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(54) **IMPLANTABLE SYSTEM**

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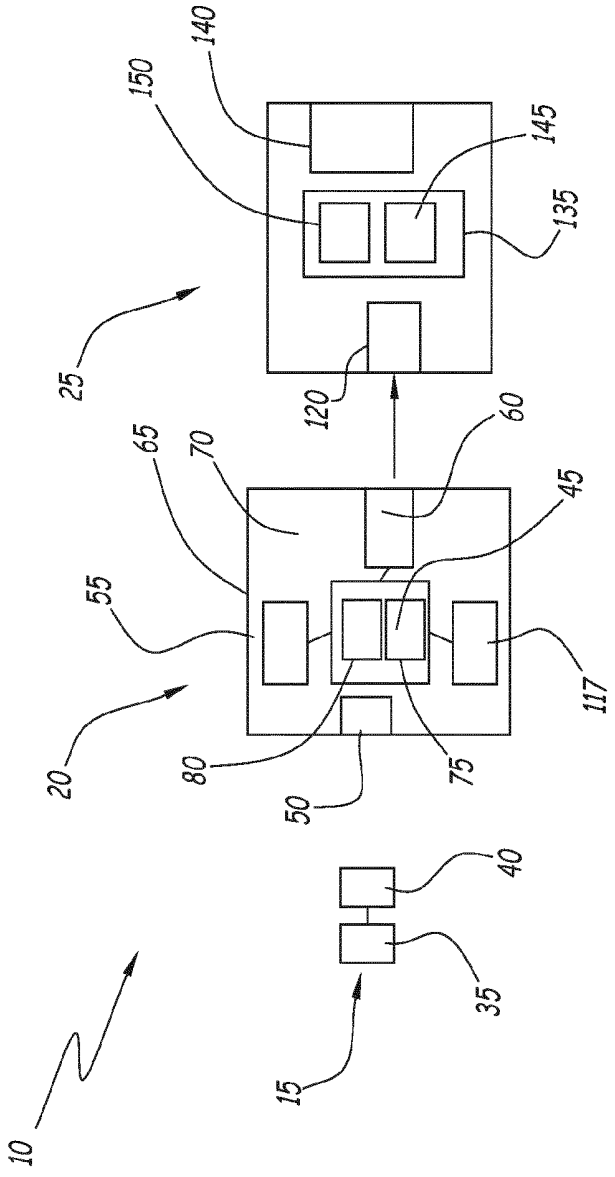
(57) **ABSTRACT**

The invention relates to an implantable system (**10**) comprising a first device (**20**), called a centralization device, which is able to be fixed in a fixation position to a wall of the stomach of a patient, the centralization device (**20**) being received in the stomach when the centralization device (**20**) is in the fixation position, and at least one second device (**25**). The implantable system (**10**) is characterized in that the centralization device (**20**) comprises a controller (**45**), an electrical supply (**55**) and an emitter/receiver (**60**) to permit communication between the centralization device (**20**) and the second device (**25**) when the second device (**25**) is in a functioning position, the second device (**25**) being situated outside the body of the patient when the second device (**25**) is in the functioning position.

Fig.1



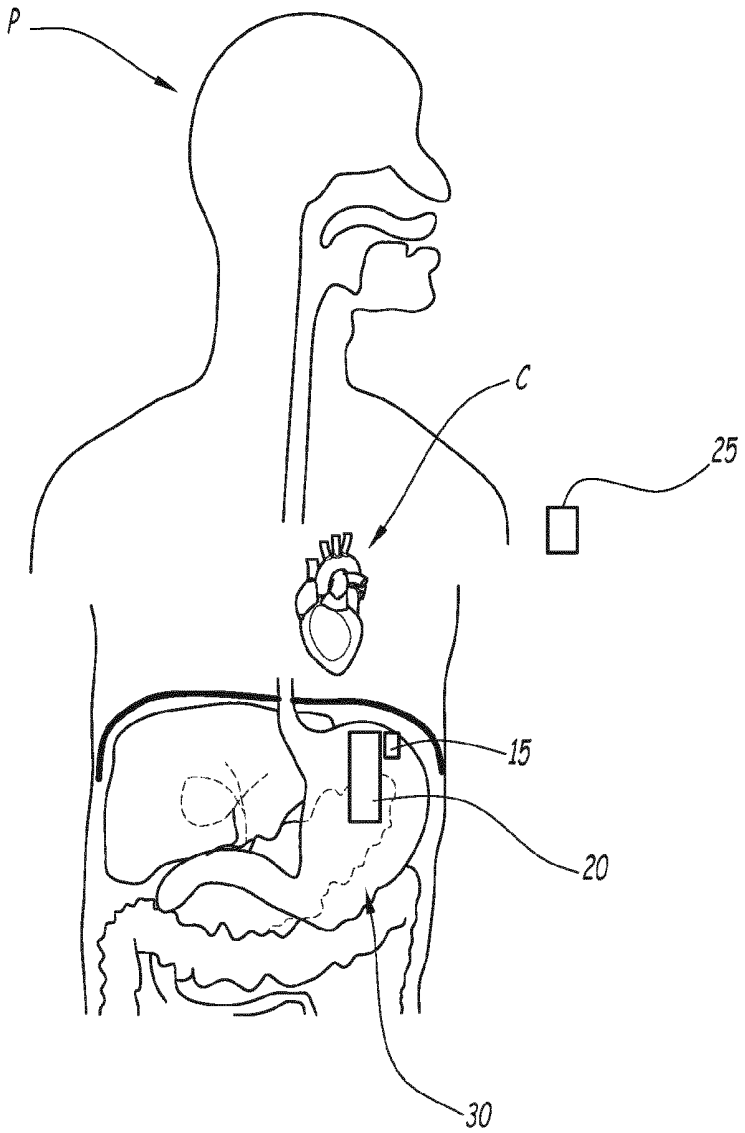
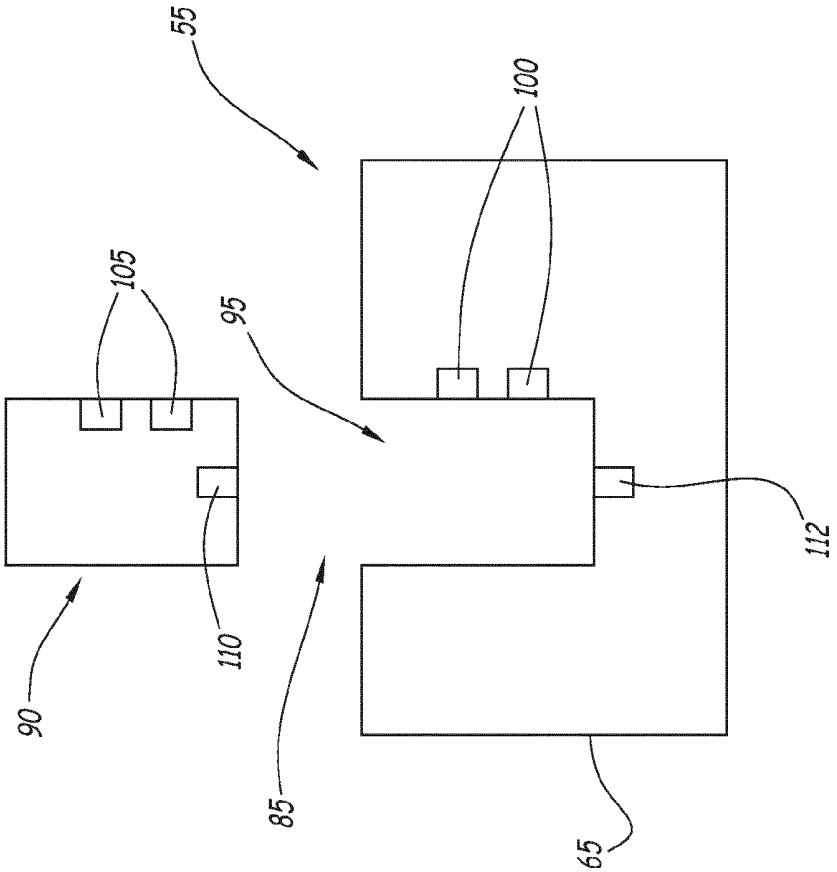


Fig.2

Fig.3



IMPLANTABLE SYSTEM

[0001] The present invention relates to an implantable system.

[0002] A large number of implantable devices are used to monitor or stimulate certain organs of the human body. For example, cardiac stimulation devices (known as pacemakers) are implanted in numerous patients. These devices usually comprise an energy source such as a battery, one or more sensors enabling the behavior of the monitored organ to be monitored and/or a stimulation module provided to exert an action on the stimulated organ.

[0003] However, the batteries of these implanted devices need to be regularly recharged or replaced. In particular, in many cases, this replacement is performed by a surgical operation. Such a procedure is relatively expensive and inconvenient for the patient as it takes place in a hospital operating theater and an anesthetic is necessary, as well as a prolonged stay in hospital for postoperative monitoring. Furthermore, as with any surgical intervention, there are risks that the patient might contract an infection during the operation.

[0004] In other cases, implanted devices of the above-mentioned type are powered from outside by an energy storage module that is carried by the patient on the outside of his body. For example, there are some power devices that transmit the energy by ultrasound waves to the stimulation device, through the patient's skin and ribcage. However, ultrasound waves pass poorly through bone and great precision is therefore required when siting the ultrasound source, if the implanted device is located in the ribcage, to ensure a good supply to the implanted device. Furthermore, such a power device outside the patient's body is unsightly.

[0005] Some implanted devices may also be fitted with wired connectors, enabling an electrical connection or a transfer of fluid between the implantable device and an external device. In this way an electrical supply current or data measured by the sensors of the implanted device are exchanged with the external device. Here again, these connectors passing through the patient's skin are unsightly and necessarily present health risks as well as severe constraints for the patient in his daily life.

[0006] A need therefore exists for an implantable system that is less constraining for the patient.

[0007] To this end, an implantable system is proposed comprising:

[0008] a first device, called a centralization device, which is able to be fixed in a fixation position to a wall of the stomach of a patient, the centralization device being received in the stomach when the centralization device is in the fixation position, and

[0009] at least one second device,

[0010] the implantable system being characterized in that the centralization device comprises a controller, an electrical supply and an emitter/receiver to permit communication between the centralization device and the second device when the second device is in a functioning position, the second device being situated outside the body of the patient when the second device is in the functioning position.

[0011] According to various embodiments, the implantable system comprises one or more of the following characteristics, taken in isolation or according to all of the technically possible combinations:

[0012] the centralization device is configured to communicate with each second device by radiofrequency communication;

[0013] the centralization device comprises a sensor able to measure a value of a physiological parameter of the patient, the emitter/receiver being configured so as to transmit to a second device the measured values, the second device considered to be able to detect a physiological phenomenon of the patient on the basis of at least one of the measured values;

[0014] the implantable system comprises two second devices, and one of the second devices comprises at least one sensor able to measure a value of a physiological parameter of the patient, the emitter/receiver being configured to receive from the second device comprising a sensor the measured values and to transmit the measured values to the other second device, the other second device being able to detect a physiological phenomenon of the patient on the basis of at least one of the values received from the emitter/receiver;

[0015] the implantable system comprises a memory able to store the measured values for a period of more than or equal to one day;

[0016] the physiological phenomenon is a cardiac pathology;

[0017] the cardiac pathology is heart failure;

[0018] the sensor is an ultrasound emitter/receiver;

[0019] the sensor is an accelerometer able to measure values of an acceleration of the centralization device and the second device is configured to calculate a physiological parameter of the heart of the patient from the measured acceleration values;

[0020] the sensor is able to measure a difference in electrical potential, an acceleration, a noise, an orientation, a pH or a temperature;

[0021] the centralization device comprises a catheter able to convey a body fluid of the patient to the sensor, the sensor being able to measure a level of a biological marker in the body fluid;

[0022] the sensor comprises at least one light source and at least one detector of light radiation, the light source being configured to illuminate at least one portion of an organ of the patient with light radiation, the detector being configured to measure a value of a level of reflection of the light radiation, the controller being configured to calculate an oxygenation level of the blood circulating in the organ illuminated by the light source, based on the level of reflection;

[0023] the system comprises a plurality of sensors, and the second device is able to detect the physiological phenomenon on the basis of the values of at least two sensors;

[0024] the physiological phenomenon is chosen from the group formed by: cardiac dysrhythmia, atrial fibrillation, syncope, heart failure, sleep apnea, chronic obstructive pulmonary disease, emphysema, epilepsy, a swallowing disorder, an eating disorder;

[0025] when the centralization device is in the fixation position, the centralization device is in the upper part of the stomach;

[0026] the electrical supply comprises a removable reserve of electrical energy and a connector able to receive the reserve of electrical energy, the reserve of electrical energy being able to electrically supply the

controller when the reserve of electrical energy is connected electrically to the connector in a connection position and preferably being configured to be swallowed by the patient and to move spontaneously to the connection position from a disconnection position in which the reserve of electrical energy is received in the stomach of the patient and is disconnected from the connector;

[0027] the electrical supply comprises an electrical energy generator able to generate an electrical current by reaction of at least one chemical species present in the body of the patient, particularly glucose;

[0028] the electrical supply comprises an electrical energy generator able to generate an electrical current by the conversion of mechanical energy into electrical energy.

[0029] Further features and advantages of the invention will emerge from the following description, given purely by way of non-limiting example and made with reference to the accompanying drawings, in which:

[0030] FIG. **1** is a diagram of an example of an implantable system comprising an electrical supply,

[0031] FIG. **2** is a schematic representation of the implantable device in FIG. **1**, implanted in the body of a patient, and

[0032] FIG. **3** is a schematic representation of the supply in FIG. **1**.

[0033] A first example of an implantable system **10** is shown in FIG. **1**.

[0034] The implantable system **10** comprises an anchor **15**, a first device **20**, called a centralization device, and at least one second device **25**.

[0035] An "implantable system" means that at least one element among the list formed by the anchor **15** of the first device **20** and by the second device **25** is provided to be implanted in the human body.

[0036] In particular, "implantable" means that at least one element among the anchor **15**, the centralization device **20** and the second device **25** is provided to remain in the body of a patient P for a period of strictly more than one week, preferably strictly more than one month, preferably longer than or equal to one year.

[0037] The implantable system **10** is shown schematically in FIG. **2** when the implantable system **10** is implanted in the body of the patient P.

[0038] The implantable system **10** is configured to detect at least one physiological phenomenon occurring in the patient P. A "physiological phenomenon" means a phenomenon concerning a function of an organ of the body of the patient P. The physiological phenomenon is a cardiac pathology. For example, the physiological phenomenon is a cardiac dysrhythmia. For example, the physiological phenomenon is an atrial fibrillation of the heart of the patient P.

[0039] As a variation, the physiological phenomenon is a syncope. According to another variation, the physiological phenomenon is a bradycardia.

[0040] According to another variation, the physiological phenomenon is a failure of the heart of the patient P.

[0041] According to the example in FIG. **2**, the anchor **15** and the centralization device **20** are each implanted in the body of the patient P. The second device **25** is shown in a functioning position in FIG. **2**.

[0042] The anchor **15** is able to be fixed in a predetermined position in the stomach **30** of the patient P.

[0043] For example, the anchor **15** is configured to be fixed in the top part of the stomach **30**. In particular, the anchor **15** is configured to be fixed in the gastric fundus of the stomach **30**. For example, the anchor **15** is provided to be fixed as closely as possible to the Angle of His in the gastric fundus.

[0044] As a variation, the anchor **15** is configured to be fixed in the lower part of the stomach **30**.

[0045] The anchor **15** is configured to support the centralization device **20**, preferably in a removable manner. In particular, the anchor **15** and the centralization device **20** are configured to be fixed to one another by a fixing device, and the anchor **15** is configured to hold the centralization device **20** in a fixation position when the anchor **15** is fixed in the stomach **30**.

[0046] The anchor **15** comprises a head **35** and a first connector **40**.

[0047] The head **35** is configured to anchor the anchor **15** in the predetermined position. In particular, the head **35** is configured to anchor the anchor **15** to the wall of the stomach **30**.

[0048] The head **35** is, for example, a gastro-intestinal clip configured to grip between two branches of the head **35** a portion of the wall of the stomach **30**.

[0049] As a variation, the head **35** is able to be sutured by a thread to the wall of the stomach.

[0050] According to another variation, the head **35** is able to be buried inside the gastric mucosa after the latter has been dissected.

[0051] The first connector **40** is configured to fix the centralization device **20** to the head **35**.

[0052] The centralization device **20** comprises at least one sensor **117**, a first controller **45**, a second connector **50**, an electrical supply **55**, a first emitter/receiver **60** and a case **65**. For example, the centralization device **20** comprises two sensors **117**.

[0053] Each sensor **117** is outside the first controller **45** but is able to communicate with the first controller **45**.

[0054] Each sensor **117** is configured to measure the value of a physiological parameter of the patient P. The physiological parameter is, for example, a parameter of an organ C.

[0055] The organ C is distinct from the stomach of the patient P. For example, at least one sensor **117** is able to measure values of a parameter of the heart.

[0056] For example, a sensor **117** is able to measure a value of an acceleration of the centralization device **20**, such as an acceleration caused by a contraction of the heart C.

[0057] As a variation or in addition, a sensor **117** is able to measure a value of a difference in electrical potential between two electrodes of the sensor **117**. The difference in electrical potential is, for example, measured between two points of the stomach wall, meaning that the two electrodes are in contact with the stomach wall. As a variation, the sensor **117** comprises only one electrode and is able to measure the difference in electrical potential between the electrode and the anchor **15**. As a variation, the anchor **15** comprises two electrodes and the sensor **117** is able to measure a difference in potential between the two electrodes of the anchor **15**.

[0058] The first controller **45** is a data processing unit. The first controller **45** comprises a first memory **75** and a first processor **80**.

[0059] The first memory **75** is able to store the values measured by the sensor **117** for a storage period of longer than or equal to one hour, preferably longer than or equal to one day, preferably longer than or equal to one week.

[0060] The first processor **80** is able to handle and/or convert the data represented as electronic or physical quantities in the first memory **75** into other similar data corresponding to physical data in the first memory **75**, in logs or other types of display, transmission or storage devices.

[0061] The first processor **80** is also configured to exchange information with the first emitter/receiver **60**.

[0062] The second connector **50** is configured to cooperate with the first connector **40** to hold the centralization device **20** in the fixation position.

[0063] For example, the second connector **50** is configured to cooperate with the first connector **40** by clicking into it.

[0064] As a variation, the second connector **50** comprises a magnet configured to fix the second connector to the first connector. The magnet is, for example, an electromagnet.

[0065] According to another variation, the first connector **40** is configured to be connected to the second connector **50** by screwing. As a variation, the first connector **40** comprises one or preferably two bayonets complementary to fixation orifices made in the second connector **50**.

[0066] Preferably, the second connector **50** is provided so that the centralization device **20** can be separated from the anchor **15**. In particular, the second connector **50** is configured so that the centralization device **20** can be separated from the anchor **15** when the anchor **15** is fixed in the stomach **30** of the patient P.

[0067] The electrical supply **55** is shown in FIG. **3**.

[0068] The electrical supply **55** is configured to supply the first controller **45** with a supply current C.

[0069] The electrical supply **55** comprises a third connector **85** and a first reserve of electrical energy **90**.

[0070] The third connector **85** is configured to receive from the first reserve of electrical energy **90** the supply current C and to supply the first controller **45** with the first supply current C.

[0071] The third connector **85** is configured to receive the first reserve of electrical energy **90**. In particular, the third connector **85** defines a cavity **95** configured to receive at least partially the first reserve of electrical energy **90** in a connection position.

[0072] According to the example in FIG. **3**, the cavity **95** emerges on the outside of the case **65**. In particular, the cavity **95** is configured to permit the insertion of the first reserve of electrical energy **90**, from the outside of the case **65**, into the cavity **95**.

[0073] The third connector **85** also comprises two first electrical contacts **100**, configured to be connected electrically to the first reserve of electrical energy **90** when the first reserve of electrical energy **90** is in the connection position. In particular, the two first electrical contacts **100** emerge on the inside of the cavity **95**.

[0074] The first reserve of electrical energy **90** is configured to store electrical energy. In particular, the first reserve of electrical energy **90** is configured to be charged with electrical energy from outside of the body of the patient P and to discharge when the first reserve of electrical energy **90** is in the connection position. For example, the first reserve of electrical energy **90** comprises a battery. As a variation, the first reserve of electrical energy **90** comprises at least one capacitor or one supercapacitor.

[0075] The first reserve of electrical energy is configured to supply the first controller **45** with the supply current C when the first reserve of electrical energy **90** is in the connection position.

[0076] According to the example in FIG. **3**, the first reserve of electrical energy **90** comprises two first electrical contacts **105** complementary to the first electrical contacts **100**.

[0077] The first reserve of electrical energy **90** can be provided to be swallowed by the patient P.

[0078] According to a variation, the first reserve of energy **90** is able to be replaced by endoscopy.

[0079] In particular, the first reserve of electrical energy **90** has a volume strictly less than 6 milliliters (ml).

[0080] The first reserve of electrical energy **90** also has three dimensions, each measured in a respective direction, each direction being perpendicular to the other two directions, and each dimension is strictly less than 5 centimeters (cm).

[0081] The first reserve of electrical energy **90** is movable between the connection position and a disconnection position. When the first reserve of electrical energy **90** is in the disconnection position, the first reserve of electrical energy **90** is received into the stomach **30** of the patient P but is not electrically connected to the third connector **85**. For example, when the first reserve of electrical energy **90** is in the disconnection position, the first reserve of electrical energy is totally extracted from the cavity **95**.

[0082] The first reserve of electrical energy **90** is configured to move spontaneously from the disconnection position to the connection position. For example, the first reserve of electrical energy **90** comprises attractors **110**.

[0083] Preferably, the first reserve of electrical energy **90** is configured to eject from the third connector **85** another spent first reserve of electrical energy **90**, if any. In other words, the first reserve of electrical energy **90** is configured so as to cause, if a spent first reserve of electrical energy **90** is in the connection position, the disconnection of the spent first reserve of electrical energy **90** and the movement of the spent first reserve of electrical energy from the connection position to the disconnection position.

[0084] The attractors **110** are configured so as to exert on the first reserve of electrical energy **90**, when the first reserve of electrical energy **90** is in the disconnection position, a force tending to move the first reserve of electrical energy **90** from the disconnection position to the connection position.

[0085] Furthermore, the attractors **110** are configured to hold the first reserve of electrical energy **90** in the connection position.

[0086] The attractors **110** comprise, for example, a first magnet able to cooperate with a second magnet **112** of the third connector **85**. As a variation, the first magnet is able to cooperate with a ferromagnetic portion of the third connector **85**. The first magnet and the second magnet **112** are, for example, electromagnets.

[0087] The first emitter/receiver **60** is configured to exchange information with the second device **25** when the second device **25** is in the operating position. The first emitter/receiver **60** thus forms means of communication with the second device **25**.

[0088] The first emitter/receiver **60** is, for example, a radiofrequency communication module. "Radiofrequency communication module" means that the first emitter/receiver **60** is configured to communicate with the second

device **25** via a signal comprising at least one radiofrequency electromagnetic wave. Radiofrequency electromagnetic waves are electromagnetic waves having a frequency of between 3 kilohertz and 3 gigahertz.

[0089] According to one embodiment, the first emitter/receiver **60** is able to exchange information with the second device **25** according to a Bluetooth Low Energy protocol. The Bluetooth Low Energy protocol is a protocol based on a "Bluetooth special interest group" standard and operating within the range of between 2400 megahertz (MHz) and 2483.5 MHz.

[0090] As a variation, methods for the transmission of information within the ranges of 402-405 megahertz (MHz) (Medical Implant Communication Service) or 2360-2390 MHz (Medical Body Area Networks) can be used.

[0091] The case **65** is configured to isolate the first controller **45** from the outside of the case **65**. For example, the case **65** defines a chamber receiving at least the first controller **45** and the first emitter/receiver **60**.

[0092] The second device **25** is not implanted inside the body of the patient P when the device **25** is in the functioning position. In particular, the second device **25** is located outside the body of the patient P when the second device **25** is in the functioning position.

[0093] For example, the second device **25** is installed in a doctor's practice. As a variation, the second device **25** is installed at the home of the patient P. As a variation, the second device **25** is carried by the patient, for example the second device is a mobile telephone such as a smartphone, a tablet, a dedicated device or even a module integrated into a mobile telephone or tablet.

[0094] The second device **25** is a display device able to transmit information to a user U.

[0095] The second device **25** is also configured to detect the physiological phenomenon on the basis of the measured values.

[0096] The second device **25** comprises a second emitter/receiver **120**, a second controller **135** and a man/machine interface **140**.

[0097] The second emitter/receiver **120** is configured to exchange information with the first emitter/receiver **60**.

[0098] The second controller **135** is configured to detect the physiological phenomenon on the basis of the values measured by the sensor **117**.

[0099] The second controller **135** comprises a second memory **145** and a second processor **150**.

[0100] The man/machine interface comprises, for example, a screen and loudspeaker.

[0101] A method for monitoring the organ C is implemented by the implantable system **10**.

[0102] The monitoring method comprises an implantation step, a measurement step, a transfer step, a detection step and a signaling step.

[0103] During the implantation step, the anchor **15** and the centralization device **20** are implanted in the body of the patient P. The second device **25** is not implanted in the body of the patient P.

[0104] During the measurement step, each sensor **117** measures the values of the parameter. For example, the sensor **117** periodically measures the values of the corresponding parameter for a predetermined period of time.

[0105] The measured values are stored in the first memory **75**.

[0106] The measured values are stored in the first memory **75** for a period longer than or equal to one hour, for example longer than or equal to one day, for example longer than or equal to one week, for example longer than or equal to one month.

[0107] During the transfer step, the measured values are transferred, by the centralization device **20**, to the second device **25**. For example, the transfer step is implemented when the patient P visits his assigned doctor's practice.

[0108] As a variation, the transfer step is implemented periodically when the patient P is at home, for example once a day. According to a variation, when the patient carries the second device **25** on his person, for example when the second device **25** is integrated into a mobile telephone, the transfer step is implemented for a period of less than or equal to one hour.

[0109] For example, thanks to the measured values of difference in potential, the second device **25** displays an electrocardiogram of the patient P.

[0110] After each transfer step, the first memory **75** is erased. In particular, the values of stored parameters are erased.

[0111] During the detection step, the second controller **135** detects the physiological phenomenon on the basis of the measured values.

[0112] According to a variation, the second controller **135** calculates the operating data on the basis of the measured values and detects the physiological phenomenon on the basis of the operating data. The operating data are data derived from the measured values. For example, a heart rate is an example of operating data calculated on the basis of measurements of a difference in potential between two electrodes or on the basis of acceleration values of the centralization device **20**. An interval of time between two waves of polarization of an atrium of the heart is another example of operating data, and a variation of this period of time is another example of operating data. A correlation coefficient obtained by an adjustment of a set of measured values with a set of reference values or a reference function is another example of operating data.

[0113] For example, the second controller **135** compares each measured value or each value of operating data to a predetermined threshold and detects the physiological phenomenon if one of the measured values exceeds or is equal to the predetermined threshold.

[0114] According to another example, the physiological phenomenon is detected if several measured values or several values of operating data exceed or are equal to a predetermined threshold for a predetermined period of time. According to a variation, the second controller **135** detects the physiological phenomenon if one or more of the measured values or values of operating data exceeds or is equal to a predetermined threshold, or even if one or more of the measured values or values of operating data is not included within a range of data framed by two predetermined thresholds.

[0115] According to another example, the physiological phenomenon is detected if several measured values or several values of operating data belong to a predetermined region of the space R^n, where R is the set of real values and n represents the number of values. According to a variation, the second controller **135** detects the physiological phenom-

enon if one or more of the measured values or values of operating data belong to a predetermined region of the space R^n.

[0116] The predetermined thresholds or the predetermined region of the space R^n are, for example, determined by an automatic learning method. The automatic learning methods are also called "machine learning". For example, the implantable system records the measured values while the patient undergoes more conventional examinations (external electrocardiogram or morphological examinations, for example ultrasound examinations, possibly performed during operating tests, for example stress tests). These more conventional examinations are chosen to permit a diagnosis to be made, and a machine learning method permits combinations of the values measured by the implantable system to be determined that correspond to the physiological or pathological phenomenon studied. In everyday life, when the measured values confirm these characteristics, the second controller **135** will detect the physiological or pathological phenomenon.

[0117] According to one variation, the second controller **135** detects the physiological phenomenon on the basis of values measured by at least two separate sensors **117**.

[0118] According to one embodiment, the second controller **135** detects atrial fibrillation on the basis of acceleration values and/or measured values of electrical voltage. The second controller **135** detects, for example, atrial fibrillation on the basis of an analysis of electrical voltage values to detect the presence or absence, in the electrocardiogram, of a representative signal of a wave P of polarization of the heart's atrium. As a variation, the analysis of the variation of the interval of time between two waves R enables atrial fibrillation to be detected.

[0119] The signaling step is then implemented.

[0120] During the signaling step, the second controller **135** commands the emission, through the man/machine interface **140**, of a warning signal for the patient P and/or his doctor.

[0121] The warning signal informs the patient P and/or his doctor that the physiological phenomenon has occurred. For example, the warning signal contains a date on which the physiological phenomenon occurred, a frequency of appearance of the physiological phenomenon, a duration of the physiological phenomenon, or even a heart rate of the patient during the physiological phenomenon.

[0122] The warning signal is, for example, simultaneously transmitted to an emergency assistance agency. For example, the warning signal is sent to an emergency assistance agency via a wireless telephone network. As a variation, the warning signal is sent via the internet.

[0123] As the centralization device **20** is in the stomach, the replacement of the first reserve of electrical energy **90** is easy and can, for example, be simply and quickly performed by an endoscopy through the esophagus. Furthermore, the replacement of the first reserve of electrical energy **90** poses few risks of infection as no incision is made.

[0124] The use of attractors **110** makes the installation of the first reserve of electrical energy **90** even simpler, even without an endoscopy, as the patient P need only swallow the first reserve of electrical energy **90**.

[0125] Furthermore, the implantable system **10** does not involve the patient P permanently carrying the means of electrical energy storage outside his body, or unsightly electrical conductors protruding from the body of the patient P. The implantable system **10** therefore imposes few constraints on the patient.

[0126] The upper part of the stomach **30** is close to the heart C, and the contractions of the heart C therefore cause the centralization device **20** to move. Since an acceleration sensor **117** is positioned in the stomach, atrial fibrillation is effectively detected, not only by an electrical measurement of the heart's activity but also by measuring the acceleration of the centralization device **20**.

[0127] The implantable system thus improves the safety of the patient P.

[0128] Furthermore, positioning the centralization device **20** in the stomach also reduces the constraints for the patient P.

[0129] Furthermore, the data acquired by the sensors **117** is processed by the second device **25**, which is located outside the patient's body. The electrical consumption of the centralization device **20** is thus limited, which reduces the frequency with which the electrical supply of the centralization device **20** must be changed. The constraints for the patient P are thus further limited.

[0130] According to a variation of the first example, the measurement step is implemented during non-continuous time ranges, separated by second time ranges during which no value is measured. According to one embodiment, the first time ranges last for **30** seconds and the second time ranges last for **30** minutes.

[0131] Thus, the first device **20** is dormant for a large proportion of time. The energy consumption of the implantation system is therefore reduced. This embodiment is particularly suitable for the detection of physiological phenomena that have a slow development, such as heart failure.

[0132] The first example of an implantable system **10** has been given for the case of detecting atrial fibrillation in the patient P. As a variation, the implantable system **10** can also enable other cardio-vascular diseases to be detected, such as heart failure. However, it should be noted that positioning the centralization device in the stomach **30** of the patient P enables the parameters of a wide variety of organs C to be measured. The implantable system **10** can therefore be adapted to detect a large number of distinct physiological phenomena.

[0133] For example, the physiological phenomenon is a respiratory disorder. Chronic obstructive pulmonary disease is an example of a respiratory disorder.

[0134] As a variation, the physiological phenomenon is emphysema.

[0135] According to another variation, the physiological phenomenon is epilepsy.

[0136] According to another variation, the physiological phenomenon is an eating disorder.

[0137] According to another variation, the physiological phenomenon is sleep apnea. For example, the sensor **117** is able to detect a contraction of the diaphragm and the second controller **135** is configured to detect sleep apnea if a period of time without contraction of the diaphragm lasts longer than or equal to a predetermined threshold.

[0138] According to another variation, the physiological phenomenon is a swallowing disorder, or even an eating disorder such as insufficient hydration.

[0139] Moreover, numerous types of sensors **117** can be used.

[0140] For example, the sensor **117** is a light emitter/receiver comprising at least one light source and at least one detector of light radiation. For example, the sensor **117** comprises two light sources. According to one embodiment, the sensor **117** then comprises two detectors of light radiation.

[0141] The light source(s) are configured to illuminate at least one portion of an organ of a patient P with light radiation. For example, each light source is configured to illuminate a portion of the heart muscle. The portion is, for example, a portion of a heart cavity.

[0142] The illuminated organ is, as a variation, a blood vessel such as the aorta of the patient P.

[0143] As a variation, the blood vessel is the vena cava.

[0144] According to another variation, the illuminated organ is the gastric wall.

[0145] According to another variation, the illuminated organ is the diaphragm.

[0146] Each light radiation has a wavelength. For example, at least one wavelength is chosen for its level of absorption or reflection by certain molecules. For example, at least one light radiation has a visible wavelength. A wavelength equal to 660 nanometers is an example of visible wavelength.

[0147] According to one variation, the light radiation of at least one light source is an infrared light radiation. For example, the infrared radiation has a wavelength equal to 950 nanometers.

[0148] According to one embodiment, one wavelength is equal to 660 nanometers and another wavelength is equal to 950 nanometers. These wavelengths are absorbed and/or reflected differently by the unsaturated hemoglobin (known as Hb) and saturated hemoglobin (known as HbO_2), and thus enable a good evaluation of the relationship between these two molecules.

[0149] The detector is configured to measure a value of a level of reflection of each light radiation on the illuminated organ. For example, the detector comprises a photodiode.

[0150] As a variation, the detector is configured to measure a level of absorption of each light radiation.

[0151] The second controller **135** is configured to receive from the detector the values of level of reflection measured, and to calculate a level of oxygenation of the blood circulating in the illuminated organ on the basis of the values received. For example, the second controller **135** is configured to calculate a level of oxygenation of the capillary blood circulating in the gastric wall. As a variation, the second controller **135** is configured to calculate a level of oxygenation of the capillary blood circulating in the heart muscle, or blood present in the cardiac cavities, or blood present in the aorta or in the vena cava.

[0152] The physiological phenomenon that the implantable system **10** is able to detect is therefore a drop in the oxygen saturation of the hemoglobin of the patient P. This drop is caused, for example, by a heart or respiratory disease.

[0153] According to another variation, at least one sensor is a sensor of a biological marker of a body fluid F of the patient P. The body fluid F is, for example, the contents of the stomach or the extracellular fluid at the stomach wall where the first device **20** is implanted.

[0154] According to another variation, the centralization device **20** comprises a first catheter configured to convey a body fluid F of the patient P from the organ C to the sensor **117**. For example, the organ C is the peritoneum and the fluid F is the peritoneal fluid.

[0155] The biological marker is, for example, glucose. As a variation the biological marker is an ion present in the body fluid F. For example, the sensor **117** is capable of measuring the pH of the body fluid F. In particular, the sensor **117** is capable of measuring the pH of the gastric contents or peritoneal fluid of the patient P.

[0156] The sensor **117** is therefore capable of measuring a level of biological marker in the body fluid F. For example, the sensor **117** is capable of measuring a glucose level in the peritoneal fluid, and the first calculator **45** is capable of estimating a blood sugar value of the patient P.

[0157] According to another variation, at least one sensor **117** is configured to estimate an orientation of the centralization device **20** in relation to the vertical. The first controller **45** is then configured to detect a position of the patient P. In particular, the first controller **45** is configured to detect a lying position, a sitting position or an intermediate position between the lying and sitting positions of the patient P.

[0158] For example, the sensor **117** comprises at least one element from the list formed by: a gyroscope, a magnetometer and an accelerometer.

[0159] According to another variation, at least one sensor **117** is capable of measuring a body temperature of the patient P. According to another variation, at least one sensor **117** is a microphone.

[0160] The sensor **117** is configured to measure a noise emitted by the organ C. The second controller **135** is capable of detecting the physiological phenomenon on the basis of the analysis of the noises measured. For example, the second controller **135** is capable of detecting a heart rate disorder, a heart valve anomaly, a lung disease or even a digestive disorder on the basis of the noises measured.

[0161] According to another variation, at least one sensor **117** is an ultrasound emitter/receiver. For example, the sensor **117** is capable of emitting at least one ultrasonic beam and of measuring a parameter of a beam reflected on all or part of the heart of the patient P. The parameter of the beam is, for example, a level of reflection, or even a phase shift.

[0162] The second controller **135** is, for example, capable of calculating a dimension or an amplitude of contraction of the heart of the patient P on the basis of measurements provided by the sensor **117**. In particular, the second controller **135** is configured to calculate an ejection fraction of the heart on the basis of the dimensions or amplitudes of contraction measured.

[0163] As a variation, the beam emitted is reflected on a blood vessel such as the aorta and the operating data comprise a variation in the diameter of the blood vessel. According to a variation, the vessel is the vena cava.

[0164] According to one embodiment, the sensor **117** is configured to evaluate a blood flow or a blood pressure in a blood vessel by Doppler effect.

[0165] A pressure sensor is another example of the sensor **117**.

[0166] According to another variation, the first device **20** comprises several sensors **117**, and the second controller **135** is configured to detect the physiological phenomenon on the basis of values measured by at least two sensors **117**. According to another variation, the second controller **135** is capable of detecting at least two distinct physiological phenomena on the basis of values measured by the sensor(s) **117**.

[0167] A second example of an implantable system **10** will now be described. The elements identical to the first example of an implantable system **10** in FIG. **1** will not be described again. Only the differences will be highlighted.

[0168] The implantable system **10** comprises two second devices **25**.

[0169] One of the two devices **25** is a display device as previously described. The other second device **25** will henceforth be referred to by the expression "measurement device". In order to distinguish one from the other, the two second devices **25** will henceforth be referred to in the second example by the expressions "display device" and "measurement device" respectively.

[0170] The measurement device **25** is implanted, in its operating position, in the body of the patient P. In particular, the measurement device **25** is implanted outside the stomach **30** of the patient P.

[0171] According to a variation, the measurement device **25** is not implanted in the body of the patient P but is carried by the patient P. For example, the measurement device **25** is fixed around a limb of the patient P by a strap. It will be noted that other operating positions and other methods of fixation can be envisaged.

[0172] The measurement device **25** does not comprise a man-machine interface **140**.

[0173] The measurement device **25** comprises at least one sensor **117**.

[0174] The second emitter/receiver **120** of the measurement device **25** is configured to transmit to the first emitter/receiver **60** the measured values.

[0175] The first memory **75** is, furthermore, configured to store the values measured by the sensor(s) of the measurement device **25**.

[0176] The first emitter/receiver **60** is configured to transmit to the display device the values measured by the sensor(s) **117** of the measurement device **25**.

[0177] The second controller **135** is then configured to detect at least one physiological phenomenon on the basis of at least one of the values measured by the sensor(s) **117** of the measurement device **25**.

[0178] The implantable system **10** is then capable of being used for the detection of physiological phenomena for which positioning of the sensor **117** in the stomach is not favorable.

[0179] According to a variation of the second example, the centralization device **20** does not comprise a sensor **117**. Only the measurement device **25** comprises at least one sensor **117**. The centralization device **20** then plays a role of storage and transmission to the display device **25** of the measured values.

[0180] According to another variation, the implantable system **10** comprises at least two measurement devices **25**.

[0181] A third example of an implantable system **10** will now be described. The elements identical to the first example of implantable system **10** will not be described again. Only the differences will be highlighted.

[0182] The electrical supply **55** does not comprise a third connector **85** or an electrical energy reserve **90**.

[0183] The electrical supply **55** comprises an electrical energy generator. An "electrical energy generator" means that the electrical energy generator is not configured to be charged with electrical energy by an electrical current.

[0184] The electrical energy generator is capable of generating at least one electrical current by reaction of at least one chemical species present in the body of the patient P. More precisely, the electrical energy generator is capable of generating the supply current C.

[0185] For example, the electrical energy generator comprises two electrodes, the electrodes being bathed in the gastric juices of the patient P when the centralization device **20** is in the fixation position. As a variation, the electrodes of the electrical energy generator are provided to be bathed in the intestine of the patient P when the centralization device **20** is in the fixation position.

[0186] Each electrode comprises at least one enzyme. As a variation, each electrode comprises at least one microorganism. For example, each electrode of the electrical energy generator comprises an electrical conductor covered with the enzyme or microorganism, the assembly thus formed being surrounded by a membrane. The membrane is, for example, configured to be passed through by certain chemical species naturally present in the stomach or intestine of the patient P.

[0187] When the electrodes of the generator of electrical energy are immersed in the gastric juices or in the intestinal fluid, one of the electrodes plays the role of anode in a redox reaction involving a first chemical species. Simultaneously, the other electrode plays the role of a cathode in a redox reaction involving a second chemical species.

[0188] By oxidation and the simultaneous reduction of the first chemical species and of the second chemical species, an electrical voltage appears between the two electrical conductors. The supply current C is then generated.

[0189] The first chemical species is, for example, glucose. The second chemical species is, for example, oxygen.

[0190] The third example of an implantable system **10** does not require an electrical energy reserve **90** to be electrically charged or the electrical energy reserve **90** to penetrate the body of the patient P.

[0191] Here, too, the constraints for the patient P are reduced.

[0192] According to a fourth example, the electrical energy generator is capable of generating at least one electrical current by conversion of a mechanical energy into an electrical energy. In particular, the electrical energy generator is capable of generating at least one electrical current on the basis of the movements of the stomach **30**.

[0193] According to a fifth example, the first controller **45** detects the physiological phenomenon on the basis of the measured values. Only one message comprising the results of the detection is transmitted to the second device **25**.

[0194] In the above description, the functions of the implantable system **10** have been separated into several examples in order to make them more easily understood by the reader. However, it will be noted that the preceding examples are capable of being combined in order to generate new embodiments.

[0195] The implantable system **10** is particularly suitable for the detection of heart failure. In this case, at least one of the sensors **117** is chosen from the assembly formed by: a sensor measuring a difference in electrical potential, an accelerometer, an ultrasound emitter/receiver, a light emitter/receiver and a microphone. For example, two sensors **117** integrated into the centralization device **20** are chosen from the assembly formed by: a sensor measuring a difference in electrical potential, an accelerometer, an ultrasound emitter/receiver, a light emitter/receiver and a microphone.

[0196] The second controller **135** is then configured to detect heart failure on the basis of values measured by the

sensors **117** and/or on the basis of operating data calculated on the basis of values measured by the sensors **117**.

[0197] For example, the second controller **135** is configured to detect heart failure on the basis of values of electrical potential.

[0198] For example, the second controller **135** is configured to detect heart failure on the basis of acceleration values.

[0199] According to one embodiment, the second controller **135** is configured to detect heart failure on the basis of a combination of values of electrical potential, acceleration and orientation of the patient.

[0200] For example, the second controller **135** if configured to detect heart failure on the basis of oxygenation level values of the blood or an ejection fraction of the heart.

[0201] For example, the second controller **135** is configured to detect heart failure on the basis of a combination of values measured by all of the sensors **117** and of values of all of the operating data.

[0202] If one of the sensors **117** is an ultrasound emitter/receiver, the second controller **135** calculates an ejection fraction of the heart on the basis of variations in the dimensions of the heart and detects heart failure if the ejection fraction is below or equal to a corresponding threshold.

[0203] As a variation, heart failure is detected on the basis of an analysis of the noises made by the heart or lung.

[0204] Moreover, the above description has been given in the case where the anchor **15** and the centralization device **20** form two separate devices. It will be noted that the centralization device **20** and the anchor are capable of forming a single device, the anchor **15** and the centralization device **20** not then being separable from one another. For example, the anchor **15** is formed in one piece with the case **65** of the centralization device **20**.

[0205] According to yet another example, the head **35** comprises at least one pad located outside the stomach **30**. For example, the head **35** comprises two pads.

[0206] Each pad is configured to rest against the outer face of the wall of the stomach **30** and to be connected to the implantable device **20** so as to exert a force tending to hold the implantable device **20** flat against the inner face of the wall of the stomach **30**. According to a variation, each pad is configured to be placed between the visceral sheet and the parietal sheet of the peritoneum and to rest against the visceral sheet in order to hold the implantable device **20** flat against the inner face of the wall of the stomach **30**.

[0207] Each pad is, for example, a plate. As a variation, each pad comprises a wire mesh stretched over a frame, in particular a flexible frame capable of being folded and inserted in an endoscope or a hollow needle.

[0208] The first connector **40** comprises, for example, one or more rings integral with the case **65**. Each pad is, for example, fixed to the implantable device **20** by one or more wires fixed to one or more of the rings.

[0209] The fixation by one or more pads allows the pressure exerted by the implantable device to be distributed over a larger surface area of the wall of the stomach **30** and so reduce the pressure thus exerted. Furthermore, this method of fixation does not entail generating in the stomach wall a fold that reduces the volume of the stomach, which is capable of generating tensions in the anchor that is fixed therein. Since the forces exerted on the stomach wall are reduced, the risks of appearance of an inflammatory reaction of the gastric mucosa are limited.

1. Implantable system (**10**) comprising:

a first device (**20**), called a centralization device, which is able to be fixed in a fixation position to a wall of the stomach (**30**) of a patient (P), the centralization device (**20**) being received in the stomach (**30**) when the centralization device (**20**) is in the fixation position, and

at least one second device (**25**),

the implantable system (**10**) being characterized in that the centralization device (**20**) comprises a controller (**45**), an electrical supply (**55**) and an emitter/receiver (**60**) to permit communication between the centralization device (**20**) and the second device (**25**) when the second device (**25**) is in a functioning position, the second device (**25**) being situated outside the body of the patient (P) when the second device (**25**) is in the functioning position, wherein:

the centralization device (**20**) comprises a sensor (**117**) able to measure a value of a physiological parameter of the patient (P), the emitter/receiver (**60**) being configured so as to transmit to a second device (**25**) the measured values, the second device (**25**) considered to be able to detect a physiological phenomenon of the patient (P) on the basis of at least one of the measured values, or

the implantable system (**10**) comprises two second devices wherein one of the second devices (**25**) comprises at least one sensor (**117**) able to measure a value of a physiological parameter of the patient (P), the emitter/receiver (**60**) being configured to receive from the second device (**25**) comprising a sensor (**117**) the measured values and to transmit the measured values to the other second device, the other second device (**25**) being able to detect a physiological phenomenon of the patient (P) on the basis of at least one of the values received from the emitter/receiver (**60**).

2. Implantable system (**10**) according to claim **1**, wherein the centralization device (**20**) is configured to communicate with each second device (**25**) by radiofrequency communication.

3. Implantable system (**10**) according to claim **1**, wherein the controller (**45**) comprises a memory (**75**) able to store the measured values for a period of more than or equal to one day.

4. Implantable system (**10**) according to claim **1**, wherein the physiological phenomenon is a cardiac pathology.

5. Implantable system (**10**) according to claim **4**, wherein the cardiac pathology is heart failure.

6. Implantable system (**10**) according to claim **1**, wherein the sensor (**117**) is an ultrasound emitter/receiver.

7. Implantable system (**10**) according to claim **1**, wherein the sensor (**117**) is an accelerometer able to measure values of an acceleration of the centralization device (**20**) and the second device (**25**) is configured to calculate a physiological parameter of the heart of the patient (P) from the measured acceleration values.

8. Implantable system (**10**) according to claim **1**, wherein the sensor (**117**) is able to measure a difference in electrical potential, an acceleration, a noise, an orientation, a pH or a temperature.

9. Implantable system (**10**) according to claim **1**, wherein the centralization device (**20**) comprises a catheter able to

convey a body fluid (F) of the patient (P) to the sensor (**117**), the sensor (**117**) being able to measure a level of a biological marker in the body fluid (F).

10. Implantable system (**10**) according to claim **1**, wherein the sensor (**117**) comprises at least one light source and at least one detector of light radiation, the light source being configured to illuminate at least one portion of an organ of the patient (P) with light radiation, the detector being configured to measure a value of a level of reflection of the light radiation, the controller (**45**) being configured to calculate an oxygenation level of the blood circulating in the organ illuminated by the light source, based on the level of reflection.

11. Implantable system (**10**) according to claim **1**, comprising a plurality of sensors (**117**), wherein the second device (**25**) is able to detect the physiological phenomenon on the basis of the values of at least two sensors (**117**).

12. Implantable system (**10**) according to claim **1**, wherein the physiological phenomenon is chosen from the group formed by: a cardiac dysrhythmia disorder, atrial fibrillation, syncope, heart failure, sleep apnea, chronic obstructive pulmonary disease, emphysema, epilepsy, a swallowing disorder, an eating disorder.

13. Implantable system (**10**) according to claim **1**, wherein the electrical supply (**55**) comprises a removable reserve of electrical energy (**90**) and a connector (**85**) able to receive the reserve of electrical energy (**90**), the reserve of electrical energy (**90**) being able to electrically supply the controller (**45**) when the reserve of electrical energy (**90**) is connected electrically to the connector (**85**) in a connection position and preferably being configured to be swallowed by the patient (P) and to move spontaneously to the connection position from a disconnection position in which the reserve of electrical energy (**90**) is received in the stomach (**30**) of the patient (P) and is disconnected from the connector (**85**).

14. Implantable system (**10**) according to claim **1**, wherein the electrical supply (**55**) comprises an electrical energy generator able to generate an electrical current by reaction of at least one chemical species present in the body of the patient (P), particularly glucose.

15. Implantable system (**10**) according to claim **1**, wherein the electrical supply (**55**) comprises an electrical energy generator able to generate an electrical current by the conversion of mechanical energy into electrical energy.

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摘要(译)

本发明涉及一种包括第一装置20的植入式系统10，该第一装置称为对中装置，该第一装置能够在固定位置上固定至患者的胃壁，该对中装置 当集中装置20处于固定位置时，20和至少一个第二装置25被接收在胃中。可植入系统10的特征在于，集中装置20包括控制器45，电源55和发射器/接收器60以允许通信 当第二设备25处于功能位置时，第二设备25位于集中设备20和第二设备25之间，并且第二设备25位于患者体外 第二个设备25处于运行位置。