UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

MEDTRONIC, INC., a Minnesota corporation, Plaintiff, v. BOSTON SCIENTIFIC CORPORATION, a Delaware corporation, GUIDANT CORPORATION, an Indiana corporation and MIROWSKI FAMILY VENTURES L.L.C., a Maryland limited liability corporation, Defendants.	)	Civil Action No. Jury Trial Demanded

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Medtronic, Inc., as and for its Complaint herein, states as follows:

THE PARTIES

1. Plaintiff Medtronic, Inc. ("Medtronic") is a Minnesota corporation with a principal place of business at 710 Medtronic Parkway NE, Minneapolis, Minnesota 55432-5604. Medtronic is the leading manufacturer and seller of medical devices in the United States and worldwide.

2. Defendant Boston Scientific Corporation ("Boston Scientific") is a Delaware corporation with a principal place of business at One Boston Scientific Place, Natick, Massachusetts 01760-1537. Upon information and belief, Boston Scientific is the parent company of Guidant Corporation.

3. Defendant Guidant Corporation ("Guidant") is an Indiana corporation with a principal place of business at 111 Monument Circle, Indianapolis, Indiana 46204-5129. Upon

information and belief, Guidant is a wholly-owned subsidiary of Boston Scientific. Upon information and belief, Boston Scientific and/or Guidant are the exclusive licensees of United States Reissue Patents RE 39,897 ("the '897 Reissue Patent") and RE 38,119 ("the '119 Reissue Patent").

4. Defendant Mirowski Family Ventures, L.L.C. ("Mirowski"), is a Maryland limited liability corporation. Upon information and belief, Mirowski is the assignee of the '119 Reissue Patent and the '897 Reissue Patent, and has the right to receive royalties, share in infringement damages, join in infringement actions, and initiate infringement actions related to the patents licensed to Guidant and/or Boston Scientific.

JURISDICTION AND VENUE

5. This action arises under the Acts of Congress relating to patents, 35 U.S.C. §§ 1 *et seq.*, and under the Federal Declaratory Judgment Act, 28 U.S.C. § 2201. This Court has subject matter jurisdiction under the provisions of 28 U.S.C. §§ 1331 and 1338 (a). Venue is proper in this judicial district under 28 U.S.C. § 1391(b) and § 1400(b).

FACTUAL BACKGROUND

6. Medtronic is engaged in the business of manufacturing, promoting, offering for sale and selling certain implantable cardiac stimulation devices that are capable of providing cardiac resynchronization therapy to treat ventricular dyssynchrony.

7. Boston Scientific, Guidant and Mirowski allege that certain of Medtronic's implantable cardiac stimulation devices infringe "at least one of" claims 15, 19, 20 and 26 of the '119 Reissue Patent, and claims 120, 162, 172, 184, 201, 211, 217, 225, 233, 248, 273, 282, 288,

294, 303, 308, 309, 314, 315, 320 and 324-328 of the '897 Reissue Patent, entitled "Method and Apparatus for Treating Hemodynamic Disfunction."

8. The '119 Reissue Patent issued from Application No. 08/547,691 ("the '691 Application") on May 20, 2003. The '691 Application is a continuation of United States Patent No. 4,928,688 ("the '688 Patent"). The '688 Patent issued on May 29, 1990.

9. The '897 Reissue Patent issued from Application No. 10/214,474 ("the '474 Application") on October 23, 2007, which is a continuation of the '119 Reissue Patent.

10. The '688 Patent, '119 Reissue Patent and '897 Reissue Patent share the same specification. Upon information and belief, the '688 Patent was assigned—and the '119 Reissue Patent and '897 Reissue Patent are assigned—to Mirowski. Copies of the '119 Reissue Patent and '897 Reissue Patent are attached to the Complaint as Exhibits A and B.

11. Upon information and belief, Eli Lilly and Company ("Lilly") and Cardiac Pacemakers, Inc. ("CPI") were the exclusive licensee and sublicensee of the '688 Patent.

12. On May 13, 1991, Medtronic entered into a Settlement and License Agreement with Lilly and CPI to settle several lawsuits between the three companies regarding various patents related to implantable pacemakers and defibrillators. On May 24, 1991, the parties entered into an Omnibus Amendment of the Settlement and License Agreement. These agreements were further amended by Letter Agreement dated April 14, 2003 (collectively "the Agreement"). As part of the Agreement, Medtronic obtained a license under a number of patents, including the '688 Patent. Medtronic also obtained a license to all patents that matured from continuations of the '688 Patent or reissues of the '688 Patent.

13. Guidant acquired an exclusive license to the '688 Patent and '119 Reissue Patent, as well as to the '474 Application—and any patent that issued from the '474 Application—through an Amended and Restated Exclusive License Agreement with Mirowski dated January 28, 2004.

14. Upon information and belief, Boston Scientific acquired Guidant in 2006.

15. Under Article III of the Agreement, if Mirowski and its exclusive licensee believe that a new Medtronic device infringes one or more claims of the patents licensed under the Agreement and Medtronic is not paying royalties on such new device, then Mirowski and its exclusive licensee must notify Medtronic of the alleged infringement. Medtronic shall then have an opportunity to cure the nonpayment of royalties and challenge the assertion of infringement through a declaratory judgment action.

16. Medtronic has previously instituted two such declaratory judgment actions, each of which has been terminated.

17. The first action was initiated against Guidant, Lilly and CPI in the Southern District of Indiana on May 19, 2003 (1:03-CV-00742), and Medtronic alleged noninfringement of the '688 patent by the InSync III. After the parties stipulated to a stay of the case in October 2003 (Dkt. No. 16), the case was dismissed without prejudice in February of 2004. (Dkt. No. 22).

18. The second action was initiated against Guidant, Lilly and CPI in the District of Delaware on September 12, 2003 (C.A. No. 03-848 (SLR)). Medtronic alleged that the claims of the '119 Reissue Patent had been improperly reissued under 35 U.S.C. § 251 and improperly recaptured subject matter that had been voluntarily surrendered during the prosecution of the '688

patent. Medtronic also alleged that it was entitled to statutory and equitable intervening rights under 35 U.S.C. § 252. This action was terminated on July 19, 2005.

19. Medtronic, Mirowski and Guidant entered into a Litigation Tolling Agreement in July 2006.

20. Under the terms of the Litigation Tolling Agreement, the parties agreed to a Declaratory Judgment Suspension period ("DJ Suspension Period") of no later than October 1, 2007. Within sixty (60) days after the expiration of the DJ Suspension Period, the parties agreed that Guidant or Mirowski must provide Medtronic with notice—in writing—of products they believe infringe no more than 30 claims of the '119 Reissue Patent or subsequent reissue patent. As required by the Tolling Agreement, a Joint Proposed Stipulated Agreement is attached to the Complaint as Exhibit C.

21. By letter on October 3, 2007 Mirowski informed Medtronic that Medtronic's InSync ICD, InSync II Marquis, InSync Maximo, InSync II Protect, InSync, InSync Sentry and Concerto devices ("the Accused Devices") infringe "at least one" of claims 15-26 in the '119 Reissue Patent, and that it intended to identify additional claims that issued from the '474 Application once the claims issued. On November 20, 2007, Mirowski informed Medtronic that at least one of claims 15, 19, 20 and 26 of the '119 are infringed by the Accused Devices.

22. By letter on November 20, 2007, Mirowski informed Medtronic that the Accused Devices infringe claims 120, 162, 172, 184, 201, 211, 217, 225, 233, 248, 273, 282, 288, 294, 303, 308, 309, 314, 315, 320 and 324-328 of the '897 Reissue Patent.

23. Under the terms of the Litigation Tolling Agreement, the parties agreed that within ninety (90) days after receiving notice of infringement from Mirwoski or Guidant, Medtronic may initiate a Final DJ action in the District of Delaware, challenging infringement, unenforceability and/or validity of the '119 Reissue Patent and any asserted claims of any subsequent reissue patent.

24. Medtronic's Accused Devices do not infringe any valid claim of the '119 Reissue Patent or the '897 Reissue Patent.

25. Each Asserted Claim of the '119 Reissue Patent and the '897 Reissue Patent is invalid because it does not meet one or more of the conditions for patentability specified in 35 U.S.C. §§ 101, 102, 103, 112, 132, 251 *et seq*.

26. Based on the facts described above, Medtronic is entitled to file this action seeking the declaratory relief demanded in this Complaint.

COUNT ONE
DECLARATORY JUDGMENT OF NON-INFRINGEMENT
BY THE ACCUSED DEVICES OF THE '119 REISSUE PATENT

27. Medtronic hereby restates and realleges the allegations set forth in paragraphs 1-26.

28. Defendants have asserted that the Accused Devices infringed and continue to infringe claims 15, 19, 20 and 26 of the '119 Reissue Patent, creating an actual controversy within this Court's jurisdiction.

29. Medtronic's Accused Devices do not infringe, either directly or indirectly, contributorily, by inducement or otherwise, any valid and enforceable claim of the '119 Reissue Patent.

30. Medtronic is entitled to a declaration that the Accused Devices do not infringe any valid and enforceable claim of the '119 Reissue Patent.

COUNT TWO
DECLARATORY JUDGMENT OF INVALIDITY
OF THE ASSERTED CLAIMS OF THE '119 REISSUE PATENT

31. Medtronic hereby restates and realleges the allegations set forth in paragraphs 1-26.

32. Each Asserted Claim of the '119 Reissue Patent is invalid because it does not meet one or more of the conditions for patentability specified in 35 U.S.C. §§ 101, 102, 103, 112, 132, 251 *et seq*.

33. Medtronic is entitled to a declaration that the Asserted Claims of the '119 Reissue Patent are invalid.

COUNT THREE
DECLARATORY JUDGMENT OF NON-INFRINGEMENT
BY THE ACCUSED DEVICES OF THE '897 REISSUE PATENT

34. Medtronic hereby restates and realleges the allegations set forth in paragraphs 1-26.

35. Defendants have asserted that the Accused Devices infringed and continue to infringe claims 120, 162, 172, 184, 201, 211, 217, 225, 233, 248, 273, 282, 288, 294, 303, 308, 309, 314, 315, 320 and 324-328 of the '897 Reissue Patent, creating an actual controversy within this Court's jurisdiction.

36. Medtronic's Accused Devices do not infringe, either directly or indirectly, contributorily, by inducement or otherwise, any valid and enforceable claim of the '897 Reissue Patent.

37. Medtronic is entitled to a declaration that the Accused Devices do not infringe any valid and enforceable claim of the '897 Reissue Patent.

COUNT FOUR
DECLARATORY JUDGMENT OF INVALIDITY
OF THE ASSERTED CLAIMS OF THE '897 REISSUE PATENT

38. Medtronic hereby restates and realleges the allegations set forth in paragraphs 1-26.

39. Each Asserted Claim of the '897 Reissue Patent is invalid because it does not meet one or more of the conditions for patentability specified in 35 U.S.C. §§ 101, 102, 103, 112, 132, 251 *et seq.*

40. Medtronic is entitled to a declaration that the Asserted Claims of the '897 Reissue Patent are invalid.

WHEREFORE, Medtronic prays for judgment as follows:

1. A declaration that Medtronic has not infringed and is not infringing, either directly, indirectly, contributorily or otherwise, any valid and enforceable claim of the '119 Reissue Patent or '897 Reissue Patent by its manufacture, sale, offer for sale, or use of the Accused Devices.

2. A declaration that the Asserted Claims of the '119 Reissue Patent and '897 Reissue Patent are invalid.

3. That Medtronic be awarded its costs, disbursements and attorneys' fees herein

in accordance with the terms of the Agreement and with Title 35 U.S.C. § 285; and

4. That Medtronic be awarded such other and further relief as this Court may deem just and proper.

JURY DEMAND

Pursuant to Fed. R. Civ. P. 38(b), plaintiffs hereby demand a trial by a jury on all issues so triable.

Respectfully submitted,

Dated: December 17, 2007 By: Arthur G. Connolly III

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EXHIBIT A

US00RE38119E

(19) **United States**

(12) **Reissued Patent**
Mower

(10) **Patent Number: US RE38,119 E**

(45) **Date of Reissued Patent: May 20, 2003**

(54) **METHOD AND APPARATUS FOR TREATING HEMODYNAMIC DISFUNCTION**

(75) Inventor: **Morton M. Mower**, Baltimore, MD (US)

(73) Assignee: **Mirowski Family Ventures, LLC**, Washington, DC (US)

(21) Appl. No.: **08/547,691**

(22) Filed: **Oct. 19, 1995**

Related U.S. Patent Documents

Reissue of:

(64) Patent No.: **4,928,688**
Issued: **May 29, 1990**
Appl. No.: **07/299,895**
Filed: **Jan. 23, 1989**

U.S. Applications:

(63) Continuation of application No. 10/214,474, filed on Aug. 8, 2002, which is a continuation of application No. 07/890,280, filed on May 29, 1992, now abandoned.

(51) **Int. Cl.**[7] **A61N 1/00**

(52) **U.S. Cl.** **607/9**

(58) **Field of Search** 607/4–28

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,937,226	A	*	2/1976	Funke
4,088,140	A	*	5/1978	Rockland et al. ..... 128/419 PG
4,332,259	A	*	6/1982	McCorkle, Jr. ..... 128/419 P
4,378,020	A	*	3/1983	Nappholz et al.
4,458,677	A	*	7/1984	McCorkle, Jr. ..... 128/419 P
4,548,203	A	*	10/1985	Tacker, Jr. et al. 128/784
4,624,260	A	*	11/1986	Baker, Jr. et al. 607/14
4,774,950	A	*	10/1988	Cohen

OTHER PUBLICATIONS

Incomplete Filling and Incoordinate Contraction as Mechanisms of Hypotension during Ventricular Tachycardia in Man, by Joao A. Lima et al., Circulation, vol. 68, No. 5 (1983).*

Aranda, et al., "A New Pacemaker for Simultaneous Biventricular Stimulation . . . ", Clin. Res., 24, 206A.

Befeler, et al., "Programmed Simultaneous Biventricular Stimulation . . . ", Eur. J. of Cardiology, 1979, pp. 369–378.

Haas, et al., "Pacemaker—Induced Cardiovascular Failure", Am. J. of Cardiology, 1974, pp. 295–299.

Lister, et al., "Effect of Pacemaker Site in . . . Heart Block", Am. J. of Cardiology, 1964, pp. 494–503.

Mann, et al., "Entrainment of Ventricular Tachycardia", J. Am. College of Cardiology, 1985, pp. 781–787.

Schlant et al., "Modification of the Law of the Heart: Influence of Early Contracting Areas (P)", Circulation, Supp. III, 1964, pp. III–153 & 154.

Tyers, "Ventricular Stimulation After A–V Block", J. Thoracic and Cardiovas. Sur., 1970, pp. 211–217.

William–Olsson, ". . . Pacemaker Electrode Cite . . . ", J. Thoracic and Cardiovas. Surg., 1963, pp. 618–621.

Zile, et al., "Relaxation and Filling Rates During Asynchrony", J. Am. Coll. Cardiol., 1987, pp. 702–709.

* cited by examiner

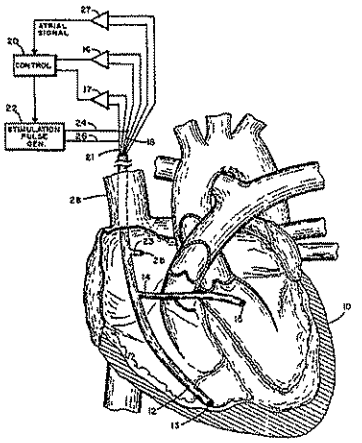
Primary Examiner—Scott M. Getzow

(74) *Attorney, Agent, or Firm*—Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

(57) **ABSTRACT**

A method of treating hemodynamic disfunction by simultaneously pacing both ventricles of a heart. At least one ECG amplifier is arranged to separately detect contraction of each ventricle and a stimulator is then activated for issuing stimulating pulses to both ventricles in a manner to assure simultaneous contraction of both ventricles, thereby to assure hemodynamic efficiency. A first ventricle is stimulated simultaneously with contraction of a second ventricle when the first fails to properly contract. Further, both ventricles are stimulated after lapse of a predetermined A-V escape interval. One of a pair of electrodes, connected in series, is placed through the superior vena cava into the right ventricle and a second is placed in the coronary sinus about the left ventricle. Each electrode performs both pacing and sensing functions. The pacer is particularly suitable for treating bundle branch blocks or slow conduction in a portion of the ventricles.

26 Claims, 2 Drawing Sheets



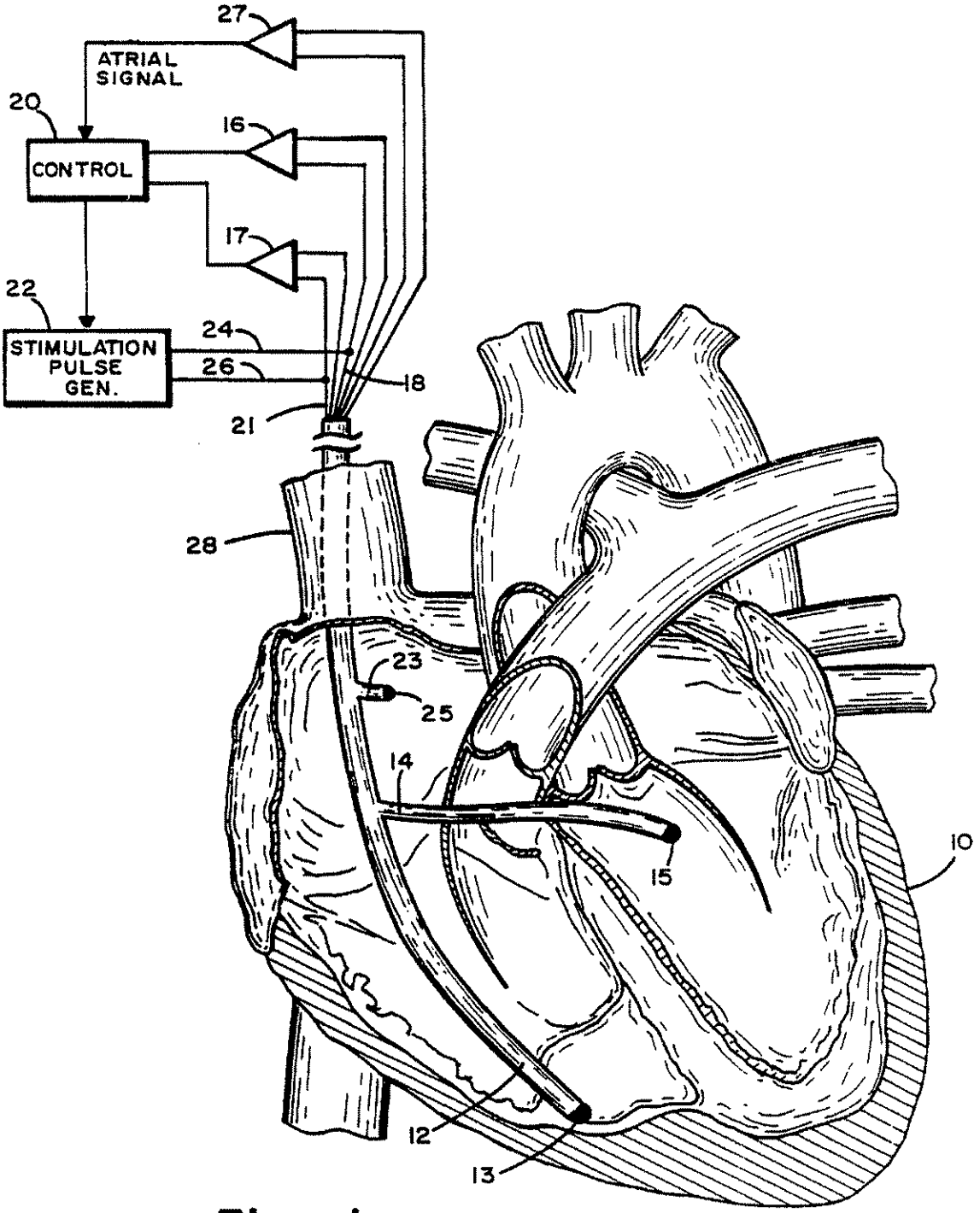

27
ATRIAL SIGNAL
20
16
CONTROL
17
22
24
STIMULATION PULSE GEN.
26
18
21
28
23
25
14
15
10
12
13

Fig. 1

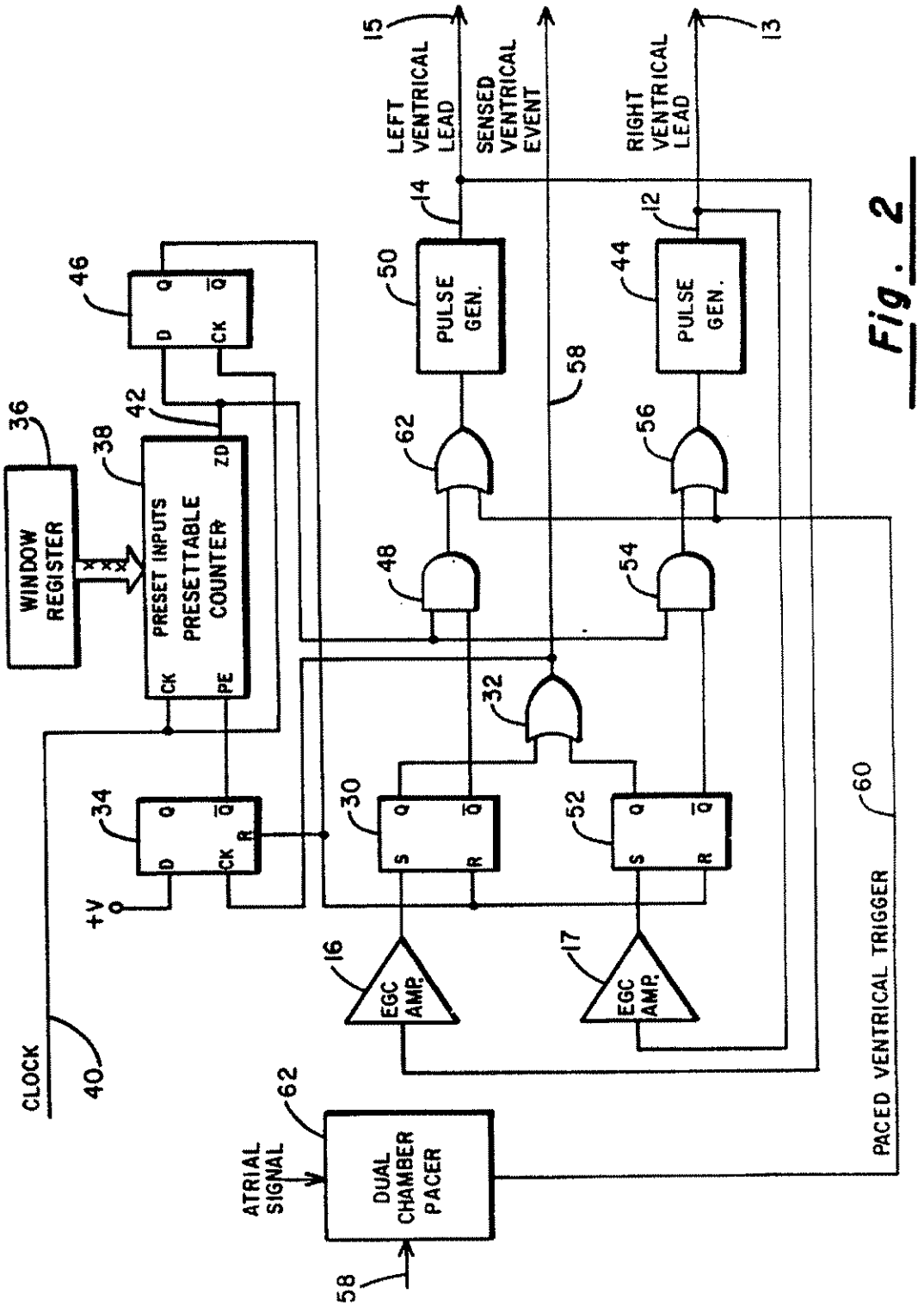

15
LEFT VENTRICAL LEAD
SENSED VENTRICAL EVENT
RIGHT VENTRICAL LEAD
13
14
12
50
PULSE GEN.
44
PULSE GEN.
46
Q
Q
D
CK
58
42
36
38
62
56
WINDOW REGISTER
PRESET INPUTS
PRESETTABLE COUNTER
ZD
CK
PE
48
54
32
34
30
52
Q
Q
D
CK
R
S
R
+V
60
16
17
EGC AMP.
EGC AMP.
CLOCK
40
62
ATRIAL SIGNAL
DUAL CHAMBER PACER
PACED VENTRICAL TRIGGER
58

Fig. 2

METHOD AND APPARATUS FOR TREATING HEMODYNAMIC DISFUNCTION

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.

Application Ser. No. 10/214,474 filed August 8, 2002 is a continuation application of the instant reissue application, Ser. No. 08/547,691, which application is, in turn, a continuation of application Ser. No. 07/890,280, filed May 29, 1992, now abandoned, which is a Reissue of Ser. No. 07/299,895, filed Jan. 23, 1989, now U.S. Pat. No. 4,928,688.

BACKGROUND OF THE INVENTION

I. Field of the Invention

This invention pertains to medical devices, but more specifically, to a method for increasing the cardiac output of a patient suffering from congestive heart failure by stimulating the heart of the patient at multiple sites simultaneously.

II. Discussion of the Prior Art

Normally, impulses from the SA node affect contraction of the atria and then propagate to the AV node. The AV node, in turn, emits a second nerve impulse which affects contraction of the ventricles. These nerve impulses affect contraction, i.e., depolarization of the tissue of the heart, in a coordinated manner to circulate blood through the body. Cardiac pacers of the type herein described generally are useful for maintaining proper functional operation of a sick heart. Of many cardiac deficiencies which have in the past been diagnosed and treated, conduction difficulties have presented significant problems for which a pacer has been used for treatment. A particular conduction deficiency, known as AV branch block, inhibits the transfer of nerve impulses from the sinoatrial (SA) node to atrial-ventricular (AV) node. When a bundle block occurs, these nerve impulses are not properly transmitted from the SA node to the AV node and ventricles.

When this condition occurs, normal treatment is to employ a pacer which locks onto the rhythmic cycle of the atrial beating signal and supplies to the ventricles a stimulating impulse at a certain time thereafter to effect contraction of the ventricles. The time period between the occurrence of the atrial beat and the normal contraction of the ventricles is known as the A-V delay period. Generally, hemodynamic efficiency is somewhat dependent to the A-V delay period, thus the pacer must emit a stimulating pulse at a time to preserve an optimum A-V delay period.

Other forms of conduction deficiency, such as myocardial scarring and bundle branch block, cause slow conduction of nerve impulses, in which case, nerve impulses are indeed passed from the SA to the AV node, but in a time period which is slower than normal. The Q-R-S complex in this case would manifest itself in being very wide and hemodynamic efficiency also becomes lower than normal.

In each of the above-mentioned cardiac deficiencies, the heart does not contract in coordinated fashion. This uncoordinated movement increases depolarization time and reults in more inefficient pumping rather than a more coordinated and simultaneous ventricular depolarization. In essence, such conduction deficiencies result in asynchrony between the left and right ventricle.

Additionally, arrhythmias of the heart produce uncoordinated ventricular contraction that affects the hemodynamic

efficiency of the heart. Specifically, the recent paper "Incomplete Filling and Incoordinate Contraction as Mechanisms of Hypotension During Ventricular Tachycardia in Man", published in Circulation, Vol. 68, No. 5, in 1983, describes that left ventricular function is severely disturbed by the disorganization of wall motion in hearts undergoing ventricular tachycardias. Moreover, it was found that hearts with impaired functions show profound reductions in pumping ability due to incoordinate contraction of the ventricles. It appears reasonable to believe, therefore, that any abnormal functioning heart that requires pacemaking or which has QRS widening will have a better hemodynamic efficiency if both ventricles are paced to contract in coordination with each other. There have been systems developed in the past employing a plurality of electrodes attached to the heart for effecting stimulation of a plurality of regions of the heart. For example, the Funke U.S. Pat. No. 3,937,226 discloses a cardiac electrical stimulation defibrillation system including a plurality of electrode terminals connected in a spaced relation on the heart. The electrodes, which provide stimulating and sensing, are each connected to amplifiers. The amplifiers are connected to electronic control circuit means configured to cause stimulation of all of the electrode terminals simultaneously in response to a sensed depolrization signal on the heart by at least one electrode terminal. In addition, the electronic control circuit is provided with a multivibrator means to synchronize the stimulation signal with the Q-R-S complex. Although Funke does teach the concept of simultaneous stimulation of a plurality of spaced electrodes, he does not disclose its specific use as a method of improving the cardiac output of patients suffering from congestive heart failure, nor does he discuss the specific placement of the electrodes about the heart.

The Rockland et al U.S. Pat. No. 4,088,140 discloses a similar system to Funke's although a specific use as a pacemaker is stated in the patent. Rockland, et al discloses a demand anti-arrythmia pacemaker including a plurality of sensing electrodes connected to the heart to sense ventricular depolarizations. Electronic circuitry is provided having two paths of operation. A first path provides stimulation to one area of the heart if depolarization of a naturally occurring heart beat fails to occur within a first predetermined time period. In this first path, it is stated that the circuitry acts as a pacemaker in the event of skipped natural heartbeats. A second path provides stimulation to a plurality of locations on the heart if a depolarization signal is sensed on the heart with a second predetermined time period. In this second path, it is stated that the circuitry acts as a synchronous multiple electrode pacemaker or a synchronous multiple electrode defibrillator. Although, one example of an electrode placed in the intraventricular section and others in a spaced relation on the heart ventricles is given, there are no teachings of the specific placement of the electrodes on the heart nor the improvement of cardiac output from a sick heart. In addition, the electrodes perform either stimulating or sensing, not both, therefore a large number of electrodes is required in this system.

The Tacker, Jr. et al and McCorkle U.S. Pat. Nos. 4,548,203, 4,458,677 and 4,332,259, respectively, disclose the specific placement of an electrode in or around both left and right ventricles of the heart. The Tacker, Jr. et al patent discloses the placement of a catheter having one electrode in the right ventricle and another outside the heart and a third electrode placed on the left ventricle. The catheter electrodes, each being paired with the left ventricular electrode, are pulsed in sequence with a predetermined time separation resulting in uniform current density delivered to

the heart. However, this pulsing scheme and configuration is disclosed for use in a ventricular defibrillation device and not for cardiac pacing to improve cardiac output wherein a more precise synchronization of stimulation signals with the Q-R-S complex is required.

The McCorkle, Jr. patents disclose the specific placement of an electrode in the right ventricle and another electrode in the coronary sinus surrounding the left ventricle for connection to a pacemaker. However, there is no specific technique disclose of providing stimulating signals to the electrodes to perform a pacemaking function.

In light of the above difficulties and shortcomings of the prior art, an objective of the present invention is to provide a cardiac pacer for increasing hemodynamic efficiency of a heart experiencing a conduction deficiency.

Another objective of the invention is to ensure a more coordinated and simultaneous ventricular depolarization of both left and right ventricles of the heart.

A yet further objective of this invention is to provide a cardiac pacer suitable for being implanted in a manner so as to impose a minimal surgical risk during implantation thereof.

A further objective of this invention is to provide a method and apparatus of separately sensing and stimulating each ventricle of the heart in order for effecting simultaneous contraction automatically of both ventricles of the heart to narrow the QRS complex of a failing heart and thereby cause an increase in blood pressure and cardiac output.

SUMMARY OF THE INVENTION

The method of the present invention involves a procedure for pacing of the heart in a particular way so as to improve its contraction pattern, and thereby augment the movement of blood through the heart. Patients suffering from severe congestive heart failure, which is found not to respond well to conventional drug therapy and to have a conduction defect in the ventricle resulting in a widen Q-R-S complex have been aided by a pacing regimen in which stimulating pulses are simultaneously applied to both ventricles by way of a demand pacemaker or asynchronous pacemaker.

It is theorized that a considerable part of the hemodynamic impairment in refractory congestive heart failure with conduction defects is due to an incoordinate contraction of the heart, so that a part of the heart muscle contracts and balloons out the part that is not contracting. When the latter area of the heart muscle does finally contract, the former has relaxed, so that a large part of the blood volume is merely shunted back and forth within the heart rather than being ejected as would happen with a more coordinate contraction pattern.

To attain the foregoing and other objectives, the present invention comprises, a bi-ventricular cardiac pacer having detecting and stimulating circuits for effecting substatially simultaneous contraction of both left and right ventricles of the heart. In the preferred embodiment, the bi-ventricular pacer comprises ECG amplifier means for separately processing sensed cardiac signals from each of the right and left ventricles. The amplified sensed signals are used to determined where possible abnormal conduction delays exist on the heart and to activate an electrical stimulator for stimulating the appropriate abnormally functioning part of the heart. More specifically, the stimulator responds to the control circuit to issue stimulating pulses simultaneously to either the left or right ventricle, as appropriate. The stimulator may be of the demand type wherein pacing pulses are only issued in the absence of a normal Q-R-S complex for

on or the other of the two ventricles (e.g., occasional bundle branch block or slow conduction), or the nondemand type wherein pacing pulses are always issued (e.g., permanent bundle branch block or slow conduction).

To convey and sense signals to and from the heart, the present invention includes a pacing lead assembly comprising first and second separate electrodes. The first electrode is preferably introduced through the superior vena cava into the right ventricle and the second electrode is introduced through the coronary sinus to the left ventricle. Both lead segments include a sensing and pacing tip electrode which serves to both sense a cardiac depolarization signal or to apply a stimulating pulse from an implanted pulse generator to the ventricle.

Additionally, to preserve a predetermined A-V delay period, additional atrial sensing electrodes may be placed on or around the atrial chambers of the heart and connected to the control circuit. The control circuit responds to the sensed atrial and ventricular depolarization signals to provide simultaneous ventricular contraction signals applied to the left and right ventricles following a preset A-V delay period.

The advantages of the present invention include a more precise and coordinated simultaneous ventricular depolarization of both the right and left ventricular to thereby increase hemodynamic efficiency of a patient experiencing congestive heart failure or weak contractions.

These together with other objects and advantages which will become subsequently apparent reside in the details of construction and operation as more fully hereinafter described and claimed, reference being had to the accompanying drawing forming a part hereof, wherein like numerals refer to like parts throughout.

BRIEF DESCRIPTION OF THE DRAWING FIGURES

FIG. **1** depicts a functional block diagram of an apparatus for carrying out the teaching of this invention; and

FIG. **2** is a logic diagram of the "CONTROL" shown in FIG. **1**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. **1** illustrates the overall pacing system which may be employed for carrying out the teachings of the invention. A pair of leads **12** and **14** with corresponding sensing/stimulating tip electrodes **13** and **15** are electrically connected, via conductors **18** and **21**, to separate ECG sense amplifiers **16** and **17** (or to a single multiplexed amplifier). The amplifiers **16** and **17** are both connected to a control circuit unit **20**. A stimulator circuit **22** is connected to the control unit **20** and has two output conductor lines **24** and **26** which are electrically connected to the conductors **18** and **21**, respectively. From this structure, signals my be separately sensed by the electrodes **13** and **15** and stimulating pacing signals may be separately delivered to the electrodes **13** and **15**, via lead branches **12** and **14**.

In operation, the electrodes **13** and **15** are disposed in or about the right and left ventricles, respectively. A preferred surgical procedure for implanting the lead **12** is to extend it through the superior vena cava **28** so that the sensing stimulating tip **13** thereof lodges in the internal chamber of the right ventricle of the heart **10**. A preferred surgical procedure for implanting lead branch **14** is to extend it through the coronary sinus (not shown) of the heart **10** so

that the sensing/stimulating tip **15** thereof lodges directly in or about the coronary simus and left ventricle. Although it is described that electrodes **13** and **15** perform both sensing and pacing, it is possible for testing and examination, that separate unipolar or bipolar sensing and stimulating electrodes may be used.

When attached to the heart, the electrodes **13** and **15** sense cardiac signals in the form of well-known Q-R-S complex at separate sites with the left and right ventricles. The ECG amplifiers **16** and **17** feed the amplified versions of these signals to the control circuit **20**.

The control circuit **20** analyzes the cardiac signals to determine whether an abnormal conduction exists. Specifically, if a cardiac signal is received from the left ventricle but not from the right ventricle, the control circuit **20** provides a control signal to the stimulator **22** to issue a stimulating pacing pulse over conductors **24** and **18** and lead branch **12** to the right ventricle, via the sensing/stimulating tip electrodes **13**. Similarly, the control circuit **20** provides a control signal to the stimulator **22** to issue a stimulating pacing pulse over lead branch **14** to the left ventricle, via sensing/stimulating tip electrode **15**, if a cardiac depolarization signal is received from the right ventricle, but not from the left ventricle. It is also possible to sense a depolarization signal from only one ventricular chamber and then unconditionally stimulate both ventricular chambers. This is wasteful of powe which is a concern only if the stimulator is totally implanted and must rely on an implanted battery power source.

The timing of the stimulating pacing pulse from the stimulator **22** is such that both ventricles will contract substantially simultaneously. Where both ventricles are unconditionally stimulated upon the occurrence of a QRS complex on only one side, the fact that ventricular site which had produced a Q-R-S complex is immediately stimulated along with the other ventricle does not cause a problem since the site producing that complex is still refractory at the time it is stimulated.

It is also possible that no cardiac signals are sensed from either ventricle, possibly resulting from complete conduction failure between the sinoatrial node and the atrialventricular node. In this case, the control circuit **20** will again activate the stimulator **22** to provide stimulating signals to both ventricles simultaneously.

In an alternative embodiment of this invention, the issuance of pacing pulses to the ventricles is time-coupled to the rhythmic cycle of the atrial beat of the heart to preserve a preset atrial-ventricular delay period of about 120 to 200 milliseconds. Additional atrial sensing is accomplished, via lead **23** and a sense electrode **25** similar to the ventricular leads **12** and **14**, but disposed in or about the right atrial chamber and connected to the control circuit **20**, via atrial sense amplifier **27**. The control circuit **20** may be configured to respond to the sensed atrial and ventricular signals to activate the stimulator for providing appropriate simultaneous stimulating signals to the ventricles as described above in accordance with the predetermined A-V delay period.

In the case where the conduction of the natural stimulating signal originating at the sinoatrial node of the heart **10** is only partially blocked or slowed, the ventricles may partially or incompletely contract, in which case hemodynanmic efficiency is reduced. Under these circumstances, provision is made in the control circuit **20** for determining whether a Q-R-S cardiac signal, although present, is weak or slow, and if so, to activate the stimulator **22** to stimulate the ventricles of the heart by passing pacing pulses simultaneously thereto.

FIG. **2** shows one embodiment of the control circuitry **20** of FIG. **1** required to perform bi-ventricular pacing. Also shown in the circuit of FIG. **2** are means for interconnecting the bi-ventricular control circuitry with conventional demand pacing circuitry to implement various additional pacing modes. It is understood that in the preferred embodiment, the circuitry shown in FIG. **1** would be preferably incorporated directly into the design of a pacer rather than its adjunctive form shown here for purposes of illustration.

To accomplish bi-ventricular pacing, activity is sensed in both the left and the right ventricle. When a ventricular contraction is sensed in either ventricle, a timer is initiated. If within a time window established by said timer, the contraction is sensed in the other ventricle, all pacing is inhibited because the natural contractions are deemed to be simultaneous. On the other hand, if ventricular contractions are not sensed in both ventricles within a period of coincidence defined by the time delay, at the end of this delay, the pacing pulse will be emitted, but only to the ventricle for which a QRS complex has not been sensed. Generally, ventricular contractions which occur with 5–10 milliseconds of each other result in sufficient hemodynamic efficiency so as to not require treatment. Hence, the delay window may be of this order of magnitude. As used herein, the term "substantially simultaneous contraction" includes the occurence of natural contractions of both ventricles with the window period or an evoked contraction of one or both ventricles immediately following the expiration of the window period.

Operation of the circuit of FIG. **2** will now be described. Electrical activity originating in the left ventricle is sensed by electrode **15** on lead **14** coupled to amplifier **16**. It is assumed that amplifier **16** contains all of the thresholding and inhibiting provisions commonly utilized in existing pacing systems to inhibit all electrical activity, save valid ventricular contractions. Similarly, electrical activity in the right ventricle is sensed by electrode **13** on lead **12** and processed by ECG amplifier **17**.

Let if first be assumed that a left ventricle contraction procedes that of the right. In this case, an R-wave signal propagates through amplifier **16** to set the Set-Reset type flip-flop **30**. a logical "1" signal passes through OR gate **32** to clock D-type of flop **34** to the "set" state which, in turn, initiates the aforementioned delay timing. Window register **36** is loaded with a digital count value which is representative of the desired delay window, e.g., 5–10 ms. This may be either a fixed, hard-wired register or, alternatively, a programmable register which may be set by telemetry means in a known manner. When the preset enable input (PE) in high, counter **38** is held at a digital count corresponding to the value held in window register **36**. When flip-flop **34** is set, the PE on counter **38** is removed, allowing the counter to be decremented with each clock pulse provided on clock line **40**. At the end of the preporgrammed window delay interval, counter **38** is decremented to zero, causing the zero detect (ZD) line **42** to go high. The leading edge of the zero detect pulse is used to trigger a ventricle pacing pulse from pulse generator **44**, via gates **54** and **56**, as required. The pulse generator circuitry **44** converts the leading edge trigger to a pulse of the proper amplitube and duration for effective stimulation of the right ventricle. Note that, since under the assumed conditions flip-flop **30** has been set, AND gate **48** is disabled and, therefore, pulse generator **50** is inhibited from generating a left ventricle pacing pulse.

Next to be considered is the case where a right ventricle contraction has not been sensed within the prescribed win-

dow interval. In this case, flip-flop **52** remains reset and AND gate **54** is enabled which allows the zero detect pulse ZD to propagate through OR gate **56** to trigger pulse generator **44**, thus stimulating the right ventricle. If, however, a right ventricle contraction has been detected, flip-flop **52** would have been set prior to the generation of the ZD pulse and, in this case, both AND gates **48** and **54** are disabled and no pacing pulse in either ventricle is generated.

It can be seen from the symmetry of the circuit that the operation is identical if the right ventricle contraction precedes the left ventricle contraction by more than the preprogrammed delay interval. In either case, the setting of either flip-flop **30** or **52** causes **52** causes the initiation of the timing window delay interval. When one of these flip-flop sets, the other must set within the window period, otherwise a pacing pulse will be generated in the unsensed ventricle.

The vi-bentriclar pacing control circuitry may be combined with other well-known pacer control circuitry such that the bi-ventriclar mode can be realized in combination with any other pacing mode, such as VVI, DDD, VOO. Line **58** is the logical OR of either of left ventricle event or a right ventricle event. It may be connected to other pacing control circuitry **62** in place of the signal which is normally responsive to only activity in the left ventricle. A sensed ventricle event thus inhibits the generation of a pacing trigger from another pacing circuitry and leaves the control of pacing in the alternate ventricle, as required; to the circuitry of FIG. **1**. If line **58** is not activated within the escape interval of the other pacing control circuitry, a paced ventricle trigger signal on line **60** is produced which propagates through both OR gate **62** and OR gate **56** to trigger pacing pulses in both ventricles.

It is also contemplated that when a ventricular depolarization signal is sensed in one or the other of the ventricles, that a stimulating pulse may also be immediately delivered, on an unconditional basis, to both ventricles, via the implanted leads **13** and **15**, thus resulting in a coordinated contraction of both ventricles.

The foregoing illustrate preferred arrangements for carrying out the objectives of this invention. Modifications and variations can obviously be made by those skilled in the art without departing from the true spirit and scope of the invention. For instance, the circuit may be employed to simultaneously pace the auricles, instead of ventricles, if such is required to improve pumping efficiency. The arrangement may also be employed as an improvement of conventional pacers thereby to improve their performance. As stated herein, the inventive arrangement can be used in an implanted device or in an external treating, diagnostic or testing device. Accordingly, the invention is limited only by the scope of the appended claims rather than by what is shown and described. Therefore, it is the intent to cover all such modifications and alternate embodiments as may come within the true scope of this invention.

What is claimed is:

1. A method for improving the hemodynamic efficiency of a sick heart comprising the steps of:

(a) detecting respective cardiac signals originating in the left and right ventricles of the heart;

(b) analyzing said cardiac signals and the absence thereof in an electronic control circuit; and

(c) providing electrical pulses from a stimulating circuit controlled by said control circuit to one, the other or both ventricles as required for effecting substantially simultaneous contraction of both ventricles, said step of analyzing including providing a control signal from said control circuit to said stimulating circuit for producing an electrical stimulating pulse to one or both ventricles in response to the absence of a detected cardiac signal from one or both ventricles within a time interval which is a small fraction of the pulse width of a detected cardiac signal.

2. The method of claim **1** wherein said step of detecting respective cardiac signals comprises deposing electrodes in or on the left and right ventricles for separately detecting the respective cardiac signals of the left and right ventricles, and applying said cardiac signals to separate ECG amplifier means connected to each of said electrodes to amplify the cardiac signal for analysis.

3. The method of claim **2** wherein said step of providing electrical pulses includes delivering an electrical pulse from said stimulating circuit to said electrodes in or on both the left and right ventricles.

4. The method of claim **1** wherein said step of analyzing further includes providing a control signal from said control circuit to the stimulating circuit to produce an electrical stimulating pulse to the left ventricle in the absence of a detected cardiac signal from the left ventricle, or to the right ventricle in the absence of a detected cardiac signal from the right ventricle, or to both ventricles in the absence of detected cardiac signals from both ventricles.

5. A method for effecting simultaneous contraction of both left and right ventricles of a heart for improving hemodynamic efficiency comprising the steps of:

separately sensing for the presence of cardiac depolarization signals from both left and right ventricles;

determining whether said cardiac depolarization signals are simultaneously present in both the left and right ventricles; and

stimulating at least one ventricle substantially simultaneously with the contraction of a least one other ventricle in the event that said cardiac depolarization signals are determined not to be simultaneously present in both ventricles.

6. A method of effecting simultaneous contraction of both left and right ventricles of a heart for improving hemodynamic efficiency comprising the steps of:

sensing the cardiac signals of the atria and separately sensing the cardiac depolarization signals of both the left and right ventricles;

determining whether said cardiac depolarization signals are simultaneously present in both the left and right ventricles;

stimulating at least one ventricle simultaneously with the contraction of at least one other ventricle after a predetermined A-V period in the event that said cardiac depolarization signals are determined not to be simultaneously present in both ventricles.

7. A method of increasing the cardiac output of a sick heart comprising the steps of:

(a) implanting a pacing lead having at least two sensing/pacing electrodes in the body such that one of said sensing/pacing electrodes is in or on the right ventricle and the other of said sensing/pacing electrodes is in or on the left ventricle;

(b) sensing depolarization signals picked up by said sensing/pacing electrodes upon their occurrence;

(c) determining whether the depolarization signals sensed in step (b) fail to occur within a predetermined time interval of one another and, if so;

(d) applying an electrical stimulating pulse to the sensing/pacing electrode associated with the ventricle not pro-

ducing a depolarization signal within said time interval at the conclusion of said time interval.

8. The method as in claim **7** wherein said predetermined time interval is in the range of from about 5 ms. to 10 ms.

9. A bi-ventricular pacemaker, comprising:

(a) sense means for sensing ventricular depolarization signals originating in or on the right and left ventricles;

(b) means coupled to said sense means for initiating a time delay of a predetermined length which is short compared to the period of a QRS complex upon detection of a ventricular depolarization signal in one of said right or left ventricles; and

(c) pulse generator means operative upon the termination of said time delay for producing a ventricular simulating pulse and applying same to the other of said right or left ventricles unless a ventricular depolarization signal occurs in said other of said right or left ventricle prior to the expiration of said time delay.

10. The bi-ventricular pacemaker as in claim **9** wherein said sense means comprises a bi-ventricular lead having a first electrode for contacting the left ventricle and sense amplifier means electrically coupled to said first and second electrodes.

11. The bi-ventricular pacemaker as in claim **10** wherein said means coupled to said sense means includes:

(a) first and second set-reset flip-flop connected to be set by an output from said sense amplifier means;

(b) presetable counter means for initially containing a digital value representative of said time delay;

(c) means for incrementing or decrementing said digital value in said presettable couter means at regular intervals until a predetermined count is reached;

(d) means responsive to the value in said counter means reaching said predetermined count for producing a control signal;

(e) logic means coupled to said first and second flip-flops and to said presettable counter means for receiving said control signals; and wherein

(f) said pulse generator means is enabled by said logic means.

12. The bi-ventricular pacemaker as in claim **11** wherein said pulse generator means is coupled to said first and second electrodes.

13. An atrial-coupled, bi-ventricular pacemaker for implantation or external use comprising atrial and ventricular sensing means for detecting cardiac signals, said sensing means including first and second ventricular electrodes connected in series for sensing and stimulating the right and left ventricles, respectively, and an atrial electrode adapted to be disposed in an atrial chamber for detecting cardiac signals of the atria, all of said electrodes being connected to separate ECG amplifier means for amplifying the sensed signals; a control circuit coupled to said ECG amplifier means for analyzing the cardiac signals picked up by said sensing means and providing a control signal; and a stimulating circuit means for producing an electrical stimulating pulse to the left ventricle in the absence of a detected cardiac signal from the left ventricle, and to the right ventricle in the absence of a detected cardiac signal from the right ventricle, and to both ventricles in the absence of detected cardiac signals from both ventricles to effect substantially simultaneous contraction of both ventricles after a predetermined A-V delay period.

14. The pacemaker of claim **13** wherein said first electrode is adapted to be placed in the right ventricle and the second electrode is adapted to be placed in the coronary sinus extending about the left ventricle.

15. A method for improving the hemodynamic efficiency of a heart comprising the steps of:

detecting a cardiac depolarization signal originating from a first ventricle;

immediately and unconditionally stimulating both ventricles for effecting a coordinated contraction of both ventricles when a cardiac depolarization signal originating from the first ventricle is detected.

16. The method of claim 15 wherein the step of immediately and unconditionally stimulating both ventricles further comprises providing electrical pulses from a stimulating circuit to both ventricles.

17. The method of claim 16 wherein said step of detecting a cardiac depolarization signal further comprises positioning electrodes in or about both ventricles for detecting cardiac depolarization signals and for conducting a signal to an electronic control circuit for controlling the stimulating circuit.

18. The method of claim 17 wherein said step of detecting a cardiac depolarization signal further comprises conducting the signal to an amplifier means to amplify the detected signal, and applying the amplified signal to the control circuit.

19. A method for improving the hemodynamic efficiency of a heart comprising the steps of:

sensing a contraction of the atria; and

stimulating both ventricles for effecting a coordinated contraction of both ventricles when a contraction of the atria is sensed and following a predetermined A-V delay period.

20. The method according to claim 19, further comprising, before said sensing step:

placing a first electrode into the right ventricle through the superior vena cava and placing a second electrode into the left ventricle through the coronary sinus;

wherein said stimulation of both ventricles is an electrical discharge through said first and second electrode.

21. The method according to claim 19, further comprising, before said sensing step:

placing a pair of sensing and pacing tip electrodes into each of the right and left ventricles;

wherein said sensing is detected through said pair of sensing tip electrodes.

22. A bi-ventricular pacemaker, comprising:

sense means for sensing ventricular depolarization signals originating from one of left and right ventricles; and

pulse generator means operative upon sensing a depolarization signal from the one of the ventricles for producing a stimulating pulse and immediately and unconditionally applying the stimulating pulse to both ventricles.

23. A bi-ventricular pacemaker according to claim 22, wherein the sense means includes a lead having a first electrode for placement in or about the left ventricle and a second electrode for placement in or about the right ventricle.

24. A bi-ventricular pacemaker according to claim 22, wherein the pulse generator means includes a sense amplifier means electrically coupled to the first and second electrodes for amplifying a sensed depolarization signal, a stimulating circuit for producing the stimulating pulse, and a control circuit operative to control the stimulating circuit in response to the amplified sensed depolarization signal.

25. A bi-ventricular pacemaker comprising:

detecting means for detecting a cardiac signal resulting from a contraction of a first ventricle;

stimulating means for effecting immediate and unconditional contraction of a second ventricle in response to the detected cardiac signal, thereby effecting simultaneous contraction of both ventricles.

26. A bi-ventricular pacemaker according to claim 25 further comprising stimulating means for providing a stimulating pulse to the first ventricle simultaneous with the effecting of the immediate and unconditional contraction of the second ventricle.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : RE 38,119 E
DATED : May 20, 2003
INVENTOR(S) : Morton M. Mower

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 8,
Line 35, "of a least" should read -- of at least --.

Column 9,
Lines 19-20, "a first electrode for contacting the left ventricle" should read -- a first electrode for contacting the right ventricle and a second electrode for contacting the left ventricle --.
Line 31, "couter" should read -- counter --.

Signed and Sealed this

Twenty-third Day of March, 2004

JON W. DUDAS
Acting Director of the United States Patent and Trademark Office

EXHIBIT B

US00RE39897E

(19) **United States**
(12) **Reissued Patent**
Mower

(10) **Patent Number: US RE39,897 E**
(45) **Date of Reissued Patent: *Oct. 23, 2007**

(54) **METHOD AND APPARATUS FOR TREATING HEMODYNAMIC DISFUNCTION**

(75) Inventor: **Morton M. Mower**, Baltimore, MD (US)

(73) Assignee: **Mirowski Family Ventures, L.L.C.**, Washington, DC (US)

(*) Notice: This patent is subject to a terminal disclaimer.

(21) Appl. No.: **10/214,474**

(22) Filed: **Aug. 8, 2002**

Related U.S. Patent Documents

Reissue of:

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Appl. No.: **07/299,895**
Filed: **Jan. 23, 1989**

U.S. Applications:

(63) Continuation of application No. 08/547,691, filed on Oct. 19, 1995, now Pat. No. Re. 38,119, which is a continuation of application No. 07/890,280, filed on May 29, 1992, now abandoned.

(51) **Int. Cl.**
A61N 1/362 (2006.01)

(52) **U.S. Cl.** **607/9**

(58) **Field of Classification Search** 607/4.28

See application file for complete search history.

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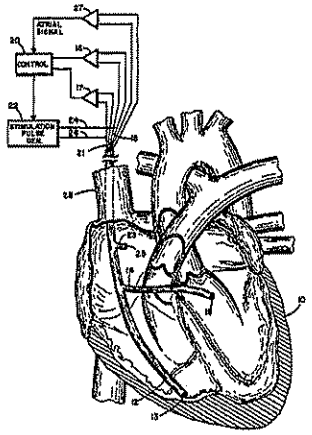
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(57) **ABSTRACT**

A method of treating hemodynamic disfunction by simultaneously pacing both ventricles of a heart. At least one ECG amplifier is arranged to separately detect contraction of each ventricle and a stimulator is then activated for issuing stimulating pulses to both ventricles in a manner to assure simultaneous contraction of both ventricles, thereby to assure hemodynamic efficiency. A first ventricle is stimulated simultaneously with contraction of a second ventricle when the first fails to properly contract. Further, both ventricles are stimulated after lapse of a predetermined A-V escape interval. One of a pair of electrodes, connected in series, in placed through the superior vena cava into the right ventricle and a second is placed in the coronary sinus about the left ventricle. Each electrode performs both pacing and sensing functions. The pacer is particularly suitable for treating bundle branch blocks or slow conduction in a portion of the ventricles.

317 Claims, 2 Drawing Sheets



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Presentation bearing bates Nos. MM0278–342 (Exhibit 125 of the Deposition of Dr. Morton M. Mower, M.D., taken Oct. 17–18, 2005).

Presentation bearing bates Nos. MM0013–79 (Exhibit 126 of the Deposition of Dr. Morton M. Mower, M.D., taken Oct. 17–18, 2005).

Presentation entitled "A History of ICD & Related Therapies" and bearing bates Nos. MM0087–139 (Exhibit 127 of the Deposition of Dr. Morton M. Mower, M.D., taken Oct. 17–18, 2005).

Presentation entitled "Cardiac Resynchronization Therapy (CRT) Reduces Hospitalizations, and CRT with Implantable Defibrillator (CRT–D) Reduces Mortality in Chronic Heart Failure: The Companion Trial" and bearing bates Nos. MM0257–77 (Exhibit 128 of the Deposition of Dr. Morton M. Mower, M.D., taken Oct. 17–18, 2005).

Presentation bearing bates Nos. MM0343–401 (Exhibit 129 of the Deposition of Dr. Morton M. Mower, M.D., taken Oct. 17–18, 2005).

Presentation entitled "Evolution of Cardiac Rhythm Management Systems: A History of Automatic Implantable Cardioverter–Defibrillator (AICD)" and bearing bates Nos. MM0402–454 (Exhibit 130 of the Deposition of Dr. Morton M. Mower, M.D., taken Oct. 17–18, 2005).

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Document showing Biventricular Pacer of American Optical Co. (Exhibit 143 of the Deposition of Dr. Morton M. Mower, M.D., taken Oct. 17–18, 2005).

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Expert Report of Eduardo De Teresa Galván (Expert for St. Jude, et al.) from *Guidant Corp.* v. *St. Jude Medical, Inc.*, No. 04–0067–SLR (D. Del.) With Accompanying Exhibits A–B).

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Supplemental Expert Report of Janice M. Jenkins, PhD, (Expert for Medtronic, Inc.) from *Medtronic, Inc.* v. *Guidant Corp.*, No. 03–848–SLR (D. Del.) (With Accompanying Exhibits 38–46).

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Trial Transcript, vol. C (Nov. 3, 2004) from *Medtronic, Inc.* v. *Guidant Corp.*, No. 03–848–SLR (D. Del.).

Updated Case Docket for *Guidant Corp.* v. *St. Jude Medical, Inc.*, No. 04–0067–SLR (D. Del.).

Defendants' (St. Jude et al.) Motion for Summary Judgment of Invalidity Based on Reissue Recapture from *Guidant Corp.* v. *St. Jude Medical, Inc.*, No. 04–0067–SLR (D. Del.).

Plaintiffs' (Guidant et al.) Opposition to Defendants' (St. Jude et al.) Motion for Summary, Judgment of Invalidity Based on Reissue Recapture from *Guidant Corp.* v. *St. Jude Medical, Inc.*, No. 04–0067–SLR (D. Del.).

Defendants' (St. Jude et al.) Reply in Support of Their Motion for Summary Judgment of Invalidity Based on Reissue Recapture from *Guidant Corp.* v. *St. Jude Medical, Inc.*, No. 04–0067–SLR (D. Del.).

Second Amended Complaint from *Guidant Corp.* v. *St. Jude Medical, Inc.*, No. 04–0067–SLR (D. Del.).

Answer to Second Amended Complaint and Counterclaims from *Guidant Corp.* v. *St. Jude Medical, Inc.*, No. 04–0067–SLR (D. Del.).

Plaintiffs' (Guidant et al.) Responses to Defendants' (St. Jude et al.) First and Second Sets of Interrogatories (1–17) from *Guidant Corp* v. *St. Jude Medical, Inc.*, No. 04–0067–SLR (D. Del.).

Plaintiffs' (Guidant et al.) Responses to Defendants' (St. Jude et al.) Third Set of Interrogatories (18–35) from *Guidant Corp* v. *St. Jude Medical, Inc.*, No. 04–0067–SLR (D. Del.).

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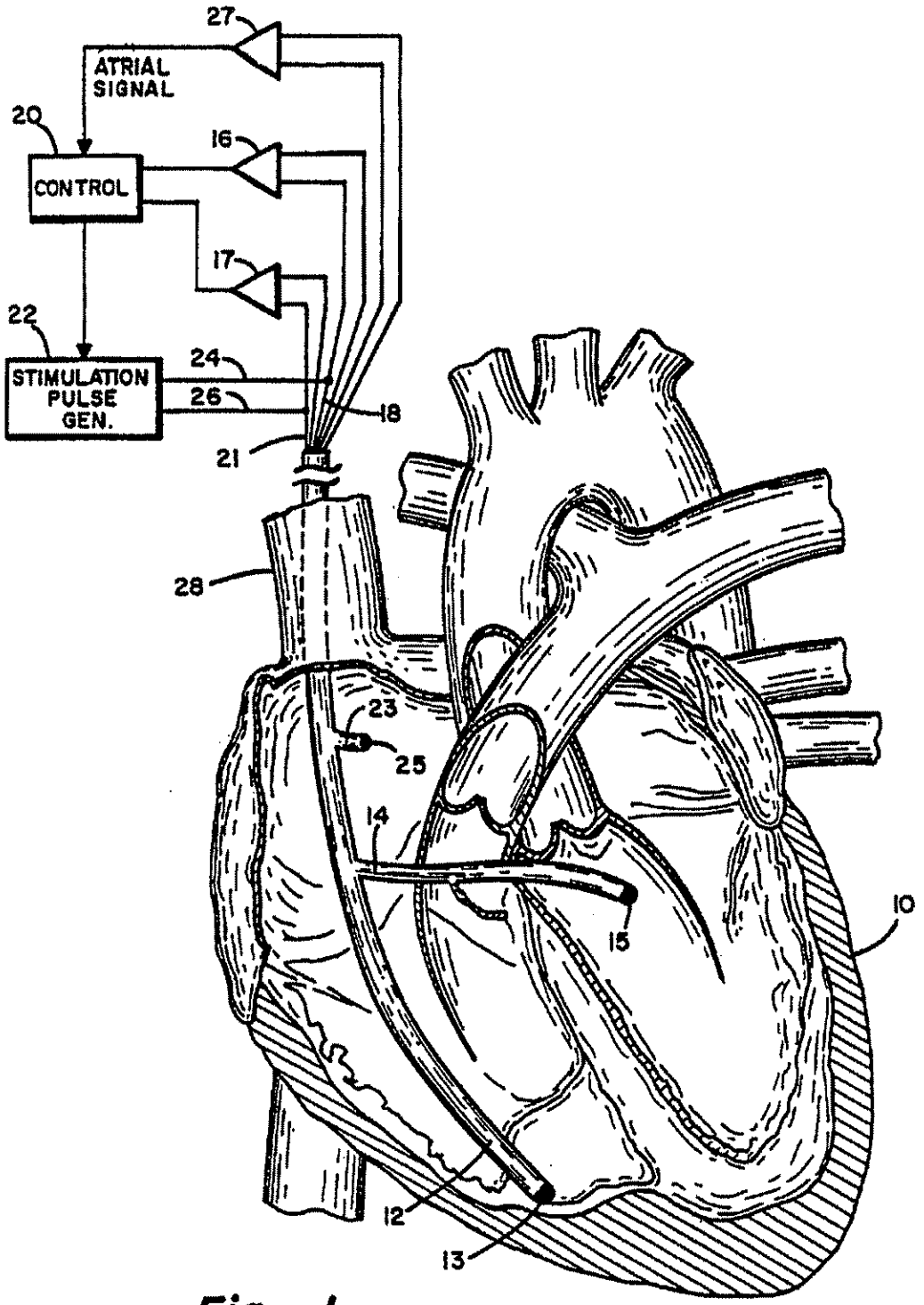

27
ATRIAL SIGNAL
20
16
CONTROL
17
22
24
STIMULATION PULSE GEN.
26
18
21
28
23
25
14
15
10
12
13

Fig. 1

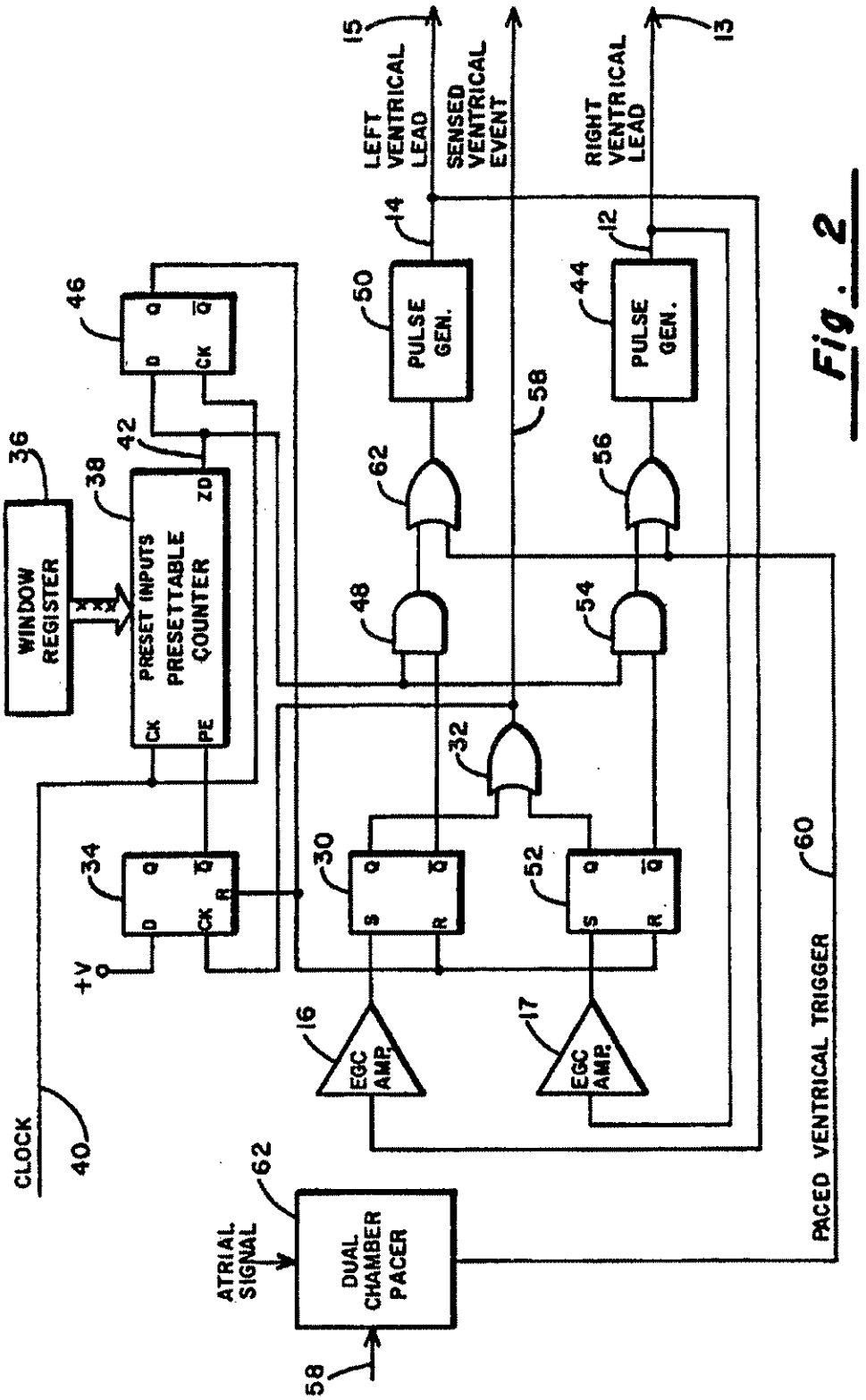

15
LEFT VENTRICAL LEAD
SENSED VENTRICAL EVENT
13
RIGHT VENTRICAL LEAD
14
12
50
PULSE GEN.
44
PULSE GEN.
46
58
42
62
56
36
38
WINDOW REGISTER
PRESET INPUTS
PRESETTABLE COUNTER
ZD
CK
PE
48
54
32
34
30
52
60
+V
16
EGC AMP.
17
EGC AMP.
CLOCK
40
62
ATRIAL SIGNAL
DUAL CHAMBER PACER
PACED VENTRICAL TRIGGER
58

Fig. 2

METHOD AND APPARATUS FOR TREATING HEMODYNAMIC DISFUNCTION

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.

CROSS REFERENCE TO RELATED APPLICATIONS

This is a continuation of Reissue application No. 08/547,691, filed Oct. 19, 1995 now U.S. Pat. No. RE 38,119 E, which is a continuation of Reissue application No. 07/890,280, filed May 29, 1992 now abandoned, which is a reissue of U.S. Pat. No. 4,928,688, all of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

I. Field of the Invention

This invention pertains to medical devices, but more specifically, to a method for increasing the cardiac output of a patient suffering from congestive heart failure by stimulating the heart of the patient at multiple sites simultaneously.

II. Discussion of the Prior Art

Normally, impulses from the SA node affect contraction of the atria and then propagate to the AV node. The AV node, in turn, emits a second nerve impulse which affects contraction of the ventricles. These nerve impulses affect contraction, i.e., depolarization of the tissue of the heart, in a coordinated manner to circulate blood through the body. Cardiac pacers of the type herein described generally are useful for maintaining proper functional operation of a sick heart. Of many cardiac deficiencies which have in the past been diagnosed and treated, conduction difficulties have presented significant problems for which a pacer has been used for treatment. A particular conduction deficiency, known as AV branch block, inhibits the transfer of nerve impulses from the sinoatrial (SA) node to atrial-ventricular (AV) node. When a bundle block occurs, these nerve impulses are not properly transmitted from the SA node to the AV node and ventricles.

When this condition occurs, normal treatment is to employ a pacer which locks onto the rhythmic cycle of a atrial beating signal and supplies to the ventricles a stimulating impulse at a certain time thereafter to effect contraction of the ventricles. The time period between the occurrence of the atrial beat and the normal contraction of the ventricles is known as the A-V delay period. Generally, hemodynamic efficiency is somewhat dependent to the A-V delay period, thus the pacer must emit a stimulating pulse at a time to preserve an optimum A-V delay period.

Other forms of conduction deficiency, such as myocardial scarring and bundle branch block, cause slow conduction of nerve impulses, in which case, nerve impulses are indeed passed from the SA to the AV node, but in a time period which is slower than normal. The Q-R-S complex in this case would manifest itself in being very wide and hemodynamic efficiency also becomes lower than normal.

In each of the above-mentioned cardiac deficiencies, the heart does not contract in coordinated fashion. This uncoordinated movement increases depolarization time and results in more inefficient pumping rather than a more coordinated and simultaneous ventricular depolarization. In essence, such conduction deficiencies result in asynchrony between the left and right ventricle.

Additionally, arrhythmias of the heart produce uncoordinated ventricular contraction that affects the hemodynamic efficiency of the heart. Specifically, the recent paper "Incomplete Filling and Incoordinate Contraction as Mechanisms of Hypotension During Ventricular Tachycardia in Man", published in Circulation, Vol. 68, No. 5, in 1983, describes that left ventricular function is severely disturbed by the disorganization of wall motion in hearts undergoing ventricular tachycardias. Moreover, it was found that hearts with impaired functions show profound reductions in pumping ability due to incoordinate contraction of the ventricles. It appears reasonable to believe, therefore, that any abnormal functioning heart that requires pacemaking or which has QRS widening will have a better hemodynamic efficiency if both ventricles are paced to contract in coordination with each other. There have been systems developed in the past employing a plurality of electrodes attached to the heart for effecting stimulation of a plurality of regions of the heart. For example, the Funke U.S. Pat. No. 3,937,226 discloses a cardiac electrical stimulation defibrillation system including a plurality of electrode terminals connected in a spaced relation on the heart. The electrodes, which provide stimulating and sensing, are each connected to amplifiers. The amplifiers are connected to electronic control circuit means configured to cause stimulation of all of the electrode terminals simultaneously in response to a sensed depolrization signal on the heart by at least one electrode terminal. In addition, the electronic control circuit is provided with a multivibrator means to synchronize the stimulation signal with the Q-R-S complex. Although Funke does teach the concept of simultaneous stimulation of a plurality of spaced electrodes, he does not disclose its specific use as a method of improving the cardiac output of patients suffering from congestive heart failure, nor does he discuss the specfic placement of the electrodes about the heart.

The Rockland et al U.S. Pat. No. 4,088,140 discloses a similar system to Funke's although a specific use as a pacemaker is stated in the patent. Rockland, et al discloses a demand anti-arrythmia pacemaker including a plurality of sensing electrodes connected to the heart to sense ventricular depolarizations. Electronic circuitry is provided having two paths of operation. A first path provides stimulation to one area of the heart if depolarization of a naturally occurring heart beat fails to occur within a first predetermined time period. In this first path, it is stated that the circuitry acts as a pacemaker in the event of skipped natural heartbeats. A second path provides stimulation to a plurality of locations on the heart if a depolarization signal is sensed on the heart within a second predetermined time period. In this second path, it is stated that the circuitry acts as a synchronous multiple electrode pacemaker or a synchronous multiple electrode defibrillator. Although, one example of an electrode placed in the intraventricular section and others in a spaced relation on the heart ventricles is given, there are no teachings of the specific placement of the electrodes on the heart nor the improvement of cardiac output from a sick heart. In addition, the electrodes perform either stimulating or sensing, not both, therefore a large number of electrodes is required in this system.

The Tacker, Jr. et al and McCorkle U.S. Pat. Nos. 4,548,203, 4,458,677 and 4,332,259, respectively, disclose the specific placement of an electrode in or around both left and right ventricles of the heart. The Tacker, Jr. et al patent discloses the placement of a catheter having one electrode in the right ventricle and another outside the heart and a third electrode placed on the left ventricle. The catheter electrodes, each being paired with the left ventricular

electrode, are pulsed in sequence with a predetermined time separation resulting in uniform current density delivered to the heart. However, this pulsing scheme and configuration is disclosed for use in a ventricular defibrillation device and not for cardiac pacing to improve cardiac output wherein a more precise synchronization of stimulation signals with the Q-R-S complex is required.

The McCorkle, Jr. patents disclose the specific placement of an electrode in the right ventricle and another electrode in the coronary sinus surrounding the left ventricle for connection to a pacemaker. However, there is no specific technique disclose of providing stimulating signals to the electrodes to perform a pacemaking function.

In light of the above difficulties and shortcomings of the prior art, an objective of the present invention is to provide a cardiac pacer for increasing hemodynamic efficiency of a heart experiencing a conduction deficiency.

Another objective of the invention is to ensure a more coordinated and simultaneous ventricular depolarization of both left and right ventricles of the heart.

A yet further objective of this invention is to provide a cardiac pacer suitable for being implanted in a manner so as to impose a minimal surgical risk during implantation thereof.

A further objective of this invention is to provide a method and apparatus of separately sensing and stimulating each ventricle of the heart in order for effecting simultaneous contraction automatically of both ventricles of the heart to narrow the QRS complex of a failing heart and thereby cause an increase in blood pressure and cardiac output.

SUMMARY OF THE INVENTION

The method of the present invention involves a procedure for pacing of the heart in a particular way so as to improve its contraction pattern, and thereby augment the movement of blood through the heart. Patients suffering from severe congestive heart failure, which is found not to respond well to conventional drug therapy and to have a conduction defect in the ventricle resulting in a widen Q-R-S complex have been aided by a pacing regimen in which stimulating pulses are simultaneously applied to both ventricles by way of a demand pacemaker or asynchronous pacemaker.

It is theorized that a considerable part of the hemodynamic impairment in refractory congestive heart failure with conduction defects is due to an incoordinate contraction of the heart, so that a part of the heart muscle contracts and balloons out the part that is not contracting. When the latter area of the heart muscle does finally contract, the former has relaxed, so that a large part of the blood volume is merely shunted back and forth within the heart rather than being ejected as would happen with a more coordinate contraction pattern.

To attain the foregoing and other objectives, the present invention comprises, a bi-ventricular cardiac pacer having detecting and stimulating circuits for effecting substatially simultaneous contraction of both left and right ventricles of the heart. In the preferred embodiment, the bi-ventricular pacer comprises ECG amplifier means for separately processing sensed cardiac signals from each of the right and left ventricles. The amplified sensed signals are used to determined where possible abnormal conduction delays exist on the heart and to activate an electrical stimulator for stimulating the appropriate abnormally functioning part of the heart. More specifically, the stimulator responds to the control circuit to issue stimulating pulses simultaneously to either the left or right ventricle, as appropriate. The stimulator may be of the demand type wherein pacing pulses are only issued in the absence of a normal Q-R-S complex for one or the other of the two ventricles (e.g., occasional bundle branch block or slow conduction), or the nondemand type wherein pacing pulses are always issued (e.g., permanent bundle branch block or slow conduction).

To convey and sense signals to and from the heart, the present invention includes a pacing lead assembly comprising first and second separate electrodes. The first electrode is preferably introduced through the superior vena cava into the right ventricle and the second electrode is introduced through the coronary sinus to the left ventricle. Both lead segments include a sensing and pacing tip electrode which serves to both sense a cardiac depolarization signal or to apply a stimulating pulse from an implanted pulse generator to the ventricle.

Additionally, to preserve a predetermined A-V delay period, additional atrial sensing electrodes may be placed on or around the atrial chambers of the heart and connected to the control circuit. The control circuit responds to the sensed atrial and ventricular depolarization signals to provide simultaneous ventricular contraction signals applied to the left and right ventricles following a preset A-V delay period.

The advantages of the present invention include a more precise and coordinated simultaneous ventricular depolarization of both the right and left ventricular to thereby increase hemodynamic efficiency of a patient experiencing congestive heart failure or weak contractions.

These together with other objects and advantages which will become subsequently apparent reside in the details of construction and operation as more fully hereinafter described and claimed, reference being had to the accompanying drawings forming a part hereof, wherein like numerals refer to like parts throughout.

BRIEF DESCRIPTION OF THE DRAWING FIGURES

FIG. **1** depicts a functional block diagram of an apparatus for carrying out the teachings of this invention; and

FIG. **2** is a logic diagram of the "CONTROL" shown in FIG. **1**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. **1** illustrates the overall pacing system which may be employed for carrying out the teachings of the invention. A pair of leads **12** and **14** with corresponding sensing/stimulating tip electrodes **13** and **15** are electrically connected, via conductors **18** and **21**, to separate ECG sense amplifiers **16** and **17** (or to a single multiplexed amplifier). The amplifiers **16** and **17** are both connected to a control circuit unit **20**. A stimulator circuit **22** is connected to the control unit **20** and has two output conductor lines **24** and **26** which are electrically connected to the conductors **18** and **21**, respectively. From this structure, signals may be separately sensed by the electrodes **13** and **15** and stimulating pacing signals may be separately delivered to the electrodes **13** and **15**, via lead branches **12** and **14**.

In operation, the electrodes **13** and **15** are disposed in or about the right and left ventricles, respectively. A preferred surgical procedure for-implanting the lead **12** is to extend it through the superior vena cava **28** so that the sensing stimulating tip **13** thereof lodges in the internal chamber of the right ventricle of the heart **10**. A preferred surgical-procedure for implanting lead branch **14** is to extend it

through the coronary sinus (not shown) of the heart **10** so that the sensing/stimulating tip **15** thereof lodges directly in or about the coronary sinus and left ventricle. Although it is described that electrodes **13** and **15** perform both sensing and pacing, it is possible for testing and examination, that separate unipolar or bipolar sensing and stimulating electrodes may be used.

When attached to the heart, the electrodes **13** and **15** sense cardiac signals in the form of well-known Q-R-S complex at separate sites within the left and right ventricles. The ECG amplifiers **16** and **17** feed the amplified versions of these signals to the control circuit **20**.

The control circuit **20** analyzes the cardiac signals to determine whether an abnormal conduction exists. Specifically, if a cardiac signal is received from the left ventricle but not from the right ventricle, the control circuit **20** provides a control signal to the stimulator **22** to issue a stimulating pacing pulse over conductors **24** and **18** and lead branch **12** to the right ventricle, via the sensing/stimulating tip electrodes **13**. Similarly, the control circuit **20** provides a control signal to the stimulator **22** to issue a stimulating pacing pulse over lead branch **14** to the left ventricle, via sensing/stimulating tip electrode **15**, if a cardiac depolarization signal is received from the right ventricle, but not from the left ventricle. It is also possible to sense a depolarization signal from only one ventricular chamber and then unconditionally stimulate both ventricular chambers. This is wasteful of power which is a concern only if the stimulator is totally implanted and must rely on an implanted battery power source.

The timing of the stimulating pacing pulse from the stimulator **22** is such that both ventricles will contract substantially simultaneously. Where both ventricles are unconditionally stimulated upon the occurrence of a QRS complex on only one side, the fact that ventricular site which had produced a Q-R-S complex is immediately stimulated along with the other ventricle does not cause a problem since the site producing that complex is still refractory at the time it is stimulated.

It is also possible that no cardiac signals are sensed from either ventricle, possibly resulting from complete conduction failure between the sinoatrial node and the atrialventricular node. In this case, the control circuit **20** will again activate the stimulator **22** to provide stimulating signals to both ventricles simultaneously.

In an alternative embodiment of the invention, the issuance of pacing pulses to the ventricles is time-coupled to the rhythmic cycle of the atrial beat of the heart to preserve a preset atrial-ventricular delay period of about 120 to 200 milliseconds. Additional atrial sensing is accomplished, via lead **23** and a sense electrode **25** similar to the ventricular leads **12** and **14**, but disposed in or about the right atrial chamber and connected to the control circuit **20**, via atrial sense amplifier **27**. The control circuit **20** may be configured to respond to the sensed atrial and ventricular signals to activate the stimulator for providing appropriate simultaneous stimulating signals to the ventricles as described above in accordance with the predetermined A-V delay period.

In the case where the conduction of the natural stimulating signal originating at the sinoatrial node of the heart **10** is only partially blocked or slowed, the ventricles may partially or incompletely contract, in which case hemodynamic efficiency is reduced. Under these circumstances, provision is made in the control circuit **20** for determining whether a Q-R-S cardiac signal, although present, is weak or slow, and if so, to activate the stimulator **22** to stimulate the ventricles of the heart by passing pacing pulses simultaneously thereto.

FIG. **2** shows one embodiment of the control circuitry **20** of FIG. **1** required to perform bi-ventricular pacing. Also shown in the circuit of FIG. **2** are means for interconnecting the bi-ventricular control circuitry with conventional demand pacing circuitry to implement various additional pacing modes. It is understood that in the preferred embodiment, the circuitry shown in FIG. **1** would be preferably incorporated directly into the design of a pacer rather than its adjunctive form shown here for purposes of illustration.

To accomplish bi-ventricular pacing, activity is sensed in both the left and the right ventricle. When a ventricular contraction is sensed in either ventricle, a timer is initiated. If within a time window established by said timer, the contraction is sensed in the other ventricle, all pacing is inhibited because the natural contractions are deemed to be simultaneous. On the other hand, if ventricular contractions are not sensed in both ventricles within a period of coincidence defined by the time delay, at the end of this delay, the pacing pulse will be emitted, but only to the ventricle for which a QRS complex has not been sensed. Generally, ventricular contractions which occur within 5–10 milliseconds of each other result in sufficient hemodynamic efficiency so as to not require treatment. Hence, the delay window may be of this order of magnitude. As used herein, the term "substantially simultaneous contraction" includes the occurrence of natural contractions of both ventricles within the window period or an evoked contraction of one or both ventricles immediately following the expiration of the window period.

Operation of the circuit of FIG. **2** will now be described. Electrical activity originating in the left ventricle is sensed by electrode **15** on lead **14** coupled to amplifier **16**. It is assumed that amplifier **16** contains all of the thresholding and inhibiting provisions commonly utilized in existing pacing systems to inhibit all electrical activity, save valid ventricular contractions. Similarly, electrical activity in the right ventricle is sensed by electrode **13** on lead **12** and processed by ECG amplifier **17**.

Let if first be assumed that a left ventricle contraction procedes that of the right. In this case, an R-wave signal propagates through amplifier **16** to set the Set-Reset type flip-flop **30**. a logical "1" signal passes through OR gate **32** to clock D-type of flop **34** to the "set" state which, in turn, initiates the aforementioned delay timing. Window register **36** is loaded with a digital count value which is representative of the desired delay window, e.g., 5–10 ms. This may be either a fixed, hard-wired register or, alternatively, a programmable register which may be set by telemetry means in a known manner. When the preset enable input (PE) in high, counter **38** is held at a digital count corresponding to the value held in window register **36**. When flip-flop **34** is set, the PE on counter **38** is removed, allowing the counter to be decremented with each clock pulse provided on clock line **40**. At the end of the preprogrammed window delay interval, counter **38** is decremented to zero, causing the zero detect (ZD) line **42** to go high. The leading edge of the zero detect pulse is used to trigger a ventricle pacing pulse from pulse generator **44**, via gates **54** and **56**, as required. The pulse generator circuitry **44** converts this leading edge trigger to a pulse of the proper amplitube and duration for effective stimulation of the right ventricle. Note that, since under the assumed conditions flip-flop **30** has been set, AND gate **48** is disabled and, therefore, pulse generator **50** is inhibited from generating a left ventricle pacing pulse.

Next to be considered is the case where a right ventricle contraction has not been sensed within the prescribed window interval. In this case, flip-flop **52** remains reset and AND gate **54** is enabled which allows the zero detect pulse ZD to propagate through OR gate **56** to trigger pulse generator **44**, thus stimulating the right ventricle. If, however, a right ventricle contraction has been detected, flip-flop **52** would have been set prior to the generation of the ZD pulse and, in this case, both AND gates **48** and **54** are disabled and no pacing pulse in either ventricle is generated.

It can be seen from the symmetry of the circuit that the operation is identical if the right ventricle contraction precedes the left ventricle contraction by more than the preprogrammed delay interval. In either case, the setting of either flip-flop **30** or **52** causes **52** causes the initiation of the timing window delay interval. When one of these flip-flop sets, the other must set within the window period, otherwise a pacing pulse will be generated in the unsensed ventricle.

The bi-ventriclar pacing control circuitry may be combined with other well-known pacer control circuitry such that the bi-ventriclar mode can be realized in combination with any other pacing mode, such as VVI, DDD, VOO. Line **58** is the logical OR of either of left ventricle event or a right ventricle event. It may be connected to other pacing control circuitry **62** in place of the signal which is normally responsive to only activity in the left ventricle. A sensed ventricle event thus inhibits the generation of a pacing trigger from another pacing circuitry and leaves the control of pacing in the alternate ventricle, as required, to the circuitry of FIG. **1**. If line **58** is not activated within the escape interval of the other pacing control circuitry, a paced ventricle trigger signal on line **60** is produced which propagates through both OR gate **62** and OR gate **56** to trigger pacing pulses in both ventricles.

It is also contemplated that when a ventricular depolarization signal is sensed in one or the other of the ventricles, that a stimulating pulse may also be immediately delivered, on an unconditional basis, to both ventricles, via the implanted leads **13** and **15**, thus resulting in a coordinated contraction of both ventricles.

The foregoing illustrate preferred arrangements for carrying out the objectives of this invention. Modifications and variations can obviously be made by those skilled in the art without departing from the true spirit and scope of the invention. For instance, the circuit may be employed to simultaneously pace the auricles, instead of ventricles, if such is required to improve pumping efficiency. The arrangement may also be employed as an improvement of conventional pacers thereby to improve their performance. As stated herein, the inventive arrangement can be used in an implanted device or in an external treating, diagnostic or testing device. Accordingly, the invention is limited only by the scope of the appended claims rather than by what is shown and described. Therefore, it is the intent to cover all such modifications and alternate embodiments as may come within the true scope of this invention.

What is claimed is:

[1. A method for improving the hemodynamic efficiency of a sick heart comprising the steps of:

(a) detecting respective cardiac signals originating in the left and right ventricles of the heart;

(b) analyzing said cardiac signals and the absence thereof in an electronic control circuit; and

(c) providing electrical pulses from a stimulating circuit controlled by said control circuit to one, the other or both ventricles as required for effecting substantially simultaneous contraction of both ventricles, said step of analyzing including providing a control signal from said control circuit to said stimulating circuit for producing an electrical stimulating pulse to one or both ventricles in response to the absence of a detected cardiac signal from one or both ventricles within a time interval which is a small fraction of the pulse width of a detected cardiac signal.]

[2. The method of claim **1** wherein said step of detecting respective cardiac signals comprises deposing electrodes in or on the left and right ventricles for separately detecting the respective cardiac signals of the left and right ventricles, and applying said cardiac signals to separate ECG amplifier means connected to each of said electrodes to amplify the cardiac signal for analysis.]

[3. The method of claim **2** wherein said step of providing electrical pulses includes delivering an electrical pulse from said stimulating circuit to said electrodes in or on both the left and right ventricles.]

[4. The method of claim **1** wherein said step of analyzing further includes providing a control signal from said control circuit to the stimulating circuit to produce an electrical stimulating pulse to the left ventricle in the absence of a detected cardiac signal from the left ventricle, or to the right ventricle in the absence of a detected cardiac signal from the right ventricle, or to both ventricles in the absence of detected cardiac signals from both ventricles.]

[5. A method for effecting simultaneous contraction of both left and right ventricles of a heart for improving hemodynamic efficiency comprising the steps of:

separately sensing for the presence of cardiac depolarization signals from both left and right ventricles;

determining whether said cardiac depolarization signals are simultaneously present in both the left and right ventricles; and

stimulating at least one ventricle substantially simultaneously with the contraction of at least one other ventricle in the event that said cardiac depolarization signals are determined not to be simultaneously present in both ventricles.]

[6. A method of effecting simultaneous contraction of both left and right ventricles of a heart for improving hemodynamic efficiency comprising the steps of:

sensing the cardiac signals of the atria and separately sensing the cardiac depolarization signals of both the left and right ventricles;

determining whether said cardiac depolarization signals are simultaneously present in both the left and right ventricles;

stimulating at least one ventricle simultaneously with the contraction of at least one other ventricle after a predetermined A-V period in the event that said cardiac depolarization signals are determined not to be simultaneously present in both ventricles.]

[7. A method of increasing the cardiac output of a sick heart comprising the steps of:

(a) implanting a pacing lead having at least two sensing/pacing electrodes in the body such that one of said sensing/pacing electrodes is in or on the right ventricle and the other of said sensing/ pacing electrodes is in or on the left ventricle;

(b) sensing depolarization signals picked up by said sensing/pacing electrodes upon their occurrence;

(c) determining whether the depolarization signals sensed in step (b) fail to occur within a predetermined time interval of one another and, if so;

(d) applying an electrical stimulating pulse to the sensing/pacing electrode associated with the ventricle not producing a depolarization signal within said time interval at the conclusion of said time interval.]

[8. The method as in claim 7 wherein said predetermined time interval is in the range of from about 5 ms. to 10 ms.]

[9. A bi-ventricular pacemaker, comprising:

(a) sense means for sensing ventricular depolarization signals originating in or on the right and left ventricles;

(b) means coupled to said sense means for initiating a time delay of a predetermined length which is short compared to the period of a QRS complex upon detection of a ventricular depolarization signal in one of said right or left ventricles; and

(c) pulse generator means operative upon the termination of said time delay for producing a ventricular simulating pulse and applying same to the other of said right or left ventricles unless a ventricular depolarization signal occurs in said other of said right of left ventricle prior to the expiration of said time delay.]

[10. The bi-ventricular pacemaker as in claim 9 wherein said sense means comprises a bi-ventricular lead having a first electrode for contacting the right ventricle and a second electrode for contacting the left ventricle and sense amplifier means electrically coupled to said first and second electrodes.]

[11. The bi-ventricular pacemaker as in claim 10 wherein said means coupled to said sense means includes:

(a) first and second set-reset flip-flop connected to be set by an output from said sense amplifier means;

(b) presetable counter means for initially containing a digital value representative of said time delay;

(c) means for incrementing or decrementing said digital value in said presettable counter means at regular intervals until a predetermined count is reached;

(d) means responsive to the value in said counter means reaching said predetermined count for producing a control signal;

(e) logic means coupled to said first and second flip-flops and to said presettable counter means for receiving said control signals; and wherein

(f) said pulse generator means is enabled by said logic means.]

[12. The bi-ventricular pacemaker as in claim 11 wherein said pulse generator means is coupled to said first and second electrodes.]

[13. An atrial-coupled, bi-ventricular pacemaker for implantation or external use comprising atrial and ventricular sensing means for detecting cardiac signals, said sensing means including first and second ventricular electrodes connected in series for sensing and stimulating the right and the left ventricles, respectively, and an atrial electrode adapted to be disposed in an atrial chamber for detecting cardiac signals of the atria, all of said electrodes being connected to separate ECG amplifier means for amplifying the sensed signals; a control circuit coupled to said ECG amplifier means for analyzing the cardiac signals picked up by said sensing means and providing a control signal; and a stimulating circuit means for producing an electrical stimulating pulse to the left ventricle in the absence of a detected cardiac signal from the left ventricle, and to the right ventricle in the absence of a detected cardiac signal from the right ventricle, and to both ventricles in the absence of detected cardiac signals from both ventricles to effect substantially simultaneous contraction of both ventricles after a predetermined A-V delay period.]

[14. The pacemaker of claim 13 wherein said first electrode is adapted to be placed in the right ventricle and the second electrode is adapted to be placed in the coronary sinus extending about the left ventricle.

15. A heart stimulating device for treating heart failure, comprising:

a sense amplifier to receive ventricular depolarization signals originating from a first ventricle;

a pulse generator, connected to the sense amplifier, to generate a stimulating pulse in the event the sense amplifier receives a ventricular depolarization signal; and

an electrode, connected to the pulse generator, to apply the stimulating pulse to a second ventricle in the event the sense amplifier receives a ventricular depolarization signal.

16. The heart stimulating device of claim 15, the electrode further comprising:

an electrode adapted to be disposed in or about the right ventricle to sense ventricular depolarization signals originating from the right ventricle.

17. The heart stimulating device of claim 15, wherein the sense amplifier receives ventricular depolarization signals originating from the right ventricle.

18. The heart stimulating device of claim 17, wherein the electrode connected to the pulse generator applies the stimulating pulse to the left ventricle.

19. The heart stimulating device of claim 15, the electrode further comprising:

an electrode adapted to be disposed in or about the left ventricle to sense ventricular depolarization signals originating from the left ventricle.

20. The heart stimulating device of claim 15, wherein the sense amplifier receives ventricular depolarization signals originating from the left ventricle.

21. The heart stimulating device of claim 20, wherein the electrode connected to the pulse generator applies the stimulating pulse to the right ventricle.

22. The heart stimulating device of claim 15, wherein the pulse generator generates the stimulating pulses immediately after the sense amplifier receives a ventricular depolarization signal.

23. The heart stimulating device of claim 15, further comprising:

a timer to initiate a delay period after the sense amplifier receives a ventricular depolarization signal.

24. The heart stimulating device of claim 23, wherein the pulse generator generates the stimulating pulse after the delay period.

25. The heart stimulating device of claim 15, wherein the sense amplifier receives ventricular depolarization signals from both the right ventricle and the left ventricle.

26. The heart stimulating device of claim 15, wherein the pulse generator generates stimulating pulses for both the right ventricle and the left ventricle.

27. A heart stimulating device for treating heart failure, comprising:

means for receiving ventricular depolarization signals originating from a first ventricle;

means for generating a stimulating pulse in the event the receiving means receives a ventricular depolarization signal; and

means for applying the stimulating pulse to a second ventricle in the event the receiving means receives a ventricular depolarization signal.

28. The heart stimulating device of claim 27, the receiving means further comprising:

an electrode means adapted to be disposed in or about the right ventricle for sensing ventricular depolarization signals originating from the right ventricle.

29. The heart stimulating device of claim 28, wherein the applying means applies the stimulating pulse to the left ventricle.

30. The heart stimulating device of claim 28, wherein the applying means applies stimulating pulses to both the left ventricle and the right ventricle.

31. The heart stimulating device of claim 27, the receiving means further comprising:

an electrode means adapted to be disposed in or about the left ventricle for sensing ventricular depolarization signals originating from the left ventricle.

32. The heart stimulating device of claim 31, wherein the applying means applies the stimulating pulse to the right ventricle.

33. The heart stimulating device of claim 31, wherein the applying means applies stimulating pulses to both the left ventricle and the right ventricle.

34. The heart stimulating device of claim 27, wherein the generator means generates the stimulating pulses immediately after the receiving means receives a ventricular depolarization signal.

35. The heart stimulating device of claim 27, further comprising:

means for initiating a delay period after the receiving means receives a ventricular depolarization signal.

36. The heart stimulating device of claim 35, wherein the generator means generates the stimulating pulse after the delay period.

37. The heart stimulating device of claim 27, wherein the receiving means receives ventricular depolarization signals from both the right ventricle and the left ventricle.

38. The heart stimulating device of claim 27, wherein the generator means generates stimulating pulses for both the right ventricle and the left ventricle.

39. A method for improving the hemodynamic efficiency of a heart, comprising:

receiving ventricular depolarization signals originating from a first ventricle;

generating a stimulating pulse in response to the receiving of a ventricular depolarization signal; and

applying the stimulating pulse to a second ventricle in response to the receiving of a ventricular depolarization signal.

40. The method of claim 39, the receiving further comprising:

receiving ventricular depolarization signals originating from the right ventricle.

41. The method of claim 40, the applying further comprising:

applying the stimulating pulse to the left ventricle.

42. The method of claim 40, the applying further comprising:

applying stimulating pulses to both the left ventricle and the right ventricle.

43. The method of claim 39, the receiving further comprising:

sensing ventricular depolarization signals originating from the left ventricle.

44. The method of claim 43, the applying further comprising:

applying the stimulating pulse to the right ventricle.

45. The method of claim 43, the applying further comprising:

applying stimulating pulses to both the left ventricle and the right ventricle.

46. The method of claim 39, the generating further comprising:

generating the stimulating pulses immediately after receiving a ventricular depolarization signal.

47. The method of claim 39, further comprising:

initiating a delay period after receiving a ventricular depolarization signal.

48. The method of claim 47, the generating further comprising:

generating the stimulating pulse after the delay period.

49. The method of claim 39, the receiving further comprising:

receiving ventricular depolarization signals from both the right ventricle and the left ventricle.

50. The heart stimulating device of claim 39, the generating further comprising:

generating stimulating pulses for both the right ventricle and the left ventricle.

51. A heart stimulating device for treating heart failure comprising:

an electrode to sense a cardiac depolarization signal from a first ventricle;

a sense amplifier, connected to the electrode, to process the cardiac depolarization signal; and

a stimulator, connected to the sense amplifier, to issue a stimulating pulse to a second ventricle in response to the ventricular cardiac depolarization signal.

52. The heart stimulating device of claim 51, wherein the electrode senses a cardiac depolarization signal from the right ventricle.

53. The heart stimulating device of claim 52, wherein the stimulator issues a stimulating pulse to the left ventricle in response to sensing a cardiac depolarization signal from the right ventricle.

54. The heart stimulating device of claim 52, wherein the stimulator issues stimulating pulses to both ventricles in response to sensing a cardiac depolarization signal from the right ventricle.

55. The heart stimulating device of claim 51, wherein the electrode senses a cardiac depolarization signal from the left ventricle.

56. The heart stimulating device of claim 55, wherein the stimulator issues a stimulating pulse to the right ventricle in response to sensing a cardiac depolarization signal from the left ventricle.

57. The heart stimulating device of claim 55, wherein the stimulator issues stimulating pulses to both ventricles in response to sensing a cardiac depolarization signal from the left ventricle.

58. The heart stimulating device of claim 51, wherein the stimulator issues the stimulating pulse immediately after the electrode senses a ventricle depolarization signal.

59. The heart stimulating device of claim 51, further comprising:

a timer to initiate a delay period after the electrode senses a ventricular depolarization signal.

60. The heart stimulating device of claim 59, wherein the stimulator issues the stimulating pulse after the delay period.

61. The heart stimulating device of claim 51, wherein the sense amplifier processes cardiac depolarization signals received from both the right ventricle and the left ventricle.

62. A heart stimulating device for treating heart failure comprising:

means for sensing a cardiac depolarization signal from a first ventricle;

means, connected to the sensing means, for receiving the cardiac depolarization signal; and

means, connected to the receiving means, for issuing a stimulating pulse to a second ventricle in response to the ventricular cardiac depolarization signal.

63. The heart stimulating device of claim 62, wherein the sensing means senses a cardiac depolarization signal from the right ventricle.

64. The heart stimulating device of claim 63, wherein the issuing means issues a stimulating pulse to the left ventricle in response to sensing a cardiac depolarization signal from the right ventricle.

65. The heart stimulating device of claim 63, wherein the issuing means issues stimulating pulses to both ventricles in response to sensing a cardiac depolarization signal from the right ventricle.

66. The heart stimulating device of claim 62, wherein the sensing means senses a cardiac depolarization signal from the left ventricle.

67. The heart stimulating device of claim 66, wherein the issuing means issues a stimulating pulse to the right ventricle in response to sensing a cardiac depolarization signal from the left ventricle.

68. The heart stimulating device of claim 66, wherein the issuing means issues stimulating pulses to both ventricles in response to sensing a cardiac depolarization signal from the left ventricle.

69. The heart stimulating device of claim 62, wherein the issuing means issues the stimulating pulse immediately after the electrode senses a ventricular depolarization signal.

70. The heart stimulating device of claim 62, further comprising:

means for initiating a delay period after the electrode senses a ventricular depolarization signal.

71. The heart stimulating device of claim 70, wherein the issuing means issues the stimulating pulse after the delay period.

72. The heart stimulating device of claim 62, wherein the receiving means receives cardiac depolarization signals from both the right ventricle and the left ventricle.

73. A method for improving the hemodynamic efficiency of a heart, comprising:

sensing a cardiac depolarization signal from a first ventricle;

receiving the ventricular cardiac depolarization signal; and

issuing a stimulating pulse to a second ventricle in response to the ventricular cardiac depolarization signal.

74. The method of claim 73, the sensing further comprising:

sensing a cardiac depolarization signal from the right ventricle.

75. The method of claim 74, the issuing further comprising:

issuing a stimulating pulse to the left ventricle in response to sensing a cardiac depolarization signal from the right ventricle.

76. The method of claim 74, the issuing further comprising:

issuing stimulating pulses to both ventricles in response to sensing a cardiac depolarization signal from the right ventricle.

77. The method of claim 73, the sensing further comprising:

sensing a cardiac depolarization signal from the left ventricle.

78. The method of claim 77, the issuing further comprising:

issuing a stimulating pulse to the right ventricle in response to sensing a cardiac depolarization signal from the left ventricle.

79. The method of claim 77, the issuing further comprising:

issuing stimulating pulses to both ventricles in response to sensing a cardiac depolarization signal from the left ventricle.

80. The method of claim 73, the issuing further comprising:

issuing the stimulating pulse immediately after the sensing of the ventricular depolarization signal.

81. The method of claim 73, further comprising:

initiating a delay period after the sensing of the ventricular depolarization signal.

82. The method of claim 81, the issuing further comprising:

issuing the stimulating pulse after the delay period.

83. The method of claim 73, the receiving further comprising:

receiving ventricular cardiac depolarization signals from both the left and the right ventricles.

84. A heart stimulating device for treating heart failure, comprising:

an electrode to sense ventricular depolarization signals originating from the right ventricle; and

a pulse generator, connected to the electrode, operative upon sensing of a ventricular depolarization signal from the right ventricle to apply a stimulating pulse to another ventricle.

85. The heart stimulating device of claim 84, wherein the pulse generator applies the stimulating pulse to the left ventricle.

86. The heart stimulating device of claim 84, wherein the pulse generator applies stimulating pulses to both the left ventricle and the right ventricle.

87. The heart stimulating device of claim 84, wherein the pulse generator applies the stimulating pulse immediately upon the sensing the ventricular depolarization signal.

88. The heart stimulating device of claim 84, further comprising:

a timer to initiate a delay period after the sensing of the ventricular depolarization signal.

89. The heart stimulating device of claim 88, wherein the pulse generator applies the stimulating pulse after the delay period.

90. A heart stimulating device for treating heart failure, comprising:

means for sensing ventricular depolarization signals originating from the right ventricle; and

means for applying a stimulating pulse to another ventricle in response to the sensing means sensing a ventricular depolarization signal originating from the right ventricle.

91. The heart stimulating device of claim 90, wherein the applying means applies the stimulating pulse to the left ventricle.

92. The heart stimulating device of claim 90, wherein the applying means applies stimulating pulses to both the left ventricle and the right ventricle.

93. The heart stimulating device of claim 90, wherein the applying means applies the stimulating pulse immediately upon the sensing of the ventricular depolarization signal.

94. The heart stimulating device of claim 90, further comprising:

means to initiate a delay period after the sensing of the ventricular depolarization signal.

95. The heart stimulating device of claim 94, wherein the applying means applies the stimulating pulse after the delay period.

96. A method for improving the hemodynamic efficiency of a heart, comprising:

sensing ventricular depolarization signals originating from the right ventricle; and

applying a stimulating pulse to another ventricle in response to the sensing of a ventricular depolarization signal originating from the right ventricle.

97. The method of claim 96, the applying further comprising:

applying the stimulating pulse to the left ventricle.

98. The method of claim 96, the applying further comprising:

applying stimulating pulses to both the left ventricle and the right ventricle.

99. The method of claim 96, the applying further comprising:

applying the stimulating pulse immediately upon the sensing of the ventricular depolarization signal.

100. The method of claim 96, further comprising:

initiating a delay period after the sensing of the ventricular depolarization signal.

101. The method of claim 100, the applying further comprising:

applying the stimulating pulse after the delay period.

102. A heart stimulating device for treating heart failure, comprising:

an electrode to sense ventricular depolarization signals originating from the right ventricle; and

a pulse generator operative upon sensing of a ventricular depolarization signal to apply a stimulating pulse to another ventricle.

103. The heart stimulating device of claim 102, wherein the pulse generator applies the stimulating pulse to the right ventricle.

104. The heart stimulating device of claim 102, wherein the pulse generator applies a stimulating pulse to both the right ventricle and the left ventricle.

105. The heart stimulating device of claim 102, wherein the pulse generator applies the stimulating pulse immediately upon the sensing of the ventricular depolarization signal.

106. The heart stimulating device of claim 102, further comprising:

a timer to initiate a delay period after the sensing of the ventricular depolarization signal.

107. The heart stimulating device of claim 106, wherein the pulse generator applies the stimulating pulse after the delay period.

108. A heart stimulating device for treating heart failure, comprising:

means for sensing ventricular depolarization signals originating from the left ventricle; and

means for applying a stimulating pulse to another ventricle in response to the sensing means sensing ventricular depolarization signals originating from the left ventricle.

109. The heart stimulating device of claim 108, wherein the applying means applies the stimulating pulse to the right ventricle.

110. The heart stimulating device of claim 108, wherein the applying means applies a stimulating pulse to both the right ventricle and the left ventricle.

111. The heart stimulating device of claim 108, wherein the applying means applies the stimulating pulse immediately upon the sensing of the ventricular depolarization signal.

112. The heart stimulating device of claim 108, further comprising:

means for initiating a delay period after the sensing of the ventricular depolarization signal.

113. The heart stimulating device of claim 112, wherein the applying means applies the stimulating pulse after the delay period.

114. A method for improving the hemodynamic efficiency of a heart, comprising:

sensing ventricular depolarization signals originating from the left ventricle; and

applying a stimulating pulse to another ventricle in response to the sensing of the ventricular depolarization signals originating from the left ventricle.

115. The method of claim 114, the applying further comprising:

applying the stimulating pulse to the right ventricle.

116. The method of claim 114, the applying further comprising:

applying a stimulating pulse to both the right ventricle and the left ventricle.

117. The method of claim 114, the applying further comprising:

applying the stimulating pulse immediately upon the sensing of the ventricular depolarization signal.

118. The method of claim 114, further comprising:

initiating a delay period after the sensing of the ventricular depolarization signal.

119. The method of claim 118, the applying further comprising:

applying the stimulating pulse after the delay period.

120. A heart stimulating device for treating heart failure, comprising:

a first electrode to sense atrial cardiac depolarization signals originating from an atrial chamber;

a second electrode to sense ventricular cardiac depolarization signals originating from a ventricular chamber;

a pulse generator operative to apply stimulating pulses to both ventricles in the event that no ventricular cardiac depolarization signals are sensed within a predetermined atrial-ventricular delay period.

121. The heart stimulating device of claim 120, further comprising:

a control circuit, connected to the first and second electrodes, to determine whether ventricular cardiac depolarization signals are sensed by the second electrode within the predetermined atrial-ventricular delay period.

122. The heart stimulating device of claim 120, wherein the pulse generator applies the stimulating pulses to both ventricles simultaneously.

123. The heart stimulating device of claim 120, wherein the pulse generator applies the stimulating pulses to each of the ventricles sequentially.

124. A heart stimulating device for treating heart failure, comprising:

means for sensing atrial cardiac depolarization signals originating from an atrial chamber;

means for sensing ventricular cardiac depolarization signals originating from a ventricular chamber;

means for applying stimulating pulses to both ventricles in the event that no ventricular cardiac depolarization signals are sensed within a predetermined atrial-ventricular delay period.

125. The heart stimulating device of claim 124, further comprising:

a control means, connected to the atrial sensing means and the ventricular sensing means, for determining whether ventricular cardiac depolarization signals are sensed by the ventricular sensing means within the predetermined atrial-ventricular delay period.

126. The heart stimulating device of claim 124, wherein the applying means applies the stimulating pulses to both ventricles simultaneously.

127. The heart stimulating device of claim 124, wherein the applying means applies the stimulating pulses to each of the ventricles sequentially.

128. A method for improving the hemodynamic efficiency of a heart, comprising:

sensing for the presence of cardiac depolarization signals from a ventricle; and

stimulating both ventricles in the event that no cardiac depolarization signals are sensed from either ventricle within a predetermined atrial-ventricular delay period.

129. The method of claim 128, wherein stimulating both ventricles further comprises generating a stimulating pulse and immediately and unconditionally applying the stimulating pulse to both ventricles.

130. The method of claim 128, wherein stimulating both ventricles further comprises generating a stimulating pulse and applying the stimulating pulse to both ventricles simultaneously.

131. The method of claim 128, wherein stimulating both ventricles further comprises generating a stimulating pulse and sequentially applying the stimulating pulse to the ventricles.

132. An atrial-coupled bi-ventricular stimulating device for treatment of congestive heart failure comprising:

atrial and ventricular sensing means for detecting cardiac signals originating in an atrium and in a ventricle;

a control circuit connected to said sensing means to receive the cardiac signals and provide a control signal; and

a stimulating circuit for effecting simultaneous contraction of both ventricles in response to the control signal of the control circuit after a predetermined A-V delay period.

133. An atrial-coupled bi-ventricular stimulating device for implantation or external use for treating heart failure comprising:

a sensing electrode adapted to be located in an atrium;

a pacing electrode adapted to be located through the coronary sinus in the left ventricle;

a sensing electrode adapted to be located in the right ventricle;

ventricular sensing means for detecting cardiac signals from the sensing electrode adapted to be in the right ventricle;

a control circuit connected to said sensing means to provide a control signal in response to detecting a cardiac signal; and

a stimulating circuit for effecting simultaneous contraction of both ventricles in response to the control signal of the control circuit after a predetermined A-V delay period.

134. The stimulating device of claim 133, wherein the sensing electrode adapted to be in the right ventricle also functions to deliver an electrical pulse from said stimulating circuit in response to the control signal of the control circuit.

135. The stimulating device of claim 133, wherein the pacing electrode delivers an electrical pulse from said stimulating circuit in response to the control signal of the control circuit.

136. A method for treating congestive heart failure comprising:

locating a sensing electrode in an atrium;

locating a pacing electrode through the coronary sinus in the left ventricle;

locating a sensing electrode in the right ventricle;

sensing for cardiac signals from the sensing electrode in the right ventricle;

detecting the cardiac signals; and

effecting simultaneous contraction of both ventricles after a predetermined A-V delay period.

137. The method of claim 136, wherein locating a sensing electrode in the right ventricle includes locating a sensing and pacing electrode in the right ventricle.

138. The method of claim 137, wherein effecting simultaneous contraction of both ventricles after a predetermined A-V delay period includes delivering an electrical pulse to the right ventricle via the sensing and pacing electrode.

139. The method of claim 136, wherein effecting simultaneous contraction of both ventricles after a predetermined A-V delay period includes delivering an electrical pulse to the left ventricle via the pacing electrode.

140. A method of effecting simultaneous contraction of both left and right ventricles of a heart for improving hemodynamic efficiency comprising:

locating a pacing electrode through the coronary sinus to the left ventricle;

sensing the cardiac signals of the atria and separately sensing the cardiac depolarization signals of the right ventricle;

detecting the cardiac signals of the atria and the cardiac depolarization signals of the right ventricle; and

stimulating the left ventricle simultaneously with the contraction of the right ventricle after a predetermined A-V delay period.

141. The method of claim 140, wherein stimulating the left ventricle simultaneously with the contraction of the right ventricle after a predetermined A-V delay period includes delivering an electrical pulse to the left ventricle via the pacing electrode.

142. The method of claim 140, wherein stimulating the left ventricle simultaneously with the contraction of the right ventricle after a predetermined A-V delay period includes stimulating both the left ventricle and the right ventricle after a predetermined A-V delay period.

143. A heart stimulating device for treating heart failure, comprising:

an electrode adapted to be disposed in or about the right ventricle to sense ventricular depolarization signals originating from the right ventricle;

a sense amplifier to receive the ventricular depolarization signals originating from the right ventricle;

a pulse generator, connected to the sense amplifier, to generate a stimulating pulse in the event the sense amplifier receives a ventricular depolarization signal originating from the right ventricle; and

an electrode, adapted to be disposed in or about the left ventricle and connected to the pulse generator, to apply

the stimulating pulse to the left ventricle in the event the sense amplifier receives a ventricular depolarization signal originating from the right ventricle.

144. The heart stimulating device of claim 143, wherein the electrode adapted to be disposed in or about the left ventricle is positioned through the coronary sinus.

145. The heart stimulating device of claim 143, wherein the electrode adapted to be disposed in or about the right ventricle stimulates the right ventricle in the event the sense amplifier receives a ventricular depolarization signal originating from the right ventricle.

146. A method for treating congestive heart failure, comprising:

receiving ventricular depolarization signals originating from the right ventricle;

generating a stimulating pulse in response to the receiving of a ventricular depolarization signal in the right ventricle; and

applying the stimulating pulse to the left ventricle in response to the receiving of a ventricular depolarization signal in the right ventricle.

147. The method of claim 146, the applying further comprising:

applying stimulating pulses to both the left ventricle and the right ventricle in response to the receiving of a ventricular depolarization signal in the right ventricle.

148. The method of claim 146, further comprising:

locating an electrode through the coronary sinus and in the left ventricle.

149. A heart stimulating device for treating heart failure, comprising:

an electrode adapted to be disposed in or about the left ventricle to sense ventricular depolarization signals originating from the left ventricle;

a sense amplifier to receive the ventricular depolarization signals originating from the left ventricle;

a pulse generator, connected to the sense amplifier, to generate a stimulating pulse in the event the sense amplifier receives a ventricular depolarization signal originating from the left ventricle; and

an electrode, adapted to be disposed in or about the right ventricle and connected to the pulse generator, to apply the stimulating pulse to the right ventricle in the event the sense amplifier receives a ventricular depolarization signal originating from the left ventricle.

150. The heart stimulating device of claim 149, wherein the electrode adapted to be disposed in or about the left ventricle is positioned through the coronary sinus.

151. The heart stimulating device of claim 149, wherein the electrode adapted to be disposed in or about the left ventricle stimulates the left ventricle in the event the sense amplifier receives a ventricular depolarization signal originating from the left ventricle.

152. A method for treating a heart suffering from heart failure, comprising:

receiving ventricular depolarization signals originating from the left ventricle;

generating a stimulating pulse in response to the receiving of a ventricular depolarization signal in the left ventricle; and

applying the stimulating pulse to the right ventricle in response to the receiving of a ventricular depolarization signal in the left ventricle.

153. The method of claim 152, the applying further comprising:

applying stimulating pulses to both the left ventricle and the right ventricle in response to the receiving of a ventricular depolarization signal in the left ventricle.

154. The method of claim 152, further comprising:

locating an electrode through the coronary sinus and in the left ventricle.

155. A method for improving the hemodynamic efficiency of a heart, comprising:

detecting a cardiac depolarization signal originating from a first ventricle; and

unconditionally stimulating both ventricles for effecting a coordinated contraction of both ventricles when a cardiac depolarization signal originating from the first ventricle is detected.

156. The method of claim 155, wherein unconditionally stimulating both ventricles includes providing electrical pulses from a stimulating circuit to both ventricles.

157. The method of claim 155, wherein detecting a cardiac depolarization signal further comprises conducting the signal to a sense amplifier to amplify the detected signal, and applying the amplified signal to a control circuit.

158. A heart stimulating device for treating heart failure, comprising:

an electrode adapted to be disposed in or about a first ventricle for detecting a cardiac depolarization signal originating from the first ventricle;

a sense amplifier to receive the cardiac depolarization signal originating from the first ventricle;

a pulse generator, connected to the sense amplifier, to unconditionally stimulate both ventricles for effecting a coordinated contraction of both ventricles when the cardiac depolarization signal from the first ventricle is detected.

159. The heart stimulating device of claim 158, further comprising an electrode adapted to be disposed in or about a second ventricle.

160. The heart stimulating device of claim 159, wherein the pulse generator unconditionally stimulates both ventricles by delivering an electronic pulse to the first ventricle via the electrode adapted to be disposed in or about the first ventricle and by delivering an electronic pulse to the second ventricle via the electrode adapted to be disposed in or about the second ventricle.

161. A method of improving the pumping ability of a heart suffering from heart failure comprising:

sensing for depolarization signals originating from a left ventricle;

sensing for depolarization signals originating from a right ventricle; and

stimulating the left ventricle and the right ventricle when a depolarization signal from either the left ventricle or the right ventricle is detected for effecting a coordinate contraction of ventricles contracting in an incoordinate manner to improve the pumping ability of the heart suffering from heart failure.

162. The method of claim 161, further comprising locating an electrode through the coronary sinus to the left ventricle.

163. The method of claim 162, further comprising locating an electrode in the right ventricle.

164. The method of claim 161, wherein stimulating the left ventricle and the right ventricle includes stimulating the left ventricle and the right ventricle within a period of time after detecting a depolarization signal from either the left ventricle or the right ventricle, the period of time being sufficient to effect a substantially simultaneous contraction of the ventricles.

165. The method of claim 164, wherein the left ventricle and the right ventricle are stimulated within 10 milliseconds after detecting the depolarization signal.

166. The method of claim 161, wherein stimulating the left ventricle and the right ventricle includes stimulating only one site in the left ventricle and only one site in the right ventricle.

167. The method of claim 161, wherein stimulating the left ventricle and the right ventricle includes stimulating the left ventricle and the right ventricle when a depolarization signal from either the left ventricle or the right ventricle is detected regardless of whether both ventricles would otherwise contract substantially simultaneously.

168. The method of claim 161, wherein stimulating the left ventricle and the right ventricle includes applying a pacing pulse to the left ventricle and applying a pacing pulse to the right ventricle.

169. The method of claim 161, wherein stimulating the left ventricle and the right ventricle includes stimulating the left ventricle substantially simultaneously with stimulating the right ventricle.

170. The method of claim 161, further comprising stimulating the left ventricle and the right ventricle if a depolarization signal from either the left ventricle or the right ventricle is not detected within a period of time.

171. A method of improving the pumping ability of a heart suffering from heart failure comprising:

sensing for depolarization signals only from one ventricle of the heart;

stimulating the left ventricle and the right ventricle when a depolarization signal from the one ventricle is detected for effecting a coordinate contraction of ventricles contracting in an incoordinate manner to improve the pumping ability of the heart suffering from heart failure.

172. The method of claim 171, further comprising locating an electrode through the coronary sinus to the left ventricle.

173. The method of claim 172, further comprising locating an electrode in the right ventricle.

174. The method of claim 171, wherein stimulating the left ventricle and the right ventricle includes stimulating the left ventricle and the right ventricle within a period of time after detecting a depolarization signal from the one ventricle, the period of time being sufficient to effect a substantially simultaneous contraction of the ventricles.

175. The method of claim 174, wherein the left ventricle and the right ventricle are stimulated within 10 milliseconds after detecting the depolarization signal.

176. The method of claim 171, wherein stimulating the left ventricle and the right ventricle includes stimulating only one site in the left ventricle and only one site in the right ventricle.

177. The method of claim 171, wherein stimulating the left ventricle and the right ventricle includes stimulating the left ventricle and the right ventricle when a depolarization signal from the one ventricle is detected regardless of whether both ventricles would otherwise contract substantially simultaneously.

178. The method of claim 171, wherein stimulating the left ventricle and the right ventricle includes applying a pacing pulse to the left ventricle and applying a pacing pulse to the right ventricle.

179. The method of claim 171, wherein stimulating the left ventricle and the right ventricle includes stimulating the left ventricle substantially simultaneously with stimulating the right ventricle.

180. The method of claim 171, further comprising stimulating the left ventricle and the right ventricle if a depolarization signal from the one ventricle is not detected within a period of time.

181. The method of claim 171, wherein the one ventricle is the right ventricle.

182. The method of claim 171, wherein the one ventricle is the left ventricle.

183. A heart failure treatment device for improving the pumping ability of a heart suffering from heart failure comprising:

a sense amplifier for receiving depolarization signals originating from left and right ventricles; and

a pulse generator, connected to the sense amplifier, that generates stimulation pulses for application to the left ventricle and the right ventricle when the sense amplifier receives a ventricular depolarization signal originating from either the left ventricle or the right ventricle for effecting a coordinated contraction of the ventricles to improve the pumping ability of the heart suffering from heart failure;

a first electrode connected to the pulse generator and adapted to be disposed in or about the left ventricle for sensing depolarization signals originating from the left ventricle and for applying a stimulation pulse to the left ventricle when the sense amplifier receives a ventricular depolarization signal originating from either the left ventricle or the right ventricle; and

a second electrode connected to the pulse generator and adapted to be disposed in or about the right ventricle for sensing depolarization signals originating from the right ventricle and for applying a stimulation pulse to the right ventricle when the sense amplifier receives a ventricular depolarization signal originating from either the left ventricle or the right ventricle.

184. The heart failure treatment device of claim 183, wherein the first electrode is adapted to be positioned through the coronary sinus to the left ventricle.

185. The heart failure treatment device of claim 183, wherein the stimulation pulse is applied to the left ventricle and the stimulation pulse applied to the right ventricle within a period of time after the sense amplifier receives a depolarization signal originating from the left ventricle or the right ventricle, the period of time being sufficient to effect substantially simultaneous contraction of the left and right ventricles.

186. The heart failure treatment device of claim 185, wherein the stimulation pulse is applied to the left ventricle and the stimulation pulse applied to the right ventricle within 10 milliseconds after the sense amplifier receives a depolarization signal originating from the left ventricle or the right ventricle.

187. The heart failure treatment device of claim 183, wherein the pulse generator generates stimulation pulses for application to the left ventricle and the right ventricle when the sense amplifier receives a ventricular depolarization signal originating from either the left ventricle or the right ventricle regardless of whether both ventricles would otherwise contract substantially simultaneously.

188. The heart failure treatment device of claim 183, wherein the stimulation pulses generated by the pulse generator are pacing pulses.

189. The heart failure treatment device of claim 183, wherein the stimulation pulse applied to the left ventricle is applied substantially simultaneously with the stimulation pulse applied to the right ventricle.

190. The heart failure treatment device of claim 183, wherein the sense amplifier includes a first sense amplifier

for receiving depolarization signals originating from the right ventricle and a second sense amplifier for receiving depolarization signals from the left ventricle.

191. The heart failure treatment device of claim 183, wherein the pulse generator generates stimulation pulses for application to the left ventricle and the right ventricle if a depolarization signal originating from either the left ventricle or the right ventricle is not detected within a period of time.

192. A heart failure treatment device for improving the pumping ability of a heart suffering from heart failure comprising:

a sense amplifier for receiving depolarization signals originating from a left ventricle or a right ventricle;

a pulse generator, connected to the sense amplifier, that generates stimulation pulses for application to the left ventricle and the right ventricle when the sense amplifier receives a ventricular depolarization signal originating from the left ventricle or the right ventricle for effecting a coordinated contraction of the ventricles to improve the pumping ability of the heart suffering from heart failure;

a first electrode connected to the pulse generator and adapted to be disposed in or about the left ventricle, the first electrode capable of sensing depolarization signals originating from the left ventricle and capable of applying a stimulation pulse to the left ventricle when the sense amplifier receives a ventricular depolarization signal originating from the left ventricle or the right ventricle; and

a second electrode connected to the pulse generator and adapted to be disposed in or about the right ventricle, the second electrode capable of sensing depolarization signals originating from the right ventricle and capable of applying a stimulation pulse to the right ventricle when the sense amplifier receives a ventricular depolarization signal originating from the left ventricle or the right ventricle.

193. The heart failure treatment device of claim 192, wherein the first electrode is adapted to be positioned through the coronary sinus to the left ventricle.

194. The heart failure treatment device of claim 192, wherein the stimulation pulse is applied to the left ventricle and the stimulation pulse applied to the right ventricle within a period of time after the sense amplifier receives a depolarization signal originating from the left ventricle or the right ventricle, the period of time being sufficient to effect substantially simultaneous contraction of the left and right ventricles.

195. The heart failure treatment device of claim 194, wherein the stimulation pulse is applied to the left ventricle and the stimulation pulse applied to the right ventricle within 10 milliseconds after the sense amplifier receives a depolarization signal originating from the left ventricle or the right ventricle.

196. The heart failure treatment device of claim 192, wherein the pulse generator generates stimulation pulses for application to the left ventricle and the right ventricle when the sense amplifier receives a ventricular depolarization signal originating from the left ventricle or the right ventricle regardless of whether both ventricles would otherwise contract substantially simultaneously.

197. The heart failure treatment device of claim 192, wherein the stimulation pulses generated by the pulse generator are pacing pulses.

198. The heart failure treatment device of claim 192, wherein the stimulation pulse applied to the left ventricle is applied substantially simultaneously with the stimulation pulse applied to the right ventricle.

199. The heart failure treatment device of claim 192, wherein the pulse generator generates stimulation pulses for application to the left ventricle and the right ventricle if a depolarization signal from the left ventricle or the right ventricle is not detected within a period of time.

200. A heart failure treatment device for improving the pumping ability of a heart suffering from heart failure comprising:

a sense amplifier for receiving depolarization signals originating from only one ventricle of the heart;

a pulse generator, connected to the amplifier for generating stimulation pulses for application to the left ventricle and the right ventricle when the sense amplifier receives a ventricular depolarization signal originating from the one ventricle for effecting a coordinated contraction of the ventricles to improve the pumping ability of the heart suffering from heart failure;

a first electrode connected to the pulse generator and adapted to be disposed in or about the left ventricle for applying a stimulation pulse to the left ventricle when the sense amplifier receives a ventricular depolarization signal originating from the one ventricle; and

a second electrode connected to the pulse generator and adapted to be disposed in or about the right ventricle for applying a stimulation pulse to the right ventricle when the sense amplifier receives a ventricular depolarization signal originating from the one ventricle.

201. The heart failure treatment device of claim 200, wherein the first electrode is adapted to be positioned through the coronary sinus to the left ventricle.

202. The heart failure treatment device of claim 200, wherein the stimulation pulse is applied to the left ventricle and the stimulation pulse applied to the right ventricle within a period of time after the sense amplifier receives a depolarization signal originating from the one ventricle, the period of time being sufficient to effect substantially simultaneous contraction of the left and right ventricles.

203. The heart failure treatment device of claim 202, wherein the stimulation pulse is applied to the left ventricle and the stimulation pulse applied to the right ventricle within 10 milliseconds after the sense amplifier receives a depolarization signal originating from the one ventricle.

204. The heart failure treatment device of claim 200, wherein the pulse generator generates stimulation pulses for application to the left ventricle and the right ventricle when the sense amplifier receives a ventricular depolarization signal originating from the one ventricle regardless of whether both ventricles would otherwise contract substantially simultaneously.

205. The heart failure treatment device of claim 200, wherein the stimulation pulses generated by the pulse generator are pacing pulses.

206. The heart failure treatment device of claim 200, wherein the stimulation pulse applied to the left ventricle is applied substantially simultaneously with the stimulation pulse applied to the right ventricle.

207. The heart failure treatment device of claim 200, wherein the one ventricle is the right ventricle.

208. The heart failure treatment device of claim 200, wherein the one ventricle is the left ventricle.

209. The heart failure treatment device of claim 200, wherein the pulse generator generates stimulation pulses for application to the left ventricle and the right ventricle if a depolarization signal from the one ventricle is not detected within a period of time.

210. A method for improving the pumping ability of a heart suffering from heart failure comprising:

sensing for depolarization signals originating from an atrium;

beginning an atrial-ventricular delay period upon sensing a depolarization signal of the atrium;

sensing for depolarization signals originating from a left ventricle;

sensing for depolarization signals originating from a right ventricle; and

stimulating the left ventricle and the right ventricle at the end of the atrial-ventricular delay period if a depolarization signal is not detected from either the left ventricle or the right ventricle during the atrial-ventricular delay period for effecting a coordinated contraction of ventricles contracting in an incoordinate manner to improve the pumping ability to the heart suffering form heart failure.

211. The method of claim 210, further comprising locating an electrode through the coronary sinus to the left ventricle.

212. The method of claim 211, further comprising locating an electrode in the right ventricle.

213. The method of claim 210, wherein stimulating the left ventricle and the right ventricle includes stimulating only one site in the left ventricle and only one site in the right ventricle.

214. The method of claim 210, wherein stimulating the left ventricle and the right ventricle includes applying a pacing pulse to the left ventricle and applying a pacing pulse to the right ventricle.

215. The method of claim 210, wherein stimulating the left ventricle and the right ventricle includes stimulating the left ventricle substantially simultaneously with stimulating the right ventricle.

216. A method for improving the pumping ability of a heart suffering from heart failure comprising:

sensing for depolarization signals originating from an atrium;

beginning an atrial-ventricular delay period upon sensing a depolarization signal of the atrium;

sensing for depolarization signals originating from only one ventricle; and

stimulating the left ventricle and the right ventricle at the end of the atrial-ventricular delay period if a depolarization signal is not detected from the one ventricle during the atrial-ventricular delay period for effecting a coordinated contraction of ventricles contracting in an incoordinate manner to improve the pumping ability to the heart suffering form heart failure.

217. The method of claim 216, further comprising locating an electrode through the coronary sinus to the left ventricle.

218. The method of claim 217, further comprising locating an electrode in the right ventricle.

219. The method of claim 216, wherein stimulating the left ventricle and the right ventricle includes stimulating only one site in the left ventricle and only one site in the right ventricle.

220. The method of claim 216, wherein stimulating the left ventricle and the right ventricle includes applying a pacing pulse to the left ventricle and applying a pacing pulse to the right ventricle.

221. The method of claim 216, wherein stimulating the left ventricle and the right ventricle includes stimulating the left ventricle substantially simultaneously with stimulating the right ventricle.

222. The method of claim 216, wherein the one ventricle is the right ventricle.

223. The method of claim 216, wherein the one ventricle is the left ventricle.

224. A heart failure treatment device for improving the pumping ability of a heart suffering from heart failure comprising:

an atrial sense amplifier for detecting depolarization signals originating from an atrium;

a ventricular sense amplifier for detecting depolarization signals originating from a left ventricle and a right ventricle;

pacing control circuitry, connected to the atrial sense amplifier, for starting an atrial-ventricular delay period when the atrial sense amplifier detects an atrial depolarization signal; and

a stimulating circuit capable of stimulating the left ventricle and the right ventricle at the end of the atrial-ventricular delay period if a depolarization signal is not detected from either the left ventricle or the right ventricle during the atrial-ventricular delay period for effecting coordinated contraction of ventricles contracting in an incoordinate manner to improve the pumping ability to the heart suffering form heart failure.

225. The heart failure treatment device of claim 224, further comprising an electrode adapted to be positioned through the coronary sinus to the left ventricle for stimulating the left ventricle.

226. The heart failure treatment device of claim 224, wherein the stimulating circuit generates pacing pulses for stimulating the left ventricle and the right ventricle.

227. The heart failure treatment device of claim 224, wherein the stimulation circuit stimulates the left ventricle substantially simultaneously with stimulation of the right ventricle.

228. The heart failure treatment device of claim 224, wherein the ventricular sense amplifiers includes a first ventricular sense amplifier connected to the pacing control circuitry for detecting depolarization signals originating from the left ventricle and a second ventricular sense amplifier connected to the pacing control circuitry for detecting depolarization signals originating from the right ventricle.

229. A heart failure treatment device for improving the pumping ability of a heart suffering from heart failure comprising:

an atrial sense amplifier capable of detecting depolarization signals originating from an atrium;

a ventricular sense amplifier capable of detecting depolarization signals originating from a left ventricle or a right ventricle;

pacing control circuitry, connected to the atrial sense amplifier, capable of starting an atrial-ventricular delay period when the atrial sense amplifier detects an atrial depolarization signal;

a stimulating circuit capable of providing stimulating pulses for application to the left ventricle and the right ventricle at the end of the atrial-ventricular delay period if a depolarization signal is not detected from the left ventricle or the right ventricle during the atrial-ventricular delay period for effecting coordinated contraction of ventricles contracting in an incoordinate manner to improve the pumping ability to the heart suffering form heart failure;

a first electrode responsive to the stimulating circuit and adapted to be disposed in or about the left ventricle, the

first electrode capable of sensing depolarization signals originating from the left ventricle and capable of providing stimulating pulses to the left ventricle when the ventricular sense amplifier receives a depolarization signal from the left ventricle or the right ventricle; and

a second electrode responsive to the stimulating circuit and adapted to be disposed in or about the right ventricle, the second electrode capable of sensing depolarization signals originating from the right ventricle and capable of providing stimulating pulses to the right ventricle when the sense amplifier receives a depolarization signal from the left ventricle or the right ventricle.

230. The heart failure treatment device of claim 229, wherein the first electrode is adapted to be positioned through the coronary sinus to the left ventricle.

231. The heart failure treatment device of claim 229, wherein the left ventricle is stimulated substantially simultaneously with stimulation of the right ventricle.

232. A heart failure treatment device for improving the pumping ability of a heart suffering from heart failure comprising:

an atrial sense amplifier for detecting depolarization signals originating from an atrium;

a ventricular sense amplifier for detecting depolarization signals originating from only one ventricle;

pacing control circuitry, connected to the atrial sense amplifier, for starting an atrial-ventricular delay period when the atrial sense amplifier detects an atrial depolarization signal; and

a stimulating circuit capable of stimulating the left ventricle and the right ventricle at the end of the atrial-ventricular delay if a depolarization signal is not detected from the one ventricle during the atrial-ventricular delay period for effecting coordinated contraction of ventricles contracting in an incoordinate manner to improve the pumping ability to the heart suffering form heart failure.

233. The heart failure treatment device of claim 232, further comprising an electrode adapted to be positioned through the coronary sinus to the left ventricle for stimulating the left ventricle.

234. The heart failure treatment device of claim 232, wherein the stimulating circuit generates pacing pulses for stimulating the left ventricle and the right ventricle.

235. The heart failure treatment device of claim 232, wherein the stimulation circuit stimulates the left ventricle substantially simultaneously with stimulation of the right ventricle.

236. The heart failure treatment device of claim 232, wherein the one ventricle is the right ventricle.

237. The heart failure treatment device of claim 232, wherein the one ventricle is the left ventricle.

238. A method of improving the pumping ability of a heart suffering from heart failure comprising:

sensing for depolarization signals originating from an atrium;

beginning an atrial-ventricular delay period upon sensing a depolarization signal of the atrium;

sensing for depolarization signals originating from a left ventricle;

sensing for depolarization signals originating from a right ventricle; and

stimulating the left ventricle and the right ventricle when a depolarization signal from either the left ventricle or the right ventricle is detected during the atrial-ventricular delay period for effecting a coordinated contraction of the ventricles contracting in an incoordinate manner to improve the pumping ability of the heart suffering from heart failure; and

stimulating the left ventricle and the right ventricle at the end of the atrial-ventricular delay period if a depolarization signal is not detected from either the left ventricle or the right ventricle during the atrial-ventricular delay period for effecting a coordinated contraction of the ventricles.

239. The method of claim 238, further comprising locating an electrode through the coronary sinus to the left ventricle.

240. The method of claim 239, further comprising locating an electrode in the right ventricle.

241. The method of claim 238, wherein the left ventricle is stimulated and the right ventricle is stimulated within a period of time after a depolarization signal from either the left ventricle or the right ventricle is detected during the atrial-ventricular delay period, the period of time being sufficient for effecting substantially simultaneous contraction of the ventricles.

242. The method of claim 241, wherein the left ventricle and the right ventricle are stimulated within 10 milliseconds of the detection of the depolarization signal.

243. The method of claim 238, wherein stimulating the left ventricle and the right ventricle includes stimulating only one site in the left ventricle and only one site in the right ventricle.

244. The method of claim 238, wherein the left ventricle and the right ventricle are stimulated when a depolarization signal from either the left ventricle or the right ventricle is detected during the atrial-ventricular delay period regardless of whether both ventricles would otherwise contract substantially simultaneously.

245. The method of claim 238, wherein stimulating the left ventricle and the right ventricle includes applying a pacing pulse to the left ventricle and applying a pacing pulse to the right ventricle.

246. The method of claim 238, wherein stimulating the left ventricle and the right ventricle includes stimulating the left ventricle substantially simultaneously with stimulating the right ventricle.

247. A method of improving the pumping ability of a heart suffering from heart failure comprising:

sensing for depolarization signals originating from an atrium;

beginning an atrial-ventricular delay period upon sensing a depolarization signal of the atrium;

sensing for depolarization signals originating from only one ventricle;

stimulating the left ventricle and the right ventricle when a depolarization signal from the one ventricle is detected during the atrial-ventricular delay period for effecting a coordinated contraction of the ventricles; and

stimulating the left ventricle and the right ventricle at the end of the atrial-ventricular delay period if a depolarization signal is not detected from the one ventricle during the atrial-ventricular delay period for effecting a coordinated contraction of ventricles contracting in an incoordinate manner to improve the pumping ability of the heart suffering from heart failure.

248. The method of claim 247, further comprising locating an electrode through the coronary sinus to the left ventricle.

249. The method of claim 248, further comprising locating an electrode in the right ventricle.

250. The method of claim 247, wherein the left ventricle is stimulated and the right ventricle is stimulated within a period of time after a depolarization signal from the one depolarization is detected during the atrial-ventricular delay period, the period of time being sufficient for effecting substantially simultaneous contraction of the ventricles.

251. The method of claim 250, wherein the left ventricle and the right ventricle are stimulated within 10 milliseconds of the detection of the depolarization signal.

252. The method of claim 247, wherein stimulating the left ventricle and the right ventricle includes stimulating only one site in the left ventricle and only one site in the right ventricle.

253. The method of claim 247, wherein the left ventricle and the right ventricle are stimulated when a depolarization signal from the one ventricle is detected during the atrial-ventricular delay period regardless of whether both ventricles would otherwise contract substantially simultaneously.

254. The method of claim 247, wherein stimulating the left ventricle and the right ventricle includes applying a pacing pulse to the left ventricle and applying a pacing pulse to the right ventricle.

255. The method of claim 247, wherein stimulating the left ventricle and the right ventricle includes stimulating the left ventricle substantially simultaneously with stimulating the right ventricle.

256. The method of claim 247, wherein the one ventricle is the right ventricle.

257. The method of claim 247, wherein the one ventricle is the left ventricle.

258. A heart failure treatment device for improving the pumping ability of a heart suffering from heart failure comprising:

an atrial sense amplifier for detecting depolarization signals originating from an atrium;

pacing control circuitry, connected to the atrial sense amplifier, for starting an atrial-ventricular delay period when the atrial sense amplifier detects an atrial depolarization signal;

a ventricular sense amplifier for detecting depolarization signals originating from a left ventricle and a right ventricle; and

a stimulating circuit for stimulating the left ventricle and the right ventricle when a depolarization signal from either the left or the right ventricle is detected by the ventricular sense amplifier during the atrial-ventricular delay period for effecting a coordinated contraction of ventricles contracting in an incoordinate manner to improve the pumping ability of the heart suffering from heart failure; and for stimulating the left ventricle and the right ventricle at the end of the atrial-ventricular delay period if a depolarization signal is not detected from either the left or right ventricles during the atrial-ventricular delay period for effecting a coordinated contraction of ventricles contracting in an incoordinate manner to improve the pumping ability of the heart suffering from heart failure.

259. The heart failure treatment device of claim 259, further comprising an electrode adapted to be positioned through the coronary sinus to the left ventricle for stimulating the left ventricle.

260. The heart failure treatment device of claim 258, wherein the stimulation circuit stimulates the left ventricle and the right ventricle within a time period after a depolarization signal from either the left or the right ventricle is detected by the ventricular sense amplifier, the time period being sufficient for effecting substantially simultaneous contraction of the left ventricle and the right ventricle.

261. The heart failure treatment device of claim 260, wherein the stimulation circuit stimulates the left ventricle and the right ventricle within 10 milliseconds of the ventricular sense amplifier detecting a depolarization signal from either the left ventricle or the right ventricle.

262. The heart failure treatment device of claim 258, wherein the stimulating circuit stimulates the left ventricle and the right ventricle when a depolarization signal from either the left ventricle or the right ventricle is detected by the ventricular sense amplifier during the atrial-ventricular delay period regardless of whether both ventricles would otherwise contract substantially simultaneously.

263. The heart failure treatment device of claim 258, wherein the stimulating circuit generates pacing pulses for stimulating the left ventricle and the right ventricle.

264. The heart failure treatment device of claim 258, wherein the stimulation circuit stimulates the left ventricle substantially simultaneously with stimulation of the right ventricle.

265. The heart failure treatment device of claim 258, wherein the ventricular sense amplifiers includes a first ventricular sense amplifier for detecting depolarization signals originating from the left ventricle and second ventricular sense amplifier for detecting depolarization signals originating from the right ventricle.

266. A heart failure treatment device for improving the pumping ability of a heart suffering from heart failure comprising:

a atrial sense amplifier for detecting depolarization signals originating from an atrium;

pacing control circuitry, connected to the atrial sense amplifier, for starting an atrial-ventricular delay period when the atrial sense amplifier detects an atrial depolarization signal;

a ventricular sense amplifier for detecting depolarization signals originating from the left ventricle or the right ventricle;

a stimulating circuit for stimulating the left ventricle and the right ventricle when a depolarization signal from the left ventricle or the right ventricle is detected by the ventricular sense amplifier during the atrial-ventricular delay period for effecting a coordinated contraction of ventricles contracting in an incoordinate manner to improve the pumping ability of the heart suffering from heart failure; and for stimulating the left ventricle and the right ventricle at the end of the atrial-ventricular delay period if a depolarization signal is not detected from the left ventricle or the right ventricle during the atrial-ventricular delay period for effecting a coordinated contraction of ventricles contracting in an incoordinate manner to improve the pumping ability of the heart suffering from heart failure;

a first electrode adapted to be disposed in or about the left ventricle, the first electrode capable of sensing depolarization signals originating from the left ventricle and capable of providing a stimulating pulse to the left ventricle in response to the stimulating circuit; and

a second electrode adapted to be disposed in or about the right ventricle, the second electrode capable of sensing depolarization signals originating from the right ventricle and capable of providing a stimulating pulse to the right ventricle in response to the stimulating circuit.

267. The heart failure treatment device of claim 266, wherein the first electrode is adapted to be positioned through the coronary sinus to the left ventricle.

268. The heart failure treatment device of claim 266, wherein the stimulating circuit generates pacing pulses for stimulating the left ventricle and the right ventricle.

269. The heart failure treatment device of claim 266, wherein the left ventricle is stimulated substantially simultaneously with stimulation of the right ventricle.

270. The heart failure treatment device of claim 266, wherein the stimulation circuit stimulates the left ventricle and the right ventricle within a time period after a depolarization signal from the left ventricle or the right ventricle is detected by the ventricular sense amplifier, the time period being sufficient for effecting substantially simultaneous contraction of the left ventricle and the right ventricle.

271. The heart failure treatment device of claim 270, wherein the stimulation circuit stimulates the left ventricle and the right ventricle within 10 milliseconds of the ventricular sense amplifier detecting a depolarization signal from the left ventricle or the right ventricle.

272. A heart failure treatment device for improving the pumping ability of a heart suffering from heart failure comprising:

an atrial sense amplifier for detecting depolarization signals originating from an atrium;

pacing control circuitry, connected to the atrial sense amplifier, for starting an atrial-ventricular delay period when the atrial sense amplifier detects an atrial depolarization signal;

a ventricular sense amplifier for detecting depolarization signals originating from only one ventricle; and

a stimulating circuit for stimulating the left ventricle and the right ventricle when a depolarization signal from the one ventricle is detected by the ventricular sense amplifier during the atrial-ventricular delay period for effecting a coordinated contraction of ventricles contracting in an incoordinate manner to improve the pumping ability of the heart suffering from heart failure; and for stimulating the left ventricle and the right ventricle at the end of the atrial-ventricular delay period if a depolarization signal is not detected from the one ventricle during the atrial-ventricular delay period for effecting a coordinated contraction of ventricles contracting in an incoordinate manner to improve the pumping ability of the heart suffering from heart failure.

273. The heart failure treatment device of claim 272, further comprising an electrode adapted to be positioned through the coronary sinus to the left ventricle for stimulating the left ventricle.

274. The heart failure treatment device of claim 272, wherein the stimulation circuit stimulates the left ventricle and the right ventricle within a time period after a depolarization signal from the one ventricle is detected by the ventricular sense amplifier, the time period being sufficient for effecting substantially simultaneous contraction of the left ventricle and the right ventricle.

275. The heart failure treatment device of claim 274, wherein the stimulation circuit stimulates the left ventricle and the right ventricle within 10 milliseconds of the ventricular sense amplifier detecting a depolarization signal from the one ventricle.

276. The heart failure treatment device of claim 272, wherein the stimulating circuit stimulates the left ventricle and the right ventricle when a depolarization signal from the one ventricle is detected by the ventricular sense amplifier during the atrial-ventricular delay period regardless of whether both ventricles would otherwise contract substantially simultaneously.

277. The heart failure treatment device of claim 272, wherein the stimulating circuit generates pacing pulses for stimulating the left ventricle and the right ventricle.

278. The heart failure treatment device of claim 272, wherein the stimulation circuit stimulates the left ventricle substantially simultaneously with the stimulation of the right ventricle.

279. The heart failure treatment device of claim 272, wherein the one ventricle is the right ventricle.

280. The heart failure treatment device of claim 272, wherein the one ventricle is the left ventricle.

281. A method of improving the pumping ability of a heart suffering from heart failure comprising:

sensing for depolarization signals originating from an atrium;

beginning an atrial-ventricular delay period upon sensing a depolarization signal of the atrium;

sensing for depolarization signals originating from a left ventricle;

sensing for depolarization signals originating from a right ventricle;

inhibiting stimulation of the left ventricle and the right ventricle when a depolarization signal from either the left ventricle or the right ventricle is detected during the atrial-ventricular delay period; and

stimulating the left ventricle and the right ventricle at the end of the atrial-ventricular delay period if a depolarization signal is not detected from either the left ventricle or the right ventricle during the atrial-ventricular delay period.

282. The method of claim 281, further comprising locating an electrode through the coronary sinus to the left ventricle.

283. The method of claim 282, further comprising locating an electrode in the right ventricle.

284. The method of claim 281, wherein stimulating the left ventricle and the right ventricle includes stimulating only one site in the left ventricle and only one site in the right ventricle.

285. The method of claim 281, wherein stimulating the left ventricle and the right ventricle includes applying a pacing pulse to the left ventricle and applying a pacing pulse to the right ventricle.

286. The method of claim 281, wherein stimulating the left ventricle and the right ventricle includes stimulating the left ventricle substantially simultaneously with stimulating the right ventricle.

287. A method of improving the pumping ability of a heart suffering from heart failure comprising:

sensing for depolarization signals originating from an atrium;

beginning an atrial-ventricular delay period upon sensing a depolarization signal of the atrium;

sensing for depolarization signals originating from only one ventricle;

inhibiting stimulation of the left ventricle and the right ventricle when a depolarization signal from the one ventricle is detected during the atrial-ventricular delay period; and

stimulating the left ventricle and the right ventricle at the end of the atrial-ventricular delay period if a depolarization signal is not detected from the one ventricle during the atrial-ventricular delay period.

288. The method of claim 287, further comprising locating an electrode through the coronary sinus to the left ventricle.

289. The method of claim 288, further comprising locating an electrode in the right ventricle.

290. The method of claim 287, wherein stimulating the left ventricle and the right ventricle includes stimulating only one site in the left ventricle and only one site in the right ventricle.

291. The method of claim 287, wherein stimulating the left ventricle and the right ventricle includes applying a pacing pulse to the left ventricle and applying a pacing pulse to the right ventricle.

292. The method of claim 287, wherein stimulating the left ventricle and the right ventricle includes stimulating the left ventricle substantially simultaneously with stimulating the right ventricle.

293. A heart failure treatment device for improving the pumping ability of a heart suffering from heart failure comprising:

an atrial sense amplifier for detecting depolarization signals originating from an atrium;

a ventricular sense amplifier for detecting depolarization signals originating from a left ventricle and a right ventricle;

pacing control circuitry, connected to the atrial sense amplifier, for starting an atrial-ventricular delay period when the atrial sense amplifier detects an atrial depolarization signal, and for inhibiting stimulation of the left ventricle and the right ventricle when a depolarization signal from either the left or the right ventricle is detected during the atrial-ventricular delay period; and

a stimulating circuit for stimulating the left ventricle and the right ventricle at the end of the atrial-ventricular delay period if a depolarization signal is not detected from either the left ventricle or the right ventricle during the atrial-ventricular delay period for effecting a coordinated contraction of ventricles contracting in an incoordinate manner to improve the pumping ability of the heart suffering from heart failure.

294. The heart failure treatment device of claim 293, further comprising an electrode adapted to be positioned through the coronary sinus to the left ventricle for stimulating the left ventricle.

295. The heart failure treatment device of claim 293, wherein the stimulating circuit generates pacing pulses for stimulating the left ventricle and the right ventricle.

296. The heart failure treatment device of claim 293, wherein the stimulation circuit stimulates the left ventricle substantially simultaneously with the stimulation of the right ventricle.

297. The heart failure treatment device of claim 293, wherein the ventricular sense amplifier includes a first ventricular sense amplifier for receiving depolarization signals originating from the right ventricle and a second ventricular sense amplifier for receiving depolarization signals from the left ventricle.

298. A heart failure treatment device for improving the pumping ability of a heart suffering from heart failure comprising:

an atrial sense amplifier for detecting depolarization signals originating from an atrium;

a ventricular sense amplifier for detecting depolarization signals originating from a left ventricle or a right ventricle;

pacing control circuitry, connected to the atrial sense amplifier, for starting an atrial-ventricular delay period when the atrial sense amplifier detects an atrial depolarization signal, and for inhibiting stimulation of the left ventricle and the right ventricle when a depolarization signal from either the left or the right ventricle is detected during the atrial-ventricular delay period;

a stimulating circuit for providing stimulating pulses for application to the left ventricle and the right ventricle at the end of the atrial-ventricular delay period if a depolarization signal is not detected from the left ventricle or the right ventricle during the atrial-ventricular delay period for effecting a coordinated contraction of ventricles contracting in an incoordinate manner to improve the pumping ability of the heart suffering from heart failure;

a first electrode adapted to be disposed in or about the left ventricle, the first electrode capable of sensing depolarization signals originating from the left ventricle and capable of providing a stimulating pulse to the left ventricle in response to the stimulating circuit; and

a second electrode adapted to be disposed in or about the right ventricle, the second electrode capable of sensing depolarization signals originating from the right ventricle and capable of providing a stimulating pulse to the right ventricle in response to the stimulating circuit.

299. The heart failure treatment device of claim 298, wherein the first electrode is adapted to be positioned through the coronary sinus to the left ventricle.

300. The heart failure treatment device of claim 298, wherein the stimulating circuit generates pacing pulses for stimulating the left ventricle and the right ventricle.

301. The heart failure treatment device of claim 298, wherein the left ventricle is stimulated substantially simultaneously with the stimulation of the right ventricle.

302. A heart failure treatment device for improving the pumping ability of a heart suffering from heart failure comprising:

an atrial sense amplifier for detecting depolarization signals originating from an atrium;

a ventricular sense amplifier for detecting depolarization signals originating from only one ventricle;

pacing control circuitry, connected to the atrial sense amplifier, for starting an atrial-ventricular delay period when the atrial sense amplifier detects an atrial depolarization signal, and for inhibiting stimulation of the left ventricle and the right ventricle when a depolarization signal from the one ventricle is detected during the atrial-ventricular delay period; and

a stimulating circuit for stimulating the left ventricle and the right ventricle at the end of the atrial-ventricular delay period if a depolarization signal is not detected from the one ventricle during the atrial-ventricular delay period for effecting a coordinated contraction of ventricles contracting in an incoordinate manner to improve the pumping ability of the heart suffering from heart failure.

303. The heart failure treatment device of claim 302, further comprising an electrode adapted to be positioned through the coronary sinus to the left ventricle for stimulating the left ventricle.

304. The heart failure treatment device of claim 302, wherein the stimulating circuit generates pacing pulses for stimulating the left ventricle and the right ventricle.

305. The heart failure treatment device of claim 302, wherein the stimulation circuit stimulates the left ventricle substantially simultaneously with the stimulation of the right ventricle.

306. The heart failure treatment device of claim 302, wherein the one ventricle is the right ventricle.

307. The heart failure treatment device of claim 302, wherein the one ventricle is the left ventricle.

308. A method for improving the pumping ability of a heart suffering from heart failure comprising:

positioning a first electrode through the coronary sinus to the left ventricle;

positioning a second electrode in the right ventricle;

applying a pacing pulse to the left ventricle through the first electrode;

applying a pacing pulse to the right ventricle through the second electrode substantially simultaneously with application of the pacing pulse to the left ventricle, wherein the pacing pulses are applied to the left ventricle and the right ventricle at a programmed rate.

309. The method of claim 308, wherein the pacing pulses are applied at the programmed rate without regard to any sensing.

310. A method of improving the pumping ability of a heart suffering from heart failure comprising:

sensing for depolarization signals originating from a first ventricle; and

stimulating a second ventricle when a depolarization signal from the first ventricle is detected for effecting a coordinate contraction of ventricles contracting in an incoordinate manner to improve the pumping ability of the heart suffering from heart failure.

311. The method of 310, further comprising locating an electrode through the coronary sinus to the left ventricle.

312. The method of claim 310, wherein the second ventricle is stimulated within a period of time after detecting a depolarization signal from the first ventricle, the period of time being sufficient to effect a substantially simultaneous contraction of both ventricles.

313. The method of claim 312, wherein the second ventricle is stimulated within 10 milliseconds after detecting the depolarization signal of the first ventricle.

314. A method of improving the pumping ability of a heart suffering from heart failure comprising:

sensing for depolarization signals originating from a left ventricle;

sensing for depolarization signals originating from a right ventricle; and

stimulating the left ventricle and the right ventricle after a time period if a depolarization signal is not detected from either the left ventricle or the right ventricle during the time period for effecting a coordinated contraction of ventricles contracting in an incoordinate manner to improve the pumping ability of a heart suffering from heart failure.

315. A method of improving the pumping ability of a heart suffering from heart failure comprising:

sensing for depolarization signals originating from only one ventricle; and

stimulating a right ventricle and a left ventricle if a depolarization signal is not detected from the one ventricle during a time period for effecting a coordinated contraction of ventricles contracting in an incoordinate manner to improve the pumping ability of a heart suffering from heart failure.

316. A method for improving the pumping ability of a heart suffering from heart failure comprising:

sensing for depolarization signals origination in an atrium;

sensing for depolarization signals originating from a left ventricle;

sensing for depolarization signals originating from a right ventricle; and

stimulating the left ventricle and the right ventricle after a time period if a depolarization signal is not detected from either the left ventricle or the right ventricle during the time period for effecting a coordinated contraction of ventricles contracting in an incoordinate manner to improve the pumping ability of a heart suffering from heart failure.

317. The method of claim 316, further comprising stimulating the left ventricle and the right ventricle when a depolarization signal from either the left ventricle or the right ventricle is detected during the time period for effecting a coordinate contraction of the ventricles.

318. The method of claim 316, wherein the time period is an atrial-ventricular delay.

319. The method of claim 316, wherein the time period is a cardiac cycle interval.

320. The method of claim 316, further comprising locating an electrode through the coronary sinus to the left ventricle.

321. The method of claim 316, wherein stimulating the left ventricle and the right ventricle includes stimulating only one site in the left ventricle and only one site in the right ventricle.

322. The method of claim 316, wherein stimulating the left ventricle and the right ventricle includes applying a pacing pulse to the left ventricle and applying a pacing pulse to the right ventricle.

323. The method of claim 316, wherein stimulating the left ventricle and the right ventricle includes stimulating the left ventricle substantially simultaneously with stimulating the right ventricle.

324. A method for improving the pumping ability of a heart suffering from heart failure comprising:

sensing for depolarization signals origination in an atrium;

sensing for depolarization signals originating from only one ventricle; and

stimulating the left ventricle and the right ventricle after a time period if a depolarization signal is not detected from the one ventricle during the time period for effecting a coordinated contraction of ventricles contracting in an incoordinate manner to improve the pumping ability of a heart suffering from heart failure.

325. The method of claim 324, further comprising stimulating the left ventricle and the right ventricle when a depolarization signal from the one ventricle is detected during the time period for effecting a coordinated contraction of the ventricles.

326. The method of claim 324, wherein the time period is an atrial-ventricular delay.

327. The method of claim 324, wherein the time period is a cardiac cycle interval.

328. The method of claim 324, further comprising locating an electrode through the coronary sinus to the left ventricle.

329. The method of claim 324, wherein stimulating the left ventricle and the right ventricle includes stimulating only one site in the left ventricle and only one site in the right ventricle.

330. The method of claim 324, wherein stimulating the left ventricle and the right ventricle includes applying a pacing pulse to the left ventricle and applying a pacing pulse to the right ventricle.

331. The method of claim 324, wherein stimulating the left ventricle and the right ventricle includes stimulating the left ventricle substantially simultaneously with stimulating the right ventricle.

* * * * *

EXHIBIT C

Exhibit A

JOINT PROPOSED STIPULATED AGREEMENT

THIS AGREEMENT is among Mirowski Family Ventures, LLC, a Limited Liability Company organized and existing under the laws of the State of Maryland, Medtronic, Inc., a Minnesota corporation, and Guidant Corporation, an Indiana corporation.

The following definitions are applicable:

"Affiliate" means a person, corporation or other entity that directly, or indirectly, through one or more intermediaries, controls, or is controlled by, or is under common control with, the party specified. "Control" means ownership, either directly or indirectly through intermediaries, of more than 50% of the shares of stock entitled to vote for the election of directors in the case of a corporation, and more than 50% of the voting power in the case of a business entity other than a corporation.

"Decided" means considered and determined by either the District Court or the Federal Circuit in the St. Jude Litigation.

"Final DJ Action" means a declaratory judgment action filed by Medtronic within ninety (90) days after receiving a notice of infringement from Guidant or Mirowski after the DJ Suspension Period has expired, including all subsequent actions through the exhaustion of all appeals.

"Guidant" means Guidant Corporation, an Indiana corporation, and its Affiliates.

"Medtronic" means Medtronic, Inc., a Minnesota corporation, and its Affiliates.

"Mirowski" means Mirowski Family Ventures, LLC, a Limited Liability Company organized and existing under the laws of the State of Maryland and any Affiliates.

"Parties" means Medtronic, Guidant and Mirowski collectively.

"St. Jude Litigation" means the action captioned *St. Jude Medical, Inc. v. Guidant Corp.*, No. 04-0067-SLR (D. Del.), including all subsequent actions through the exhaustion of all appeals.

"Subsequent Reissue Patent(s)" means any patent claiming priority to U.S. Patent No. Re 38,119.

"The '119 Patent" means U.S. Patent No. Re 38,119 entitled "Method and Apparatus for Treating Hemodynamic Disfunction".

The Final DJ Action will be conducted under the following parameters:

Medtronic will be bound on a claim-by-claim basis only for: (i) enforceability, including inequitable conduct and patent misuse; (ii) invalidity under 35 U.S.C. § 101, § 102, and

§ 103; or (iii) each separate validity issue arising under 35 U.S.C. § 112, regardless of the claim construction adopted in the St. Jude Litigation; but only if such issues are adjudicated in the St. Jude Litigation. Thus, for each claim of the '119 Patent or any Subsequent Reissue Patent(s) that was Decided, Medtronic will not challenge validity or enforceability on any basis that was Decided as not being sufficient to render the claim invalid or unenforceable.

(1) For example, if the claims asserted in the St. Jude Litigation are Decided not to be unenforceable, then Medtronic would be precluded from challenging enforceability of those claims even though Medtronic would have or could have presented a different inequitable conduct defense.

(2) For another example, if the claims asserted in the St. Jude Litigation are Decided not to be invalid under either 35 U.S.C. § 101, § 102 or § 103, Medtronic could not thereafter challenge validity of those claims under either 35 U.S.C. § 101, § 102 or § 103 (including newly discovered prior art) regardless of any differences in claim construction.

(3) For another example, if the asserted claims in the St. Jude Litigation are Decided not to be invalid under 35 U.S.C. § 112 for lack of best mode, then Medtronic would not be precluded from challenging validity of those claims on the other individual non-adjudicated issues under 35 U.S.C. § 112 such as enablement or written description, but Medtronic would be precluded from challenging validity of those claims on the adjudicated best mode component of 35 U.S.C. § 112 even though Medtronic would have or could have presented a different best mode defense.

Neither Party will be bound by the claim construction in the St. Jude Litigation, however, any Party may offer or argue for all or part of the claim construction in the St. Jude Litigation in the Final DJ Action.

JS44

CIVIL COVER SHEET

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by the Rules of Court. This form, approved by the Judicial Conference of the united States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the Civil Docket Sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

Medtronic, Inc.

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF _____
EXCEPT IN U.S. PLAINTIFF CASES)

(c) ATTORNEYS FIRM NAME, ADDRESS AND PHONE NO.
Connolly Bove Lodge & Hutz LLP, 1007 N. Orange Street, PO Box 2207, Wilmington, DE 19899, Arthur G. Connolly, III, Esq. (302) 658-9141

DEFENDANTS

Boston Scientific Corporation, Guidant Corporation and Mirowski Family Ventures, L.L.C.

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT _____
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

ATTORNEYS (IF KNOWN)

II. BASIS OF JURISDICTION

(PLACE AN "X" IN ONE BOX ONLY)

- ☐1 U. S. Government Plaintiff
- [X]3 Federal Question (U. S. Government Not A Party)
- ☐2 U. S. Government Defendant
- [] Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES

(PLACE AN "X" IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT)

	PTF	DEF		PTF	DEF
Citizen of This State	☐1	☐1	Incorporated or Principal Place of Business in This State	☐ 4	☒ 4
Citizen of Another State	☐2	☐2	Incorporated and Principal Place of Business in Another State	☒ 5	☐5
Citizen or Subject of a Foreign Country	☐3	☐3	Foreign Nation	☐6	☐6

IV. ORIGIN

(PLACE AN "X" IN ONE BOX ONLY)

[X]1 Original Proceeding ☐2 Removed from State Court ☐3 Remanded from Appellate Court ☐4 Reinstated or Reopened ☐5 Transferred from Another District (specify) ☐6 Multidistrict Litigation ☐7 Appeal to District Judge from Magistrate Judgment

V. NATURE OF SUIT *(PLACE AN "X" IN ONE BOX ONLY)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 440 Other Civil Rights

PERSONAL INJURY
- ☐ 362 Personal Injury - Med. Malpractice
- ☐ 365 Personal Injury - Product Liability
- ☐ 366 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Other

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt. Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

BANKRUPTCY
- ☐ 422 Appeal
- ☐ 443 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- [X] 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS - Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce/ICC Rates/etc.
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 810 Selective Service
- ☐ 850 Securities/commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of InformationAct
- ☐ 900 Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes
- ☐ 890 Other Statutory Actions

VI. CAUSE OF ACTION

(CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE. DO NOT CITE JURISDICTIONAL STATUTES UNLESS DIVERSITY) **35 U.S.C. §§ 1 *et seq.*, and Federal Declaratory Judgment Act 28 U.S.C. § 2201**

VII. REQUESTED IN COMPLAINT:

DEMAND: **Declaratory Judgment** CHECK YES only if demanded in complaint:

CHECK IF THIS IS A **CLASS ACTION** **JURY DEMAND:** ☒ YES ☐ NO

☐ UNDER F.R.C.P. 23

VIII. RELATED CASE(S) IF ANY

DATE December 17, 2007 SIGNATURE OF ATTORNEY OF RECORD Arthur G. Connolly III (#2667)

FOR OFFICE USE ONLY
RECEIPT #_____ AMOUNT_____ APPLYING IFP_____ JUDGE_____ MAG. JUDGE_____

AO FORM 85 RECEIPT (REV. 9/04)

United States District Court for the District of Delaware

Civil Action No. -07-823-

ACKNOWLEDGMENT OF RECEIPT FOR AO FORM 85

NOTICE OF AVAILABILITY OF A UNITED STATES MAGISTRATE JUDGE TO EXERCISE JURISDICTION

I HEREBY ACKNOWLEDGE RECEIPT OF 3 COPIES OF AO FORM 85.

12/17/07
(Date forms issued)

Lilly Van Dyk
(Signature of Party or their Representative)

Lilly Van Dyk
(Printed name of Party or their Representative)

Note: Completed receipt will be filed in the Civil Action