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(54) **SYSTEMS FOR TREATING GASTROESOPHAGEAL REFLUX DISEASE**

SYSTEM ZUR BEHANDLUNG DER MAGEN-/SPEISERÖHREN-REFLUXKRANKHEIT

SYSTÈMES DE TRAITEMENT D'UN REFLUX GASTRO SOPHAGIEN PATHOLOGIQUE

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Description

FIELD

[0001] This invention relates generally to an apparatus for electrical stimulation of the biological systems. More particularly, this invention relates to systems for treating gastroesophageal reflux disease (GERD) comprising an electrical stimulation device adapted to be implanted by laparoscopic or endoscopic techniques, and comprising an external computing device enabling a patient to interface with the implanted stimulation device.

BACKGROUND

[0002] Gastro-esophageal reflux disease (GERD) is a common problem and is expensive to manage in both primary and secondary care settings. This condition results from exposure of esophageal mucosa to gastric acid and bile as the gastro-duodenal content refluxes from the stomach into the esophagus. The acid and bile damages the esophageal mucosa resulting in heartburn, ulcers, bleeding, and scarring, and long term complications such as Barrett's esophagus (pre-cancerous esophageal lining) and adeno-cancer of the esophagus.

[0003] Lifestyle advice and antacid therapy are advocated as first line treatment for the disease. However, since most patients with moderate to severe cases of GERD do not respond adequately to these first-line measures and need further treatment, other alternatives including pharmacological, endoscopic, and surgical treatments are employed.

[0004] The most commonly employed pharmacological treatment is daily use of H2 receptor antagonists (H2RAs) or proton-pump inhibitors (PPIs) for acid suppression. Since gastro-esophageal reflux disease usually relapses once drug therapy is discontinued, most patients with the disease, therefore, need long-term drug therapy. However, daily use of PPIs or H2RAs is not universally effective in the relief of GERD symptoms or as maintenance therapy. Additionally, not all patients are comfortable with the concept of having to take daily or intermittent medication for the rest of their lives and many are interested in nonpharmacological options for managing their reflux disease.

[0005] Several endoscopic procedures for the treatment of GERD have been tried. These procedures can be divided into three approaches: endoscopic suturing wherein stitches are inserted in the gastric cardia to plicate and strengthen the lower esophageal sphincter, endoscopic application of energy to the lower esophagus, and injection of bulking agents into the muscle layer of the distal esophagus. These procedures, however, are not without their risks, besides being technically demanding and involving a long procedure time. As a result, these procedures have largely been discontinued.

[0006] Open surgical or laparoscopic fundoplication is also used to correct the cause of the disease. However, surgical procedures are associated with significant morbidity and small but not insignificant mortality rates. Moreover, long-term follow-up with patients treated by surgery suggests that many patients continue to need acid suppressive medication. There is also no convincing evidence that fundoplication reduces the risk of esophageal adenocarcinoma in the long term.

[0007] While electrical stimulation has been suggested for use in the treatment of GERD, an effective electrical stimulation system has yet to be demonstrated. In particular, the prior art teaches that effective electrical stimulation requires active, real-time sensing for a patient's swallow and, based on a sensed swallow, to immediately cease stimulation. For example, certain prior art approaches require the constant sensing of certain physiological changes in the esophagus, such as changes in esophageal pH, to detect acid reflux and/or esophageal motility and, based on such sensed changes, initiating or terminating an electrical stimulation to instantaneously close or open the LES, respectively, thereby avoiding an acid reflux episode. Other prior art approaches require continuous stimulation with sensing for swallow and stopping stimulation to allow for normal swallow to happen. This creates a complex device and has not proven to be feasible or effective in practice.

[0008] Therefore, there is still a need for a safe and effective method of treatment that can help alleviate symptoms of GERD in the long term, without adversely affecting the quality of life of the patients. In particular, there is a need for simple, efficient GERD device and treatment methods that does not inhibit a patient from swallowing and do not rely on an instantaneous response from the patient's LES to avoid episodes of acid reflux. There is a need for treatment protocols and devices which are programmed to implement such protocols, which can be easily programmed and do not require complex physiologic sensing mechanisms in order to operate effectively and safely. In addition, there is still a need for minimally invasive and effective treatment for obesity. Moreover, there is not only a need for better devices in stimulation based therapies, but there is also a need for a safe and minimally invasive method and system that enables easy and expeditious deployment of such devices at any desired location in the body.

[0009] It is further desirable to have a system for the treatment of GERD which includes a stimulator and an optional sensor adapted to be placed in a patient's LES tissue.

[0010] It is further desirable to have a system for the treatment of GERD which includes an active implantable medical device (AIMD) and temporary sensor adapted to be placed in a patient's GI lumen where the sensors are designed to naturally dissolve or pass out through the lumen and the AIMD is adapted to dynamically acquire, process, measure the quality of, and use sensed data only when the sensor is present.

[0011] It is further desirable to have a system for the temporary treatment of GERD which includes an AIMD,

which is adapted to be placed in a patient's GI lumen, designed to naturally dissolve or pass out through the lumen, and is adapted to deliver electrical stimulation to tissue at or in the vicinity of the LES. Such temporary stimulation scheme can additionally be used for prescreening of patients likely to benefit from permanent stimulation.

[0012] It would further be desirable for the stimulator to use periodic or occasional sensing data to improve the treatment of GERD by dynamically detecting when a sensor is present, determining when a sensor is transmitting, or capable of transmitting, data, and processing the sensed data using an application having a special mode which opportunistically uses the sensed data to change stimulation parameters.

[0013] It is also desirable to automate the setting or calibration of some or all device parameters in order to reduce the need for medical follow-up visits, reduce burdens on healthcare providers and patients, decrease the rate of programming mistakes, and improve outcomes, thereby improving the treatment of GERD.

SUMMARY

[0014] The invention is defined by claim 1. Preferred embodiments are defined by the dependent claims. Further embodiments disclosed herein are for exemplary purpose only.

DESCRIPTION OF THE DRAWINGS

[0015]

Figure 1 is a first exemplary esophageal pH trace of a patient receiving non-specific LES electrical stimulation;

Figure 2 is a second exemplary esophageal pH trace of the same patient receiving LES electrical stimulation therapy following the implantation of a patient specific optimization;

Figure 3 is a flowchart detailing one process for optimizing the operational parameters of a patient device; and,

Figure 4 is a flowchart detailing another process for optimizing the operational parameters of a patient device.

DETAILED DESCRIPTION

[0016] The present specification describes methods and systems for treating gastroesophageal reflux disease (GERD) by implanting an electrical stimulation device using laparoscopic or endoscopic techniques, capturing an eating event and detecting eating, using an implantable electrical stimulation device, enabling a patient to interface with an implanted stimulation device, and applying treatment processes.

[0017] It should be appreciated that the systems and methods described herein can be used with a plurality of different devices, including those electrical stimulation devices disclosed in U.S. Patent No. 7,702,395, U.S. Patent Application Numbers 10/557,362 and 12/598,871, United States Patent Number 6,901,295, PCT Application No. PCT/US08/56479, United States Patent Application Numbers 12/030,222, 11/539,645, 12/359,317, and 13/041,063, and PCT Application Numbers PCT/US09/55594 and PCT/US10/35753.

Devices Adapted to Be Implanted Using Laparoscopic Surgical Techniques

[0018] In one embodiment, surgical or endoscopic techniques are used to implant an electrical stimulation device to treat GERD in a manner that is less invasive than those currently employed.

[0019] In one embodiment, an electrical stimulation device, or portions thereof, is adapted to be placed within or proximate the lower esophageal sphincter using laparoscopic surgical techniques and programmed to treat GERD, diurnal GERD, nocturnal GERD, and/or transient lower esophageal sphincter relaxation (tLESR). The outer surface of the device has electrodes attached thereto which comprise conductors at least 1 mm in length. The device may be a conventional pulse generator, a miniature pulse generator, or a microstimulator.

[0020] In one embodiment, the electrodes are adapted to be placed in the right anterior quadrant of the LES. In one embodiment, the electrodes are adapted to be placed the furthest possible distance from cardiac tissue while still being positioned to stimulate the LES. In one embodiment, the electrodes are positioned at least 1 mm and, more preferably, at least 5 mm from the patient's cardiac tissue. In another embodiment, the electrodes are positioned at a distance at least 1/4, and more preferably, greater than 1/2 the shortest distance between two electrodes, from the patient's cardiac tissue. In another embodiment, the electrodes are positioned such that the electric field is less than 75% of the maximum electric field between two electrodes.

[0021] In one embodiment, the device has a plurality of structures or members which serve to anchor the device in the patient's tissue whereby the structures or members are configured to enable anchoring using sutures or nitinol suturing techniques.

[0022] In one embodiment, the device has a plurality of fixation points, structures, or members which serve to fix the device in the patient's tissue, preferably using clips.

[0023] In one embodiment, the device has at least one protrusion or needle for forming a pathway through a patient's tissue, where the pathway serves to enable electrode implantation into the muscularis of the patient's LES. In various embodiments, the protrusion or needle measures from 10 - 25 mm in length.

[0024] In one embodiment, the device comprises at least one electrode of sufficient length that allows the electrode to be placed entirely within the LES, without

extending beyond the LES.

[0025] In one embodiment, the device is at least 1 cm long and no more than 10 cm long to minimize fibrosis within the peritoneal cavity.

[0026] In one embodiment, the device has a form factor, and is contained entirely within a housing, that can be inserted into a conventional laparoscopic trocar. The device has dimensions greater than 6 mm, but less than 25 mm, in diameter. In another embodiment, the device is physically configured and/or adapted to be delivered and anchored through a single port laparoscopic procedure. In another embodiment, the device is physically configured and/or adapted to be delivered and anchored using an articulated trocar in a laparoscopic procedure. In another embodiment, the device is physically configured and/or adapted to be delivered and anchored into the peritoneal cavity through an incision that is created and/or sized for a laparoscopic port.

[0027] In one embodiment, the device has a local energy source, such as a battery, that has one or more of the following characteristics: the energy source is rechargeable; has a recharge frequency of once per day for 6 hours, once per week for approximately 60 minutes, once per month, or once per year, comprises lithium ion battery technology, comprises solid state battery technology, comprises lithium polymer battery technology, comprises super capacitor technology; is not rechargeable, is not rechargeable and/or has an implant life of at least one year.

[0028] In one embodiment, the device comprises an energy receiving unit that is adapted to be anchored into the abdominal wall in order to maximize coupling between an energy transmitting unit and an energy receiving unit.

[0029] In one embodiment, the device has electrodes which are permanently attached by insulated conductors. In another embodiment, the electrodes attached to insulated conductors are detachable from the device.

[0030] In one embodiment, the device is adapted to be attached to the abdominal wall, on either the subcutaneous side or the peritoneal side, and/or adapted to be attached to the submucosa or outer surface or serosa of the stomach wall.

[0031] In one embodiment, the device is physically configured or adapted to be placed entirely within the submucosa adjacent to the LES.

[0032] In one embodiment, the device is adapted to be implanted within a patient such that the device is oriented between 45 degrees and 135 degrees within a standing patient in relation to a ground surface, which is at 0 degrees.

[0033] In one embodiment, the device comprises a plurality of electrodes which are adapted to be implanted such that they face the same LES muscularis.

Eating Detection Systems

[0034] In one embodiment, the present system is used to detect an eating event based upon an implanted transmitter and an implanted receiver, which are separated by a distance in a range of 0.5cm to 20cm, or preferably 1-2cm. In one embodiment, the system comprises an implantable transmitter and receiver pair which are used to determine if a patient has ingested a quantity of liquid, solids, or both.

[0035] In one embodiment, the transmitter is adapted to be placed in or on the abdominal wall. In one embodiment, the transmitter is adapted to be placed on the outer anterior stomach wall, to be placed on the serosal surface of the stomach, to cross the LES, to cross the esophagus, or cross the cardia sphincter.

[0036] In one embodiment, the receiver is adapted to be placed in or on the abdominal wall. In one embodiment, the receiver is adapted to be placed on the outer anterior stomach wall.

[0037] In one embodiment, the transmitter and receiver are placed such that the distance between the transmitter and receiver is only modulated, changed, or otherwise affected by ingested liquid, food, or both. A controller monitors the distance between the transmitter and receiver. As the distance changes, the controller determines whether the distance change is indicative of whether a patient has ingested liquid, food, or both. In one embodiment, the distance between the transmitter and receiver is continuously measured to determine if liquid, food, or both is continuously being ingested. In one embodiment, the distance between the transmitter and receiver is continuously measured to differentiate if liquid, food, or both has been ingested.

[0038] The distance between the transmitter and receiver pair may be measured using ultrasonic sensors, electric field sensors, magnetic field sensors, electromagnetic field sensors, and/or optical sensors.

Patient Interfacing Systems

[0039] In one embodiment, the system is adapted to be used to treat GERD using treatment algorithms and systems for collecting patient data, which are used to optimize treatment efficacy.

[0040] In one embodiment, the specification provides apparatuses and methods for collecting diet or lifestyle data from patients that are related to and are used to evaluate reflux events and/or GERD symptoms. Such data can be, for example, meal times, the type of food ingested, the type of liquid ingested, exercise regimens, sleep routines, as well as data related to time and severity of reflux symptoms.

[0041] The specification describes an apparatus used for said lifestyle data collection as well as storage and communication of said data. In one embodiment, the apparatus takes the form of a stand-alone device specially designed for this purpose. In another embodiment, the apparatus is an embedded component of a system used for health related purposes within the patient, such as a charger for an implantable device that includes lifestyle

data collection and communication capabilities. In another embodiment, the apparatus includes software running on general purpose systems such as computers, smartphones, or other mobile devices. The device can be battery operated, portable, and handheld or have a desktop form factor using mains power. In another embodiment, such data is collected using paper diary and input into the external device by a health care professional and inputted into the device using wireless communication.

[0042] In one embodiment, the device performs multiple functions to enable the treatment of patients. For example, the device is adapted to be used for wireless charging of an implantable pulse generator (IPG) battery used as an energy source for an electrical stimulator for the LES. In another embodiment, the device can be integrated into a physician controlled computing device which is used in a clinic to wirelessly program the device parameters and which may also be used to collect patient input. Another example is that of a diagnostic pH monitoring device adapted to receive patient lifestyle data. Various combinations of the devices mentioned can be implemented and be interconnected using wireless or wired communication so that patient data is available when decisions are taken on parameter setting of the stimulation device.

[0043] In another embodiment, the device is programmable to implement changes in GERD treatment algorithms based on any patient data collected.

[0044] One objective of the device is to treat, prevent, or otherwise minimize inappropriate relaxations of the LES while allowing appropriate relaxations of the LES, such as for vomits, swallows, or burps. Another objective of the device is to stimulate the LES while not inhibiting normal physiological relaxations of the LES, such as for vomits, swallows, or burps. Another objective of the device is to reduce a patient's esophageal pH and/or modulate a patient's LES pressure while not causing a patient's cardia sphincter to completely close.

[0045] In some embodiments of the present specification, an apparatus for combining data from implantable sensors with patient input is used for optimizing GERD treatment algorithms. Preferably, a sensor generates a signal indicative of the swallowing of food and/or content thereof, providing information related to eating habits of the patient. An analysis module typically determines a quality of the food, for example, whether it is predominantly solid or liquid, and stores this information in an electronic memory. Alternatively or additionally, the analysis module determines other characteristics of the ingested material, for example, the nutritional, chemical, and/or caloric content. "Food," as used in the context of the present patent application and in the claims, is to be understood as including a bolus of solid food, a liquid, or both a solid food bolus and a liquid. "Swallowing," as used in the context of the present patent application and in the claims, is to be understood as being indicative of the onset of eating as defined by the contraction of musculature of the esophageal body and relaxation of the LES to pass food from the esophagus into the stomach.

[0046] In some embodiments of the present invention, swallowing is detected by tracking the electrical activity in muscle tissue in the stomach, in the esophagus or in other parts of the GI tract. Typically, the commencement of enhanced electrical activity is also detected in muscle tissue in the stomach. Measurement of the time delay between swallowing and the commencement of electrical activity in the antrum is typically used to differentiate between solid and liquid matter, which are generally passed at different rates through the stomach.

[0047] Alternatively or additionally, swallowing is detected by at least one sensor placed at a site on the gastrointestinal tract wherein the sensor generates a signal indicative of swallowing. Appropriate sites include, but are not limited to, a site on the esophagus, a site on the stomach, and a site on the throat.

[0048] Whenever detection of swallowing is described in the present patent application with respect to any specific sensor such as a sensor in the LES, it is to be understood as being by way of example, and not as excluding, detection by a sensor located elsewhere on the gastrointestinal tract.

[0049] Typically, electrical activity response criteria of the stomach of an individual patient are determined and calibrated by measuring the response of the patient's stomach to various types of solid and liquid food. To ensure appropriate compliance, calibration is typically performed under the supervision of a healthcare worker.

[0050] For some applications, various supplemental sensors are also applied to the gastrointestinal tract or elsewhere on or in the patient's body. These supplemental sensors, which may comprise pH sensors, blood sugar sensors, ultrasound transducers or mechanical sensors, typically convey signals to a control unit of the apparatus indicative of a characteristic of solids or liquids ingested by the patient. For example, an ultrasound transducer may be coupled to indicate whether ingesta are solid or liquid, and a pH sensor may indicate that an acidic drink such as tomato juice was consumed rather than a more basic liquid such as milk.

[0051] In some embodiments, the data collected from the patient is used to adjust the parameters of electrical stimulation applied to the lower esophageal sphincter with the intent of enhancing its tone using an implantable neuro-stimulating system.

[0052] In such applications the electrical stimulation is optimally delivered intermittently rather than continuously. Such intermittent stimulation is beneficial to preserve battery life of the implantable device and also to minimize the risk of physiological adaptation to the electrical stimulation that might reduce its efficacy over time or require increasing levels of energy to be delivered.

[0053] In another embodiment, the sensor is a pH sensor that records the pH data indicative of a reflux event and such data is used to design a stimulation algorithm to treat GERD. In this embodiment the stimulation could be programmed to be delivered a fixed time prior to such

measured event to prevent future reflux events.

Adjusting stimulation time based on meal times and related symptoms

[0054] In many GERD patients, there is significant association between food intake and symptoms. In some embodiments, the stimulation timing is adjusted manually or automatically to meal times so as to optimize efficacy of electrical stimulation of the LES in treating GERD.

[0055] Additionally, treatment algorithms take into account the unique association between stimulation session timing and the enhancement effect on the tone of the LES. Two important elements of this effect are critical in setting stimulation timing: latency effect and residual effect.

[0056] The latency effect means that the impact on tone is not immediate upon initiation of electrical stimulation but rather some time delay, typically between 5 minutes and one hour, needs to pass before the tone reaches optimal enhancement. In addition, the electrical stimulation is known to have a residual effect beyond the time of cessation of stimulation that typically lasts between 20 minutes and 6 hours but can last up to 24 hours. All of the above means that initiation of the stimulation session needs to start enough time before any potential meal time in order to "cover" the expected reflux events or symptoms following the meal.

[0057] In order to tailor the stimulation time to eating habits of different patients and to the changes of eating habits of each patient over time, some embodiments use patient input and/or data from physiological sensors.

Utilization of patient input

[0058] In a preferred embodiment the patient input data includes answers to the following exemplary questions:

> *1. At what times do you start your three most important meals of the day (three can vary from 1-8)*
> *2. When you have GERD symptoms, do they usually - mark one answer:*
>
> > *(a) follow meals?*
> > *(b) happen during night time or when you lay down?*
> > *(c) occur both when you lay down and after meals?*
> > *(d) occur at a specific time of the day unrelated to meals or body position?*
>
> *3. What times of day do you typically feel reflux symptoms (allow 2-6 answers)?*

[0059] The answers to the above questions can typically be used as follows: If the answer to Q2 is (a) or (c), then specific stimulation sessions are programmed to start prior to, or in proximity to, the start of meals associated with symptoms. Setting the timing of stimulation to the earliest reported start of the meal is beneficial because of the known latency effect of electrical stimulation on LES tone. The latency period is between about 15 minutes to one hour so a preferred embodiment will program stimulation session to start one hour before the earliest reported time of meal start.

[0060] Answers to the questions above should be preferably obtained before the first time stimulation parameters are set and then be verified occasionally or as patients habit change.

[0061] An exemplary stimulation algorithm may include sessions 30 minutes before each meal, when a supine position is detected and specific times prior to reported GERD events. However, in a patient with erratic lifestyles, the total number of daily sessions can be equally spaced during the day such as every 2 hours or every 4 hours. In another embodiment, based on predominant upright reflux or predominant supine reflux, more sessions could be programmed for the upright or supine period, respectively.

Utilization of pH input in conjunction with patient input

[0062] In a preferred embodiment, acid exposure traces (pH esophageal traces) from the subject are also used in conjunction with the meal diary of the subject, if available, to determine optimal treatment. Such traces are used as follows:

> 1. Meal times indicated on the pH traces are used in combination with meal periods reported by the patient on the patient communication system. Such combination can be performed so that meal times from both sources are super-imposed and the combined set of meal times is used in the same way as a patient diary to adjust stimulation times.
> 2. Acid exposure events are analyzed so that time relations to various patient conditions (as indicated on the pH trace) are noted. Such conditions can be meal times, supine position and reported symptoms.

[0063] In a preferred embodiment, the acid exposure events are used in different stages of the patient treatment cycle to optimize treatment as follows:

> During the pre-treatment stage, acid exposure times indicate if the patient has a tendency to reflux following meals, during sleep or both, serving as a validation to the patient questionnaire as described. Such validation is used in some embodiments to adjust parameters so that if at least one of the following conditions is fulfilled, then supine stimulation is programmed in the IPG: (a) patient questionnaire reports supine symptoms (b) in more than 0-5% of supine time acid exposure is noted in the pH trace or (c) any esophageal pH event is associated with pa-

tient symptom.

[0064] During the patient treatment stage, if a patient reports GERD symptoms, sub-optimal improvement in GERD and/or symptoms appearing in specific times, then the questionnaire is repeated and parameters adapted as necessary. The pH traces indicate times during which treatment is not optimal and therefore an enhanced stimulation regime is required. The pH traces are further used to prescribe the said treatment enhancement where as acid exposure events are first related to patient reports or other external information such as meal times, supine time, exercise time etc. and a stimulation session is added about one hour prior to the expected acid exposure event or preferably adjustable between 5 minutes and two hours before an expected reflux event. The pH trace can be related to the patient questionnaire in the following way: If an acid event is detected at a certain time and a meal is indicated about 0-2 hours prior to that event, then the patient is asked about the earliest time that such a meal is typically started so that the enhanced treatment addresses not only the events of the specific day of the test but also the variable meal times that the patient reports.

[0065] An example of using a combination of patient reports and pH traces for treating a patient is described. The patient is a GERD patient that presented with high acid exposure and GERD symptoms prior to treatment. The patient was implanted with an IPG that was programmed to deliver stimulation irrespective of patient meal times and symptom times of acid exposure periods. During the first two weeks of treatment, the patient received a stimulation session at 2 pm, at the time at which the device detected sleep (using an accelerometer that sensed when the patient had decreased motion and was in a supine posture for at least 30 minutes), and 8 hours following the sleep detection using the above algorithm.

[0066] Following two weeks of treatment, the patient was still complaining of GERD symptoms with only a small improvement compared to baseline. At week 2, the patient was questioned about eating habits and his pH trace was reviewed so as to adjust the stimulation times. The patient was reporting meals at about 2 pm, which was verified in his baseline pH trace. The pH trace also showed a short meal at 4:30 pm. The patient also complained of symptoms between 5 and 6 pm so a 4 pm stimulation session was added. Finally, a 6 pm stimulation was added to address post dinner symptoms. At week 4, the patient was questioned again about symptoms and this time a dramatic improvement was noted. The pH exposure trace on the current stimulation algorithm confirmed an improvement or normalization of esophageal acid exposure.

[0067] Additional patients underwent similar processes with similar results, demonstrating the importance of tailoring stimulation time to precede meals and other events that are precursors of pH exposure and GERD symptoms.

[0068] Referring to Figure 1, an esophageal pH trace of the patient is shown wherein the shaded periods 105 indicate meal times and wherein areas with esophageal pH<4 are considered abnormal acid exposure periods 110. The X-axis is time of day and the Y-axis is the pH at each given time. As shown, the patient presents with many events of acid exposure mainly post meals (e.g. post 11 am breakfast 110a, post 1-2 pm lunch 110b and post 9:30 pm dinner 110c) as well as during night time (supine time 115 marked as time between about 1 am and 8:30 am). Total acid exposure is 10.4% of the time, which is considered abnormal (4% is the threshold for normal exposure). Such high acid exposure can result in various issues such as GERD symptoms, esophagitis, or Barrett's esophagus.

[0069] Referring to Figure 2, an esophageal pH trace of the patient is shown after the patient, whose trace is shown in Figure 1, has been treated with electrical stimulation using the patient specific algorithm for 4 weeks. The trace demonstrates that the majority of the esophageal acid exposure periods 210 are prevented and the esophagus acid exposure decreased to only 3.6% of the recording time, which is considered normal.

Methods and Utilities related to a Patient communication device

[0070] The following will describe a new component of the GERD treatment that can utilize patient input, communicate with the implantable pulse generator (IPG) and/or communicate externally with a clinic or other service provider. Such an apparatus, namely a "patient communication device", can preferably include a processing unit that can integrate and analyze patient input with or without additional data as described above, such as pH data, and integrate the data to form a treatment recommendation in the form of stimulation session times, amplitudes, duration, etc. The patient communication device operates via an online service in which a patient can access his key physiological data and answer questions, such as those on the patient questionnaire that will help existing or new doctors program the patient's IPG. Use of the patient communication device frees the patient from being tied to one particular doctor and prevents the patient from being in a situation where they need treatment adjustment but don't have access to their data.

[0071] In one embodiment, any computer running the appropriate software and having online access can function as a patient communication device. Additionally or alternatively, the patient communication device can be a smart phone or other mobile device running the software so that the patient can use it without a need for a computer.

[0072] Figures 3 and 4 are flowcharts describing exemplary embodiments of different methods by which the online service and patient communication device operate to tailor GERD therapy for a specific patient. At steps 302 and 402, the patient communication device acquires

sensed physiological data from sensors within the patient and, in steps 304 and 404, stores the data online using cloud based storage. The stored data is reviewed by a processor at steps 306 and 406 or a health care provider in a clinic or hospital setting at steps 308 and 408. In various embodiments, the sensed physiological data includes any one or more of esophageal pH, stomach pH, ingestion of food (using distance sensors as described above), supine position, patient weight, patient physical activity, and blood glucose level.

[0073] Using the sensed physiological data as a basis, either the remote processor at steps 310 and 410 or the health care provider at steps 312 and 412, generates a set of questions designed to further modify the GERD therapy. In various embodiments, the questions include any one or more of those in the questionnaire and questions regarding timing of reflux symptoms, duration of reflux symptoms, intensity of reflux symptoms, meal times, types of food ingested, types of liquid ingested, sleep times, and exercise regimens. At steps 314 and 414, the online service transmits the question set to the patient communication device which then presents it to the patient. At steps 316 and 416, the patient answer the questions directly on the patient communication device and the answers are stored in the cloud based storage at steps 318 and 418. The answers are also reviewable by a remote processor or a health care provider in a clinic or hospital setting.

[0074] In one embodiment, as shown at step 320 in Figure 3, a processor located at the clinic or hospital automatically compares the sensed physiological data and the patient's answers and at step 324 automatically generates a set of operational parameters for the IPG specific to the patient's data. In another embodiment, as shown at step 322, a health care provider reviews the data and patient answers and then at step 326 programs operational parameters for the IPG. In another embodiment, as shown in step 420 in Figure 4, a processor is located within the patient communication device automatically compares the sensed physiological data and the patient's answers and at step 424 automatically generates a set of operational parameters for the IPG specific to the patient's data. In yet another embodiment, as shown at step 422, the patient compares the data and his answers and at step 426 programs the IPG using the patient communication device. In various embodiments, the operational parameters include any one or more of stimulation start times, stimulation duration, and stimulation amplitude.

[0075] The generated or programmed operational parameters are then transmitted to the IPG. When the operational parameters are generated remotely by a processor or programmed remotely by a health care provider, said parameters are transmitted by the online service to the patient communication device at step 328, which then transmits the parameters to the IPG at step 330. When the operational parameters are generated locally by a processor on the patient communication device or are programmed by the patient using the patient communication device, then the patient communication device transmits said parameters directly to the IPG at step 428.

[0076] In a preferred embodiment, the patient questionnaire is applied using a patient communication device, being convenient for the patient as well as facilitating electronic data collection and analysis. Accessing the questionnaire is done via a web page to which patients log-on with a code from anywhere and the data will be transferred to the treating clinic electronically through an electronic database utilizing cloud based storage that is accessible by the clinic. In one embodiment, information relating to the patient, including the pH data, programming parameters, and patient's answers, is stored in the memory and in relation to a user account that is controlled by the patient and accessible using a network accessible computing device. Patient data will be protected from unauthorized access by standard web site protection tools such as SSL/HTTPS.

[0077] In a preferred embodiment, the clinic can communicate with the patient through the patient communication device. There can be various uses for such a communication channel, such as patient periodic reminders advising him/her to log in and answer the questionnaire. The means of communications can be standard, such as emails or instant phone messages, or can use special software and/or communication interfaces. When the patient uses a mobile application, the entire communication between the patient and the clinic can take place through the mobile application including patient reminders, questionnaire answering and data transfer to the clinic. The clinic can use the application or the other communication channels used for patient reminders to send him other relevant material such as medication information, scheduling of the next clinic visit, diet recommendations, and advice on various products and services that can be determined based on the patient profile stored in the clinic whereas such profile can be adapted from time to time based on the data communicated by the patient. The patient communication channel can be used for collecting additional medical information from the patient that can be used as initial screening information and may trigger (possibly in conjunction with physician review) scheduling in-person visits and specific tests.

[0078] In another preferred embodiment, the patient communication device can be centered around a patient charger that is used by the patient to wirelessly charge an implantable IPG with a rechargeable battery. Such a charger can have a screen for displaying patient messages and a keyboard for keying in information by the patient. It can also serve as a way station that can have a communication channel (wireless or wired) with a cell phone or a computer connected to the web to serve as a user interface, communication channel or both.

[0079] In embodiments in which the patient communication device can also establish a communication channel with the IPG, it can be adapted to configure or adjust the stimulation parameters to treat GERD of the subject. The patient communication device is adapted to monitor,

using the received data, information regarding the applied stimulation, the information selected from the group consisting of: an amount of time per day that the implantable control unit drives the stimulator to apply the stimulation to the GI tract, and a number of times per day that the implantable control unit drives the stimulator to apply the stimulation to the patient and the time of day thereof.

[0080] For some applications, the patient communication system includes an output element, which is adapted to output the information regarding the applied stimulation. In a preferred embodiment, the GI tract includes the lower esophageal sphincter (LES) of the subject, and the one or more sensors are adapted to generate the respective sensor signals responsively to the GI tract physiological parameter of the esophagus and/or LES. For some applications, the patient communication device is adapted to monitor changes in the electrical properties of the esophageal tissue indicative of swallowing and/or the content of each swallow. Such electrical properties can include, for example, sensing of electrical action potentials and/or changes in the tissue impedance. In some embodiments, a gastric slow wave rate of the subject can be used as indicative of digestive state to improve the analytical capabilities of the system.

[0081] In one embodiment, the IPG is adapted to store data using patient input. The data is recorded using the accelerometer in the IPG. The patient can communicate the information to the IPG by simply tapping on the IPG and the tapping is recorded by the accelerometer. In this embodiment, the number or intensity of taps could represent a specific event. For example, one tap on the device may indicate start of a meal event, while two taps may indicate start of a reflux event. The event data can be recorded for download by the clinic to modify the stimulation algorithm or can be used by the IPG directly to modify the stimulation algorithm without input of a health care provider. The information gathered by the IPG will continuously modify the patient's lifestyle and GERD profile and adjust the stimulation algorithm to address the changing patient profile.

[0082] In another embodiment, an external device is used which produces a vibration with a characteristic that is specific to the event. The patient will place this device on the site of the IPG implant and press a specific event button on the external device which will then vibrate with the characteristic specific to the event. The vibrations are transmitted through the human tissue to the IPG which registers the specific event. The event data can be recorded for download by the clinic to modify the stimulation algorithm or can be used by the IPG directly to modify the stimulation algorithm without input of a health care provider. The information gathered by the IPG will continuously modify the patient's lifestyle and GERD profile and adjust the stimulation algorithm to address the changing patient profile.

[0083] In another embodiment, the IPG is adapted to store information regarding eating habits of the subject as detected by the swallowing sensors. For some applications, the IPG includes an output element, which is adapted to output the eating habit information. For some applications, the patient communication device is adapted to integrate and verify patient answers to the questionaires with the eating detection data received from the IPG. The patient communication device can be adapted to transmit the integrated eating habit information to the clinic via the communication channel.

[0084] For some applications, the patient communication device is adapted to receive, analyze and integrate indication of non-GI tract physiological parameters. Such parameters can include an indication of a weight of the subject, level of physical activity of the patient, blood glucose of the patient, etc. The patient communication device can generate a message to the IPG for adjustment of parameters and/or a transmission of the information to the clinic.

[0085] For some applications, the IPG is adapted to modify a parameter of the stimulation at least in part responsively to the information. For example, the stimulation parameter may include an intensity of the stimulation, and the IPG is adapted to modify the intensity of the stimulation at least in part responsively to the information, and/or the stimulation parameter may include a timing parameter of the stimulation, and the IPG is adapted to modify the timing parameter of the stimulation at least in part responsively to the information.

[0086] In an embodiment, the patient communication device is adapted to be coupled to a remote service provider. In one embodiment, the remote service provider can analyze the patient data, for example, pH and symptom data, and convert it into parameter setting changes recommended for a given patient, thereby making the work of the clinic easier and shorter. For some applications, the apparatus includes an external cradle, and the patient communication device is adapted to be removably coupled to the cradle, and to be coupled to the service provider via the cradle. For some applications, the patient communication device is adapted to receive information from the service provider. Alternatively or additionally, the patient communication device is adapted to send information to the service provider selected from the group consisting of at least a portion of the received data and information derived from an analysis of at least a portion of the received data.

[0087] In an embodiment, the patient communication device is configured to serve as a charger for the IPG. In such a case, the patient communication device includes a power source, and is adapted to drive the power source to wirelessly transfer energy via one or more transducers, and the implantable pulse generator includes a rechargeable battery, and is adapted to receive the transmitted energy, using one or more transducers, and charge the battery using the energy.

[0088] In one embodiment, the patient communication device is adapted to be located remotely from the subject. In such an embodiment, the patient communication device is not capable of recharging the IPG. Data is trans-

mitted between the patient communication device and the IPG via RF communication at a distance of up to 3 meters. In another embodiment, the patient communication device is adapted to be located proximate the subject.

[0089] In another embodiment, the patient communication device is adapted to be coupled wired or wirelessly to a point-of-sale terminal. In one embodiment, the online service monitors the patient's compliance with the recommended treatment, diet, or exercise regimen or scheduled appointment, determines a degree of compliance, and generates a reward for the patient based on the degree of compliance. In an embodiment, generating the reward includes providing a financial incentive to the patient. In one embodiment, providing the financial incentive is based on a measure of successful responses to the clinic communication requests. In various embodiments, the financial incentive comprises any one or more of the following: refunding to the patient a portion of the purchase price of the device/and or software; providing a discount to the patient on routine medical care; and, providing a free device charging session for rechargeable devices.

[0090] For some applications, a method includes sending a reminder from the service provider to the site, and communicating the reminder to the subject. In an embodiment, the method includes analyzing, at the service provider, the eating-related information. For some applications, analyzing the eating-related information includes developing a recommendation based on the eating-related information, sending the recommendation from the service provider to the site, and communicating the recommendation to the subject from the site. For example, the recommendation may be selected from the group consisting of a recommended food and a recommended recipe. For some applications, the recommendation is commercial in nature.

[0091] For some applications, receiving of data from the IPG includes logging the data, and providing the financial incentive includes providing the financial incentive responsively to the logged data.

[0092] In an embodiment, providing the financial incentive includes providing the financial incentive in response to determining, responsively to the data, that the subject has followed a prescribed regimen. For some applications, the regimen includes a diet regimen intended to improve GERD symptoms, and providing the financial incentive includes providing the financial incentive upon determining, responsively to the data, that the subject has adhered to the prescribed diet regimen. Alternatively or additionally, the regimen includes an exercise regimen, and providing the financial incentive includes providing the financial incentive upon determining, responsively to the data, that the subject has adhered to the prescribed exercise regimen.

[0093] For some applications, functionality described herein with respect to a patient communication device is embodied that can communicate with a stationary or portable receiving device located in the clinic and is configured to collect data from the patient communication system.

Claims

1. A system for treating gastroesophageal reflux disease (GERD) in a patient, the system comprising:

   an implantable device, having a plurality of dimensions, adapted for placement proximate to a patient's lower esophageal sphincter (LES) using endoscopic or laparoscopic or surgical techniques and programmed to treat esophageal dysfunction, the implantable device comprising a stimulator enclosed within a housing and a plurality of electrodes, wherein said plurality of electrodes are attached to the outer surface of the housing ; and
   a computing device external to the patient, **characterized in that** the computing device is adapted to:

   a) electronically present the patient with questions relating to symptoms arising from the patient's GERD, electronically receive answers from the patient, and receive data in relation to the pH in the patient's lower esophagus (LES); and
   b) generate programming parameters based on the analysis in step a), wherein the programming parameters establish start times for initiating electrical stimulation of the LES and end times for terminating electrical stimulation of the LES,

   wherein the implantable device is programmable with the programming parameters generated by the computing device.

2. The system of claim 1 wherein the electrodes are adapted to be placed in a right or left anterior quadrant of the LES.

3. The system of claim 1 wherein the housing comprises a needle having a length in the range of 5 - 50 mm and, more preferably, in the range of 10 - 25 mm, for creating a pathway for electrode implantation into a muscularis of the LES.

4. The system of claim 1 wherein the electrodes are of sufficient length to allow the plurality of electrodes to be placed entirely within the LES.

5. The system of claim 1 wherein the electrodes are of sufficient length to allow the plurality of electrodes to be placed proximate to the LES wherein the elec-

trical field generated stimulates the LES.

6. The system of claim 1 wherein the dimensions are at least 6mm long and no more than 10cm long to minimize fibrosis within a peritoneal cavity.

7. The system of claim 1 wherein the implantable device is adapted to be inserted into a laparoscopic trocar and has a diameter of greater than 6mm but less than 25mm.

8. The system of claim 1 wherein said implantable device has an energy source that is rechargeable.

9. The system of claim 8 wherein the implantable device has a recharge frequency of no more than once per day for 6 hours.

10. The system of claim 1 wherein said implantable device has an energy source that is a battery and wherein said battery is a solid state battery, lithium ion battery, or super capacitor battery.

11. The system of claim 1 wherein said implantable device has an energy receiving unit and wherein said energy receiving unit is anchorable to an abdominal wall of the patient to maximize coupling between energy transmitting and receiving units.

12. The system of claim 1 wherein said implantable device is not rechargeable and has an implant life of at least 1 year.

13. The system of claim 1 wherein said electrodes are permanently attached to the housing by insulated conductors no longer than 65 cm.

14. The system of claim 1 wherein the electrodes are attached to the housing by insulated conductors which are detachable from the housing and are no longer than 65 cm.

15. The system of claim 1 wherein the device is adapted to be attached to an abdominal wall of the patient; or be attached to the outer surface or serosa of a stomach wall of the patient; or be delivered and anchored through a single port laparoscopic procedure; or be delivered using an articulated trocar in a laparoscopic procedure; or
be delivered into a peritoneal cavity of the patient through an incision that is created for a laparoscopic port.

16. The system of any one of the preceding claims, wherein the system further comprises at least one pH sensor adapted to monitor the pH of the patient's lower esophagus and capable of transmitting the sensed pH data to the computing device.

Patentansprüche

1. Ein System zur Behandlung der gastroösophagealen Refluxkrankheit (GERD) bei einem Patienten, wobei das System Folgendes beinhaltet:

   eine implantierbare Vorrichtung mit einer Vielzahl von Dimensionen, die zum Platzieren nahe des unteren Ösophagussphinkters (LES) eines Patienten unter Verwendung endoskopischer oder laparoskopischer oder chirurgischer Techniken angepasst ist und zum Behandeln einer ösophagealen Dysfunktion programmiert ist, wobei die implantierbare Vorrichtung einen von einem Gehäuse umschlossenen Stimulator und eine Vielzahl von Elektroden beinhaltet, wobei die Vielzahl von Elektroden an der Außenfläche des Gehäuses befestigt ist; und
   eine Rechenvorrichtung außerhalb des Patienten, **dadurch gekennzeichnet, dass** die Rechenvorrichtung angepasst ist, um:

      a) dem Patienten elektronisch Fragen zu unterbreiten, die sich auf Symptome, die Folge der GERD des Patienten sind, beziehen, elektronisch Antworten von dem Patienten zu empfangen und Daten in Bezug auf den pH-Wert im unteren Ösophagus (LES) des Patienten zu empfangen; und
      b) Programmierparameter auf Basis der Analyse in Schritt a) zu generieren, wobei die Programmierparameter Startzeiten für das Initiieren der elektrischen Stimulation des LES und Stoppzeiten für das Beenden der elektrischen Stimulation des LES bestimmen,

   wobei die implantierbare Vorrichtung mit den von der Rechenvorrichtung generierten Programmierparametern programmierbar ist.

2. System gemäß Anspruch 1, wobei die Elektroden angepasst sind, um in einem rechten oder linken vorderen Quadranten des LES platziert zu werden.

3. System gemäß Anspruch 1, wobei das Gehäuse eine Nadel mit einer Länge im Bereich von 5-50 mm und noch bevorzugter im Bereich von 10-25 mm zum Erzeugen eines Weges für die Implantierung der Elektroden in eine Muskularis des LES beinhaltet.

4. System gemäß Anspruch 1, wobei die Elektroden eine ausreichende Länge haben, um zu erlauben, dass die Vielzahl der Elektroden zur Gänze innerhalb des LES platziert wird.

5. System gemäß Anspruch 1, wobei die Elektroden eine ausreichende Länge haben, um zu erlauben,

dass die Vielzahl der Elektroden nahe des LES platziert wird, wobei das erzeugte elektrische Feld den LES stimuliert.

6. System gemäß Anspruch 1, wobei die Dimensionen mindestens 6 mm lang und nicht mehr als 10 cm lang sind, um eine Fibrose innerhalb einer Bauchhöhle zu minimieren.

7. System gemäß Anspruch 1, wobei die implantierbare Vorrichtung angepasst ist, um in einen laparoskopischen Trokar eingeführt zu werden, und einen Durchmesser von mehr als 6 mm, aber weniger als 25 mm aufweist.

8. System gemäß Anspruch 1, wobei die implantierbare Vorrichtung eine Energiequelle aufweist, die wiederaufladbar ist.

9. System gemäß Anspruch 8, wobei die implantierbare Vorrichtung eine Wiederaufladefrequenz von nicht mehr als einmal täglich für 6 Stunden aufweist.

10. System gemäß Anspruch 1, wobei die implantierbare Vorrichtung eine Energiequelle aufweist, die eine Batterie ist, und wobei die Batterie eine Festkörperbatterie, eine Lithiumionenbatterie oder eine Superkondensator-Batterie ist.

11. System gemäß Anspruch 1, wobei die implantierbare Vorrichtung eine Energie empfangende Einheit aufweist, und wobei die Energie empfangende Einheit an einer Bauchwand des Patienten verankerbar ist, um die Kopplung zwischen Energie übertragenden und empfangende Einheiten zu maximieren.

12. System gemäß Anspruch 1, wobei die implantierbare Vorrichtung nicht wiederaufladbar ist und eine Implantatlebensdauer von mindestens 1 Jahr aufweist.

13. System gemäß Anspruch 1, wobei die Elektroden durch isolierte Leiter, die nicht länger als 65 cm sind, dauerhaft an dem Gehäuse befestigt sind.

14. System gemäß Anspruch 1, wobei die Elektroden durch isolierte Leiter, die von dem Gehäuse abnehmbar sind und nicht länger als 65 cm sind, dauerhaft an dem Gehäuse befestigt sind.

15. System gemäß Anspruch 1, wobei die Vorrichtung angepasst ist, um
an einer Bauchwand des Patienten befestigt zu werden; oder
an der Außenfläche oder Serosa einer Magenwand des Patienten befestigt zu werden; oder
durch ein Single-Port-Laparoskopie-Verfahren zugeführt und verankert zu werden; oder unter Verwendung eines artikulierten Trokars in einem laparoskopischen Verfahren zugeführt zu werden; oder durch einen Schnitt, der für einen Laparoskopie-Port erzeugt wird, in eine Bauchwand des Patienten geführt zu werden.

16. System gemäß einem der vorhergehenden Ansprüche, wobei das System ferner mindestens einen pH-Wert-Sensor beinhaltet, der angepasst ist, um den pH-Wert des unteren Ösophagus des Patienten zu überwachen, und der die wahrgenommenen pH-Wert-Daten an die Rechenvorrichtung übermitteln kann.

Revendications

1. Un système destiné à traiter le reflux gastro-oesophagien pathologique (RGOP) chez un patient, le système comprenant :

un dispositif implantable, ayant une pluralité de dimensions, conçu pour un placement à proximité du sphincter inférieur de l'oesophage (SIO) d'un patient à l'aide de techniques endoscopiques, laparoscopiques ou chirurgicales et programmé pour traiter un dysfonctionnement oesophagien, le dispositif implantable comprenant un stimulateur renfermé dans un boîtier et une pluralité d'électrodes, ladite pluralité d'électrodes étant fixées à la surface externe du boîtier ; et
un dispositif informatique externe au patient, **caractérisé en ce que** le dispositif informatique est conçu pour :

a) présenter par voie électronique au patient des questions relatives aux symptômes résultant du RGOP du patient, recevoir par voie électronique des réponses du patient, et recevoir des données en rapport avec le pH dans la partie inférieure de l'oesophage (SIO) du patient ; et
b) générer des paramètres de programmation sur la base de l'analyse à l'étape a), les paramètres de programmation établissant des moments de début pour démarrer une stimulation électrique du SIO et des moments de fin pour mettre un terme à la stimulation électrique du SIO,

dans lequel le dispositif implantable peut être programmé avec les paramètres de programmation générés par le dispositif informatique.

2. Le système de la revendication 1 dans lequel les électrodes sont conçues pour être placées dans un quadrant antérieur droit ou gauche du SIO.

3. Le système de la revendication 1 dans lequel le boîtier comprend une aiguille d'une longueur dans la plage de 5 à 50 mm et, plus préférablement, dans la plage de 10 à 25 mm, destinée à créer une voie de passage pour l'implantation d'électrode dans une musculeuse du SIO.

4. Le système de la revendication 1 dans lequel les électrodes sont de longueur suffisante pour permettre à la pluralité d'électrodes d'être placées entièrement dans le SIO.

5. Le système de la revendication 1 dans lequel les électrodes sont de longueur suffisante pour permettre à la pluralité d'électrodes d'être placées à proximité du SIO, le champ électrique généré stimulant le SIO.

6. Le système de la revendication 1 dans lequel les dimensions sont d'au moins 6 mm de long et d'au plus 10 cm de long afin de minimiser la fibrose dans une cavité péritonéale.

7. Le système de la revendication 1 dans lequel le dispositif implantable est conçu pour être inséré dans un trocart laparoscopique et présente un diamètre supérieur à 6 mm, mais inférieur à 25 mm.

8. Le système de la revendication 1 dans lequel ledit dispositif implantable présente une source d'énergie qui est rechargeable.

9. Le système de la revendication 8 dans lequel le dispositif implantable présente une fréquence de recharge au plus une fois par jour pendant 6 heures.

10. Le système de la revendication 1 dans lequel ledit dispositif implantable possède une source d'énergie qui est une batterie et dans lequel ladite batterie est une batterie à l'état solide, une batterie lithium-ion ou une batterie de type supercondensateur.

11. Le système de la revendication 1 dans lequel ledit dispositif implantable possède une unité de réception d'énergie et dans lequel ladite unité de réception d'énergie peut être ancrée à une paroi abdominale du patient afin de maximiser le couplage entre des unités d'émission et de réception d'énergie.

12. Le système de la revendication 1 dans lequel ledit dispositif implantable n'est pas rechargeable et présente une durée de vie d'implant d'au moins 1 an.

13. Le système de la revendication 1 dans lequel lesdites électrodes sont fixées de manière permanente au boîtier par des conducteurs isolés dont la longueur n'excède pas 65 cm.

14. Le système de la revendication 1 dans lequel les électrodes sont fixées au boîtier par des conducteurs isolés qui peuvent être détachés du boîtier et dont la longueur n'excède pas 65 cm.

15. Le système de la revendication 1 dans lequel le dispositif est conçu pour
être fixé à une paroi abdominale du patient ; ou
être fixé à la surface externe ou la séreuse d'une paroi stomacale du patient ; ou
être délivré et ancré par le biais d'une procédure laparoscopique à trocart unique ; ou être délivré à l'aide d'un trocart articulé dans une procédure laparoscopique ; ou
être délivré dans une cavité péritonéale du patient par le biais d'une incision qui est créée pour un trocart laparoscopique.

16. Le système de n'importe laquelle des revendications précédentes, le système comprenant en outre au moins un détecteur de pH conçu pour surveiller le pH de la partie inférieure de l'oesophage du patient et capable de transmettre les données de pH détectées au dispositif informatique.

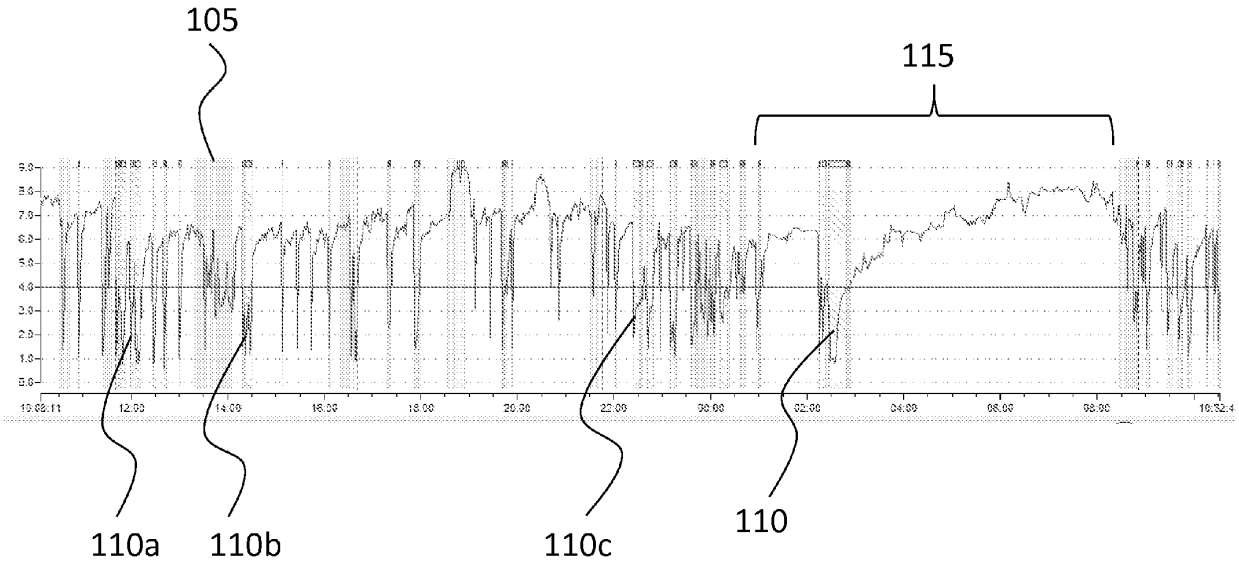

Figure 1

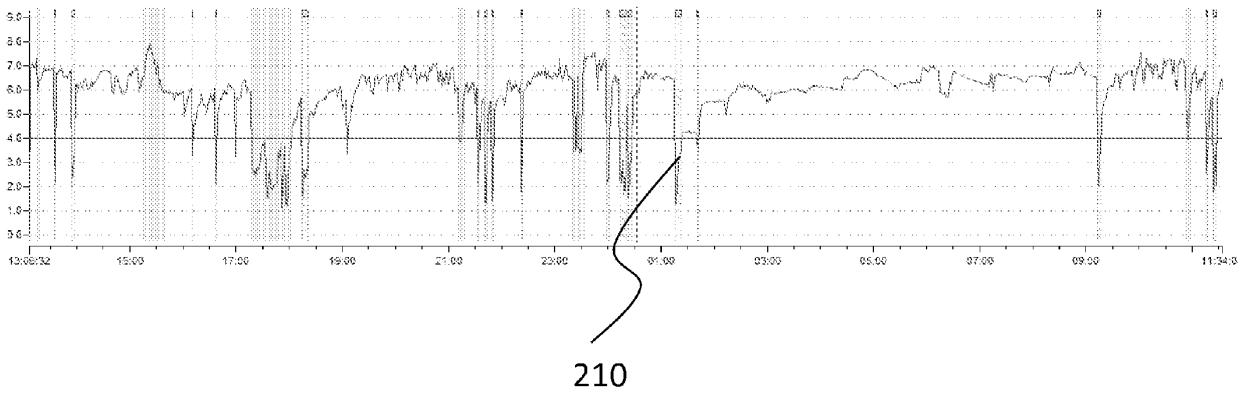

Figure 2

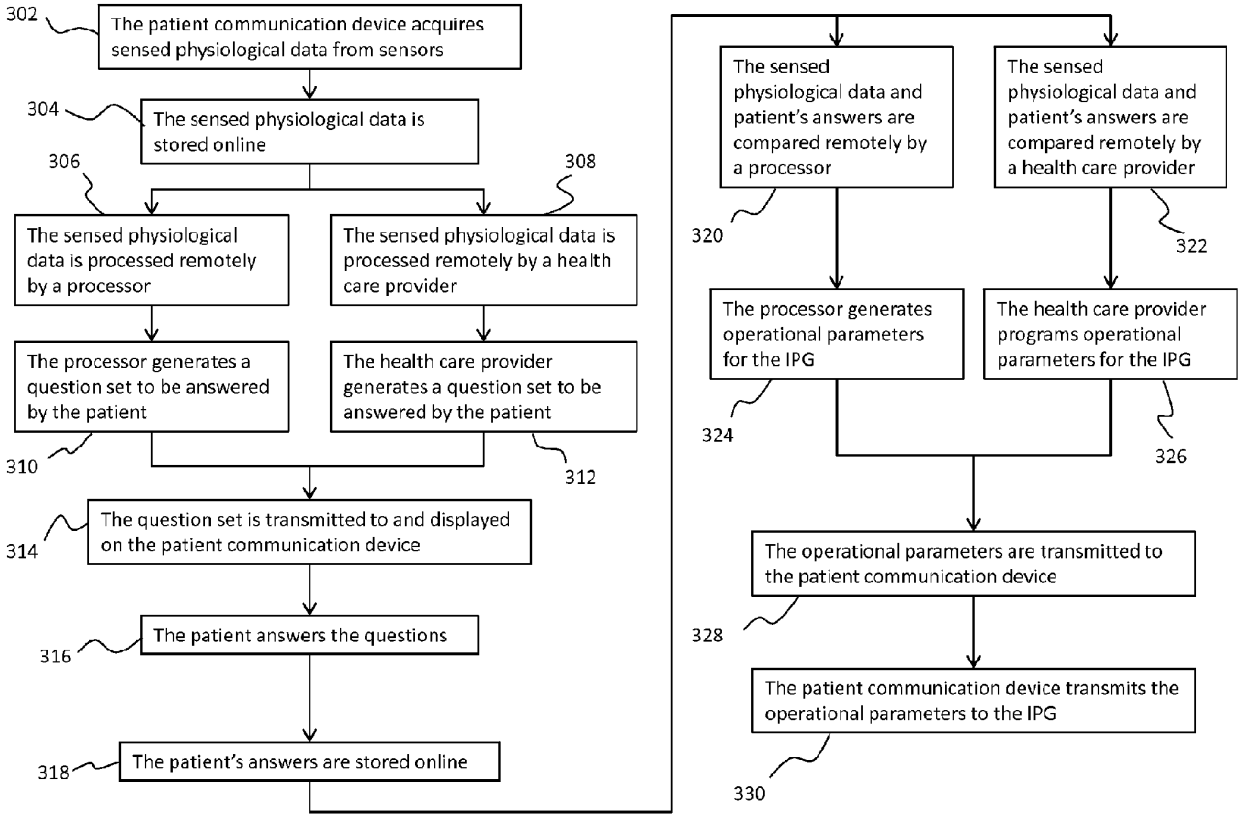
302
The patient communication device acquires sensed physiological data from sensors
304
The sensed physiological data is stored online
306
308
The sensed physiological data is processed remotely by a processor
The sensed physiological data is processed remotely by a health care provider
The processor generates a question set to be answered by the patient
The health care provider generates a question set to be answered by the patient
310
312
314
The question set is transmitted to and displayed on the patient communication device
316
The patient answers the questions
318
The patient's answers are stored online
The sensed physiological data and patient's answers are compared remotely by a processor
The sensed physiological data and patient's answers are compared remotely by a health care provider
320
322
The processor generates operational parameters for the IPG
The health care provider programs operational parameters for the IPG
324
326
The operational parameters are transmitted to the patient communication device
328
The patient communication device transmits the operational parameters to the IPG
330

Figure 3

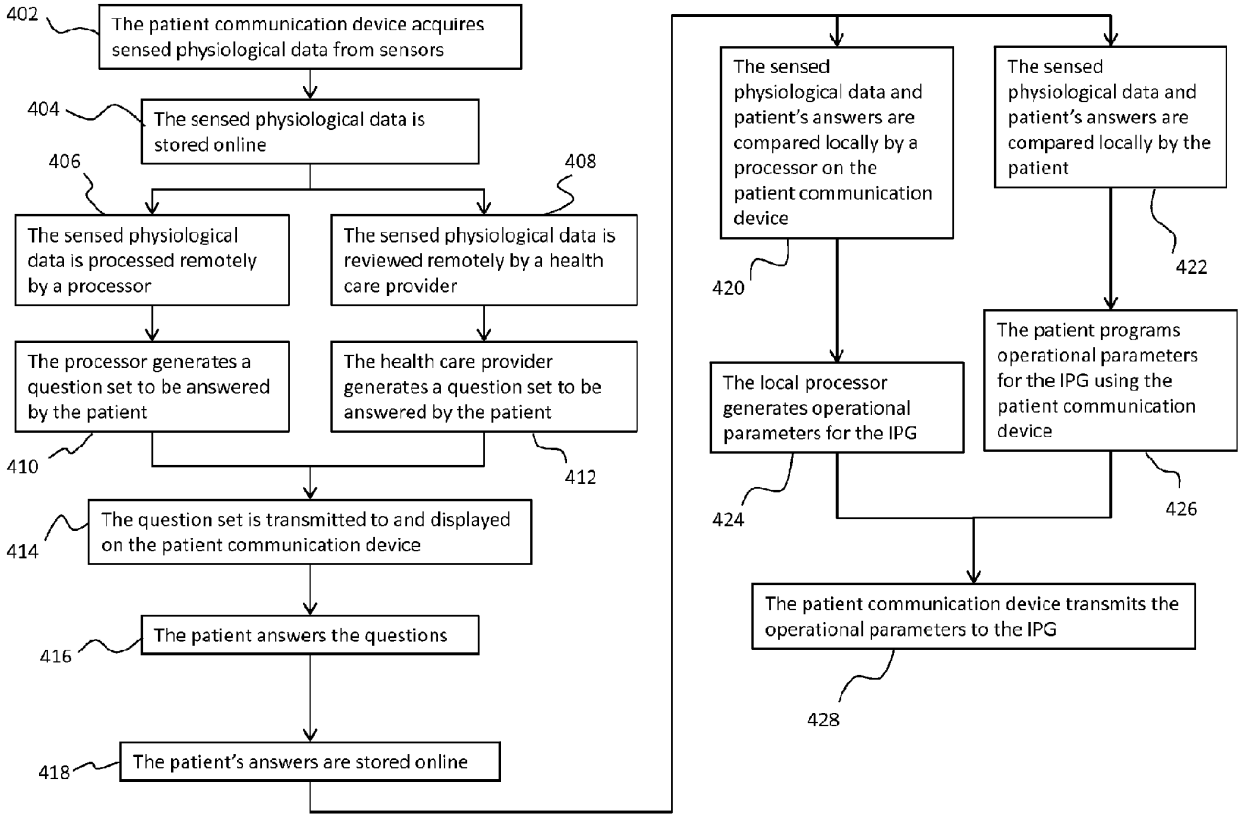
402
The patient communication device acquires sensed physiological data from sensors
404
The sensed physiological data is stored online
406
408
The sensed physiological data is processed remotely by a processor
The sensed physiological data is reviewed remotely by a health care provider
The processor generates a question set to be answered by the patient
The health care provider generates a question set to be answered by the patient
410
412
414
The question set is transmitted to and displayed on the patient communication device
416
The patient answers the questions
418
The patient's answers are stored online
The sensed physiological data and patient's answers are compared locally by a processor on the patient communication device
The sensed physiological data and patient's answers are compared locally by the patient
420
422
The local processor generates operational parameters for the IPG
The patient programs operational parameters for the IPG using the patient communication device
424
426
The patient communication device transmits the operational parameters to the IPG
428

Figure 4

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	用于治疗胃食管反流病的系统和方法		
公开(公告)号	EP2696792A4	公开(公告)日	2014-10-01
申请号	EP2012771852	申请日	2012-04-14
[标]申请(专利权)人(译)	恩多斯蒂姆股份有限公司		
申请(专利权)人(译)	ENDOSTIM INC.		
当前申请(专利权)人(译)	ENDOSTIM INC.		
[标]发明人	POLICKER SHAI SHARMA VIRENDER K		
发明人	POLICKER, SHAI SHARMA, VIRENDER K.		
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外部链接	Espacenet		

摘要(译)

用于治疗胃食管反流病（GERD）的系统和方法包括在患者食管中，下食管括约肌（LES）附近的区域内微创植入刺激装置。 通过在线服务向患者提供与其疾病有关的问卷。 可以在移动设备（例如手机）或具有网络访问权限的计算机上访问问卷。 卫生保健提供者使用在线服务一起分析传感器的数据和调查表的答案。 数据和答案用于通过移动设备或计算机对刺激设备进行编程，以优化治疗效果。