

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization International Bureau



(43) International Publication Date  
10 June 2004 (10.06.2004)

PCT

(10) International Publication Number  
**WO 2004/047918 A1**

(51) International Patent Classification<sup>7</sup>:

**A61N 1/39**

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.

(21) International Application Number:

PCT/US2003/037155

(22) International Filing Date:

20 November 2003 (20.11.2003)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

10/302,747 22 November 2002 (22.11.2002) US

(71) Applicant: **CARDIAC PACEMAKERS, INC. [US/US];**  
4100 Hamline Avenue North, St. Paul, MN 55112 (US).

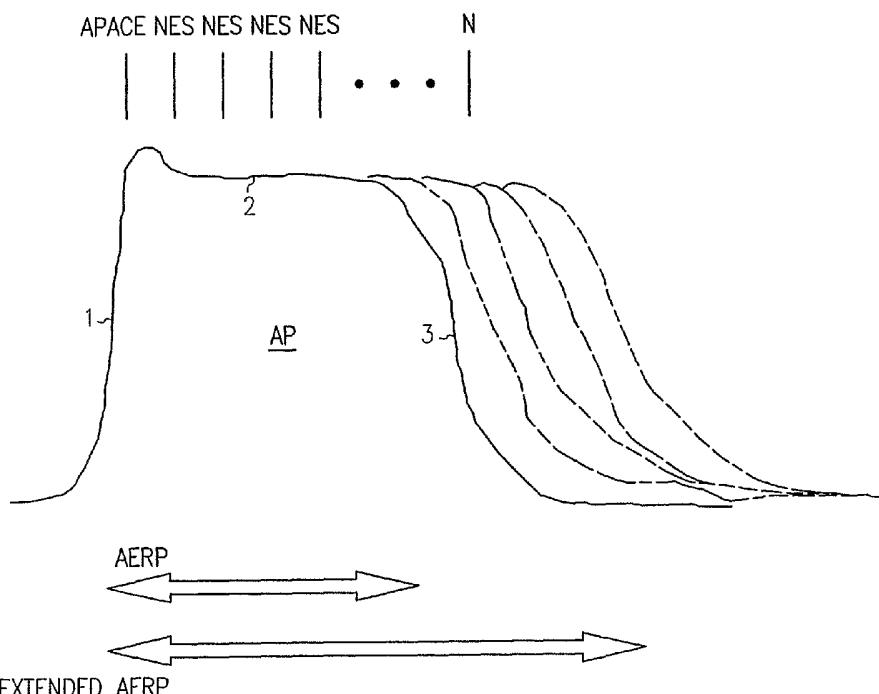
(84) Designated States (*regional*): ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: PACING THERAPY FOR EXTENDING ATRIAL REFRACTORY PERIOD



WO 2004/047918 A1

(57) **Abstract:** A device and method are presented for prolonging the atrial effective refractory period with pacing therapy. Such refractory period prolongation renders the atrial tissue less susceptible to the onset of atrial fibrillation. A particularly useful application is during the period after application of electrical therapy to the atria to terminate an episode of atrial fibrillation.

**PACING THERAPY FOR EXTENDING ATRIAL REFRACTORY PERIOD**Field of the Invention

This invention pertains to cardiac rhythm management devices and methods for  
5 operating such devices.

Background

Tachyarrhythmias are abnormal heart rhythms characterized by a rapid heart rate, typically expressed in units of beats per minute (bpm). They can occur in either 10 chamber of the heart (i.e., ventricles or atria) or both. Examples of tachyarrhythmias include ventricular tachycardia, ventricular fibrillation, atrial tachycardia, atrial flutter, and atrial fibrillation. Tachycardia is characterized by a rapid rate, either due to an ectopic excitatory focus or abnormal excitation by normal pacemaker tissue. Fibrillation occurs when the chamber depolarizes in a chaotic fashion with abnormal 15 depolarization waveforms as reflected by an EKG.

An electrical shock applied to a heart chamber can be used to terminate most tachyarrhythmias. The electric shock terminates the tachyarrhythmia by depolarizing all of the myocardium simultaneously and rendering it refractory. A class of cardiac 20 rhythm management devices known as an implantable cardioverter/defibrillator (ICD) provides this kind of therapy by delivering a shock pulse to the heart when the device detects fibrillation. ICDs can be designed to treat either atrial or ventricular tachyarrhythmias, or both, and may also incorporate cardiac pacing functionality for delivering either bradycardia pacing or anti-tachycardia pacing (ATP). In ATP, the heart is competitively paced with one or more pacing pulses in an effort to interrupt the 25 reentrant circuit causing the tachycardia.

The most dangerous tachyarrhythmias are ventricular tachycardia and ventricular fibrillation, and ICDs have most commonly been applied in the treatment of those conditions. ICDs are also capable, however, of detecting atrial fibrillation and delivering a shock pulse to the atria in order to terminate the arrhythmia. Although not 30 immediately life-threatening, it is important to treat atrial fibrillation for several reasons.

First, atrial fibrillation is associated with a loss of atrio-ventricular synchrony which can be hemodynamically compromising and cause such symptoms as dyspnea, fatigue, vertigo, and angina. Atrial fibrillation can also predispose to strokes resulting from emboli forming in the left atrium. Although drug therapy and/or in-hospital cardioversion are acceptable treatment modalities for atrial fibrillation, ICDs configured to treat atrial fibrillation offer a number of advantages to certain patients, including convenience and greater efficacy. (As the term is used herein, atrial fibrillation should also be taken to include atrial flutter, which although clinically distinct, has similar consequences and may be treated similarly.)

10        Although atrial fibrillation can be successfully treated with electrical therapy from an implantable cardiac rhythm management device, it would be preferable to prevent an episode of atrial fibrillation from occurring. Another problem associated with defibrillation shock therapy is early recurrence of atrial fibrillation or ERAF. ERAF is defined as the recurrence of atrial fibrillation within a few minutes after 15 successful cardioversion with atrial shock therapy. Certain patients are more prone than others to experience ERAF, and these patients may experience difficulty with repeated atrial defibrillation therapy. Reducing the incidence of ERAF would improve the efficacy of atrial defibrillation by electrical therapy and expand the population of patients for whom it is an acceptable therapy option.

20

### Summary

25        The length of the atrial effective refractory period (AERP) is one factor that determines the susceptibility of the atria to the onset of atrial fibrillation. By pacing the atria and delivering one or more non-excitatory stimulation pulses during the refractory period following each pace, the atrial effective refractory period can be extended. An implantable cardiac rhythm management device can be configured and programmed to deliver such AERP-extension pacing for a specified period of time automatically in response to a detected condition or in response to a command delivered by an external programmer. The non-excitatory stimulation pulses may be delivered in conjunction 30 with any bradycardia atrial pacing mode. The bradycardia pacing mode may also

employ overdrive pacing of the atria to increase the frequency of pacing and of non-excitatory stimulation for lengthening the AERP. The atrial sites where the pacing pulses and non-excitatory stimuli are delivered may be the same or different. One particularly useful application of AERP-extension pacing is to lessen the occurrence of 5 early recurrence of atrial fibrillation following delivery of electrical stimulation therapy to the atria in the form of either an atrial defibrillation shock or atrial anti-tachycardia pacing. AERP-extension pacing may also be delivered periodically during normal pacing as a preventative measure.

10

#### Brief Description of the Drawings

15

Fig. 1 is an atrial action potential waveform.

Fig. 2 is a block diagram of an exemplary cardiac rhythm management device.

Fig. 3 shows the pacing events during AERP-extension pacing in relation to an ECG.

Figs. 4A and 4B illustrate an exemplary system for overdrive pacing of the atria.

#### Detailed Description

Atrial fibrillation is a condition in which the electrical activity of the atrium becomes very rapid and disorganized. Instead of the sinus node providing the normal 20 excitation to the atrium, rapid circulating waves of abnormal waves of depolarization continuously stimulate the atrium, resulting in a rapid atrial rate that can exceed 400 beats per minute. Research has shown that a combination of slow intra-atrial conduction and a short atrial refractory period in the atrial myocardial substrate contribute to conditions necessary to sustain the multiple re-entrant waves of 25 depolarization responsible for atrial fibrillation.

Like all excitable tissue, cardiac muscle cells are capable of generating a rapid change in transmembrane electrical potential, called an action potential, when the resting potential of the cell is depolarized to a threshold potential. The resulting depolarization then initiates the intracellular reactions responsible for mechanical 30 contraction and propagates to adjacent cells as a wave of excitation that spreads

throughout the myocardium. Fig. 1 illustrates an action potential AP of an atrial muscle cell as might be recorded from an intracellular electrode when the cell is excited due to either conduction of excitation from adjacent tissue or application of a pacing pulse. The action potential may be divided into an excitation phase 1 where the cell rapidly 5 depolarizes, a plateau phase 2 where the depolarized state is maintained, and a repolarization phase 3 where the cell returns to its resting membrane potential. Myocardial cells are refractory to excitation for a period of time after being depolarized when no further action potentials can be generated. The refractory period can be subdivided into an absolute refractory period during which no stimulus is capable of 10 exciting the cells and causing an action potential, and a relative refractory period during which a larger than normal stimulus is required to generate an action potential. The combination of the absolute and relative refractory periods in an atrial muscle cell is referred to as the atrial effective refractory period (AERP). As shown in Fig. 1, the duration of the AERP corresponds roughly to the duration of the action potential.

15 The refractoriness of myocardial cells can be prolonged if the cells are stimulated during the refractory period with non-excitatory electrical pulses which can be either below or above the normal threshold potential for initiating an action potential. Fig. 1 shows an atrial pacing pulse A-pace that causes the action potential AP and which is then followed by a number n of non-excitatory stimulus pulses NES delivered during 20 the plateau phase when the atrial cell is absolutely refractory. Since the cell is absolutely refractory, the non-excitatory stimulus pulses can be either subthreshold or suprathreshold. As shown in the figure, the application of the non-excitatory stimulus pulses causes extension of the AERP, effectively changing the atrial substrate and thus reducing the susceptibility of the tissue to fibrillation.

25 As described below, a cardiac rhythm management device can be configured to deliver atrial pacing together with non-excitatory stimuli during the refractory period after a pace to thereby extend the AERP. Such AERP-extension pacing may be employed to lessen the probability that atrial fibrillation will occur whenever conditions warrant, such as during the period following the application of an atrial defibrillation 30 shock or atrial ATP therapy.

### 1. Hardware Platform

Cardiac rhythm management devices are implantable devices that provide electrical stimulation to selected chambers of the heart in order to treat disorders of cardiac rhythm and include pacemakers and implantable cardioverter/defibrillators. Such devices are usually implanted subcutaneously on the patient's chest, and are connected to an electrode for each stimulated or sensed heart chamber by leads threaded through the vessels of the upper venous system into the heart. A pacemaker is a cardiac rhythm management device that paces the heart with timed pacing pulses. The term "pacemaker" as used herein should be taken to mean any device with a pacing functionality, such as an implantable cardioverter/defibrillator with a pacemaker incorporated therein.

In the description that follows, a microprocessor-based cardiac rhythm management device will be referred to as incorporating the system and method that is the present invention. In the embodiment to be described, the invention is implemented with a controller made up of a microprocessor executing programmed instructions in memory. It should be appreciated, however, that certain functions of a cardiac rhythm management device could be controlled by custom logic circuitry either in addition to or instead of a programmed microprocessor. As used herein, the terms "circuitry" or "programmed controller" should be taken to encompass either custom circuitry (i.e., dedicated hardware) or processor-executable instructions contained in a memory along with associated circuit elements.

Fig. 2 shows a system diagram of a microprocessor-based cardiac rhythm management device with pacing functionality that is suitable for delivering therapy to treat AF and to extend the atrial effective refractory period. The controller 10 of the device is a microprocessor that communicates with a memory 12 via a bidirectional data bus. The memory 12 may comprise, for example, a ROM (read-only memory) for program storage and a RAM (random-access memory) for data storage. The device has atrial sensing and pacing channels comprising electrodes 34a-b, leads 33a-b, sensing amplifiers 31a-b, pulse generators 32a-b, and atrial channel interfaces 30a-b which

communicate bidirectionally with microprocessor 10. A ventricular sensing/pacing channel comprising electrode 24, lead 23, sensing amplifier 21, pulse generator 22, and ventricular channel interface 20 is also provided. The device may also have additional channels for sensing and/or pacing additional atrial sites or the ventricles. In the 5 illustrated device, a single electrode is used for sensing and pacing in each channel, known as a unipolar lead. Other embodiments may employ bipolar leads that include two electrodes for outputting a pacing pulse and/or sensing intrinsic activity. The channel interfaces 30a-b include analog-to-digital converters for digitizing sensing signal inputs from the sensing amplifiers and registers which can be written to by the 10 microprocessor in order to output pacing pulses, change the pacing pulse amplitude, and adjust the gain and threshold values for the sensing amplifiers. A shock pulse generator 50 is interfaced to the controller for delivering atrial defibrillation shock pulses via a pair of shock electrodes 51a and 51b placed in proximity to an atrial region. A telemetry interface 40 allows for communicating with an external programmer.

15 The controller 10 controls the overall operation of the device in accordance with programmed instructions stored in memory, including controlling the delivery of paces via the pacing channels, interpreting sense signals received from the sensing channels, and implementing timers for defining escape intervals and sensory refractory periods. The sensing circuitry of the pacemaker detects a chamber sense when an electrogram 20 signal (i.e., a voltage sensed by an electrode representing cardiac electrical activity) generated by a particular channel exceeds a specified detection threshold. A chamber sense may be either an atrial sense or a ventricular sense depending on whether it occurs in the atrial or ventricular sensing channel. Pacing algorithms used in particular pacing modes employ such senses to trigger or inhibit pacing.

25 The controller may also determine the intrinsic rate of the atria and/or ventricles by measuring the interval between successive senses. Atrial arrhythmias such as fibrillation can be detected in this manner using a rate-based criterion. The device may be configured to deliver electrical stimulation therapy to the atria when an atrial tachyarrhythmia is detected such as a defibrillation shock or atrial anti-tachycardia 30 pacing. Upon such detection of atrial fibrillation, for example, the controller may be

programmed to cause the delivery of a defibrillation shock to the atria. If subsequent sensing determines that the atrial fibrillation persists, the device may repeat the shock a specified number of times until successful termination of the fibrillation is achieved. The device terminates atrial fibrillation by delivering a shock pulse to the atria, but the resulting depolarization also spreads to the ventricles. There is thus a risk that such an atrial shock pulse can actually induce ventricular fibrillation, a condition much worse than atrial fibrillation. The ventricles are especially vulnerable to induction of fibrillation by a depolarizing shock delivered at a time too near the end of the preceding ventricular contraction (i.e., close to the T wave on an EKG). The risk of inducing ventricular fibrillation can be reduced by delaying the delivery of an atrial shock pulse until the intrinsic ventricular rhythm is below a specified maximum rate and then delivering the shock synchronously with a sensed ventricular depolarization or R wave. The device may also have a shock pulse generator and shock electrode pair for delivering defibrillation shocks to the ventricles.

15

## 2. Pacing Modes

Bradycardia pacing modes refer to pacing algorithms used to pace the atria and/or ventricles in a manner that enforces a certain minimum heart rate. Such modes are generally designated by a letter code of three positions where each letter in the code refers to a specific function of the pacemaker. Pacemakers can enforce a minimum heart rate either asynchronously or synchronously. In asynchronous pacing, the heart is paced at a fixed rate irrespective of intrinsic cardiac activity. Because of the risk of inducing an arrhythmia with asynchronous pacing, most pacemakers for treating bradycardia are programmed to operate synchronously in a so-called demand mode where sensed cardiac events occurring within a defined interval either trigger or inhibit a pacing pulse. Inhibited demand pacing modes utilize escape intervals to control pacing in accordance with sensed intrinsic activity. In an inhibited demand mode, a pacing pulse is delivered to a heart chamber during a cardiac cycle only after expiration of a defined escape interval during which no intrinsic beat by the chamber is detected.

20 For example, a ventricular escape interval can be defined between ventricular events so

as to be restarted with each ventricular sense or pace. A pacemaker can also be configured to pace the atria on an inhibited demand basis. An atrial escape interval is then defined as the maximum time interval in which an atrial sense must be detected after a ventricular sense or pace before an atrial pace will be delivered.

5 Pacing protocols for ATP therapy can generally be divided into two classes: those that deliver one or more pulses in timed relation to detected depolarizations and those that deliver a continuous pulse train for a specified time beginning after a detected depolarization. Both types of ATP protocols attempt to block the reentrant depolarization wavefront causing the tachycardia with a second depolarizing wavefront  
10 produced by a pacing pulse. Protocols of the first group may vary according to parameters that define the number of pulses delivered and the particular timing employed. Protocols of the second group include so-called burst pacing in which a short train of pulses is delivered for a specified time and may vary according to parameters that define the duration, frequency, and timing of the pulses.

15

### 3. Device configuration

A device such as illustrated in Fig. 2 may be configured to deliver atrial pacing with atrial effective refractory period extension in a number of ways. In an exemplary dual-site configuration, the electrode of a first pacing channel is disposed in the right atrium for pacing that atrium, and the electrode of a second pacing channel is placed near the left atrium via the coronary sinus for delivery of the non-excitatory stimuli. Other configurations may use an atrial pacing channel and one or more dedicated stimulation channels where the pacing and one or more non-excitatory stimulus electrodes are placed at multiple atrial sites. Other devices may use the same pacing  
20 channel and electrode for delivering both pacing and non-excitatory pulses in a single-site configuration. With either a single-site or multiple-site configuration, the controller of the device is programmed with an AERP-extension mode that paces an atrium via the pacing channel using a bradycardia pacing mode and delivers one or more non-excitatory stimuli after a pacing pulse as described above. Fig. 3 shows an example of  
25 events in the pacing channel or channels PC in relation to an ECG. An atrial pacing  
30

5 pulse AP is followed by n non-excitatory stimulation pulses NSP, where the pulses NSP are delivered during the atrial refractory period and hence their amplitudes may be either above or below the threshold voltage needed to excite the atrial tissue. The atrial refractory period is defined in the programming of the device as a specified time period following the atrial pace. The atrial refractory period may be individually defined for a particular patient or selected as a nominal value representing the refractory period of a typical atrial fiber (e.g., 150 ms).

#### 4. Overdrive pacing

10 The bradycardia pacing mode employed with the AERP-extension mode is preferably an inhibited demand mode where atrial senses inhibit atrial paces. Since the non-excitatory stimuli that extend the refractory period are only output during paced beats, it may be desirable to increase the frequency of atrial pacing by decreasing the atrial escape interval so that the pacing rate is greater than the intrinsic heart rate, termed 15 overdrive pacing. Such an overdrive atrial pacing mode may be implemented by dynamic adjusting the atrial escape interval so that the interval is decreased when an atrial sense is detected and slowly increased after each paced beat.

20 In one embodiment of atrial overdrive pacing, the atrial escape interval is adjusted to decrease toward a programmed minimum value by measuring an A-A interval (defined as the time interval between the atrial sense and the preceding atrial sense or pace) when an atrial sense occurs and then computing an updated atrial escape 25 interval based upon the measured A-A interval. When an atrial pace is delivered, on the other hand, the atrial escape interval is made to slowly increase so that the atrial pacing rate decays toward its programmed base value. Figs. 4A and 4B show an exemplary implementation of an overdrive pacing system made up of a pair of filters 515 and 516 which may be implemented as software executed by the controller 10 (a.k.a. firmware) and/or with discrete components. Filter 515 is employed to compute the updated atrial escape interval when an atrial sense occurs, and filter 516 is used when an atrial pace is delivered. When an atrial sense occurs, the measured A-A interval is input to a 30 recursive digital filter 515 whose output is the updated atrial escape interval. The filter

515 multiplies the measured A-A interval by a filter coefficient A and then adds the result to the previous value of the output (i.e., the present atrial escape interval) multiplied by a filter coefficient B. The operation of the filter is thus described by  $AEI_n = X(AA_n) + Y(AEI_{n-1})$ , where X and Y are selected coefficients,  $AA_n$  is the most recent A-  
5 A interval duration, and  $AEI_{n-1}$  is the previous value of the atrial escape interval. The filter thus causes the value of the atrial escape interval to move toward the present A-A interval multiplied by a scaling factor at a rate determined by the filter coefficients. When an atrial pace is delivered due to expiration of the atrial escape interval without an atrial sense, filter 516 multiplies the present atrial escape interval by a filter  
10 coefficient Z so that  $AEI_n = Z(AEI_{n-1})$ . To provide stable operation, the coefficient Z must be set to a value greater than 1. Filter 516 then causes the atrial escape interval to increase in an exponential manner with each pace as successive values of the escape interval are input to the filter up to a value corresponding to the base atrial escape interval. In order to overdrive the atria, the coefficients of filters 515 and 516 are  
15 selected so that the atrial escape interval decreases rapidly toward a value less than the present A-A interval when an atrial sense occurs and increases slowly toward a programmed base value when a pace is delivered.

##### 5. Initiation of AERP-extension pacing

20 The controller may be programmed to enter the AERP-extension mode for a specified time period either upon command from an external programmer, periodically or at other specified times during normal operation, or in response to sensed events. One particular situation where AERP-extension pacing may be especially beneficial is in the period following an atrial defibrillation shock. It has been found that the atria are  
25 in a supervulnerable period lasting approximately one minute immediately following an atrial defibrillation shock. During this time, the atrial effective refractory period is shortened from its value during the atrial fibrillation. This condition predisposes the patient to post-shock re-initiation of the atrial fibrillation, commonly referred to as early recurrence of atrial fibrillation or ERAF. To deal with this situation, the device can be  
30 programmed so that, upon detection of atrial fibrillation, an atrial defibrillation shock is

delivered to terminate the fibrillation followed by AERP-extension pacing for a specified time period. The device may also be programmed to deliver AERP-extension pacing for a specified time following delivery of atrial anti-tachycardia pacing.

Although the invention has been described in conjunction with the foregoing specific embodiment, many alternatives, variations, and modifications will be apparent to those of ordinary skill in the art. Such alternatives, variations, and modifications are intended to fall within the scope of the following appended claims.

What is claimed is:

1. A cardiac rhythm management device, comprising:
  - an atrial sensing channel for sensing atrial electrical activity;
  - 5 an atrial pacing channel for delivering atrial pacing pulses;
  - a shock pulse generator for delivering atrial defibrillation shocks;
  - a controller programmed with executable instructions for performing functions which include:
    - detecting atrial fibrillation;
    - 10 delivering an atrial defibrillation shock after atrial fibrillation is detected;
    - delivering atrial pacing pulses in accordance with a pacing mode for a specified period of time following an atrial defibrillation shock; and,
    - delivering one or more non-excitatory stimulation pulses to an atrium during an atrial refractory period after an atrial pacing pulse.
- 15 2. The device of claim 1 wherein the non-excitatory stimulation pulses are of lesser amplitude than the atrial pacing pulses.
3. The device of claim 1 wherein the non-excitatory stimulation pulses are of equal 20 or greater amplitude than the atrial pacing pulses.
4. The device of claim 1 wherein the non-excitatory stimulation pulses are delivered through the atrial pacing channel.
- 25 5. The device of claim 1 further comprising an atrial stimulation channel for delivering the non-excitatory stimulation pulses.
6. The device of claim 1 further comprising a plurality of atrial stimulation channels and wherein the controller is programmed to deliver non-excitatory atrial

stimulation pulses through the plurality of atrial stimulation channels after an atrial pace during the specified period of time.

7. The device of claim 1 wherein the controller is programmed to deliver atrial 5 pacing pulses in an overdrive pacing mode for the specified period of time following delivery of an atrial defibrillation shock.
8. The device of claim 1 further comprising a ventricular sensing channel for 10 sensing ventricular electrical activity and wherein the controller is programmed to deliver the atrial defibrillation shock in synchrony with an R wave.
9. A method for treating atrial fibrillation, comprising:
  - sensing atrial electrical activity in order to detect atrial fibrillation;
  - delivering an atrial defibrillation shock upon detection of atrial fibrillation;
  - 15 delivering atrial pacing pulses to an atrial pacing site in accordance with a pacing mode for a specified period of time following an atrial defibrillation shock; and,
  - delivering one or more non-excitatory stimulation pulses to an atrial stimulation site during the atrial refractory period after an atrial pacing pulse.
- 20 10. The method of claim 9 wherein the non-excitatory stimulation pulses are of lesser amplitude than the atrial pacing pulses.
11. The method of claim 9 wherein the non-excitatory stimulation pulses are of 25 equal or greater amplitude than the atrial pacing pulses.
12. The method of claim 9 further comprising delivering the non-excitatory stimulation pulses to an atrial stimulation site different from the atrial pacing site.
13. The method of claim 9 wherein the atrial pacing site is in one atrium and the 30 atrial stimulation site is in the contralateral atrium.

14. The method of claim 9 further comprising delivering non-excitatory atrial stimulation pulses to a plurality of atrial stimulation sites after an atrial pace during the specified period of time.
- 5 15. The method of claim 9 further comprising delivering atrial paces in an overdrive pacing mode for the specified period of time following delivery of an atrial defibrillation shock.
16. A cardiac rhythm management device, comprising:
  - 10 an atrial sensing channel for sensing atrial electrical activity;
  - a first atrial pacing channel for delivering pacing pulses to an atrium;
  - a controller programmed with executable instructions for performing functions which include:
    - 15 detecting atrial fibrillation;
    - delivering atrial anti-tachycardia pacing after detection of atrial fibrillation;
    - delivering atrial pacing pulses in accordance with a bradycardia pacing mode for a specified period of time following the atrial anti-tachycardia pacing; and,
    - delivering one or more non-excitatory atrial stimulation pulses during the atrial refractory period after an atrial pacing pulse while pacing with the bradycardia pacing mode.
17. The device of claim 16 wherein the non-excitatory stimulation pulses are of lesser amplitude than the atrial pacing pulses.
- 25 18. The device of claim 16 further comprising a second atrial pacing channel for delivering the non-excitatory stimulation pulses.
19. The device of claim 16 wherein the controller is programmed to deliver atrial pacing pulses in an overdrive pacing mode for the specified period of time following delivery of the atrial anti-tachycardia pacing.

20. The device of claim 16 further comprising a plurality of atrial stimulation channels and wherein the controller is programmed to deliver non-excitatory atrial stimulation pulses through the plurality of atrial stimulation channels after an atrial pace during the specified period of time.

5

21. A method for treating atrial fibrillation, comprising:  
sensing atrial electrical activity in order to detect atrial fibrillation;  
delivering atrial anti-tachycardia pacing upon detection of atrial fibrillation;  
delivering atrial pacing pulses to an atrial pacing site in accordance with a bradycardia pacing mode for a specified period of time following the anti-tachycardia pacing; and,  
delivering one or more non-excitatory stimulation pulses to an atrium during the atrial refractory period after an atrial pacing pulse while pacing in the bradycardia pacing mode.

15

22. The method of claim 21 wherein the non-excitatory stimulation pulses are of lesser amplitude than the atrial pacing pulses.

23. The method of claim 21 further comprising delivering the non-excitatory stimulation pulses to an atrial stimulation site different from the atrial pacing site.

24. The method of claim 21 wherein the atrial pacing site is in one atrium and the atrial stimulation site is in the contralateral atrium.

25. 25. The method of claim 21 further comprising delivering non-excitatory atrial stimulation pulses to a plurality of atrial stimulation sites after an atrial pace during the specified period of time.

26. The method of claim 21 further comprising delivering pacing pulses to the atria in an overdrive pacing mode for the specified period of time following delivery of the atrial anti-tachycardia pacing.

5 27. A cardiac rhythm management device, comprising:  
means for sensing atrial electrical activity in order to detect atrial fibrillation;  
means for delivering an atrial defibrillation shock upon detection of atrial fibrillation;  
means for delivering atrial pacing pulses to an atrial pacing site in accordance  
10 with a pacing mode for a specified period of time following an atrial defibrillation shock; and,  
means for delivering one or more non-excitatory stimulation pulses to an atrial stimulation site during the atrial refractory period after each atrial pacing pulse during the specified period of time.

15 28. The device of claim 27 wherein the non-excitatory stimulation pulses are of lesser amplitude than the atrial pacing pulses.

20 29. The device of claim 27 wherein the non-excitatory stimulation pulses are of equal or greater amplitude than the atrial pacing pulses.

30. The device of claim 27 further comprising means for delivering the non-excitatory stimulation pulses to an atrial stimulation site different from the atrial pacing site.

25 31. The device of claim 27 wherein the atrial pacing site is in one atrium and the atrial stimulation site is in the contralateral atrium.

32. The device of claim 27 further comprising means for delivering non-excitatory atrial stimulation pulses to a plurality of atrial stimulation sites after an atrial pace during the specified period of time.

5 33. The device of claim 27 further comprising means for delivering atrial paces in an overdrive pacing mode for the specified period of time following delivery of an atrial defibrillation shock.

34. A cardiac rhythm management device, comprising:  
10 means for sensing atrial electrical activity in order to detect atrial fibrillation;  
means for delivering atrial anti-tachycardia pacing upon detection of atrial fibrillation;  
means for delivering atrial pacing pulses to an atrial pacing site in accordance with a bradycardia pacing mode for a specified period of time following the anti-tachycardia pacing; and,  
15 means for delivering one or more non-excitatory stimulation pulses to an atrium during the atrial refractory period after each atrial pacing pulse during the specified period of time.

20 35. The device of claim 34 wherein the non-excitatory stimulation pulses are of lesser amplitude than the atrial pacing pulses.

36. The device of claim 34 further comprising means for delivering the non-excitatory stimulation pulses to an atrial stimulation site different from the atrial pacing site.  
25

37. The device of claim 34 wherein the atrial pacing site is in one atrium and the atrial stimulation site is in the contralateral atrium.

38. The device of claim 34 further comprising means for delivering non-excitatory atrial stimulation pulses to a plurality of atrial stimulation sites after an atrial pace during the specified period of time.

5 39. The device of claim 34 further comprising means for delivering pacing pulses to the atria in an overdrive pacing mode for the specified period of time following delivery of the atrial anti-tachycardia pacing.

10

15

1/4

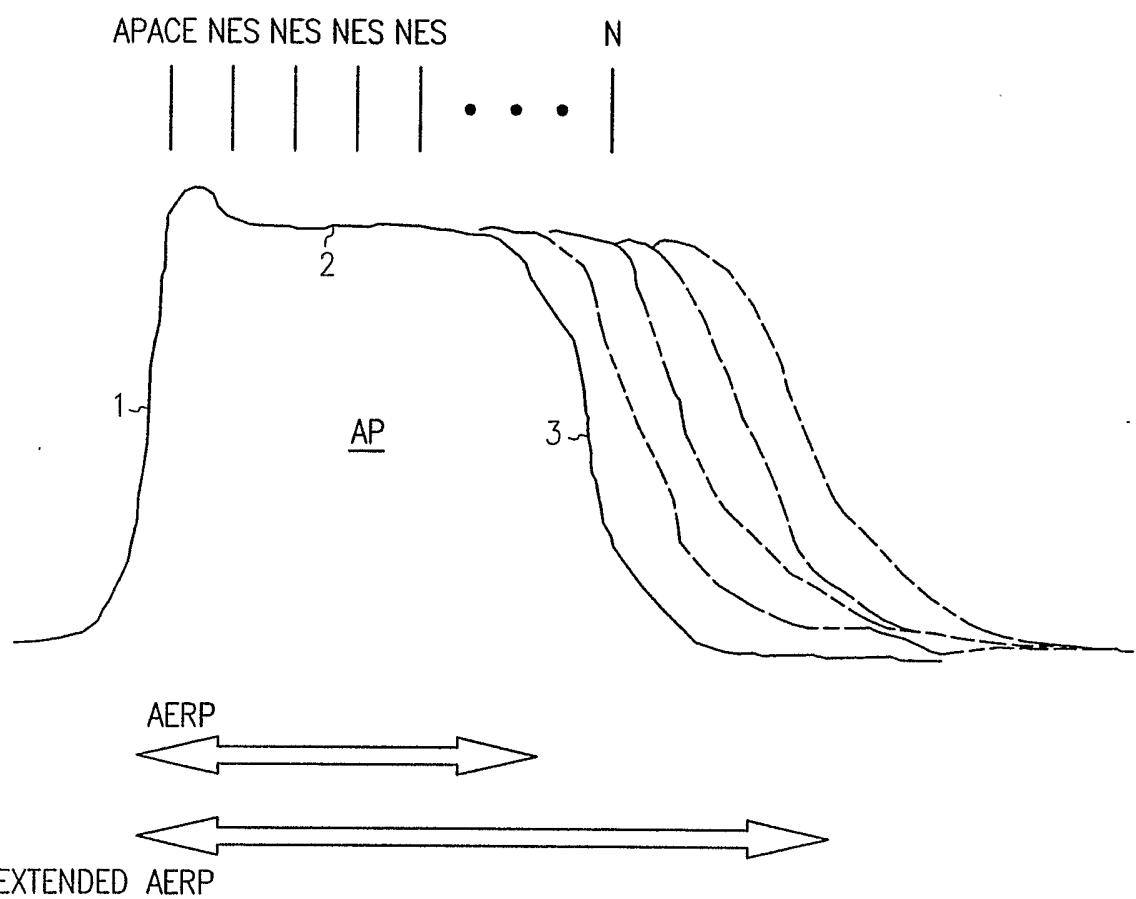


FIG. 1

2/4

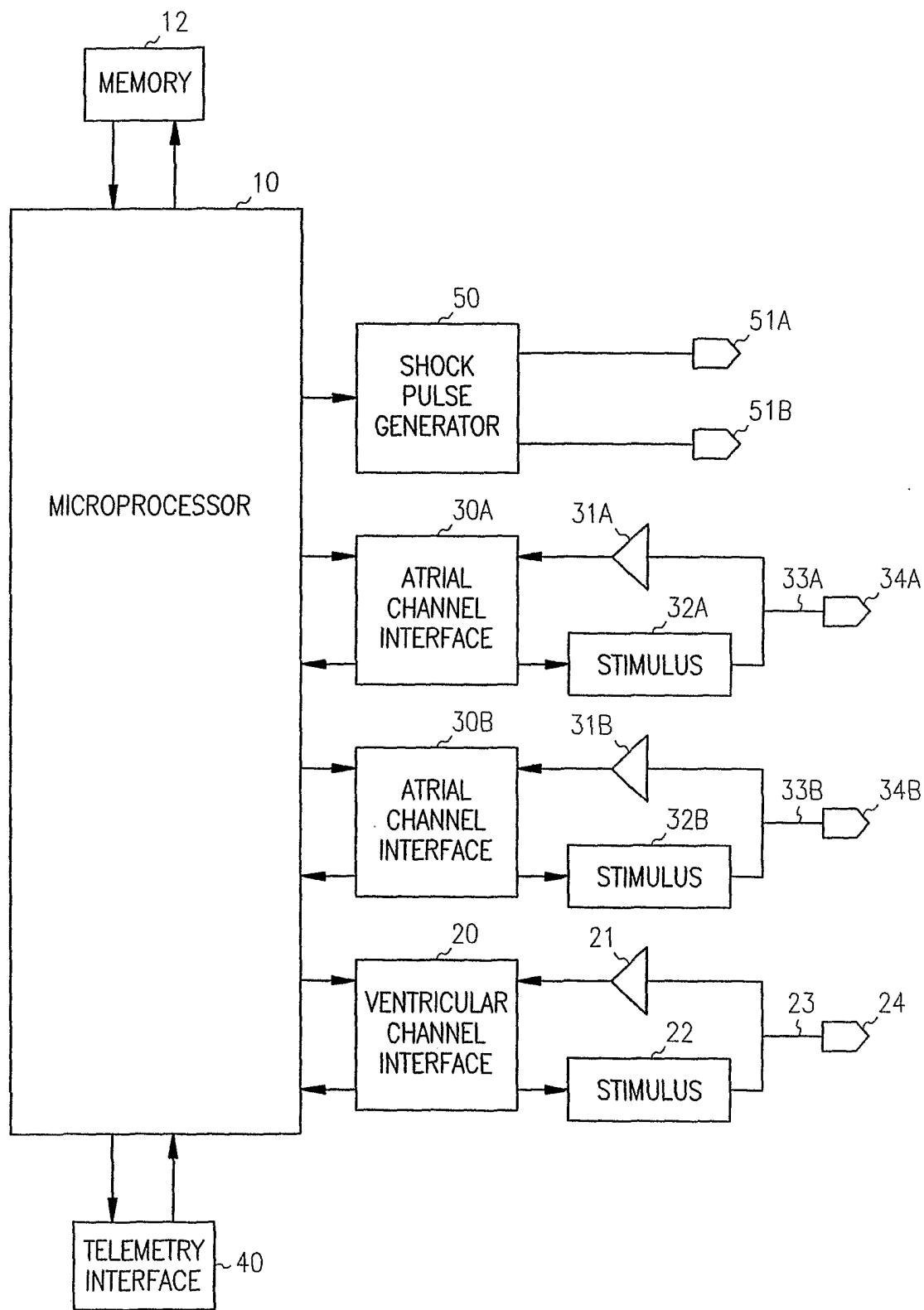


FIG. 2

3/4

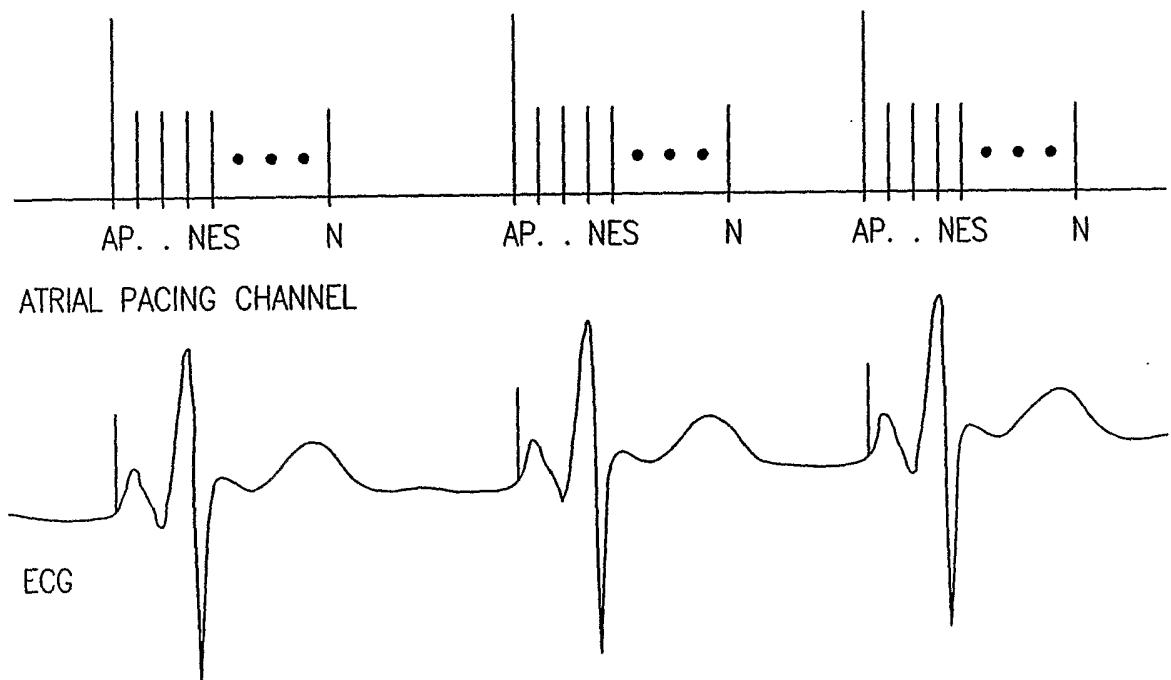


FIG. 3

4/4

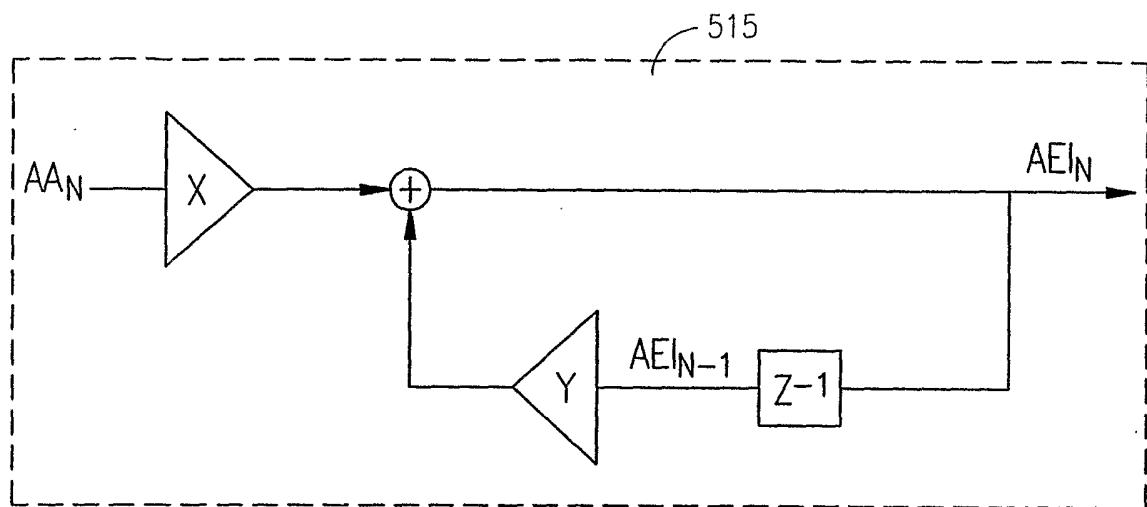


FIG. 4A

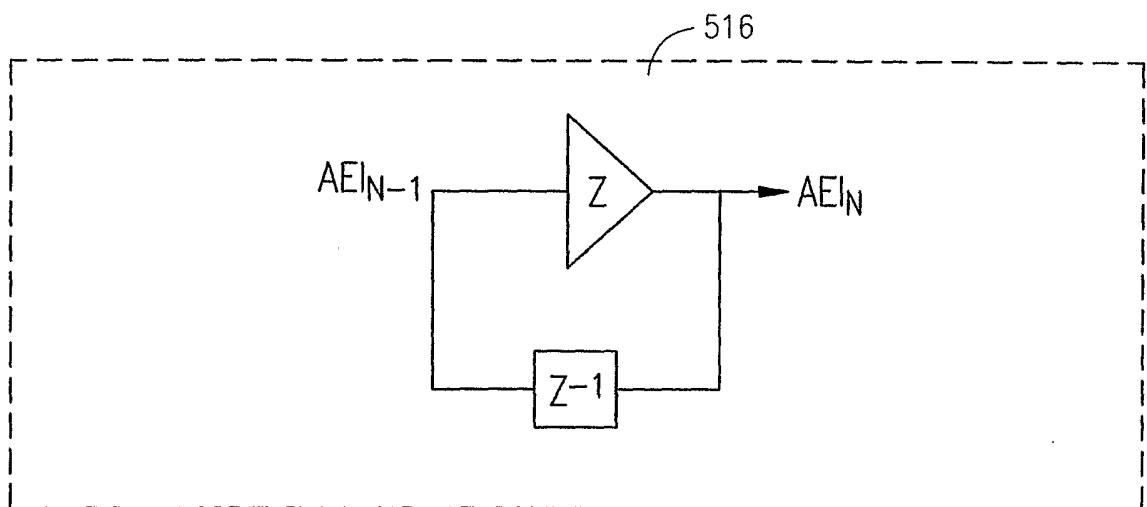


FIG. 4B

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 03/37155

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 7 A61N1/39

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 334 221 A (BARDY GUST H) 2 August 1994 (1994-08-02) column 3, line 4 – line 23 column 9, line 29 – line 44 column 12, line 56 – line 65 ---	1, 16, 27, 34
A	EP 1 118 352 A (PACESETTER INC) 25 July 2001 (2001-07-25) paragraph '0038! ---	1, 16, 27, 34
A	EP 0 811 399 A (INCONTROL INC) 10 December 1997 (1997-12-10) abstract ---	1, 16, 27, 34
A	WO 97/27797 A (FENSTER MAIER ;BEN HAIM SHLOMO (IL)) 7 August 1997 (1997-08-07) page 9, paragraph 2 ---	1, 16, 27, 34 -/-

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

\* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

\*&\* document member of the same patent family

Date of the actual completion of the international search

27 April 2004

Date of mailing of the International search report

06/05/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Petter, E

# INTERNATIONAL SEARCH REPORT

Int'l Application No  
PCT/US 03/37155

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 741 311 A (BAHR BRENT A ET AL) 21 April 1998 (1998-04-21) column 2, line 27 – line 42 column 3, line 17 – line 28 ----	1,16,27, 34
A	US 2001/018600 A1 (GARBEROGLIO BRUNO ET AL) 30 August 2001 (2001-08-30) paragraphs '0009!–'0013! ----	1,16,27, 34

## INTERNATIONAL SEARCH REPORT

national application No.  
PCT/US 03/37155

### Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: **9-15, 21-26**  
because they relate to subject matter not required to be searched by this Authority, namely:  
**Rule 39.1(iv) PCT – Method for treatment of the human or animal body by therapy**
2.  Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple Inventions in this international application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.  As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4.  No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

#### Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 03/37155

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
US 5334221	A	02-08-1994	AU AU CA DE DE EP JP WO	661179 B2 4410393 A 2138043 A1 69307510 D1 69307510 T2 0647151 A1 7504597 T 9400192 A1	13-07-1995 24-01-1994 06-01-1994 27-02-1997 31-07-1997 12-04-1995 25-05-1995 06-01-1994
EP 1118352	A	25-07-2001	US EP US	6377852 B1 1118352 A2 6701187 B1	23-04-2002 25-07-2001 02-03-2004
EP 0811399	A	10-12-1997	US US CA EP CA	5645569 A 5676687 A 2205326 A1 0811399 A2 2205271 A1	08-07-1997 14-10-1997 04-12-1997 10-12-1997 11-04-1998
WO 9727797	A	07-08-1997	AU AU AU CA CN EP WO IL US WO US US	724404 B2 1206797 A 1954597 A 2240943 A1 1211930 A 0910429 A1 9725098 A1 125136 A 2002052632 A1 9727797 A2 6317631 B1 6330476 B1	21-09-2000 01-08-1997 22-08-1997 17-07-1997 24-03-1999 28-04-1999 17-07-1997 31-07-2003 02-05-2002 07-08-1997 13-11-2001 11-12-2001
US 5741311	A	21-04-1998		NONE	
US 2001018600	A1	30-08-2001	EP US	1023917 A1 6240314 B1	02-08-2000 29-05-2001