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(54) CARDIAC MONITORING VIA GASTROINTESTINAL STIMULATOR

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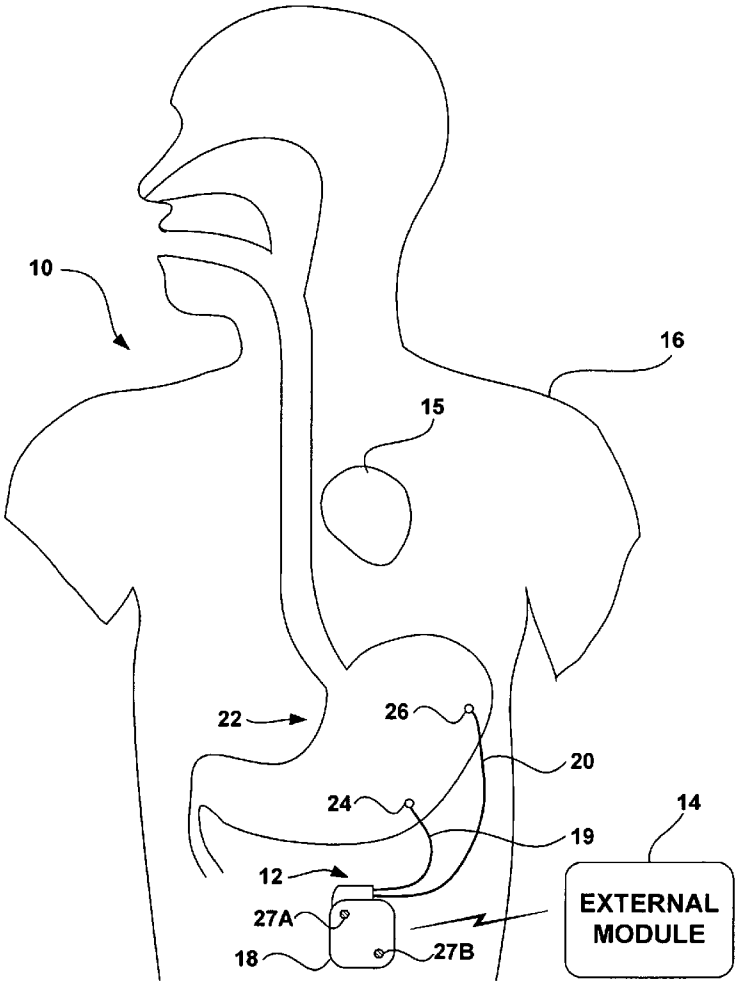
(57) **ABSTRACT**

The invention is directed to techniques for delivering electrical stimulation to a gastrointestinal tract of a patient via an implantable stimulator and monitoring electrical activity of a patient's heart by sensing cardiac signals via electrodes coupled to the implantable stimulator. The implantable stimulator may analyze the cardiac signals and generate a cardiac therapy recommendation for the patient, or may communicate the cardiac signals via telemetry circuitry to an external device for analysis. The sensed cardiac signals may be electrocardiogram (ECG) signals.



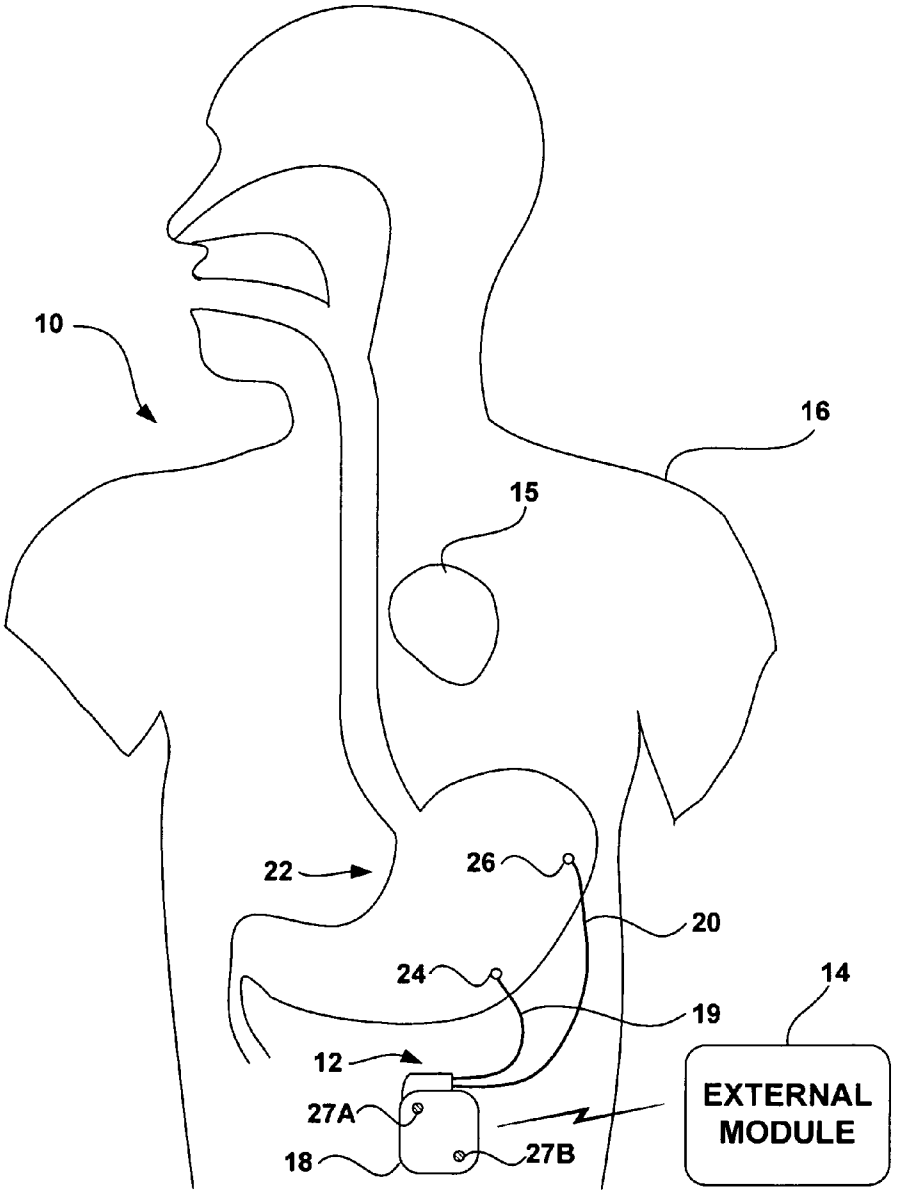


FIG. 1A

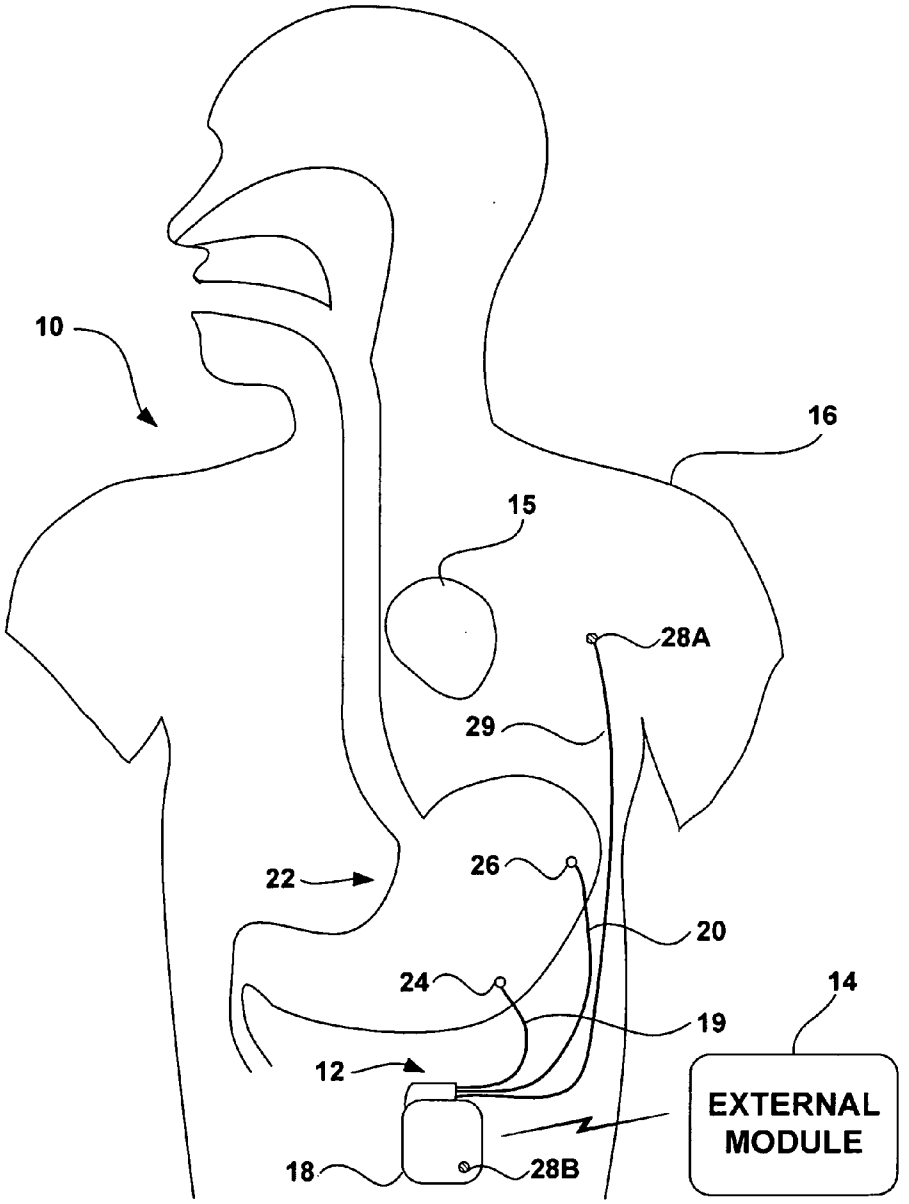


FIG. 1B

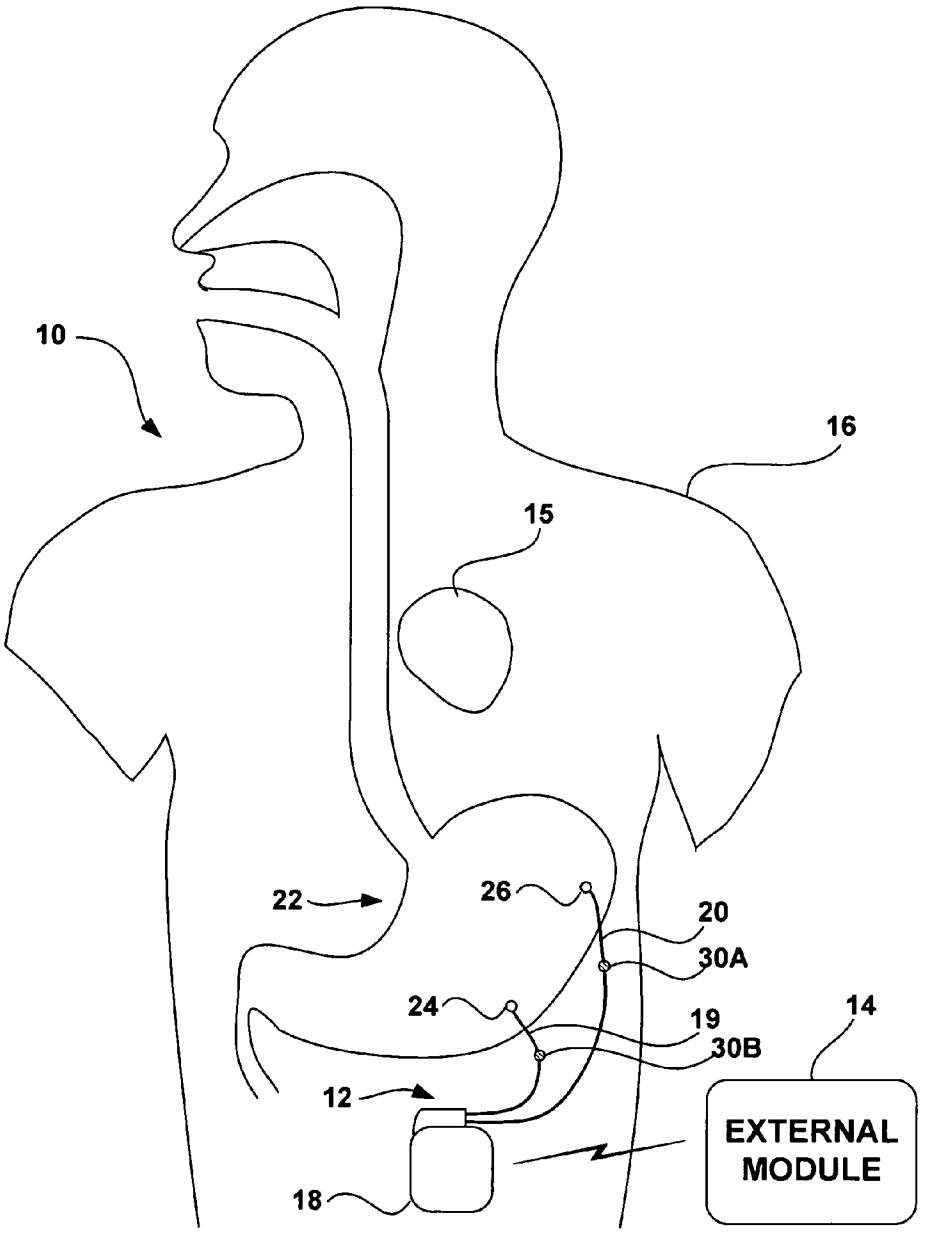


FIG. 1C

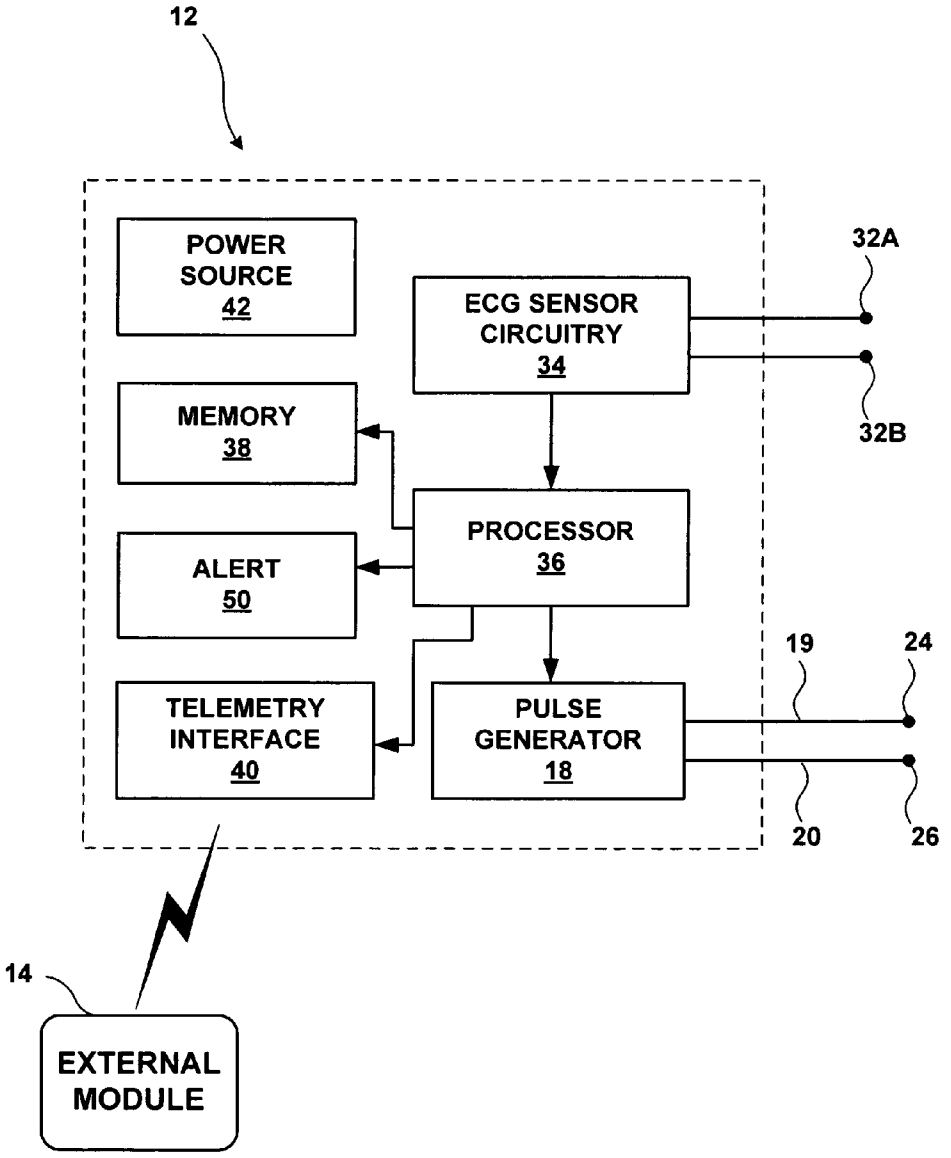

12
POWER SOURCE 42
ECG SENSOR CIRCUITRY 34
32A
32B
MEMORY 38
PROCESSOR 36
ALERT 50
TELEMETRY INTERFACE 40
PULSE GENERATOR 18
19
24
20
26
14
EXTERNAL MODULE

FIG. 2

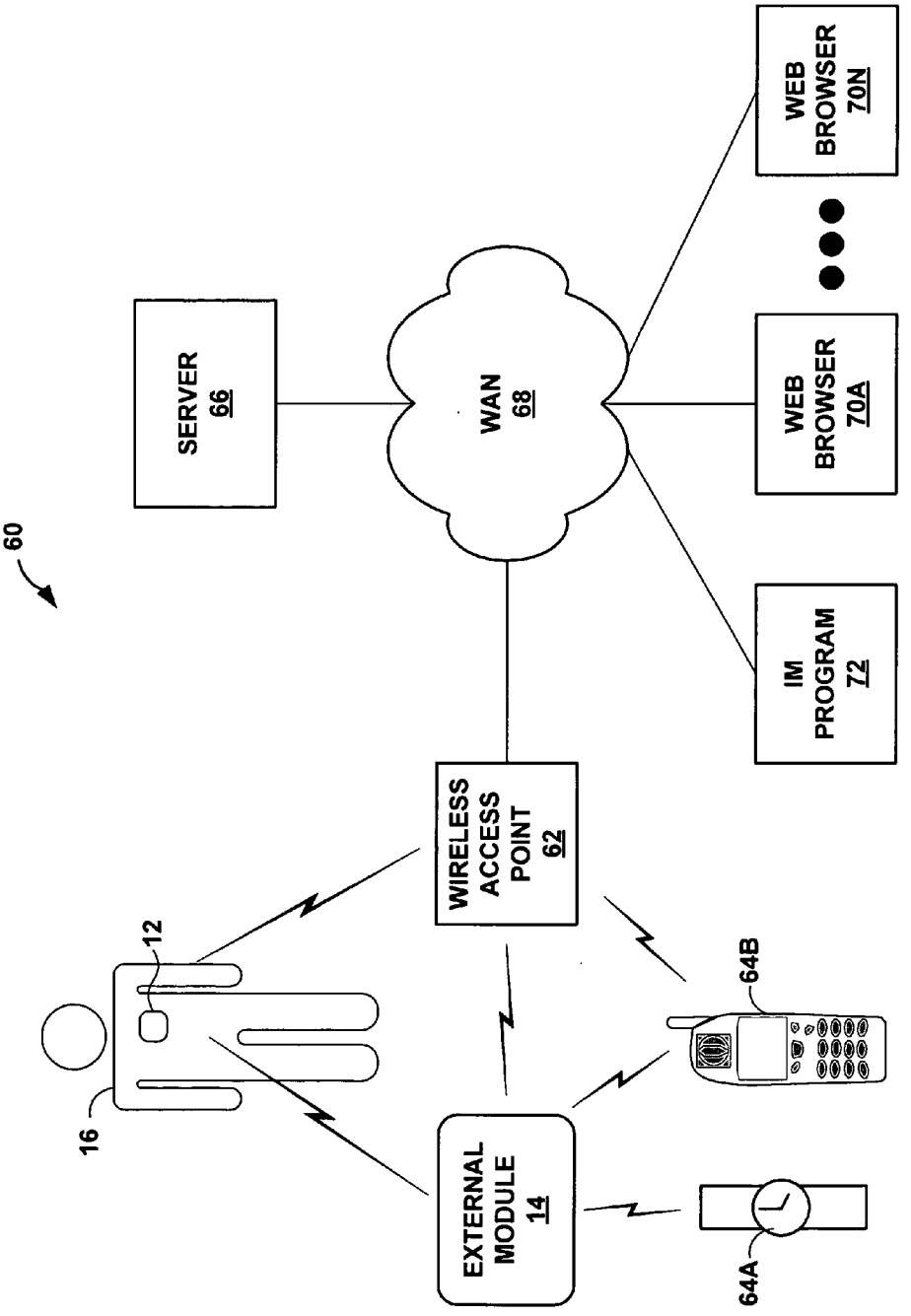

60
SERVER 66
WAN 68
WEB BROWSER 70N
WEB BROWSER 70A
IM PROGRAM 72
WIRELESS ACCESS POINT 62
12
16
64B
EXTERNAL MODULE 14
64A

FIG. 3

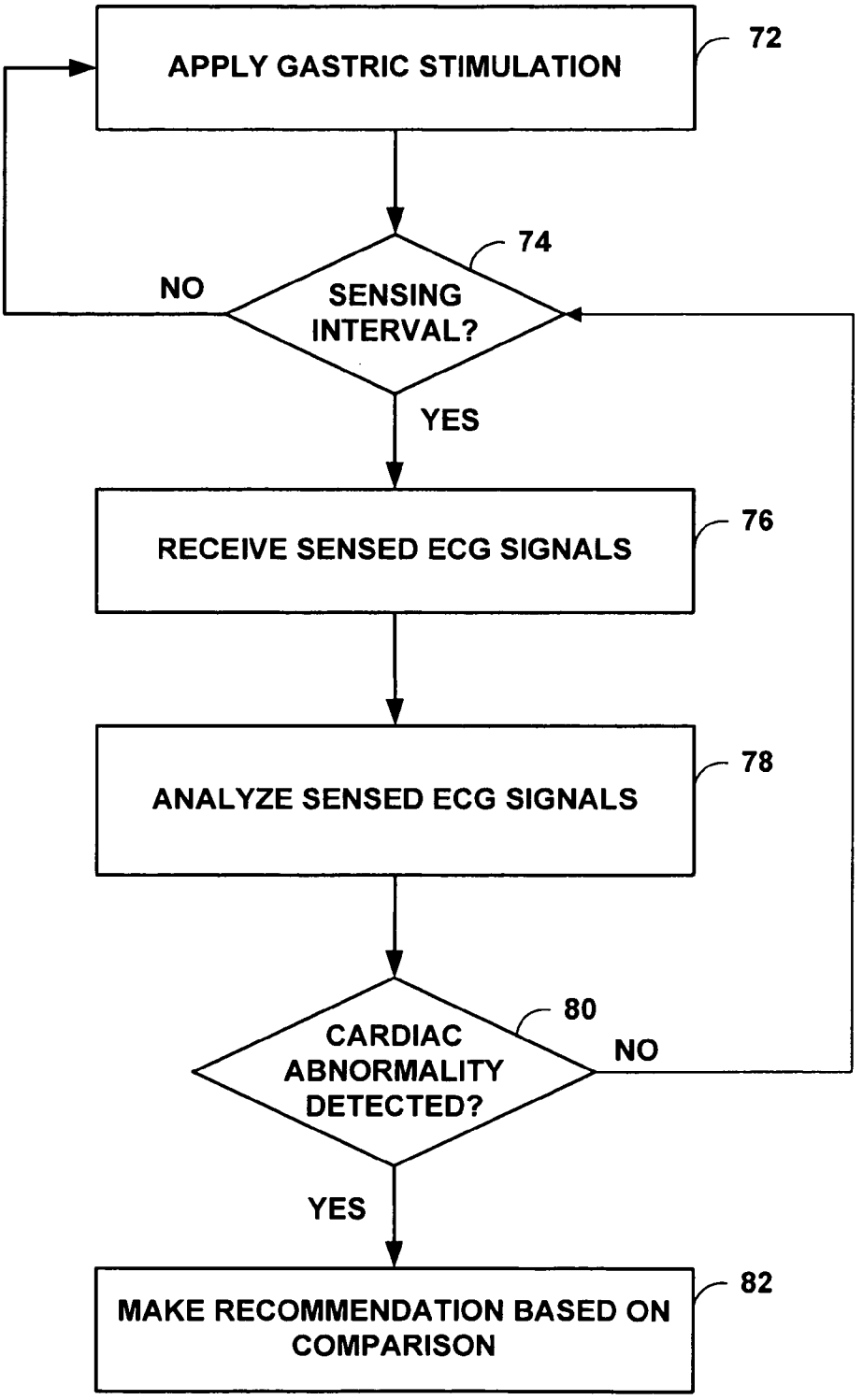

APPLY GASTRIC STIMULATION
72
74
NO
SENSING INTERVAL?
YES
RECEIVE SENSED ECG SIGNALS
76
ANALYZE SENSED ECG SIGNALS
78
80
CARDIAC ABNORMALITY DETECTED?
NO
YES
MAKE RECOMMENDATION BASED ON COMPARISON
82

FIG. 4

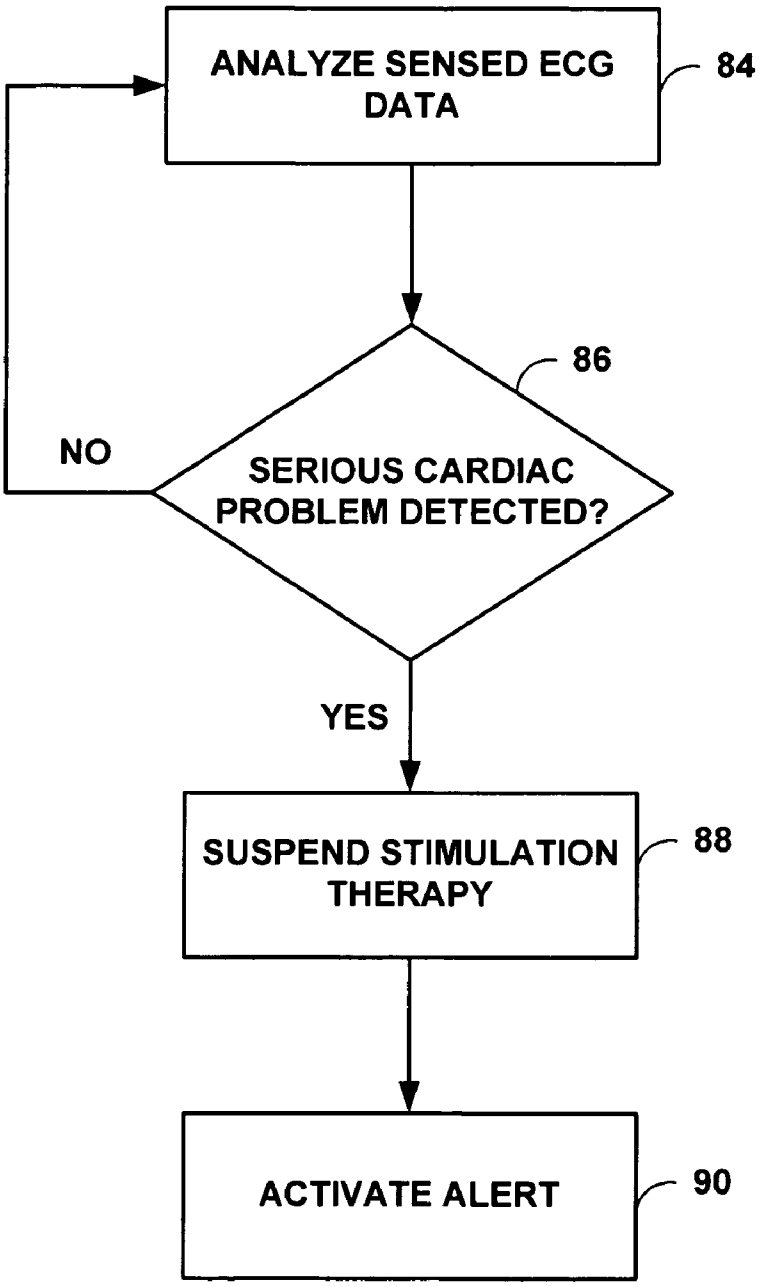

ANALYZE SENSED ECG DATA
84
86
NO
SERIOUS CARDIAC PROBLEM DETECTED?
YES
SUSPEND STIMULATION THERAPY
88
ACTIVATE ALERT
90

FIG. 5

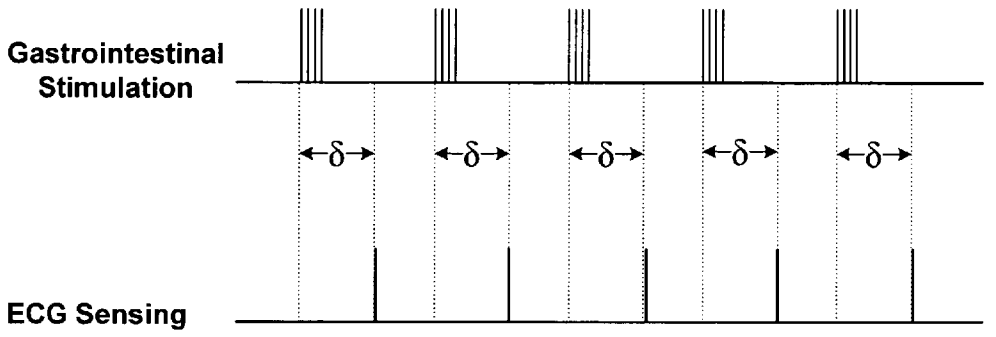


FIG. 6

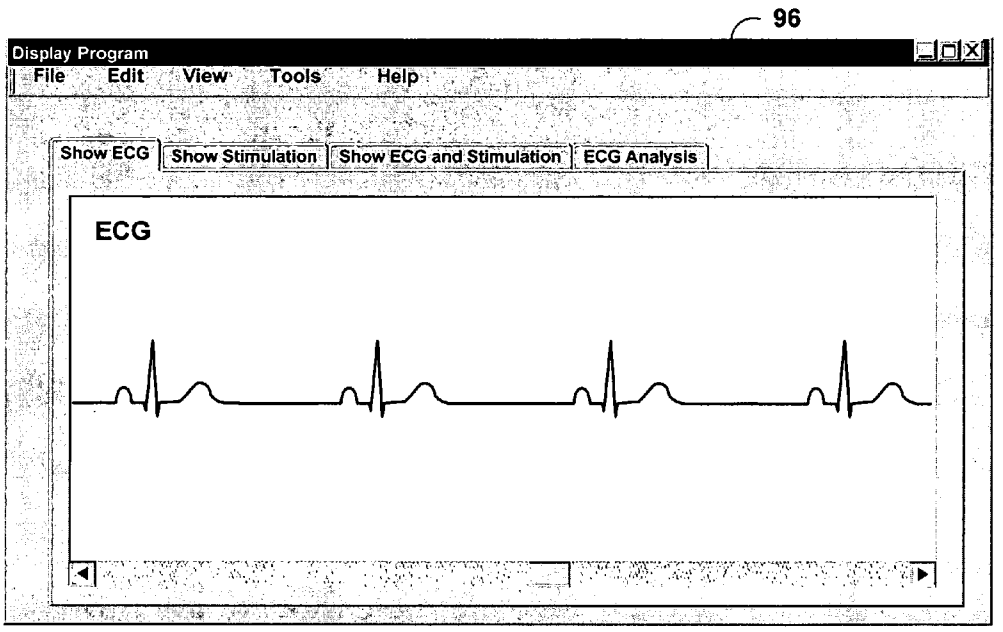

96
Display Program
File
Edit
View
Tools
Help
Show ECG
Show Stimulation
Show ECG and Stimulation
ECG Analysis
ECG

FIG. 7A

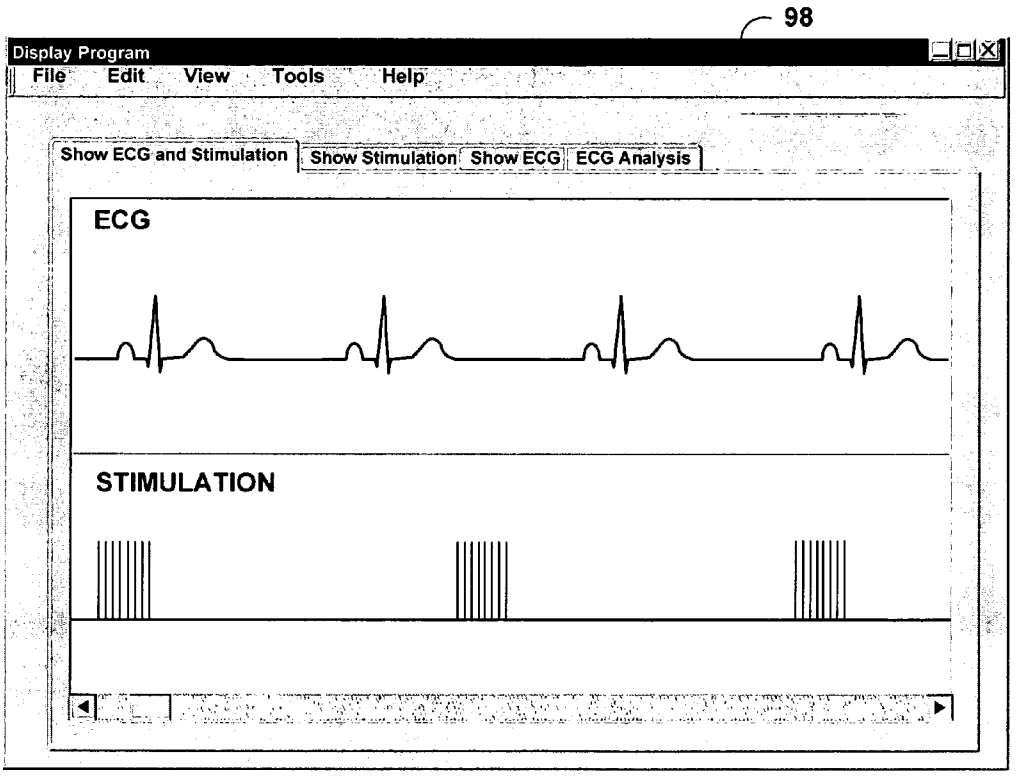

98
Display Program
File
Edit
View
Tools
Help
Show ECG and Stimulation
Show Stimulation
Show ECG
ECG Analysis
ECG
STIMULATION

FIG. 7B

CARDIAC MONITORING VIA GASTROINTESTINAL STIMULATOR

TECHNICAL FIELD

[0001] The invention relates to implantable medical devices and, more particularly, to implantable gastrointestinal stimulators.

BACKGROUND

[0002] Obesity is a serious health problem for many people. Patients who are overweight often have problems with mobility, sleep, high blood pressure, and high cholesterol. Some other serious risks associated with obesity include diabetes, cardiac arrest, stroke, kidney failure, and mortality. An obese person may be at a greater risk for developing cardiac problems.

[0003] Multiple factors contribute to obesity, including physical inactivity and overeating. Existing therapies include diet, exercise, appetite suppressive drugs, metabolism enhancing drugs, surgical restriction of the gastric tract, and surgical modification of the gastric tract. These therapies may result in little or no weight loss up to weight loss of nearly 50% of initial body weight.

[0004] Electrical stimulation of the gastrointestinal tract has been proposed to treat obesity, as well as to increase gastric motility and to treat symptoms of gastroparesis. For example, electrical stimulation of the gastrointestinal tract, and especially the stomach, is effective in suppressing symptoms of nausea and vomiting secondary to diabetic or idiopathic gastroparesis.

[0005] Typically, electrical stimulation involves the use of electrodes implanted in the wall of a target organ. The electrodes are electrically coupled to an implanted or external pulse generator via implanted or percutaneous leads. The pulse generator delivers a stimulation waveform via the leads and electrodes.

SUMMARY

[0006] In general, the invention is directed to techniques for monitoring electrical activity of a patient's heart by sensing cardiac signals via an implantable stimulator that delivers stimulation pulses to the patient's gastrointestinal tract. The implantable stimulator may analyze the cardiac signals and generate a cardiac therapy recommendation for the patient, or communicate the cardiac signals via telemetry circuitry to an external device for analysis. The sensed cardiac signals may be electrocardiogram (ECG) signals.

[0007] In some embodiments, the cardiac signals may be transmitted to a central network server, such as a server of a patient management system. The server may present, via a web browser, web pages containing information, analysis, or recommendations to the patient or a physician, family member, friend, or caregiver of the patient. When analysis of the cardiac signals indicates a serious cardiac problem such as ventricular fibrillation or fast ventricular tachycardia, the implantable stimulator may initiate an alert procedure. For example, the implantable stimulator may issue an emergency communication that is relayed by an external module to an emergency response system to request immediate emergency assistance. In some embodiments, the patient may receive an alert, for example, from an implanted device, a wristwatch, a cellular telephone, or other device, that may advise the patient to seek immediate medical attention.

[0008] The techniques may provide an opportunity for early diagnosis of underlying cardiac problems or disease in patients implanted with gastric stimulators. The sensing and analysis of the cardiac signals may also provide a clinician an opportunity to identify patients for whom an implantable cardiac device would be beneficial. Moreover, the sensing and analysis of the cardiac signals may allow a patient or doctor to be alerted to a serious or life-threatening cardiac event, which may allow the patient to obtain prompt medical attention.

[0009] In one embodiment, the disclosure provides a method comprising delivering electrical stimulation to a gastrointestinal tract of a patient via an implantable stimulator, and sensing cardiac signals via a plurality of electrodes coupled to the implantable stimulator.

[0010] In another embodiment, the disclosure provides an implantable device comprising a plurality of electrodes, a pulse generator that delivers electrical stimulation to a gastrointestinal tract of a patient via at least some of the electrodes, and a processor that senses cardiac signals via at least some of the electrodes.

[0011] In a further embodiment, a system comprises an implantable device that delivers electrical stimulation to a gastrointestinal tract of a patient with a pulse generator and senses cardiac signals via a plurality of electrodes, and an external module, wherein the implantable device transmits information based on the cardiac signals to the external module via a telemetry interface associated with the implantable device.

[0012] In yet another embodiment, an implantable device comprises means for delivering electrical stimulation to a gastrointestinal tract of a patient via an implantable stimulator, and means for sensing cardiac signals via a plurality of electrodes coupled to the implantable stimulator.

[0013] In another embodiment, a computer-readable medium comprises instructions that cause a programmable processor to deliver electrical stimulation to a gastrointestinal tract of a patient via an implantable stimulator, and sense cardiac signals via a plurality of electrodes coupled to the implantable stimulator.

[0014] The details of one or more embodiments of the invention are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the invention will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF DRAWINGS

[0015] FIGS. **1A-1C** are schematic diagrams illustrating implantable stimulation systems with various configurations of ECG sensors.

[0016] FIG. **2** is a block diagram illustrating an implantable stimulator in greater detail in accordance with an embodiment of the invention.

[0017] FIG. **3** is a block diagram illustrating an example system in which a patient receives stimulation therapy, and information based on sensed ECG signals is communicated to the patient, a physician, or a family member.

[0018] FIG. **4** is a flowchart illustrating an example mode of operation of a processor in analyzing sensed electrocardiogram (ECG) data.

[0019] FIG. **5** is a flowchart illustrating an example mode of operation of a processor in detecting cardiac problems.

[0020] FIG. **6** is a timing diagram illustrating delivery of stimulation and sensing periods for sensing ECG data.

[0021] FIGS. **7**A and **7**B are exemplary screen illustrations depicting example reports showing ECG and stimulation information as viewed on a user interface.

DETAILED DESCRIPTION

[0022] FIG. **1**A is a schematic diagram illustrating an implantable stimulation system **10**. System **10** is configured to provide gastric stimulation therapy, and is also configured to perform cardiac sensing and monitoring. As shown in FIG. **1**A, system **10** includes an implantable gastric stimulator **12**. Gastric stimulation therapy may be provided to treat obesity, gastroparesis, or other gastrointestinal disorders or diseases. The combination of gastric stimulation therapy and cardiac monitoring may be particularly valuable, because overweight or obese patients may also be at risk for developing cardiac problems. Hence, an implanted gastric stimulator provides a useful platform to monitor the patient for cardiac problems.

[0023] Cardiac signals are sensed by a plurality of electrodes attached to implantable stimulator **12**. The signals may be electrocardiogram (ECG) signals that detect electrical activity of the heart **15** of patient **16**. The sensed ECG signals are analyzed to determine whether the heart **15** or associated blood vessels of patient **16** are performing normally, or suffering from abnormalities, damage, or disease. Information obtained by analyzing the ECG signals of patient **16** may be used to provide alerts to patient **16** or a physician, or may be used to generate a cardiac therapy recommendation based on the analysis. For example, a clinician may recommend that patient **16** should be implanted with a cardiac device based on the analysis. In some embodiments, system **10** may be configured to control gastric stimulation parameters as a function of detected cardiac activity.

[0024] As further shown in FIG. **1**A, system **10** may include an implantable stimulator **12** and external module **14** shown in conjunction with patient **16**. Stimulator **12** includes a pulse generator **18** that generates electrical stimulation pulses. One or more leads **19**, **20** carry the electrical stimulation pulses to stomach **22**. Leads **19**, **20** each include one or more electrodes **24**, **26** for delivery of the electrical stimulation pulses to stomach **22**. Although the electrical stimulation pulses may be delivered to other areas within the gastrointestinal tract, such as the esophagus, duodenum, small intestine, or large intestine, delivery of stimulation pulses to stomach **22** will generally be described in this disclosure for purposes of illustration.

[0025] The stimulation pulses may be configured to treat obesity by inducing sensations of nausea or satiety to reduce appetite and discourage overeating by the patient, and/or by increasing gastric motility to reduce caloric absorption by the patient. Although described for exemplary purposes in terms of a stimulator for treating obesity, the techniques of the invention may be applied more generally in the context of gastrointestinal stimulation for treatment of a variety of conditions. For example, stimulation pulses may be applied to regulate gastrointestinal motility, to treat symptoms of gastroparesis, or for treatment of other conditions. For example, electrical stimulation of the gastrointestinal tract, and especially the stomach, may be effective in suppressing symptoms of nausea and vomiting secondary to diabetic or idiopathic gastroparesis.

[0026] System **10** also includes sensing electrodes **27**A, **27**B for sensing electrical activity of the heart **15** of patient **16**. In the exemplary embodiment of FIG. **1**, electrodes **27**A, **27**B are provided on the housing of implantable stimulator **12**. The spacing of electrodes **27**A and **27**B may be on the order of about one inch (2.5 cm) but can be larger or smaller depending on the exact size of the implantable stimulator **12**. Smaller devices and closer spacing may require greater amplification of the detected cardiac signals.

[0027] Implantable stimulator **12** receives cardiac signals sensed by electrodes **27**A, **27**B and stores information based on the cardiac signals in memory associated with the implantable stimulator. For example, implantable stimulator **12** may store an electrocardiogram (ECG) generated based on the sensed cardiac signals. In a typical implementation, the ECG represents a difference in potential between two or more electrodes placed upon or within the body of the patient. A processor within implantable stimulator **12** detects the ECG signals associated with the contraction of the heart **15** and amplifies the ECG signals so that the ECG signals can be analyzed and/or displayed for analysis.

[0028] Sensing of ECG signals may occur continuously, periodically, or intermittently, as therapy dictates. For example, sensing intervals may alternate with intervals of gastric stimulation. As another example, sensing intervals and gastric intervals may overlap or occur simultaneously. Information relating to the sensed data may be stored in memory within pulse generator **18** for retrieval and analysis at a later time. Alternatively, the sensed data may be immediately transmitted to external module **14** by wired or wireless telemetry, e.g., as raw sensed data or pre-processed data indicating ECG signals or particular cardiac events.

[0029] At the surface lining of stomach **22**, leads **19**, **20** penetrate into tissue such that electrodes **24** and **26** are positioned to deliver stimulation to the stomach. The stimulation pulses generated by stimulator **12** may cause the smooth muscle of stomach **22** to contract and slowly move contents from the entrance toward the exit of the stomach. Alternatively, or additionally, the electrical stimulation pulses may stimulate nerves within stomach **22** to cause muscle contraction and thereby restore or enhance gastrointestinal motility. Alternatively, as mentioned above, the stimulation pulses may be applied to induce nausea or satiety in response to monitored parameters. The induced sensation of nausea or satiety may reduce a patient's desire to consume large portions of food. Enhanced motility may serve to speed food through the gastrointestinal tract and reduce caloric absorption. Again, the stimulation pulses may be delivered elsewhere within the gastrointestinal tract, either as an alternative to stimulation of stomach **22** or in conjunction with stimulation of the stomach.

[0030] Implantable stimulator **12** may be constructed with a biocompatible housing, such as titanium, stainless steel, or a polymeric material, and is surgically implanted within

patient **16**. Although illustrated as being implanted near stomach **22** of patient **16**, implantable stimulator **12** may alternatively be implanted in other areas of patient **16**, such as the upper thorax, chest area, or buttocks. The implantation site may be a subcutaneous location in the side of the lower abdomen or the side of the lower back, or other appropriate site. Pulse generator **18** is housed within the biocompatible housing, and includes components suitable for generation of electrical stimulation pulses. Electrical leads **19** and **20** are flexible, electrically insulated from body tissues, and terminated with electrodes **24** and **26** at the distal ends of the respective leads. The leads may be surgically or percutaneously tunneled to stimulation sites on stomach **22**. The proximal ends of leads **19** and **20** are electrically coupled to pulse generator **18** via internal conductors to conduct the stimulation pulses to stomach **22** via electrodes **24**, **26**.

[**0031**] Leads **19**, **20** may be placed into the muscle layer or layers of stomach **22** via an open surgical procedure, or by laparoscopic surgery. Leads also may be placed in the mucosa or submucosa by endoscopic techniques, or by an open surgical procedure or laparoscopic surgery. Electrodes **24**, **26** may form a bipolar pair of electrodes. Alternatively, pulse generator **18** may carry a reference electrode to form an "active can" arrangement, in which one or both of electrodes **24**, **26** are unipolar electrodes referenced to an electrode on the pulse generator housing. A variety of polarities and electrode arrangements may be used.

[**0032**] The stimulation pulses delivered by implantable stimulator **12** are characterized by stimulation parameters such as a voltage or current amplitude, pulse width, and pulse rate. In addition, in some embodiments, the stimulation parameters may include electrode combination and polarity that specify different combinations of electrodes, if available, and polarities of the electrodes as anodes or cathodes. The stimulation parameters may be fixed, adjusted in response to sensed physiological conditions within or near stomach **22**, or adjusted in response to patient input entered via external module **14**. For example, in some embodiments, patient **16** may be permitted to adjust stimulation amplitude and turn stimulation on and off using external module **14**.

[**0033**] As an illustration, the stimulation pulses delivered by stimulator **12** may have a pulse amplitude in a range of approximately 1 to 10 volts, a pulse width in a range of approximately 50 microseconds to 10 milliseconds, and a pulse rate in a range of approximately 1 to 100 Hz. The pulse rate is more preferably in a range of approximately 2 to 40 Hz, and even more preferably in a range of approximately 5 to 20 Hz. The terms pulse rate and pulse frequency may be used interchangeably in this description. In some embodiments, an instant start to delivery of the stimulation pulses may be provided. However, a gradual ramp up in stimulation intensity may be applied to prevent muscle shock and patient discomfort. This ramp may be in the form of a gradually increasing pulse rate, amplitude, or pulse width.

[**0034**] Stimulator **12** also may include telemetry electronics to communicate with external module **14**. External module **14** may be a small, battery-powered, portable device that accompanies patient **16** throughout a daily routine. External module **14** may have a simple user interface, such as a button or keypad, and a display or lights. External module **14** may be a hand-held device configured to permit activation of stimulation and adjustment of stimulation parameters. Alternatively, external module **14** may form part of a larger device including a more complete set of programming features including complete parameter modifications, firmware upgrades, data recovery, or battery recharging in the event stimulator **12** includes a rechargeable battery. External module **14** may be a patient programmer, a physician programmer, or a patient monitor. In some embodiments, external module **14** may be a general purpose device such as a cellular telephone, a wristwatch, a personal digital assistant (PDA), or a pager.

[**0035**] In some example embodiments, implantable stimulator **12** may communicate the sensed ECG signals to external module **14**. The communication may occur wirelessly, or in the case of a percutaneous lead implantable stimulator **12** may have a wired connection. However, in most cases in which implantable stimulator **12** is fully implanted, communication between implantable stimulator **12** and external module **14** will occur wirelessly. Communication may occur continuously, periodically, or intermittently. External module **14** may analyze the ECG signals. Alternatively, external module **14** may transmit the received ECG signals to another device for analysis, such as a central server accessed by external module **14** via the Internet. In other embodiments, implantable stimulator **12** may include a processor that performs analysis of the ECG signals, and communicates information obtained based on the analysis to external module **14**. Accordingly, the computing resources for analysis of ECG signals may be provided within stimulator **12**, external module **14**, or elsewhere.

[**0036**] Analysis of the ECG signals may be performed to detect a variety of cardiac conditions, such as atrial fibrillation, ventricular fibrillation, atrial tachycardia, ventricular tachycardia, bradycardia, wide QRS complexes due to unsynchronized ventricular contractions, ectopic events, ischemic events, asystole, ST elevation, premature atrial contraction, bundle branch block, myocardial infarction, irregular heart rate, long QT syndrome, or other heart conditions detectable by analyzing ECG signals. In some embodiments, an activity sensor or minute ventilation sensor may also be included in conjunction with implantable stimulator. For example, an activity sensor (e.g., an accelerometer) or minute ventilation sensor may be disposed within the housing of implantable stimulator **12**, or attached to implantable stimulator via a lead. In one embodiment, sensing electrodes **27** may be used to simply sense heart rate. For example, data sensed by the activity sensor or minute ventilation sensor may be used with the heart rate or ECG signals to detect conditions such as chronotropic incompetence.

[**0037**] External module **14** may present feedback to patient **16** regarding ECG signals. Alternatively, such feedback may be presented by a central server, e.g., via a web page, to patient **16**, or a caregiver, family member, or health service provider of patient **16**. Stimulator **12** may provide an alert to patient **16** to indicate, for example, that a serious cardiac event has occurred or is occurring. Stimulator **12** may adjust stimulation therapy in response to the ECG signals. For example, stimulator may increase or decrease the level or duration of stimulation.

[**0038**] In some embodiments, system **10** may include multiple implantable stimulators **12** to stimulate a variety of regions of stomach **22**. Stimulation delivered by the multiple

stimulators may be coordinated in a synchronized manner, or performed without communication between stimulators. Also, the electrodes may be located in a variety of sites on the stomach, or elsewhere in the gastrointestinal tract, dependent on the particular therapy or the condition of patient **12**.

[**0039**] The electrodes carried at the distal end of each lead **19**, **20** may be attached to the wall of stomach **22** in a variety of ways. For example, the electrode may be surgically sutured onto the outer wall of stomach **22** or fixed by penetration of anchoring devices, such as hooks, barbs or helical structures, within the tissue of stomach **22**. Also, surgical adhesives may be used to attach the electrodes. In any event, each electrode is implanted in acceptable electrical contact with the smooth muscle cells within the wall of stomach **22**. In some cases, the electrodes may be placed on the serosal surface of stomach **22**, within the muscle wall of the stomach, or within the mucosal or submucosal region of the stomach.

[**0040**] FIG. **1**B is a schematic diagram illustrating implantable stimulation system **10** in which another exemplary arrangement of sensing electrodes is employed. As shown in FIG. **1**B, an electrode **28**A extends away from the implantable stimulator **12** via lead **29**. In the example of FIG. **1**B, lead **29** is a dedicated lead provided for cardiac sensing, and is provided in addition to gastric leads **19**, **20**. Another electrode **28**B is positioned on the housing of implantable stimulator **12**. Electrodes **28**A, **28**B are dedicated to sensing of ECG signals. The configuration of FIG. **1**B may achieve a greater inter-electrode spacing than other configurations. In some embodiments, electrode **28**A and lead **29** may be positioned intravenously. Alternatively, electrode **28**A may be formed as a subcutaneous patch and placed anywhere in the thorax of patient, but more preferably in the upper chest region near heart **15**.

[**0041**] FIG. **1**C is a schematic diagram illustrating an implantable stimulation system **10** in which yet another exemplary arrangement of sensing electrodes is employed. As shown in FIG. **1**C, one or both of leads **19**, **20** may carry a sense electrode **30**A, **30**B, in addition to stimulation electrodes **24**, **26**, to sense ECG signals. Sense electrodes **30**A, **30**B may be positioned at other areas on leads **19**, **20** than the areas shown.

[**0042**] The electrode configurations of the devices shown in FIGS. **1**A-**1**C are exemplary only, and other combinations and configurations of electrodes may be used. For example, one or more electrodes may be located on an edge of the housing of implantable stimulator **12**. The electrodes placed on the edge of implantable stimulator **12** may constitute insulated pins of feedthroughs extending through the housing. The housing of implantable stimulator **12** may include the "can" as well as a header on the can. As another example, a plurality of electrodes may be provided as an array of electrodes. As yet another example, sensing may be performed via stimulation electrodes **24**, **26**. In this case, electrodes **24**, **26** perform the dual role of stimulation and sensing, e.g., on an alternating basis. Although FIGS. **1**A-**1**C illustrate an implantable stimulator including two sense electrodes, more than two sense electrodes may be provided. In one embodiment, four or more electrodes may be coupled to the stimulator or adjacent to the stimulator, and a physician may select which of the electrodes will be activated for a given patient.

[**0043**] FIG. **2** is a block diagram illustrating various components of implantable stimulator **12** in greater detail in accordance with an embodiment of the invention. In FIG. **2**, implantable stimulator **12** includes ECG sensors **32**A and **32**B ("ECG sensors **32**"). ECG sensors **32**A and **32**B may be configured in any of the arrangements described above with respect to FIGS. **1**A-**1**C. In some embodiments, implantable stimulator **12** may include more than two ECG sensors. Signals detected by ECG sensors **32** may be representative of electrical activity of the heart **15** of patient **16**. ECG sensor circuitry **34** receives the sensed ECG signals, and supplies the ECG signals to a processor **36**. ECG sensor circuitry **34** may amplify and filter the ECG signals to condition the signals before supplying the signals to processor **36**.

[**0044**] Processor **36** processes the received ECG signals, and may analyze the ECG signals. The received ECG signal is typically converted to digital values prior to processing by processor **36**, and stored in memory **38**. For example, processor **36** may analyze the ECG signals to provide diagnostic information used to determine the onset of an arrhythmia or other cardiac conditions. Processor **36** may also determine a type of arrhythmia or other cardiac problem by analyzing the rate and morphology of the sensed cardiac signals. For example, processor **36** may analyze heart rate variability and features of the ECG signals such as the P wave, QRS complex, T wave, QT interval, PR interval, ST segment, or other features.

[**0045**] As examples, irregular or absent P waves may signify arrhythmia, while the shape of the P waves may be a sign of atrial problems. Very wide and deep Q waves may signify myocardial infarction. Abnormalities in the QRS complex may be a sign of bundle branch block, ventricular origin of tachycardia, ventricular hypertrophy or other ventricular abnormalities. T wave abnormalities may signify electrolyte disturbance, such as hyperkalemia and hypokalemia. Upward or downward displacement of the ST segment may indicate damage to the cardiac muscle or strain on the ventricles. The ST segment can be depressed or elevated depending on the ECG vector in myocardial infarction or ischemia.

[**0046**] ECG signal characteristics indicative of cardiac problems are well known to those skilled in the art of cardiology. Accordingly, the possible ECG signal characteristics described above are for purposes of illustration and should not be considered limiting of the invention as broadly embodied and described herein. Rather, the invention may be applied to obtain and analyze any of a variety of ECG signal characteristics obtained by an implantable gastrointestinal stimulator to identify cardiac problems that may indicate the need for immediate cardiac care or referral for possible cardiac therapy.

[**0047**] Memory **38** may include any form of volatile memory, non-volatile memory, or both. In addition to data sensed via ECG sensors **32**, memory **38** may store records concerning measurements of sensed ECG signals, communications to patient **16**, or other information pertaining to operation of implantable stimulator **12**. Memory **38** may also store information about patient **16** and stimulation therapy parameters. In addition, processor **36** is typically programmable, and programmed instructions reside in memory **38**.

[0048] Wireless telemetry in stimulator **12** may be accomplished by radio frequency (RF) communication or proximal inductive interaction of implantable stimulator **12** with external module **14** via telemetry interface **40**. Processor **36** controls telemetry interface **40** to exchange information with external module **14**. Processor **36** may transmit operational information and sensed information to external module **14** via telemetry interface **40**. For example, processor **36** may transmit sensed ECG signals, or other information relating to analysis of ECG signals. Also, in some embodiments, pulse generator **18** may communicate with other implanted devices, such as stimulators or sensors, via telemetry interface **40**.

[0049] Power source **42** delivers operating power to the components of implantable stimulator **12**. Power source **42** may include a battery and a power generation circuit to produce the operating power. In some embodiments, the battery may be rechargeable to allow extended operation. Recharging may be accomplished through proximal inductive interaction between an external charger and an inductive charging coil within implantable stimulator **12**. In other embodiments, an external inductive power supply may transcutaneously power implantable stimulator **12** whenever stimulation therapy is to occur.

[0050] Implantable stimulator **12** is coupled to electrodes **24**, **26** by leads **19**, **20**, respectively. Implantable stimulator **12** provides stimulation therapy to the gastrointestinal tract of patient **16**. Pulse generator **18** includes suitable pulse generation circuitry for generating a voltage or current waveform with a selected amplitude, pulse width, and frequency. In some embodiments, processor **36** may determine whether to direct application of electrical stimulation to patient **16** and/or adjust stimulation parameters based upon sensed ECG data. Alternatively, or additionally, processor **36** may be responsive to instructions from external module **14** to direct application of electrical stimulation and/or adjust stimulation parameters. Processor **36** may include at least one programmable timing counter (not shown) that is used to measure timing intervals. For example, the timing counter may measure timing intervals of sensing intervals or stimulation intervals.

[0051] Processor **36** may also record the occurrence of electrical stimulation within memory **38** for use in determining whether additional electrical stimulation is desired to increase an amount of negative biofeedback provided to the patient **16**. For example, processor **36** stores an occurrence of electrical stimulation in memory **38**. The next time processor **36** determines electrical stimulation is needed, processor **36** may search memory **38** to determine when the prior electrical stimulation occurred in order to estimate whether electrical stimulation for an extended period of time may be useful.

[0052] If a patient **16** consumes food on more occasions or for longer durations than may be specified in a particular treatment plan for obesity, electrical stimulation for extended periods of time beyond a baseline time period may be useful to encourage patients to reduce the duration or number of occasions in which food is consumed. Similarly, a record of the prior occurrence of electrical stimulation may be used to ensure that a minimum amount of time passes between the detection of gastric activity. When gastric activity is detected before the minimum amount of time has passed, electrical stimulation may also be provided for an extended period of time to discourage patient **16** from eating food as often.

[0053] In embodiments where processor **36** analyzes ECG signals, processor **36** may communicate results of the analysis to patient **16** in a number of ways. Implantable stimulator **16** may wirelessly transmit information to external module **14** using telemetry interface **40**. External module **14** may notify patient **16** when the ECG signals indicate a cardiac problem. External module **14** may notify patient **16** in the form of a visible or audible notification, e.g., emitted by a light, LED, display, or audio speaker. A visible notification may be presented as text, graphics, one or more blinking lights, illumination of one or more lights, or the like. An audible notification may take the form of an audible beep, ring, speech message, or the like. In addition to transmitting a communication to an external module **14**, telemetry interface **40** may be configured to wirelessly transmit information about the history or status of implantable stimulator **12** to a physician for patient **16**.

[0054] In addition, or in the alternative, implantable stimulator **12** may include an alert module **50** that is implanted in the body of patient **16**. When activated by processor **36**, alert module **50** can notify patient **16** directly without use of external module **14**. Alert module **50** may, for example, notify patient **16** audibly or by vibration. For example, alert module **50** may take the form of a piezoelectric transducer that is energized in response to a signal from processor **36** in order to emit a sound or vibration. Alternatively, alert module **50** may apply electrical stimulation to the patient **16** at a level or in a pattern that is noticeable. In each case, patient **16** may receive a communication that implantable stimulator **12** has detected a serious cardiac event or condition. The communication may mean that patient **16** must seek immediate medical attention.

[0055] FIG. **3** is a block diagram illustrating an example system **60** in which patient **16** receives stimulation therapy, and information based on sensed ECG signals is communicated to patient **16**, a call center, a physician, or a family member. As shown in FIG. **3**, implantable stimulator **12** communicates wirelessly with external module **14** via radio frequency (RF) telemetry, but the communication may also be transmitted via a wired connection, an optical connection, or a transcutaneous communication link. External module **14** may be a patient programmer, i.e., a device dedicated to receiving user input pertaining to electric stimulation and transmitting corresponding commands to implantable stimulator **12**. Implantable stimulator **12** may be interrogated by, or may voluntarily transmit information to, external module **14**. As discussed above, the information obtained from implantable stimulator **12** may be preprocessed by implantable stimulator **12**, processed by external module **14**, or both.

[0056] As shown, external module **14** may communicate with general purpose devices **64**A, **64**B. In the illustrated example, external module **14** communicates with general purpose devices including a wristwatch **64**A and a cellular telephone **64**B. In other examples, external module **14** may communicate with a pager, personal digital assistant (PDA), or other general purpose device (not shown), which may be carried by patient **16**. General purpose devices **64** may display text or graphical indications to patient **16**. In some

embodiments, external module **14** may itself be a general purpose device such as a pager, cellular telephone, or PDA.

[**0057**] External module **14** may transfer information to a docking station (not shown) upon being placed in the docking station. In other embodiments, external module **14** may wirelessly transfer data to wireless access point (WAP) **62**. Alternatively, implantable stimulator **12** may communicate directly with WAP **62**. WAP **62** may communicate information to cellular telephone **64**B. In some embodiments, WAP **62** may transfer information to a server **66** via wide area network (WAN) **68**. Server **66** may be a central server of a patient management system, and WAN **68** may be the Internet.

[**0058**] Server **66** may present web pages containing information via web browsers **70**A-**70**N ("web browsers **70**") to users such as patient **16**, or a doctor, family member, friend, or caregiver of patient **16**. Server **66** may also present information via an instant message (IM) program **72** to patient **16** or other user. Patient **16** may view the information presented by web browser **70**A and IM program **72** on a home computer. For example, server **66** may cause patient **16** to receive an alert via wristwatch **64**A, cellular telephone **64**B, or IM program **72** that instructs patient **16** to seek medical attention when patient **16** has an ECG that indicates a serious cardiac condition.

[**0059**] In some embodiments, some or all of the analysis operations discussed above with respect to processor **36** of FIG. **2** may be performed externally to implantable stimulator **12**, such as within external module **14** or within server **66**. For example, processor **36** of implantable stimulator **12** may collect ECG data and communicate the collected ECG data to external module **14** via telemetry interface **40**. External module **14** may process and analyze the data, or may send the data to server **66** for processing and analysis.

[**0060**] In another embodiment, processor **36** may provide some processing of the data, and external module **14** or server **66** may provide additional processing and analysis. For example, processor **36** may determine information relating to an ECG signal, such as characteristics of the P wave, QRS complex, T wave, QT interval, PR interval, ST segment, and provide this information to external module **14**. External module **14** or server **66** may then make a diagnosis or recommendation based on the information. Alternatively, external module or server **66** may present the information to a clinician, who makes a diagnosis or recommendation based on the information. For example, the clinician may recommend that patient **16** be implanted with a cardiac device based on the information.

[**0061**] Certain information obtained based on the ECG signals may be presented to patient **16** and/or other users (e.g., a doctor, family member, or caregiver of patient **16**) by any of external module **14**, devices **64**, web browsers **70** or IM program **72**. The information may relate to the analysis of ECG signals, such as whether the patient's heart **15** is functioning normally. Information may be presented via visible or audible output media provided by external module **14**, such as lights, LEDs, a display or an audio speaker. An audio message may take the form of an audible beep, ring, speech message or the like. The patient **16**, physician, family members, or other caregivers may use the information to take action, such as seeking medical attention for patient **16**, or determining that patient **16** is a candidate for an implanted cardiac device or other cardiac therapy.

[**0062**] FIG. **4** is a flowchart illustrating an example mode of operation of processor **36** in analyzing sensed electrocardiogram (ECG) data. Processor **36** causes pulse generator **18** to apply electrical stimulation to stomach **22** via electrodes **24** and **26** (FIG. **1**A) (**72**). If processor **36** determines that processor **36** is within a sensing interval (for example, based on a programmable timing counter that measures timing intervals) (YES branch of **74**), processor **36** receives ECG signals sensed by sensors **32** (FIG. **2**) (**76**). If processor **36** is not within a sensing interval (NO branch of **74**), processor **36** will continue to apply gastric stimulation. In some embodiments, implantable stimulator **12** may stop applying gastric stimulation during sensing intervals. In other embodiments, sensing may occur continuously at all times or for extended periods at selected times of day.

[**0063**] Processor **36** may analyze the sensed ECG signals (**78**), or as described above, processor **36** may communicate the ECG signals to external module **14** for analysis. If processor **36** detects a cardiac abnormality (**80**), such as an arrhythmia or other condition, processor **36** may make a recommendation based on the comparison (**82**). In a situation where processor **36** detects a cardiac abnormality (that is not immediately life threatening), processor **36** may communicate to a clinician via external module **14** and server **66** a recommendation that patient **16** be implanted with an implantable cardiac device or undergo other clinical procedures such as atrial ablation or stenting. Therapy controller **58** may also cause a list of suggested actions to be displayed to patient **16**, such as to lower cholesterol, eat more healthfully, or exercise more. Alternatively or additionally, therapy controller **58** may modify stimulation therapy parameters in response to the analysis. Processor **36** may perform some or all of the above steps hourly, daily, on demand, or at other time interval as configured by a user.

[**0064**] FIG. **5** is a flowchart illustrating another example mode of operation of a processor in detecting cardiac problems. Processor **36** analyses the sensed ECG signals (**84**). If processor **36** detects a serious cardiac problem based on the analysis (e.g., ventricular fibrillation or fast ventricular tachycardia) (**86**), processor **36** may completely suspend stimulation therapy by implantable stimulator **12** until further notice (**88**). For example, where implantable stimulator **12** alternates stimulation intervals with sensing intervals, if processor **36** detects a serious cardiac problem during a sensing interval, even when the sensing interval ends and the next stimulation interval begins, processor **36** may suspend stimulation therapy, and in some cases, may continue sensing beyond the proscribed sensing interval.

[**0065**] Processor **36** may be configured with particular parameters that, if detected, constitute a serious problem, which may trigger the steps shown in FIG. **5**. For example, processor **36** may follow the steps when patient **16** is experiencing ventricular fibrillation or fast ventricular tachycardia. In response to the detection of a serious cardiac problem, processor **36** may also initiate an alert procedure (**90**). For example, processor **36** may issue a communication to an emergency response system via external module **14**. The communication may request an immediate emergency response by a paramedic or other emergency responder. In some embodiments, implantable stimulator **12** may include or communicate with a global positioning system (GPS) unit that allows processor **36** to report the location of patient **16** to the emergency response system. Processor **36** may also

issue an emergency communication that is relayed by external module **14** to a doctor via server **66**.

[**0066**] As another example, processor **36** may also activate alert module **50** to issue an alert to patient **16**. Alert module **50** may, for example, notify patient **16** audibly or by vibration. Alternatively, alert module **50** may apply electrical stimulation to the patient **16** at a level or in a pattern that is noticeable. In each case, patient **16** may receive a communication that implantable stimulator **12** has detected a serious cardiac event or condition. The communication may mean that patient **16** must seek immediate medical attention. Processor **36** may perform some or all of the above steps hourly, daily, on demand, or at other time interval as configured by a user.

[**0067**] FIG. **6** is a timing diagram illustrating one example embodiment in which gastric stimulation periods alternate with sensing periods for sensing ECG data. As shown in FIG. **6**, the stimulation pulses delivered by implantable stimulator **12** to stomach **22** are delivered as a series of pulse bursts. Each burst is characterized by a pulse rate for pulses delivered within the burst, a burst rate, and a burst length. For example, the stimulation pulses delivered by stimulator **12** may have a pulse amplitude in a range of approximately 1 to 10 volts, a pulse width in a range of approximately 50 microseconds to 10 milliseconds, and a pulse rate in a range of approximately 1 to 100 Hz. The pulse rate is more preferably in a range of approximately 2 to 40 Hz, and even more preferably in a range of approximately 5 to 20 Hz.

[**0068**] In the example of FIG. **6**, each burst contains pulses delivered at a rate of approximately 40 Hz. The burst rate may be in a range of approximately 3 to 15 bursts per minute, which is approximately 1 to 5 times the typical gastric slow wave frequency in a healthy patient. The burst length may be in a range of approximately 10 to 50 percent of the burst period, i.e., the period between successive bursts. In the example of FIG. **6**, the bursts delivered to stomach **22** are synchronized to alternate with sensing intervals. In particular, there is a time delay δ between the delivery of each burst of gastric stimulation and the start of a sensing period or interval. The term "sensing period" may refer to extended periods of time in which sensing occurs continuously. In some embodiments, sensing periods may overlap with stimulation periods. In other embodiments, sensing may occur continuously at all times. In these embodiments, processor **36** may filter out stimulation pulses from the sensed data.

[**0069**] FIG. **7**A is an exemplary screen illustration depicting an example report **96** displaying ECG information as viewed on a user interface. For example, report **96** may be viewed by a clinician of patient **16** on web browser **70**A of FIG. **3** or on a display associated with external module **14**. In particular, report **96** shows an ECG signal recorded by implantable stimulator **12**. The clinician may analyze the ECG signal to determine whether patient **16** shows any signs of cardiac problems, abnormalities, or disease. The clinician may also analyze trend reports showing ECG information over longer time periods. The clinician may make recommendations to patient **16** based on the analysis of the ECG information. For example, the clinician may determine based on the ECG information that patient **16** is an appropriate candidate for an implantable cardiac device. In some embodiments, report **96** may be viewed by patient **16**, or a family member or caregiver of patient **16**.

[**0070**] FIG. **7**B is an exemplary screen illustration depicting an example report **98** displaying ECG information and stimulation information as viewed on a user interface. As in FIG. **7**A, report **98** may be viewed by a clinician, patient **16**, or a family member or caregiver of patient **16**, on web browser **70**A or a display of external module **14**. Report **98** allows a user to see the ECG information in the context of gastrointestinal stimulation therapy that is applied. Report **98** may aid the user in understanding any effects of stimulation therapy on the operation of the heart. Such information may be displayed in an embodiment in which both sensing intervals and stimulation intervals occur in an overlapping or simultaneous manner, as opposed to occurring in alternating intervals.

[**0071**] Various embodiments of the invention have been described. These and other embodiments are within the scope of the following claims.

1. A method comprising:

delivering electrical stimulation to a gastrointestinal tract of a patient via an implantable stimulator; and

sensing cardiac signals via a plurality of electrodes coupled to the implantable stimulator.

2. The method of claim 1, further comprising storing information based on the cardiac signals in a memory associated with the implantable stimulator.

3. The method of claim 1, further comprising transmitting information based on the cardiac signals from the implantable stimulator to an external module via a telemetry interface associated with the implantable stimulator.

4. The method of claim 3, further comprising displaying the information based on the cardiac signals via the external module.

5. The method of claim 1, further comprising:

analyzing information based on the cardiac signals; and

generating a cardiac therapy recommendation based on the analysis.

6. The method of claim 5, wherein generating a cardiac therapy recommendation comprises recommending that the patient be implanted with a cardiac device.

7. The method of claim 5, wherein generating a cardiac therapy recommendation comprises activating an implanted alert module.

8. The method of claim 7, wherein activating an implanted alert module comprises alerting the patient using one of an audio transducer, vibration in the implantable device, or stimulation by the implanted device of patient tissue.

9. The method of claim 5, wherein analyzing information comprises detecting based on the cardiac signals one of atrial fibrillation, ventricular fibrillation, atrial tachycardia, ventricular tachycardia, bradycardia, wide QRS complexes due to unsynchronized ventricular contractions, ectopic events, ischemic events, asystole, ST elevation, premature atrial contraction, bundle branch block, irregular heart rate, long QT syndrome, chronotropic incompetence, and myocardial infarction.

10. The method of claim 9, further comprising initiating an alert procedure upon detecting one of ventricular fibrillation and fast ventricular tachycardia based on the cardiac signals.

11. The method of claim 10, wherein initiating an alert procedure comprises issuing a communication to an emergency response system.

12. The method of claim 1, wherein sensing cardiac signals comprises sensing the cardiac signals via a plurality of electrodes, wherein at least one electrode extends away from the implantable stimulator via a lead.

13. The method of claim 1, wherein sensing cardiac signals comprises sensing the cardiac signals via a plurality of electrodes, wherein at least one electrode is disposed on a housing of the implantable stimulator.

14. The method of claim 1, further comprising alternating delivery of electrical stimulation to the gastrointestinal tract with sensing intervals of sensing the cardiac signals.

15. An implantable device comprising:

a plurality of electrodes;

a pulse generator that delivers electrical stimulation to a gastrointestinal tract of a patient via at least some of the electrodes; and

a processor that senses cardiac signals via at least some of the electrodes.

16. The device of claim 15, further comprising a memory that stores information based on the cardiac signals.

17. The device of claim 15, further comprising a telemetry interface that transmits information based on the cardiac signals to an external module.

18. The device of claim 15, wherein the processor analyzes information based on the cardiac signals and generates a cardiac therapy recommendation based on the analysis.

19. The device of claim 18, wherein the processor activates an implanted alert module based on the analysis.

20. The device of claim 15, wherein the sensed cardiac signals are electrocardiogram (ECG) signals.

21. The device of claim 15, wherein the plurality of electrodes comprises at least one electrode that extends away from the implantable device via a lead.

22. The device of claim 15, wherein the plurality of electrodes comprises at least one electrode that is disposed on a housing of the implantable stimulator.

23. A system comprising:

an implantable device that delivers electrical stimulation to a gastrointestinal tract of a patient with a pulse generator and senses cardiac signals via a plurality of electrodes; and

an external module, wherein the implantable device transmits information based on the cardiac signals to the external module via a telemetry interface associated with the implantable device.

24. The system of claim 23, further comprising a network server, wherein the external module transmits information based on the cardiac signals to the server and the server transmits the information to one or more network clients for viewing via a web browser, and wherein the web browser displays the information on a web page.

25. The system of claim 24, wherein the information based on the cardiac signals is displayed via one of the external module and the web page.

26. The system of claim 24, wherein the server analyzes information based on the cardiac signals and generates a cardiac therapy recommendation based on the analysis.

27. The system of claim 23, wherein the external module analyzes information based on the cardiac signals and generates a cardiac therapy recommendation based on the analysis.

28. The system of claim 23, wherein the external module is one of a patient monitor, a patient programmer, a physician programmer, a cellular telephone, a wristwatch, a personal digital assistant (PDA), and a pager.

29. An implantable device comprising:

means for delivering electrical stimulation to a gastrointestinal tract of a patient via an implantable stimulator; and

means for sensing cardiac signals via a plurality of electrodes coupled to the implantable stimulator.

30. A computer-readable medium comprising instructions that cause a programmable processor to:

deliver electrical stimulation to a gastrointestinal tract of a patient via an implantable stimulator; and

sense cardiac signals via a plurality of electrodes coupled to the implantable stimulator.

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