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## OTHER PUBLICATIONS

Cooper, M., "Postextrasystolic Potentiation: Do We Really Know What It Means and How to Use It?," *Circulation*, vol. 88, No. 6, p. 2962-2971 (Dec. 1993).

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(57) **ABSTRACT**

An implantable stimulator and monitor measures a group of heart failure parameters indicative of the state of heart failure employing EGM signals, measures of blood pressure including absolute pressure  $P$ , developed pressure ( $DP = \text{systolic } P - \text{diastolic } P$ ), and/or  $dP/dt$ , and measures of heart chamber volume ( $V$ ) over one or more cardiac cycles. These parameters include: (1) relaxation or contraction time constant  $\tau$ ; (2) mechanical restitution (MR), i.e., the mechanical response of a heart chamber to premature stimuli applied to the heart chamber; (3) recirculation fraction (RF), i.e., the rate of decay of PESP effects over a series of heart cycles; and (4) end systolic elastance ( $E_{ES}$ ), i.e., the ratios of end systolic blood pressure  $P$  to volume  $V$ . These heart failure parameters are determined periodically regardless of patient posture and activity level. The physician can determine whether a particular therapy is appropriate, prescribe the therapy for a period of time while again accumulating the stored patient data for a later review and assessment to determine whether the applied therapy is beneficial or not, thereby enabling periodic changes in therapy, if appropriate. Drug therapies and electrical stimulation therapies, including PESP stimulation, and pacing therapies including single chamber, dual chamber and multi-chamber (bi-atrial and/or bi-ventricular) pacing can be delivered. In patient's prone to malignant tachyarrhythmias, the assessment of heart failure state can be taken into account in setting parameters of detection or classification of tachyarrhythmias and the therapies that are delivered.

**8 Claims, 21 Drawing Sheets**

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graph TD
    S700([START]) --> S702{RELEASE EVENT?}
    S702 -- NO --> S702
    S702 -- YES --> S704[DETERMINE PACING DI]
    S704 --> S706[TIME OUT PACING DI]
    S706 --> S708{PACING DI EXPIRED?}
    S708 -- NO --> S702
    S708 -- YES --> S710[DELIVER PULSE/PULSE]
    S710 --> S712[IMPLANT HEART SENSES BLOCK  
PRESERVE TO DEVELOP A  
REGULAR RHYTHM  
OVER HEART CYCLE]
    S712 --> S714[ANALYZE HEART CHAMBERS  
BLOCK REPEATS AND TIME-LOCKED  
VOLUME SIGNALS  
ANALYZE HEART CYCLE]
    S714 --> S716[DETECT IN VOLUME SIGNALS  
AND IN VOLUME SIGNALS]
    S716 --> S718[DETERMINE QRS SYSTOLIC POINT  
R0, V0 AND V0 SIGNALS]
    S718 --> S720[TEMPORARILY STORE END  
SYSTOLIC R0 AND V0 SIGNALS]
    S720 --> S722[INCREMENT R0 DATA SET COUNT]
    S722 --> S724{DATA SET SUFFICIENT  
PERFORMANCE COUNT?}
    S724 -- NO --> S722
    S724 -- YES --> S726[DETERMINE R0 SLOPE AND R02 OF  
HEART RATE AND VOLUME  
R0 AND V0 SIGNALS]
    S726 --> S728{SLOPE OF R0 IS  
DETERMINED?}
    S728 -- NO --> S726
    S728 -- YES --> S730[STORE R0 SLOPE AND R02 OF  
HEART RATE AND VOLUME  
R0 AND V0 SIGNALS]
    S730 --> S732[END]
  
```

```

graph TD
    S718[S718 DETERMINE QND SYSTOLIC POINT  
E2 AND E2B POINTS] --> S720[S720 TEMPORARILY STORE END  
SYSTOLIC E2B AND E2 POINTS]
    S720 --> S722[S722 INCREMENT E2 DATA SET COUNT]
    S722 --> S724{S724 DATA SET  
"PROGRAMMED COUNT"?}
    S724 -- NO --> S718
    S724 -- YES --> S726{S726 DETERMINE IF SLOPE AND SLOPE  
THRESHOLD OF E2 AND E2B POINTS  
E2 AND E2B POINTS}
    S726 -- NO --> S718
    S726 -- YES --> S730[S730 STORE THE DETERMINED SLOPE OF  
E2 AND E2B SYSTOLIC P  
AND E2B POINTS]
    S730 --> S732[END]
    
```

```

graph TD
    S718[S718 DETERMINE QND SYSTOLIC POINT  
E2 AND E2B POINTS] --> S720[S720 TEMPORARILY STORE END  
SYSTOLIC E2B AND E2 SIGNALS]
    S720 --> S722[S722 INCREMENT E2 DATA SET COUNT]
    S722 --> S724{S724 DATA SET COUNT  
"PROGRAMMED COUNT"?}
    S724 -- NO --> S718
    S724 -- YES --> S726{S726 DETERMINE IF SLOPE AND SLOPE  
THRESHOLD OF E2 AND E2B SIGNALS  
E2 AND E2B SIGNALS}
    S726 -- NO --> S718
    S726 -- YES --> S730[S730 STORE THE DETERMINED SLOPE OF  
E2 AND E2B SYSTOLIC P2  
AND P2B SIGNALS]
    S730 --> S732[END]
    
```

```

graph TD
    S718[S718 DETERMINE QND SYSTOLIC POINT  
E2 AND E2B POINTS] --> S720[S720 TEMPORARILY STORE END  
SYSTOLIC E2B AND E2 SIGNALS]
    S720 --> S722[S722 INCREMENT E2 DATA SET COUNT]
    S722 --> S724{S724 DATA SET COUNT  
"PROGRAMMED COUNT"?}
    S724 -- NO --> S718
    S724 -- YES --> S726{S726 DETERMINE IF SLOPE AND SLOPE  
THRESHOLD OF E2 AND E2B SIGNALS  
E2 AND E2B SIGNALS}
    S726 -- NO --> S718
    S726 -- YES --> S730[S730 STORE THE DETERMINED SLOPE OF  
E2 AND E2B SYSTOLIC P2  
AND P2B SIGNALS]
    S730 --> S732[END]
    
```

```

graph TD
    S718[S718 DETERMINE QND SYSTOLIC POINT  
E2 AND E2B POINTS] --> S720[S720 TEMPORARILY STORE END  
SYSTOLIC E2B AND E2 SIGNALS]
    S720 --> S722[S722 INCREMENT E2 DATA SET COUNT]
    S722 --> S724{S724 DATA SET COUNT  
"PROGRAMMED COUNT"?}
    S724 -- NO --> S718
    S724 -- YES --> S726{S726 DETERMINE IF SLOPE AND SLOPE  
THRESHOLD OF E2 AND E2B SIGNALS  
E2 AND E2B SIGNALS}
    S726 -- NO --> S718
    S726 -- YES --> S730[S730 STORE THE DETERMINED SLOPE OF  
E2 AND E2B SYSTOLIC P2  
AND P2B SIGNALS]
    S730 --> S732[END]
    
```

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graph TD
    S718[S718 DETERMINE QND SYSTOLIC POINT  
E2 AND E2B POINTS] --> S720[S720 TEMPORARILY STORE END  
SYSTOLIC E2B AND E2 SIGNALS]
    S720 --> S722[S722 INCREMENT E2 DATA SET COUNT]
    S722 --> S724{S724 DATA SET COUNT  
"PROGRAMMED COUNT"?}
    S724 -- NO --> S718
    S724 -- YES --> S726{S726 DETERMINE IF SLOPE AND SLOPE  
THRESHOLD OF E2 AND E2B SIGNALS  
E2 AND E2B SIGNALS}
    S726 -- NO --> S718
    S726 -- YES --> S730[S730 STORE THE DETERMINED SLOPE OF  
E2 AND E2B SYSTOLIC P2  
AND P2B SIGNALS]
    S730 --> S732[END]
    
```

```

graph TD
    S718[S718 DETERMINE QND SYSTOLIC POINT  
E2 AND E2B POINTS] --> S720[S720 TEMPORARILY STORE END  
SYSTOLIC E2B AND E2 SIGNALS]
    S720 --> S722[S722 INCREMENT E2 DATA SET COUNT]
    S722 --> S724{S724 DATA SET COUNT  
"PROGRAMMED COUNT"?}
    S724 -- NO --> S718
    S724 -- YES --> S726{S726 DETERMINE IF SLOPE AND SLOPE  
THRESHOLD OF E2 AND E2B SIGNALS  
E2 AND E2B SIGNALS}
    S726 -- NO --> S718
    S726 -- YES --> S730[S730 STORE THE DETERMINED SLOPE OF  
E2 AND E2B SYSTOLIC P2  
AND P2B SIGNALS]
    S730 --> S732[END]
    
```

```

graph TD
    S718[S718 DETERMINE QND SYSTOLIC POINT  
E2 AND E2B POINTS] --> S720[S720 TEMPORARILY STORE END  
SYSTOLIC E2B AND E2 SIGNALS]
    S720 --> S722[S722 INCREMENT E2 DATA SET COUNT]
    S722 --> S724{S724 DATA SET COUNT  
"PROGRAMMED COUNT"?}
    S724 -- NO --> S718
    S724 -- YES --> S726{S726 DETERMINE IF SLOPE AND SLOPE  
THRESHOLD OF E2 AND E2B SIGNALS  
E2 AND E2B SIGNALS}
    S726 -- NO --> S718
    S726 -- YES --> S730[S730 STORE THE DETERMINED SLOPE OF  
E2 AND E2B SYSTOLIC P2  
AND P2B SIGNALS]
    S730 --> S732[END]
    
```

```

graph TD
    S718[S718 DETERMINE QND SYSTOLIC POINT  
E2 AND E2B POINTS] --> S720[S720 TEMPORARILY STORE END  
SYSTOLIC E2B AND E2 SIGNALS]
    S720 --> S722[S722 INCREMENT E2 DATA SET COUNT]
    S722 --> S724{S724 DATA SET COUNT  
"PROGRAMMED COUNT"?}
    S724 -- NO --> S718
    S724 -- YES --> S726{S726 DETERMINE IF SLOPE AND SLOPE  
THRESHOLD OF E2 AND E2B SIGNALS  
E2 AND E2B SIGNALS}
    S726 -- NO --> S718
    S726 -- YES --> S730[S730 STORE THE DETERMINED SLOPE OF  
E2 AND E2B SYSTOLIC P2  
AND P2B SIGNALS]
    S730 --> S732[END]
    
```

```

graph TD
    S718[S718 DETERMINE QND SYSTOLIC POINT  
E2 AND E2B POINTS] --> S720[S720 TEMPORARILY STORE END  
SYSTOLIC E2B AND E2 SIGNALS]
    S720 --> S722[S722 INCREMENT E2 DATA SET COUNT]
    S722 --> S724{S724 DATA SET COUNT  
"PROGRAMMED COUNT"?}
    S724 -- NO --> S718
    S724 -- YES --> S726{S726 DETERMINE IF SLOPE AND SLOPE  
THRESHOLD OF E2 AND E2B SIGNALS  
E2 AND E2B SIGNALS}
    S726 -- NO --> S718
    S726 -- YES --> S730[S730 STORE THE DETERMINED SLOPE OF  
E2 AND E2B SYSTOLIC P2  
AND P2B SIGNALS]
    S730 --> S732[END]
    
```

```

graph TD
    S718[S718 DETERMINE QND SYSTOLIC POINT  
E2 AND E2B POINTS] --> S720[S720 TEMPORARILY STORE END  
SYSTOLIC E2B AND E2 SIGNALS]
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THRESHOLD OF E2 AND E2B SIGNALS  
E2 AND E2B SIGNALS}
    S726 -- NO --> S718
    S726 -- YES --> S730[S730 STORE THE DETERMINED SLOPE OF  
E2 AND E2B SYSTOLIC P2  
AND P2B SIGNALS]
    S730 --> S732[END]
    
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graph TD
    S718[S718 DETERMINE QND SYSTOLIC POINT  
E2 AND E2B POINTS] --> S720[S720 TEMPORARILY STORE END  
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    S724 -- YES --> S726{S726 DETERMINE IF SLOPE AND SLOPE  
THRESHOLD OF E2 AND E2B SIGNALS  
E2 AND E2B SIGNALS}
    S726 -- NO --> S718
    S726 -- YES --> S730[S730 STORE THE DETERMINED SLOPE OF  
E2 AND E2B SYSTOLIC P2  
AND P2B SIGNALS]
    S730 --> S732[END]
    
```

## U.S. PATENT DOCUMENTS

5,024,222 A	6/1991	Thacker .....	128/419 PG
5,213,098 A	5/1993	Bennett et al. ....	128/419 PG
5,328,442 A	7/1994	Levine .....	600/17
5,331,966 A	7/1994	Bennett et al. ....	128/696
5,417,717 A	5/1995	Salo et al. ....	607/18
5,564,434 A	10/1996	Halperin et al. ....	128/748
5,626,623 A	5/1997	Kieval et al. ....	607/23
5,800,464 A	9/1998	Kieval .....	607/9
6,021,345 A	2/2000	Karagueuzian et al. ....	600/518
6,090,047 A	7/2000	Kass et al. ....	600/485
6,104,949 A	8/2000	Pitts Crick et al. ....	600/547
6,141,586 A	10/2000	Mower .....	607/9

## OTHER PUBLICATIONS

Dell'Italia, Louis, "Mechanism of Postextrasystolic Potentiation in the Right Ventricle," *Amer. Jour. Of Cardiol.*, vol. 65, p. 736-741 (Mar. 15, 1990).

Franz et al., "Electrical and Mechanical Restitution of the Human Heart at Different Rates of Stimulation," *Circulation Research*, vol. 53, No. 6, p. 815-822 (Dec. 1983).

Freeman et al., "Evaluation of Left Ventricular Mechanical Restitution in Closed-chest Dogs Based on Single-Beat Elastance," *Circulation Research*, vol. 67, No. 6, p. 1437-1445 (Dec. 1990).

Geschwind et al., "Sympathetic Nervous System Activation in Postextrasystolic Potentiation: Role of Catecholamine Release in Enhancement of Ventricular Function," *JACC*, vol. 4, No. 2, p. 215-225 (Aug. 1984).

Juggi et al., "Intracellular Kinetics of the Activator Calcium of Rat Heart after Ischemic Arrest and Cardioplegia: Quantitative Comparison of Right and Left Ventricles," *Can. J. Cardiol.*, vol. 8, No. 4, p. 387-395 (May 1992).

Kuijer et al., "Post-Extrasystolic Potentiation Without a Compensatory Pause in Normal and Diseased Hearts," Abstract (accepted for publication Dec. 20, 1989).

Mesaeli et al., "Mechanical Restitution and Post Extrasystolic Potentiation of Perfused Rat Heart: Quantitative Comparison of Normal Right and Left Ventricular Responses," *Can. J. Cardiol.*, vol. 8, No. 2, p. 164-172 (Mar. 1992).

Pidgeon, et al., "The Relationship Between the Strength of the Human Heart Beat and the Interval Between Beats," *Circulation*, vol. 65, No. 7, p. 1404-1410 (Jun. 1982).

Prabhu et al., "Effect of Tachycardia Heart Failure on the Restitution of Left Ventricular Function in Closed-Chest Dogs," *Circulation*, vol. 91, No. 1, p. 177-185 (Jan. 1, 1995).

Prabhu et al., "Kinetics of Restitution of Left Ventricular Relaxation," *Circulation Research*, vol. 70, No. 1, p. 29-38 (Jan. 1992).

ter Keurs et al., "Characterization of Decay of Frequency Induced Potentiation and Post-Extrasystolic Potentiation," *Cardiovascular Research*, vol. 24, p. 903-910 (1990).

van der Werf et al., "Postextrasystolic Potentiation in Man," *European Journal of Cardiology*, vol. 4/supplement, p. 131-141 (1976).

Wisenbaugh et al., "Mechanics of Postextrasystolic Potentiation in Normal Subjects and Patients With Valvular Heart Disease," *Circulation*, vol. 74, No. 1, p. 10-20 (Jul. 1986).

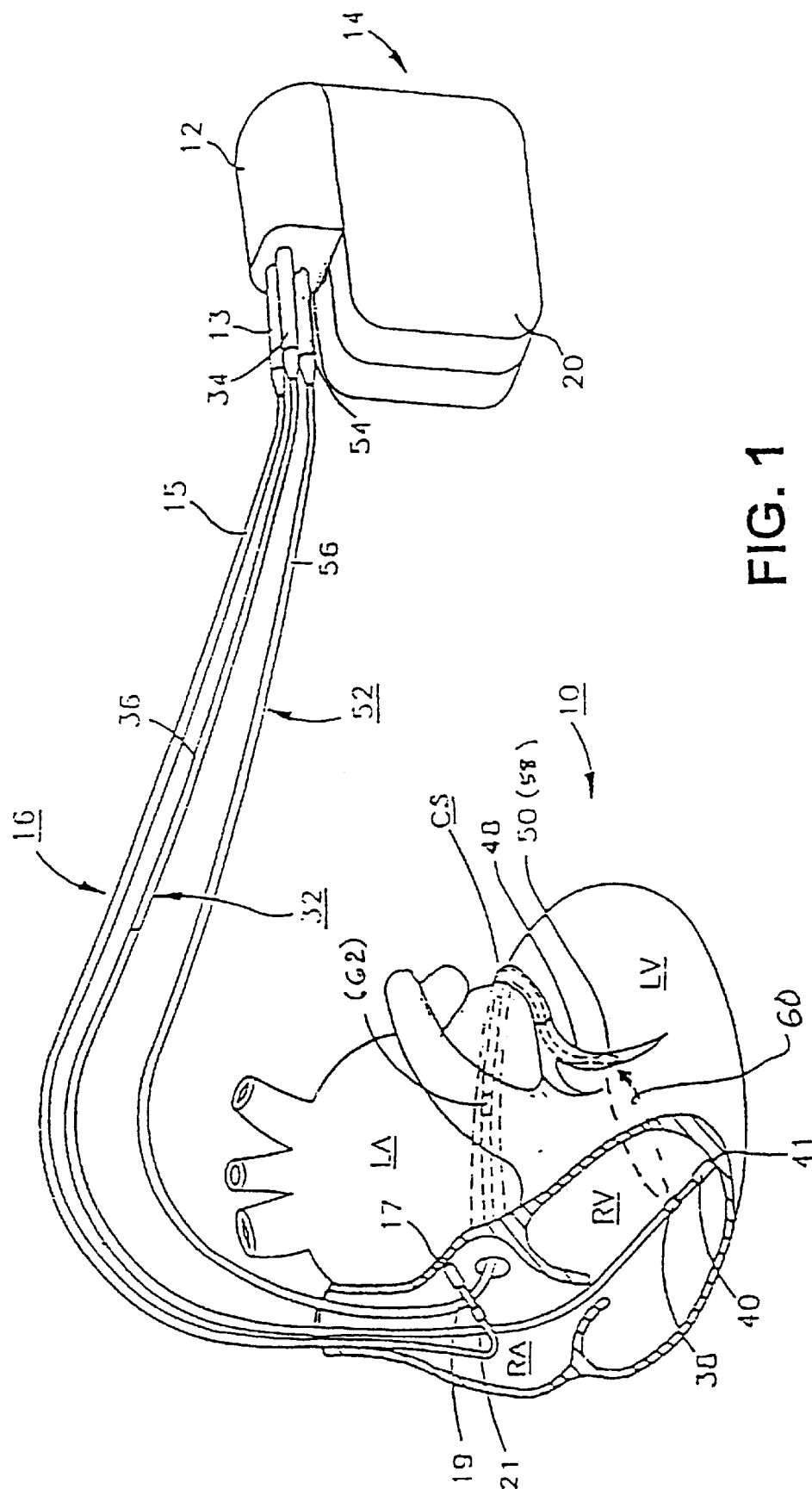


FIG. 1

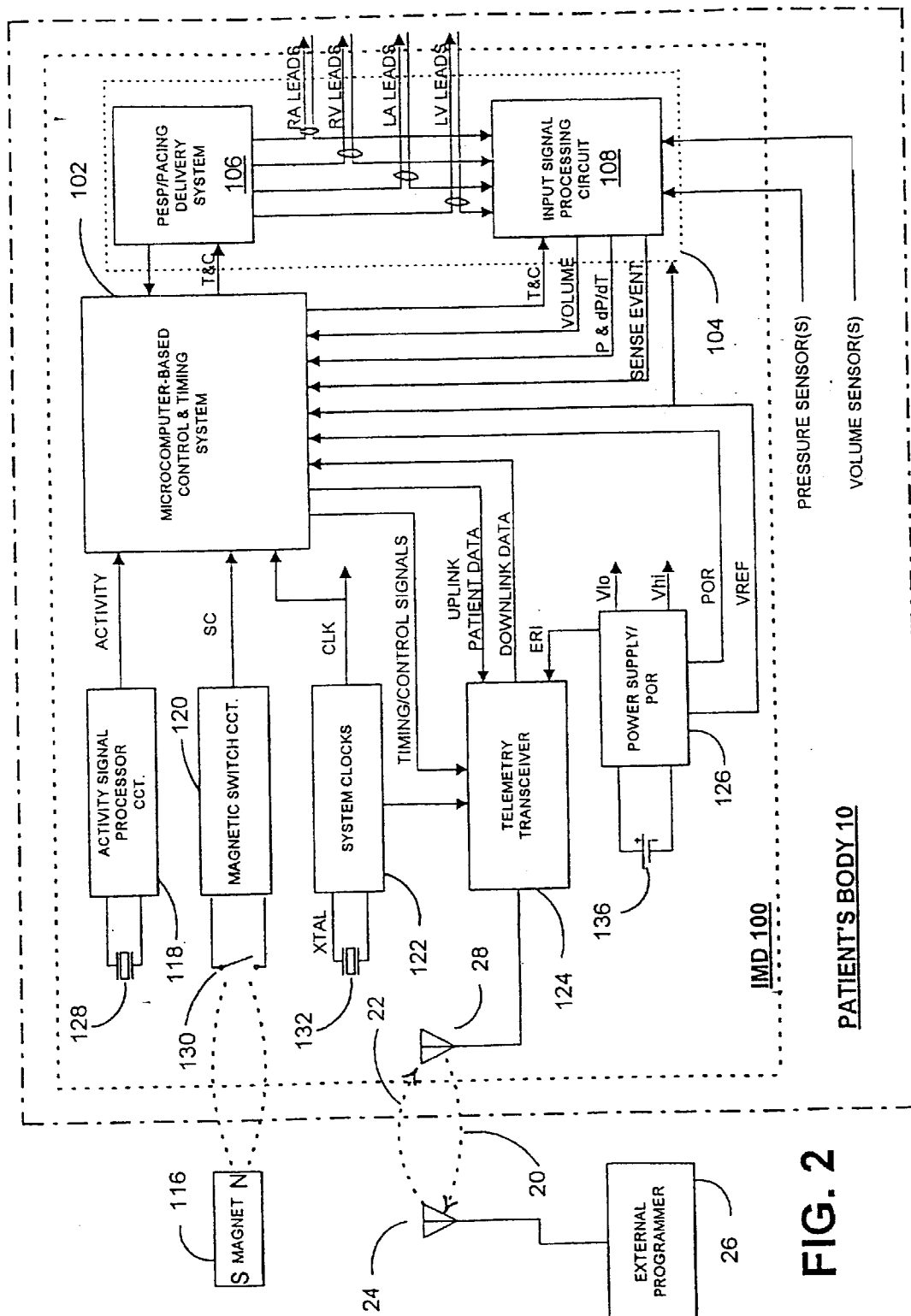


FIG. 2

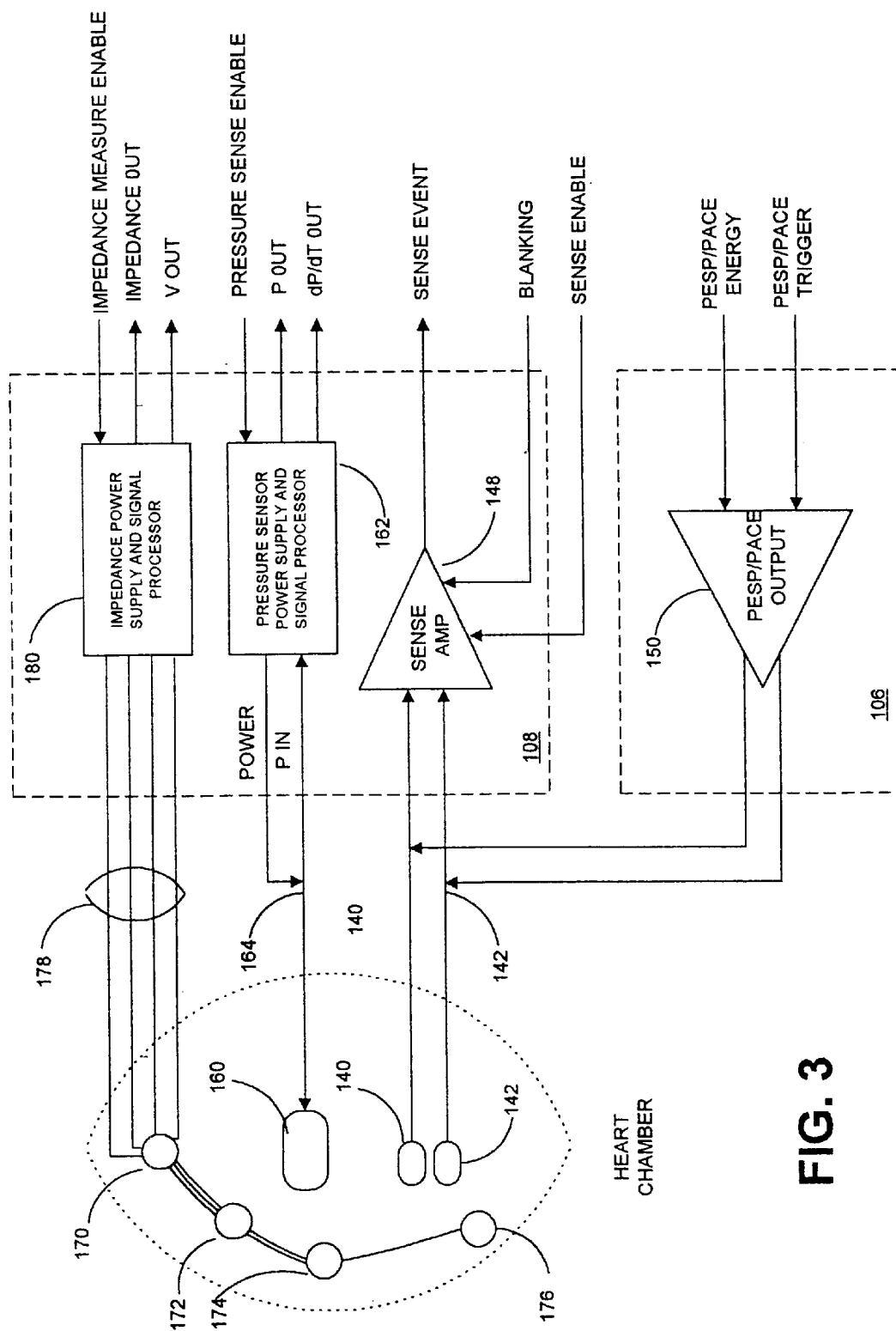


FIG. 3

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