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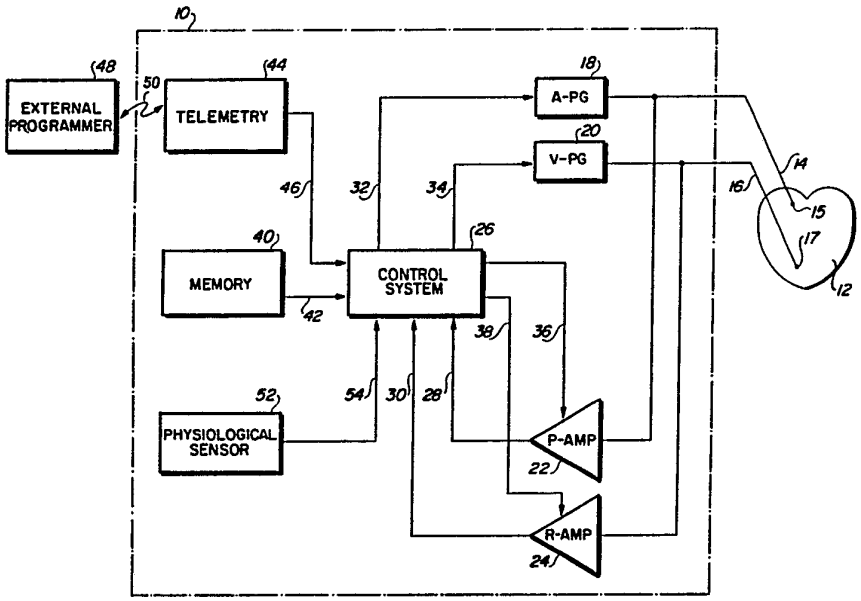
(54) Title: PROGRAMMABLE PACEMAKER

(57) Abstract

An atrial rate based programmable pacemaker (10) including means for preventing the heart (12) from being paced at an upper rate limit for prolonged periods of time which paces the heart at a rate that tracks the atrial rate up to the upper rate limit of the pacemaker, at which point the pacemaker stimulates the heart at the upper rate limit, but also continues to monitor the atrial rate. If the monitored atrial rate exceeds a second upper rate limit, a fast atrial arrhythmia or tachycardia condition is deemed to exist, and the pacemaker automatically switches from its existing mode of operation to an alternate mode of operation in an attempt to break or terminate the fast atrial condition. Leads (14) and (16) carry stimulating pulses to electrodes (15 and 17), from an atrial pulse generator (18) and a ventricular pulse generator (20). Control system (26) generates trigger signals which are sent to atrial pulse generator (18) and ventricular pulse generator (20) over two signal lines (32 and 34). Amplifiers (22 and 24) are disabled by a blanking signal presented to these amplifiers from the control system over signal lines (36) and (38). Memory circuit (40) is coupled to control system (26) by data/address bus (42). Telemetry circuit (44) is connected to control system (26) by command/data bus (46). Telemetry circuit (44) is coupled to external programming device (48) by communication link (50).



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PROGRAMMABLE PACEMAKER

Background of the Invention

Field of the Invention - The present invention relates generally to programmable implantable pacemakers, and more particularly to an implantable dual chamber pacemaker programmed to operate in an atrial rate based mode, wherein mode switching means are provided for automatically switching the mode of operation of the pacemaker from one mode to another in the event the sensed atrial rate exceeds a prescribed upper rate limit.

Modern programmable pacemakers are generally of two types: (1) single chamber pacemakers, and (2) dual chamber pacemakers. In a single chamber pacemaker, the pacemaker provides stimulation pulses to, and/or senses cardiac activity within, a single chamber of the heart, e.g., either the right ventricle or the right atrium. In a dual chamber pacemaker, the pacemaker provides stimulation pulses to, and/or senses cardiac activity within, two chambers of the heart, e.g., both the right ventricle and the right atrium. Typically, only the right atrium and/or the right ventricle is coupled to the pacemaker because of the relative ease with which a pacing lead can be transvenously inserted into either of these chambers. However, the left atrium and left ventricle can also be paced just as effectively providing that suitable electrical contact is made therewith.

In general, both single and dual chamber pacemakers are classified by type according to a three letter code. In this code, the first letter identifies the chamber of the heart that is paced (i.e., that chamber where a stimulation pulse is

delivered), with a "V" indicating the ventricle, an "A" indicating the atrium, and a "D" indicating both the atrium and ventricle. The second letter of the code identifies the chamber wherein cardiac activity is sensed, using the same letters to identify the atrium or ventricle or both, and wherein a "0" indicates no sensing takes place.

The third letter of the code identifies the action or response that is taken by the pacemaker. In general, three types of action or responses are recognized: (1) an Inhibiting ("I") response wherein a stimulation pulse is delivered to the designated chamber after a set period of time unless cardiac activity is sensed during that time, in which case the stimulation pulse is inhibited; (2) a Trigger ("T") response wherein a stimulation pulse is delivered to a prescribed chamber of the heart a prescribed period after a sensed event; (3) or a Dual ("D") response wherein both the Inhibiting mode and Trigger mode are evoked, inhibiting in one chamber of the heart and triggering in the other.

Thus, for example, a DVI pacemaker is a pacer (note that throughout this application, the terms "pacemaker" and "pacer" may be used interchangeably) that paces in both chambers of the heart, but only senses in the ventricle, and that operates by inhibiting stimulation pulses when prior ventricular activity is sensed. Because it paces in two chambers, it is considered as a dual chamber pacemaker. A VVI pacer, on the other hand, is a pacer that paces only in the ventricle and senses only in the ventricle. Because only one chamber is involved, it is classified as a single chamber pacemaker. It should be noted that most dual chamber pacemakers can be programmed to operate in a single chamber mode.

Much has been written and described in the art about the various types of pacemakers and the advantages and disadvantages of each. For example, reference is made to U.S. Patent No. 4,712,555, to Thornander et al., co-invented by the present applicant, wherein some helpful background information about pacemakers and the manner in which they interface with a patient's heart is presented. This patent is hereby incorporated herein by reference.

One of the most versatile programmable pacemakers available today is the DDD pacemaker. This pacer represents a fully automatic pacemaker which is capable of sensing and pacing in both the atrium and ventricle. When functioning properly, the DDD pacer represents the dual chamber pacemaker with the least number of drawbacks. It is typically implanted in patients in an effort to maintain AV synchrony while providing bradycardia support.

In general, DDD pacing has four functional states: (1) P-wave sensing, ventricular pacing (PV); (2) atrial pacing, ventricular pacing (AV); (3) P-wave sensing, R-wave sensing (PR); and (4) atrial pacing, R-wave sensing (AR). Advantageously, for the patient with complete or partial heart block, the PV state of the DDD pacer tracks the atrial rate, which rate is set by the heart's S-A node, and then paces in the ventricle at a rate that follows this atrial rate. Because the rate set by the S-A node represents the rate at which the heart should beat in order to meet the physiologic demands of the body, at least for a heart having a properly functioning S-A node, the rate maintained in the ventricle by such a pacemaker is truly physiologic.

Those skilled in the art have long recognized the advantages of using an atrial rate based pacemaker. For example, U.S. Patent No. 4,624,260, to Baker, Jr.,

et al., discloses a microprocessor-controlled dual chamber pacemaker having conditional atrial tracking capability. Similarly, U.S. Patent No. 4,485,818, to Leckrone et al., discloses a microprocessor-based pacer which may be programmed to operate in one of a plurality of possible operating modes, including an atrial rate tracking mode.

Unfortunately, in some instances, it is possible for a given patient to develop fast atrial rhythms which result from pathological tachycardias and fibrillation. In these cases, the DDD pacer will pace the ventricle in response to the sensed atrial disrhythmia up to the programmed maximum tracking rate. While this upper rate limit is designed into the pacemaker to protect the patient from being paced too fast, it is not desirable to pace at the maximum upper rate limit for a long period of time, else the heart cannot efficiently perform its function of pumping blood through the body.

Therefore, attempts have been made in the art to prevent such atrial arrhythmias from developing. For example, U.S. Patent No. 4,722,341, to Hedberg et al., teaches an atrium-controlled pacemaker wherein the pacemaker temporarily switches from an atrial rate based mode to a non-atrial rate based mode for a fixed number of stimulation pulses if the sensed atrial activity indicates an atrial arrhythmia may be developing. Unfortunately, however, for some patients, a temporary switching from one mode to another may not be sufficient to correct or arrest the arrhythmia.

What is needed is an atrial rate based pacemaker which will not only sense the atrial arrhythmia once it develops, but which will also take whatever corrective action is needed, for however long (i.e., not just temporarily), to prevent the heart from being

paced at the maximum upper limit for long periods of time.

It is known that the dual chamber pacemaker itself may undesirably support (and even induce) some cardiac arrhythmias. This process is described, for example, in U.S. Patent No. 4,788,980, to Buchanan et al., where such arrhythmias are referred to as a pacer mediated tachycardia, or PMT. The referenced patent discloses a particular technique for recognizing a PMT and terminating it once it develops. Similarly, U.S. Patent No. 4,712,556, to Baker, proposes another technique for identifying PMT's, and proposes yet another technique for terminating such PMT. Still another patent, U.S. Patent No. 4,554,921, to Boute et al., teaches modifying the atrial refractory period of the pacemaker in an attempt to break or terminate a PMT.

Regardless of the source of the arrhythmia, however, whether caused by a PMT or by other factors, if left unchecked, the DDD pacer will track the fast atrial rate and pace the ventricles up to the maximum tracking rate for a long period of time, resulting in low cardiac output. What is needed, therefore, is a method or technique for preventing an atrial rate based pacemaker from pacing the heart at the maximum pacing rate for prolonged periods of time, even when an atrial arrhythmia is present.

Sometimes it is possible at the time of implant of a pacemaker to determine whether an atrial fibrillation, atrial flutter, or atrial tachycardia condition is going to develop. In such instances, the pacemaker may always be programmed to operate in a different mode of operation, the leads may be repositioned within the heart, or other actions may be taken to minimize the likelihood of such arrhythmias occurring. Unfortunately, however, it is not always

possible at the time of implant to determine whether a patient will develop an arrhythmia as a result of pacing.

Therefore, if such arrhythmias subsequently occur, they must be treated using other techniques, such as through the administration of drugs. Needless to say, the administration of drugs requires the attendance of a physician. Unfortunately, however, a physician is not always present when such arrhythmias develop, and even when a physician is available, such drugs undesirably also suppress the ability of the S-A node to increase the sinus rate during periods of exercise, emotional stress, or other physiologic stress. Thus, the use of such drugs effectively prevents the pacer from functioning as a true physiologic rate-responsive pacer.

What is needed is an approach for dealing with arrhythmias which develop after implant without necessitating the attendance of a physician and without compromising the pacer's ability to function as a physiologic rate-responsive pacer.

It is also possible that the atrial arrhythmia may be caused by the pacemaker's inability to sense P-waves. In such an instance, the paced competition with the native atrial activity may precipitate an atrial tachycardia or fibrillation. This inability to sense P-waves may be caused by numerous factors, but is usually caused by electrode dislodgement or movement, tissue growth, or other events which may occur several days or weeks after implant.

The ability of the pacemaker to sense P-waves is referred to as atrial sensitivity. At implant, the atrial sensitivity is adjusted based on various tests in order to ensure that P-waves are sensed with an adequate margin of safety. However, even this margin of safety may disappear over time, and it thus becomes

necessary for a physician to reprogram the atrial sensitivity so that P-waves will be sensed. However, until reprogramming of the atrial sensitivity takes place, there is some possibility that P-waves will not be sensed, resulting in the undesirable atrial arrhythmias described above.

Thus, what is needed is a pacemaker which includes means for periodically checking, and adjusting as required, the atrial sensitivity, thereby assuring that P-waves will always be sensed by the pacemaker. U.S. Patent No. 4,708,144, to Hamilton et al., represents one approach known in the art for automatically controlling the sensitivity of the pacemaker.

Further, with an atrial rate based dual chamber pacemaker, there is always the problem that a sustained activity period of the patient, resulting in a naturally high sinus rate, may be interpreted by the pacemaker as a pathological atrial arrhythmia. Hence, an atrial rate based pacemaker needs to incorporate some means to readily distinguish a sustained pathological atrial arrhythmia from a sustained activity period, and take appropriate action in each instance.

Advantageously, the pacemaker described herein, including the method of operating such pacemaker, addresses the above and other needs.

Summary of the Invention

The disadvantages and limitations of the background art discussed above are overcome by the present invention. With this invention, an atrial rate based programmable pacemaker is provided which advantageously includes means for preventing the heart from being paced at the upper rate limit of the pacemaker for prolonged periods of time in the event

the atrial rate exceeds a prescribed upper rate limit. The pacemaker includes means for operating in a prescribed dual chamber mode of operation, such as DDD, wherein the heart is paced at a rate that follows or tracks the atrial rate up to the upper rate limit of the pacemaker. When the atrial rate exceeds the upper rate limit, the pacemaker stimulates the heart at the upper rate limit, but also continues to monitor the atrial rate.

If the monitored atrial rate exceeds a second upper rate limit, e.g., a tachycardia rate limit, a pathological atrial arrhythmia or tachycardia condition is deemed to exist, and the pacemaker automatically switches from its existing mode of operation to an alternate mode of operation, e.g., a single chamber mode of operation. This mode switching is performed for the purpose of breaking or terminating the fast atrial condition. While in the alternate mode of operation, the atrial and/or ventricular rate continues to be monitored, and as soon as the rate drops to an acceptable level, the pacemaker automatically switches back to its initial atrial rate based mode.

In one embodiment of the invention, an external physiological sensor may optionally be utilized in the pacemaker to control the pacing rate of the pacemaker in the alternate pacing mode. This action ensures that the pacemaker is attempting to pace the heart at an appropriate heart rate based on the patient's actual physiologic needs at a time when the heart may be beating at an excessive rate, e.g., during a tachycardia or other arrhythmia. As with the first embodiment, as soon as the atrial or ventricular rate drops to an acceptable level, the pacemaker automatically switches back to its initial mode of operation.

In a still further embodiment, the pacemaker includes means for periodically verifying that atrial sensing is occurring. If a determination is made that atrial sensing is not occurring, an adjustment mode is initiated during which the sensitivity of the atrial channel is automatically adjusted, as required.

It is thus a feature of the present invention to provide a programmable pacemaker which prevents the heart from being paced at the maximum rate of the pacemaker for prolonged periods of time. It is a further feature of the invention to provide such a pacemaker wherein the pacemaker continues to sense the rate of cardiac activity even when that rate exceeds the upper rate limit of the pacemaker.

Yet another feature of the invention is to provide such a pacemaker wherein the mode of operation of the pacer automatically switches from a first mode to a second mode in the event the sensed cardiac activity exceeds a prescribed second upper limit, this second upper limit being above the pacemaker's normal upper rate limit. While in this second mode of operation, an additional feature of the invention provides for the continued sensing of the prescribed cardiac activity and the automatic switching of the pacemaker back to its first mode of operation as soon as the prescribed cardiac activity returns to a normal level.

Still another feature of the invention provides such an automatic mode switching pacemaker wherein the pacing rate of the pacemaker while in its second mode of operation is controlled by an external physiological sensor, such as an activity sensor. A still further feature of the invention provides a programmable pacemaker wherein the sensitivity of the sense amplifier(s) used to sense cardiac activity may

be automatically adjusted at prescribed times or intervals.

Finally, all of the aforesaid advantages and objectives are achieved without incurring any substantial relative disadvantage.

Description of the Drawings

These and other advantages of the present invention are best understood with reference to the drawings, in which:

Figure 1 is a block diagram of a dual chamber programmable pacemaker;

Figure 2 is a block diagram of one possible embodiment of the control logic of the pacemaker of Figure 1;

Figure 3 is a simplified state diagram of the pacemaker of Figure 1 when operating in accordance with one embodiment of the present invention; and

Figures 4A and 4B are flow chart diagrams illustrating the operation of the pacemaker of Figure 1.

Detailed Description of the Preferred Embodiment

The following description is of the best presently contemplated mode of practicing the invention. This description is not to be taken in a limiting sense but is made merely for the purpose of describing the general principles of the invention. The scope of the invention should be ascertained with reference to the appended claims.

Before describing the invention in more detail, a brief review of cardiac physiology may be helpful. Essentially, the heart is a pump which pumps blood throughout the body. It consists of four chambers, two atria and two ventricles. In order to efficiently perform its function as a pump, the atrial muscles and

ventricular muscles must contract in a proper sequence and timed relationship.

In a given cardiac cycle (corresponding to one "beat" of the heart), the two atria contract, forcing the blood therein into the ventricles. A short time later, the two ventricles contract, forcing the blood therein to the lungs (right ventricle) or through the body (left ventricle). Meanwhile, blood from the body fills up the right atrium and blood from the lungs fills up the left atrium, waiting for the next cycle to begin. A typical healthy adult heart may beat at a rate of 60-70 beats per minute (bpm) while at rest, and may increase its rate to 140-180 bpm when the adult is engaging in strenuous physical exercise, or undergoing other physiologic stress.

The healthy heart controls its own rhythm naturally from its S-A node, located in the upper portions of the right atrium. The S-A node generates an electrical impulse at a rate commonly referred to as the "sinus" rate. This impulse is delivered to the atrial tissue when the atria are to contract; and, after a suitable delay (on the order of 40-80 milliseconds), is delivered to the ventricular tissue when the ventricles are to contract.

When the atria contract, a detectable electrical signal referred to as a P-wave is generated. When the ventricles contract, a detectable electrical signal referred to as an R-wave is generated. The R-wave is much larger than the P-wave, principally because the ventricular muscle tissue is much more massive than is the atrial muscle tissue. The atrial muscle tissue need only produce a contraction sufficient to move the blood a very short distance, from the respective atrium to its corresponding ventricle. The ventricular muscle tissue, on the other hand, must produce a contraction sufficient to push the blood

over a long distance, e.g., through the complete circulatory system of the entire body.

Other electrical signals or waves are also detectable within a cardiac cycle, such as a Q-wave (which immediately precedes an R-wave), an S-wave (which immediately follows an R-wave), and a T-wave (which represents the repolarization of the ventricular muscle tissue).

It is the function of a pacemaker to provide electrical stimulation pulses to the appropriate chamber(s) of the heart (atria or ventricles) in the event the heart is unable to beat on its own, i.e., in the event either the S-A node fails to generate its own natural stimulation pulses at an appropriate sinus rate, or in the event such natural stimulation pulses are not delivered to the appropriate cardiac tissue. Most modern pacemakers accomplish this function by operating in a "demand" mode wherein stimulation pulses from the pacemaker are provided to the heart only when it is not beating on its own, as sensed by monitoring the appropriate chamber of the heart for the occurrence of a P-wave or an R-wave. If a P-wave or an R-wave is not sensed within a prescribed period of time (which period of time is most often referred to as the "escape interval"), then a stimulation pulse is generated at the conclusion of this prescribed period of time and delivered to the appropriate heart chamber via a pacemaker lead.

Further details associated with cardiac physiology and the operation of the heart as controlled or monitored by a pacemaker may be found in U.S. Patent 4,712,555, to Thornander et al., which patent was incorporated by reference above.

Referring now to Figure 1, a simplified block diagram of a dual chamber pacemaker 10 is illustrated. The pacemaker 10 is coupled to a heart 12 by way of

leads 14 and 16, the lead 14 having an electrode 15 which is in contact with one of the atria of the heart, and the lead 16 having an electrode 17 which is in contact with one of the ventricles of the heart. The leads 14 and 16 carry stimulating pulses to the electrodes 15 and 17, respectively, from an atrial pulse generator (A-PG) 18 and a ventricular pulse generator (V-PG) 20, respectively.

Further, electrical signals from the atria are carried from the electrode 15, through the lead 14, to the input terminal of an atrial channel sense amplifier (P-AMP) 22. Electrical signals from the ventricles are carried from the electrode 17, through the lead 16, to the input terminal of a ventricular sense channel amplifier (R-AMP) 24.

Controlling the dual chamber pacer 10 is a control system 26. The control system 26 receives the output signals from the atrial amplifier 22 over a signal line 28. Similarly, the control system 26 receives the output signals from the ventricular amplifier 20 over a signal line 30. These output signals are generated each time that a P-wave or an R-wave is sensed within the heart 12.

The control system 26 also generates trigger signals which are sent to the atrial pulse generator 18 and the ventricular pulse generator 20 over two signal lines 32 and 34, respectively. These trigger signals are generated each time that a stimulation pulse is to be generated by the respective pulse generator 18 or 20. The atrial trigger signal is referred to simply as the "A-pulse", and the ventricular trigger signal is referred to as the "V-pulse".

During the time that either an A-pulse or V-pulse is being delivered to the heart, the corresponding amplifier, P-AMP 22 or R-AMP 24, is typically disabled

by way of a blanking signal presented to these amplifiers from the control system over signal lines 36 and 38, respectively. This blanking action prevents the amplifiers 22 and 24 from becoming saturated from the relatively large stimulation pulses which are present at their input terminals during this time. This blanking action also helps prevent residual electrical signals present in the muscle tissue as a result of the pacer stimulation from being interpreted as P-waves or R-waves.

Still referring to Figure 1, the pacer 10 also includes a memory circuit 40 which is coupled to the control system 26 by a suitable data/address bus 42. This memory circuit 40 allows certain control parameters, used by the control system 26 in controlling the operation of the pacemaker, to be programmably stored and modified, as required, in order to customize the operation of the pacer 10 to suit the needs of a particular patient. Further, data sensed during the operation of the pacer 10 may be stored in the memory 40 for later retrieval and analysis.

A telemetry circuit 44 is further included in the pacer 10. This telemetry circuit 44 is connected to the control system 26 by way of a suitable command/data bus 46. In turn, the telemetry circuit 44, which is included within the implantable pacer 10, may be selectively coupled to an external programming device 48 by means of an appropriate communication link 50, which communication link 50 may be any suitable electromagnetic link, such as an RF (radio frequency) channel.

Advantageously, through the external programmer 48 and the communication link 50, desired commands may be sent to the control system 26. Similarly, through this communication link 50 and the programmer 48, data

(either held within the control system 26, as in a data latch, or stored within the memory 40,) may be remotely received from the pacer 10. In this manner, non-invasive communications may be established with the implanted pacer 10 from a remote, non-implanted, location.

The pacer 10 in Figure 1 is referred to as a dual chamber pacemaker because it interfaces with both the atria and the ventricles of the heart. Those portions of the pacer 10 which interface with the atria, e.g., the lead 14, the P-wave sense amplifier 22, the A-pulse generator 18, and corresponding portions of the control system 26, are commonly referred to as the atrial channel. Similarly, those portions of the pacer 10 which interface with the ventricles, e.g., the lead 16, the R-wave sense amplifier 24, the V-pulse generator 20, and corresponding portions of the control system 26, are commonly referred to as the ventricular channel.

In accordance with one embodiment of the present invention, the pacemaker 10 further includes a physiological sensor 52 which is connected to the control system 26 of the pacer over a suitable connection line 54. While this sensor 52 is illustrated in Figure 1 as being included within the pacer 10, it is to be understood that the sensor 52 may also be external to the pacer 10, yet still be implanted within or carried by the patient.

A common type of sensor 52 is an activity sensor, such as a piezoelectric crystal, which is mounted to the can or case of the pacemaker. Other types of physiologic sensors are also known, such as sensors which sense the oxygen content of blood, respiration rate, pH of blood, body motion, and the like. The type of sensor used is not critical to the present invention. Any sensor which is capable of sensing

some physiological parameter which is relatable to the rate at which the heart should be beating may be used.

Such sensors are commonly used with "rate-responsive" pacemakers in order to adjust the rate (escape interval) of the pacer in a manner which tracks the physiological needs of the patient. In accordance with one embodiment of the present invention, the sensor 26 is used to control the escape interval or pacing rate of the pacer 10 when the pacer 10 is operating in an alternate mode of operation other than an atrial rate based mode of operation. This is described more fully below in connection with the description of Figure 4A.

Referring next to Figure 2, a block diagram of one embodiment of the control system 26 of the pacer 10 is illustrated. It is noted that other embodiments of a control system 26 may also be utilized, such as a microprocessor-based control system. A representative microprocessor-based system is described, for example, in copending U.S. Patent Application No. 07/301,934, filed January 25, 1989, entitled "Microprocessor Controlled Rate-Responsive Pacemaker Having Automatic Rate Response Threshold Adjustment", assigned to the same assignee as is the present application. This patent application is hereby incorporated herein by reference.

The control system shown in Figure 2 is based on a state machine wherein a set of state registers 60 define the particular state of the pacer 10 at any instant in time. In general, and as an overview of state machine operation, each state, by design, causes a certain activity or function to be carried out. Several states are executed in a sequence during a given cardiac cycle. The sequence of states which is executed in a particular cardiac cycle is determined by the particular events which occur, such as the

sensing of a P-wave or an R-wave, as well as the current state, as certain states can only be entered from certain other states.

Only one state may exist at any instant of time, although several different state machines (or control systems) may operate in parallel to control diverse functions. For example, the telemetry circuit 44 (Figure 1) preferably utilizes its own state machine, such as is described in the above-cited copending patent application. This telemetry circuit state machine operates essentially independently of the control system state machine shown in Figure 2.

At the heart of the control system 26 is the state logic 62. It is the state logic which controls the "state" of the state registers 60, and hence the function or operation which will next be carried out by the system. The state logic 62 receives as inputs the current state of the state registers 60, made available over a state bus 64 (which state bus 64 directs the state of the system to several sections of the control system), as well as other signals indicating the current status of the system or events which have occurred.

The output signals from the P-AMP 22 (Figure 1) and the R-AMP 24 (Figure 1) are directed to an input decode logic circuit 66. The input decode logic circuit 66 generates appropriate logic signals "IPW" (Inhibiting P-Wave) and "IRW" (Inhibiting R-Wave) which are selected by a multiplexer 68 and sent to rate-determining logic 70. These signals are also sent to the state logic 62. The function of the rate-determining logic 70 is to determine the rate at which either the IPW or IRW signals are occurring.

A signal representative of this rate is sent, as an output signal from the rate determining logic 70, to the state logic 62 over a signal line 72. The

rate-determining logic 70 further receives a sensor rate signal from the sensor 52 (Figure 1), and (depending upon the particular state of the system, as defined by the state registers 60, and as made available to the rate-determining logic 70 over the state bus 64) sends a rate signal to the state logic 62 over signal line 72 indicative of this sensor rate.

Still referring to Figure 2, a memory control circuit 74 provides the needed interface between the circuits of the control system 26 and the memory 40 (Figure 1). This memory control circuit 74 may be any conventional memory access circuit which sends or receives data to or from memory at a specified address. Data retrieved from the memory 40 may be sent to either the state logic 62 over signal line(s) 75 or to a programmable timer 76 over a signal line(s) 77. Data sent to the memory 40 may be either the current state of the system (obtained off of the state bus 64), or other selected signals from the state logic 62 (as made available over signal line(s) 73).

The function of the programmable timer 76 is to define a prescribed time interval, the length of which is set by the signal(s) received from the memory control 74 over the signal line(s) 77, and the starting point of which begins coincident with the start of the current state, as obtained from the state bus 64. The timer 76 further generates a time-out (T.O.) signal when this prescribed time interval has elapsed.

During this prescribed time interval, the timing function may be reset by a reset signal, typically obtained from the input decode logic 66, although some states (as obtained from the state bus 64) may also effectuate an immediate reset of the timer 76. The time-out signal is sent to a time-out decode logic 78. It is the function of the time-out decode logic 78 to

generate the appropriate trigger signals which are sent to the A-pulse generator 18 or the V-pulse generator 20 (Figure 1). Further, an appropriate logic signal(s) is sent to the state logic 62 by the time-out decode logic 78 over the signal line(s) 80 in order to notify the state logic 62 that the respective trigger signals have been generated.

An oscillator 82, preferably a crystal-controlled oscillator, generates a basic clock signal C0 which controls the operation of the system logic. This clock signal C0 is sent to clock logic circuits 84, where other appropriate clock signals, such as clock signals C1, C2, and C3, are generated, all derived from the basic clock signal C0. These clock signals are distributed throughout the control system 26 in order to appropriately synchronize the various events and state changes which occur within the pacemaker.

The rate of the basic clock signal C0 is not critical to the present invention. In general, a rate of 25-40 Khz for the basic clock rate C0 is adequate. This rate provides a basic time increment of 25-40 microseconds each clock cycle, and this is more than enough time to effectively control the pacemaker operation. If desired, a faster basic clock rate may be used, particularly by the memory control 74, to speed up the data transfer between the control system 26 and the memory 40, although for most pacemaker operations, a fast data transfer rate is not essential.

In operation, the control system of Figure 2 starts at an initial state, wherein the state registers 60 assume a prescribed value which defines the initial state. For example, assuming four flip-flops are used for the state registers 60, an initial state might be "1000" (hexadecimal "8") wherein the first flip-flop assumes a "1" state, and the remaining

three flip-flops each assume a "0" state. This state may be defined as a V-A Delay (VAD) state wherein a prescribed VA interval is initiated. This interval may be considered as the "escape interval" mentioned previously.

As soon as the memory control 74 detects that the VAD state has been initiated, as evidenced by the "1000" appearing on the state bus 64, it retrieves from the memory 40 an appropriate data word, previously programmed into the memory 40 from the external programmer 48, which defines the desired length of the V-A delay. This data word is sent to the programmable timer and sets the length of the time period which is to be measured during the VAD state.

The timer 76 is essentially just a counter which counts down (or counts up), using a specified clock signal, to the value specified in the data word. When the counting has been completed, and assuming that the counter has not been reset by the occurrence of a P-wave or an R-wave, the counter or timer 76 is said to have "timed-out", and an appropriate time-out signal is generated which is sent to the time-out decode logic 78.

The decode logic 78, in turn, recognizes that the current state of the system is the VAD state (as determined by monitoring the state bus 64), and therefore that the VA interval (escape interval) has timed out without any cardiac activity having been sensed, generates an A-pulse trigger signal, sent to the A-pulse generator 18, so that the atrium can be stimulated. At the same time, an appropriate logic signal(s) is sent to the state logic 62 over the signal line(s) 80 to alert the state logic to the fact that the timer 76 has timed out.

The state logic 62, in response to receiving the signal(s) from the time-out decode logic 78, and also

in response to the current VAD state, triggers the next state of the prescribed sequence. For DDD operation, this state is typically a blanking state, or BLANK state, during which the P and R sense amplifiers, 22 and 24, are disabled. Accordingly, the state logic generates appropriate signal(s) on signal lines 36 and 38 to blank the P-wave sense amplifier 22 and the R-wave sense amplifier 24, respectively, and also causes the state registers 60 to change to a BLANK state, which state could be defined, for example, by the flip-flops of the state registers 62 assuming a "0001" (hex "1") condition.

This BLANK state, detected on the state bus 64, causes the memory control circuitry 74 to retrieve an appropriate data word from the memory 40 which defines the length of the blanking interval, which data word is loaded into the programmable timer 76. As soon as the timer 76 times out, indicating that the prescribed blanking interval has elapsed, a time-out signal is generated which is sent to the time-out decode logic 78. Upon receipt of this time-out signal, and in response to the current state being a BLANK state, the time-out decode logic 78 sends an appropriate logic signal to the state logic 62. The state logic 62 responds by steering the state registers 62 to assume the next state in the prescribed sequence, which may be, for example, an A-V Delay (AVD) state.

At the beginning of the AVD state, another value is loaded into the programmable timer 76 which defines the length of the AV interval. If the timer 76 times out without being reset, indicating that no P-waves or R-waves have been sensed, the decode logic 78 generates a V-pulse trigger signal, and notifies the state logic 62 of this event. The state logic 62, in turn, causes the next appropriate state to be entered, which state may be another blanking state, or BLANK

state, similar to the one described above, but having perhaps a different duration. At the conclusion or timing out of this second BLANK state, the next state in the prescribed sequence is initiated, which state may be a refractory (REF) state.

In the manner described above, the control system 26 assumes one state after another, thereby controlling the operation of the pacemaker 10. In general, a state is changed when the timer 76 times out, or when a prescribed event occurs. For example, if during the VAD state an IPW signal is received (indicating that a P-wave has been sensed), the input decode logic 66 generates a reset signal to reset the timer 76, and the state logic 62 responds by immediately (typically within the next few clock cycles) changing the state to the next appropriate state, for example, an AVD state.

Further, if during the AVD state an IRW signal is received (indicating that an R-wave has been sensed), the input decode logic 66 generates another reset signal to reset the timer 76, and the state logic responds by immediately changing the state to the next appropriate state, for example, a refractory (REF) state. It is noted that the state of the control system 26 could also be changed by receipt of an appropriate command from the telemetry system.

The control system 26 of Figure 2 may be realized using dedicated hardware circuits, or by using a combination of hardware and software (or firmware) circuits. The appropriate sequence of states for a given mode of operation, such as DDD or VVI, for example, may be defined by appropriate control of the memory control 74 and the state logic 62. These circuit elements, in turn, are most easily controlled through an appropriate software or firmware program which is placed or programmed into the pacemaker

memory circuits. The manner of accomplishing such programming is well known in the art.

A detailed description of the various circuits of the control system 26 of Figure 2 will not be presented herein because all such circuits may be conventional, or may be patterned after known circuits available in the art. Reference is made, for example, to the above incorporated by reference U.S. Patent No. 4,712,555, to Thornander et al., wherein a state-machine type of operation for a pacemaker is described; and to U.S. Patent No. 4,788,980, to Buchanan et al., wherein the various timing intervals used within the pacemaker and their interrelationship are more thoroughly described.

It is noted that a dual chamber programmable pacemaker may have up to eighteen states associated with its control system. These states are described fully in the above-referenced patent application. A summary of these states is presented below in Table 1.

TABLE 1
States of the Pacemaker Control System

State	Symbol	Description
0	APW	A-Pulse (A-Pulse triggered)
1	BLANK	V-Sense Input Inhibit (Blank)
2	AREF	A Refractory
3	SIPW	Sensed Inhibiting P-wave (P-wave sensed)
4	AVD	A-V Delay
5	CROSS	Crosstalk Sense
6	VPW	V-Pulse (V-Pulse triggered)

7	STRW	Sensed Inhibiting R-wave (R-wave sensed)
8	VAD	V-A Delay
9	SHORT1	Shorten A-V Delay a first prescribed amount if IPW during SHORT1 with Physiologic A-V Delay On
A	MTR	Max Track Rate
B	SHORT2	Shorten A-V Delay a second prescribed amount if IPW during SHORT2 with Physiologic A-V Delay On
C	RRT	Lengthen VA interval if at low battery
D	RNOISE	R Noise sensed during VREF or RNOISE
E	LIPW	Latched IPW -- P-wave sensed in MTR
F	PNOISE	P Noise sensed during AREF or PNOISE
(none)	VREF	V Refractory, independent 1-bit state machine synchronized to pulse generator when AREF starts
(none)	ABSREF	Absolute Refractory for a prescribed period, starts when AREF starts

In addition to the states identified in Table 1, the present invention preferably incorporates two additional states: (1) an ARC (Atrial Rate Check) state, and an ARV (Atrial Rate Verify) state. At least the ARV state is preferably defined by an independent 1-bit state machine which operates in parallel with the system state machine.

The operation of the pacemaker control system 26 of Figures 1 and 2 as it relates to the present invention may be better understood by reference to the

state diagram of Figure 3. The state diagram of Figure 3 illustrates in each circle a particular state which the system may assume. The connecting lines between the circles illustrate the various events which may cause the state to change.

Before explaining Figure 3, however, it should be emphasized that Figure 3 depicts a simplified state diagram. That is, for purposes of clarity only a portion of the states shown in Table 1 are used by the pacemaker represented by Figure 3. Further, some of the states which may be used in the pacemaker, as identified in Table 1, such as the absolute refractory state, ABSREF, the ventricular refractory state, VREF, and the atrial refractory state, AREF, are combined in the pacemaker state diagram of Figure 3 as simply a refractory state, REF. This is done for simplicity of explanation because the various responses which may be taken by the pacemaker during the AREF or VREF states, for example, to better distinguish noise from other events, may remain unchanged for the present invention.

In other words, for purposes of understanding the present invention it is sufficient to assume that during a refractory period or state no action is taken until the refractory state, REF, times out, and the next state is entered. Other states identified in Table 1, such as the CROSS, RRT, RNOISE, LIPW, SHORT1 and SHORT2 states are not included in the description which follows because they play no part in the invention. In fact, for purposes of the present invention, a pacemaker may function without these states.

Other states shown in Table 1, such as the SIPW and SIRW states, are referred to in the state diagram of Figure 3 as "events" (IPW and IRW) which simply trigger the state of the control system to shift from

one state to another. In practice, a logic designer may choose to define a temporary state, such as an SIPW or SIRW state, to indicate that a P-wave or an R-wave has been detected by receipt of an IPW or IRW signal. However, for purposes of understanding the present invention, it is sufficient to simply recognize that the sensing of a P-wave (IPW) or the sensing of an R-wave (IRW) is an event which can affect (change) the state of the control system.

Referring then to the state diagram of Figure 3, the operation of the present invention will be described. As has been indicated, the present invention is directed to a particular manner of controlling or operating a pacemaker which is operating in an atrial rate based mode, such as DDD. The bracketed portion 90 of Figure 3 essentially represents a simplified state diagram of a DDD pacer. That is, a VAD state is entered.

If a timeout occurs without a P-wave being sensed, then an APW state is entered during which an A-pulse is delivered to the atrium, followed by a BLANK state, followed by an AVD state. If the AVD state times out without an R-wave being sensed, then a VPW state is entered during which a V-pulse is delivered to the ventricle, followed by a BLANK state, followed by a refractory, or REF, state, followed by a maximum tracking rate (MTR) state. If the MTR state times out without a P-wave being sensed, then the VAD state is reinitiated.

Assuming that no P-waves or R-waves are sensed, the above cycle repeats itself with an A-pulse being generated after every VAD state and a V-pulse being generated after every AVD state. Notice that the MTR state assures that these stimulation pulses will not be delivered at a rate which exceeds a maximum upper limit (which upper limit is programmable). That is,

the MTR state inserts a known time delay into the sequence of states which separates the A-pulse and the V-pulse by a set time period. In effect, this set time period defines a maximum upper rate limit (URL) at which the heart can be paced by the pacemaker. Advantageously, this set time period can be programmed to any desired value, thereby allowing the URL to be programmably selected.

In accordance with conventional DDD operation, if a P-wave is sensed (IPW) during either the VAD or MTR states, the AVD state is entered. The present invention modifies this operation by inserting an intermediate state, identified as an ARC (Atrial Rate Check) state, into the sequence. The ARC state is entered upon the occurrence of an IPW. During the ARC state, the atrial rate is checked or measured. This operation is carried out by the rate-determining logic 70 of Figure 2, or its equivalent.

If the rate is below a prescribed threshold limit, hereafter a tachycardia rate limit (TRL), then the AVD state is entered, and the normal DDD operation continues. This tachycardia rate limit, or TRL, is set at a rate higher than the maximum upper rate limit, or URL, of the pacemaker. Thus, the ARC state is entered (that is, the atrial rate is checked or measured) even when the pacer is stimulating the heart at the URL. If during the ARC state a determination is made that the atrial rate exceeds the TRL (identified in Figure 3 as a "HIGH" event), then an atrial rate verify (ARV) state is entered during which the atrial rate continues to be monitored.

The ARV state is maintained for so long as the atrial rate remains above a third prescribed rate threshold, referred to as T_3 herein. The sensing that the atrial rate exceeds T_3 during the ARV state is identified in Figure 3 as a "HIGH" event.

During the ARV state, the pacemaker switches from the DDD mode of operation to an alternate mode of operation. This alternate mode of operation is preferably a non-atrial rate based mode, such as VVI. The bracketed portion 92 of the state diagram of Figure 3 represents a simplified state diagram of a VVI pacer. So long as the pacer remains in the ARV state, the VVI mode (or other desired mode) is enabled and the pacer functions in a conventional VVI fashion (or other desired mode).

However, in the event a determination is made in the ARV state that the atrial rate has decreased to an acceptable level (which event is identified in Figure 3 as a "PASS" event), that is, to a level less than the threshold T_3, then the pacemaker switches back to operate in the initial atrial rate based mode.

The above operation is further illustrated in the flow chart of Figure 4A. As seen in Figure 4A, the DDD mode of operation is initialized at block 94. During the normal DDD operation, a determination is made as to whether a P-wave has been sensed (block 96). If not, a determination is made as to whether the atrial channel sensitivity needs to be adjusted, as shown in the block diagram of Figure 4B, explained below. If a P-wave is sensed, a determination is next made (block 98) as to whether the atrial rate (P-wave rate) exceeds a first rate limit threshold, T_1, which first rate limit is the upper rate limit (URL) of the pacemaker.

This operation is carried out by the rate-determining logic 70 (Figure 2) using any suitable technique. Typically, atrial rate is determined by simply measuring the period or interval between successive P-waves, as described for example in U.S. Patent No. 4,722,341, to Hedberg et al. Preferably, however, in accordance with the present invention,

several P-waves are monitored, and an average P-rate value is obtained, or other rate measuring techniques are used (such as maintaining a running average of the P-waves over the last several cycles), thereby filtering out any abnormal or one-of-a-kind fast P-waves that may occasionally occur.

If the P-wave rate is less than the first threshold rate limit, T_1, then the pacemaker continues to operate in conventional DDD fashion (cycling back through block 100). If, however, the determination made at block 98 indicates that the atrial rate exceeds the first rate threshold T_1, a second determination is made (block 102) as to whether the atrial rate exceeds a second rate threshold value, T_2. This second rate threshold T_2 may be thought of as a tachycardia rate limit (TRL), and represents a programmable value indicative of the maximum P-wave rate that will be tolerated for a particular patient before action is taken to stop the fast atrial rate.

If the atrial rate is less than the TRL, or T_2, then the pacer continues to pace at the URL (block 104), and the P-wave continues to be monitored (cycling through block 106). If, however, a determination is made at block 102 that the atrial rate exceeds the TRL, then the pacer mode is switched from DDD to an alternate mode of operation (block 114), such as VVI or VVT.

Before switching to the alternate mode of operation, a determination is also made (block 108) as to whether an activity sensor, such as the sensor 52 (Figure 2), is to be used with the pacer during its alternate mode of operation. If so, the sensor is enabled (block 110) and the control system of the pacemaker is modified appropriately so as to be controlled exclusively by the sensor (block 112). That is, the sensor provides a rate-determining signal

which sets the value of the escape interval or pacing interval used by the pacer during its alternate mode of operation. In this manner, the pacer can better attempt to bring the heart under control by providing stimulation pulses only as dictated by the sensor, not as dictated by the arrhythmatic heart.

After the pacer has been switched to operate in the alternative mode of operation (block 114), the pacer continues to operate in this mode in conventional manner at the same time that the atrial rate is monitored (block 116). Periodically, e.g., every cardiac cycle, or every n cardiac cycles, where n is an integer greater than one, the atrial rate is again checked (block 118). If a determination is made that the atrial rate has dropped below a third prescribed rate threshold, T_3, then the pacer is switched back to its initial atrial rate based mode of operation (block 94).

The pacer continues to operate in this initial mode in accordance with the process described above, that is, as indicated by the flow chart of Figure 4A. If the determination made at block 118 indicates that the atrial rate has not dropped below the threshold T_3, then the pacer continues to operate in the alternate mode of operation (block 116) in a conventional manner, except that the atrial rate continues to be monitored. During this time, the pacer is in the ARV state, as described above in connection with the state diagram of Figure 3.

Typical values for the rate threshold limits T_1, T_2 and T_3 may be on the order of 150-180 bpm for T_1, 200-230 bpm for T_2, and 100-150 bpm for T_3.

Referring next to Figure 4B, another feature of the present invention will be described. In the preferred embodiment of the present invention, this feature is included within the same pacer as are the

mode switching features of Figure 4A, and hence Figure 4B is drawn as a continuation or extension of the flow chart of Figure 4A. As previously indicated, sometimes it is the pacer's inability to sense a P-wave while operating in an atrial rate based mode which gives rise to a cardiac arrhythmia. Hence, it is desirable to determine whether P-waves are being sensed and, if not, to adjust the sensitivity of the P-wave sense amplifier so that they can be sensed. Thus, in Figure 4A, one of the first determinations which is made (block 96) is whether a P-wave is sensed. If not, then the process described in Figure 4B is invoked.

Upon entering the process of Figure 4B, a decision is initially made as to whether the A-channel sensitivity is to be verified (block 120). This block is present in the flow chart simply to emphasize that A-channel sensitivity verification may be a selectable option programmed into the pacemaker. If the option is off --if the atrial channel sensitivity is not to be verified-- then the process simply returns back to Fig 4A and conventional DDD operation continues (block 100). If the option is on, then the pacer mode is switched to a test/verify mode (block 122).

In accordance with this special test/verify mode, the atrial channel is monitored for a prescribed period of time (block 124), such as 5-10 seconds, to determine if any P-waves are sensed (block 126). If P-waves are sensed, then the process makes a determination whether the test should be performed again (block 128). This determination (to test again) is preferably an option which can be programmed into the pacemaker at implant and later modified, as required, by the physician. For example, it may be desirable for a given patient to monitor the atrium for the prescribed period of time (block 124) for

several consecutive time periods, e.g. five periods of 5-10 seconds each.

If a P-wave is regularly sensed during all of these time periods, then a final decision can be made at block 128 to terminate the test/verify mode. In such case, the pacer mode is switched back to DDD, or another initial atrial rate based mode, (through block 130) and the normal operation of the pacer for that mode continues (block 100). If however, a P-wave is not sensed during the prescribed time period, or is not regularly sensed during all of the time periods during which the test is performed, than such is an indication that the A-channel sensitivity probably needs to be adjusted.

It is noted that "atrial channel sensitivity" refers to the ability of the P-wave sense amplifier 22, Figure 1, to sense P-waves. By adjusting the gain of this amplifier, which adjustment can be made using techniques known in the art, the magnitude of the P-waves which are detected by the amplifier may be optimally set.

Accordingly, for the case where P-waves are not being sensed, the sensitivity of the atrial sense amplifier is adjusted by a prescribed increment (block 132). Sensitivity settings are typically measured in millivolts, and this incremental adjustment is preferably on the order of 0.1-0.3 millivolts per increment. After making this incremental adjustment, another determination is made (block 134) as to whether P-waves are being sensed. If so, then this new sensitivity is maintained (block 136), the pacer is switched back to the DDD or other atrial rate based mode (block 138), and the normal operation of the pacer continues for that mode (block 100).

Where P-waves are not sensed at block 134, even after the sensitivity has been adjusted by the

specified incremental amount, a determination is made as to whether further incremental adjustments of the sensitivity are possible (block 140). If so, then the next incremental adjustment is made and the process continues until a P-wave is sensed. If not, i.e., if there is no further adjustment range possible, then a major failure of the atrial channel exists, and the pacer immediately ceases its efforts to monitor P-waves and instead switches to monitoring R-waves (block 142).

If the R-wave rate is determined to be above a prescribed threshold (block 144), for example, above the TRL, then the heart is still experiencing a tachycardia or other arrhythmia and the pacer mode is immediately switched to a different mode of operation (block 146), as required, in order to break the tachycardia and to provide the safest possible mode of operation for the patient. For example, a VOO mode may be initiated (ventricular pacing, no sensing).

This "safe" mode of operation continues (block 148) until a reprogramming command is received (block 150). Operation of the pacer in this new "safe" mode advantageously alerts the physician (who is the only one who can effectuate a reprogramming change) as to the difficulties the pacer had in sensing P-waves, and the arrhythmias that were experienced by the patient. The physician may then determine an appropriate course of action, e.g., reprogram to a still different mode of operation (block 154), perform additional tests, or the like.

At the point in the process where the R-wave rate is tested (block 144), if it is determined that the R-wave rate is not greater than the prescribed threshold, then the heart is probably not experiencing an arrhythmia, and any desired mode of operation can be initiated by the pacemaker (block 152), such as a

VVI or VVT mode. This mode continues (block 148) until a new reprogramming command is received (block 150).

As described above, the present invention thus provides a pacer which provides all the advantages of atrial rate based pacing, but which also avoids some of the problems associated with atrial rate based pacing in the event an atrial arrhythmia condition develops. More particularly, if the atrial rate exceeds a prescribed upper rate limit, T_2, then the pacer is switched automatically to a non atrial rate based mode.

Further, during this non-atrial rate based pacing mode, the rate of the pacer is controlled by a physiological sensor, such as an activity sensor. As soon as the atrial rate falls below another prescribed rate threshold, T_3, then the pacing mode automatically switches back to the initial atrial rate based mode. Moreover, the pacer includes means for automatically adjusting the sensitivity of the atrial channel in the event P-waves are not consistently sensed.

It should be noted that the automatic adjusting procedures described herein for adjusting the atrial channel may be used to adjust the atrial channel sensitivity in either direction, thereby allowing an optimum value of sensitivity to be automatically maintained.

Although an exemplary embodiment of the present invention has been shown and described, it will be apparent to those having ordinary skill in the art that a number of changes, modifications, or alterations to the invention as described herein may be made, none of which depart from the spirit or scope of the present invention. All such changes, modifications, and alterations should therefore be seen as within the scope of the present invention.

Accordingly, the complete scope of the present invention should be determined with reference to the claims set forth below.

CLAIMS

What is claimed is:

1. An improved dual chamber pacemaker having programmable modes of operation, said pacemaker being capable of stimulating the atrial and the ventricular chambers of the heart, said pacemaker including programming means for selectively allowing the pacemaker to be programmed to operate in an atrial rate based mode of operation, and atrial sensing means for sensing atrial activity occurring in the atrial chamber, including atrial rate of said atrial activity, wherein the improvement comprises:

first sensing means for monitoring said atrial rate and sensing whether said atrial rate exceeds a first prescribed threshold;

means for providing a stimulating pulse to a selected chamber of the heart at a maximum upper rate in the event said atrial rate sensed by said first sensing means exceeds said first prescribed threshold;

second sensing means for monitoring said atrial rate above said first prescribed threshold and sensing whether said atrial rate exceeds a second prescribed threshold, said second threshold being at a higher rate than said first threshold; and

means for automatically switching the mode of operation of said pacemaker from said atrial rate based mode of operation to a selected alternate mode of operation in the event said atrial rate exceeds said second prescribed threshold.

2. The programmable pacemaker of claim 1 further comprising:

third sensing means for monitoring said atrial rate during said alternate mode of operation and sensing whether it drops below a third prescribed threshold; and

means for automatically switching the mode of operation of said pacemaker from said alternate mode of operation back to said atrial rate based mode of operation in the event said atrial rate falls below said third prescribed threshold.

3. The programmable pacemaker of claim 2 wherein said first, second and third prescribed thresholds are programmably selectable through said programming means.

4. The programmable pacemaker of claim 2 wherein said first prescribed threshold comprises a rate which is at least equal to said maximum upper rate at which stimulating pulses are provided to the selected chamber of the heart.

5. The programmable pacemaker of claim 4 wherein said first prescribed threshold comprises a rate which is at least 150 beats per minute and said second prescribed threshold comprises a rate which is at least 200 beats per minute.

6. The programmable pacemaker of claim 1 further comprising:

a physiological sensor coupled to said pacemaker, wherein said automatic switching means is capable of coupling said physiological sensor to said stimulating pulse providing means during said alternate mode of operation, and for modifying the operation of said pulse providing means to provide stimulating pulses to a selected chamber of the heart at a rate controlled by said physiological sensor during said alternate mode of operation.

7. The pacemaker of claim 1 further comprising:

atrial sensitivity adjustment means for automatically checking the sensitivity of said atrial sensing means at selected intervals to determine its ability to sense P-waves, and for automatically adjusting said atrial sensing means to sense P-waves in the event that P-waves are not being sensed.

8. The pacemaker of claim 7 wherein said atrial sensitivity adjustment means comprises:

means for switching said pacemaker to a test mode of operation;

means for monitoring said atrial sensing means during said test mode for a prescribed period of time to determine if any P-waves are detected; and

means for adjusting said atrial sensing means so that lower amplitude P-waves can be detected by said atrial sensing means in the event no P-waves are detected by said monitoring means during said prescribed period of time.

9. The pacemaker of claim 8 wherein said means for adjusting said atrial sensing means comprises:

means for adjusting the sensitivity of said atrial sensing means in a series of incremental adjustments until said P-waves are detected.

10. The pacemaker of claim 9 wherein said pacemaker further comprises:

means for switching the pacemaker mode of operation from said test mode to a prescribed alternate mode of operation in the event P-waves are not detected after the sensitivity of said atrial sensing means has been adjusted through all of said fixed incremental adjustments, whereby said alternate

mode of operation provides an indicia that said atrial sensing means was unable to detect P-waves.

11. A dual chamber pacemaker having first and second channels, said first and second channels including sensing means for sensing cardiac activity and pulse generating means for providing pacing pulses in the absence of cardiac activity in the atrial and the ventricular chambers of the heart, respectively, said pacemaker comprising:

control means for controlling said sensing means and said pulse generating means of said first and second channels in a prescribed mode of operation, said control means comprising:

means for detecting a rate of cardiac activity as sensed by said sensing means in said first channel; and

means for triggering said pulse generating means to provide pacing pulses in said second channel at a rate which is the lesser of said rate of cardiac activity detected in said first channel or a maximum tracking rate; and

means for automatically changing said prescribed mode of operation in the event said rate of cardiac activity detected in said first channel exceeds a specified threshold level, said specified threshold level comprising a rate which is greater than said maximum tracking rate.

12. The pacemaker of claim 11 further comprising:

means for automatically changing the mode of operation of said pacemaker back to said prescribed mode of operation in the event said rate of cardiac activity detected in said first channel drops below a second specified threshold level, said second

specified threshold level comprising a rate that is less than said maximum tracking rate.

13. The pacemaker of claim 11 further comprising:

means for automatically adjusting the ability of said first channel to sense cardiac activity.

14. The pacemaker of claim 11 further comprising:

a physiological sensor for sensing physiological events indicative of a need to change the rate of said pulse generating means, and wherein said means for automatically changing the prescribed mode of operation comprises means for coupling said physiological sensor to said pulse generating means and for controlling said pulse generating means to provide pulses in said second channel at a rate determined by the physiological events sensed by said physiological sensor.

15. A method of operating a dual chamber programmable pacemaker, said pacemaker being capable of operating in a variety of modes of operation and being initially programmed to operate in an atrial rate based mode of operation, said pacemaker comprising means for sensing cardiac activity in the atrial and the ventricular chambers of a heart, and means for selectively providing a stimulating pulse to either chamber of the heart at prescribed times and under prescribed conditions, the method comprising the steps of:

(a) sensing when the atrial rate exceeds a first rate threshold;

(b) providing a stimulating pulse to a selected chamber of the heart at a maximum upper rate in the event the atrial rate sensed in step (a) exceeds said first rate threshold;

(c) monitoring the atrial rate above said first rate threshold up to a second rate threshold; and

(d) automatically switching the mode of operation of said pacemaker from said atrial rate based mode of operation to a selected alternate mode of operation in the event the atrial rate exceeds said second rate threshold.

16. The method of claim 15 further comprising the steps of:

(e) monitoring the atrial rate during said alternate mode of operation; and

(f) automatically switching the mode of operation of said pacemaker from said alternate mode of operation back to said atrial rate based mode of operation in the event the atrial rate falls below a third rate threshold.

17. The method of claim 15 further comprising the step of:

(e) controlling the rate at which stimulating pulses are provided by said pacemaker during said alternate mode of operation in accordance with a rate signal provided by a physiological sensor coupled to said pacemaker.

18. The method of claim 15 further comprising the step of:

(e) checking the sensitivity of the atrial sensing means at selected intervals to determine its ability to sense P-waves; and

(f) automatically adjusting the sensitivity of the atrial sensing means to sense P-waves in the event that P-waves are not being sensed.

19. The method of claim 18 wherein the step of checking the sensitivity of the atrial sensing means comprises:

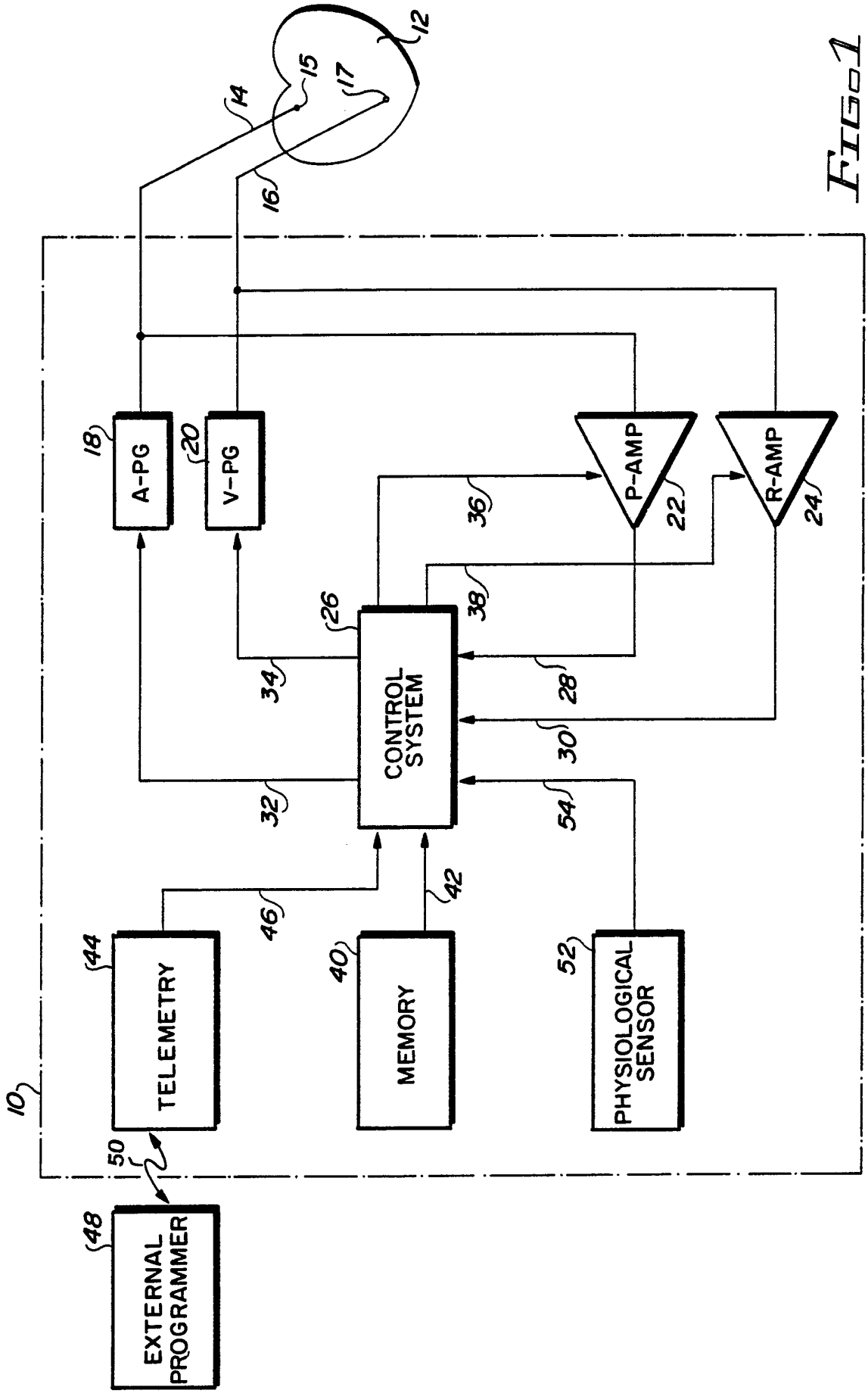
monitoring the atrial sensing means for a prescribed period of time to determine if any P-waves are detected.

20. The method of claim 18 wherein the step of adjusting the sensitivity to sense P-waves comprises:

changing the sensitivity of the atrial sensing means by a first discrete increment;

checking the sensitivity of the atrial sensing means to determine if P-waves are sensed;

if P-waves are not sensed, changing the sensitivity of the atrial sensing means again by a second discrete increment, checking the sensitivity of the atrial sensing means again to determine if P-waves are sensed, and so on, through a series of discrete increments, until P-waves are sensed.


12
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A-PG
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V-PG
P-AMP
22
R-AMP
24
36
38
26
CONTROL SYSTEM
34
28
30
32
54
42
46
44
TELEMETRY
40
MEMORY
52
PHYSIOLOGICAL SENSOR
10
50
48
EXTERNAL PROGRAMMER

Fig. 1

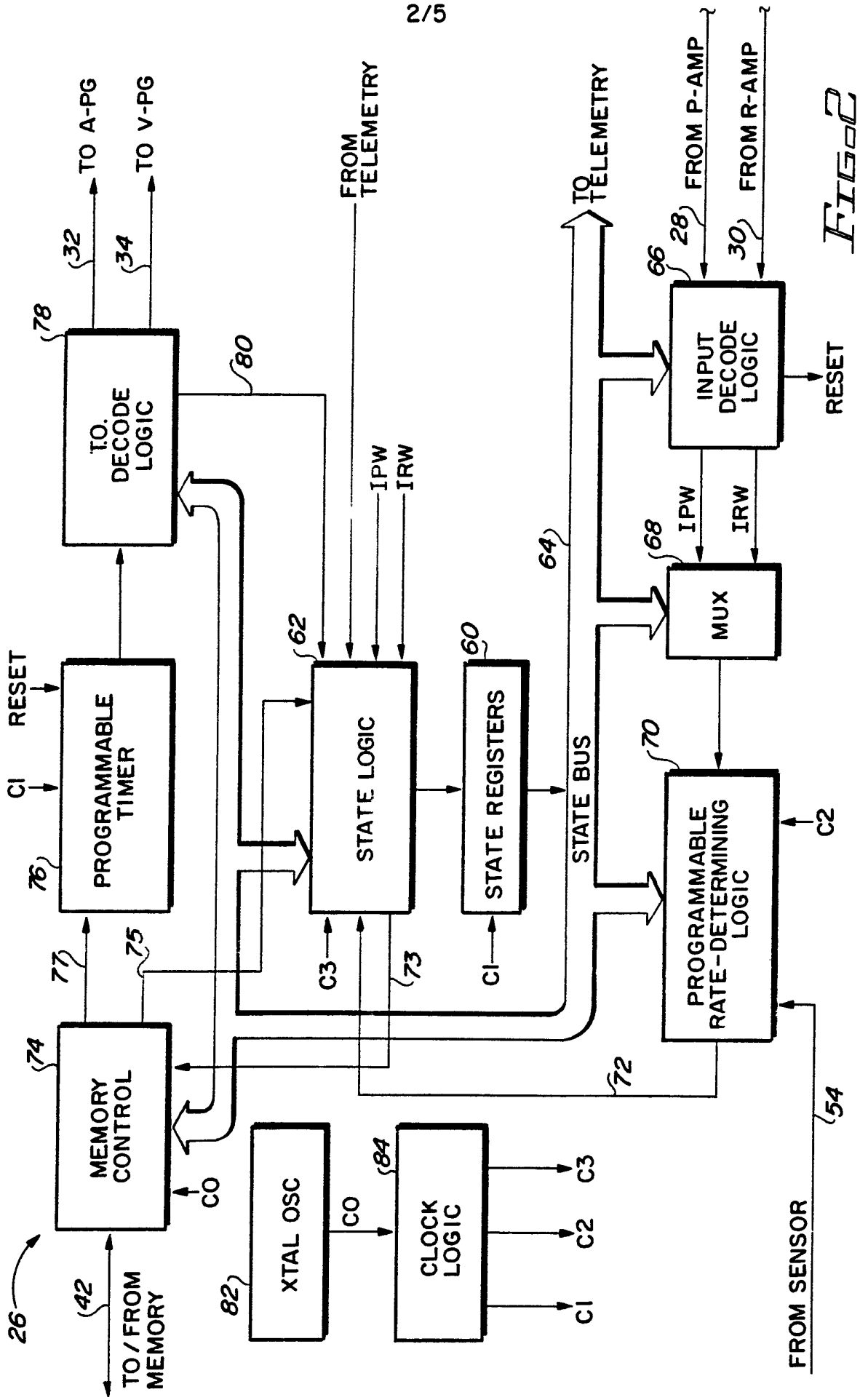
TO A-PG
TO V-PG
FROM TELEMETRY
TO TELEMETRY
FROM P-AMP
FROM R-AMP
32
34
78
80
TO. DECODE LOGIC
66
28
30
INPUT DECODE LOGIC
RESET
IPW
IRW
64
68
MUX
62
60
STATE LOGIC
STATE REGISTERS
STATE BUS
70
PROGRAMMABLE RATE-DETERMINING LOGIC
C2
RESET
CI
PROGRAMMABLE TIMER
76
77
75
C3
73
CI
74
MEMORY CONTROL
CO
72
54
FROM SENSOR
26
42
TO/FROM MEMORY
82
XTAL OSC
CO
84
CLOCK LOGIC
C3
C2
CI

Fig. 2

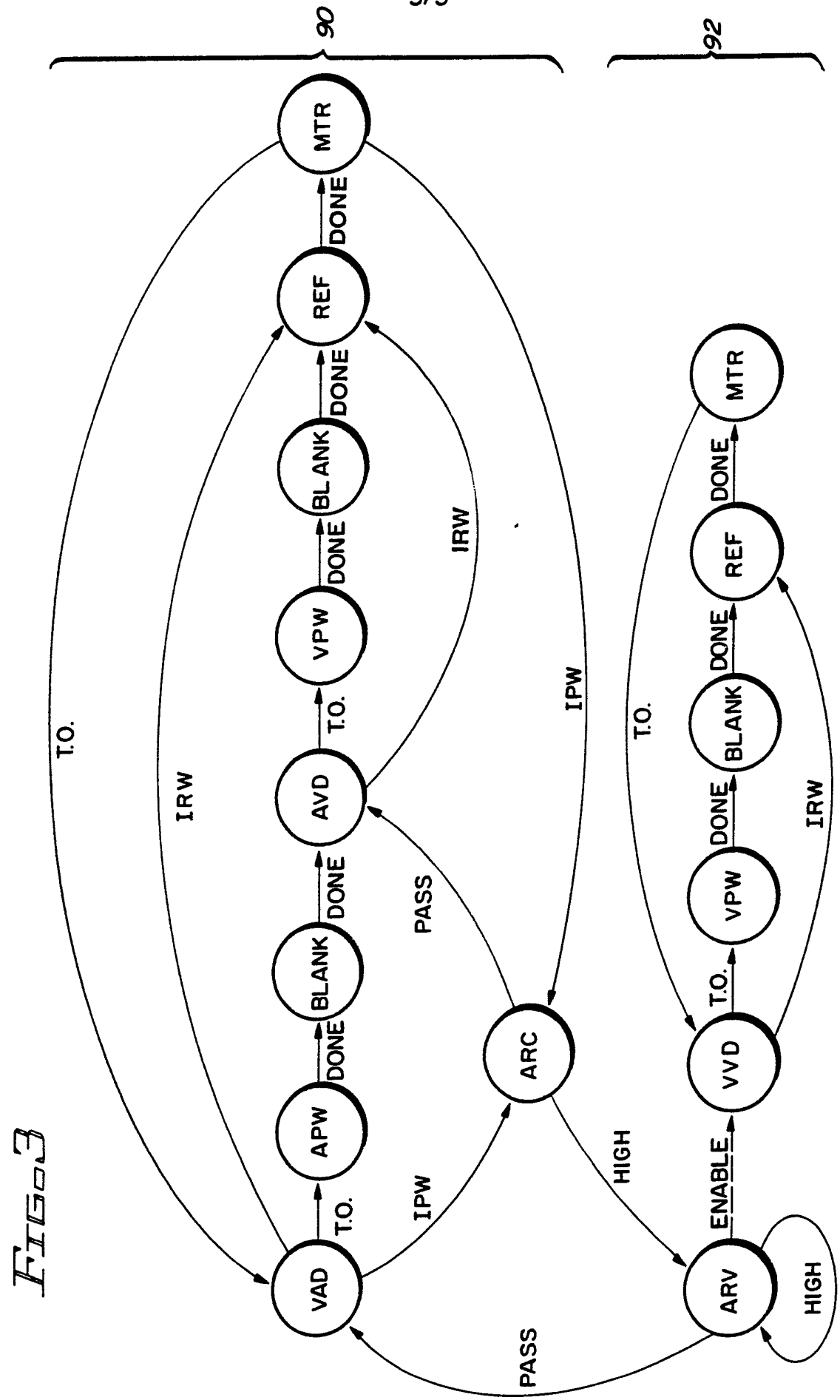
90
92
MTR
REF
BLANK
VPW
AVD
APW
BLANK
VAD
ARC
T.O.
DONE
IRW
IPW
PASS
HIGH
MTR
REF
BLANK
VPW
VVD
ARV
ENABLE
T.O.
DONE
IRW
PASS
HIGH

Fig. 3

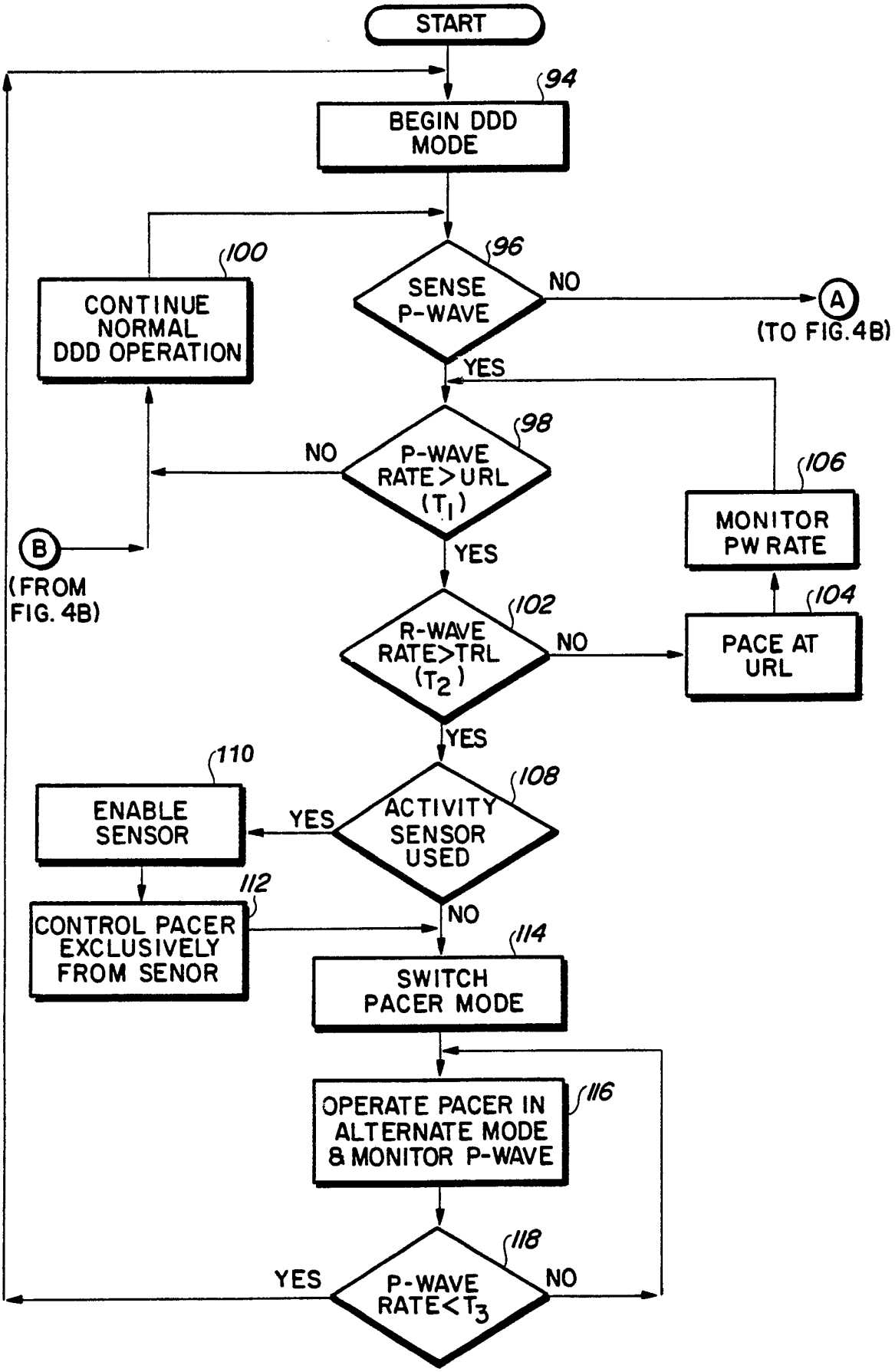
START
94
BEGIN DDD MODE
96
SENSE P-WAVE
NO
A
(TO FIG.4B)
YES
100
CONTINUE NORMAL DDD OPERATION
98
P-WAVE RATE > URL (T_1)
NO
YES
106
MONITOR PW RATE
B
(FROM FIG. 4B)
102
R-WAVE RATE>TRL (T_2)
NO
104
PACE AT URL
YES
110
ENABLE SENSOR
YES
108
ACTIVITY SENSOR USED
112
CONTROL PACER EXCLUSIVELY FROM SENOR
NO
114
SWITCH PACER MODE
116
OPERATE PACER IN ALTERNATE MODE & MONITOR P-WAVE
118
P-WAVE RATE < T_3
YES
NO

FIG-4A

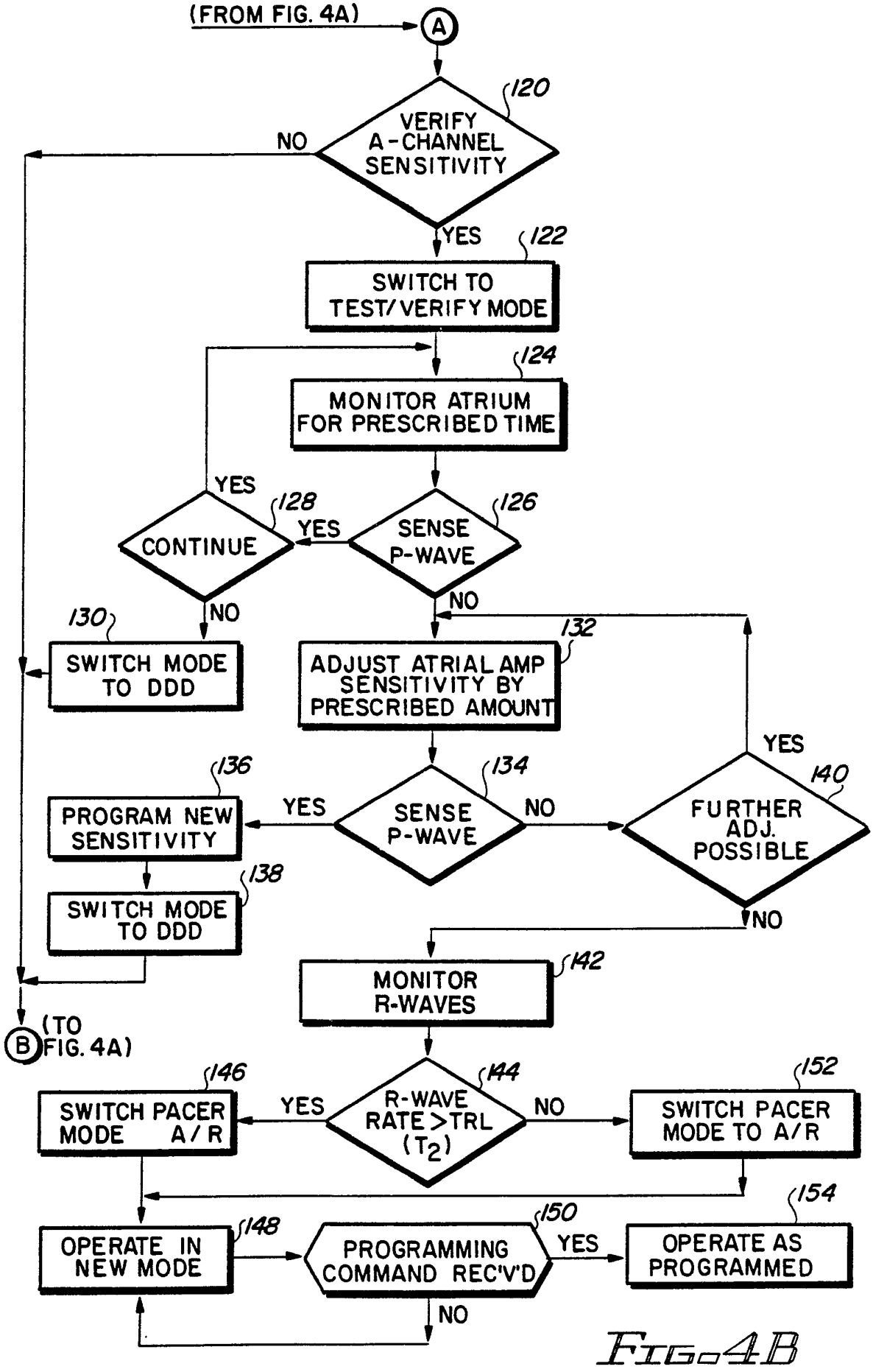
(FROM FIG. 4A)
A
120
VERIFY A-CHANNEL SENSITIVITY
NO
YES
122
SWITCH TO TEST/VERIFY MODE
124
MONITOR ATRIUM FOR PRESCRIBED TIME
YES
128
CONTINUE
YES
126
SENSE P-WAVE
NO
130
SWITCH MODE TO DDD
NO
132
ADJUST ATRIAL AMP SENSITIVITY BY PRESCRIBED AMOUNT
136
PROGRAM NEW SENSITIVITY
YES
134
SENSE P-WAVE
NO
YES
140
FURTHER ADJ. POSSIBLE
NO
138
SWITCH MODE TO DDD
142
MONITOR R-WAVES
B
(TO FIG. 4A)
146
SWITCH PACER MODE A/R
YES
144
R-WAVE RATE>TRL (T_2)
NO
152
SWITCH PACER MODE TO A/R
154
148
OPERATE IN NEW MODE
150
PROGRAMMING COMMAND REC'V'D
YES
OPERATE AS PROGRAMMED
NO

FIG. 4B

INTERNATIONAL SEARCH REPORT

International Application No PCT/US90/02648

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5): A61N 1/00
U.S. CL.: 128/419PG

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
U.S.	128/419PG, 419P

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
A	U.S., A, 4,305,396 (WITTKAMPF ET AL.) 15 December 1981, See entire document.	1-20
A	U.S., A, 4,712,556 (BAKER, JR.) 15 December 1987, See entire document.	1-20
A	U.S., A, 4,830,006 (HALUSKA ET AL.) 16 May 1989, See entire document.	1-20

* Special categories of cited documents: [15]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

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

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

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

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
01 AUGUST 1990	22 AUG 1990
International Searching Authority [1]	Signature of Authorized Officer [20]
ISA/US	G. MANUEL

Form PCT/ISA/210 (second sheet) (May 1986)