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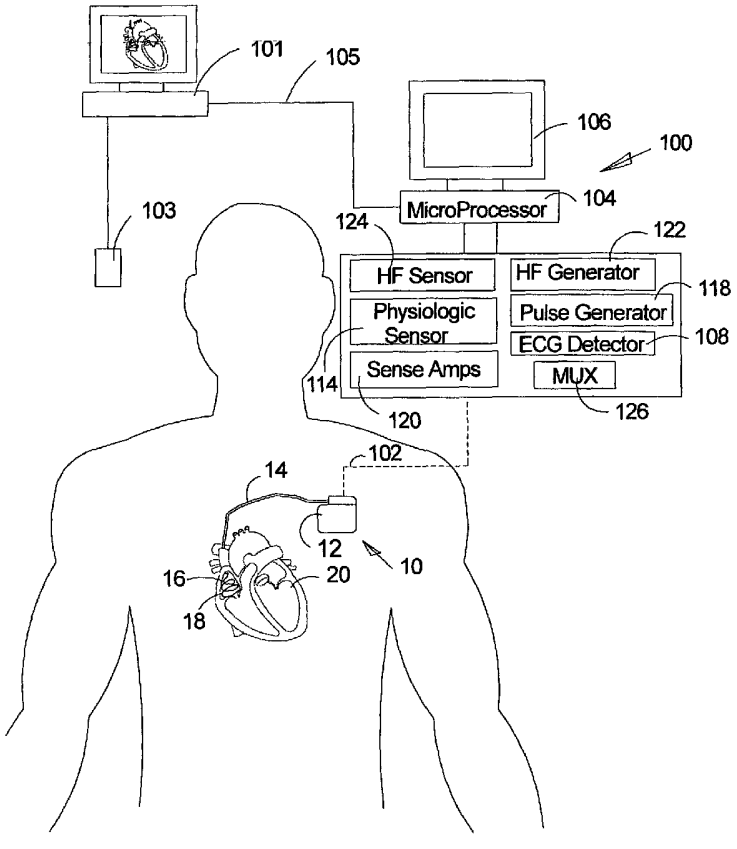

(57) Abstract: A cardiac stimulation apparatus and multi-electrode pacing lead for prevention or treatment of atrial fibrillation. The multi-electrode lead will distribute electrodes throughout the right atrium to provide a choice of pacing sites at locations best suited to multi-focal control of the rapid atrial heartbeats that may precede atrial fibrillation. Cardiac electrical activity is sensed in four dimensions (three spatial dimensions, X, Y, and Z, and in time). The system triangulates the location of a given event in three spatial dimensions, and then paces the heart in areas that will disrupt the propagation of the arrhythmia. Termination involves delivering low voltage pulses to large areas of the heart, either simultaneously or in rapid sequence.

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CARDIAC STIMULATION APPARATUS AND METHOD FOR TREATMENT OF ATRIAL FIBRILLATION

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of provisional applications 60/287,272, filed April 27, 2001 and 60/287,145, filed April 27, 2001, and 60/288,358 filed May 3, 2001, which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

A. Field of the Invention

This disclosure relates to cardiac stimulation devices and in particular to a cardiac stimulation apparatus and multi-electrode lead and method for the treatment of atrial fibrillation.

B. Description of the Prior Art

The heart is a mechanical pump that is stimulated by electrical impulses. The mechanical action of the heart results in the flow of blood. During a normal heartbeat, the right atrium fills with blood from the returning veins. The right atrium then contracts and moves blood into the right ventricle. When the right ventricle contracts, it pumps blood to the lungs. Blood returning from the lungs moves into the left atrium, and, after left atrium contraction, is pumped into the left ventricle, which then pumps it throughout the body. Four heart valves keep the blood flowing in the proper directions.

The electrical signal that drives this mechanical contraction usually starts in the sino-atrial node, a collection of specialized heart cells in the right atrium that automatically depolarize. In a normal heartbeat, a single, uniform depolarization wave front passes across all the cells of both atria, contracting the atria.

In atrial fibrillation, this single, uniform wave front breaks up into multiple, rapid and irregular depolarizing wave fronts, or "reentrant wavelets". The wavelets

propagate throughout the atria, interrupting the regular propagation of the normal uniform activation front. The result is atrial contractions that take place over small areas of the heart and occur so rapidly that there is little blood flow to the ventricles.

Atrial fibrillation has more than one etiology and therefore is very difficult to treat. Pharmacological treatment (drugs), ablation, defibrillation, and overdrive pacing have all been tried with limited success. Drugs are both difficult for patients to tolerate and ineffective over long periods of time. The NHLBI sponsored Cardiac Arrhythmia Suppression Trial (CAST, 1998) used two anti-arrhythmic drugs to see if suppression of premature ventricular contractions (PVCs) would decrease patient mortality. While the drugs suppressed PVCs, they also caused a two to three fold increase in mortality. The EMERALD study evaluated the capability of the drug Dofetilide (TM) to convert atrial fibrillation and to maintain normal sinus rhythm. While the drug was effective in converting patients with atrial fibrillation, the high doses requires had detrimental effects in some patients. Circulation 99: 2486-2491, 1999.

In many cases a limited number of discrete groups of cells, typically in or near pulmonary veins of the left atrium, fire independently and disturb the propagation of the regular activation wave front. Electrophysiologists will frequently ablate these ectopic foci to eliminate the source of the conflicting activation fronts. The electrophysiologist first develops an electrical conduction map of the heart, locates the foci and then kills the focal cells, usually with radio frequency (RF) energy. But ablation is imprecise. In many cases the attending physician must ablate several times in order to kill the aberrant cells. Ablation is also a permanent procedure. Once dead, the cardiac myocytes do not regenerate and in many cases the patient requires a pacemaker. However, in cases where fibrillation is caused by an identifiable group of cells that is regularly misfiring, ablation may be the only alternative. Ablation is also used to create conduction blocks to uniformly channel the activation wave front and block disrupting reentry by the offshoot wavelets, but this, again, is a very invasive procedure.

Defibrillation is another method for treating atrial fibrillation. A defibrillation lead is placed in the right atrium along with an implantable defibrillator. The defibrillator senses the rapidly beating atrium and sends out a high voltage (up to 700V), high-

energy (up to 15 Joules) pulse that interrupts the fibrillation. But defibrillation does not prevent atrial fibrillation from recurring and the patient can be shocked multiple times per day. Patients resist this treatment. Atrial defibrillators are enormously painful and most patients decide they would rather live with atrial fibrillation and tolerate the discomfort and associated risk of stroke.

Atrial fibrillation has also defeated all attempts to develop pacing systems to prevent it. Some approaches, in particular bi-atrial and dual-site right atrial overdrive pacing, have recently shown promise for reducing the incidence of atrial fibrillation, but not for preventing it. Overdrive pacing involves implanting a standard pacemaker lead into the right atrium and pacing the atrium at a rate slightly faster than the normal sinus rhythm of the patient. This method is beneficial if the fibrillation is sufficiently slow and if the pacing pulse is sufficiently large. However, it is not effective for a large number of patients.

These pacing methods are fundamentally simple adaptations of conventional rate and rhythm control technology to the problem of controlling atrial fibrillation. Only a limited number (1-3) of electrodes is deployed, each electrode with a separate lead. This means that, minimally, the choice of optimal pacing site or sites is severely constrained. Furthermore, these severe constraints on electrode placements necessarily restrict the ability of conventional pacing systems to detect and control the complex reentrant wavelets that lead to and underlie atrial fibrillation.

BRIEF SUMMARY OF THE INVENTION

In view of the disadvantages of the prior art, it is an objective of the present invention to develop a cardiac stimulation apparatus and multi-electrode pacing lead for prevention of atrial fibrillation. The multi-electrode lead will distribute electrodes throughout the right atrium to provide a choice of pacing sites at locations best suited to multi-focal control of the rapid atrial heartbeats that may precede atrial fibrillation. This will allow physicians maximum flexibility to optimize pacing site position and pacing sequence to the individual patient's anatomy and physiology. As atrial arrhythmias frequently occur in patients suffering from other heart diseases and conditions, the lead may also be used in conjunction with either a multi-focal

ventricular lead or a conventional ventricular pacing lead.

The cardiac stimulation apparatus and multi-electrode pacing lead described herein will make it possible to sense cardiac electrical activity in four dimensions (three spatial dimensions, X, Y, and Z, and in time) in order to nearly instantaneously identify individual arrhythmic wavelets. It will also allow delivery of low voltage pacing pulses to one or more of at least 5 and preferably 32 electrically isolated electrodes spaced throughout the right atrium. This will effectively block the propagation of these wavelets and damp out the developing fibrillation.

The invention pertains to an implantable cardiac sensing and stimulation system with the appropriate sensing and pacing circuitry (pulse generator) and a multi-electrode lead attached to the stimulator and shaped for insertion into at least an atrial chamber of the heart. The sensing and stimulation system is adaptable to sense intrinsic cardiac activity and to generate a stimulation pulse responsive to that electrical activity.

The lead consists of a multi-electrode array that has been specifically shaped to fit in the right atrium and to distribute electrodes to various strategic locations in the right atrium. One form of multi-electrode lead has been described in US application 09/761,333, the disclosure of which is incorporated herein by reference.

Fast heartbeats (tachyarrhythmias and fibrillations) can be treated with a multi-electrode catheter and pacing system by either preventing or terminating the event. Prevention uses the ability of the system to identify and triangulate the location of a given event in three spatial dimensions, and then pace the heart in areas that will disrupt the propagation of the arrhythmia. Termination involves delivering low voltage pulses to large areas of the heart, either simultaneously or in rapid sequence. These pulses will have the same effect as a high-energy defibrillation pulse in capturing the heart and re-synchronizing the electrical activity of the heart but without the complications, both technological and physiological, and pain of a high-energy shock.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 shows an implantable cardiac stimulation apparatus and multi-electrode lead for treatment of atrial fibrillation and programmer.

Fig. 2 is a block diagram of selected components of the implantable cardiac stimulation apparatus.

Fig. 3 is a block diagram of a first embodiment of an output control circuit for use in the implantable cardiac stimulation device of Fig. 2.

Fig. 4 is a block diagram of a second embodiment of an output control circuit for use in the implantable cardiac stimulation device of Fig. 2.

Fig. 5 is a block diagram of a first embodiment of a sense detection circuit for use in the implantable cardiac stimulation device of Fig. 2.

Fig. 6 is a block diagram of a second embodiment of a sense detection circuit for use in the implantable cardiac stimulation device of Fig. 2.

Fig. 7 is a block diagram of an adapter for connecting a multi-electrode lead to a standard IS-1 pacemaker connector.

Fig. 8 is a representation of a multi-electrode lead and connector with a distal end of the lead implanted in the right atrium of a heart.

Fig. 9 is a plan view of a first embodiment of an electrode for the multi-electrode lead.

Fig. 10 is a cross-section view of a second embodiment of an electrode for the multi-electrode lead.

Fig. 11 is a through section of the multi-electrode lead.

Fig. 12 is a flow chart of a program for identifying implanted positions of the electrodes of the multi-electrode lead in three dimensions.

Fig. 13 is a flow chart for treatment of atrial fibrillation.

DETAILED DESCRIPTION OF THE INVENTION

The subject invention pertains to an implantable cardiac stimulation system 10 including a cardiac stimulator 12 with various electronic circuits, and a multi-electrode lead 14 attached to the stimulator 12, as shown in Fig. 1. The lead 14 has a distal end 16 disposed, for example, in one of the atrial chambers, such as the right atrium 18 of heart 20. In Fig.1, end 16 is shown having a general spiral shape. The system 10 is adapted to deliver therapy in the form of electrical pulses. The cardiac stimulator 12

contains electronic components common to current cardiac stimulators such as a battery, microprocessor control circuit, ROM, RAM, an oscillator, reed switch and antenna for communication, output circuits, and sense circuits. These components are well known to those of skill in the art. In addition the cardiac stimulator 12 has a plurality of independent sensing and stimulating circuits for each heart chamber, as will be explained below.

Cardiac Stimulator

Fig. 2 illustrates important elements of the cardiac stimulator 12 in block diagram. The cardiac stimulator 12 comprises a logic control and timing circuit 22, which may include a microprocessor and memory, but which could also be implemented in a specialized circuit. The logic control and timing circuit 22 receives input from a sense detection circuit 24 and issues control instructions to an output control circuit 26. To accommodate the many electrodes used in the apparatus, multiple sense amplifiers 28a, 28b ... 28n are provided, each in electrical communication with an electrode through the lead 14 and with the sense detection circuit 24. Similarly, the output control circuit 26 is electrically connected to a plurality of output circuits 30a, 30b ... 30n. The output circuits 30a, 30b ... 30n produce stimulating pulses or high frequency, non-simulating signals at electrodes in the heart through the lead 14. The logic control and timing circuit 22 may operate in accordance with a program stored into memory. The program in memory is received through a transceiver 25 (for instance from programmer 100). As part of this programming, the electrodes designated for stimulation, as described below, are stored in memory. During its operation, the microprocessor of the logic control and timing circuit 22 sets the output control circuit 26 and the sense detection circuit 24 in accordance with the appropriate electrode designations. Thereafter, the sensing detection circuit 24 senses intrinsic activity and other signals within the heart 20 and provides corresponding indication signals to the microprocessor. The logic control and timing circuit 22 then issues appropriate commands to the output control circuit 26. The output control circuit 26 generates appropriate stimulation pulses. These pulses are steered to the designated electrode or electrodes.

Output Circuits

Figures 3 and 4 show two embodiments of output control circuits 26 and output circuits 30a, 30b ... 30n. The embodiment of Fig. 3 comprises a communications controller 32 that receives control signals from the logic control and timing circuit 22 (Fig. 2). Output of the communications controller 32 is sent to an amplitude controller 34 that controls the voltages produced by a plurality of voltage amplifiers 36a, 36b ... 36n. In parallel, the communications controller 32 also regulates a pulse timing controller 38. Signals from the pulse timing controller 38 close and open switches 40a, 40b ... 40n, thereby delivering stimulation pulses or high frequency signals to the heart through electrodes on the lead 14.

The embodiment of Fig. 4 also uses a communication controller 32 and pulse timing controller 38, but the amplitude controller 34 and the plurality of voltage amplifiers 36a, 36b ... 36 n are replaced by a single voltage amplifier 42. To achieve the same effect of multiple pulses to selected electrodes, the signals from the pulse timing controller are sent to a multiplexer 44, comprising a switch matrix controller 46 and a plurality of switches 48a, 48b ... 48n. The switches 48a, 48b ... 48n must be opened and closed in a synchronized manner. The embodiment of Fig. 4 gains space and energy efficiency by minimizing the number of voltage amplifiers.

Sense Circuits

A variety of apparatus may also be used to sense signals from multiple electrodes through the sense detection circuit 24. A first embodiment is illustrated in Fig. 5. In the embodiment of Fig. 5, a communication controller 50 in the sense detection circuit 24 communicates with the logic control and timing circuit 22 (Fig. 2). The communication controller 50 is in electrical communication with a sense amp controller 52 and a sense event timing analysis unit 54. The sense amplifier controller 52 regulates amplification levels on the sense amplifiers 36a, 36b ... 36n such that significant signals are detected and noise is rejected. Each amplifier has independent sensitivity (gain) and filter characteristics. The sense event timing analysis unit 54 receives output from the sense amplifiers 36a, 36b ... 36n and collects that

information into a description of a moving wave front. Both intervals between sensed events and the sequence of channels or electrodes are used to describe the wave front. The description of the wave front is communicated to the logic control and timing circuit 22 for use in determining the appropriate therapy.

A second embodiment, illustrated in Fig. 6, employs a multiplexer in a manner similar to the second embodiment of the output control circuit, described in connection with Fig. 4, above. In this second embodiment of the sense detection circuit 24, the sense amp controller 52 controls a single amplifier 56. The sense event timing analysis unit 54 analyses the output of the single amplifier 56 and produces the description of the moving wave front. A sense timing controller 58, in electrical communication with both the communication controller 50 and the sense event timing analysis unit 54, controls a multiplexer 60 through a switch matrix controller 62. The switch matrix controller 62 opens and closes a plurality of switches 64a, 64b ... 64n, selectively connecting the electrodes of the lead 14 to the sense amplifier 56. As explained above, replacing multiple dedicated sense amplifiers 36a, 36b ... 36n with a single amplifier 56 exchanges flexibility and simplified control for energy efficiency.

The multiplexers 44, 60 of the embodiments of the output control circuit of Fig. 4 and of the sense detection circuit of Fig. 6 may be combined external to the cardiac stimulator 12 in an alternative configuration, illustrated in part in Fig. 7. Fig. 7 shows an adapter 66 for connecting a multi-electrode lead to a cardiac stimulator having an IS-1 connector in the header of the stimulator 12. IS-1 connectors are well known and many physicians are familiar with their operation and use. For the adapter 68 a male IS-1 connector 68 is connected to the multiplexers 44, 60 in an independent package. The multiplexers are connected either directly to the lead 14 or indirectly through a multi-electrode connector 70. Dual chamber pacemakers having two IS-1 connectors in a single header are well known. In cardiac stimulators 12 according to the present invention using IS-1 connectors rather than a specialized multi-electrode connector, a first IS-1 connector might be used to carry both the voltage from the voltage amp 42 and signals from the pulse timing circuit 38 and a second IS-1 connector might be used to carry both the signals to the sense amplifier 56 and the

control signals from the sense timing controller 58. Alternatively, one IS-1 connector might be dedicated to the control signals from the sense timing controller 58 and the pulse timing circuit 38 while another IS-1 connector might be dedicated to the signals delivered to and received from the heart, that is, to pulses from the voltage amp 42 and to sensed events.

Multi-electrode Lead

Details of the multi-electrode lead 14 are shown in Fig. 8. The lead 14 includes an external biocompatible polymer tube 72 having a straight portion 74 and a shaped portion 76. The tube may be made of polyurethane or other similar materials that may be thermally shaped so that the shaped portion 76 retains any desired configuration. In Figs.1 and 8, the shaped portion 76 is shown as having a spiral shape, but many other shapes may be selected as well. The spiral or coil shaped lead of Fig. 1 and 8 places electrodes around the entire atrial chamber of the heart. This embodiment allows complete sensing and stimulating control around the entire chamber.

It will be apparent that numerous shapes could be selected to address the clinical needs of a particular patient. Moreover, because the position of the electrodes in the heart is determined as much by physiology and implantation technique as by the characteristics of the lead, the effectiveness of the electrodes is best determined after implantation and is substantially independent from the location of a given electrode along the lead. Apparatus and methods for identifying optimum electrodes are therefore described hereinafter.

Attached to tube 72 of the lead 14 of any configuration, there are provided a plurality of electrodes E1, E2, E3, E4, E5, ...En. Preferably electrodes E1... En are formed of coils 71 of exposed wire or cable wound about the tube 72, as shown in Fig. 9. The wire Wn passes through a predrilled hole 75 in the tube 72. The predrilled hole 75 determines the exact location of the electrode. By changing the position and spacing of the hole, leads may be designed to cluster more electrodes along a selected segment of the lead. Since the electrodes fully circumvent the tube

72, it is likely that at least some part of the electrode will be adjacent the cardiac wall. Moreover, circumferential electrodes are unlikely to perforate the heart. Preferably the coil 71 and wire Wn are formed of one continuous wire. The loops of the coil 71 are welded 77 or otherwise connected together to provide additional structural stability. Each electrode is connected to corresponding wires W1, W2, W3 ... Wn which extend through the length of tube 72 and which are shown exiting through end 80 for the sake of clarity. Wires W1, W2, W3...Wn are insulated, so that they are not shorted to each other within the tube 72. The lead 14 is more particularly disclosed in co-pending commonly assigned application S.N. 09/245,246 filed February 5,1999, and incorporated herein by reference. Preferably the end 80 of tube 72 and the ends of wires W1, W2, W3, etc. are coupled to a connector 82 for attaching the lead 14 to the cardiac stimulator 12. The connector 82 may have a plurality of pins Pi. Each wire W1 ... Wn is associated with a pin.

An alternative configuration for an electrode 81 is illustrated in Fig. 10. In this configuration, a multi-filar coil 83 comprises as many insulated wire coils as there are electrodes on the lead. The multi-filar coil 83 lies within the tube 72. At a location of an electrode 81, an end 85 of one of the wires is passed through a hole 87 in the tube 72 and laid on an inner ring 89. A hole may also be provided in the inner ring for the wire or two inner rings may be used, one ring on either side of the wire. An outer ring 91 is placed over the inner ring or rings and crimped, capturing the end 85 of the wire between the inner and outer rings. The electrical and mechanical connection between the rings and the wire may also be improved by welding or other methods. A circumferential bead 93 of glue may seal the ends of the rings and reduce sharp edges.

In addition to spiral coil or ring electrodes E1 ... En, a distal tip electrode Ed may also be provided. The distal tip electrode Ed may also have an active fixation mechanism, for example a helical screw 84 or tines, to secure the lead to the interior wall of the heart.

The tube 72 can be formed with a longitudinal cavity 86, as shown in the cross sectional view of Fig. 11, taken along line 11-11 of Fig. 9. The cavity 86 holds the

wires W1, W2, W3 etc. The lead 14 could be straightened by inserting a substantially straight stylet 90 into cavity 92. The stylet 90 is also flexible but is less flexible than the lead 14 so that as it is inserted into the cavity 86, it forces the tube 72 to straighten. The lead 14 is then inserted into the heart or into a vein near the heart. After implantation of the lead 14, the stylet 90 is withdrawn and the lead 14 flexes back and takes a configuration shown, for example, in Fig. 1 or 8.

The lead is a multi-electrode catheter that contains more than five and up to 128 independent electrodes. In the preferred embodiment described in this application the lead will have 32 electrodes. Each electrode on the lead is capable of sensing the heart's electrical activity and delivering an electrical pulse to the heart. The delivery of therapy can be for multi-site stimulation for atrial fibrillation and for optimized bradycardia pacing.

The lead is made up of an external biocompatible thermoplastic polymer tube such as polyurethane, and has electrodes that extend around the circumference of the tubing and are connected to internal conductors. Each conductor is coated with an electrical insulator, thereby insuring the electrical isolation of each of the electrodes. By choosing the appropriate polymer tubing, the lead can be thermally shaped to conform to virtually any configuration without the aid of a pre-shaped metal wire or shape memory alloy wire. Thus the lead can be fully constructed and later customized to fit a given chamber of the heart or a particular patient's pathology. One embodiment uses a coil-shaped catheter that places electrodes around the entire right atrium of the heart. This embodiment allows complete sensing and stimulating control of the entire chamber. Another possible embodiment places a spiral configuration in the right atrium and continues (the same lead) into the right ventricle with a straight section. The correct number of electrodes can be spaced appropriately for the intended application. Any of these possible shapes can be combined to make numerous configurations. The lead configurations presented here are only intended to be examples.

What makes this lead particularly useful for the treatment of atrial fibrillation is that the size, spacing, and final geometry of the lead is designed and can be altered for the treatment of atrial fibrillation.

For a multi-electrode lead placed into the right atrium there are several possibilities for spacing of the electrodes. If capturing and pacing the entire right atrium is desired, then evenly spaced electrodes can be used. Assume the right atrium is nearly circular in shape with a 30mm diameter. For two turns of lead in the right atrium, 188mm of lead will need to have electrodes on it. With a spacing of 6mm between electrodes it is possible to place 31 electrodes in direct apposition to the chamber wall (188/6=31). If the spacing is increased to 10mm then 18 electrodes can be placed.

Since many atrial fibrillations are associated with the pulmonary veins of the left atrium, the entrant site of a wavelet into the right atrium is on the septal wall separating these two chambers. In order to most effectively identify and block those pathways, more electrodes can be placed on the septum. The lead can be constructed so that the tip is anchored in the atrial appendage and the lead spirals around the right atrium. If the first electrode is 12mm from the tip, electrodes one through ten can be placed on 2mm centers, along the septum. Another gap of 12mm before the eleventh electrode is reached means this electrode is on the lateral free wall. Another gap of 12mm means 10 more electrodes (numbers twelve through twenty-one) are located on the second turn of the lead and are also positioned on the septum.

The electrodes not adjacent to the septum can be placed in multiple independent sites to capture the atrium. The spacing of the electrodes is limited by the size of the electrodes. Especially along the septal wall, there is a minimum spacing interval for a given length or size of electrode. In the preferred embodiment of the lead the electrodes will consist of 4 turns of 0.076mm diameter wire with a total length of 0.304mm (4 X 0.076). If the spacing between the electrodes is the same length as the electrodes, then for a 20 mm length of septal wall, the maximum number of electrodes that can be placed into a 20mm length is 32 (20mm divided by 0.608.) Which means that up to 32 electrodes can be placed on the septum for each turn of the lead.

Similarly, the minimum length of an electrode is 0.152mm and if the gap between electrodes is equivalent to the length of the electrodes then the maximum

number of electrodes that can be placed along the septal wall is 65 (20 divided by 0.304).

Programmer

A programmer 100 may be used to program the cardiac stimulator 12, usually by electromagnetic signals. In particular, for use with this system, the programmer may be temporarily connected directly to the lead 14, as shown in Fig. 1 by dotted line 102. This connection may be made to the lead alone, or it may be made through the cardiac stimulator 12. This connection is used after the lead has been implanted to characterize the location of the electrodes, as explained in detail below. The programmer 100 comprises a microprocessor 104 for performing various functions in connection with programming the cardiac stimulator. In addition, in order to characterize the electrodes of the lead, and provide sufficient information for selecting therapies suitable for treating atrial fibrillation, the programmer may be provided with pulse or frequency generators 118. The programmer may also have sensing circuits 120 for sensing electrical events in the heart where the cardiac stimulator 12 is not used for this purpose. Finally, the programmer may have a high frequency generator 122 and high frequency sensor circuit 124, for providing non-stimulating high frequency signals that may be used to calculate the three dimensional positions of the electrodes within the patient's heart.

A cardiac visualization device 101 may also be provided. The device 101 may be a fluoroscope or ultrasonogram apparatus. A sensor 103 emits and detects radiation such as ultrasound or electromagnetic radiation. The resulting images may be digitized and communicated to the microprocessor 104 by a communications link 105. Alternatively, an operator may select optimal electrodes through the microprocessor based in part on data displayed by the visualization device.

Electrode Identification

The process of identifying the optimum electrode or electrodes or a pattern of electrodes may be performed using several different approaches. For treatment of atrial fibrillation, the location of the electrode in the heart is important, not necessarily

the position of any given electrode along the lead. An implanted lead may assume many configurations. The lead may overlap itself, whereby electrodes proximal on the lead are closer to the valve between the atrium and the ventricle than are more distal electrodes. However, in many cases, the relative location of the electrodes in the heart may be determined by inspection under fluoroscopy by visual approximation. This information or mapping would be used either in the programmer or the cardiac stimulator or both. The mapping could be used as a starting point for additional location algorithms or as a model for measuring cardiac performance or providing appropriate therapy.

The connection between electrodes and pins may be determined either by manufacturing such that the first electrode is connected to the first pin, the second electrode to the second pin, and so on, or by measurements. A test apparatus may be provided wherein an electrical signal is supplied to each electrode in turn and the pins sampled to identify the pin receiving the signal. The mapping of electrodes to pins would then be communicated to a cardiac stimulator at the time of implantation so that the lead and cardiac stimulator could function together as a unit.

The relative position of the electrodes can also be determined by measuring certain phenomenon and calculating a three dimensional position for each electrode. To determine the relative positions of the electrodes in three-dimensional space, calculations can be performed either in an external device such as the programmer 100, or in the cardiac stimulator 12. Because such calculations may be relatively energy expensive, calculation in an external device may be preferred. Details of the algorithms used to make this determination are provided in commonly assigned co-pending application SN _____ filed April 25, 2002 and entitled "Method and Apparatus for Determining Spatial Relation of Multiple implantable Electrodes ", incorporated herein by reference. As illustrated in Fig. 13, the 3-D electrode positioning system operates by applying a periodic signal 130 to several subgroups of the electrodes and measuring 132 the signal induced on selected remaining electrodes. The number of subgroups employed is sufficient to over-determine a system of non-linear equations representing the distribution of the voltage (or

potential) at each of the electrodes and in the surrounding tissue. A set of non-linear equations is developed 134 that specify position vectors for each of the electrodes with respect a co-ordinate system. Several means are available to extract 136 the electrode positions relative to tissue boundaries once the equations have been extracted. One of these, the method of non-linear least squares, is well known in the literature. (See, e.g. Golub and Van Loan, Matrix Computations,1989, Johns Hopkins.) The location of the electrodes may also be estimated by fluoroscopic observation or other techniques.

The subject invention pertains to an implantable lead and pulse generator that can detect and deliver therapy to stop atrial fibrillation. With the single or two electrode systems used in conventional systems, it is only possible discriminate events in time. There is no spatial resolution. With a multiple electrode system, it is possible to sense and deliver therapy is four dimensions (3D space- X, Y, and Z coordinates, and time). In atrial fibrillation it is possible to have multiple arrhythmic wavelets propagating almost randomly in the atria. Traditional single point sensing cannot resolve these wavelets, and often it misses them entirely. The invention described here has the ability to map these wavelets, in real time and apply targeted, low voltage, pacing pulses to block the wavelets.

As illustrated in the flow chart 140 in Figure 13, a plurality of electrodes are implanted 142 within an atrial chamber of a patient's heart, and reentrant wavelets are sensed at multiple sites within the heart. At least five electrodes are needed for locating 144 the electrodes by signals emitted from the electrodes themselves. At least three electrodes and preferably many more electrodes are provided to deliver therapy. The apparatus identifies 146 a wave front associated with a wavelet. Because the three-dimensional locations of the electrodes are known, electrodes can be selected 148 that direct or block the propagation of wave front. In general, a model of the wave front can be developed because the wave front reaches different electrodes at different times. Such information as the speed and direction of the wave front allow the apparatus to select electrodes that the wave front will encounter next. The heart can be stimulated through selected electrodes to interrupt the wavelet. The heart may be stimulated at a selected group of electrodes simultaneously or

sequentially, such that the refractory properties of the heart tissue may be expected to interrupt the reentrant wavelet that is causing the atrial fibrillation. It may be possible to triangulate 152 an origin for a wavelet and select 154 a set of electrodes around the origin. Stimulating 156 the heart through a set of electrodes surrounding the identified origin may interrupt the regeneration of the wavelet.

Once the propagation pattern of the reentrant wave front has been established, various forms of stimulation may be employed 158 to interrupt the pattern that sustains the atrial fibrillation. For example, the anti-tachycardia pulses may comprise a train of pulses. The pulses may be delivered at an interval adapted to the frequency of repetition of said wave front. The pulses may be delivered, for example, at the same rate as the recurrence of the reentrant wavelet. The pattern may advance or regress to find a terminating relationship with the wavelet. Alternatively, the set of pulses may be applied at slightly increasing or decreasing intervals until the wavelet is terminated.

The implantable cardiac stimulator may also deliver 160 pulses at an electrode closest to a reentrant wavelet and at successive electrodes 162 dependent on the physical location of each electrode from said electrode closest to said reentrant wavelet. Generally this will be along a projected path of the wavelet as determined from the sensing of the wavelet in a previous cycle.

The implantable cardiac stimulator may determine 164 that the wavelet or wavelets causing the atrial fibrillation are occurring generally in a particular region of the heart. A set of electrodes in and around the region may be used to simultaneously stimulate the heart at multiple electrodes to produce an electrical field throughout the region to terminate the activity of the heart in that region and allow a regular pattern to be re-established. Generally a field of between 4V/cm and 10 V/cm should be induced within the selected region, and more preferably, a voltage field of about 6 V/cm. The magnitude of each of said pulses may be determined 166 based on the logical model representative of relative location of the electrodes in the heart of the patient. The effect of a charge or pulse diminishes with distance from the point of stimulation. Consequently, it is possible to predict the field strength at a given distance from a point or electrode resulting from a charge of a particular magnitude.

Since the location and spacing of the electrodes is known, the requisite voltages at each electrode in the selected region can be determined such that a field of at least a selected magnitude can be produced 168.

The implantable cardiac stimulator may detect a reentrant wave front and stimulate the heart at each one of multiple electrodes at a selected interval after the arrival 170 of the wave front at each of the electrodes. Thus the tissue may be rendered refractory and unresponsive to a reentrant wavelet before the wavelet returns in a succeeding cycle. The atrial fibrillation may thereby be interrupted.

Numerous other modifications may be made to this invention without departing from its scope as defined in the attached claims.

CLAIMS

What is claimed is:

1. A method for terminating an atrial fibrillation comprising
implanting at least five electrodes within the right atrium of a patient's heart,
sensing reentrant wavelets at multiple sites within the heart,
identifying a wave front of a wavelet,
selecting electrodes that direct or block the propagation of said wave front, and
stimulating the heart through said selected electrodes to interrupt the wavelet.

2. The method of claim 1 further comprising
identifying a location of origin for each wavelet;
selecting a set of electrodes around each of said locations, and
stimulating the heart through each of said sets of electrodes to interrupt each of said wavelets.

3. The method of claim 2 further comprising stimulating the heart through said selected electrodes simultaneously.

4. The method of claim 2 further comprising stimulating the heart through said selected electrodes sequentially.

5. The method of claim 1 further comprising stimulating the heart through said selected electrodes simultaneously.

6. The method of claim1 further comprising stimulating the heart through said selected electrodes sequentially.

7. A method for terminating an atrial fibrillation comprising
implanting at least five electrodes within the right atrium of a patient's heart,
sensing fibrillation wavelets at multiple sites with in the heart, and
stimulating the heart through at least some of said electrodes to interrupt the

atrial fibrillation.

8. The method according to claim 7 wherein all of said electrodes stimulate the heart.

9. The method of claim 8 wherein said electrodes stimulate the heart simultaneously.

10. The method of claim 8 wherein said electrodes stimulate the heart sequentially.

11. The method of claim 7 wherein a subset of the total number of electrodes stimulate the heart.

12. The method of claim 7 wherein identifying a location comprises locating a position for each electrode in vivo,

detecting the arrival of a wave front at at least two electrodes, and

triangulating said location of origin from the time of detected arrival of said wave front.

13. A method for terminating an atrial fibrillation comprising

implanting at least five electrodes within the right atrium of a patient's heart,

sensing fibrillation wavelets propagating within the heart,

identifying a path for a wavelet;

stimulating the heart through at least some of said electrodes along said path of said wavelet to interrupt the atrial fibrillation.

14. The method of claim 13 wherein identifying said path comprises identifying origin, speed and direction of said wavelet.

15. An implantable cardiac stimulator comprising

an implantable lead having at least three electrodes,

a cardiac stimulator connectable to said lead to place said electrodes in electrical communication with said stimulator;

at least one detector coupled to said electrodes for detecting electrical phenomenon in the patient's body;

at least one logical model representative of relative location of said electrodes in the heart of a patient;

means for detecting the velocity of propagating cardiac wave fronts past said electrodes, and

an output circuit providing an anti-tachycardia/defibrillation therapy to said patient in response to a detected wave front having a velocity greater than a selected tachycardia velocity.

16. The implantable cardiac stimulator of claim 15 further comprising means for identifying a sequence of electrodes detecting a reentrant wave front.

17. The implantable cardiac stimulator of claim 16 further comprising means for determining a time delay between events sensed at said electrodes.

18. The implantable cardiac stimulator of claim 15 further comprising means for delivering anti-tachycardia pulses at successive electrodes dependent on the physical location of each electrode from an electrode closest to an origin of an identified ectopic beat.

19. The implantable cardiac stimulator of claim 18 wherein the means for delivering anti-tachycardia pulses at successive electrodes further comprises means for predicting arrival of a propagated wave front at a particular electrode and for initiating an anti-tachycardia pulse at said electrode prior to the predicted arrival of said propagated wave front.

20. The implantable cardiac stimulator of claim 15 further comprising means for delivering anti-tachycardia pulses at at least one electrode along an identified wave

front.

21. The implantable cardiac stimulator of claim 20 wherein said anti-tachycardia pulses comprise a train of pulses.

22. The implantable cardiac stimulator of claim 20 wherein said anti-tachycardia pulses comprise pulses delivered at an interval adapted to the frequency of repetition of said wave front.

23. The implantable cardiac stimulator of claim 20 wherein said anti-tachycardia pulses comprise pulses delivered at varying intervals.

24. The implantable cardiac stimulator of claim 15 further comprising means for delivering anti-tachycardia pulses at an electrode closest to a reentrant wavelet and at successive electrodes dependent on the physical location of each electrode from said electrode closest to said reentrant wavelet.

25. The implantable cardiac stimulator of claim 15 further comprising means for simultaneously stimulating the heart at multiple electrodes to produce an electrical field of between 4V/cm and 10 V/cm within a selected region of the heart.

26. The implantable cardiac stimulator of claim 25 wherein said voltage field is about 6 V/cm.

27. The implantable cardiac stimulator of claim 25 further comprising means for determining the magnitude of each of said pulses based on the logical model representative of relative location of said electrodes in the heart of the patient.

28. The implantable cardiac stimulator of claim 15 further comprising means for detecting a reentrant wave front and means for stimulating the heart at each one of multiple electrodes at a selected interval after the arrival of said wave front at said

each one of said multiple electrodes.

29. The implantable cardiac stimulator of claim 28 further comprising means to produce an electrical field of from 4 V/cm to 10 V/cm in a selected region of the heart.

30. The implantable cardiac stimulator of claim 29 wherein said voltage field is about 6 V/cm.

31. The implantable cardiac stimulator of claim 29 further comprising means for determining the magnitude of each of said pulses based on the logical model representative of relative location of said electrodes in the heart of the patient.

32. An implantable cardiac stimulator comprising

an implantable lead having at least three electrodes,

a cardiac stimulator connectable to said lead to place said electrodes in electrical communication with said stimulator;

at least one detector coupled to said electrodes for detecting electrical phenomenon in the patient's body;

at least one logical model representative of relative location of said electrodes in the heart of a patient;

means for identifying a sequence of electrodes detecting a reentrant wave front, and

an output circuit providing an anti-tachycardia/defibrillation therapy to said patient in response to said detected reentrant wave front.

33. An implantable cardiac stimulator comprising

an implantable lead having at least three electrodes,

a cardiac stimulator connectable to said lead to place said electrodes in electrical communication with said stimulator;

at least one detector coupled to said electrodes for detecting electrical phenomenon in the patient's body;

at least one logical model representative of relative location of said electrodes in the heart of a patient;

means for detecting a reentrant wave front,

and means for stimulating the heart at each one of multiple electrodes at a selected interval after the arrival of said wave front at said each one of said multiple electrodes.

34. An implantable cardiac stimulator comprising

an implantable lead having at least three electrodes,

a cardiac stimulator connectable to said lead to place said electrodes in electrical communication with said stimulator;

at least one detector coupled to said electrodes for detecting electrical phenomenon in the patient's body;

at least one logical model representative of relative location of said electrodes in the heart of a patient;

means for detecting a region of the heart having reentrant wave fronts, and

an output circuit stimulating the heart at multiple electrodes to produce an electrical field of between 4V/cm and 10 V/cm within a selected region of the heart.

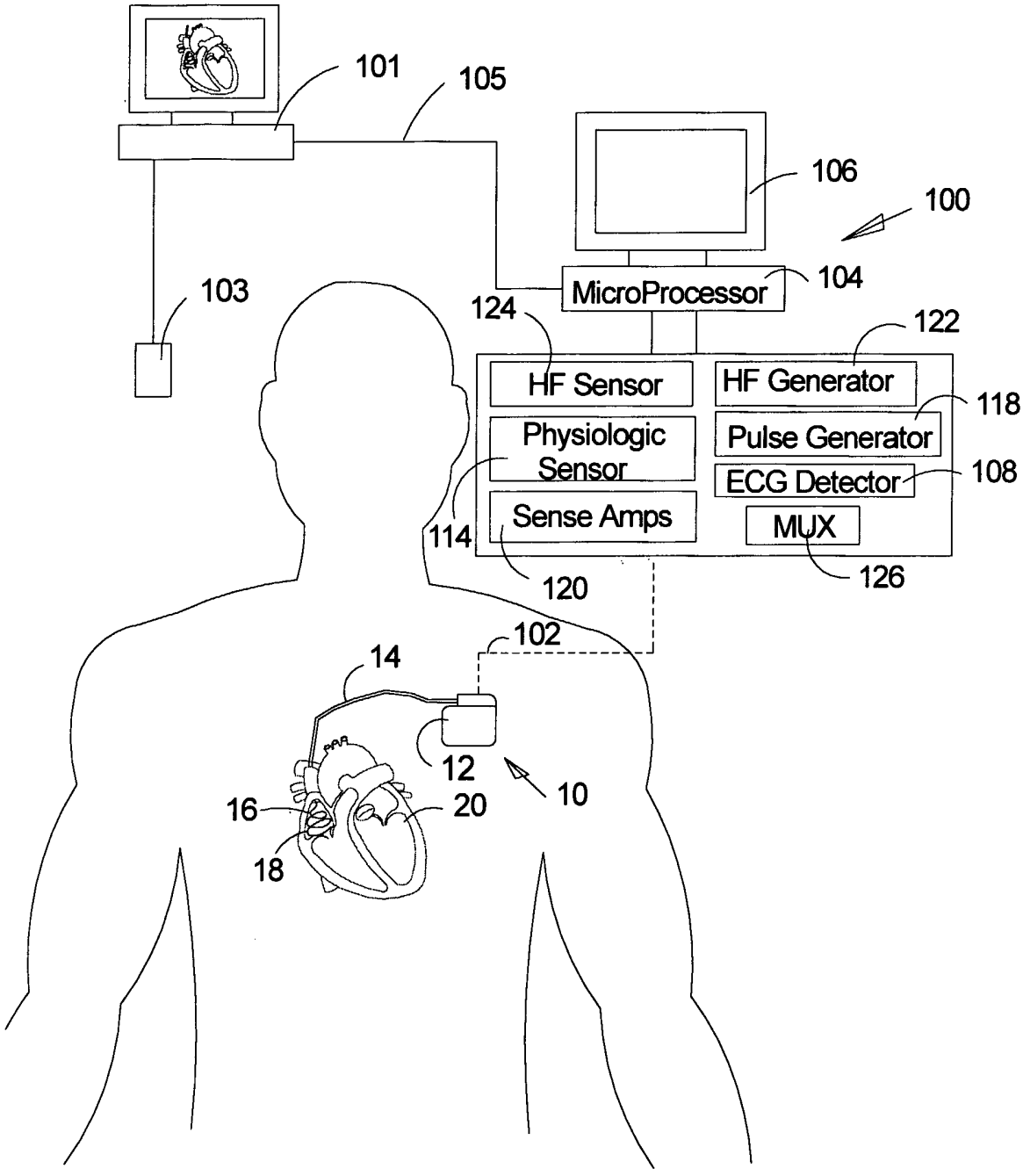
101
105
106
100
103
MicroProcessor
104
124
122
HF Sensor
HF Generator
118
Physiologic Sensor
Pulse Generator
ECG Detector
108
Sense Amps
MUX
114
120
126
102
14
12
10
16
20
18

Fig. 1

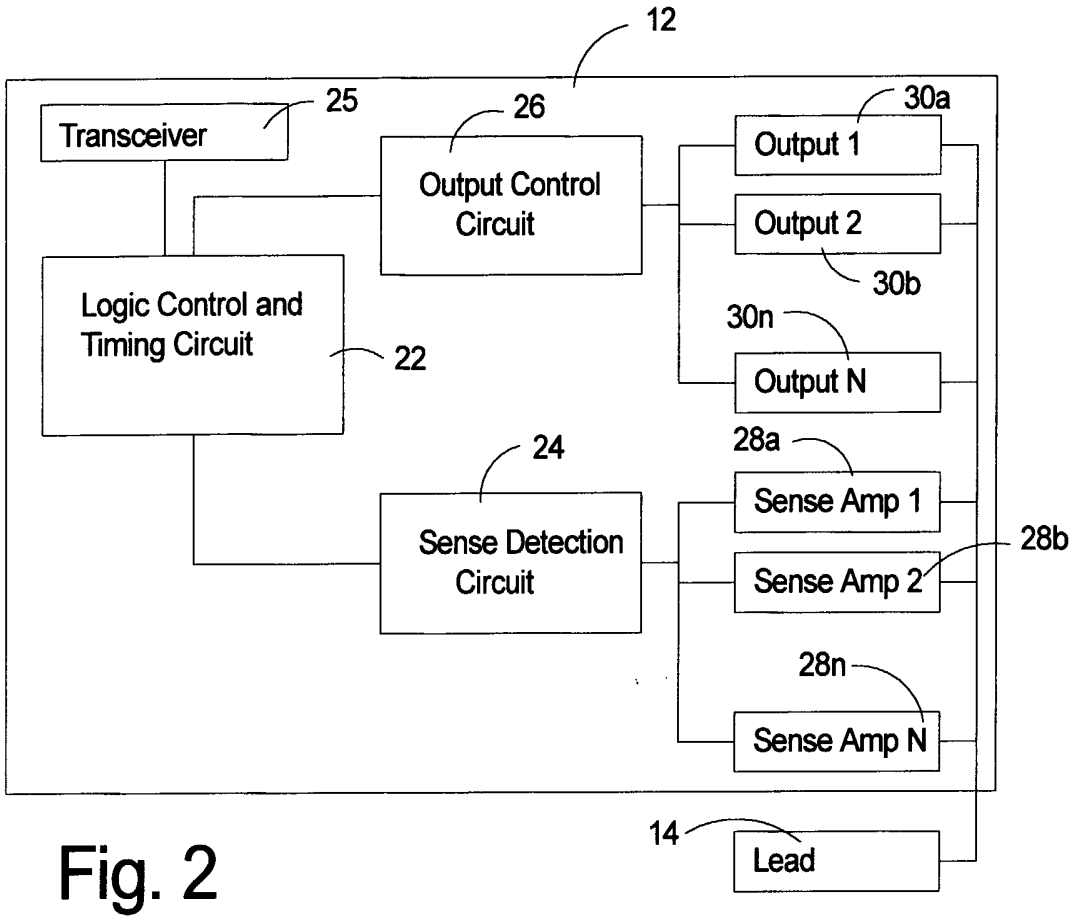
12
Transceiver
25
26
Output Control Circuit
30a
Output 1
Output 2
30b
Logic Control and Timing Circuit
22
30n
Output N
24
28a
Sense Amp 1
Sense Detection Circuit
28b
Sense Amp 2
28n
Sense Amp N
14
Lead

Fig. 2

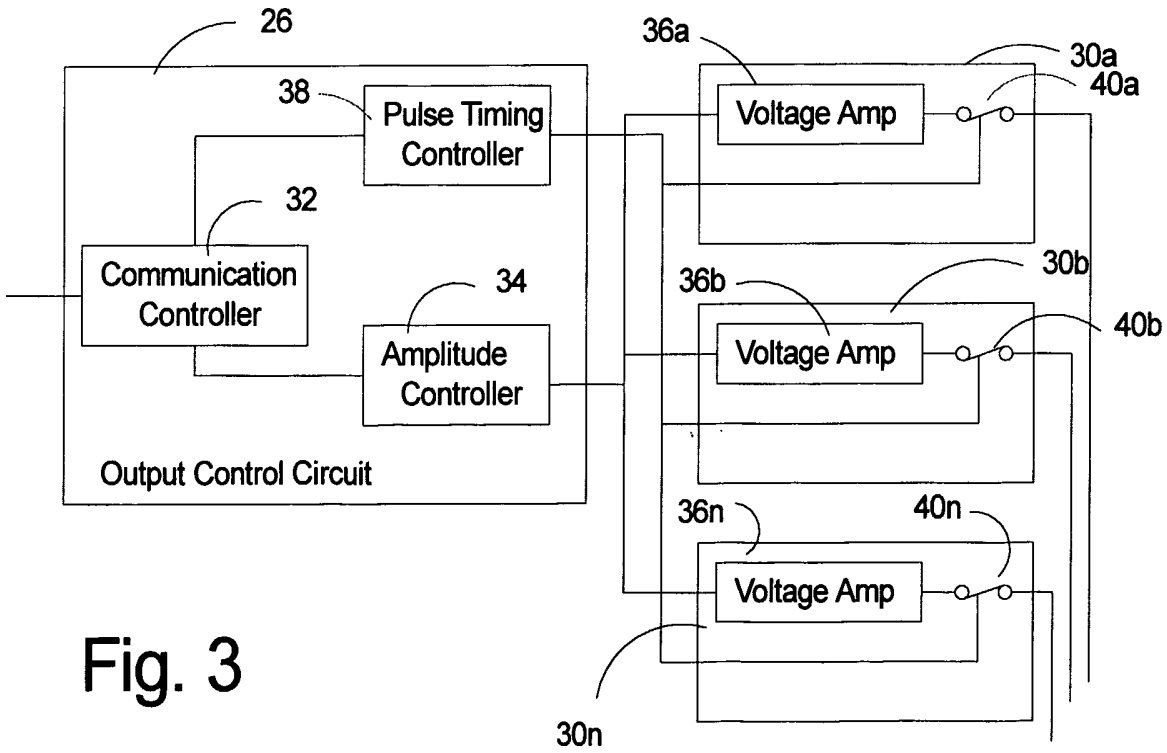
26
36a
30a
40a
38
Pulse Timing Controller
Voltage Amp
32
Communication Controller
34
36b
30b
40b
Amplitude Controller
Voltage Amp
Output Control Circuit
36n
40n
Voltage Amp
30n

Fig. 3

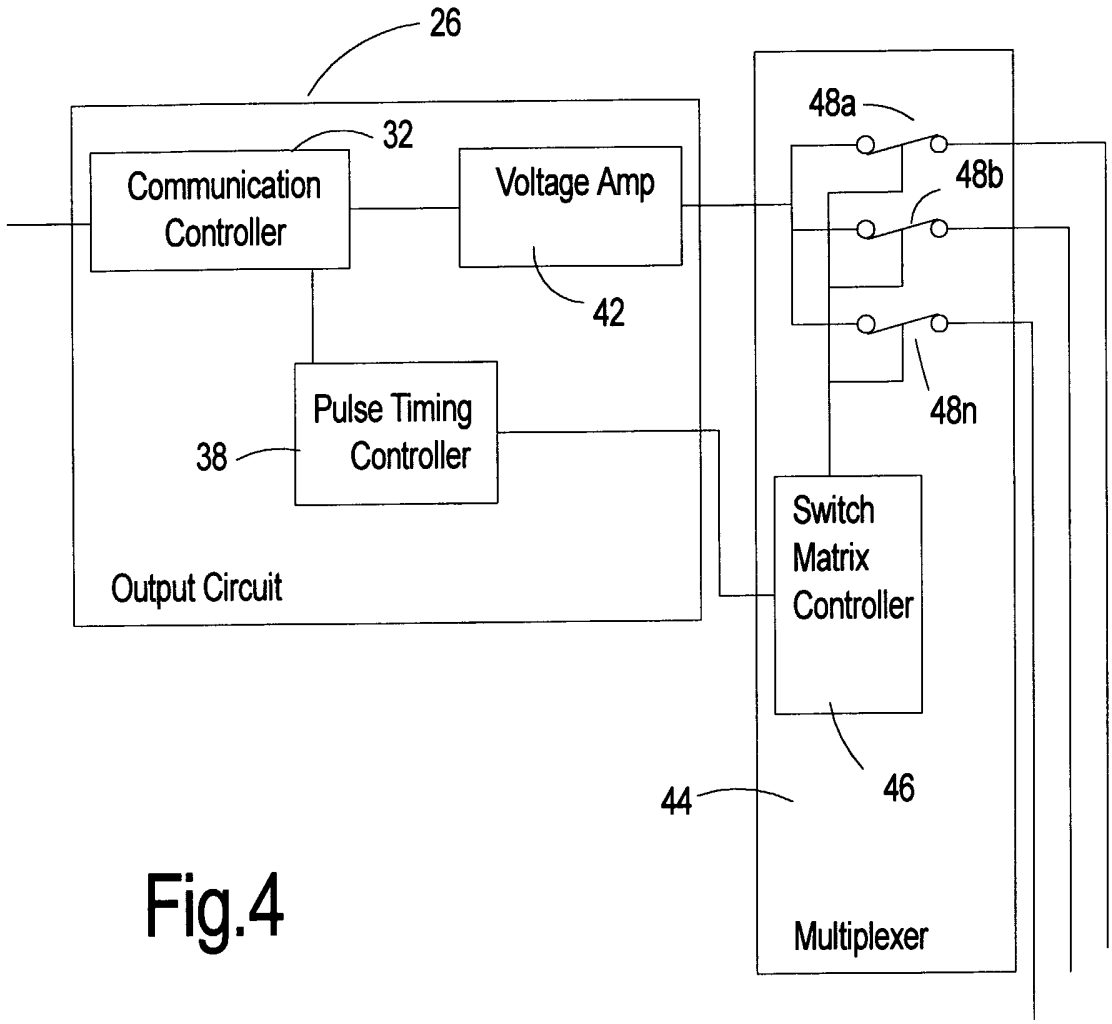
26
32
Communication Controller
Voltage Amp
42
Pulse Timing Controller
38
Output Circuit
48a
48b
48n
Switch Matrix Controller
46
44
Multiplexer

Fig.4

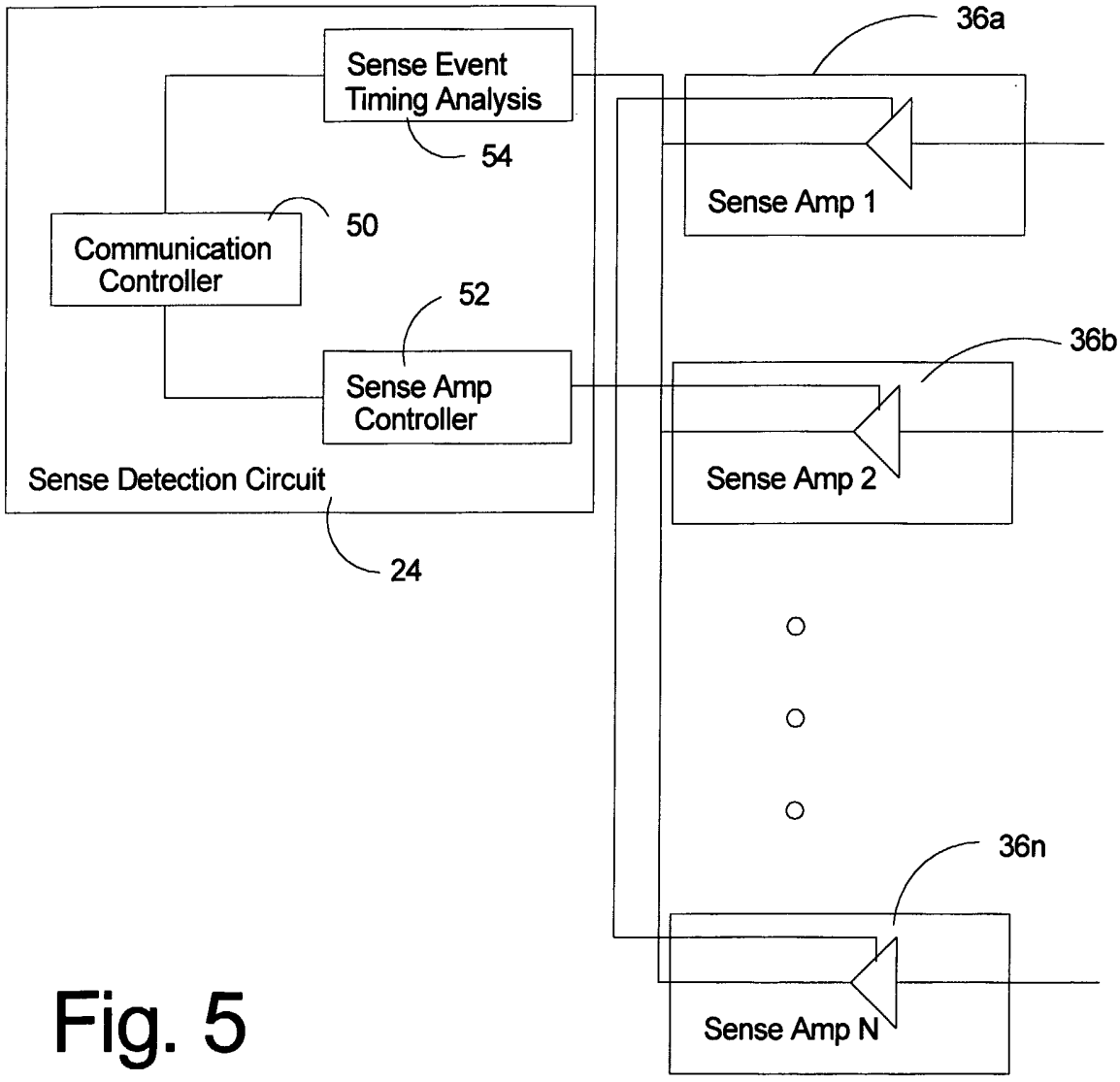
Sense Event Timing Analysis
54
Communication Controller
50
52
Sense Amp Controller
Sense Detection Circuit
24
36a
Sense Amp 1
36b
Sense Amp 2
36n
Sense Amp N

Fig. 5

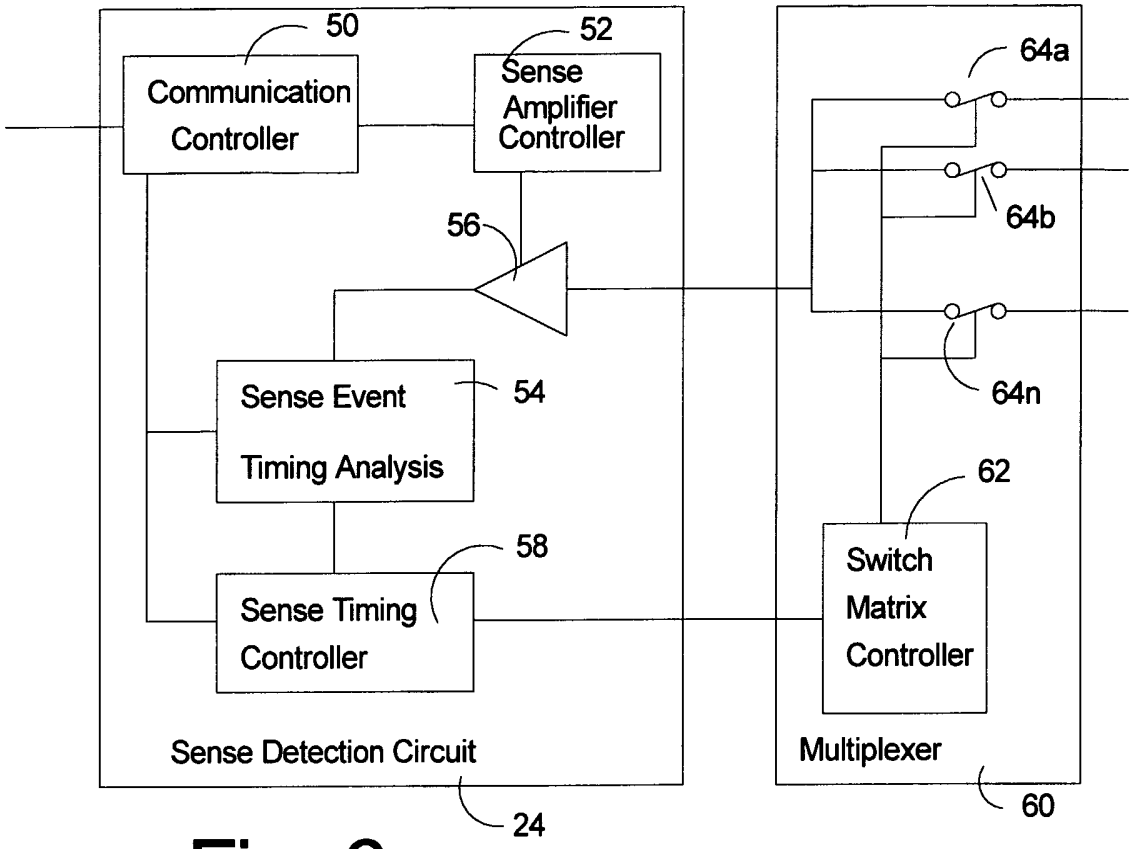
50
Communication Controller
52
Sense Amplifier Controller
64a
64b
56
Sense Event Timing Analysis
54
64n
62
58
Switch Matrix Controller
Sense Timing Controller
Sense Detection Circuit
Multiplexer
24
60

Fig. 6

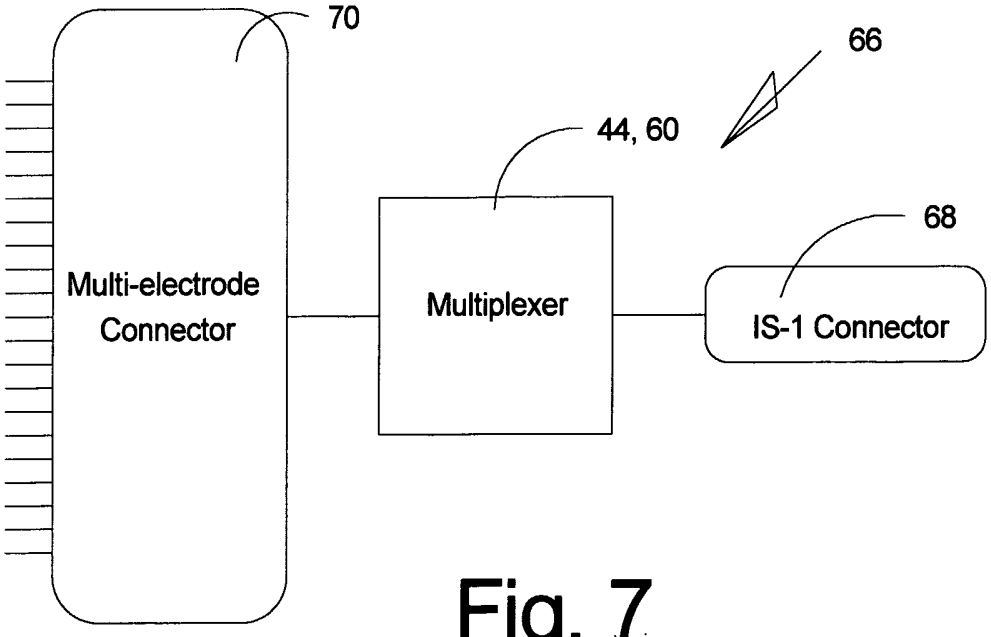
70
66
44, 60
68
Multi-electrode Connector
Multiplexer
IS-1 Connector

Fig. 7

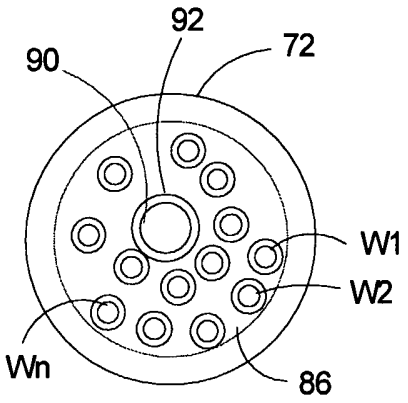

Fig. 11

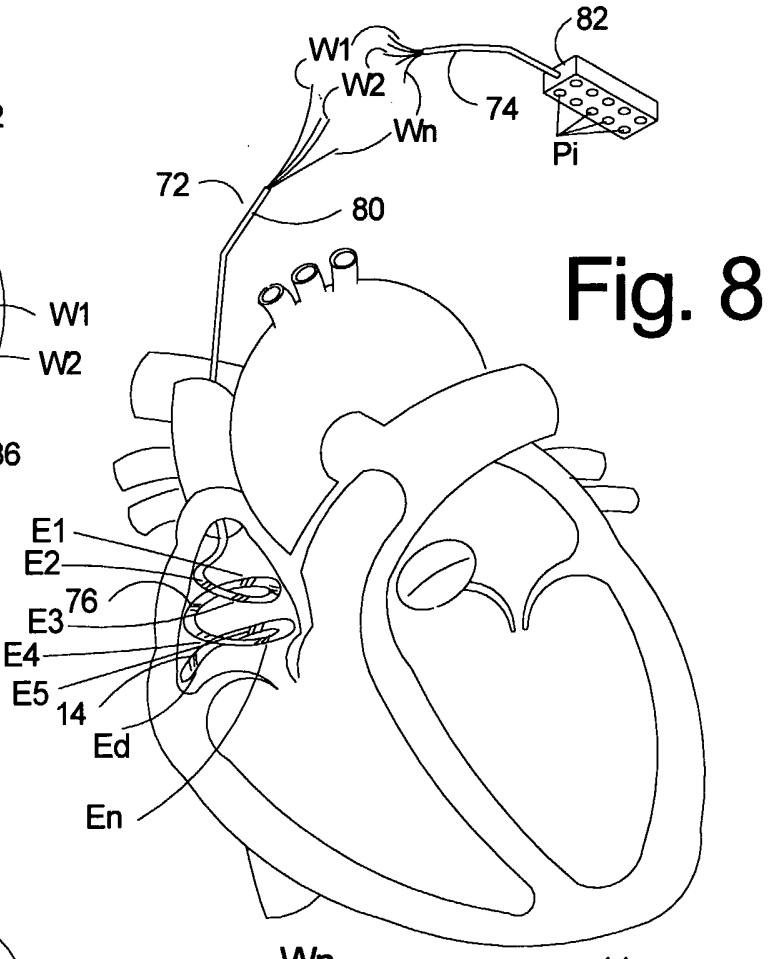

Fig. 8

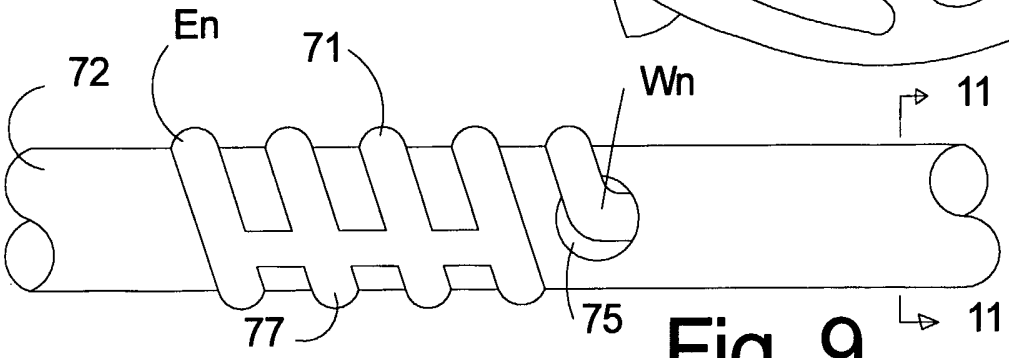

Fig. 9

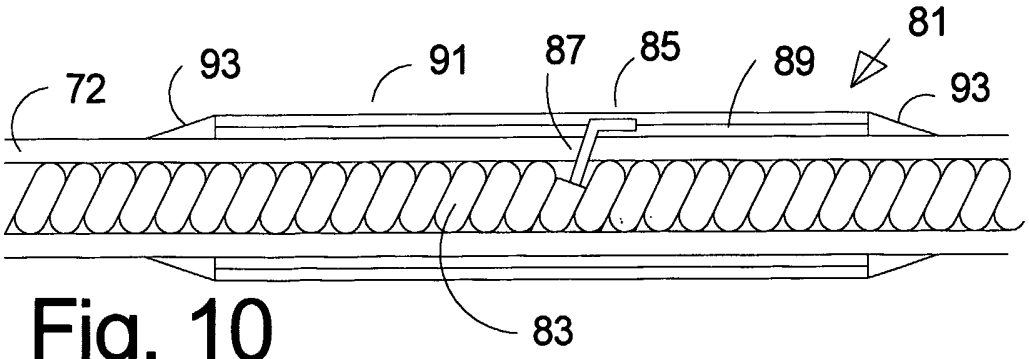

Fig. 10

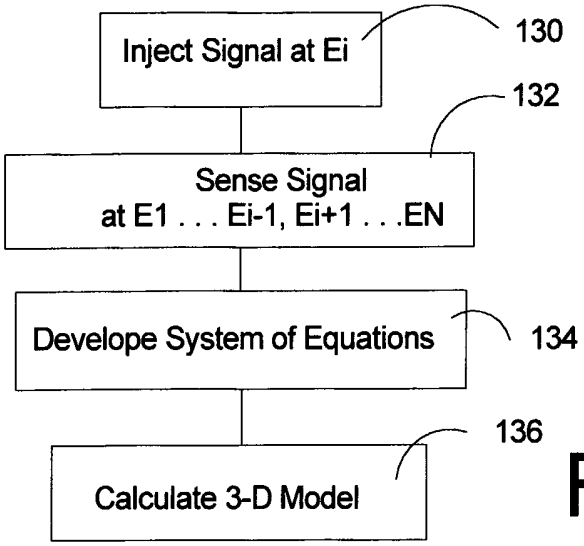
Inject Signal at Ei
130
132
Sense Signal at E1 . . . Ei-1, Ei+1 . . .EN
Develope System of Equations
134
136
Calculate 3-D Model

Fig. 12

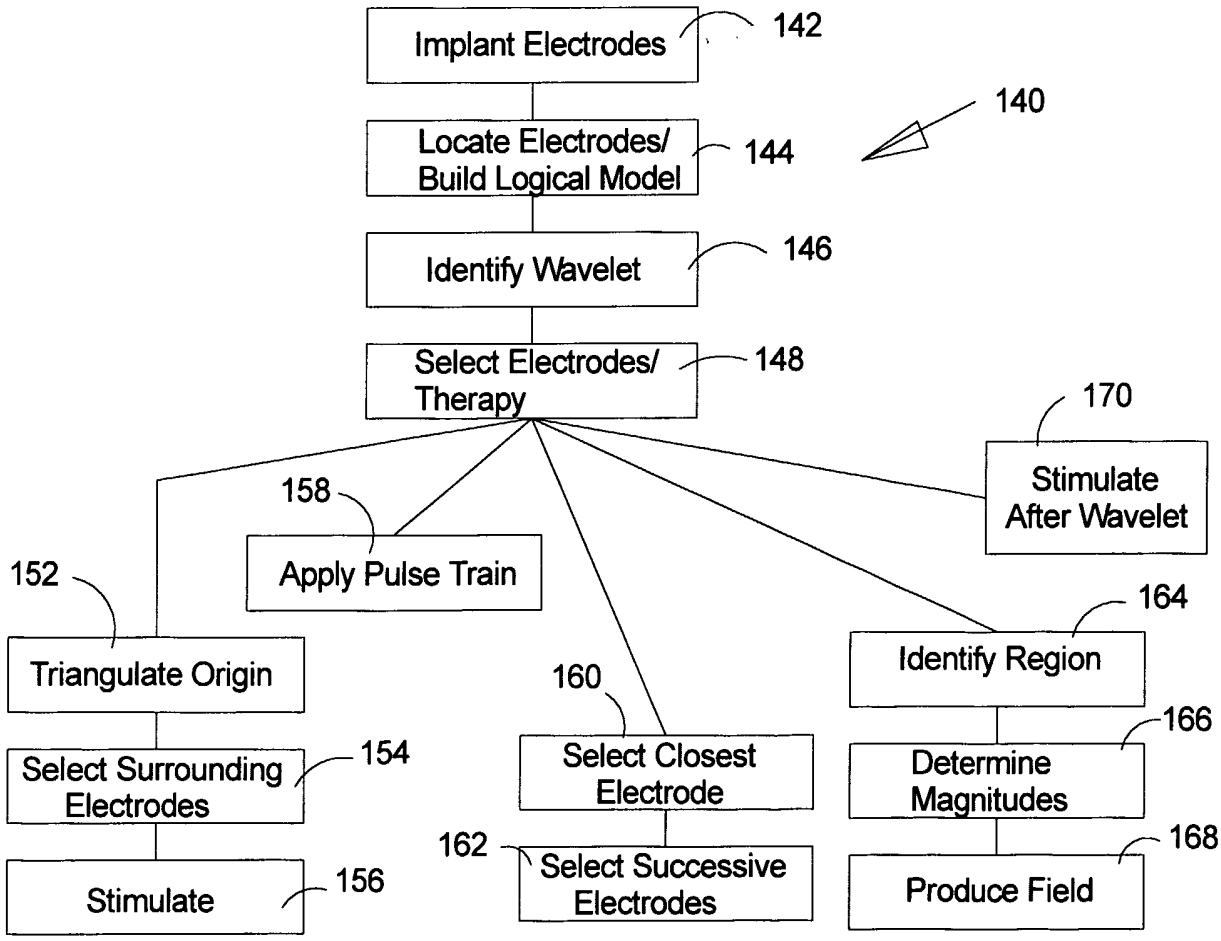
Implant Electrodes
142
140
Locate Electrodes/ Build Logical Model
144
Identify Wavelet
146
Select Electrodes/ Therapy
148
170
Stimulate After Wavelet
158
Apply Pulse Train
152
164
Triangulate Origin
Identify Region
160
166
Select Surrounding Electrodes
154
Select Closest Electrode
Determine Magnitudes
162
168
Stimulate
156
Select Successive Electrodes
Produce Field

Fig. 13