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(54) **CARDIAC PACEMAKER WITH HYSTERSIS BEHAVIOR**

4,363,325 * 12/1982 Roline et al. .
4,856,523 * 8/1989 Sholder et al. .
4,972,834 * 11/1990 Begemann et al. .

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* cited by examiner

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(*) Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

(57) **ABSTRACT**

A pacemaker having a hysteresis feature which permits intrinsic heart activity, controlled by the sinus node to resume optimally after pacing. The pacemaker has a programmable lower rate and upper rate, a programmable lower hysteresis rate (LRH) corresponding to a lower rate hysteresis interval (LRHI), and a programmable rate (IR) intermediate an upper pacing rate (UR) and a lower pacing rate (LR). A microprocessor measures the average rate of change M_{AVG} in the intervals between consecutive ventricular depolarizations, and compares the last intrinsic escape interval RR_N to the lower rate hysteresis interval (LRHI).

If the last intrinsic escape interval RR_N is longer than the lower rate hysteresis interval (LRHI), and if the value of M_{AVG} is greater than a first preselected value SL_1 but less than a second preselected value SL_2 , the pacemaker stimulates at the lower rate hysteresis (LRH) and thereafter gradually increases the pacing rate up to the intermediate rate (IR). A time counter maintains a continuous pacing at the intermediate rate (IR) for a predefined period of time, and the pacing rate is gradually decreased toward the lower pacing rate (LR).

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(22) Filed: **Oct. 24, 1995**

Related U.S. Patent Documents

Reissue of:

(64) Patent No.: **5,284,491**
Issued: **Feb. 8, 1994**
Appl. No.: **07/842,818**
Filed: **Feb. 27, 1992**

(51) **Int. Cl.**⁷ **A61N 1/362**

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

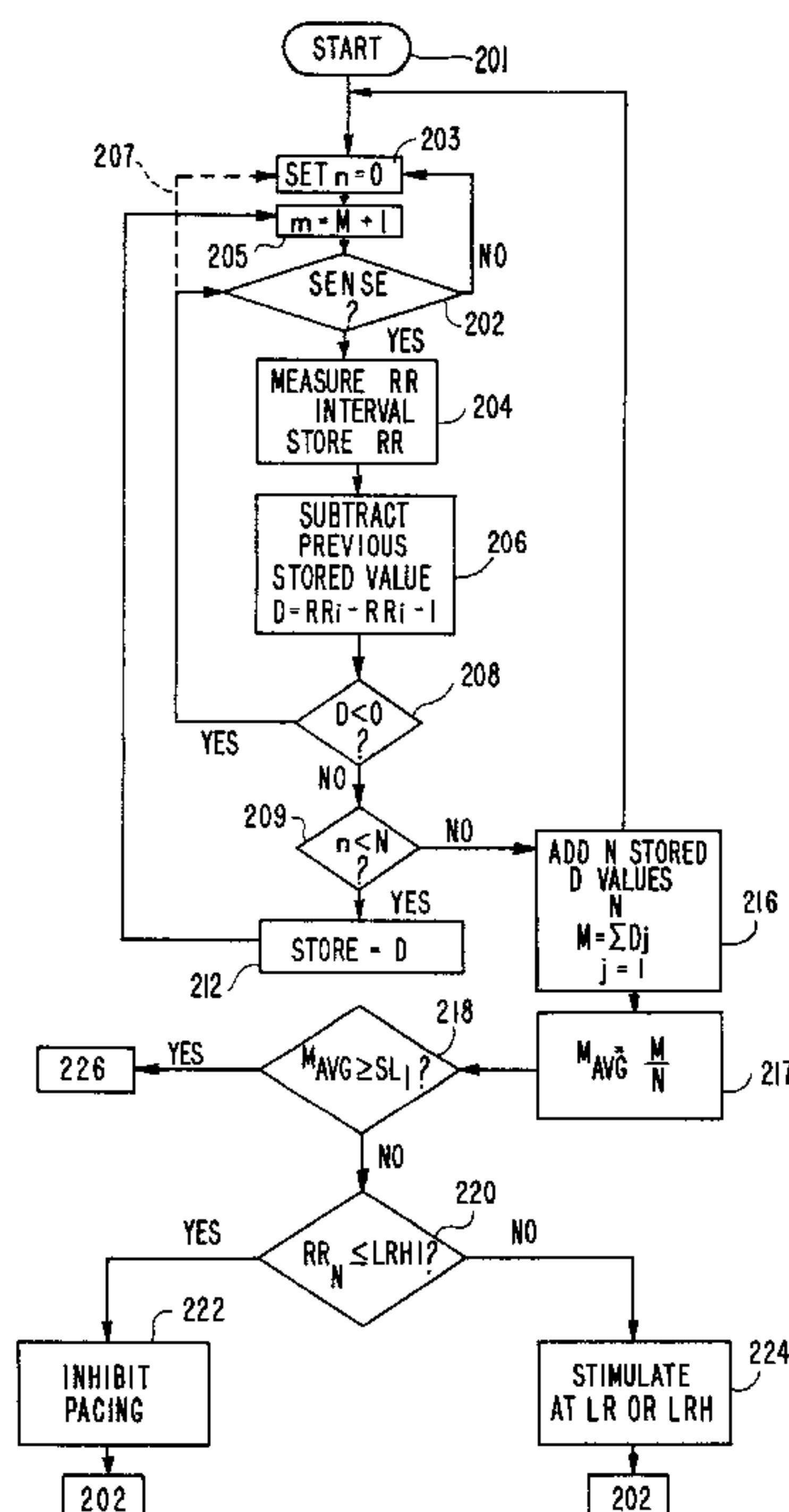
(58) **Field of Search** **607/17, 9**

(56) **References Cited**

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3,857,399 * 12/1974 Zacouto .
3,921,642 * 11/1975 Preston et al. .
4,169,480 * 10/1979 Digloy et al. .

31 Claims, 7 Drawing Sheets



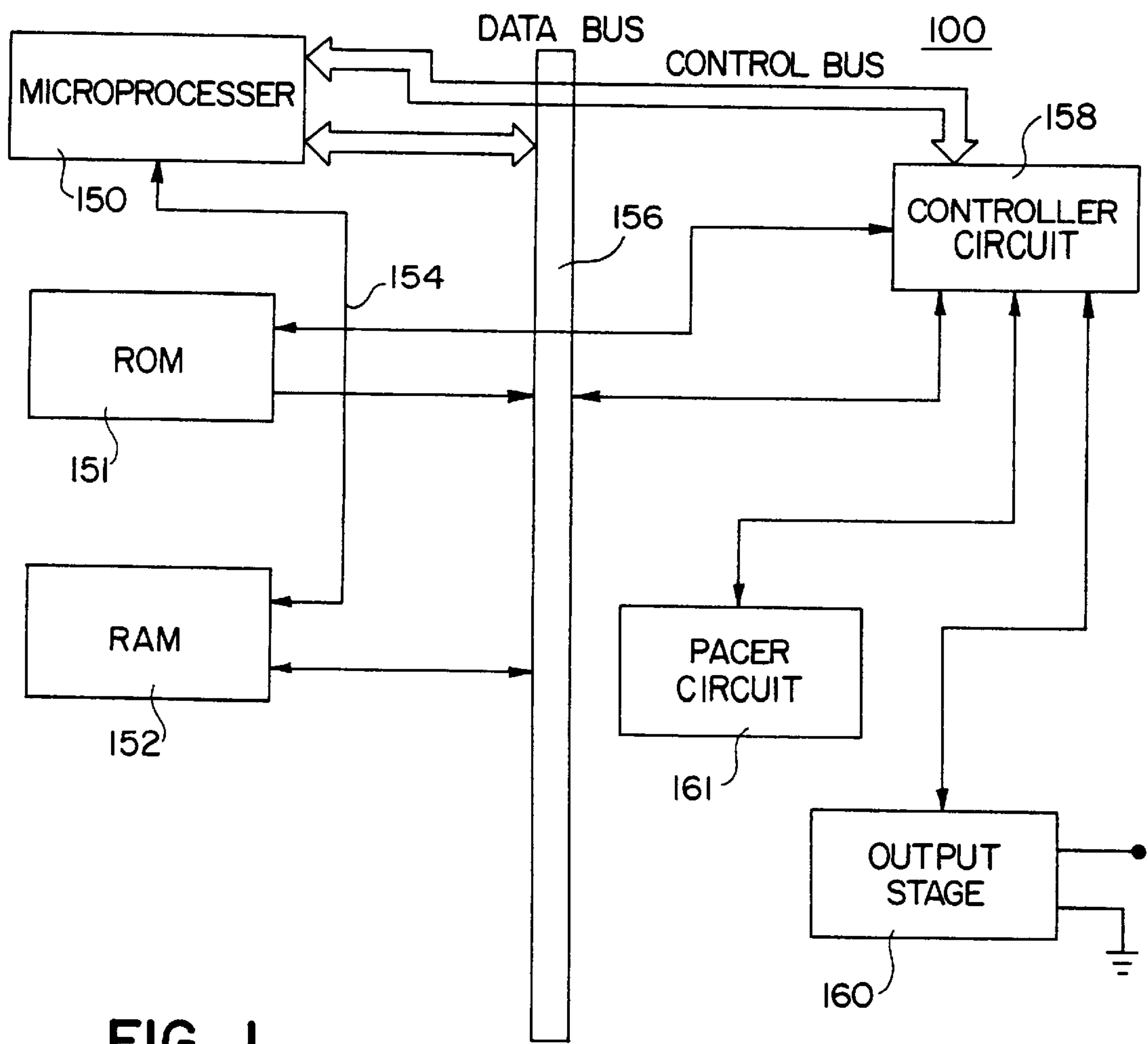


FIG. 1

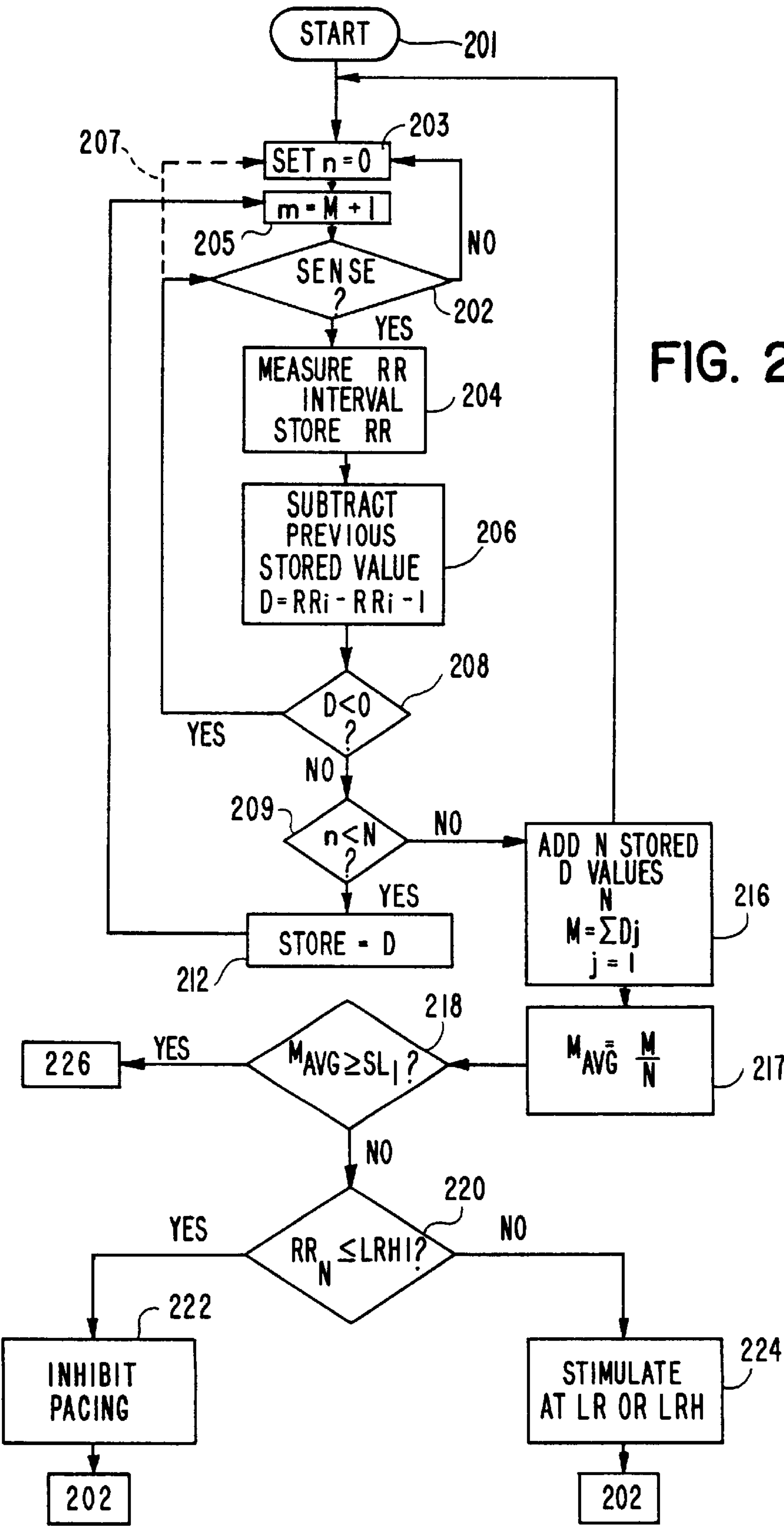
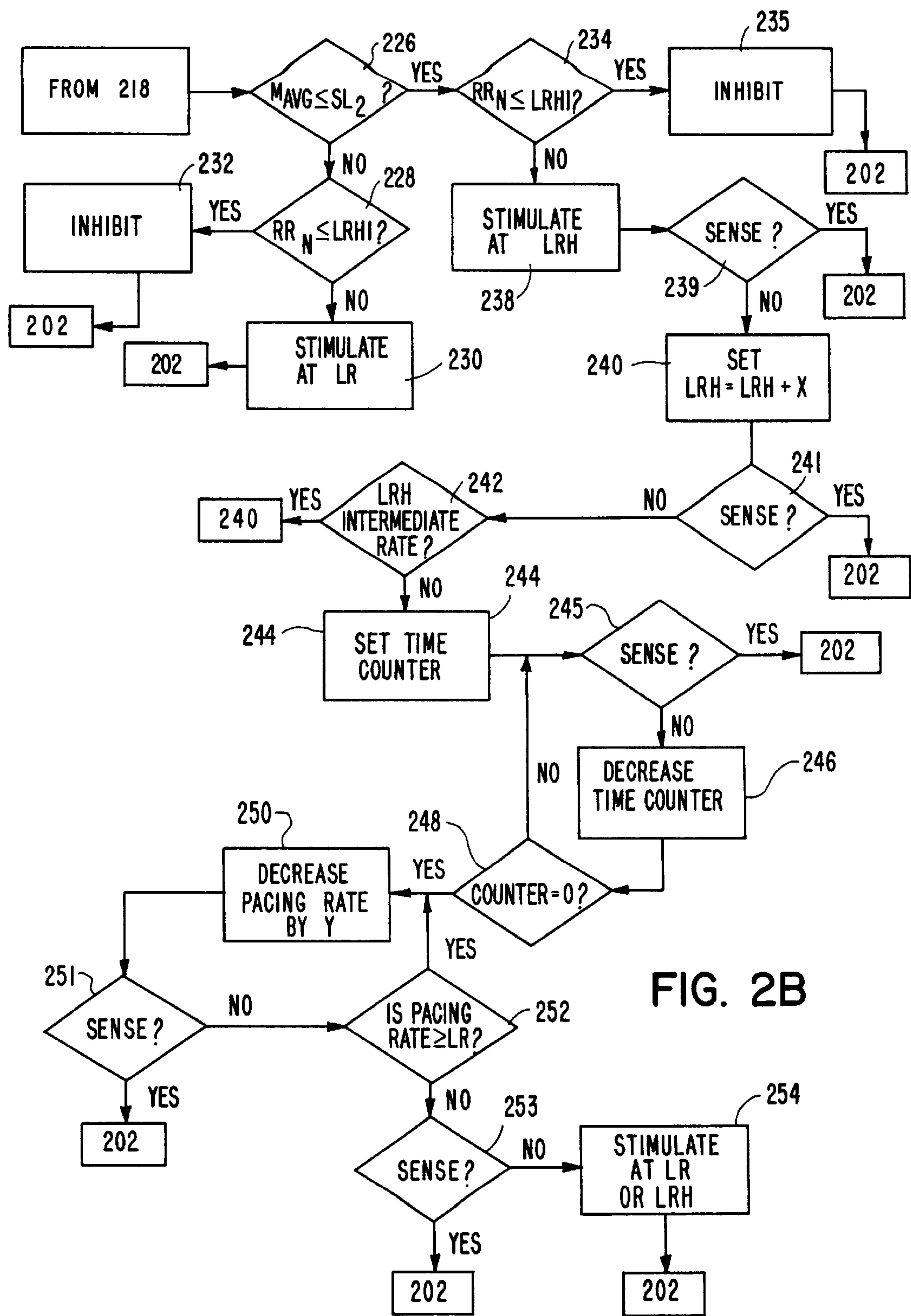


FIG. 2A



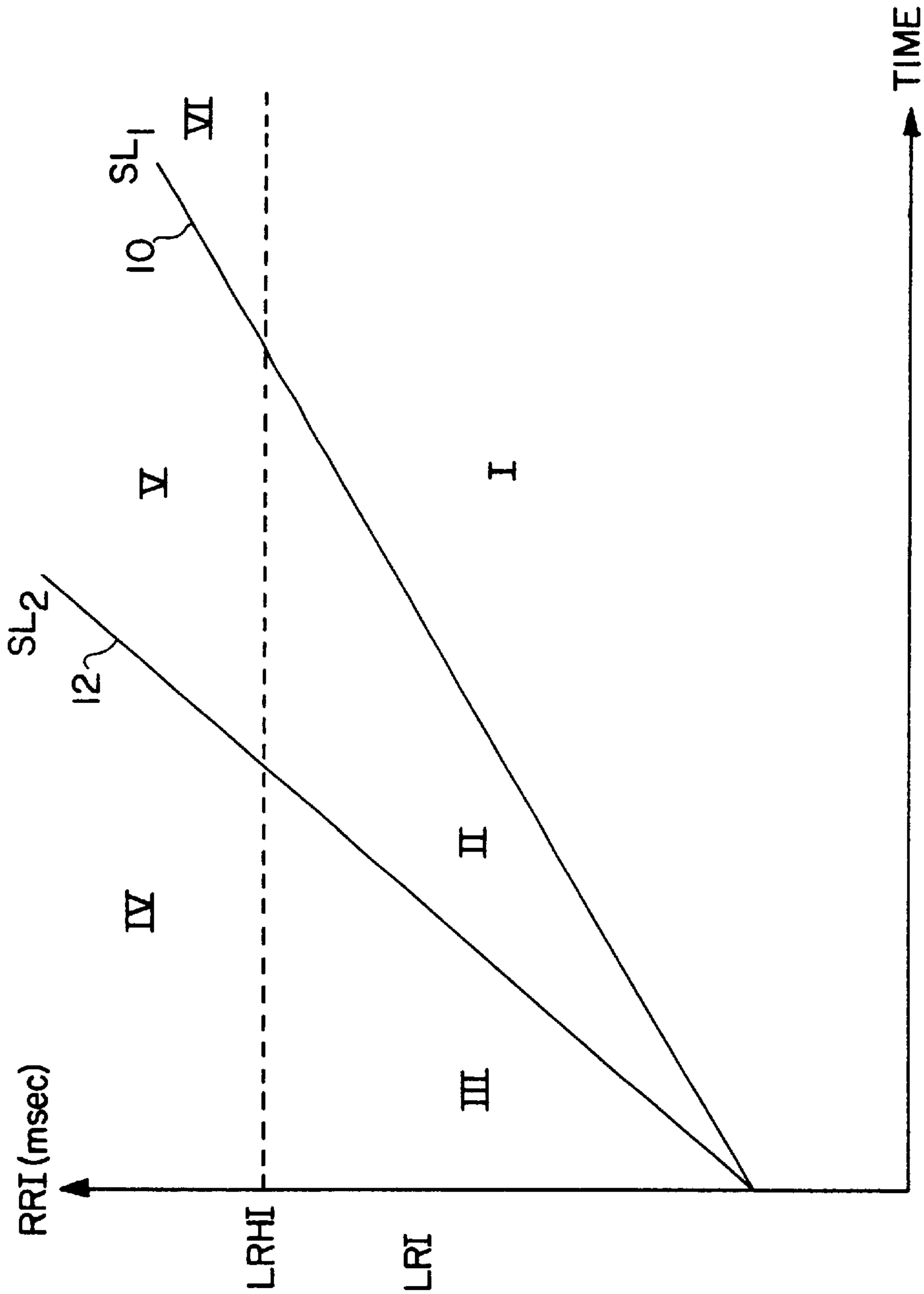


FIG. 3

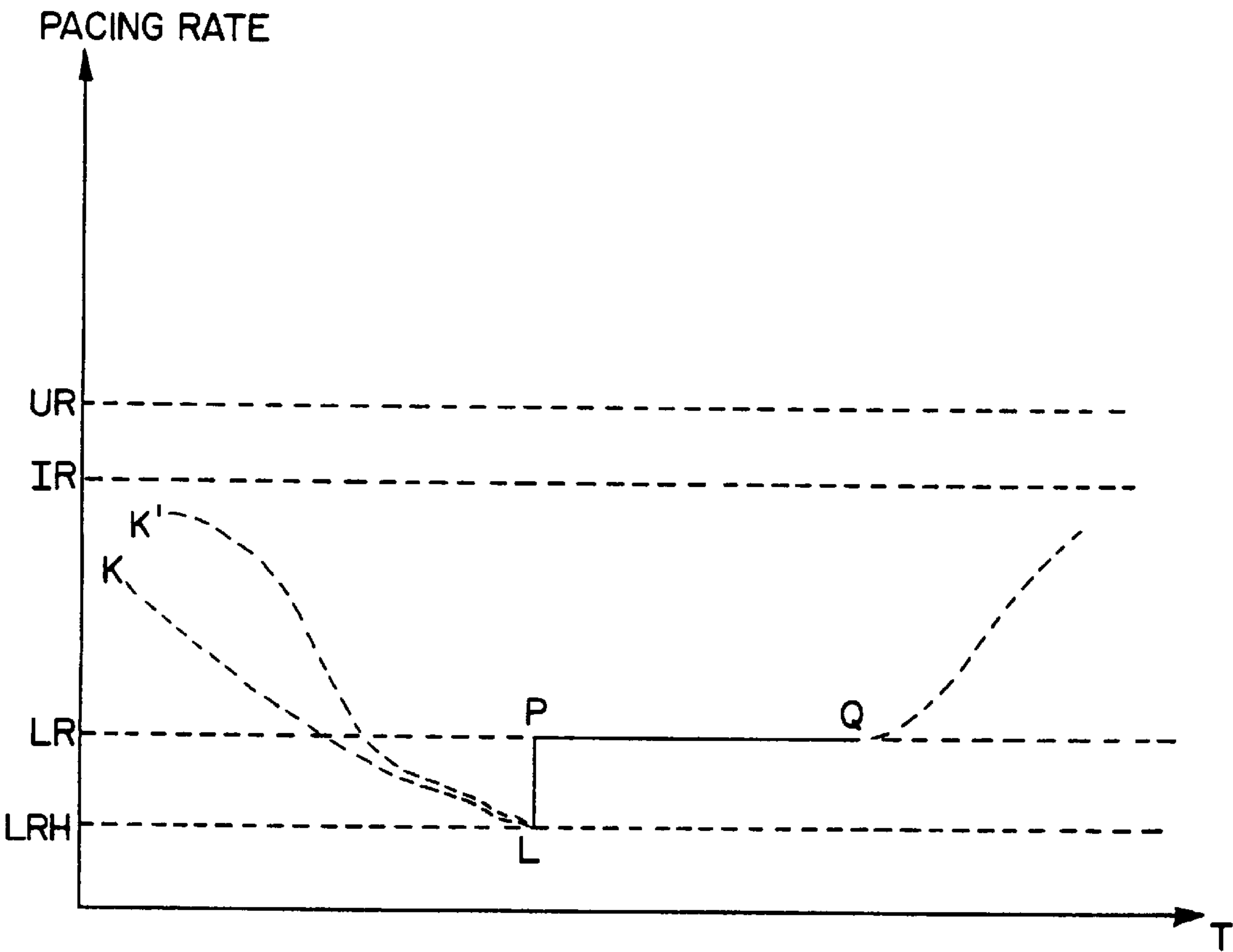


FIG. 4

--- SENSE ONLY
— PACE

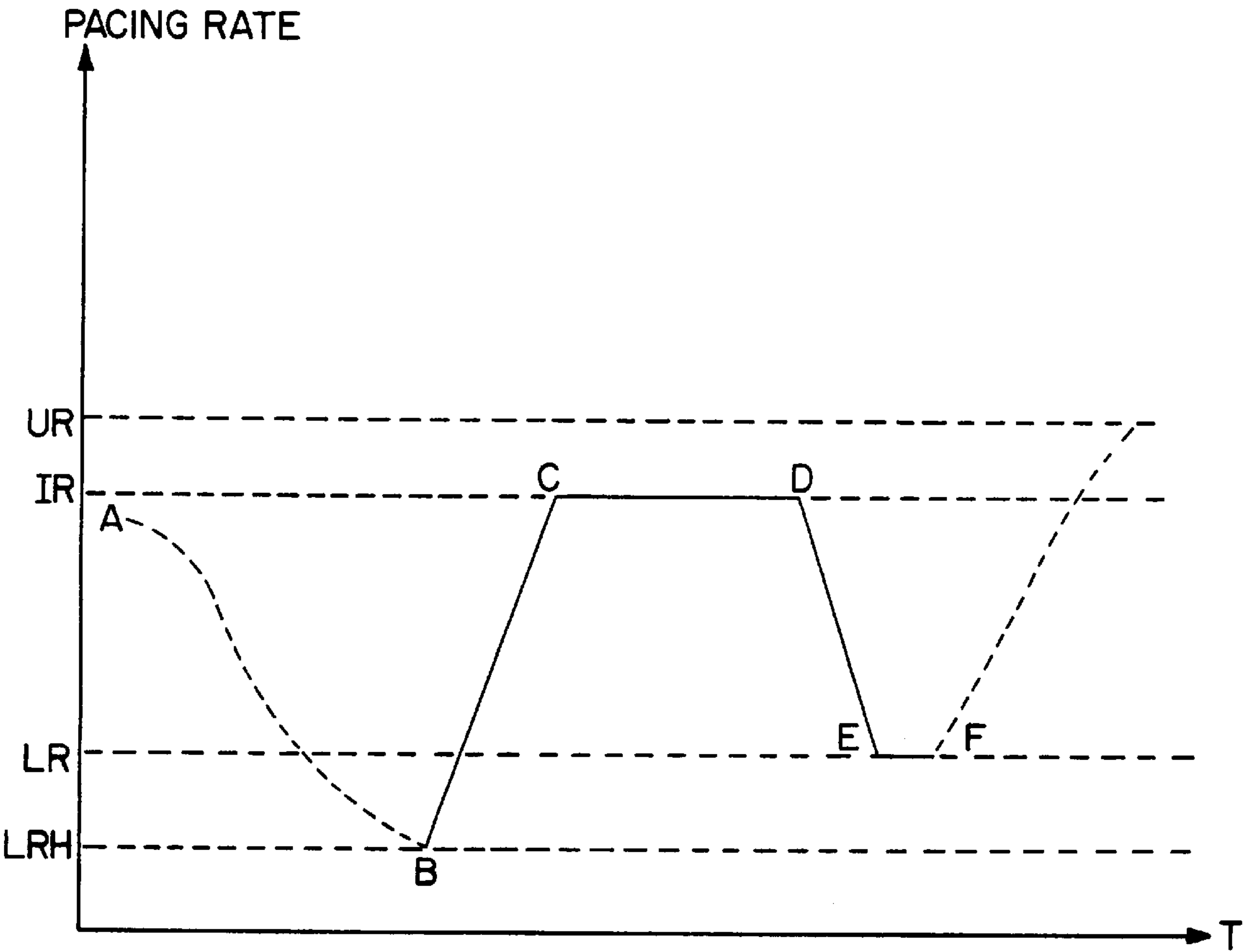


FIG. 5

--- SENSE ONLY
— PACE

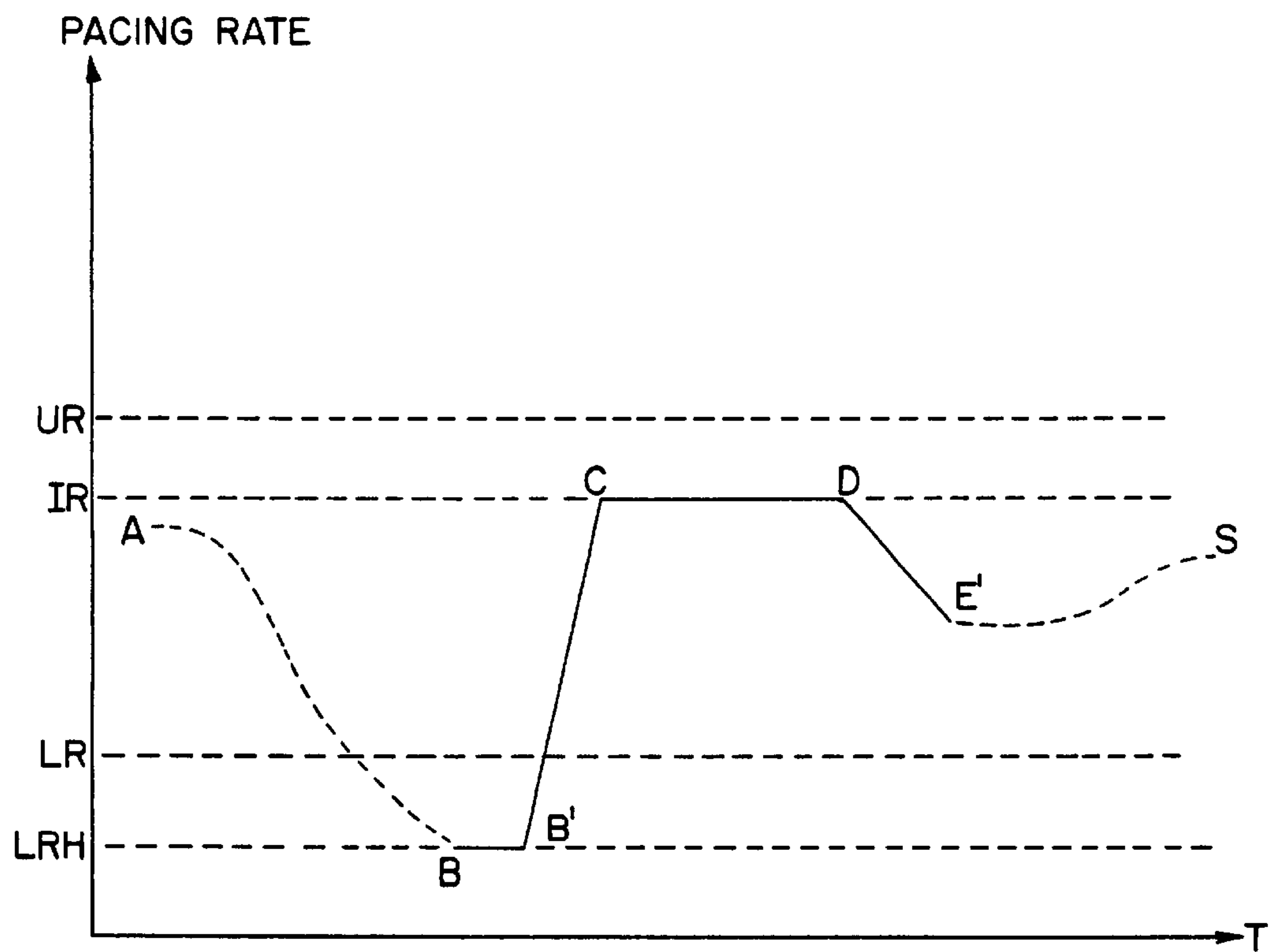


FIG. 6

--- SENSE ONLY
— PACE

CARDIAC PACEMAKER WITH HYSTERSIS BEHAVIOR

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.

BACKGROUND OF THE INVENTION

The present invention relates to cardiac pacemakers, and more specifically to a pacemaker having a selectable hysteresis feature which compensates for sinus node malfunction.

It is well known that natural heart activity, including the depolarization of the sinus node provides optimum hemodynamic performance. Atrial or ventricular stimulations induced by such devices as cardiac pacemakers, generally delay or inhibit natural heart activity by preventing the depolarization of the sinus node.

The hysteresis feature was developed to address this concern, by allowing the pacemaker to follow the sensed sinus node depolarization to a certain predetermined rate below the programmed lower rate of the pacemaker. As such, the escape interval in conventional demand pacemakers equipped with hysteresis feature, is longer than the lower rate interval, for enabling the patient's intrinsic rhythm to control the heart as long as the intrinsic rate is maintained above a predetermined minimum rate. However, in selected patients, these conventional pacemakers do not generally allow the natural heart activity to resume normally after pacing.

The following patents provide a brief historical background for the development and use of the hysteresis feature as it relates to cardiac pacing technology. U.S. Pat. No. 4,856,523, entitled "RATE-RESPONSIVE PACEMAKER WITH AUTOMATIC MODE SWITCHING AND/OR VARIABLE HYSTERESIS RATE," issued to Sholder et al, on Aug. 15, 1989, describes the inclusion of the hysteresis feature in a rate-responsive pacemaker, in an attempt to prevent competition between the pacemaker and the heart's SA node, when the anterograde conduction path is restored. The Sholder patent proposes to vary the hysteresis rate as a function of the pacemaker sensor rate, to a predetermined level upon sensing of the natural heart contraction during the escape interval, as illustrated in FIG. 3B and 4.

U.S. Pat. No. 4,363,325 entitled "MODE ADAPTIVE PACER," issued to Roline et al, on Dec. 14, 1982, and assigned to Medtronic, Inc., discloses a multiple-mode pacer which automatically switches from an atrial synchronous mode to a ventricular inhibited mode when the intrinsic atrial rate drops below a preset hysteresis rate. The Roline patent is incorporated herein by reference.

While the above cited patents and other publications and studies relating to the hysteresis feature have attempted with varying degrees of success to allow the patient's intrinsic rhythm to control, none was completely successful in causing the natural heart activity to resume optimally after pacing.

SUMMARY OF THE INVENTION

Briefly, the above and further objects and features of the present invention are realized by providing a new and improved pacemaker having a hysteresis feature which permits intrinsic heart activity, controlled by the sinus node to resume optimally after pacing.

The pacemaker has a programmable lower rate and upper rate, a programmable lower hysteresis rate (LRH) corresponding to a lower rate hysteresis interval (LRHI), and a programmable rate (IR) intermediate an upper pacing rate (UR) and a lower pacing rate (LR). A microprocessor measures the average rate of change in the intervals between consecutive ventricular depolarizations M_{AVG} , and compares the last intrinsic escape (RR_N) interval to the lower rate hysteresis interval (LRHI).

If the last intrinsic ventricular interval (RR_N) will be longer than the lower rate hysteresis interval (LRHI), and if the value of M_{AVG} is greater than a first preselected value SL_1 but less than a second preselected value SL_2 , the pacemaker stimulates at the lower rate hysteresis (LRH) and thereafter gradually increases the pacing rate up to the intermediate rate (IR) while the pulse generator is in the demand mode. A time counter maintains a continuous pacing at the intermediate rate (IR) for a predefined period of time, and the pacing rate is gradually decreased down to the lower pacing rate (LR).

The accompanying Table I summarizes the features offered by the present invention, and correlates these features to FIGS. 2A through 6.

TABLE 1

FIG. 2A (Step)	FIG. 2B (Step)	FIG. 3 (Region)	FIG. 4 (Curve)	FIG. 5 (Curve)	FIG. 6 (Curve)
220, 222		I	KL		
220, 224		VI	LPQ		
	226, 228, 232	III	K'L		
	226, 228, 230	IV	LPQ		
	226, 234, 236	II		AB	AB
	226, 234, 238-254	V		BCDEF	BB'CDE'R

BRIEF DESCRIPTION OF THE DRAWINGS

The above and other options, features and advantages of the present invention will be more apparent from the following more particular description thereof, presented in conjunction with accompanying drawings, wherein:

FIG. 1 is a block diagram showing the primary functional blocks of the pacemaker according to the present invention;

FIGS. 2A and 2B are flow charts of a simplified software program suitable for use in the pacemaker of FIG. 1;

FIG. 3 is an illustration of two exemplary generally increasing limit functions SL_1 and SL_2 which determine the behavior of the pacemaker according to the software program of FIGS. 2A and 2B;

FIG. 4 is a response curve illustrating the variation of the pacing rate according to the present invention;

FIG. 5 is another response curve illustrating pacing rate variation according to the present invention; and

FIG. 6 is yet another response curve illustrating pacing rate variation according to the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the drawings and more particularly to FIG. 1 thereof, there is illustrated a block diagram of the

components of the pacemaker **100** of the present invention. Block **150** illustrates a microprocessor chip, such as the CDP **1802** microprocessor made by RCA. The microprocessor **150** is connected to a ROM memory **151** and to a RAM memory **152** via a data bus **156**. An address bus **154** interconnects the ROM memory **151**, the RAM memory **152**, and a controller circuit **158**. The controller circuit **158**, in turn, controls a pacer circuit **161** and a pacemaker output stage **160** for stimulating the heart. The pacemaker **100** could be used for single chamber or dual chamber pacing.

FIGS. **2A** and **2B** together illustrate the flow diagram of a program **200** which is stored in the ROM memory **151**, and which is run once each cycle in the pacemaker **100**. Alternatively, the program **200** could be stored in the RAM memory **152**. The program **200** does not contain all the steps which are carried out by the microprocessor **150**, but it includes those steps that illustrate the operation of the pacemaker **100** according to the present invention. Several variables of the software-controlled operations can be reprogrammed through the RAM memory **152**.

Before proceeding with a more detailed explanation of the present invention, it would be helpful to review the following definitions:

"Intrinsic rhythm" or "intrinsic rate" of the heart is the rate at which the heart naturally beats on its own, without being stimulated by a pacemaker-provided stimulus.

"Hysteresis" means extension of the range of rates at which inhibition of the pacemaker pulses will occur. The base pacing interval is increased by the hysteresis interval. Thus, hysteresis provides a longer escape interval, thereby giving the heart an opportunity to beat on its own before the pacer provides stimulation pulses.

"Pacing Rate" is the rate at which the stimulation pulses are provided from the heart from the pacemaker.

Starting at step **201**, the program **200** is initiated, and the intrinsic ventricular depolarizations are sensed at **202**. While the program **200** uses ventricular events for carrying out the invention, it should be understood that atrial events can alternatively be used.

The program **200** measures, at step **204**, the intrinsic escape interval, such as the RR interval between two successive sensed ventricular events, and calculates, at step **206**, a parameter "D", as follows:

$$D = RR_i - RR_{i-1}, \quad (1)$$

where RR_i is the RR interval which has been recently measured at step **204**; and RR_{i-1} is the RR interval preceding RR_i . It therefore follows that the parameter D is indicative of the rate of change of the RR interval.

In this respect, if D were found to have a positive value, it is an indication that the RR interval is increasing with time, and consequently the intrinsic rate of the heart is dropping. The reverse holds true where D has a negative value, indicating that the RR interval is decreasing and that the intrinsic rate is increasing. Additionally, the absolute value of D represents the rate of change of the intervals of the intrinsic ventricular depolarizations, which is also illustrated by the slope the curve AB in FIGS. **5** and **6**, as it will be described later in greater detail.

If at step **208** the value of D is found to be negative, this value will not be used since it represents an increase in the intrinsic ventricular depolarization rate, and the above subroutine, including steps **202**, **204**, **206** and step **208**, is repeated until a positive value of D is found. The dashed line

207 indicates that if the value of D is found to be negative, then the attending physician will have the option to either cause the software to set $n=0$, at step **203**, or to restart at step **202**. The preferred embodiment of the present invention relates principally to precipitous drops in heart rates, and consequently only positive values of D are added and stored at **212** by the random access memory RAM **152**.

While the preferred embodiment includes adding only those positive values of D, it will become apparent to those skilled in the art that consecutive D values could alternatively be added. The feature of selecting between consecutive and positive D values is a programmable feature, and is selectable by the attending physician.

In order to detect and ascertain the occurrence of precipitous heart rate drops, the software **200** calculates the average rate of increase M_{AVG} of a preselected number "N" of RR intervals. Preferably, M_{AVG} is calculated over a predetermined period of time "T". If during that period T, the value of M_{AVG} is less than a first limit function SL_1 , then this is an indication that the intrinsic heart rate has not dropped rapidly enough to warrant the use of corrective measures, such as the activation of the hysteresis feature. If on the other hand, the value of M_{AVG} reaches or exceeds the first limit SL_1 , but is less than a second limit SL_2 , the pacemaker is instructed to take appropriate measures, as will be described later in greater detail.

To achieve this function, the program **200** stores the calculated positive values of D, at step **212**, and counts the number of events "n" indicative of a positive D value. When the count reaches a preprogrammed number "N" of stored beats or reaches the time period T, the program **200** calculates the sum "M" of the N stored values D, as follows:

$$M = \sum_{j=1}^N D_j, \quad (2)$$

where j is an integer that varies between 1 and N; and where N is the number of stored beats.

The value of M is then averaged at step **217** over the number of stored beats N, as follows:

$$M_{AVG} = \frac{M}{N} \quad (3)$$

In the preferred mode of the present invention the above parameters are assigned the following values:

N=6 beats.

T=15 seconds. It should, however, be understood that different values or ranges of values can alternatively be employed within the scope of the invention.

Digressing from the flow chart of FIG. **2A**, and turning to FIG. **3**, there is a shown lower limit function SL_1 and an upper limit function SL_2 which are identified by the numeral references **10** and **12**, and which divide the quadrant into six regions: I, II, III, IV, V and VI. Each one of these regions will now be described in greater detail in relation to FIGS. **2A** through **5**. The horizontal coordinate axis represents time "t", and the vertical coordinate axis represents RR intervals "RRI".

As used in this specification, the LRI and LRHI parameters in the following context:

"LRI" means the Lower Rate Interval which corresponds to the lower pacing rate "LR" of the pacemaker, where LRI in milliseconds equals 60,000 divided by LR in beats per minute. LR is typically programmed to 70 beats per minute.

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"LRHI" means the Lower Rate Hysteresis Interval that corresponds to the lower rate hysteresis "LRH" which is typically programmed to 50 beats per minute. LRHI in milliseconds equals 60,000 divided by LRH in beats per minute.

By comparing the average rate of change M_{AVG} to the programmable limit functions SL_1 and SL_2 , it would be possible to identify the region which corresponds to the mode of operation of the pacemaker 100. SL_1 and SL_2 are boundaries between regions defining distinctly different operation of the pacemaker 100. For clarity purposes, the six regions are defined as follows:

"Region I" is the portion of the quadrant defined by the lower limit function SL_1 and by the RRI and time axes. The pacemaker 100 operates in Region I whenever the value of M_{AVG} is less than SL_1 ; and the last intrinsic ventricular escape interval RR_N is shorter than the lower rate hysteresis interval LRHI. Pacing is inhibited in Region I, as illustrated by the curve KL in FIG. 4, and by step 222 of FIG. 2A. The curve KL shows the heart rate decreasing at a slow rate.

"Region II" is the portion of the quadrant defined by the limit functions SL_1 and SL_2 , and by the lower rate hysteresis interval LRHI axis. The pacemaker 100 operates in Region II whenever the value of M_{AVG} is greater than SL_1 , but less than SL_2 ; and the last intrinsic ventricular escape interval RR_N is shorter than LRHI. Pacing is inhibited in Region II, as illustrated by the curve AB in FIGS. 5 and 6, and by step 236 of FIG. 2B. The curve AB shows the heart rate decreasing at an intermediate rate.

"Region III" is the portion of the quadrant defined by the upper limit function SL_2 , by the LRI axis and by the lower rate hysteresis interval LRHI axis. The pacemaker 100 operates in Region III whenever the value of M_{AVG} is greater than SL_2 ; and the last intrinsic escape interval RR_N is shorter than LRHI. Pacing is inhibited in Region III, as illustrated by the curve K'L in FIG. 4, and by the step 232 of FIG. 2B. The curve K'L shows the heart rate decreasing precipitously, as opposed to curve KL, which represents a more modest heart rate drop in Region I.

"Region IV" is the portion of the quadrant above the lower rate hysteresis interval LRHI axis, and defined by the RRI axis and by the upper limit function SL_2 . The pacemaker 100 operates in Region IV whenever the value of M_{AVG} is greater than SL_2 ; and the last intrinsic escape interval RR_N will be longer than LRHI. As illustrated by the curve LPQ in FIG. 4, and by the step 230 of FIG. 2B, pacing is carried out at the lower rate LR. It should however be understood that pacing could be alternatively carried out at the lower rate hysteresis LRH.

"Region V" will be the portion of the quadrant above the lower rate hysteresis interval LRHI axis, between the two limit functions SL_1 and SL_2 . The pacemaker 100 operates in Region V whenever the value of M_{AVG} is less than SL_2 but greater than SL_1 , and the last intrinsic escape interval RR_N is longer than LRHI. As illustrated by the curves BCDEF and BB'CDE'R in FIGS. 5 and 6 respectively, and by steps 238 through 254 of FIG. 2B, pacing starts at the lower rate hysteresis rate LRH and gradually increases until the pacing rate reaches an intermediate pacing rate IR. Pacing at IR is maintained for a predetermined period of time, and is thereafter gradually reduced until it reaches the lower rate LR. Pacing is maintained at the lower rate until the intrinsic rate exceeds the pacemaker lower rate, as illustrated by the curve FG in FIG. 5. The pacemaker operation in Region V is triggered by an intermediate rate of decrease in the intrinsic heart rate.

"Region VI" is the portion of the quadrant defined by the lower limit function and by the lower limit function SL_1 . The

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pacemaker 100 operates in Region VI whenever the value of M_{AVG} is less than SL_1 ; and the last intrinsic ventricular escape interval RR_N will be longer than the lower rate hysteresis interval LRHI. As illustrated by the curve LPQ in FIG. 4, and by the step 224 of FIG. 2A, pacing is carried out at the lower rate LR. It should however be understood that pacing could be alternatively carried out at the lower rate hysteresis LRH.

Returning now to FIG. 2A, the program 200 compares M_{AVG} to SL_1 and step 218. If M_{AVG} is less than SL_1 , then a further determination is made at step 220 whether the last ventricular intrinsic escape interval RR_N is less than or equal to LRHI. If it is, the pacemaker 100 operates in Region I, and pacing is inhibited, as indicated by step 222 in FIG. 2A and by the response curve KL in FIG. 4.

If the intrinsic escape interval (RR_N) is determined at step 220, to be equal to or tend to exceed LRHI, and if there is no sensed event at a shorter interval, while the pacemaker is still in the demand mode, the pacemaker 100 will operate in Region IV, and stimulation is carried out at the lower pacing rate LR, as illustrated by the curve LPQ in FIG. 4. The curves in FIGS. 4, 5 and 6 which are drawn in dashed lines indicate that pacing is inhibited, while the curves drawn in solid lines indicate that pacing is occurring.

Returning now to step 218 in the flow chart of FIG. 2A, if the program 200 determines that M_{AVG} is greater than or equal to SL_1 then a further determination is made at step 226 whether M_{AVG} is less than or equal to SL_2 . If M_{AVG} is found to be greater than SL_2 then the pacemaker 100 will operate in either Region III or Region IV. A further decision is made at step 228 whether the last intrinsic escape interval RR_N is less than or equal to the lower rate hysteresis interval (LRHI).

If the program 200 determines that RR_N is less than or equal to LRHI then the pacemaker 100 will operate in Region III, and as indicated by step 232 of FIG. 2B, and by the curve K'L in FIG. 4, pacing will be inhibited. If on the other hand, it is determined at step 228, that RR_N is greater than LRHI, then the pacemaker 100 will operate in Region IV and as indicated by step 230 of FIG. 2B, and by the curve LPQ in FIG. 4, pacing is carried out at the lower pacing rate (LR).

The pacemaker 100 identifies and reacts to intermediate drops in the intrinsic heart rate, whenever M_{AVG} is found to be intermediate the limit functions SL_1 and SL_2 , as follows:

$$SL_1 \leq M_{AVG} \leq SL_2 \quad (4)$$

In the above condition, the pacemaker is caused to pace at a gradually increasing pacing rate until it reaches a predetermined intermediate pacing rate (IR) which is lower than, or in certain circumstances, equal to, the upper pacing rate (UR). Demand pacing is maintained at the intermediate pacing rate (IR) for a predetermined period of time, and is thereafter reduced gradually.

With reference to FIG. 2B, the program 200 determines at step 234 whether the last intrinsic escape interval RR_N is less than or equal to LRHI. If it is, then the pacemaker 100 will operate in Region II, and as indicated by step 236, and by the curve AB in FIGS. 5 and 6, pacing is inhibited.

If however, it is determined at step 234 that RR_N will tend to be longer than LRHI, then the condition set forth in equation (6) above is satisfied, and the pacemaker 100 will operate in Region V, and will respond by pacing at the lower rate hysteresis (LRH) for a predetermined period of time or a preset number of beats, as illustrated by the dashed line BB' in FIG. 6, and by step 238 in FIG. 2B.

It should however be understood that the pacemaker **100** could alternatively bypass step **238** and start pacing along curve BC (FIG. 5), with one paced beat at the lower rate hysteresis (LRH). In this respect, pacing is started at point B (FIG. 5) and the pacing rate is incrementally increased until it reaches the intermediate rate (IR). The intermediate rate IR is programmable, and could be changed by the attending physician. The incremental increase in the pacing rate is illustrated by the curves BC in FIGS. 5 and 6. During this period, the pacemaker **100** is in the inhibited mode for single chamber pacemakers, or in the DDD or fully automated mode for dual chamber pacemakers.

The incremental increase of the pacing rate is achieved by steps **240** through **244**, whereby the value of the pacing rate is incrementally increased by a center increment value X (step **240**), and a determination is made at step **242** whether the pacing rate is less than or equal to IR. Once IR is reached, then, as indicated by step **244**, a time counter is set to maintain the continuous pacing at that intermediate rate (IR) for a preselected programmable period of time, such as for five minutes. This continuous pacing at the intermediate rate is illustrated by curve CD in FIGS. 5 and 6. If during the execution of the subroutine **244** through **248**, an intrinsic rhythm is sensed at **245**, then the intrinsic rate prevails, and pacing is inhibited.

Once the counter time lapses, then, as illustrated by the curves DE and DE' in FIG. 5 and 6 respectively, the pacing rate is gradually decreased from the intermediate pacing rate (IR), toward the lower pacing rate (LR). This decrement is achieved by the subroutine **250-252**, where the pacing rate is decreased by a counter decrement value Y until the pacing rate reaches the lower rate LR.

If decremental pacing is maintained until it reaches the lower rate LR, the pacemaker **100** starts pacing at that lower rate, as illustrated by the curve EF in FIG. 5, and the routine **200** is repeated. If an intrinsic rhythm is sensed at any time during the decremental change (curve DE') in the pacing rate, then the intrinsic rate prevails, and pacing is inhibited, as illustrated by the curve E'RS in FIG. 6. The subroutine **200** is thereafter repeated.

It is therefore clear that the new approach described in the present invention teaches away from the conventional hysteresis response feature. In the present invention, whenever an intermediate drop in the heart rate occurs and the hysteresis feature is activated, the natural heart rate resumes and is tracked until it reaches the hysteresis rate. Thereafter, the pacing rate is increased until the intermediate rate (IR) is reached. Pacing at that intermediate rate is maintained for a predetermined period of time, and thereafter allowed to gradually decay toward the lower rate.

It should become apparent to those skilled in the art after reviewing the present description, that the present invention can be made an integral part of single chamber and dual chamber pacemakers which operate in one or more of the programmed modes: SSI, SSIR, DDD, DDDR, DVI, DVIR, DDI and/or DDIR. The present hysteresis feature can be applied to the atrial and/or ventricular channels of a dual chamber pacemaker.

While the following ranges reflect exemplary values of IR, LR, UR, LRH, SL_1 and SL_2 , it should be understood to those skilled in the art that other values and ranges can also be employed and/or programmed.

$$100 \text{ bpm} \leq UR \leq 150 \text{ bpm.}$$

$$80 \text{ bpm} \leq IR \leq 100 \text{ bpm.}$$

$$60 \text{ bpm} \leq LR \leq 80 \text{ bpm.}$$

$$40 \text{ bpm} \leq LRH \leq 60 \text{ bpm.}$$

$$2\% \leq SL_1 \leq 10\%.$$

$$5\% \leq SL_2 \leq 20\%.$$

$$4 \text{ beats} \leq N \leq 16 \text{ beats.}$$

While particular embodiments of the present invention have been disclosed, it is to be understood that various different modifications are possible and are contemplated within the scope and spirit of the specification, drawings, abstract, and appended claims.

What is claimed is:

1. In a pacemaker having a programmable lower rate and upper rate, a programmable lower rate hysteresis (LRH) corresponding to a lower rate hysteresis interval (LRHI), and a programmable intermediate pacing rate (IR) the improvement comprising:

- A. means for measuring rate of change M_{AVG} of successive cardiac intrinsic escape intervals;
- B. means for comparing M_{AVG} to a first predefined limit SL_1 ;
- C. means for comparing the last intrinsic escape interval to the lower rate hysteresis interval (LRHI); and
- D. means for stimulating a heart at the lower rate hysteresis (LRH) and for gradually incrementing a pacing rate until the pacing ratio reaches the intermediate pacing rate (IR) if the last intrinsic escape interval is longer than the lower rate hysteresis interval (LRHI) and if said M_{AVG} is greater than SL_1 .

2. The pacemaker according to claim 1 further comprising:

- A. time counter means for maintaining continuous pacing at the intermediate rate (IR) for a predefined period of time; and
- B. means for allowing gradual decay of the pacing rate after said selected period of time has lapsed.

3. The pacemaker according to claim 2, wherein said selected programmable time is set equal to five minutes.

4. The pacemaker according to claim 1, wherein said means for measuring the rate of change M_{AVG} comprising:

- A. means for measuring intervals between two successive ventricular depolarizations (RR intervals); and
- B. means for averaging the rate of change M_{AVG} of said successive RR intervals.

5. The pacemaker according to claim 4, wherein said means for averaging the rate of change of said RR intervals comprises:

- A. means for calculating a difference D between two successive RR intervals;
- B. means for comparing said difference D to a predetermined reference value;
- C. means for storing those values of D which are greater than said reference value;
- D. means for calculating a sum M of N stored values of D, wherein N is a predetermined positive integer; and
- E. means for setting M_{AVG} equal to M/N .

6. The pacemaker according to claim 5, wherein said means for averaging M_{AVG} comprising means for averaging the values of D greater than said reference value over a predefined period of time.

7. The pacemaker according to claim 6, wherein said reference value is zero, and wherein only positive values of D are stored and added.

8. The pacemaker according to claim 5, wherein N is set equal to six beats.

9. The pacemaker according to claim 4, further including means for comparing M_{AVG} to a second predetermined limit SL_2 wherein SL_2 has a value greater than that of SL_1 .

10. The pacemaker according to claim 9, wherein said means for stimulating gradually increments the pacing rate until the pacing rate reaches the intermediate pacing rate (IR), if the last intrinsic escape interval RR_N is longer than LRHI, and if M_{AVG} is greater than or equal to SL_1 but less than or equal to SL_2 .

11. The pacemaker according to claim 9, further comprising means for inhibiting stimulation if M_{AVG} is greater than SL_2 , and if the RR_N interval is less than or equal to LRHI.

12. The pacemaker according to claim 11, further comprising means for stimulating at the lower rate if M_{AVG} is greater than SL_2 , and if the RR_N interval will be longer than LRHI.

13. The pacemaker according to claim 11, further comprising:

A. means for inhibiting stimulation if M_{AVG} is greater than SL_2 , and if the RR_N interval is less than or equal to LRH; and

B. means for stimulating at the lower rate if M_{AVG} is greater than SL_2 , and if the RR_N interval will be longer than LRHI.

14. The pacemaker according to claim 4, further including means for inhibiting stimulation if M_{AVG} is less than SL_1 , and if the last intrinsic escape interval RR_N is less than or equal to LRHI.

15. The pacemaker according to claim 14, further comprising means for stimulating at the lower rate if M_{AVG} is less than SL_1 , and if the RR_N interval will be greater than LRHI.

16. A method for pacing with a pacemaker having a programmable lower rate and upper rate, a programmable lower hysteresis rate (LRH) corresponding to a lower rate hysteresis interval (LRHI), and a programmable intermediate pacing rate (IR), the pacing method comprising the steps of:

A. measuring a rate of change of M_{AVG} of successive intrinsic escape intervals;

B. comparing M_{AVG} to a first predetermined limit SL_1 ;

C. comparing a last intrinsic escape interval RR_N to the lower rate hysteresis interval (LRHI); and

D. stimulating at the lower rate hysteresis (LRH) and gradually incrementing a pacing rate until it reaches the intermediate pacing rate (IR) if the RR_N interval will be longer than the lower rate hysteresis interval (LRHI) and if said M_{AVG} is greater than SL_1 .

17. The pacing method according to claim 16 further comprising the steps of:

A. maintaining continuous pacing at the intermediate rate (IR) for a predefined period of time; and

B. allowing gradual decay of the pacing rate after said selected period of time has lapsed.

18. The pacing method according to claim 17, wherein, said step of measuring the rate of change M_{AVG} comprises:

A. measuring intervals between two successive ventricular depolarizations (RR intervals); and

B. averaging the rate of change M_{AVG} of said successive RR intervals;

19. The pacing method according to claim 18, wherein said step of averaging the rate of change of said RR intervals comprises:

A. calculating a difference D between two successive RR intervals;

B. comparing the difference D to a predetermined reference value;

C. storing those values of D which are greater than said reference value;

D. calculating a sum M of N stored values of D, wherein N is a predetermined positive integer; and

E. setting M_{AVG} equal to M/N .

20. The pacing method according to claim 19, further comprising the step comparing M_{AVG} to a second predetermined limit SL_2 , wherein SL_2 has a value greater than that of SL_1 .

21. The pacing method according to claim 20, wherein said step of stimulating comprises gradually incrementing the pacing rate until it reaches the intermediate pacing rate (IR), if the RR_N interval will be longer than LRHI, and if M_{AVG} is greater than or equal to SL_1 but less than or equal to SL_2 .

22. The pacing method according to claim 18, further comprises:

A. the step of inhibiting stimulation if M_{AVG} is less than SL_1 , and if the last sensed RR interval is less than or equal to LRHI;

B. the step of stimulating at the lower rate if M_{AVG} is less than SL_1 , and if the RR_N interval will be longer than LRHI;

C. the step of inhibiting stimulation if M_{AVG} is greater than SL_2 , and if the RR_N interval is less than or equal to LRHI; and

D. the step of stimulating at the lower rate if M_{AVG} is greater than SL_2 , and if the RR_N interval will be longer than LRHI.

23. A cardiac pacemaker comprising:

means for sensing depolarizations,

means for controlling the timing and delivery of pacing pulses to a heart, means for measuring the rate of depolarization from said sensed depolarizations and means for comparing the current rate to a recent past average rate and from said determining the rate of decrease, and means responsive to said means for determining rate decrease for generating control signals to said control means for pacing at predetermined rates above a lower pacing rate if said rate of decrease exceeds predetermined amounts.

24. A method of pacing the heart including the steps:

1) sensing electrical depolarizations within a heart chamber;

2) making a determination based on sensed depolarizations in said chamber of the intrinsic heart rate;

3) comparing the current intrinsic heart rate with previously sensed intrinsic heart rate to determine whether a rapid drop in heart rate of a predetermined size has occurred;

4) on the discovery of a rapid drop in heart rate of said predetermined size, pacing at predetermined rates higher than a lower pacing rate.

25. A method according to claim 22 further comprising after step 4:

decreasing the pacing rate gradually until either an intrinsic rate is established above the lower rate or the lower rate is reached whereupon pacing continues at the lower rate.

26. The method as set forth in claim 24 wherein if the activity sensor indicates a sensor rate that is higher than the lower rate, pacing at the sensor rate.

27. A cardiac pacemaker, as set forth in claim 23 and further comprising means for decreasing the pacing rate

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gradually until either an intrinsic rate is established above the lower rate or the lower rate is reached whereupon pacing continues at the lower rate.

28. A cardiac pacemaker as set forth in claim 27 further comprising means for pacing at an activity sensor rate if 5 said activity sensor rate is higher than the lower.

29. A heart stimulator comprising:

pulse generator means for generating and emitting stimulation pulses to a heart at a rate;

detector means for sensing events in said heart, including 10 spontaneous heartbeats; and

control means, connected to said pulse generator means and to said detector means, for controlling the emission of stimulation pulses by said pulse generator means for 15 causing the emission of a stimulation pulse if a spontaneous heartbeat rate as sensed by said detector

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means drops below a defined lower rate within a predetermined period and for causing said pulse generator means, when said spontaneous heartbeat rate falls below said defined lower rate within said period, to emit said stimulation pulses at rates faster than said defined lower rate.

30. A heart stimulator as set forth in claim 29 wherein after emitting said stimulation pulses at a rate faster than said lower rate, said control means subsequently slows the rate of emission of said stimulation pulses down to said defined lower rate.

31. A heart stimulator as in claim 29 or 30 wherein if a sensor rate is higher than said defined lower rate, said, said means for controlling the timing and delivery of pacing pulses paces at a rate indicated by said sensor rate.

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