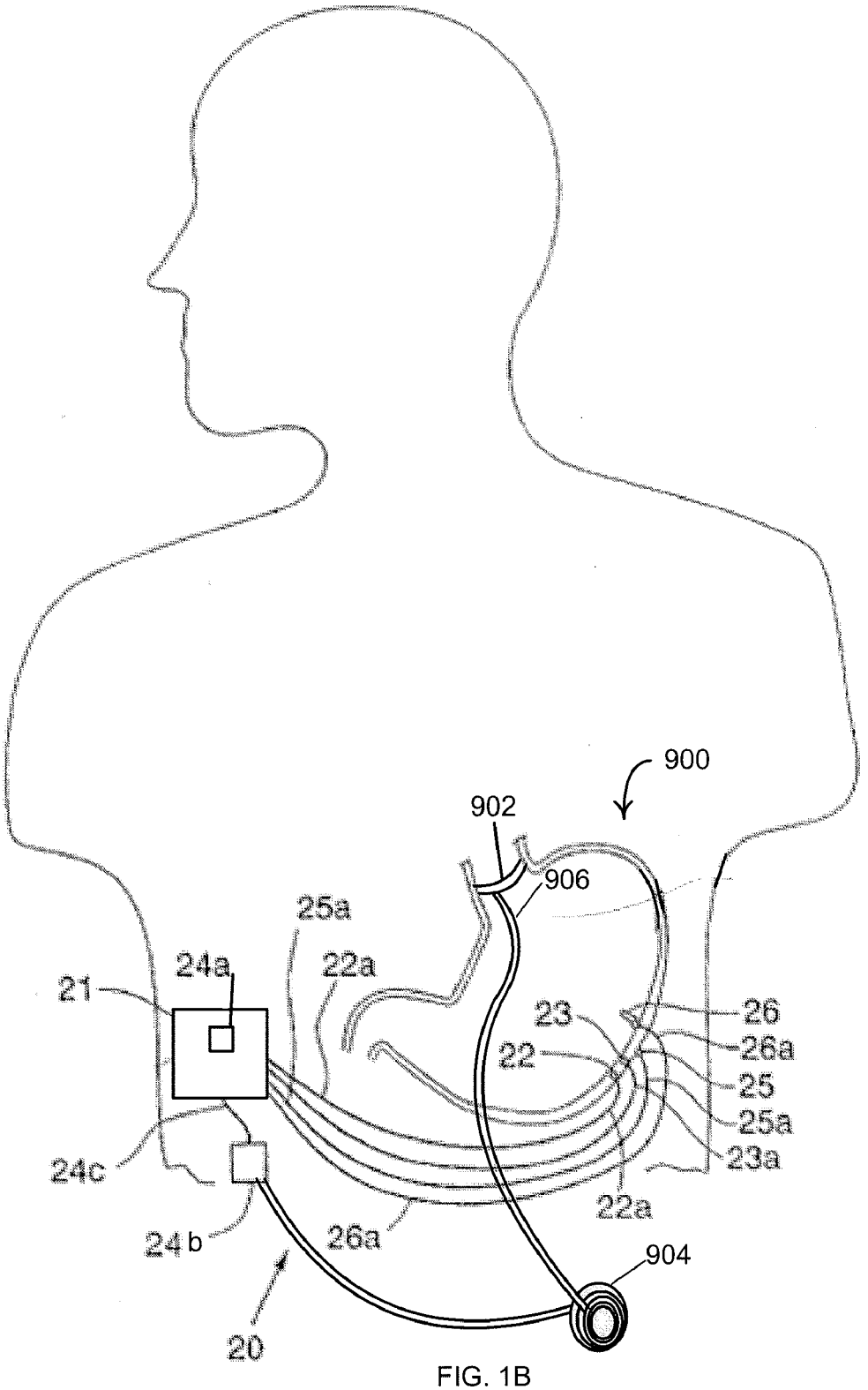

900
902
906
25a
22a
24a
21
23
26
26a
22
25
25a
23a
24c
22a
24b
26a
904
20

FIG. 1B

FIG. 1C

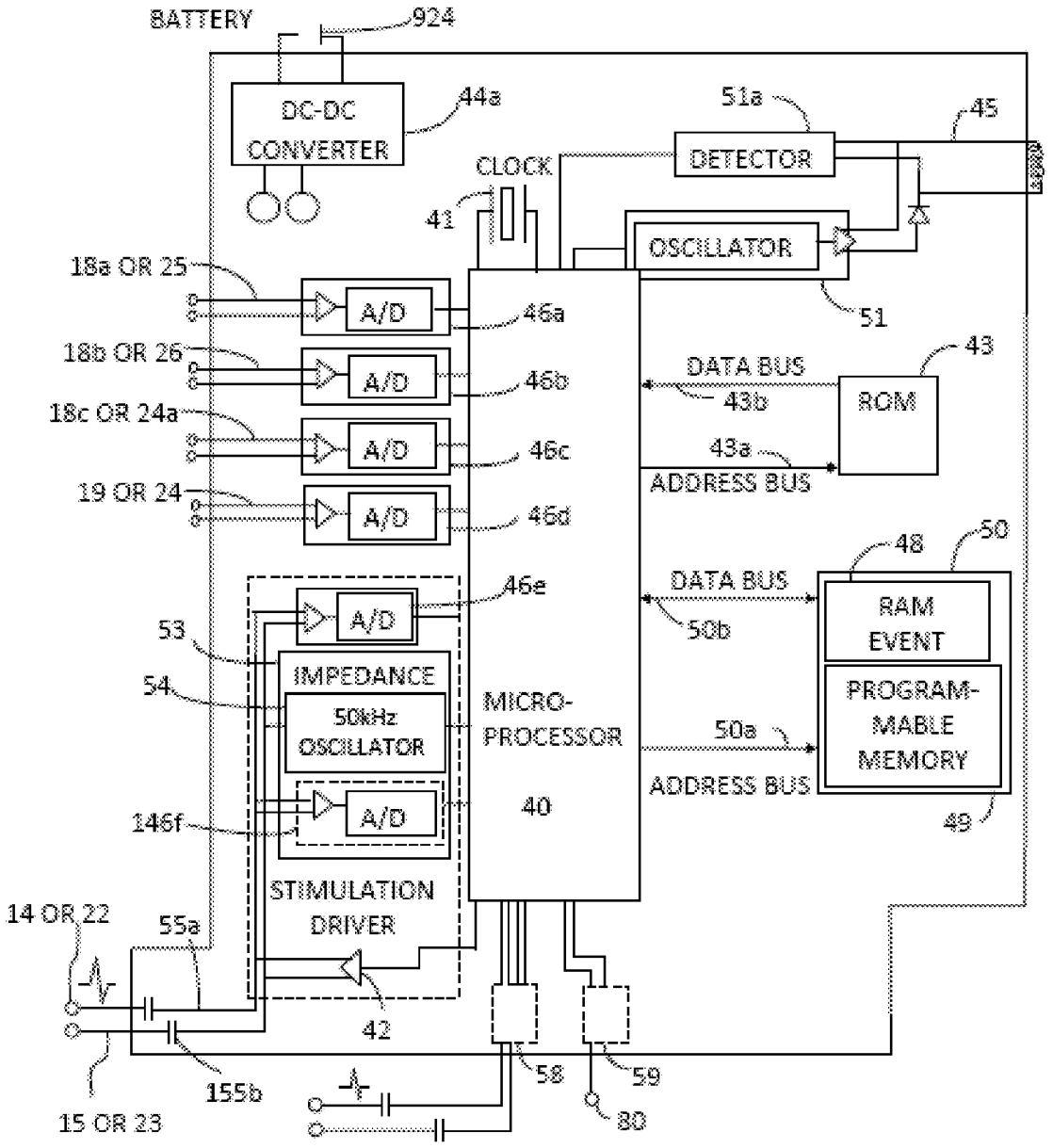
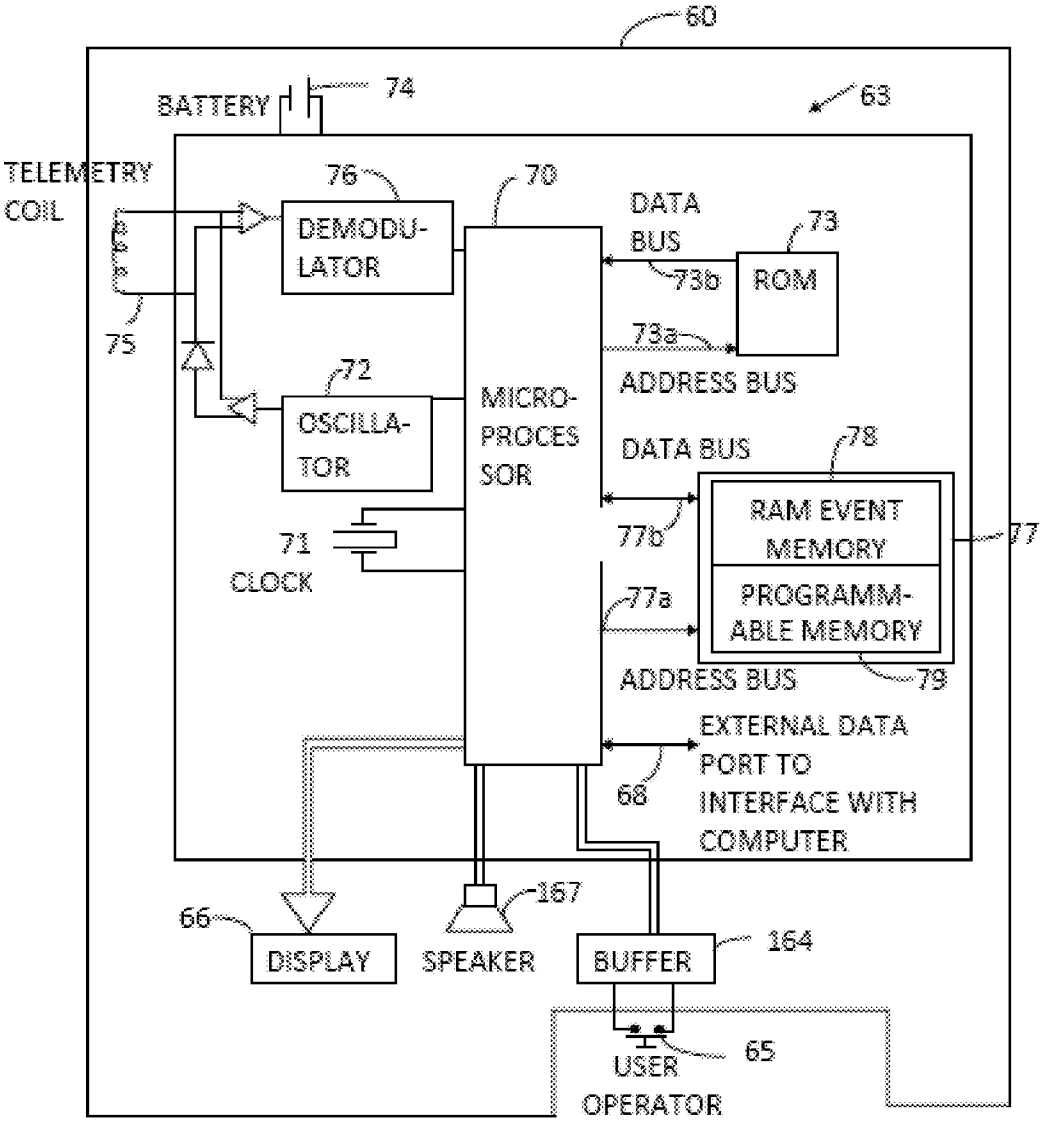

BATTERY
924
DC-DC CONVERTER
44a
51a
DETECTOR
45
CLOCK
41
OSCILLATOR
51
18a OR 25
A/D
46a
18b OR 26
A/D
46b
18c OR 24a
A/D
46c
19 OR 24
A/D
46d
DATA BUS
43b
ROM
43
43a
ADDRESS BUS
48
50
DATA BUS
50b
RAM EVENT
PROGRAM-MABLE MEMORY
50a
ADDRESS BUS
49
46e
A/D
53
IMPEDANCE
54
50kHz OSCILLATOR
MICRO-PROCESSOR
40
146f
A/D
STIMULATION DRIVER
14 OR 22
55a
42
58
59
155b
15 OR 23
80

FIG. 1D


60
BATTERY
74
63
TELEMETRY COIL
76
DEMODU-LATOR
70
DATA BUS
73
73b
ROM
73a
ADDRESS BUS
75
72
OSCILLA-TOR
MICRO-PROCES SOR
DATA BUS
78
77b
RAM EVENT MEMORY
77
71 CLOCK
77a
PROGRAMM-ABLE MEMORY
ADDRESS BUS
79
EXTERNAL DATA PORT TO INTERFACE WITH COMPUTER
68
66
DISPLAY
167
SPEAKER
BUFFER
164
65
USER OPERATOR

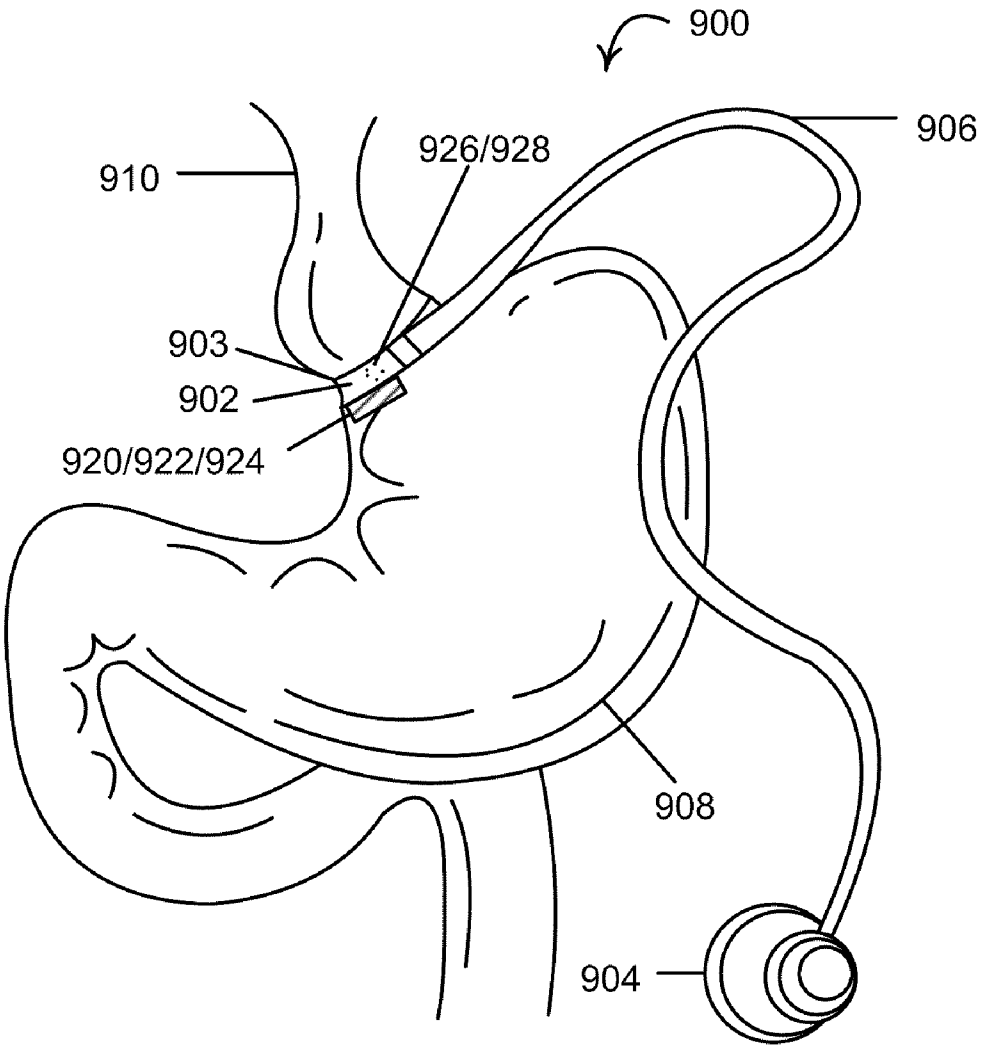


FIG. 2A

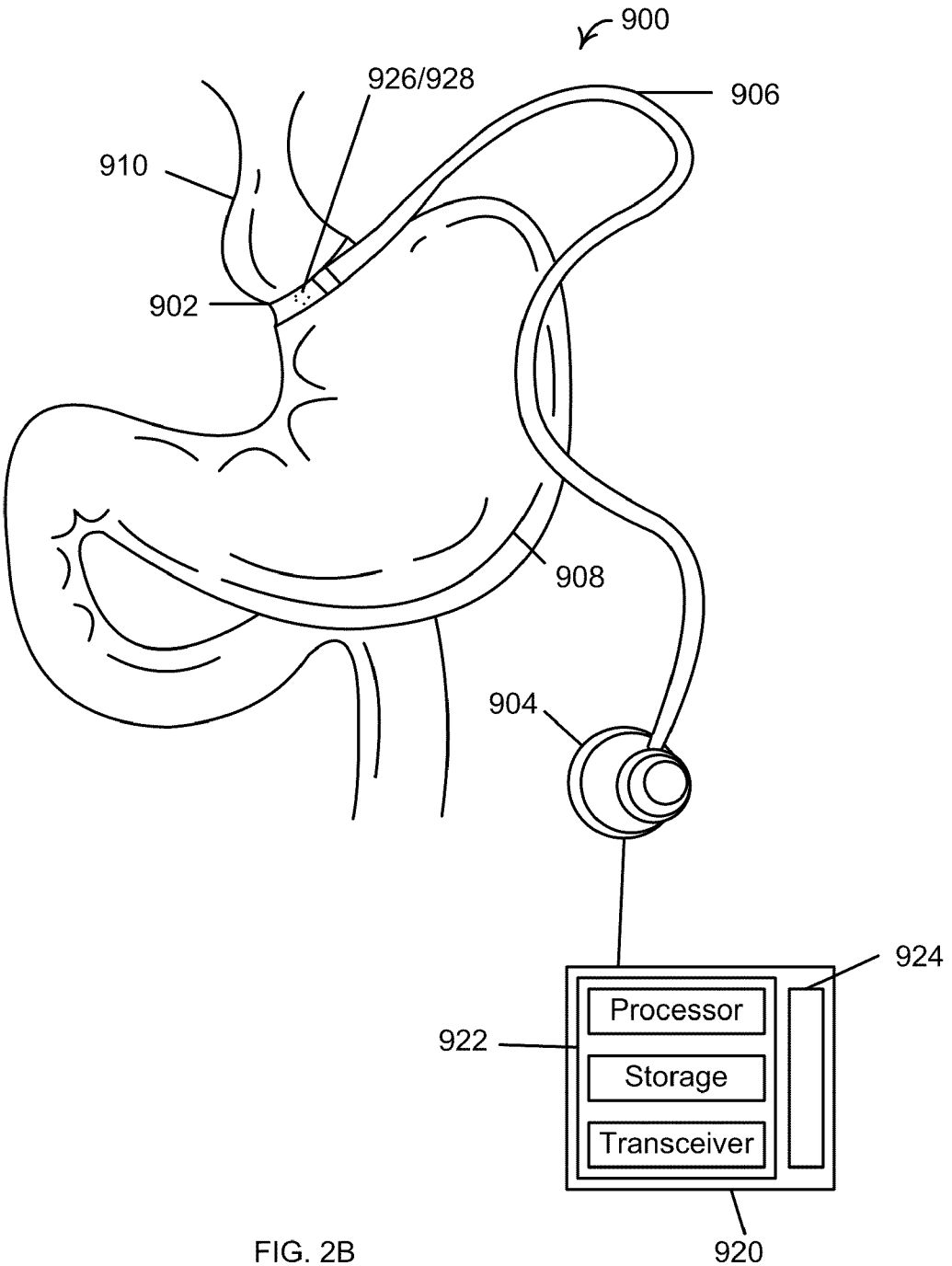

900
926/928
906
910
902
908
904
924
Processor
922
Storage
Transceiver
920

FIG. 2B

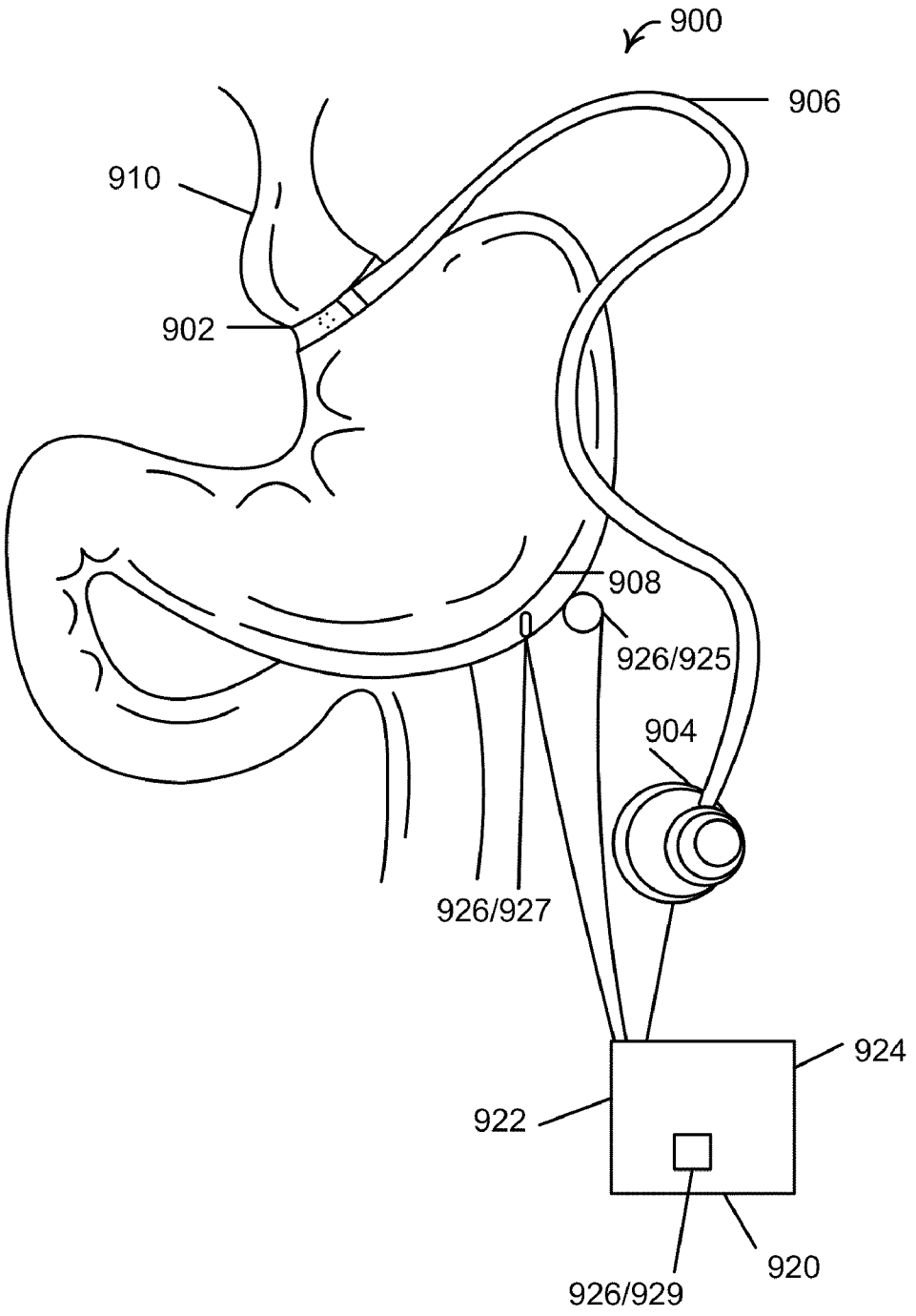


FIG. 2C

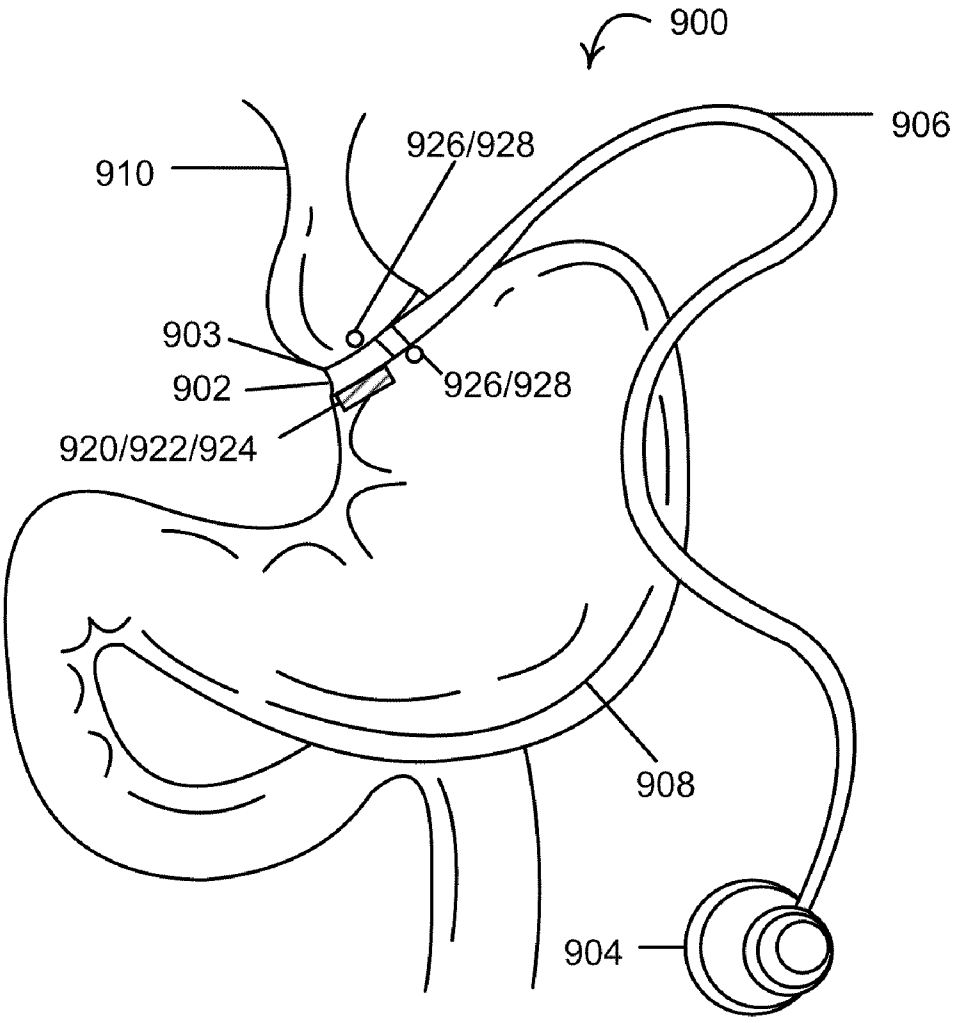


FIG. 2D

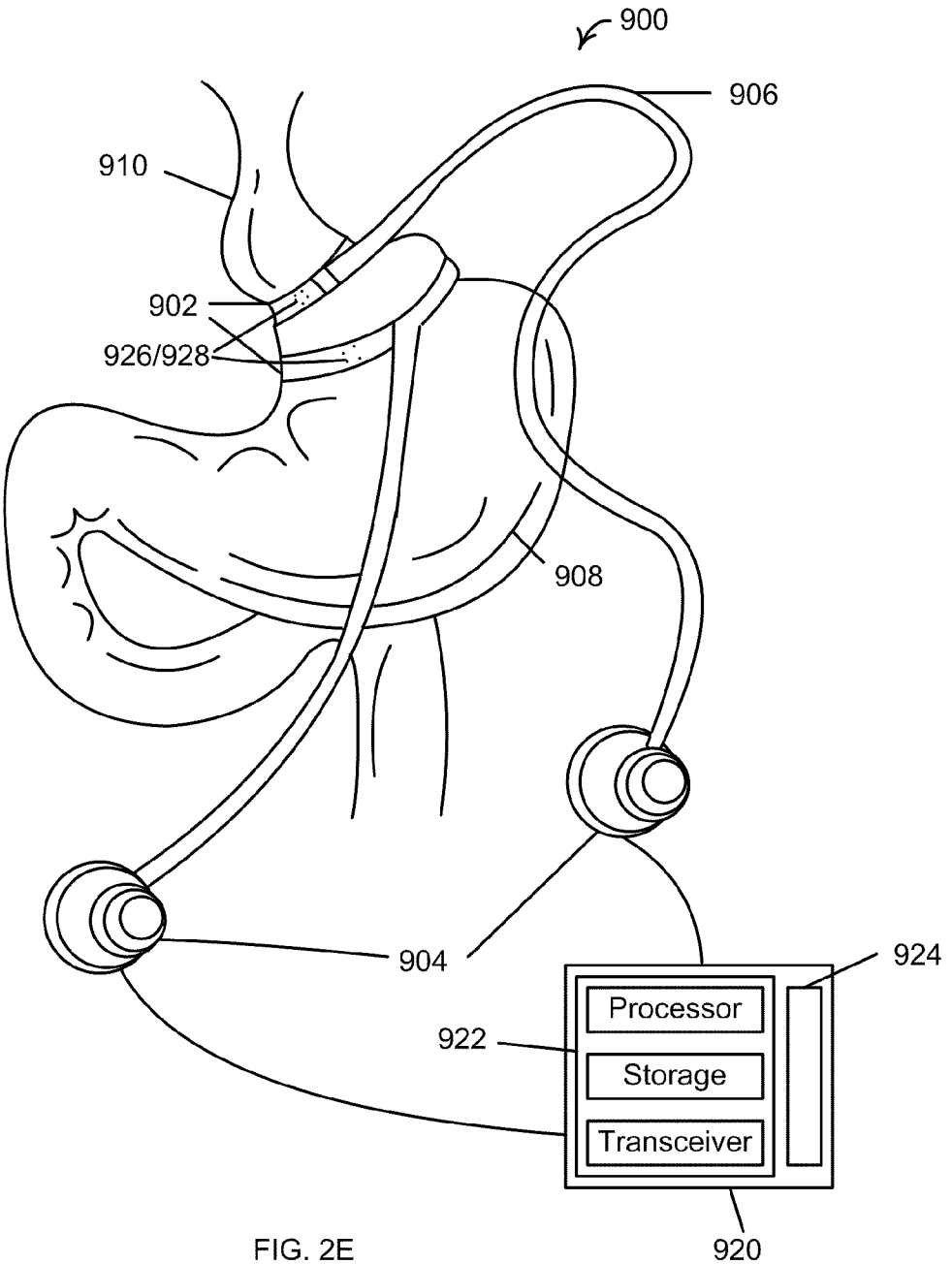

900
906
910
902
926/928
908
904
924
Processor
922
Storage
Transceiver
920

FIG. 2E

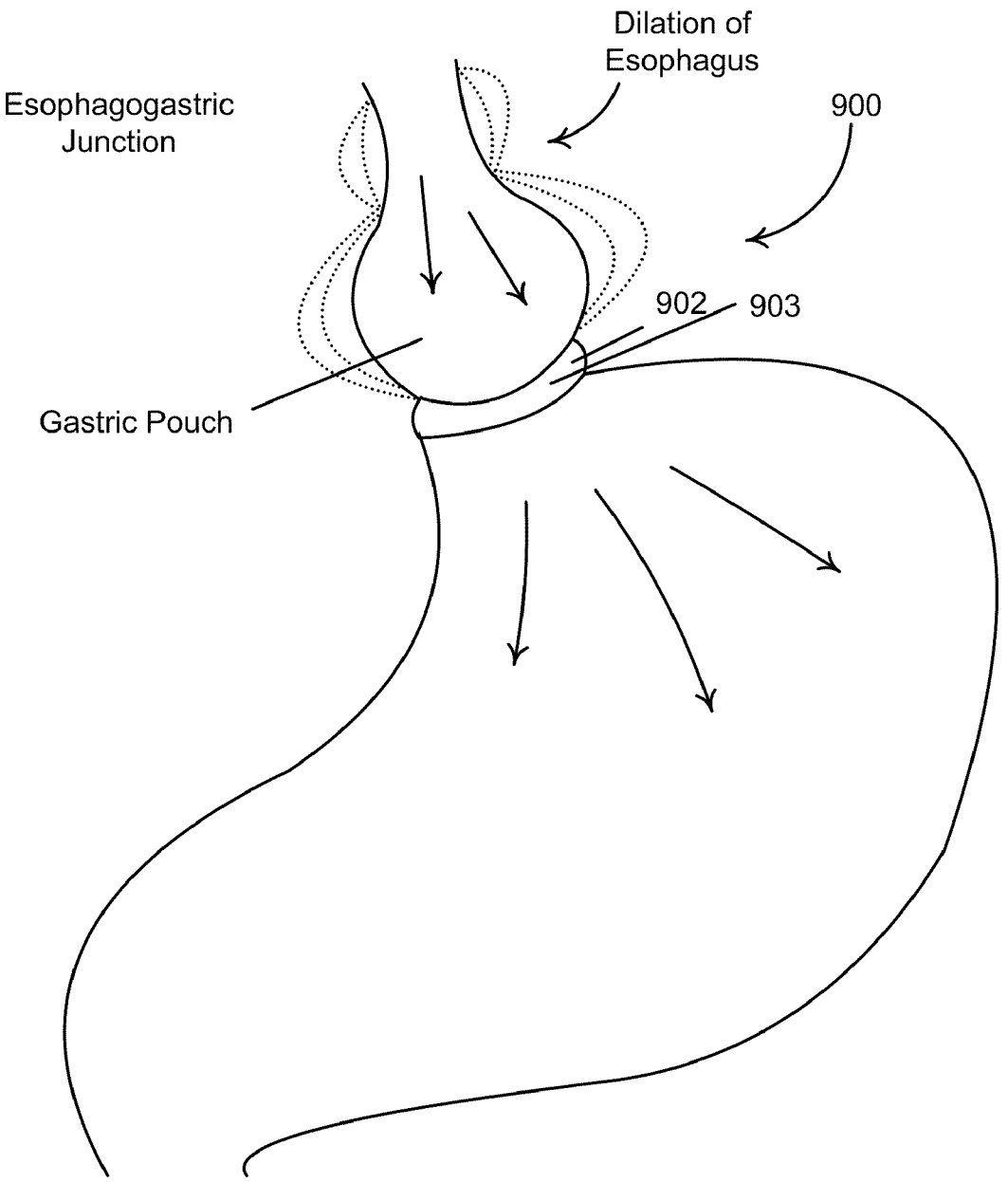

Dilation of
Esophagus
Esophagogastric
Junction
900
902
903
Gastric Pouch

FIG. 3

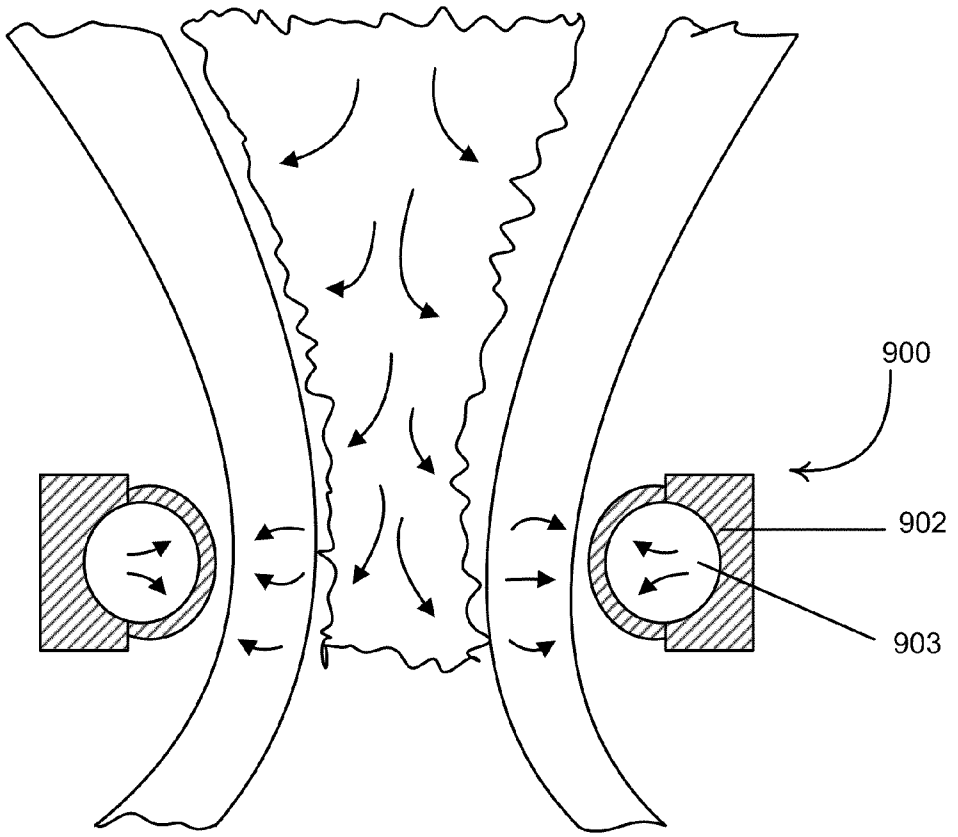


FIG. 3A

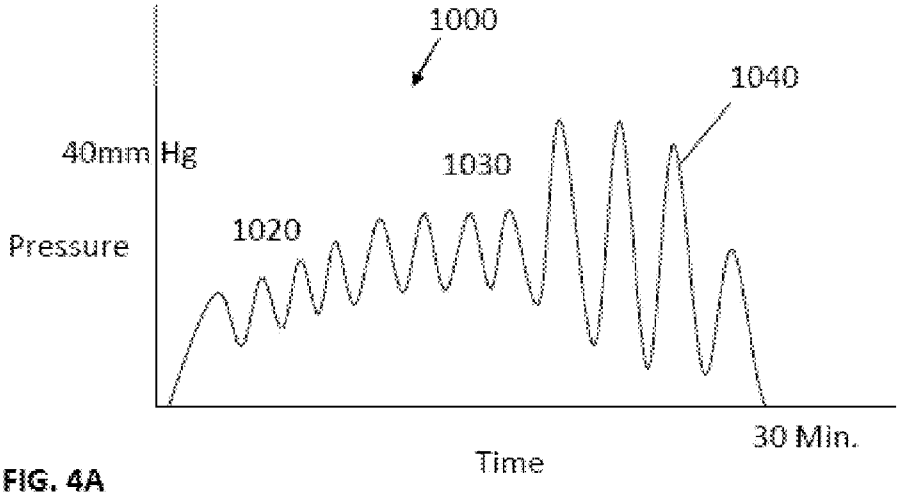

1000
1040
40mm Hg
1030
Pressure
1020
30 Min.
Time

FIG. 4A

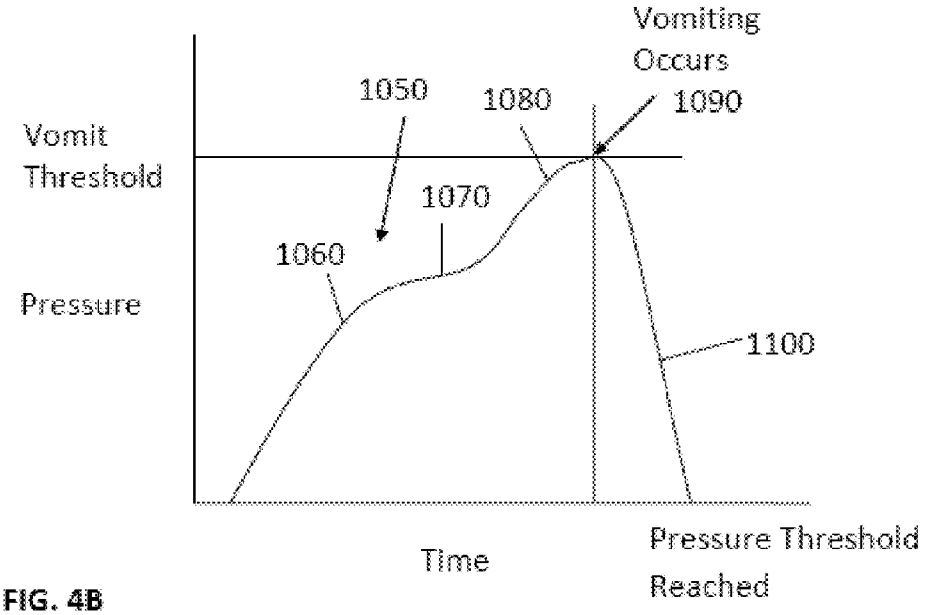

Vomiting
Occurs
1050
1080
1090
Vomit
Threshold
1070
1060
Pressure
1100
Time
Pressure Threshold
Reached

FIG. 4B

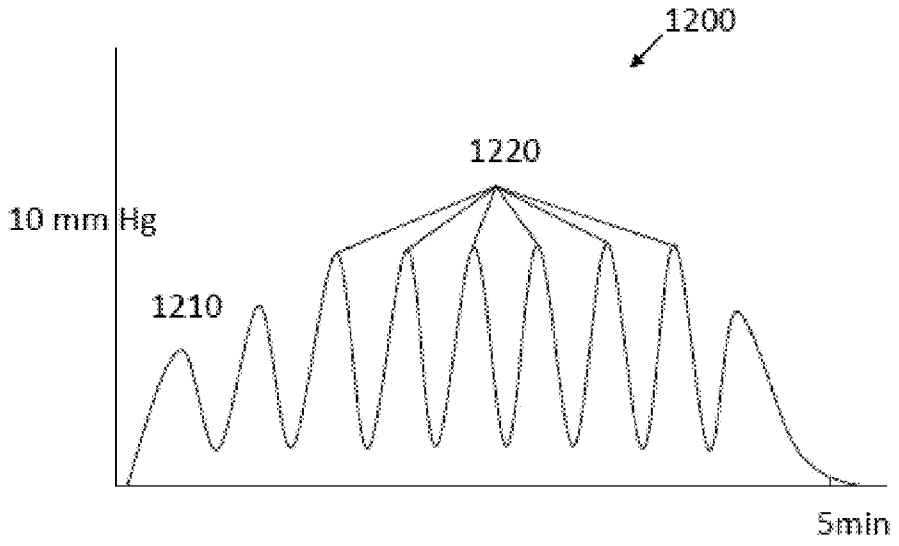

1200
1220
10 mm Hg
1210
5min

FIG. 4C

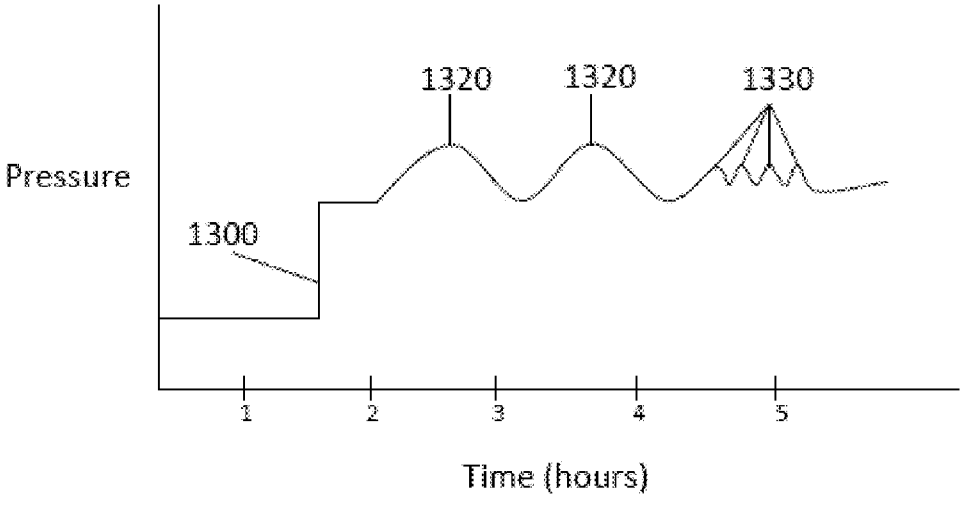

1320
1320
1330
Pressure
1300
1
2
3
4
5
Time (hours)

FIG. 5

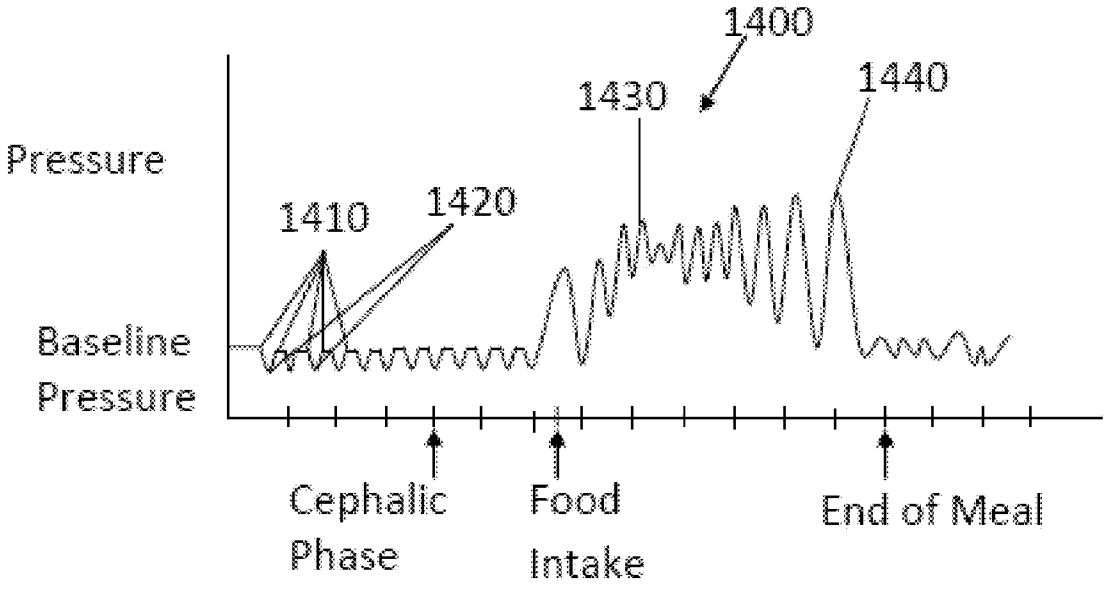

1400
1430
1440
Pressure
1410
1420
Baseline
Pressure
Cephalic
Phase
Food
Intake
End of Meal

FIG. 6

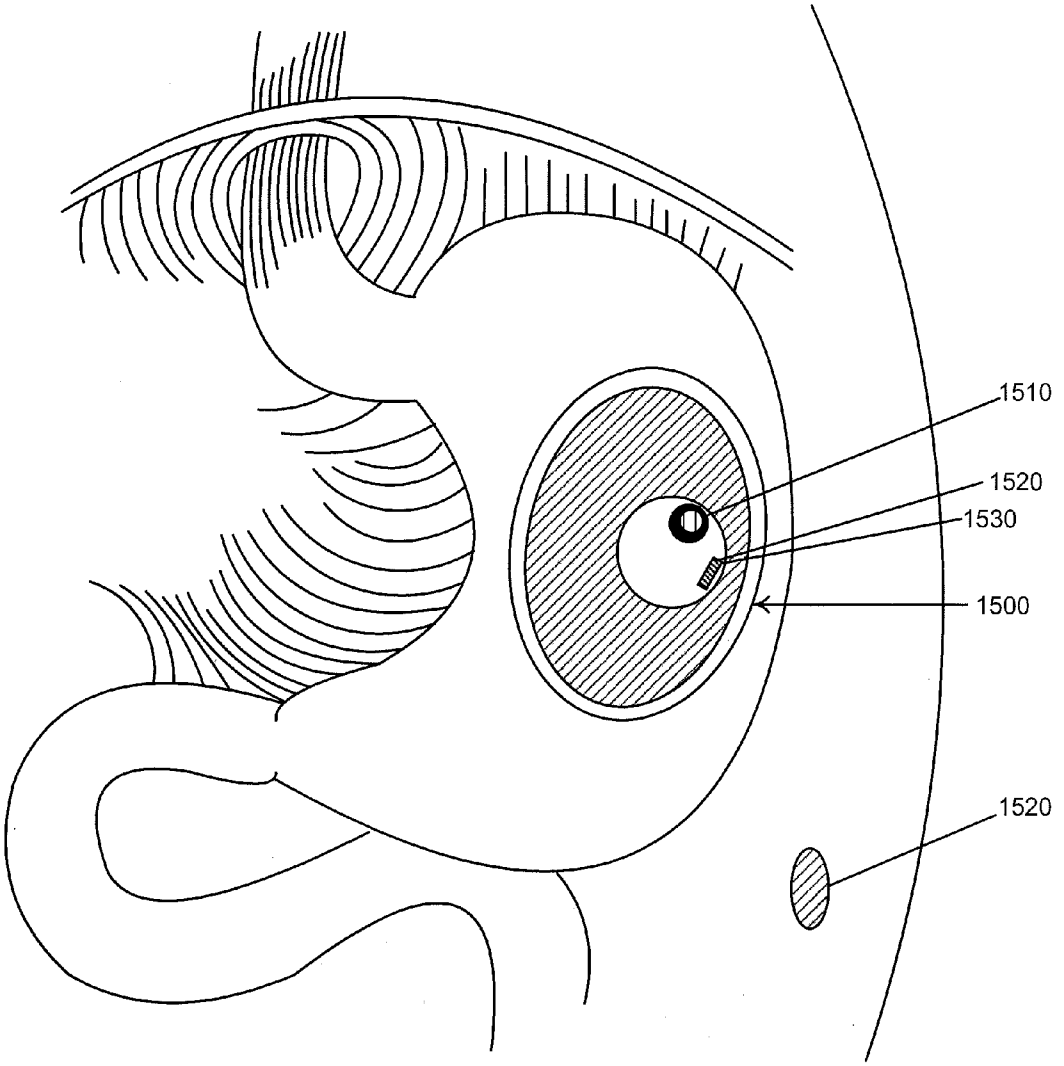


FIG. 7

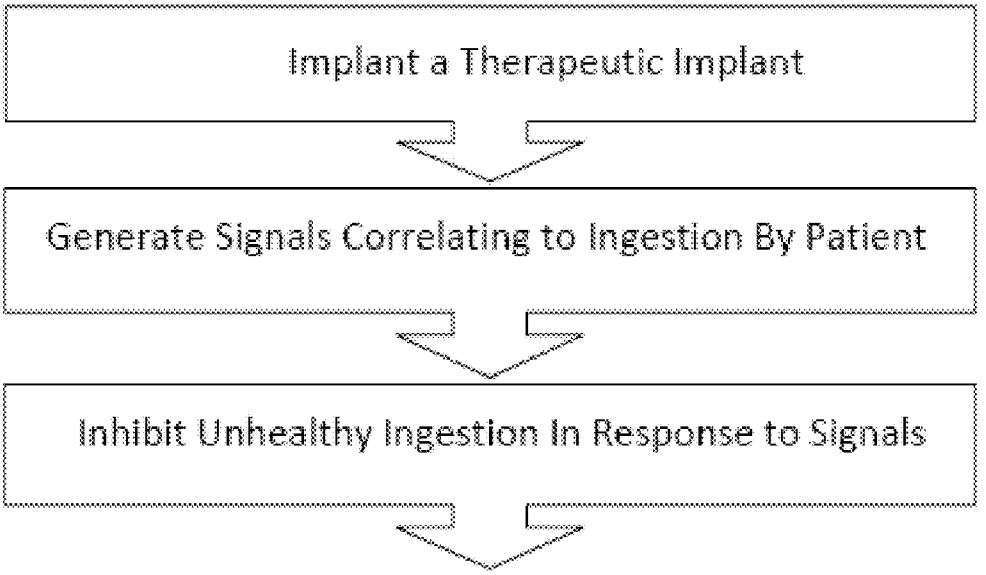

Implant a Therapeutic Implant
Generate Signals Correlating to Ingestion By Patient
Inhibit Unhealthy Ingestion In Response to Signals

FIG. 8

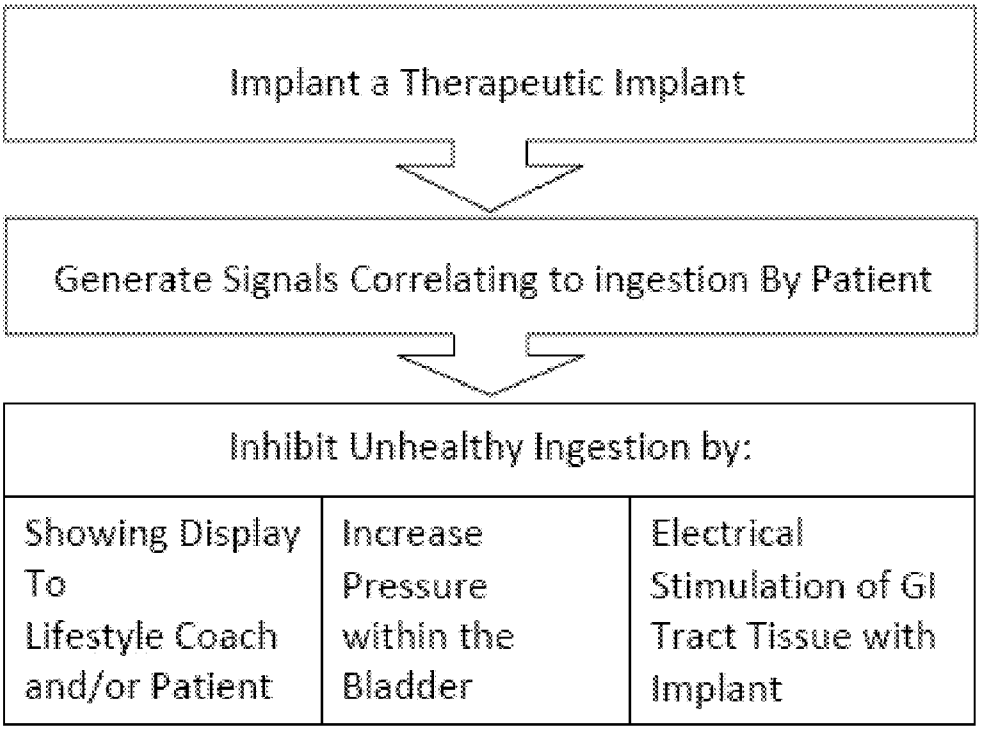

Implant a Therapeutic Implant
Generate Signals Correlating to ingestion By Patient
Inhibit Unhealthy Ingestion by:
Showing Display To Lifestyle Coach and/or Patient
Increase Pressure within the Bladder
Electrical Stimulation of GI Tract Tissue with Implant

FIG. 8A

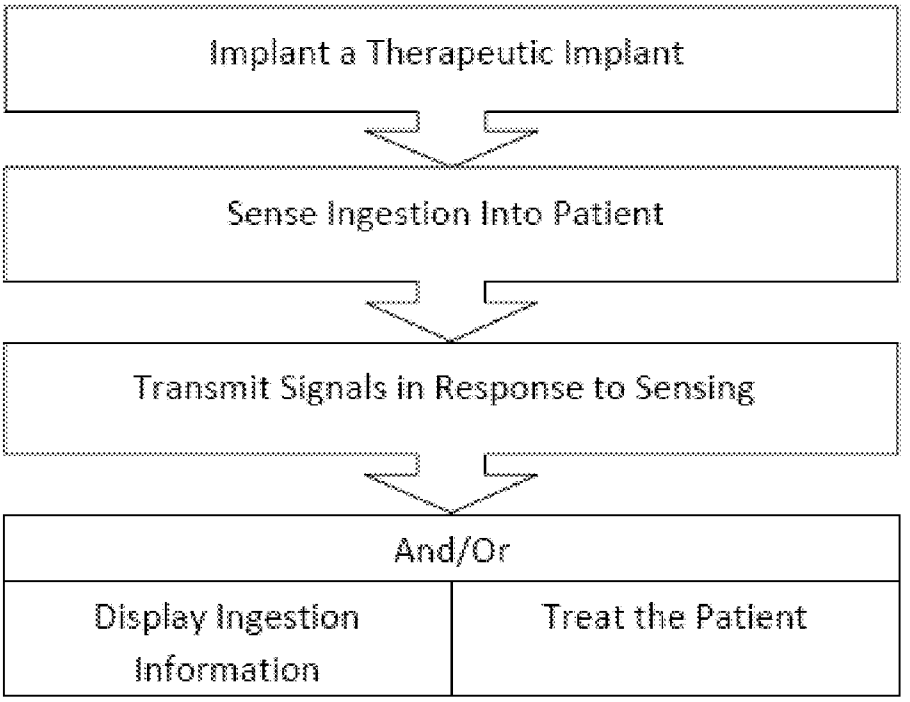

Implant a Therapeutic Implant
Sense Ingestion Into Patient
Transmit Signals in Response to Sensing
And/Or
Display Ingestion Information
Treat the Patient

FIG. 8B

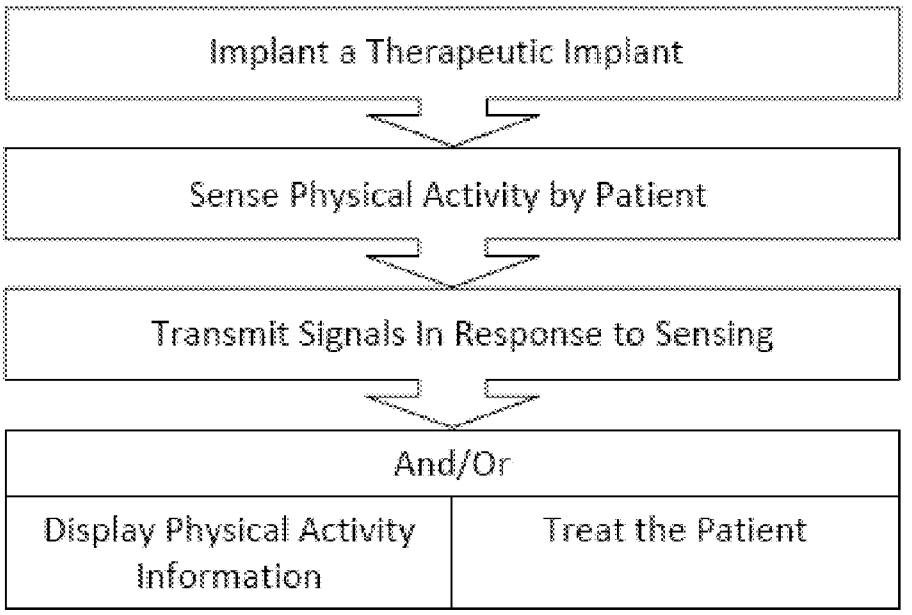

Implant a Therapeutic Implant
Sense Physical Activity by Patient
Transmit Signals In Response to Sensing
And/Or
Display Physical Activity Information
Treat the Patient

FIG. 8C

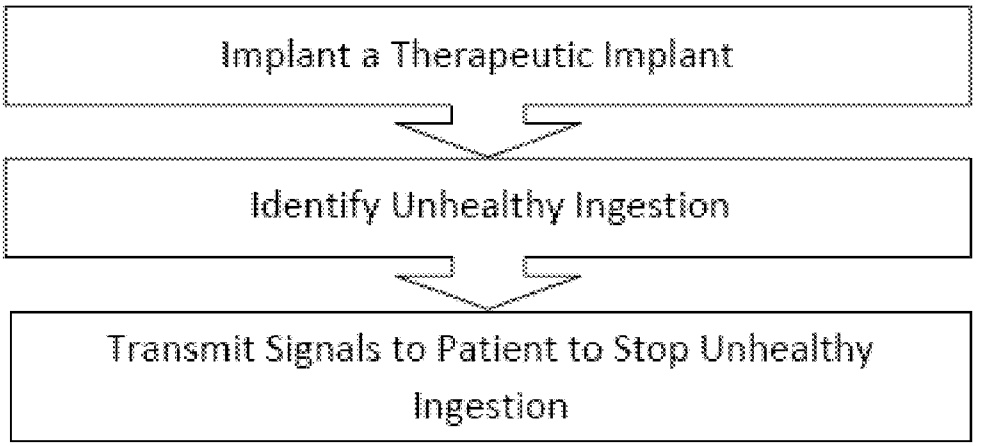

Implant a Therapeutic Implant
Identify Unhealthy Ingestion
Transmit Signals to Patient to Stop Unhealthy Ingestion

FIG. 8D

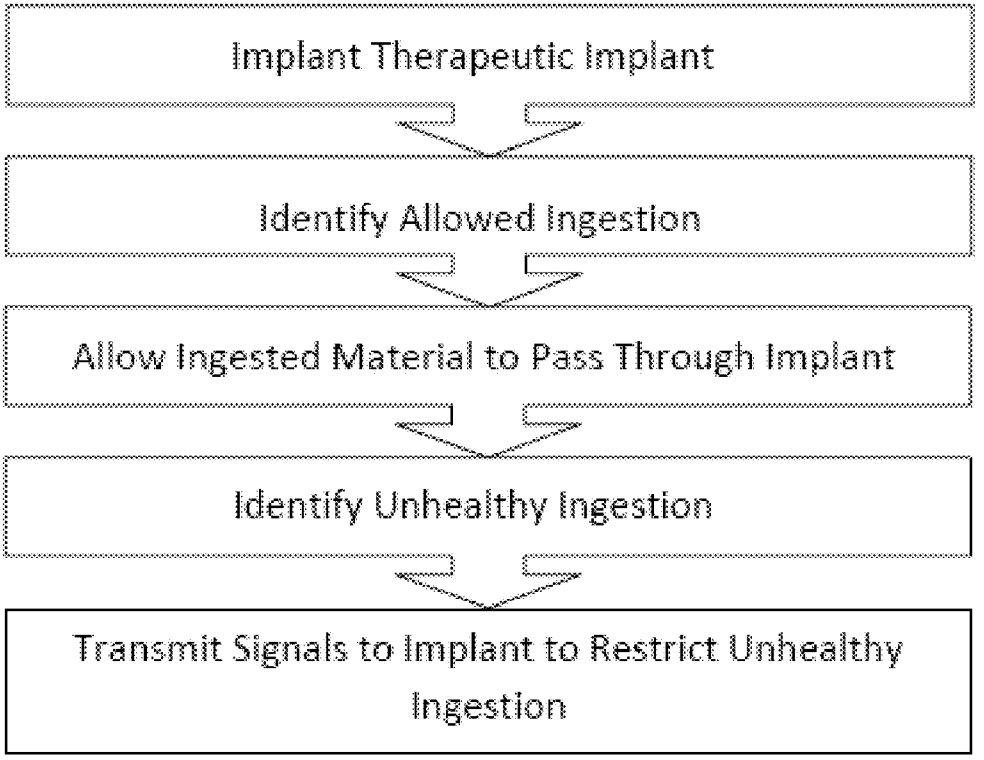

Implant Therapeutic Implant
Identify Allowed Ingestion
Allow Ingested Material to Pass Through Implant
Identify Unhealthy Ingestion
Transmit Signals to Implant to Restrict Unhealthy Ingestion

FIG. 8E

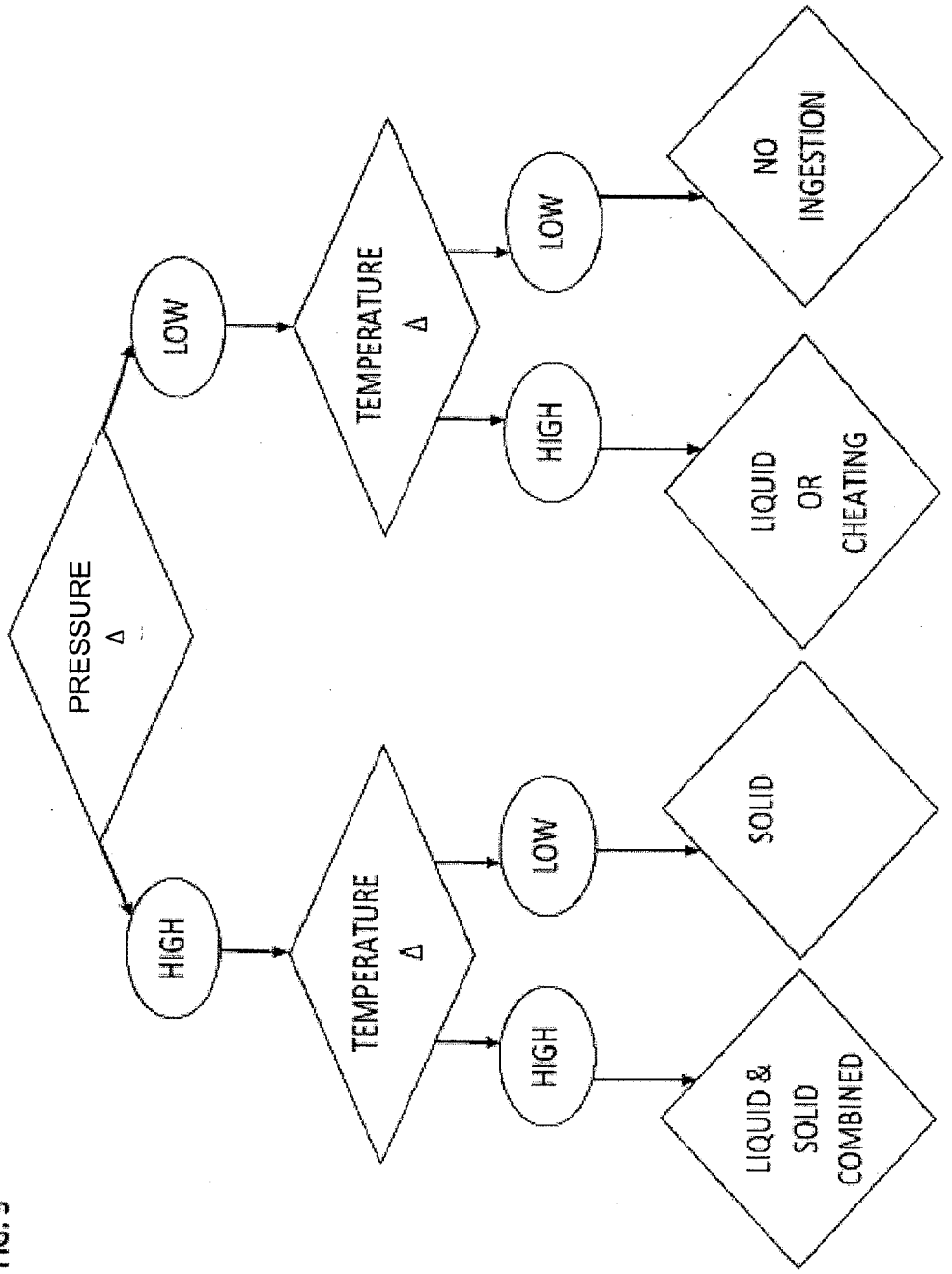

PRESSURE Δ
HIGH
LOW
TEMPERATURE Δ
TEMPERATURE Δ
LOW
HIGH
LOW
HIGH
SOLID
LIQUID & SOLID COMBINED
LIQUID OR CHEATING
NO INGESTION

FIG. 9

FEEDBACK SYSTEMS AND METHODS TO ENHANCE OBSTRUCTIVE AND OTHER OBESITY TREATMENTS

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] The present application claims the benefit under 35 USC 119(e) of U.S. Provisional Application No. 61/166,636 filed Apr. 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: U.S. application Ser. No. 12/145,430 filed Jun. 24, 2008; U.S. application Ser. No. 10/950,345 filed Sep. 23, 2004 (Allowed); U.S. Application No. 61/122,315 filed Dec. 12, 2008; U.S. application Ser. No. 12/637,452 filed Dec. 14, 2009, and U.S. application Ser. 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 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 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).

[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, 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.

[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.

[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 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.

[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 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.

[0036] 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.

[0037] 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.

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

[0039] 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.

[0040] In some embodiments, the implant body includes a gastric balloon. Altering the implant body includes altering a fluid pressure within the gastric balloon.

[0041] 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.

[0042] 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.

[0043] 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.

[0044] 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.

[0045] In some embodiments an optical sensor is coupled to the processor.

[0046] In some embodiments a pH sensor is coupled to the processor.

[0047] 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.

[0048] 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.

[0049] 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.

[0050] 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.

[0051] 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 sen-

sors 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.

[0052] 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.

[0053] In some embodiments the sensor includes an activity sensor.

[0054] In some embodiments the sensor includes a heart rate sensor.

[0055] In some embodiments the sensor includes a core body temperature sensor.

[0056] In some embodiments the sensor includes a sleep detector.

[0057] In many embodiments of the therapeutic implant, the signals are transmitted by the processor to a data server.

BRIEF DESCRIPTION OF THE DRAWINGS

[0058] FIG. **1** shows an exemplary system **100** suitable for implementation of embodiments of the present invention.

[0059] FIG. **1**A shows an exemplary gastric band sensor system implant **900** for use in the system of FIG. **1**.

[0060] FIG. **1**B-D illustrate the electrical stimulation component of the gastric band sensor system implant **900**.

[0061] FIGS. **2**A-**2**C illustrate alternative embodiments of system **900**.

[0062] FIG. **2**D shows an embodiment of system **900** comprising two pressure sensors **928** coupled to the fluid-filled cuff **903**.

[0063] FIG. **2**E shows an alternative embodiment of system **900** comprising at least two lap bands, each lap band comprising at least one sensor **926**.

[0064] FIG. **3** illustrates ingestion of food or drink into a stomach.

[0065] FIG. **3**A shows a cross-sectional view of the superior portion of the stomach constricted by a lap band **902** with a fluid filled cuff **903**.

[0066] FIGS. **4**A-**4**C show the pressure waveforms from pressure sensor signals one might expect with food or drink input. More specifically, FIG. **4**A shows the expected pressure waveforms from an ingestion of food **1000**. FIG. **4**B illustrates an overeating event. FIG. **4**C shows the expected pressure waveforms **1200** from a drinking event.

[0067] FIG. **5** shows the pressure waveforms **1300** that occur with injection of fluid, e.g. saline, into the port of the lap band.

[0068] FIG. **6** shows pressure waveforms from peristaltic waves **1400**.

[0069] FIG. **7** shows an exemplary intragastric balloon-sensor-monitor system **1500**.

[0070] FIG. **8** shows a method of treating a patient with an unhealthy ingestion pattern **2000**.

[0071] FIG. **8**A-E show alternative treatments method comprising the therapeutic implant.

[0072] FIG. **9** schematically shows a system and method for classification of ingestion events based on signals from a plurality of sensors.

DETAILED DESCRIPTION OF THE INVENTION

[0073] The present invention often takes advantage of processors to enhance obesity therapies that rely on restrictive implants disposed along the gastrointestinal tract. Some 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 applicable to any treatment in which presenting feedback regarding patients' eating and/or exercise habits is desired.

[0074] 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 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 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 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 improvements may be particularly effective at promoting and/or maintaining healthy activities when ultimate health goals remain distant.

[0075] 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 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 also provides stimulation of the stomach to reduce caloric intake.

[0076] 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 "coaching sessions" and increased accuracy of the sensor data will improve outcomes for the patients.

[0077] 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, 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 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 to 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.

[0078] 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 Weight-Watchers.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.

[0079] 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).

[0080] 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).

[0081] 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.

[0082] 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 functions will be implemented by modules, with each module comprising data processing hardware and associated software configured to perform the desired function. The mod-

ules 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 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.

[0083] The electronic circuitry of the various devices of system **100** communicates via RF 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 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 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.

[0084] Sensor **114** is coupled to the stomach so as to generate signals responsive to 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 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 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 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 Jun. 24, 2008 and U.S. patent application Ser. No. 10/950,345, filed on Sep. 23, 2004, both of which have 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. 61/122,315, filed on Dec. 12, 2008 and U.S. patent application Ser. No. 12/637,452, filed on Dec. 14, 2009 which were also previously incorporated herein by reference.

[0085] 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 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 ability 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 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 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 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.

[0086] The server **130** contains a number of algorithms designed to evaluate the 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 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 intake is meeting daily, weekly, or monthly goals.

[0087] 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 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 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.

[0088] 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 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 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 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 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.

[0089] 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).

[0090] 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 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.

[0091] Portal **150** may facilitate networking with identified friends using known social 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 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 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.

[0092] To enhance the efficacy of coaching and overall feedback, portal **150** may allow 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 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 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 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 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.

[0093] 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 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 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.

[0094] 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 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.

[0095] FIG. **1**A shows an exemplary gastric band sensor system implant **900**. This embodiment includes a gastric band, laparoscopically implanted, also known as a lap band **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 Medical Innovation Development, and Heliogast® Band from Helioscopie, MiniMizer Extra from Bariatric 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 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**.

[0096] 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.), 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.

[0097] FIG. **1**B illustrates the electrical stimulation component of the gastric band sensor system implant **900**. The stimulator **20** comprises a housing **21** implanted subcutaneously within a patient. The stimulator further comprises leads **22***a*, **23***a* extending from the housing **21** through the abdomen and to the stomach **100** where electrodes **22**, **23** at the end of the leads **22***a*, **23***a* 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.

[0098] The housing **21** further comprises a sensor **24***a* located on the housing **21** and/or a sensor **24***b* located elsewhere in the patient and coupled to the electronic circuitry **29**, (FIG. **1**B) in the housing **21** by lead **24***c*. The sensor **24***a* or **24***b* may, for example, include an accelerometer that is con-

figured 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 **25***a*, **26***a* 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 **22***a*, **23***a* and **24***c*, **25***a*, **26***a* 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.

[0099] 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.

[0100] An embodiment of the electronic circuitry **29** is illustrated in FIG. **1**C. 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.

[0101] 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 **44***a* to provide a higher voltage, which is utilized for electrical stimulation pulses. The DC-to-DC converter **44***a* 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.

[0102] 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.

[0103] 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 **43***a* and the ROM **43** provides the stored program instruction to the controller **40** via data bus **43***b*. The controller/processor **40** controls the telemetry coil **45**, which communicates with an external control or programming device **60** (FIG. **1**D), 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 100 kHz-5 Mhz 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 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 **51** a and communicated to controller **40**. The detector circuit may be selected based on the modulation used for the telemetry signals.

[0104] The circuit **29** may also be coupled through A/D converters (with amplifiers) **46***a*, **46***b*, **46***c*, **46***d* to one or more sensors **25**, **26**, **24***a*, **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 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. **1**D.

[0105] Controller **40** is coupled to RAM **50** via an address bus **50***a* for addressing a location in RAM **50** and a bi-directional data bus **50***b* for delivering information to and from RAM memory **50**. The RAM memory **50** includes event memory **48** that temporarily stores data recorded by sensors **24***a*, **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 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 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 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.

[0106] The electrodes **22**, **23** are coupled through A/D converters **46***e* and **46***f* to the microprocessor **40**. A/D converter **46***e* 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 **46***f* converts the electrical signal sensed by the 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**.

[0107] 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 information is provided to the processor **40** through A/D converter **46***e*. The electrodes **22**, **23** are coupled through coupling capacitors **55***a* and **55***b* respectively, to output of electrical stimulation driver **42** and input of A/D converters **46***e*, **46***f*.

[0108] The impedance circuit **53** comprises a constant current source oscillator **54** that oscillates at a frequency of 50-100 kHz, and A/D converter **46***f* 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 **46***f* to a digital signal representative of impedance. A/D converter **46***f* has a bandwidth that includes the 50 kHz 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 **46***f* A/D converter **46***e* has a bandwidth that filters out the 50-100 kHz signal. Further, when a stimulation signal is being delivered, the controller **40** does not receive signals from A/D converters **46***e* and **46***f* 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.

[0109] An additional circuit **58** may be provided in the electronic circuitry **29** comprised 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

[0110] Additional stimulating sensing electrodes and corresponding signal processing circuits may also be provided.

[0111] FIG. **1**C 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 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 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 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.

[0112] 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 **73***a* and the ROM **73** provides the stored program instruction to the controller **70** via data bus **73***b*.

[0113] 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** (FIG. **1**B) through its telemetry coil **45**. Controller **70** is coupled to an oscillator **72** that provides an RF signal, preferably having a characteristic frequency of 500 kHz 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**.

[0114] The data is delivered to the event memory **78** in RAM **77** by way of data bus **77***b* for temporary storage. The

data may be retrieved from RAM **77** by addressing the storage location via the address bus **77***a*.

[0115] Event memory **78** temporarily stores data sensed by sensors **24***a*, **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.

[0116] The stimulator **20** may be programmed to deliver electrical stimulation in response to sensed parameters. The sensors **24***a*, **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 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 sensor that provide information on biochemical compositions relating to the stomach such as secretions.

[0117] 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; activity level of a subject; wakefulness of a subject; time of a daily cycle or schedule; contractions of the stomach, etc.

[0118] 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, 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.

[0119] For example, the combined determination of temperature changes indicating 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 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.

[0120] 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.

[0121] As shown in FIG. **1**A, the sensor **928** may be mounted in fluid communication with port **904**. FIGS. **2**A-**2**C illustrate alternative embodiments of system **900**. FIG. **2**A 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. **2**B 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**.

[0122] FIG. **2**C 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.

[0123] FIG. **2**D shows an embodiment of system **900** comprising two pressure sensors **928** coupled to the fluid-filled cuff **903**. One pressure sensor **928** may 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.

[0124] FIG. **2**E 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 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 supe-

riorly-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

[0125] FIG. **3** illustrates ingestion of food or drink into a stomach. As food intake occurs pressure increases within the lap band, in the upper portion of the stomach and in the lower esophagus. The lower esophagus and upper portion or the stomach will expand to accommodate the incoming food as shown by dashed lines in FIG. **3**. FIG. **3**A shows a cross-sectional view of the superior portion of the stomach constricted by a lap band **902** with a 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 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.

[0126] FIGS. **4**A-**4**C show the pressure waveforms from pressure sensor signals one might expect with food or drink input. FIG. **4**A 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**).

[0127] FIG. **4**B 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.

[0128] FIG. **4**C 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.

[0129] 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.

[0130] FIG. **5** shows the pressure waveforms **1300** that occur with injection of fluid, e.g. 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 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.

[0131] 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 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 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.

[0132] 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.

[0133] 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, 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 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:

[0134] 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, U.S. Patent Application Ser. No. 61/166,636.

[0135] 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 or lead could, but need not have any stimulating electrodes. Suitable trans-gastric temperature sensing probes and ingestion analysis may described in (or may be modified from those described in) U.S. Provisional Patent Application No. 61/122,315, filed on Dec. 12, 2008, the full disclosure of which is incorporated herein by reference, and U.S. patent application Ser. No. 12/637,452 filed on Dec. 14, 2009.

Food or Drink Classification:

[0136] 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 timing and duration of the intake. The diagnostics may be used in monitoring patient's weight loss therapy.

[0137] As shown in FIG. **2**D and **2**E, 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 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.

[0138] 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. 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.

Caloric Determination:

[0139] 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 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.

Lap Band Adjustment:

[0140] 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.

[0141] In other embodiments, the implanted device may be capable of electrical 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.

[0142] 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 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.

[0143] In one embodiment the lap band sensor system is capable of automatically 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 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:

[0144] System **900** would optionally include a 3D accelerometer and/or a heart rate 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 U.S. Provisional Patent Application No. 61/241,154 which is hereby 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.

[0145] 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:

[0146] 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 developed by ReShape Medical™ Inc.

[0147] 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 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.

[0148] 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 a monitoring device placed outside the balloon, where a pressure sensor **1520** is attached to the surface of the monitoring device.

[0149] 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. 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:

[0150] 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 port for the laparoscopic tools.

[0151] 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:

[0152] 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**. 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 content detection.

[0153] In some cases, as shown in FIG. **8**A, 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 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**.

[0154] In some cases, as shown by FIG. **8**B, 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**.

[0155] In some cases, as shown by FIG. **8**C, 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 calorie intake has been larger than the calorie output, or vice versa.

[0156] In some cases, as shown in FIG. **8**D, 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**.

[0157] FIG. **8**E 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**.

[0158] 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 extendible 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.

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