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(54) **HEMODYNAMIC PERFORMANCE ENHANCEMENT THROUGH ASYMPTOMATIC DIAPHRAGM STIMULATION**

VERSTÄRKUNG EINER HÄMODYNAMISCHEN LEISTUNG DURCH ASYMPTOMATISCHE MEMBRANENSTIMULATION

AMÉLIORATION APPORTÉE À DES PERFORMANCES HÉMODYNAMIQUES PAR LE BIAIS D'UNE STIMULATION DE DIAPHRAGME ASYMPTOMATIQUE

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Description

Cross-Reference to Related Application

[0001] This application claims filing-date priority to U.S. Provisional Patent Application Serial No. 61/739,704, filed December 19, 2012, for "Hemodynamic Performance Enhancement Through Asymptomatic Diaphragm Stimulation to the Diaphragm/Heart Interface".

Background and Summary of the Invention

[0002] The present invention pertains to an implantable medical system, and to an associated methodology, employing, and managed by electrical circuit structure, which features logic-including, internal-control circuitry referred to herein as computer structure, or more simply as a computer, for enhancing hemodynamic performance in subjects with cardiac disease through applying carefully timed, regular, per-cardiac-cycle, synchronized, asymptomatic, electrical pulsed stimulation to the diaphragm intended to induce short-term occurrences of biphasic diaphragmatic motion. In particular, it relates to such a system and methodology which, in relation to each such stimulation, and through operation of the included control circuitry (which forms part of what is referred to as electrical circuit structure), monitors and records information regarding resulting, induced diaphragmatic-motion for later review, and to accommodate potential, telemetry-adjusted, systemic-performance adaptation to improve diaphragmatic stimulation characteristics so as to maximize the sought hemodynamic-performance enhancement. The system preferably additionally permits, in a modified form, selective, remote-telemetry-implemented communication from outside the anatomy to allow for other kinds of system-behavioral adjustments, such as ones that relate to timing matters.

[0003] The term "hemodynamic performance" is used synonymously herein with the terms "cardiovascular performance" and "cardiac function". The biphasic diaphragmatic motion produced by electrical stimulation, in accordance with practice of the invention, is what is called herein caudal-followed-by-cranial motion of the diaphragm. The included "computer-structure" logic componentry, which may be hard-wired to perform its intended functions, or more preferably fully or partially programmable, as by telemetry, may also feature an appropriate microprocessor. It may also include, or be appropriately internally associated with, a suitable "state machine" for implementing various important timing controls, as will be explained below.

[0004] Pulsed stimulation of the type just above mentioned, properly characterized and applied, triggers, in each case, a very short (only a few tens of milliseconds) pulse-like, biphasic (singular-caudal-followed-by-singular-cranial) motion of the diaphragm, and, relatedly also, a substantially following pumping-relevant motion of the left ventricle in the heart which rests on the diaphragm.

This stimulation creates this motion-generating activity in a manner which, when properly and synchronously timed in relation to the onset of left-ventricular contraction, improves hemodynamic performance through enhancing the important cardiac pumping functions of both (a) late diastolic filling, and (b) early systolic contraction.

[0005] Asymptomatic stimulation implemented in the practice of the present invention is also referred to herein as PIDS stimulation - the acronym PIDS standing for the phrase "pacing induced diaphragmatic stimulation". The mentioned monitoring and recording for later stimulation-characteristic review, and possible revision purposes, are linked with systemically control-circuitry-performed comparing of actual induced diaphragmatic-motion waveforms with a provided and internally stored reference waveform.

[0006] Of key importance in all featural expressions of the present invention, systemic and methodologic, are (1) that sensing of what is referred to herein as a valid electrical or mechanical V-event, and (2) that related, sensing-based, ultimate applying of electrical stimulation to the diaphragm, take place, with the system installed for use with a subject, from an implanted systemic disposition directly adjacent, and preferably in contact with, a selected surface region in the subject's diaphragm. Preferably, but not necessarily, this selected surface region, which may be either an inferior (preferred), or a superior, surface region in the diaphragm, and which may be chosen to be at many different, diaphragmatic surface locations, is disposed left-lateral relative to the subject's anatomy - and under all circumstances, out of contact with the heart.

[0007] A V-event, in either category (electrical or mechanical), is defined herein as being either the onset of left-ventricular contraction, or a cardiac electrical or mechanical event having a predictably known relationship to such an onset. A valid electrical V-event is treated as being either the electrical R or Q wave, and a valid mechanical V-event is treated as being the S1 heart sound. Cardiac-cycle-by-cardiac-cycle, synchronized, diaphragmatic stimulation is timed, selectively in different ways - anticipatory (early), or following (late) -- in relation to per-cardiac-cycle, detected, valid V-events.

[0008] Of special importance in certain featural expressions of the present invention, systemic and methodologic, is the effective incorporation in the proposed system and associated methodology of a focus, through the use of a system-included accelerometer, preferably multi-axial in character, and even more preferably three-dimensional in nature, on the monitoring and recording of the mechanical waveform of per-cardiac-cycle, mechanical diaphragmatic biphasic motion which is *actually* produced by applied, electrical diaphragmatic stimulation in comparison with a preset, diaphragmatic-motion reference waveform. Information regarding non-conformance of these two waveforms - computer acquired and recorded according to the invention -- is important for periodic system-performance review, and in this context, is very

useful to support the making, when desired, of appropriate, per-cardiac-cycle, electrical stimulation-character modifications to enhance such performance.

[0009] It should be noted that while different embodiments of the invention may use different-axial-sensitivity accelerometers, preferred in most applications is the inclusion and use of a three-dimensional, i.e., three-axis, accelerometer. Accordingly, the preferred systemic and methodologic invention descriptions presented herein-below are described in the context of employment of a three-dimensional accelerometer.

[0010] Two, principal, implantable systemic forms, or embodiments, of the invention are proposed, one of which features, as an entirety - i.e., as a singularity -- a self-contained, self-powered, singular capsule construction, and the other of which features a distribution, also self-powered, of components organized into two arrangements of components separated by an interconnecting, cross-communication lead structure.

[0011] Other forms of the invention, not pictured or discussed herein, and differing specifically from the two, just-mentioned currently principal, preferred forms, are recognized to be very suitably possible to address different implantation applications, wherein the various system components, described below for the two invention forms particularly set forth herein, become organized in different implantable ways.

[0012] Regarding systemic performance functionality in the context of the present invention disclosure, the same, basic invention methodology, in terms of the important, end-result achieving of hemodynamic/cardio-vascular performance enhancement through triggered pulses of biphasic motion introduced into the diaphragm (as above outlined), is implemented in both of the specifically herein described systemic invention forms.

[0013] Stimulation-induced diaphragmatic movements, as just generally described above, are, in relation to normal respiration-motion frequency (typically about 0.2-0.3-Hz), and as mentioned, short-term, relatively high-frequency (typically about 12-15-Hz), pulse-like motions. These quick motions are superimposed on the regular, and much lower frequency, diaphragmatic respiration movements. The initial, short-term caudal movement effected by diaphragmatic stimulation pulls on the left ventricle, and if well timed, such stimulation-resulting "pulling" increases the atrial contribution to left-ventricular filling during late diastole (i.e., a so-called "atrial kick") with a resulting subsequent increase in stroke volume via the recognized, Frank-Starling mechanism. The secondary, stimulation-induced movement of the diaphragm which is cranial, and which is also much faster than regular diaphragmatic respiratory motion, causes the left ventricle to be "kicked" upwardly, and if this secondary movement occurs in the early part of systole, and prior to the closure of the mitral valve, it enhances cardiac function further by increasing the momentum of ventricular contraction.

[0014] Accordingly, in relation to achieving desired he-

modynamic-enhancement, it is important to optimize the timing between the onset of ventricular contraction and diaphragmatic stimulation so that the actual timing and impact of the mentioned caudal and cranial components of motion as they affect cardiac function are maximized. Such maximizing is subject-specific, in relation, of course, to a given subject's particular cardiac structure (electrically and mechanically), and accordingly, medically-determined, properly associated, subject-specific timing requirements are initially "set into the system of the invention", as will be explained. When all operational parameters are properly "put in place", the present invention successfully accomplishes appreciable hemodynamic-performance optimization.

[0015] As mentioned above, two, fully implantable, and fully self-powered, principal embodiments of the system of the present invention are specifically illustrated and described herein, one of which, as stated above, is a single-unit, self-contained, capsule-form arrangement, and the other of which has a distributed-component, communication-lead-line-interconnecting form.

[0016] According to one manner of describing generally the structural nature of the present invention, what is proposed is a system including (a) bi-modal (cardiac-electrical-activity sensing in one mode, and related diaphragmatic electrical stimulating in the other mode) electrode structure operatively connectable to a selected surface region in a subject's diaphragm, and (b) monitoring and controlling circuit structure which is connected to the electrode structure, and operable (1) to receive and process electrode-structure-sensed electrical cardiac activity when the electrode structure, under the influence of the circuit structure, is functioning in its sensing mode, and (2), based on such receiving and processing, to communicate to the diaphragm via the electrode structure, when the latter is functioning, also under the influence of the circuit structure, in its stimulating mode, appropriate diaphragmatic stimulation.

[0017] In a more particular sense respecting this just-above-presented systemic expression of the invention, (a) the selected, diaphragmatic surface region is disposed (1) preferably, but not necessarily, at a location which is lateral, and even more specifically left-lateral, within a subject's anatomy, and (2) in all instances out of contact with, the subject's heart, and (b) the mentioned circuit structure includes computer structure which specifically operates, relative to the circuit structure's delivery of electrical stimulation through the electrode structure, to control appropriately predetermined timed relationships relative to noted presences, in received and monitored cardiac-cycle electrical-activity information, of valid electrical V-events. Additionally, contemplated in the practice of the invention are two, different categories of such predetermined timed, or timing, relationships, one of which involves anticipation of a next-expected, valid, cardiac-cycle, electrical V-event, and the other of which involves a following of the last-sensed, valid, cardiac-cycle, electrical V-event. These same, two catego-

ries of timing relationships are equally applicable to another form of the system of the invention, discussed below, which further includes an accelerometer (single or plural-axis), also referred to herein as a mechanical sensing structure, that is designed to detect heart sounds, and in particular S1 heart sounds, as valid mechanical V-events.

[0018] An augmented form (the "another form" of the invention mentioned immediately above) of this just-presented description of the invention is one in which the proposed system further includes specifically a three-dimensional accelerometer (called also a mechanical sensing structure), (a) disposed adjacent, and operatively associated with, the electrode structure for contact-associated disposition in a motion-sensing relationship with, and with respect to, the subject's diaphragm, (b) operatively connected to the mentioned circuit structure, and (c) constructed to be responsive to any motion produced in the subject's diaphragm as a consequence of electrical diaphragmatic stimulation, and in relation to such responsiveness, to generate and communicate to the circuit structure a diaphragmatic-motion confirmation signal possessing a waveform which is directly indicative of such motion.

[0019] In a further way of thinking about the accelerometer-including system form of the invention, the circuit structure's included computer structure features a waveform monitoring and recording substructure for comparing the waveform of a communicated confirmation signal with a reference waveform, and recording the conformation-signal waveform for subsequent review.

[0020] Another way of thinking about the invention, in relation to the inclusion therein of an accelerometer, is that, in accordance with a modified form of the invention, (a) an included accelerometer functions, additionally, for sensing, in a subject's cardiac cycles, cardiac-cycle, S1 heart-sound, mechanical activity - a valid mechanical V-event -- which is discernible at the selected, diaphragmatic surface region, and that (b), the included circuit structure receives this mechanical valid V-event information from the accelerometer, and is operable, in predetermined timed relationships to noted presences, in such received mechanical S1-heart-sound, of valid V-event information, to deliver asymptomatic electrical stimulation through the electrode structure to the subject's diaphragm for the purpose of triggering the intended biphasic, caudal-followed-by-cranial, motion of the diaphragm.

[0021] A further modified form of the basic system of the invention, contemplated for implementation in certain applications, and representationally pictured, described and included herein in each of the two principal embodiments disclosed, is one wherein the computer structure which forms part of the included circuit structure possesses timing-adjustment substructure capable of making an adjustment periodically in the predetermined timed relationship which determines when, in relation to a sensed, valid V-event, electrical diaphragmatic stimulation occurs. This modification is versatile in its utility, offering

the possibility of adjusting, either remotely, or internally automatically if desired, such stimulation timing in a manner aimed at further enhancing a subject's hemodynamic performance if, and as, the subject's heart-behavior conditions change over time.

[0022] These and other systemic aspects of the invention, preferred and modified, are discussed below herein.

[0023] From a methodologic point of view the invention offers a method for improving the hemodynamic performance of a subject's heart including, from adjacent a selected surface region in the subject's diaphragm which is out of contact with, the heart, (1) sensing and noting the presences in the subject's cardiac cycles of a selected one of (a) per-cycle valid electrical, and (b) per-cycle valid mechanical, V-events, (2) based upon such sensing, and upon noting each of such selected, V-event presences, applying, in a predetermined timed relationship to such a noting, associated, asymptomatic electrical stimulation directly to the diaphragm, preferably at the selected diaphragmatic surface region, for the purpose of triggering biphasic, caudal-followed-by-cranial motion of the diaphragm, (3) following the applying step, monitoring the waveform of resulting diaphragmatic motion, (4) after performing the monitoring step, comparing the monitored diaphragmatic-motion waveform with a reference, diaphragmatic-motion waveform, and (5) on completion of the comparing step, recording the monitored, diaphragmatic-motion waveform for later review.

[0024] The invention methodology further includes (1) choosing the selected diaphragmatic surface region to be on one of (a) the inferior, and (b) the superior, side of the diaphragm, and (2) choosing the selected, per-cycle valid V-event whereby, if it is to be electrical, it is one of (a) the R wave, and (b) the Q wave, and if mechanical, it is the S1 heart sound. Both documents US 2006/122661 A1 and US 2009/024176 A1 disclose an implantable device which detect cardiac activity and provide stimulation in same region. Their disclosure fails to mention detecting ventricular contraction events. Further, the US2009 document fails to disclose synchronizing diaphragmatic stimulation with detecting electrical cardiac activity.

[0025] These and various other features and advantages that are offered by the system and methodology of the present invention will become more fully apparent as the detailed description of the invention which follows below is read in conjunction with the accompanying drawings. Several exemplary embodiments are disclosed throughout the present text. The invention and scope of protection however is defined in the appended claims.

Descriptions of the Drawings

[0026]

Fig. 1 is an isometric, electrode-side, facial view of a fully implantable fully self-contained, self-powered, singular capsule-form embodiment of the system of

the present invention.

Fig. 2 is a same-scale, lateral isometric view of the embodiment shown in Fig. 1, slightly rotated about two axes relative to what is seen in Fig. 1.

Fig. 3 is a plan view of the invention embodiment shown in Figs. 1 and 2, drawn on about the same scale used in these two figures, and pictured with the body of the capsule in this embodiment opened to show internally contained electrical circuitry, an accelerometer, and an included battery.

Fig. 4, which uses the same drawing scale as that seen in Fig. 3, is a lateral cross section taken generally from the lower side of Fig. 3.

Fig. 5 is a basic block/schematic diagram illustrating electrical and mechanical componentry employed in the system of the invention and incorporated both in the invention embodiment pictured in Figs. 1-4, inclusive, and in the still-to-be-mentioned, alternative embodiment shown in Fig. 8.

Fig. 6A is a frontal view of an internal portion of a subject's anatomy illustrating preferred, implanted positioning therein proposed for the system embodiment shown in Figs. 1-4, inclusive.

Fig. 6B is similar to, and is drawn on about the same scale as that employed in, Fig. 6A, except that it shows an alternative placement in the anatomy for the system of Figs. 1-4, inclusive.

Figs. 7A, 7B present enlarged-scale, fragmentary portions of the anatomical structure shown in Figs. 6A, 6B, with the system of Figs. 1-4, inclusive, removed for clarity purposes, illustrating, specifically, biphasic mechanical movement, or motion, of the heart resulting from electrical stimulation, and resulting mechanical motion, of the diaphragm and heart in accordance with practice of the methodology of the present invention. Fig. 7A pictures a condition of asymptomatic-stimulation-produced caudal diaphragmatic motion, and Fig. 7B a condition of related, immediate-time-following, cranial diaphragmatic motion.

The statements just made, which draw relationships between conditions pictured in Figs. 7A, 7B, with respect to Figs. 6A, 6B, respectively, are equally applicable to relationships that exist between Figs. 7A, 7B, and still-to-be-described Figs. 9A, 9B.

Fig. 8 illustrates an alternative, fully implantable systemic embodiment of the present invention -- one which has a distributed structural characteristic resulting from the condition that certain components in this embodiment are arranged in two assemblies that are separated from one another by an interconnecting communication lead structure.

Figs 9A, 9B are similar to Figs. 6A, 6B, respectively, differing in that they illustrate two, alternative, proposed internal anatomical placements for certain ones of the components included in the embodiment of the invention pictured in Fig. 8.

In Figs. 6A, 6B, 9A and 9B, the exposed anatomical

contents are greatly simplified in order to avoid unnecessary complexity without compromising disclosure necessity, and in this context, lower portions of the left-side phrenic nerve structure have been removed to afford better viewing clearance to see the positioning illustrated therein for implanted system structure.

The various structural and anatomical elements shown in Figs. 1-7B, inclusive, and in Figs. 9A and 9B, and the several moved anatomical positions, and changed anatomical configurations, pictured in Figs. 7A and 7B, are not necessarily drawn to scale.

Figs. 10 and 11 present two, different, laddergram illustrations picturing, respectively, what are referred to herein as early diaphragmatic, and late diaphragmatic, electrical stimulation.

Fig. 12 is a two-trace, common-time-base, graphical presentation relating to electrical V-event sensing, associated cardiac-cycle-synchronized, diaphragmatic stimulation, and resulting diaphragmatic and left-ventricle biphasic mechanical motions.

Fig. 13 furnishes an enlarged view of a single cardio cycle event pictured between a pair of spaced, vertical, short dashed lines in Fig. 12.

Fig. 14 is a high-level, block/schematic diagram illustrating both the basic, and one modified, form of the architecture of the methodology of the present invention.

30 Detailed Description of the Invention

[0027] Turning now to the drawings, and referring first of all to Figs. 1-5, inclusive, indicated generally at 20 is one preferred form of a self-contained, self-powered, fully implantable medical system constructed in accordance with the present invention for improving the hemodynamic performance of a subject's heart. System 20 accomplishes such improvement, as will be explained, through applying specially timed, cardiac-cycle-synchronized, asymptomatic, electrical stimulation directly to the subject's diaphragm to produce very short duration, relatively high-frequency (as mentioned above), bi-phasic motion of the diaphragm, which motion becomes communicated/applied directly to the underside of the left ventricle in the heart to create, essentially, a diaphragmatic-motion-following, bi-phasic "pumping" motion in and for the underside of, and thus within, the left-ventricle.

[0028] System 20, as seen in Figs. 1-4, inclusive, has what is referred to herein as a singular capsule form 22. This form features a small, easily implantable, elongate, thin, non-electrically-conductive, and appropriately bi-compatible capsule body, or capsule, 24 having the shape shown, with a length herein of about 1.25-inches, a width of about 0.5-inches, and a thickness of about 0.125-inches. Body 24, has a hollow interior 24a (see Figs. 3 and 4), and possesses an elongate, outside, diaphragm-contacting face 24b (see Figs. 1 and 2), also referred to herein as an electrode face, near the opposite

ends of which are positioned two, spaced (by about 1-inches), and outwardly exposed, bimodal electrodes 26, 28, referred to collectively herein as bimodal electrode structure. Electrodes 26, 28 present exposed, circular faces 26a, 28a, each having a diameter herein of about 0.15-inches. Generally speaking, these electrodes function, in an implanted-condition operation of system 20, both to sense heart-related electrical activity - done in a so-called first, or one, mode of operation, and to apply controlled, asymptomatic, electrical stimulation to the diaphragm - done in a so-called second, or other, independent mode of operation.

[0029] The specific capsule shape illustrated in Figs.1-4, inclusive, and the several specific dimensions just mentioned, are not critical, and may be varied selectively according user wishes to suit different, particular implantation applications. What is important, of course, is that the shape and dimensions of capsule 24 be suitable and comfortable, and designed for minimally invasive placement for operational residence within a subject's anatomy. As will be explained below, while preferred placement involves, effectively, stabilized attachment to a surface region which is near the upper portion of a subject's diaphragm (inferior or superior), there may be other diaphragmatic locations that are suitable for placement. The same statements just made about shape and sizing, addressed initially specifically herein with respect to the capsule form of the invention now being discussed, are also applicable to a still-to-be-described, second preferred embodiment pictured in Fig. 8. Respecting each of the two, principal forms of the invented system disclosed herein, while users/installers of it may readily choose various, different, appropriate, and preferably minimally-invasive, surgical procedures to carry out implantation within a subject's anatomy, laparoscopy is considered to be a good choice for system placement on the inferior side of the diaphragm, and thoracotomy, a good choice for such placement on the superior side of the diaphragm.

[0030] A suitable, conventional, non-electrically-conductive, biocompatible mesh 30 (see Figs. 1 and 2), is affixed to capsule face 24b to facilitate, following system implantation, natural-process anatomical bonding, for positional stabilization, to a selected surface region (inferior or superior) in/on a subject's diaphragm. Inclusion of such a mesh is optional, but useful. As will be further discussed, inferior surface-region placement on the diaphragm is preferred, and also preferably, though not necessarily, at a diaphragmatic location which is left-lateral in a subject's anatomy. Additionally, under all circumstances involving superior surface-region placement, such placement should be one where capsule 24 is out of direct contact with the heart.

[0031] Included in system 20, housed within the hollow interior 24a in capsule body 24, are various electrical and mechanico-electrical, system-operational components, including an electrical circuit structure 32 which, through the included presence in it of logic-including, internal-

control circuitry (still to be pointed out in the drawings), manages all system electrical-performance activity, a battery 34 which furnishes all needed operating power for the system, and a multi-axial (three-dimensional herein) accelerometer, or mechanical sensing structure, 36 which, with the system in an appropriate anatomically implanted condition, senses a variety of mechanical and sound activities, such as diaphragmatic-motion activities, and heart sounds. Regarding the accelerometer's sensing of diaphragmatic-motion activity, a sensing capability enhanced by its proposed, and intended, implanted placement in what is referred to herein as a motion-sensing relationship directly on the diaphragm, it produces an important electrical, diaphragmatic-motion confirmation signal for delivery to electrical circuit structure 32, which signal is directly indicative of the waveform of such motion. This signal is significantly useful for assuring that actually applied electrical diaphragmatic stimulation is as best-suited as possible for triggering the desired biphasic diaphragmatic movement intended to maximize hemodynamic performance enhancement. This assuring comes about because, according to the methodology of the present invention, the waveform represented by the accelerometer's supplied confirmation signal is regularly compared with a reference waveform "known" to the system of the invention.

[0032] Heart sounds sensed by the included accelerometer are useful for many purposes, and especially the S1 heart sound which is used, in an already (above) mentioned, modified form of the invention to act, and be recognized as, a valid mechanical V-event in relation to which appropriate timing for the application of a diaphragmatic stimulation is measured.

[0033] Other interesting information which may be obtained, if desired, from the response of the system-included accelerometer, not directly related to the practice and methodology of the present invention, but nevertheless available, for example, to a physician monitoring various subject conditions that may, in different ways, have a relationship to hemodynamic performance, include subject activity levels, subject body posture, respiratory information, such as respiration rate, sleep-disordered breathing events, heart murmurs, and perhaps others.

[0034] An operative connection between circuit structure 32 and accelerometer 36 is represented in Fig. 5 by conductors 36a, 36b.

[0035] Electrodes 26, 28 are operatively connected to circuit structure 32 for bimodal (sensing/stimulating) operation through what may be thought of as bidirectionally employed conductors 26b, 28b, respectively, and these electrodes, circuit structure 32, battery 34, and accelerometer 36 are all appropriately operatively interconnected to function collaboratively in manners shortly to be described.

[0036] Appropriate, conventional, analogue-to-digital, and digital-to-analogue converters, not specifically shown in the drawings, are incorporated where needed.

[0037] Electrical circuit structure 32, as mentioned

generally above, features what is referred to as logic-including, internal-control circuitry, also referred to herein as computer structure, or more simply as a computer, 38, possessing waveform monitoring and recording substructure 40, and optionally (representationally present herein), timing adjustment substructure 42. Preferably, computer 38, which could, if desired, be fully hard-wired to perform its intended functions, is herein incorporated and configured with a microprocessor, or the like, so as to be at least partially, if not fully, algorithmically software-programmable structure -- programmable, in the system now being described, not only initially, but, if desired at later times, by close-proximity telemetry communication accommodated through a system-included, conventional, short-range radio 44 having an antenna 44a. Computer 38 also includes a suitable, conventionally designed "state machine" (not specifically, separately illustrated in the drawings) for implementing various important timing controls, as will be explained below herein.

[0038] Choices for, and appropriate organizations of, specific electrical circuitry elements, including logic-structure computer-associated elements, and all hard-wired-managed, and/or software-dictated-and-managed, operational "programming" which controls systemic and methodologic functioning of the invention, are designable and includable employing conventional, state-of-the-art devices, algorithms, and other knowledge in the possessions of those persons who are generally skilled in the relevant arts, and for that reason are not specifically detailed herein. The systemic structural descriptions presented herein, as well as the methodological, operational features of the invention discussed, will well arm those generally-skilled persons to practice all aspects of the present invention.

[0039] Turning attention now to Figs. 6A, 6B, 7A, 7B, along with continued references, as appropriate and helpful, to Figs. 1-5, inclusive, Fig. 6A furnishes, as stated earlier, a frontal view of an internal portion 46 of a subject's anatomy illustrating, generally at 48, preferred, implanted positioning therein proposed for the system 20 pictured in Figs. 1-4, inclusive. In Fig. 6A, system 20 is simply illustrated by a very evident, generally horizontally disposed, thickened, dark line, and specifically, what is illustrated, is that capsule 24 in this system is placed at a selected surface region 48a on the inferior side of the subject's diaphragm 50. More specifically, capsule 24 is positioned left-laterally in the subject's anatomy, clearly out of contact with the subject's heart 52, and actually in a modest state of compression between the inferior side of diaphragm 50 and the subject's immediately underlying liver, seen generally, and fragmentarily only, at 54. In a very specific sense, capsule 24 is disposed with its electrode face 24b (not specifically seen or marked in Fig. 6A) facing the inferior surface of the diaphragm, with electrodes 26, 28 (also not specifically seen in this figure) directly contacting diaphragmatic surface region 48a.

[0040] In relation to what is seen in Fig. 6A, and as was mentioned earlier herein, capsule 24 has been implanted

through conventional laparoscopy -- a surgical practice which forms no part of the present invention.

[0041] Turning attention to Fig. 6B, this figure also shows just-mentioned, internal, anatomical portion 46, and is similar to Fig. 6A, except that it shows an alternative placement in the subject's anatomy for capsule 24 in system 20. In Fig. 6B, capsule 24 has been placed on the superior surface of diaphragm 50 at an implantation position generally shown at 56, and specifically on a selected, diaphragmatic surface region 56a, which has a left-lateral disposition in the subject's anatomy similar to the left-lateral implantation disposition pictured on the underside of diaphragm 50 in Fig. 6A. Here, capsule 24 is disposed with its electrode face 24b (not specifically seen or marked) facing the superior surface of the diaphragm, and with electrodes 26, 28 (also not specifically shown in Fig. 6B) directly in contact with the diaphragm.

[0042] In the disposition shown in Fig. 6B for capsule 24, the capsule is slightly compressed between the superior surface of diaphragm 50 and the underside of the subject's left lung 58.

[0043] In relation to the positioning shown for capsule 24 in Fig. 6B, and as was mentioned earlier herein, this capsule has been implanted through conventional thoracotomy -- another surgical procedure which also forms no part of the present invention.

[0044] Turning attention now to Figs. 8, 9A, 9B, indicated generally at 60 in these three figures, and focusing attention initially here on what is shown in the Fig. 8, is the second, above-mentioned, principal form of the invention, which is a self-powered, implantable, distributed form of the invention -- distributed in the sense that it includes a pair of spaced component assemblies 62, 64, operatively interconnected by appropriate, elongate, communication lead structure 66. Except for the fact that this form of the invention has the just-mentioned distributed nature, and the further fact that it's distributed componentry, when implanted in a subject's anatomy as pictured generally in Figs. 9A, 9B is uniquely associated with this distributed embodiment form, it includes all of the operatively interconnected electrical and mechanoelectrical componentry described above for system form 20 - interconnected as illustrated schematically in Fig. 5. Additionally, the performance of system 60 is essentially identical to that of system 20.

[0045] Included within component assembly 62 are a cylindrical housing 68, from one side of which projects a spiral-form, diaphragm-attaching electrode 70, and in which is appropriately mounted a three-dimensional accelerometer 72 represented by a small thickened and darkened line in Fig. 8, and next to housing 68, and represented by a small rectangle, another electrode 74 which, together with electrode 70, form the previously mentioned bimodal electrodes. Collectively, electrodes 70, 74 constitute the bimodal electrodes structure discussed above.

[0046] Shown immediately to the right of component assembly 62 in Fig. 8, and visually linked to the image

of this component assembly by a curved, double-arrow-headed arrow 76, is a symbolic representation 78 of assembly 62, which symbolic representation is employed (as can be seen) in each of Figs. 9A, 9B to enable a simpler way of picturing there the respective presences of assembly 62 in the anatomical images presented in these two figures.

[0047] Electrode 70, the spiral-form electrode, is designed to enable spiral, attachable embedment into the structure of a subject's diaphragm for securing component assembly 62 in place, and in a manner whereby both electrodes 70, 74 will essentially be in contact with a selected surface region in the diaphragm, with accelerometer 72 in an appropriate motion-sensing relationship relative to, and effectively in contact with, the diaphragm.

[0048] Lead structure 66 includes conductors (not illustrated in specific detail) which are appropriately connected to electrodes 70, 74, and to accelerometer 72, which conductors extend in the lead structure to component assembly 64.

[0049] Component assembly 64 includes all of the system electrical circuitry, the system battery, and the system radio and antenna (not specifically pictured in Fig. 8), such as those, same elements illustrated in Fig. 5. The length of lead structure 66 is a matter of user choice, and will typically be chosen, of course, to accommodate intended implantation disposition of system 60 within a particular subject's anatomy.

[0050] Focusing now on Figs. 9A and 9B, and beginning with what is shown in Fig. 9A, here, one can see that system 60, as was true for the illustration provided in Fig. 6A for system 20, is disposed at previously mentioned implantation position 48 on also previously mentioned inferior diaphragmatic surface region 50a. One will note that only, within system 60, component assembly 62 is shown in Fig. 9A, with lead structure 66 broken away, and component assembly 64 not specifically pictured. A reason for this is that what is important to note with respect to what is seen in Fig. 9A is the diaphragmatic positioning of component assembly 62, with one recognizing that implantation of the other end of system 60, namely, component assembly 64, can be located at the user's choice, and suitably, anywhere in the subject's anatomy below diaphragm 50.

[0051] Fig. 9B, which, as has already been mentioned, is very similar to Fig. 6B, shows system 60 disposed at previously mentioned implantation position 56 on also previously mentioned diaphragmatic surface region 50b, located on the superior side of diaphragm 50.

[0052] Here, too, lead structure 66 is broken off with component assembly 64 omitted from Fig. 9B, one here recognizing that the installer of system 60 will choose an appropriate, above-the-diaphragm placement site for component assembly 64.

[0053] Addressing attention now, briefly, to the implantation dispositions shown in Figs. 6A, 6B, and 9A, 9B, for systems 20, 60, respectively, which dispositions, are left-

lateral in the subject's anatomy, and either inferior (preferred) or superior relative to the diaphragm, in each of these dispositions the electrodes and the accelerometers are essentially in direct contact with the described and illustrated surface regions in the diaphragm, out of direct contact with the heart. Additionally, in each of the system dispositions shown in these four figures, the electrodes in the respective systems are well positioned to detect easily heart-associated electrical activity, and the accelerometers are similarly positioned to detect easily heart sounds, and, of course, diaphragmatic movement/motion.

[0054] Having now completed descriptions of what is illustrated in Figs. 6A, 6B, 9A, 9B, I to turn attention to Figs. 7A and 7B. As a reminder, and as was pointed out in the text above regarding the descriptions of the drawings, in each of Figs. 7A, 7B, system components of the invention have been omitted so that one can more easily focus on the motion-created nature of, and behaviors associated with, diaphragmatic electrical stimulation produced by operations of the systems of the invention. In each of these two figures, and recognizing that they present enlarged, and very small fragmentary regions drawn from the anatomical presentations seen in Figs. 6A, 6B and 9A, 9B, the anatomical left side of diaphragm 50 is shown in solid outline in a non-stimulated condition relative to the adjacent anatomical components, and particularly relative to heart 52 and its left ventricle.

[0055] As indicated by a downwardly-pointing arrow 80 in Fig. 7A, on the initiation of an electrical stimulating pulse applied to diaphragm 50, the diaphragm moves downwardly rapidly in a caudal direction to a position which is somewhat exaggeratedly illustrated for it in dashed lines at 50A in this figure. This caudal movement of the diaphragm, because of the diaphragm's intimate association with the base of the left ventricle in heart 52, pulls downwardly on this ventricle to produce the position for the lower part of the heart and ventricle shown in dashed lines at 52A in Fig. 7A.

[0056] Fig. 7B pictures relevant, moved relationships which exist immediately following the conditions shown in Fig. 7A. More specifically, an upwardly pointing arrow 82 in Fig. 7B shows conditions wherein diaphragm 50 has moved upwardly in a cranial direction to the exaggerated, moved position for it shown in dashed lines at 50B -- a diaphragmatic movement which drives upwardly on the underside of the left ventricle in the heart to create a heart and left ventricle moved condition pictured in dashed lines at 52B.

[0057] The time-sequential moved conditions pictured in Figs. 7A, 7B, are, essentially, repeated synchronously in each cardiac cycle of a subject's heart in accordance with what constitutes herein predetermined timing associated with, and triggered by, the sensed occurrence of a valid, electrical or mechanical V-event, sensed either electrically by the bimodal electrode structure functioning in its "one", sensing mode as established for it by operatively connected electrical circuit structure 32, or me-

chanically by the included system accelerometer. As will be explained shortly, with the system of the invention implanted and operating in a subject's anatomy, and set to "look for", and employ, for example, valid electrical V-events as "triggers" for implementing a cardiac-cycle-synchronized, shortly-to-follow diaphragmatic stimulation, cardiac-cycle-synchronized, stimulation-produced diaphragmatic movements, biphasic in nature as described above, occur in every cardiac cycle, except in what may be referred to as a non-normal cardiac cycle in which there occurs, unexpectedly, an electrical V-event which "looks like", but is not, an appropriate, valid, electrical V-event that presents itself during that cardiac cycle's associated refractory period. More will be said about this special circumstance shortly in relation to what is shown in Fig. 10. The occurrence of such a non-valid electrical V-event within a cardiac cycle's refractory period creates a situation where, in order to protect against lack of efficiency and potential difficulty, no related, next-following electrical stimulation is applied to the diaphragm.

[0058] Figs. 10 and 11, as mentioned earlier, present conventional-style laddergrams which picture, respectively, what are referred to herein as (a) early, or anticipatory, diaphragmatic stimulation (PIDS), and (b) late, or following, diaphragmatic stimulation (PIDS). As just indicated in the preceding sentence, in discussions now following regarding these two drawing figures, as well as in still-to-be-presented discussions respecting Figs. 12 and 13, the previously identified term PIDS will, at times, be used, in the text (and in the illustrating drawings) to identify diaphragmatic stimulation.

[0059] As a preliminary orientation to the manners in which Figs. 10 and 11 are drawn, each figure includes a pair of vertically spaced, horizontal time lines, labeled "V" and "P", where V stands for a V-event, and P stands, in a shortened manner, for the acronym PIDS (electrical diaphragmatic stimulation). The time lines in these two drawing figures effectively cover four, representative cardiac cycles, and each figure includes, at its lower left side, a self-explanatory, graphical-symbol legend which is associated with the several, and various, graphical indicia that are distributed along the time lines above in the figure.

[0060] Except for the specific discussions now to follow which explain certain, important predetermined timing settings pictured in these drawings - settings that relate to notable operations of the system of the invention, I believe that those who are generally skilled in the relevant art will clearly understand the information conveyed by the related sequences of events pictured in these two drawing figures, especially in the context of understanding that operation of the system of the present invention involves cardiac-cycle-synchronized sensing of valid V-events, electrical or mechanical, and the using of such sensed and noted events as triggers for the implementation of a then-following, electrical diaphragmatic stimulation.

[0061] Having said this, it should be evident that the upper time line in each of these two drawings pictures, among other things, a sequential series of sensed V-events, and that the lower time line represents respectively associated, thereafter-following PIDS stimulations. Angular, sloping dashed lines which extend in each of Figs. 10 and 11 downwardly and to the right between the upper and lower time lines relate to what are referred to herein as V-PIDS timing periods or delays, and also as predetermined timed relationships - parameters that are functional in the operation of the system of the invention in accordance either with (a) user-selected presetting of these delays, (b) used re-setting of these delays after a period of system operation, and/or (c) on-the-fly, system-internal, systemically self-effected adjustments of such delays, where such system-internal adjustments are permitted (i.e., user-selectively accommodated by appropriately system-included, conventional logic programming). In all embodiments of the system of the invention that are currently contemplated, adjustments in the V-PIDS delay parameter, both in a necessary pre-setting manner with the system in an implanted (or not) condition, and later, if desired, in a system-implanted re-setting situation, are permitted via remote telemetry, or otherwise. The graphically illustrated V-PIDS delays "represented" by the sloping, dashed lines in Figs. 10 and 11, are actually measureable, i.e. visualizable, graphically in these figures in a manner and direction which is horizontally parallel to the time lines, and not angularly.

[0062] Saying a little bit more in an orientation sense regarding Figs. 10 and 11, the relational, sensed V-events and associated stimulation occurrences pictured may now be thought of as being presented, for further and discussion illustration purposes herein, in the context of an implementation of the invention wherein it is valid, electrical V-events have been selected to be the markers, i.e., the triggers, for PIDS stimulation.

[0063] Continuing with description relating to matters shown graphically in Figs. 10 and 11, there are two, important, and importantly related, timing periods that are taken into account in the practice of the present invention, one of which, the V-PIDS delay period, has just been discussed, and the other of which is the length of the so-called refractory period that exists in each of a subject's cardiac cycles, immediately following a sensed, valid V-event in that cycle. In these two figures, the relevant refractory periods are represented graphically by elongate, vertically-thin, horizontal rectangles distributed along the time lines. The graphical legends presented in Figs. 10 and 11 make clear which illustrated "rectangles" these are.

[0064] Timing operations, with respect to these two time periods are under the control of two, logic-based timers that are realized/implemented, and "operated", so-to-speak, in appropriate timing-tracking manners by the previously-mentioned, included-logic state machine in its association with the electrical-circuitry-included logic, or computer, structure.

[0065] The time-period associated with the timer which deals with tracking a cardiac-cycle refractory period, a period which, as was just mentioned, begins immediately following the sensing of a chosen, valid V-event, involves subject-specific data that is pre-known, for example, to a medical practitioner using the system of the invention, and who is familiar with the particular subject to be equipped with the system. For a given subject, and as a precursor typically to implantation, and certainly to activation, of the system of the present invention with respect to that subject, two pieces of subject-specific information are relevant to establishing what will be, at least initially, a preset duration for a timed refractory period. Required for this determination are (1) knowledge of the expected likely heart-rate range of the subject, and (2) knowledge regarding the specifically chosen event (electrical in the situation now being discussed) in each of the subject's cardiac cycles which will be treated as the valid V-event from which a measured time will be observed to determine the application of a following, diaphragmatic stimulation. In the description now underway with respect to Figs. 10 and 11, and, in fact, in the operational description of the system and methodology of the invention still to come, all operational behavior will be described, for illustration purposes, in the setting of a pre-selection having been made for the detected onset of the electrical R wave in each cardiac cycle being the valid, triggering V-event. A conventional, appropriately programmed, ECG-watching approach is used herein to detect this onset in relation to ECG electrical information regularly sensed by the system bimodal electrode structure functioning in its "one", sensing mode under the control of the system electrical circuit structure.

[0066] Of the two, alternative V-PIDS delay-time possibilities contemplated for practice of the present invention, I have found that, in most applications, so-called early PIDS stimulation is preferable, and it is for this reason that Fig. 10, in the two-drawing-figure, pictorial-numeric sequence which has been selected for the presentations in the drawings of Figs. 10 and 11, has been chosen to illustrate such stimulation. Early PIDS stimulation, and the relevant V-PIDS time delay associated with it, lead effectively to a condition for the application of diaphragmatic stimulation at the beginning of a short time interval which lies, in time, as a precursor to the onset of an anticipated V-event in a particular cardiac cycle (to be explained). In a manner of thinking, therefore, one can imagine that the actual (precursor) time gap existing between such early PIDS stimulation and the shortly following onset of a valid, "anticipated", and soon to be next-sensed, valid V-event constitutes a negative time interval in the cardiac cycle where stimulation is to take place. Because of this, and because such stimulation must be measured from an already-having-occurred, sensed valid V-event, the system and methodology of the present invention perform this measurement beginning from the just previously sensed, valid V-event in the immediately prior cardiac cycle.

[0067] Continuing with this thought, and recognizing that proper establishment, for successful systemic operation, in an early-PIDS manner of functioning, of an appropriate a V-PIDS delay interval following the occurrence of the sensed V-event which is employed to trigger stimulation action, it is important to know, and this is done by an averaging technique, just how to anticipate a next-expected valid V-event. To this end, and employing conventional algorithmic programming well-known to those generally skilled in the relevant art, once the system of the invention has begun its operation, and after the first few cardiac cycles associated with that operation, a running average is performed based (in the present system implementation) upon the four, prior cardiac cycles to assess an average timing expected between successive, valid V-events. This average is "made known" within the logic componentry in the system for every successive cardiac cycle after the first four cycles which mark the beginning of system operation, and accordingly, on-the-fly, so-to-speak, a V-PIDS timing delay, "represented" in Fig. 10 by the previously-mentioned, sloping dashed lines, is calculated by performing, effectively, a subtraction, from the then-available averaged timing determined between successive, valid V-events, of the brief, precursor interval (just mentioned above) the beginning of which is intended to define the moment of triggering of a PIDS stimulation in anticipation of the expected, very shortly following, next-valid, and sensed, V-event.

[0068] If desired, the system of the present invention may be structured in a conventional manner to allow the making of a change associated with early PIDS stimulation through the making of a change in settings available to the system describing, differently, the short precursor (subtraction anticipatory) interval just discussed.

[0069] Continuing with the discussion regarding what is shown in Fig.10, this figure illustrates the potential problem-creating possibility (mentioned earlier) of an errant V-event which occurs, outside of normal cardiac behavior, within a particular cardiac cycle's refractory period. Looking specifically toward the right side of what is shown in Fig. 10, seen along the upper time line is a presentation of the occurrence of such an errant V-event which has taken place during the illustrated cycle's refractory period. To the right of this indication in the upper time line, and specifically below the associated, lower time line, text is presented indicating that there is not to be an immediately-next-following PIDS stimulation -- a protective measure, as noted earlier.

[0070] Directing attention now to Fig. 11, and as a reminder about the nature of the teaching which is evident in this figure, Fig. 11 describes what has been referred to as a late PIDS stimulation situation. This situation is very easy to understand, in the sense that to implement it, all that is required is a system setting for a predetermined V-PIDS delay time which is very short, typically, and which, within a common cardiac cycle, shortly follows a sensed, valid V-event.

[0071] In relation to a final point to mention regarding

Figs. 10 and 11, small blackened rectangles distributed, as shown, along the V time lines in these figures mark short, conventionally-system-implemented blanking periods that are created and exist to prevent a stimulation pulse from producing unintended cardiac electrical activity. In the early PIDS situation, these blanking periods fall outside of the cardiac-cycle refractory periods. In the late PIDS situation, they occur during refractory periods.

[0072] Turning attention now to Figs. 12 and 13, Fig. 12 illustrates, along two, vertically spaced, time-related time lines, (1) an upper graphical trace of an ECG waveform received from subject-implanted system electrodes, picturing a large plurality of successive subject cardiac cycles, including the evident presences of cycle-synchronized PIDS stimulations, and (2) a lower graphical trace of related output information received from the implanted-system-included accelerometer showing both the lower-frequency characteristic of normal respiration, and the superimposed, higher-frequency, cardiac-cycle-synchronized, biphasic diaphragmatic motions that have resulted from the PIDS stimulations shown above in the electrically illustrated cardiac cycles. The waveforms of these biphasic diaphragmatic motions, captured and recorded, as they are, for later reporting by the system of the present invention, are importantly useful for helping a medical professional, in the setting of actually seeing the waveform of what biphasic, diaphragmatic, stimulation-produced motion looks like, to assess both, ultimately, the quality of a subject's hemodynamic performance, and also the quality of enhancement-assistance thereof furnished by the invention.

[0073] Fig. 13 furnishes an enlarged, and time-stretched, view of fragments of the two traces presented in Fig. 12, selected from the region in Fig. 12 marked by the two, vertical, laterally-spaced dashed lines that mark a display region for Fig. 13 designated 84 in Fig. 12.

[0074] What can be seen by looking at these two drawing figures, very clearly, is that each illustrated PIDS stimulation, which is short-term and pulse-like in nature, produces, in the represented subject's diaphragm's movement, a related, cardiac-cycle-synchronized, relatively high frequency, biphasic, caudal-followed-by-cranial movement of the diaphragm. It is this relatively high-frequency, biphasic, diaphragmatic motion, caudal-followed-by-cranial in nature, which, in the context of there being a properly waveform-shaped motion of the diaphragm, enhances a subject's hemodynamic performance through the effective delivery of that diaphragmatic motion to the underside of the heart's left ventricle, as explained earlier.

[0075] As was mentioned earlier herein, internal programming, hard-wired and/or algorithmically programmed/programmable, is in many ways completely conventional in nature in terms of specific tasks that are performable during operation of the system of the present invention. While, as has already been mentioned above, there are certain settings that, preferably, are introduced as initial settings introduced to the circuitry logic structure

provided in the system of the invention -- put there into place by the system user/installer/implanter -- there are certain operational features and re-settings which may, over time, be adjusted and/or introduced, either remotely through short-range telemetry accommodated by radio 44, or automatically internally in association with a systemic capability, if such a capability is selectively provided, for the system to self-monitor and self-adjust various aspects of its own activities. With regard to telemetry-implemented operational modifications, as well as potentially internally self-implemented operational modifications, again, those generally skilled in the relevant arts will know how to do this based upon the systemic and methodologic descriptions of the invention presented in this text and pictured in the associated drawing figures.

[0076] Regarding such potential modifications, and various associated activities, I recognize to be a very interesting category of easily-accomplishable self-modification, the making of changes in the above-identified and discussed V-PIDS time-delay settings. As was also pointed out earlier herein, importantly, with respect to self-implemented operational modifications, the system and methodology of the present invention do not allow for the self-implemented making of any changes in the character of electrical diaphragmatic stimulation. It is, of course, entirely possible for a system user who is monitoring a subject's hemodynamic performance condition, to make such modifications remotely by telemetry.

[0077] An important and special feature of the present invention involves the capturing and recording of accelerometer data associated with the nature of actual, stimulation-produced diaphragmatic biphasic movement. This capture and recording, in association with an importantly implemented, and uniquely contemplated, comparison of captured, actual diaphragmatic motion waveforms with a system-stored, carefully chosen, reference waveform, yields reportable information that allows a system user to initiate stimulation adjustments to improve matters. This comparison activity produces system-stored comparison data which is retrievable by telemetry to furnish valuable confirmatory evidence of the viability of the implemented diaphragmatic stimulation respecting the maximizing and achieving of hemodynamic performance.

[0078] Before describing a typical operation of the system with respect to a particular subject, let us turn attention to Fig. 14 in the drawings which illustrates, in block/schematic form, both the basic, and a modified, form of the architecture of the methodology of the present invention. The "overall" archaeology, as shown in Fig. 14, is illustrated generally at 86. It includes, as steps represented in block form, six different blocks, including block 88 (Sensing), block 90 (Applying), block 92 (Monitoring), block 94 (Comparing), block 96 (Recording), and block 98 (Choosing). Blocks 88-96, inclusive, are drawn each with a solid-line outline to signify that they describe, effectively, the basic, or core, methodology of the invention. Block 98, which is outlined with a dashed line, rep-

resents one modified form of the invented methodology. Reading from left to right in Fig. 14, the several blocks there pictured are connected in the order of associated behaviors, with arrow-headed, right-pointing lines connecting these blocks, as shown, to symbolize, the flow of methodologic activity.

[0079] The present invention thus offers a method for improving the hemodynamic performance of a subject's heart including, from adjacent a selected surface region in the subject's diaphragm which is out of contact with the heart, (1) Sensing and noting (Block 88) the presences in the subject's cardiac cycles of a selected one of (a) per-cycle valid electrical, and (b) per-cycle valid mechanical, V-events, (2) based upon such sensing, and upon noting each of such selected, V-event presences, Applying (Block 90), in a predetermined timed relationship to such a noting, associated, asymptomatic electrical stimulation directly to the diaphragm, preferably at the selected diaphragmatic surface region, for the purpose of triggering biphasic, caudal-followed-by-cranial motion of the diaphragm, (3) following the applying step, Monitoring (Block 92) the waveform of resulting diaphragmatic motion, (4) after performing the monitoring step, Comparing (Block 94) the monitored diaphragmatic-motion waveform with a reference, diaphragmatic-motion waveform, and (5) on completion of the comparing step, Recording (Block 96) the monitored, diaphragmatic-motion waveform for later review.

[0080] The invention methodology, in a modified form, further includes (1) Choosing (Block 98) the selected diaphragmatic surface region to be on one of (a) the inferior, and (b) the superior, side of the diaphragm, and (2) choosing the selected, per-cycle valid V-event whereby, if it is to be electrical, it is one of (a) the R wave, and (b) the Q wave, and if mechanical, it is the S1 heart sound.

[0081] Presenting now a description of typical system preparation, implantation, and operation with respect to a particular, selected subject, this description will be based upon the implantation in a subject of that form of the system of the invention which is pictured in Figs. 1-5, inclusive, and installed as illustrated in Fig. 6A. Further, this description will be based upon a predetermination that the triggering of diaphragmatic stimulation will be based upon the sensing, in the subject's cardiac cycles, of valid electrical V-events, with the chosen, valid electrical V-event being the onset of the R wave. The operational description which now follows will also rest upon a pre-decision that early PIDS stimulation is what is to take place, and that until, as will shortly be described, a more concrete idea is reached for defining an exact V-PIDS delay interval, the system logic structure -- effectively, the state machine portion of this structure -- will be "told" to begin with a V-PIDS delay time of zero.

[0082] Also initially determined, and this, before system implantation, is what kind of a timing interval to pre-assign to the refractory period timer operated by the state machine, and this timing interval will be based upon subject-specific information drawn from pre-knowledge

about the subject's expected likely heart-rate range, and typical refractory period time length beginning with the onset of the R wave, and ending with the end of that refractory period.

5 **[0083]** Also completely predetermined will be system settings that establish, essentially fixedly, the character of electrical PIDS stimulation designed to be clearly asymptomatic in nature.

10 **[0084]** Much of this pre-implantation information, relevant to preparing the system of the invention for best-possible work with the selected subject, will involve a further category of information, known to the appropriate medical personnel, regarding how to assess, with the system operating, maximally-achievable, enhanced hemodynamic performance.

15 **[0085]** With system pre-settings based upon the just-described preliminary choices made, the system is implanted appropriately, as illustrated in Fig. 6A, and is switched into operation, with the system user immediately collecting appropriate data to assess needed adjustment, from zero, to establish in the state machine the most appropriate early-PIDS time interval now to be "reset" for per-cycle calculation of the important V-PIDS delay period. Those persons skilled in the medical arts will know well how to make this assessment, and with this knowledge in hand, will, through short-range telemetry, introduce into the logical structure of the state machine, as just mentioned, the appropriate V-PIDS delay information.

20 **[0086]** With the early PIDS, V-PIDS delay period thus set, the system of the invention now simply regularly estimates, through the on-the-fly averaging technique described above, a proper point in time, following the sensing in one cardiac cycle of a valid electrical V-event, to apply diaphragmatic stimulation in the following cardiac cycle appropriately, and shortly, before the next-sensed, valid electrical V-event. Errant electrical V-events sensed during a cardiac cycle's refractory period will not be used to trigger stimulation. Valid electrical V-event sensing will take place through the system-included, bimodal electrode structure placed by the system electrical circuit structure in its "one", sensing mode, and electrical stimulation delivered to the diaphragm, under the controlling influence of the system electrical circuit structure, will be delivered by the same, efficiently employed, bimodal electrode operating in its "other", stimulating mode. Interesting to note here, specifically, is that the incorporation in the system of the present invention of the described, bimodal electrode structure offers the simplicity of utilizing simply one pair of electrodes to perform, seriatim, electrical-activity sensing, and electrical diaphragmatic stimulation.

45 **[0087]** Each sensed, valid electrical V-event will result in asymptomatic electrical stimulation of the subject's diaphragm to produce high-frequency, biphasic, caudal-followed-by-cranial diaphragmatic movement, and this cycle-by-cycle activity will synchronously drive the left ventricle of the subject's heart in a biphasic, pumping-

assist manner which will enhance hemodynamic performance as described above.

[0088] The system accelerometer will accurately follow the stimulation-induced biphasic diaphragmatic movement which is associated with each diaphragmatic stimulation, and will, cycle-by-cycle, communicate to the electrical circuit structure the mentioned, related, diaphragmatic-motion confirmation signal whose associated waveform will be compared with that of the mentioned, carefully-chosen reference waveform to generate, for storage and later retrieval, cardiac-cycle-by-cardiac-cycle waveform comparison data.

[0089] All of this activity will be occurring, as mentioned, entirely synchronously with the subject's cardiac-cycle-by-cardiac-cycle heart rate.

[0090] The operational description just presented, wherein the preselected, valid V-event has been chosen to be electrical and to be associated specifically with the detected onset of a cardiac cycle R wave, closely also describes both (a) an alternative system operation based upon selection of the Q wave as being the valid electrical V-event, and (b) another, alternative system operation based, instead, on mechanical V-event sensing, wherein a selected, valid mechanical V-event is chosen to be the S1 heart sound -- an event which will be sensed by the system-included accelerometer. In this latter, alternative operational setting, the accelerometer plays the dual roles of sensing valid V-events, and tracking and reporting on stimulation-produced diaphragmatic movements.

[0091] Accordingly, while two, important, principal, systemic embodiments of the invention have been illustrated and described herein in detail, and certain modifications suggested, and while, also, preferred and modified forms of system-implemented methodology and system operation have been discussed and illustrated, I recognize that other variations and modifications may come to the minds of those generally skilled in the relevant arts, are possible, and may be made.

Claims

1. A fully implantable medical system for improving a subject's cardiovascular performance through electrical diaphragmatic stimulation comprising a bi-modal electrode structure (26, 28) operatively connectable to a selected surface region (48a; 56a) in the subject's diaphragm, wherein it is configured to function in a first mode designed to cause the electrode structure (26, 28) to sense, from adjacent such a surface region, the subject's electrical cardiac activity, and a second mode designed to cause the electrode structure (26, 28) to effect cardiac-cycle-synchronized, electrical diaphragmatic stimulation at the location of the same, mentioned surface region, and an electrical circuit structure (32), operatively connected to the electrode structure (26, 28), operable

to collect, while the electrode structure is functioning in the first mode, the sensed electrical cardiac activity, and, while the electrode structure is functioning in the second mode, to communicate to the electrode structure to effect diaphragmatic stimulation, wherein the electrical circuit structure (32) is operable to note a presence of a valid electrical V-event corresponding to an onset of a left-ventricular contraction or a cardiac electrical event having a predictably known relationship to such an onset, in such received cardiac-cycle electrical-activity information, and to deliver asymptomatic, cardiac-cycle-synchronized, electrical stimulation through the electrode structure (26, 28) to the diaphragm in a predetermined timed relationship to the valid electrical V-event, the electrical stimulation being configured to trigger a biphasic motion of the diaphragm, which biphasic motion comprises a caudal motion of the diaphragm followed by a cranial motion of the diaphragm.

- 2. The fully implantable medical system of claim 1, wherein the bimodal electrode structure (26, 28) is placeable in contact with the selected surface region (48a; 56a) of the subject's diaphragm at a location which is out of contact with the heart, and in the first mode cardiac-cycle electrical activity discernible at the selected surface region is sensed, and in the second mode, which is independent from the first mode, the stimulation to the diaphragm is asymptomatic.
- 3. The system of claim 1, wherein a predetermined timed relationship is one of (a) one which anticipates the next-expected, valid, cardiac-cycle, electrical V-event, and (b), one which follows the last-sensed, valid, cardiac-cycle, electrical V-event.
- 4. The system of any of claims 1 to 3 with respect to which a valid, selected-character, electrical V-event is one of (a) the R wave, and (b) the Q wave in the subject's electrical cardiac-cycle activity.
- 5. The system of any of claims 1 to 4 further comprising an accelerometer which is (a) disposed adjacent, and operatively associated with, said electrode structure (26, 28) for contact-associated disposition in a motion-sensing relationship with, and with respect to, the subject's diaphragm, (b) operatively connected to said circuit structure (32), and (c) constructed to respond to electrical-stimulation-induced motion produced in the subject's diaphragm by generating, and communicating to said circuit structure, a diaphragmatic-motion confirmation signal possessing a waveform which is directly indicative of such motion, wherein the accelerometer is preferably a multi-axis accelerometer, and even more preferably a three-dimensional accelerometer.

6. The system of any of claims 1 to 5, wherein said circuit structure (32) includes algorithmically programmed computer structure having timing-adjustment substructure (42) capable of making an adjustment in the mentioned predetermined timed relationships.
7. The system of any of claims 1 to 6, wherein the system is self-contained, self-powered and operable nominally in each of a subject's cardiac cycles for enhancing hemodynamic performance of the subject's heart through cardiac-cycle-synchronized, asymptomatic electrical stimulation of the diaphragm, and comprises
 a system capsule (24) having a face (24b) placeable contactively on one of (a) the inferior, and (b) the superior, side of the diaphragm at the selected location which is out of contact with the heart,
 a pair of spaced, bimodal electrodes (26, 28) carried on said capsule (24), and exposed on said face (24b), operable, through contact with the diaphragm, in the first mode to sense heart-associated electrical activity, and in the second mode to apply electrical stimulation to the diaphragm, wherein
 a three-dimensional accelerometer is disposed within said capsule, operatively associated with said electrodes (26, 28), and operable to sense both mechanical motion of the diaphragm, and heart sounds, and
 the electrical circuit structure (32) is disposed within said capsule (24), operatively connected to said electrodes (26, 28) and to said accelerometer, including algorithmically programmed computer structure (38) which is structured, and operable, when the system is in an operative condition implanted within the subject's anatomy, and nominally during each of the subject's cardiac cycles, (a) to observe electrical heart activity sensed by said electrodes (26, 28), (b) in a selected, timed manner relative to the presence, if any, of a predetermined, valid electrical V-event noted in the sensed, cardiac-cycle, electrical heart activity, to apply asymptomatic electrical stimulation to the diaphragm through said electrodes, and (c) following such stimulation, to observe and record for later review any diaphragmatic motion sensed by said accelerometer.
8. The system of claim 7, wherein the selected diaphragmatic location is left lateral in the subject's anatomy.
9. The system of claim 7 or 8, wherein the selected, timed manner associated with applying electrical stimulation to the diaphragm is one of (a) one which anticipates the next-expected, valid, cardiac-cycle, electrical V-event, and (b) one wherein the selected, timed manner associated with applying electrical stimulation to the diaphragm is one which follows the last-sensed, valid, cardiac-cycle electrical V-event.
10. The system of claim 1, further comprising a mechanical sensing structure (36), operatively securable adjacent a selected surface region (50a; 50b) in the subject's diaphragm, designed to sense mechanical information originating from the subject's cardiac activity.
11. The fully implantable medical system of claim 10, wherein
 the electrode structure (26, 28) is placeable in contact with the selected surface region (50a; 50b) of the subject's diaphragm at a location which is out of contact with the heart, for applying asymptomatic electrical stimulation to the diaphragm at the selected surface region,
 the mechanical sensing structure (36) comprises a three-dimensional accelerometer disposed adjacent, and operatively associated with, said electrode structure (26, 28) for placement, in association with the electrode structure, adjacent the same, selected surface region (50a; 50b) of the diaphragm and in a contact-associated, motion-sensing relationship with the diaphragm, operable for sensing, in the subject's cardiac cycles, cardiac-cycle mechanical activity discernible at the selected, diaphragmatic surface region, and
 the circuit structure (32) is operatively connected both to said electrode structure (26, 28), and to said accelerometer for receiving from the accelerometer information respecting the subject's cardiac-cycle mechanical activity which is sensed by the accelerometer.
12. The system of claim 10 with respect to which a valid, mechanical V-event is the S1 heart sound in the subject's cardiac-cycle mechanical activity.
13. The system of claim 11 or 12, wherein said accelerometer, additionally, is constructed to be responsive to any motion produced in the subject's diaphragm as a consequence of electrical diaphragmatic stimulation, and in relation to such responsiveness, to communicate to said circuit structure (32) a diaphragmatic-motion confirmation signal possessing a waveform which is directly indicative of such motion.
14. The system of claim 5 to 9 or 13, wherein said circuit structure (32) includes algorithmically programmed computer structure (38) having a waveform monitoring and recording substructure (40) for comparing the waveform of a communicated confirmation signal with a reference waveform, and recording the confirmation-signal waveform for subsequent review.
15. The system of any of the preceding claims which is

one of (a) self-contained as a singular, overall unit, and (b) distributed between a spaced pair of component assemblies (62, 64) operatively interconnected by communication lead structure (66), and where in the selected surface region (48a; 56a; 50a; 50b) is disposed on one of (a) the inferior side, and (b) the superior side, of the diaphragm.

Patentansprüche

1. Vollständig implantierbares medizinisches System zum Verbessern der kardiovaskulären Leistungsfähigkeit eines Probanden durch elektrische Zwerchfellstimulation, das Folgendes umfasst:

eine bimodale Elektrodenstruktur (26, 28), die mit einer ausgewählten Oberflächenregion (48a; 56a) im Zwerchfell des Probanden wirkverbunden werden kann, wobei sie dafür konfiguriert ist, in einem ersten Modus zu arbeiten, der dafür ausgelegt ist, die Elektrodenstruktur (26, 28) zu veranlassen, neben der Oberflächenregion die elektrische Herzaktivität des Probanden zu detektieren, und in einem zweiten Modus zu arbeiten, der dafür ausgelegt ist, die Elektrodenstruktur (26, 28) zu veranlassen, eine Herzzyklus-synchronisierte, elektrische Zwerchfellstimulation an der Stelle derselben, erwähnten Oberflächenregion herbeizuführen, und

eine Stromkreisstruktur (32), die mit der Elektrodenstruktur (26, 28) wirkverbunden ist und dafür geeignet ist, während die Elektrodenstruktur im ersten Modus arbeitet, die detektierte elektrische Herzaktivität zu erfassen, und während die Elektrodenstruktur im zweiten Modus arbeitet, mit der Elektrodenstruktur zu kommunizieren, um die Zwerchfellstimulation herbeizuführen,

wobei die Stromkreisstruktur (32) dafür geeignet ist, in solchen empfangenen Informationen über eine elektrische Herzzyklusaktivität das Vorliegen eines validen elektrischen Ventrikulär-Ereignisses, das einem Einsetzen einer linksventrikulären Kontraktion entspricht, oder eines elektrischen Herzereignisses, das eine vorher-sagbar bekannte Beziehung zu einem solchen Einsetzen aufweist, festzustellen, und eine asymptotische, Herzzyklus-synchronisierte, elektrische Stimulation durch die Elektrodenstruktur (26, 28) in einer zuvor festgelegten, zeit-gesteuerten Beziehung zu dem validen elektrischen Ventrikulär-Ereignis an das Zwerchfell anzulegen, wobei die elektrische Stimulation dafür konfiguriert ist, eine biphasische Bewegung des Zwerchfells auszulösen, wobei die biphasische Bewegung eine kaudale Bewegung

des Zwerchfells, gefolgt von einer kranialen Bewegung des Zwerchfells, umfasst.

2. Vollständig implantierbares medizinisches System nach Anspruch 1, wobei die bimodale Elektrodenstruktur (26, 28) an einer Stelle, die keinen Kontakt mit dem Herz hat, in Kontakt mit der ausgewählten Oberflächenregion (48a; 56a) des Zwerchfells des Probanden gebracht werden kann, und im ersten Modus eine elektrische Herzzyklusaktivität, die an der ausgewählten Oberflächenregion feststellbar ist, detektiert wird, und im zweiten Modus, der von dem ersten Modus unabhängig ist, die Stimulation des Zwerchfells asymptotisch ist.
3. System nach Anspruch 1, wobei eine zuvor festgelegte, zeitgesteuerte Beziehung eine von Folgenden ist: (a) eine, die das nächste erwartete, valide, Herzzyklus-bezogene elektrische Ventrikulär-Ereignis vorwegnimmt, und (b) eine, die dem zuletzt detektierten, validen, Herzzyklus-bezogenen, elektrischen Ventrikulär-Ereignis folgt.
4. System nach einem der Ansprüche 1 bis 3, in Bezug auf das ein valides, einer ausgewählten Art entsprechendes, elektrisches Ventrikulär-Ereignis eines von (a) der R-Welle und (b) der Q-Welle in der elektrischen Herzzyklusaktivität des Probanden ist.
5. System nach einem der Ansprüche 1 bis 4, das des Weiteren einen Beschleunigungsmesser umfasst, der: (a) für eine Kontakt-bezogene Disposition in einer bewegungsdetektierenden Beziehung mit dem, und mit Bezug auf das, Zwerchfell des Probanden neben der Elektrodenstruktur (26, 28) angeordnet und mit dieser wirkverbunden ist, (b) mit der Stromkreisstruktur (32) wirkverbunden ist, und (c) dafür konstruiert ist, auf eine durch elektrische Stimulation induzierte Bewegung anzusprechen, die im Zwerchfell des Probanden erzeugt wird, indem er ein Zwerchfellbewegungs-Bestätigungssignal erzeugt und an die Stromkreisstruktur übermittelt, das eine Wellenform aufweist, die direkt eine solche Bewegung repräsentiert, wobei der Beschleunigungsmesser bevorzugt ein Mehrachsen-Beschleunigungsmesser und besonders bevorzugt ein dreidimensionaler Beschleunigungsmesser ist.
6. System nach einem der Ansprüche 1 bis 5, wobei die Stromkreisstruktur (32) eine algorithmisch programmierte Computerstruktur enthält, die eine Zeitjustierungs-Teilstruktur (42) aufweist, die in der Lage ist, eine Justierung der erwähnten zuvor festgelegten, zeitgesteuerten Beziehungen vorzunehmen.
7. System nach einem der Ansprüche 1 bis 6, wobei das System in sich geschlossen ist, sich selbst mit

Energie versorgt und nominell in jedem der Herzzyklen eines Probanden arbeiten kann, um die hämodynamische Leistungsfähigkeit des Herzens des Probanden durch Herzzyklus-synchronisierte, asymptotische elektrische Stimulation des Zwerchfells zu verbessern, und Folgendes umfasst:

- eine Systemkapsel (24) mit einer Fläche (24b), die an der ausgewählten Stelle, die nicht in Kontakt mit dem Herz steht, in Kontakt mit (a) der Unterseite oder (b) der Oberseite des Zwerchfells angeordnet werden kann,
 ein Paar voneinander beabstandeter, bimodaler Elektroden (26, 28), die auf der Kapsel (24) getragen werden, auf der Fläche (24b) frei liegen und durch Kontakt mit dem Zwerchfell in dem ersten Modus arbeiten können, um eine Herzbezogene elektrische Aktivität zu detektieren, und in dem zweiten Modus arbeiten können, um eine elektrische Stimulation an das Zwerchfell anzulegen, wobei
 ein dreidimensionaler Beschleunigungsmesser innerhalb der Kapsel angeordnet ist, mit den Elektroden (26, 28) wirkverbunden ist und dafür ausgelegt ist, sowohl eine mechanische Bewegung des Zwerchfells als auch Herztöne zu detektieren, und
 die Stromkreisstruktur (32) innerhalb der Kapsel (24) angeordnet ist, mit den Elektroden (26, 28) und dem Beschleunigungsmesser wirkverbunden ist, eine algorithmisch programmierte Computerstruktur (38) enthält, die strukturiert ist, und wenn das System in einem Betriebszustand ist, in dem es in der Anatomie des Probanden implantiert ist, und nominell während eines jeden der Herzzyklen des Probanden, dafür ausgelegt ist, (a) die durch die Elektroden (26, 28) detektierte elektrische Herzaktivität zu beobachten, (b) in einer ausgewählten, zeitgesteuerten Weise, in Bezug auf ein eventuelles Vorliegen eines zuvor festgelegten, validen, elektrischen Ventrikulär-Ereignisses, das in der detektierten, Herzzyklus-bezogenen elektrischen Herzaktivität festgestellt wird, durch die Elektroden eine asymptotische elektrische Stimulation an das Zwerchfell zu anzulegen, und (c) im Anschluss an eine solche Stimulation jede durch den Beschleunigungsmesser detektierte Zwerchfellbewegung für eine spätere Begutachtung zu beobachten und aufzuzeichnen.
8. System nach Anspruch 7, wobei sich die ausgewählte Zwerchfellstelle links seitlich in der Anatomie des Probanden befindet.
9. System nach Anspruch 7 oder 8, wobei die ausgewählte, zeitgesteuerte Weise, die mit dem Anlegen einer elektrischen Stimulation an das Zwerchfell ver-

knüpft ist, eine von Folgenden ist: (a) eine, die das nächste erwartete, valide, Herzzyklus-bezogene elektrische Ventrikulär-Ereignis vorwegnimmt, und (b) eine, wobei die ausgewählte, zeitgesteuerte Weise, die mit dem Anlegen einer elektrischen Stimulation an das Zwerchfell verknüpft ist, eine ist, die dem zuletzt detektierten, validen, Herzzyklus-bezogenen, elektrischen Ventrikulär-Ereignis folgt.

10. System nach Anspruch 1, das des Weiteren eine mechanische Detektionsstruktur (36) umfasst, die neben einer ausgewählten Oberflächenregion (50a; 50b) im Zwerchfell des Probanden wirkverbunden werden kann und dafür ausgelegt ist, mechanische Informationen zu detektieren, die aus der Herzaktivität des Probanden stammen.
11. Vollständig implantierbares medizinisches System nach Anspruch 10, wobei
 die Elektrodenstruktur (26, 28) in Kontakt mit der ausgewählten Oberflächenregion (50a; 50b) des Zwerchfells des Probanden an einer Stelle, die nicht in Kontakt mit dem Herz steht, angeordnet werden kann, um eine asymptotische elektrische Stimulation an das Zwerchfell an der ausgewählten Oberflächenregion anzulegen,
 die mechanische Detektionsstruktur (36) einen dreidimensionalen Beschleunigungsmesser umfasst, der neben der Elektrodenstruktur (26, 28) angeordnet und mit dieser wirkverbunden ist, um - in Verbindung mit der Elektrodenstruktur - neben derselben, ausgewählten Oberflächenregion (50a; 50b) des Zwerchfells und in einer Kontakt-bezogenen, bewegungsdetektierenden Beziehung mit dem Zwerchfell angeordnet zu werden, und dafür geeignet ist, in den Herzzyklen des Probanden eine mechanische Herzzyklusaktivität zu detektieren, die in der ausgewählten Zwerchfell-Oberflächenregion feststellbar ist, und
 die Stromkreisstruktur (32) sowohl mit der Elektrodenstruktur (26, 28) als auch mit dem Beschleunigungsmesser wirkverbunden ist, um von dem Beschleunigungsmesser Informationen zu empfangen, die die mechanische Herzzyklusaktivität des Probanden, die durch den Beschleunigungsmesser detektiert wird, betreffen.
12. System nach Anspruch 10, in Bezug auf das ein valides, mechanisches Ventrikulär-Ereignis der S1-Herzton in der mechanischen Herzzyklusaktivität des Probanden ist.
13. System nach Anspruch 11 oder 12, wobei der Beschleunigungsmesser außerdem so konstruiert ist, dass er auf eine Bewegung anspricht, die im Zwerchfell des Probanden infolge der elektrischen Zwerchfellstimulation erzeugt wird, und im Zusammenhang mit einem solchen Ansprechen an die Stromkreis-

struktur (32) ein Zwerchfellbewegungs-Bestätigungssignal übermittelt, das eine Wellenform aufweist, die direkt eine solche Bewegung repräsentiert.

14. System nach Anspruch 5 bis 9 oder 13, wobei die Stromkreisstruktur (32) eine algorithmisch programmierte Computerstruktur (38) enthält, die eine Wellenformüberwachungs- und -aufzeichnungs-Teilstruktur (40) aufweist, um die Wellenform eines übermittelten Bestätigungssignals mit einer Referenzwellenform zu vergleichen und die Bestätigungssignalwellenform zur anschließenden Begutachtung aufzuzeichnen.
15. System nach einem der vorangehenden Ansprüche, das eines von Folgendem ist: (a) eine in sich geschlossene, singuläre Gesamteinheit, und (b) verteilt zwischen einem voneinander beabstandeten Paar Komponentenbaugruppen (62, 64), die durch eine Kommunikationsleitungsstruktur (66) wirkverbunden sind, und wobei die ausgewählte Oberflächenregion (48a; 56a; 50a; 50b) (a) auf der Unterseite oder (b) auf der Oberseite des Zwerchfells angeordnet ist.

Revendications

1. Système médical entièrement implantable pour améliorer la performance cardiovasculaire d'un sujet par une stimulation diaphragmatique électrique comprenant une structure d'électrodes bimodales (26, 28) pouvant être reliée de manière fonctionnelle à une région de surface sélectionnée (48a ; 56a) dans le diaphragme du sujet, où elle est configurée pour fonctionner dans un premier mode conçu pour amener la structure d'électrodes (26, 28) à détecter, à partir d'une telle région de surface adjacente, l'activité cardiaque électrique du sujet, et un deuxième mode conçu pour amener la structure d'électrodes (26, 28) à effectuer une stimulation diaphragmatique électrique synchronisée sur le cycle cardiaque à l'emplacement de la même région de surface mentionnée, et une structure de circuit électrique (32), reliée de manière fonctionnelle à la structure d'électrodes (26, 28), pouvant fonctionner pour collecter, tandis que la structure d'électrodes fonctionne dans le premier mode, l'activité cardiaque électrique détectée, et, tandis que la structure d'électrodes fonctionne dans le deuxième mode, pour communiquer avec la structure d'électrodes afin d'effectuer une stimulation diaphragmatique, dans lequel la structure de circuit électrique (32) peut fonctionner pour noter la présence d'un événement V électrique valide correspondant à l'apparition

d'une contraction ventriculaire gauche ou d'un événement électrique cardiaque ayant une relation connue de manière prévisible avec une telle apparition, dans de telles informations d'activité électrique de cycle cardiaque reçues, et pour délivrer une stimulation électrique asymptotique synchronisée sur le cycle cardiaque à travers la structure d'électrodes (26, 28) au diaphragme selon une relation temporisée prédéterminée avec l'événement V électrique valide, la stimulation électrique étant configurée pour déclencher un mouvement biphasique du diaphragme, lequel mouvement biphasique comprend un mouvement caudal du diaphragme suivi d'un mouvement crânien du diaphragme.

2. Système médical entièrement implantable de la revendication 1, dans lequel la structure d'électrodes bimodales (26, 28) peut être placée en contact avec la région de surface sélectionnée (48a ; 56a) du diaphragme du sujet à un emplacement qui est hors de contact avec le coeur, et dans le premier mode, une activité électrique de cycle cardiaque discernable au niveau de la région de surface sélectionnée est détectée, et dans le deuxième mode, qui est indépendant du premier mode, la stimulation du diaphragme est asymptotique.
3. Système de la revendication 1, dans lequel une relation temporisée prédéterminée est l'une (a) d'une relation qui anticipe l'événement V électrique de cycle cardiaque valide suivant prévu, et (b) d'une relation qui suit l'événement V électrique de cycle cardiaque valide détecté en dernier.
4. Système de l'une des revendications 1 à 3, par rapport auquel un événement V électrique à caractère sélectionné valide est l'une (a) de l'onde R, et (b) de l'onde Q dans l'activité de cycle cardiaque électrique du sujet.
5. Système de l'une des revendications 1 à 4, comprenant en outre un accéléromètre qui est (a) disposé de manière adjacente et associé de manière fonctionnelle à ladite structure d'électrodes (26, 28) pour une disposition associée au contact selon une relation de détection de mouvement avec le diaphragme du sujet, et par rapport à celui-ci, (b) relié de manière fonctionnelle à ladite structure de circuit (32), et (c) construit pour répondre à un mouvement induit par stimulation électrique produit dans le diaphragme du sujet en générant, et communiquant à ladite structure de circuit, un signal de confirmation de mouvement diaphragmatique possédant une forme d'onde qui indique directement un tel mouvement, où l'accéléromètre est de préférence un accéléromètre multiaxe, et encore plus préférablement un accéléromètre tridimensionnel.

6. Système de l'une des revendications 1 à 5, dans lequel ladite structure de circuit (32) comporte une structure informatique programmée algorithmiquement ayant une sous-structure d'ajustement de temporisation (42) capable d'effectuer un ajustement dans les relations temporisées prédéterminées mentionnées.
7. Système de l'une des revendications 1 à 6, dans lequel le système est autonome, auto-alimenté et peut fonctionner essentiellement dans chacun des cycles cardiaques d'un sujet pour améliorer la performance hémodynamique du coeur du sujet par une stimulation électrique asymptotique synchronisée sur le cycle cardiaque du diaphragme, et comprend une capsule de système (24) ayant une face (24b) pouvant être placée par contact sur l'un (a) du côté inférieur et (b) du côté supérieur du diaphragme à l'emplacement sélectionné qui est hors de contact avec le coeur, une paire d'électrodes bimodales espacées (26, 28) portées sur ladite capsule (24) et exposées sur ladite face (24b), pouvant fonctionner, par contact avec le diaphragme, dans le premier mode pour détecter une activité électrique associée au coeur, et dans le deuxième mode pour appliquer une stimulation électrique au diaphragme, où un accéléromètre tridimensionnel est disposé à l'intérieur de ladite capsule, associé de manière fonctionnelle auxdites électrodes (26, 28), et peut fonctionner pour détecter à la fois le mouvement mécanique du diaphragme et les bruits du coeur, et la structure de circuit électrique (32) est disposée à l'intérieur de ladite capsule (24), reliée de manière fonctionnelle auxdites électrodes (26, 28) et audit accéléromètre, y compris une structure informatique programmée algorithmiquement (38) qui est structurée, et peut fonctionner, lorsque le système est dans un état fonctionnel implanté dans l'anatomie du sujet, et essentiellement pendant chacun des cycles cardiaques du sujet, (a) pour observer une activité cardiaque électrique détectée par lesdites électrodes (26, 28), (b) de manière temporisée sélectionnée par rapport à la présence, le cas échéant, d'un événement V électrique valide prédéterminé noté dans l'activité cardiaque électrique de cycle cardiaque détectée, pour appliquer une stimulation électrique asymptotique au diaphragme à travers lesdites électrodes, et (c) après une telle stimulation, pour observer et enregistrer pour examen ultérieur tout mouvement diaphragmatique détecté par ledit accéléromètre.
8. Système de la revendication 7, dans lequel l'emplacement diaphragmatique sélectionné est latéral gauche dans l'anatomie du sujet.
9. Système de la revendication 7 ou 8, dans lequel la manière temporisée sélectionnée associée à l'application d'une stimulation électrique au diaphragme est l'une (a) d'une manière qui anticipe l'événement V électrique de cycle cardiaque valide suivant prévu et (b) d'une manière où la manière temporisée sélectionnée associée à l'application d'une stimulation électrique au diaphragme est une manière qui suit l'événement V électrique de cycle cardiaque valide détecté en dernier.
10. Système de la revendication 1, comprenant en outre une structure de détection mécanique (36), pouvant être fixée, de manière fonctionnelle, de manière adjacente à une région de surface sélectionnée (50a ; 50b) dans le diaphragme du sujet, conçue pour détecter des informations mécaniques provenant de l'activité cardiaque du sujet.
11. Système médical entièrement implantable de la revendication 10, dans lequel la structure d'électrodes (26, 28) peut être placée en contact avec la région de surface sélectionnée (50a ; 50b) du diaphragme du sujet à un emplacement qui est hors de contact avec le coeur, pour appliquer une stimulation électrique asymptotique au diaphragme au niveau de la région de surface sélectionnée, la structure de détection mécanique (36) comprend un accéléromètre tridimensionnel disposé de manière adjacente à ladite structure d'électrodes (26, 28), et associé de manière fonctionnelle à celle-ci, pour le placement, en association avec la structure d'électrodes, de manière adjacente à la même région de surface sélectionnée (50a ; 50b) du diaphragme et selon une relation de détection de mouvement associée au contact avec le diaphragme, pouvant fonctionner pour détecter, dans les cycles cardiaques du sujet, une activité mécanique de cycle cardiaque discernable au niveau de la région de surface diaphragmatique sélectionnée, et la structure de circuit (32) est reliée de manière fonctionnelle à la fois à ladite structure d'électrodes (26, 28) et audit accéléromètre pour recevoir à partir de l'accéléromètre des informations relatives à l'activité mécanique de cycle cardiaque du sujet qui est détectée par l'accéléromètre.
12. Système de la revendication 10 par rapport auquel un événement V mécanique valide est le bruit du coeur S1 dans l'activité mécanique de cycle cardiaque du sujet.
13. Système de la revendication 11 ou 12, dans lequel ledit accéléromètre est en outre construit pour être sensible à tout mouvement produit dans le diaphragme du sujet à la suite d'une stimulation diaphragmatique électrique, et en rapport avec une telle sensi-

bilité, pour communiquer à ladite structure de circuit (32) un signal de confirmation de mouvement diaphragmatique possédant une forme d'onde qui indique directement un tel mouvement.

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14. Système des revendications 5 à 9 ou de la revendication 13, dans lequel ladite structure de circuit (32) comporte une structure informatique programmée algorithmiquement (38) ayant une sous-structure de surveillance et d'enregistrement de forme d'onde (40) pour comparer la forme d'onde d'un signal de confirmation communiqué à une forme d'onde de référence et pour enregistrer la forme d'onde de signal de conformation pour examen ultérieur.

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15. Système de l'une des revendications précédentes, qui est l'un (a) d'un système autonome tel qu'une unité globale singulière, et (b) d'un système réparti entre une paire espacée d'ensembles de composants (62, 64) reliés entre eux de manière fonctionnelle par une structure conductrice de communication (66), et dans lequel la région de surface sélectionnée (48a ; 56a ; 50a ; 50b) est disposée sur l'un (a) du côté inférieur et (b) du côté supérieur du diaphragme.

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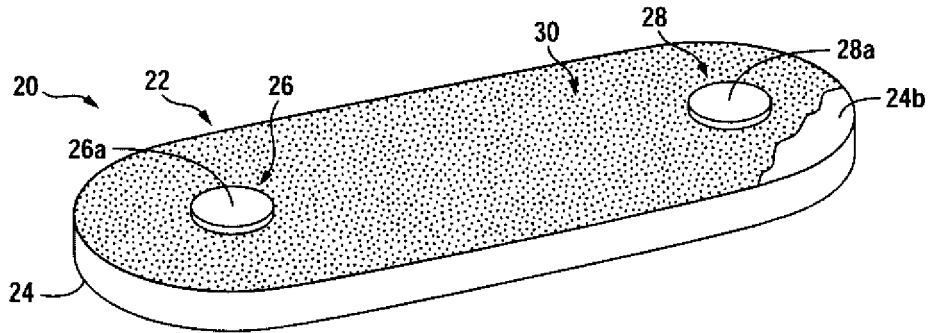


FIG. 1

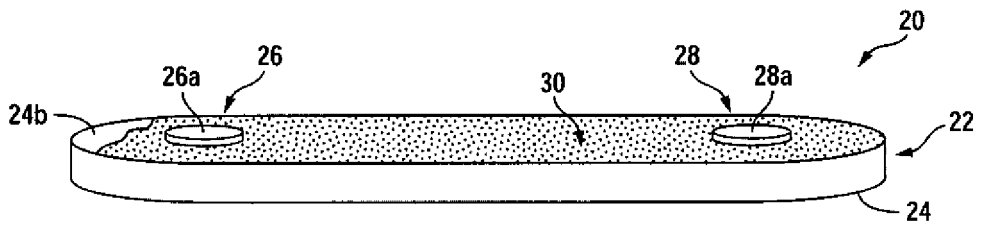


FIG. 2

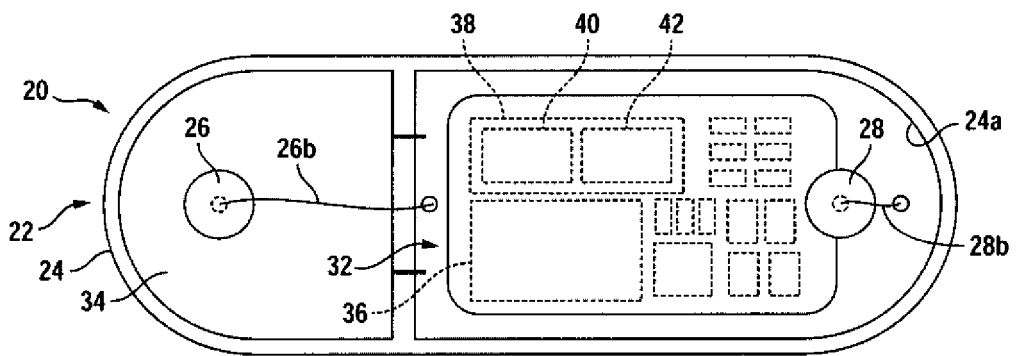
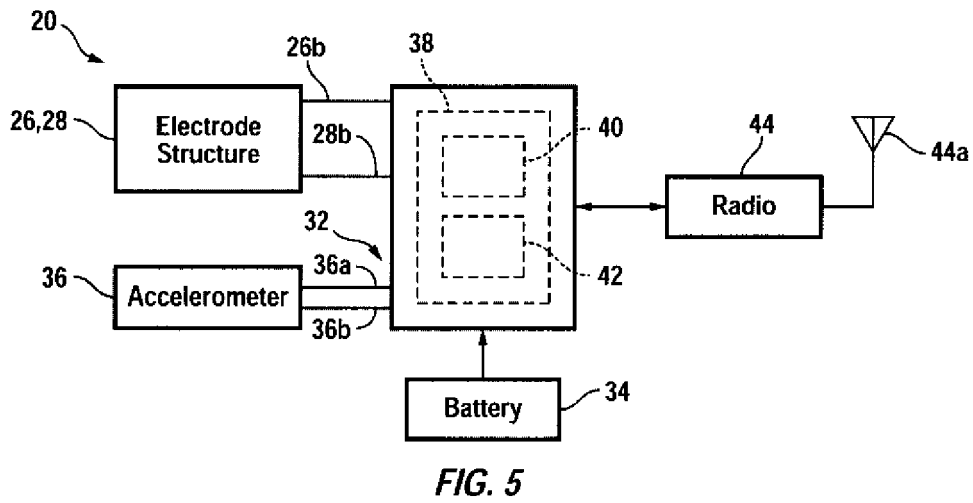
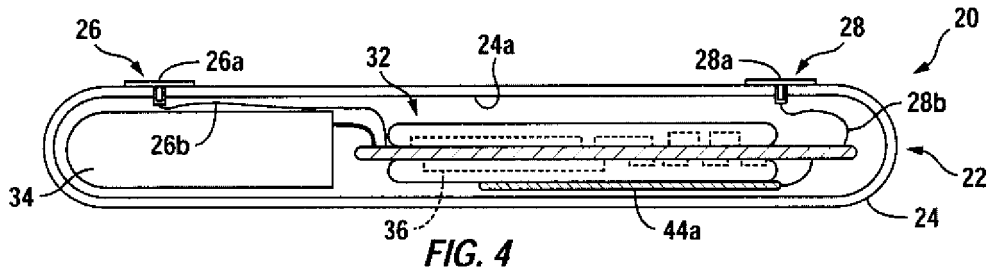


FIG. 3



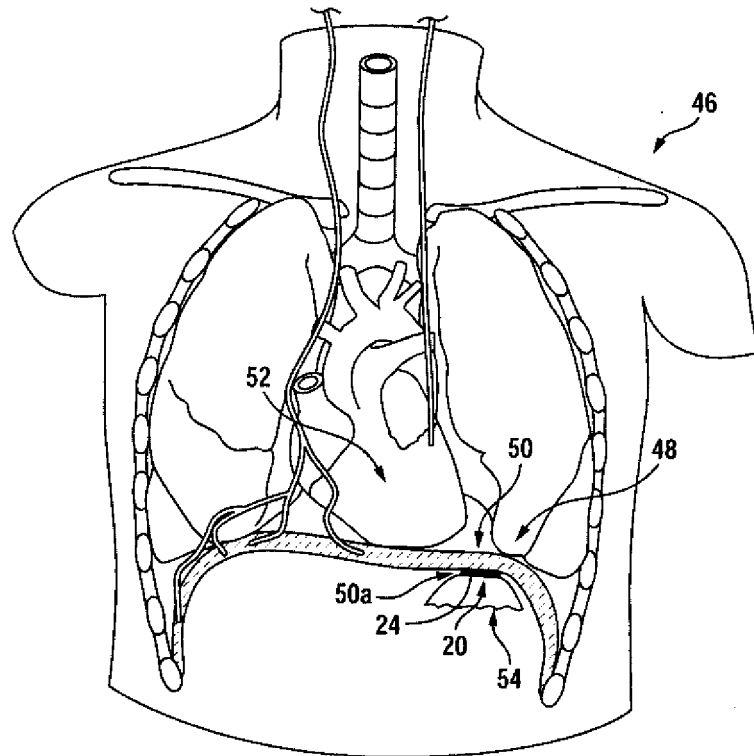


FIG. 6A

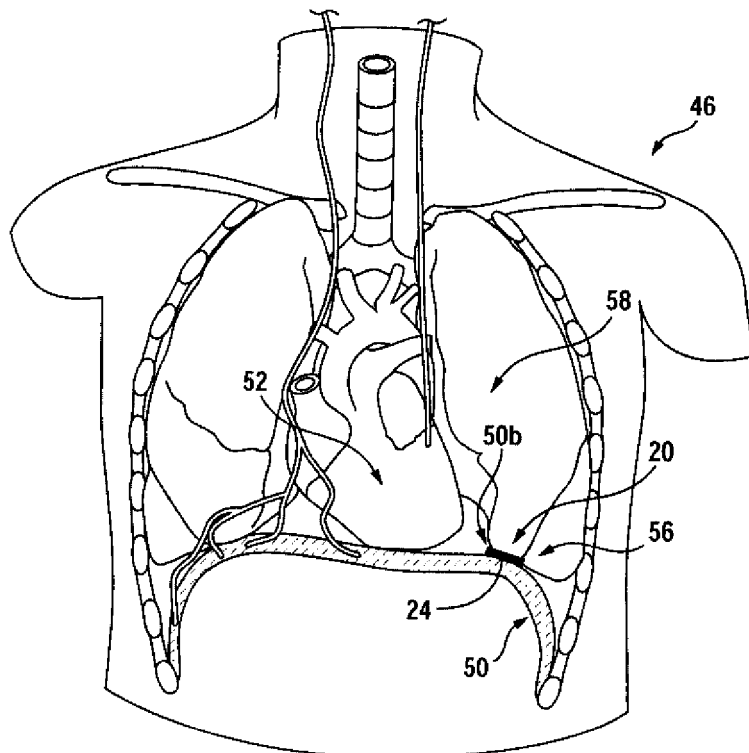


FIG. 6B

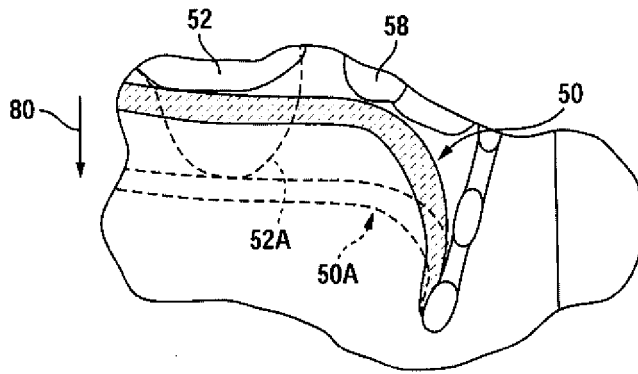


FIG. 7A

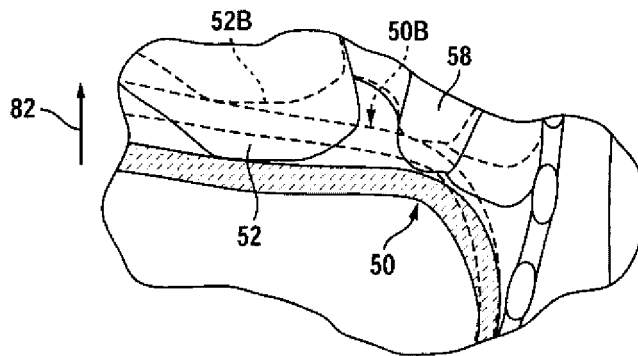


FIG. 7B

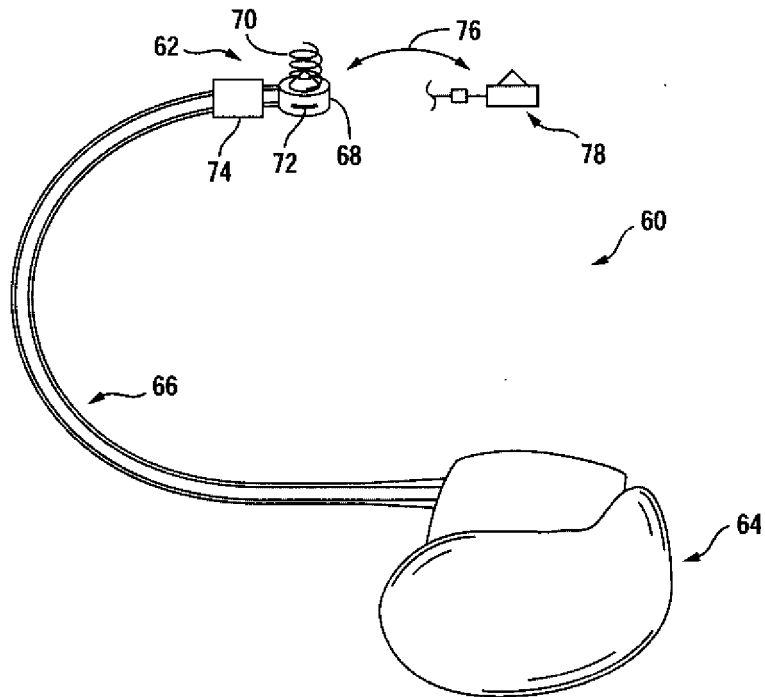


FIG. 8

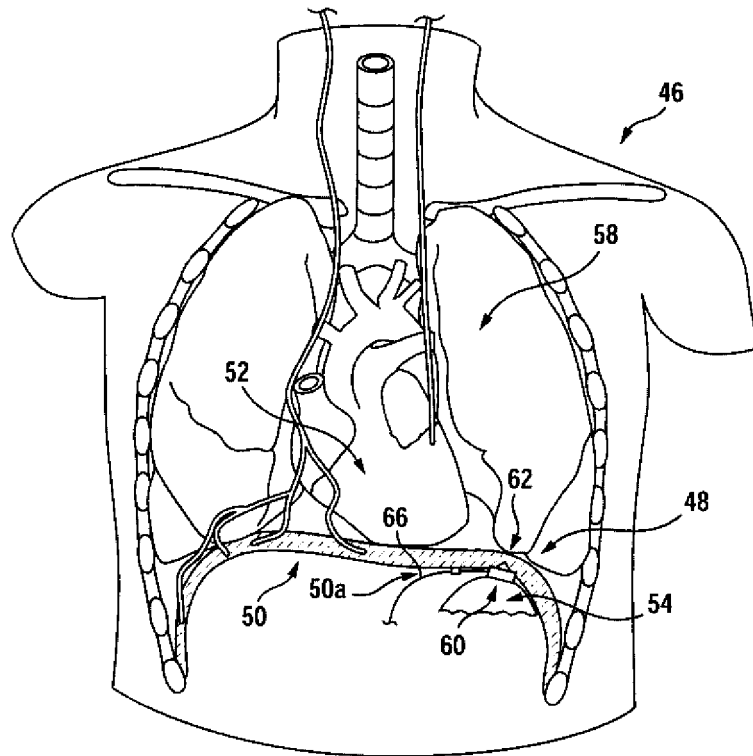


FIG. 9A

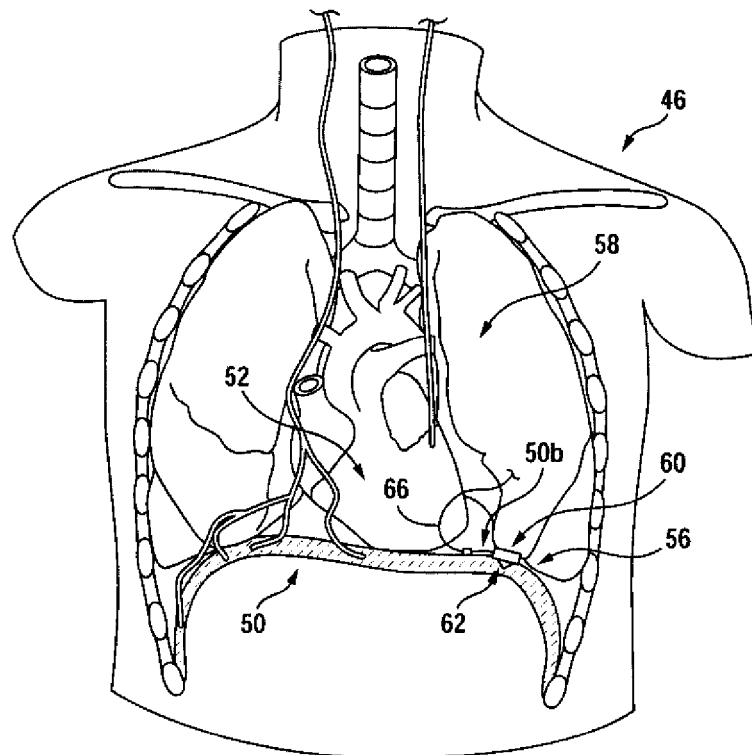


FIG. 9B

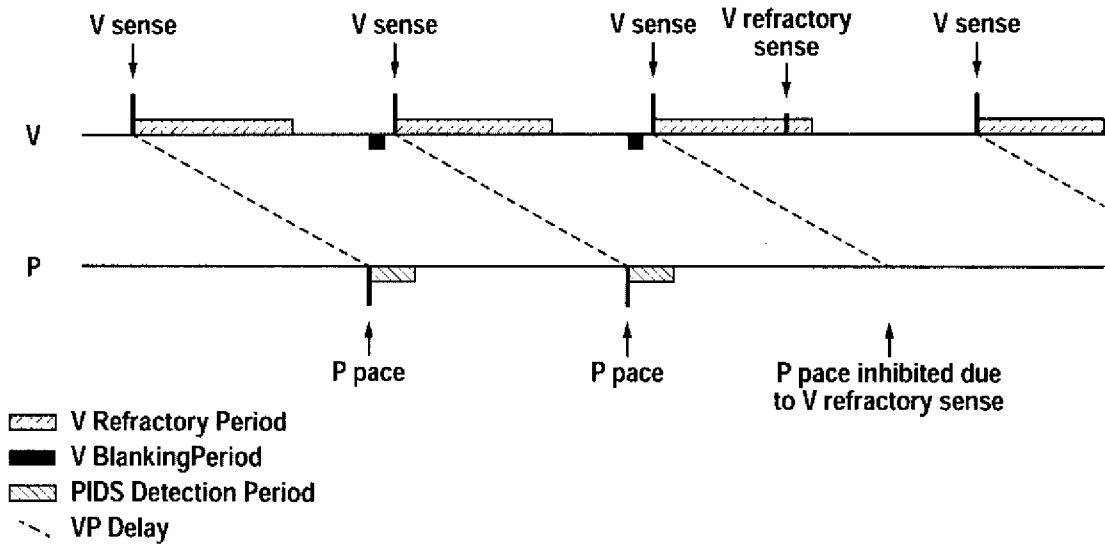


FIG. 10

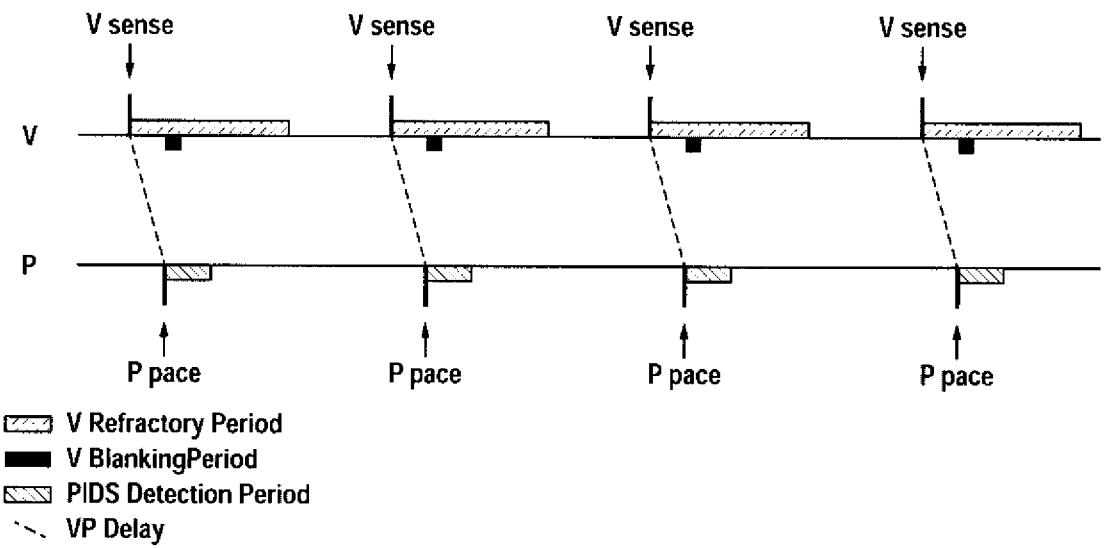


FIG. 11

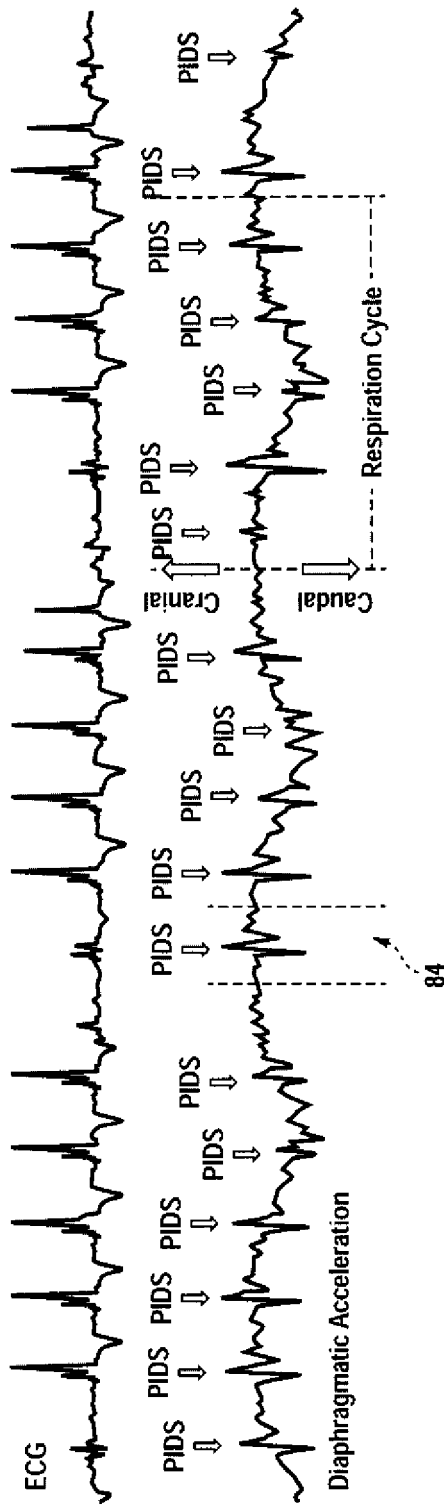


FIG. 12

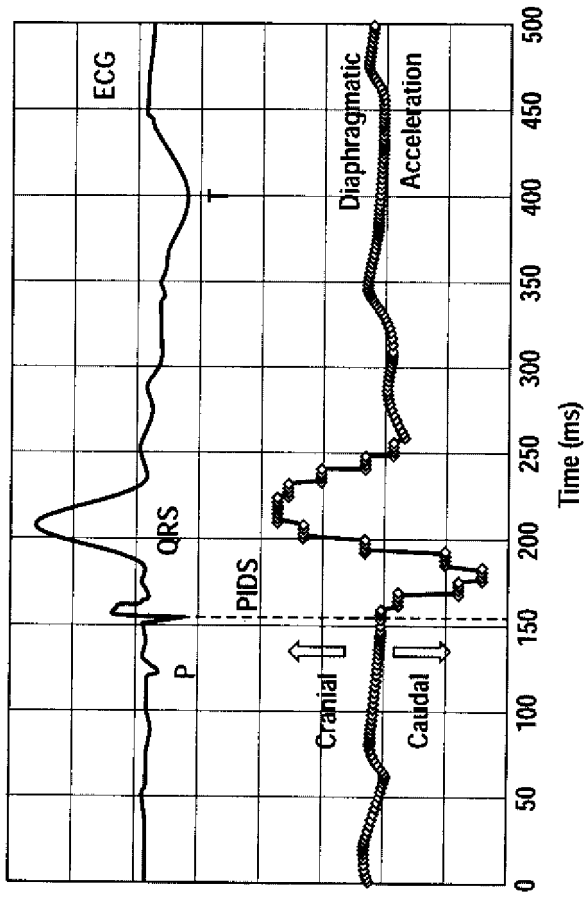


FIG. 13

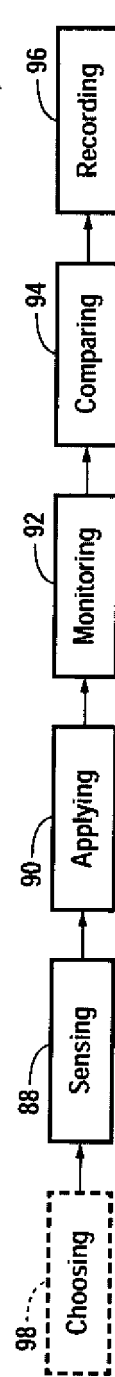


FIG. 14

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	通过无症状隔膜刺激增强血流动力学性能		
公开(公告)号	EP2934668B1	公开(公告)日	2018-08-22
申请号	EP2013865191	申请日	2013-12-16
[标]申请(专利权)人(译)	伊诺维思医疗公司		
申请(专利权)人(译)	inovise医疗公司		
当前申请(专利权)人(译)	viscardia, Inc.		
[标]发明人	BAUER PETER T		
发明人	BAUER, PETER, T.		
IPC分类号	A61B5/00 A61B5/0456 A61B5/0452 A61N1/36 A61B5/113 A61N1/365 A61N1/362		
CPC分类号	A61N1/3627 A61B5/02438 A61B5/0452 A61B5/0456 A61B5/113 A61B5/4836 A61B5/686 A61B5/6867 A61B5/721 A61B5/7246 A61B2562/063 A61N1/3601 A61N1/36585		
优先权	61/739704 2012-12-19 US		
其他公开文献	EP2934668A1 EP2934668A4		
外部链接	Espacenet		

摘要(译)

一种可植入系统和方法，用于改善心脏的血液动力学性能，其特征在于：(a)可放置在隔膜上的双峰电极，与心脏不接触，具有一种用于感测心脏电活动的模式，以及另一种用于应用心动周期同步的模式，对膈肌的无症状电刺激以触发双相膈肌运动，(b)与电极相邻的加速度计，用于感测心音，刺激引起的膈肌运动，和(c)电路结构，连接到电极和加速度计，可在预定的时间关系中操作，以在感测的电和机械，心脏活动之一中记录的有效V事件的存在，以递送膈刺激。该电路结构包括加速度计连接的计算机结构，用于能够选择性地检查刺激产生的横向运动的后续操作修改，并且以修改的形式，可以另外包括能够在所述定时关系中进行调整的定时调整子结构。

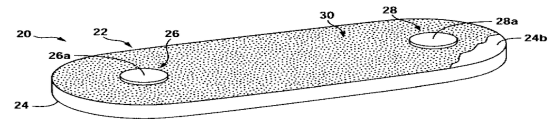


FIG. 1

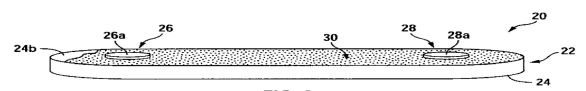


FIG. 2

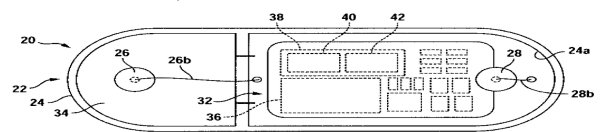


FIG. 3