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(54) **APPARATUS FOR MONITORING HEART RATE AND ABNORMAL RESPIRATION**

VORRICHTUNG ZUR ERMITTLUNG VON HERZRATE UND ANORMALER BEATMUNG

APPAREIL DE SURVEILLANCE DE DEBIT CARDIAQUE ET DE RESPIRATION ANORMALE

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(73) Proprietor: **MEDTRONIC, INC.**
Minneapolis, Minnesota 55432-5604 (US)

(72) Inventors:
- **JENSEN, Donald, N.**
  Derwood, MN 20855 (US)
- **RUETZ, Linda, L.**
  New Brighton, MN 55112 (US)
- **CONDIE, Catherine, R.**
  Shoreview, MN 55126 (US)
- **CHO, Yong, Kyun**
  Maple Grove, MN 55369 (US)
- **STROBEL, Ulla**
  CH-8032 Zurich (CH)

(74) Representative: **Hughes, Andrea Michelle**
Frank B. Dehn & Co.
St Bride's House
10 Salisbury Square
London EC4Y 8JD (GB)

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Description

BACKGROUND OF THE INVENTION

[0001] The present invention relates generally to implantable medical devices and more particularly to implantable medical devices intended for use in monitoring a patient's heart rhythm and abnormal respiration.

[0002] Implantable pacemakers and cardioverters monitor the heart's rhythm in order to detect arrhythmias and deliver appropriate therapies to terminate detected arrhythmias. In conjunction with this function, the ability of the device is to store information with regard to monitored heart rhythms has dramatically increased over the past two years. Examples of implantable pacemakers and defibrillators which have the capability of storing information related to monitored heart rhythms include U.S. Patent No. 5330,513 issued to Nichols et al., U.S. Patent No. 6,129,745 issued to Sun et al. and U.S. Patent No. 5, 447, 519 issued to Peterson. In addition, there have recently been developed subcutaneously implantable monitoring devices that do not deliver any anti-arrhythmia therapies to the heart but simply store information regarding a patient's heart rhythms for later uplink to an external device. Such devices are disclosed in U.S. Patent No. 5,851,221 issued to Rieder et al., U.S. Patent No. 5,535,752 and U.S. Patent No. 5,564,434 issued to Halperin et al.

[0003] In conjunction with implantable devices as described above, information stored relating to a patient's heart rhythm may include information relating to heart rate trends over time, as disclosed in U.S. Patent No. 5,088,488 issued to Markowitz et al., U.S. Patent No. 4,364,397 and U.S; Patent No. 4,360,030 issued to Citron et al., as well as information relating to heart rate variability over time, as disclosed in U.S. Patent No. 5,957,861 issued to Combs et al., U.S. Patent No. 6,045,513 issued to Stone et al. and U.S. Patent No. 5,876,353 issued to Riff.

[0004] Typically, measurements of heart rate trend in such devices are accomplished by continually measuring heart rate over a defined time period, and calculating average heart rates for successive shorter time periods within the defined time period for later telemetry to an external device. Gradual increases in average heart rate over extended time periods are known to be an indicator of decompensation, a phenomenon that takes place during the progression of clinical heart failure.

[0005] US-A-4 702 253 discloses a device according to the preamble of claim 1.

SUMMARY OF THE INVENTION

[0006] The present invention is directed toward an implantable device as defined in claim 1, having enhanced capabilities for monitoring a patient's heart rate and respiration trends over extended periods of time. The information collected by the implantable device is stored and telemetered to an associated external device such as a device programmer for display and analysis. Heart rates are measured by measuring the time intervals between sensed depolarizations of a chamber of the patient's heart and preceding sensed depolarizations or delivered pacing pulses. Intervals may be measured in the ventricle and/or atrium of the patient's heart The measured intervals are referred to hereafter as "heart intervals". The measured heart intervals during defined time periods are used to calculate average heart rates or average heart intervals associated with the time periods. Preferably the average heart rate takes the form of a mean heart rate, but in some embodiments, the median heart rate over the time periods may be employed or the most common heart rate or interval based on a histogram of measured heart intervals or other equivalent value may be substituted. For purposes of the present application, the term "average heart rate" should be understood to include mean, median or any other equivalent values indicative of the general heart rate or heart interval.

[0007] Rather than simply measuring average heart rate values over successive time periods, the implantable device instead measures successive average values of heart rates measured during discontinuous time periods, preferably chosen to occur during times of particular interest, for example during defined time periods during the night and/or day. Preferably the measurements are taken and stored over a period of weeks or months. In a first embodiment, measurements are during the night during a period of time in which the patient is likely to be sleeping. In this context, measurement of , the trend of night heart rates taken, for example over the period of time between 12:00 a.m. and 4:00 a.m. is believed to be particularly valuable. Night heart rate is predominantly controlled by the parasympathetic nervous system. The progression of heart failure is usually associated with abnormal excitation of the parasympathetic nervous system, leading to increases in night heart rate.

[0008] In addition, long-term trends of daytime heart rates may also be collected, for example over periods of time between 8:00 a.m. and 8:00 p.m. Daytime heart rate is primarily controlled by the sympathetic nervous system and thus differences in day and night heart rates can be used as a measure of autonomic dysfunction and have been shown to be different in heart failure patients when compared to age matched individuals with normal hearts. In the context of an implantable pacemaker, comparisons of trends of day and night heart rates to the lower or base pacing rate of the pacemaker may also provide useful physiological information. This comparison may be especially valuable in pacemakers which store information regarding trends of physiologic sensor outputs or regarding trends of pacing rates based upon physiologic sensor outputs as in U.S. Patent No. 6,045,513, filed May 13, 1998 by Stone et al.

[0009] In a preferred embodiment of the invention, the implantable device includes a sensor indicative of exercise level either measured directly using a physiologic

sensor such as an accelerometer or piezo-electric sensor or measured indirectly by means of a sensor of metabolic demand such as a pressure sensor, oxygen saturation sensor, stroke volume sensor or respiration sensor. In this embodiment of the invention, measurements of heart rhythms are made only in response to the sensor's determination that the patient is at rest, in order to produce a long-term trends of resting heart rates during the defined time intervals. Even over relatively long time frames, a patient's level of activity may vary substantially, and changes in average heart rates can be masked by such variations in exercise level. By limiting the measurements of heart rates to times during which the patient is known to be at rest, a more accurate indication of the true long-term progression of heart rates can be obtained. In such embodiments the implantable device may collect heart rate information continuously during longer time periods, typically extending at least over several hours. During the longer time periods the device may define a series of shorter time periods, typically extending over several minutes, and will employ heart rate information collected during a preceding one of the shorter time periods only if the sensor indicates the patient was at rest during the shorter time period.

[0010] In some preferred embodiments, particularly those intended for use in patients known to suffer from tachyarrhythmias, the implantable device is also configured to reject intervals between depolarizations associated with tachyarrhythmias. In such embodiments the implantable device may define a minimum cumulative duration of non-rejected heart intervals as a prerequisite to calculation of an average rate value for a defined time period.

[0011] In devices employing physiologic sensors, the device may correspondingly also store values indicative of the general levels of sensor output during daytime and nighttime periods may also be collected. In such embodiments, average sensor output values, including the various types of averages discussed above in conjunction with calculation of average heart rates may be employed. Alternatively, a sum or total of all generated sensor outputs during relevant time periods may be employed.

[0012] According to one aspect of the invention, the physiologic sensor is an implanted impedance sensor employed to measure respiration rates. Systems using impedance sensors to measure patient respiratory trends are disclosed in U.S. Patent No. 5,957,861 issued Combs et al, U.S. Patent No. 5,876,353 issued to Riff et al, or U.S. Patent No. 5,562,711 issued to Yerich et al.

[0013] As discussed in the cited patents, respiration rates are often tracked using minute ventilation. Minute ventilation is defined as the total amount of gas that is moved into, and out of, the lungs in one minute. This measurement is generally obtained in a clinical stetting using a flow meter positioned within a patient's mouth. However, the inventors have shown that minute ventilation can also be closely approximated by measuring the changes in tissue impedance that occur as the lungs expand and contract during breathing, as may be detected by an implanted impedance sensor.

[0014] The current invention provides a system for monitoring minute ventilation in a manner that extends beyond the clinical setting so that long-term trends in patient health may be more accurately evaluated. For example, the invention may be used to detect otherwise unrecognized acute disease or acute deterioration in the status of chronic disease. Early detection of otherwise unrecognized acute disease permits treatment that can potentially prevent, or minimize, further progression of the disease.

[0015] According to one aspect of the invention, minute ventilation is recorded when the patient is at rest as determined by an activity sensor or a metabolic rate sensor. In another embodiment, minute ventilation is recorded at predetermined time periods such as between the hours of twelve midnight and two in the morning. Short and long term changes in minute volume can be used to detect conditions such as Cheyne-Stokes respiration and sleep apnea.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016]

Figure 1 illustrates an implantable pacemaker/cardioverter/ defibrillator of a type useful in practicing the present invention, in conjunction with a human heart.

Figure 2 illustrates an implantable medical device of a type useful in practicing the present invention, in conjunction with a human heart.

Figure 3 illustrates an implantable monitor of a type useful in practicing the present invention.

Figure 4 is a perspective view of a programmer of a type useful in practicing the present invention.

Figure 5 is a functional schematic diagram of an implantable pacemaker/cardioverter/defibrillator of a type useful in practicing the present invention.

Figure 6 is a functional schematic diagram of an implantable pacemaker of a type useful in practicing the present invention.

Figure 7 is a functional schematic diagram of an implantable monitor of a type useful in practicing the present invention.

Figure 8 is a functional schematic diagram of a programmer of a type useful in practicing the present invention.

Figure 9 is a functional flow chart illustrating a first method of monitoring heart rate trends, which may be employed in conjunction with the present invention.

Figure 10 is a functional flow chart illustrating a second method of monitoring heart rate trends, which may be employed in conjunction with the present invention.

Figure 11 is a functional flow chart illustrating a meth-

od of monitoring sensor output trends, which may be employed in conjunction with the present invention. Figure 12 is a functional flow chart illustrating a method of monitoring breathing trends, which may be employed in conjunction with the present invention. Figure 13 is a flowchart illustrating the use of heart rate and respiration trend data as is generated by use of the current invention

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0017] Figure 1 illustrates a defibrillator and lead set of a type in which the present invention may usefully be practiced. The ventricular lead includes an elongated insulative lead body 16, carrying three mutually insulated conductors. Located adjacent the distal end of the lead are a ring electrode 24, an extendable helix electrode 26, mounted retractably within an insulative electrode head 28, and an elongated coil electrode 20. Each of the electrodes is coupled to one of the conductors within the lead body 16. Electrodes 24 and 26 are employed for cardiac pacing and for sensing ventricular depolarizations. At the proximal end of the lead is a bifurcated connector 14 that carries three electrical connectors, each coupled to one of the coiled conductors.

[0018] The atrial/SVC lead includes an elongated insulative lead body 15, also carrying three mutually insulated conductors. Located adjacent the J-shaped distal end of the lead are a ring electrode 21 and an extendible helix electrode 17, mounted retractably within an insulative electrode head 19. Each of the electrodes is coupled to one of the conductors within the lead body 15. Electrodes 17 and 21 are employed for atrial pacing and for sensing atrial depolarizations. An elongated coil electrode 23 is provided, proximal to electrode 21 and coupled to the third conductor within the lead body 15. At the proximal end of the lead is a bifurcated connector 13 that carries three electrical connectors, each coupled to one of the coiled conductors.

[0019] The coronary sinus lead includes an elongated insulative lead body 6, carrying one conductor, coupled to an elongated coiled defibrillation electrode 8. Electrode 8, illustrated in broken outline, is located within the coronary sinus and great vein of the heart. At the proximal end of the lead is a connector plug 4, which carries an electrical connector, coupled to the coiled conductor.

[0020] The pacemaker/cardioverter/defibrillator 10 includes a hermetic enclosure 11 containing the electronic circuitry used for generating cardiac pacing pulses for delivering cardioversion and defibrillation shocks and for monitoring the patient's heart rhythm. Pacemaker/cardioverter/defibrillator 10 is shown with the lead connector assemblies 4, 13 and 14 inserted into the connector block 12, which serves as a receptacle and electrical connector for receiving the connectors, 4, 13 and 14 and interconnecting the leads to the circuitry within enclosure 11. An activity sensor 30 is illustrated schematically by broken outline, and may be an accelerometer or a piezoelectric transducer. Sensor 30 may be used for verifying that the patient is at rest, in conjunction with measurement of long-term heart rate and/or breathing trends according to the present invention as well as for regulation of pacing rate based upon demand for cardiac output.

[0021] Optionally, insulation of the outward facing portion of the housing 11 of the pacemaker/cardioverter/defibrillator 10 may be provided or the outward facing portion may instead be left uninsulated, or some other division between insulated and uninsulated portions may be employed. The uninsulated portion of the housing 11 optionally serves as a subcutaneous defibrillation electrode, used to defibrillate either the atria or ventricles. Other lead configurations and electrode locations may of course be substituted for the lead set illustrated. For example, atrial defibrillation and sensing electrodes might be added to either the coronary sinus lead or the right ventricular lead instead of being located on a separate atrial lead, allowing for a two-lead system.

[0022] Figure 2 illustrates an Implantable Medical Device (IMD) of a type appropriate for use in practicing the present invention in conjunction with its associated lead system, illustrated in relation to a patient's heart. The IMD 120 includes a hermetic enclosure 124 that may contain electronic circuitry used for generating cardiac pacing pulses and/or for monitoring the patient's heart rhythm. An activity sensor 126 is illustrated schematically by broken outline, and may be an accelerometer or a piezoelectric transducer as discussed above in conjunction with Figure 1. Mounted to the enclosure 124 is a header 122 which serves as a receptacle and electrical connector for receiving the connectors 132 and 134 of leads 128 and 130 and interconnecting the leads to the circuitry within enclosure 124.

[0023] In one embodiment, IMD 120 is a hemodynamic monitor of the type described in commonly-assigned U.S. Patent Number 5,535,752 to Halperin.

[0024] In that embodiment, lead 128 includes a physiologic sensor 144 which may take the form of an oxygen sensor, pressure sensor, temperature sensor, other sensor of any of the various types employed for monitoring demand for cardiac output or for measuring heart hemodynamics. Sensor 144 may be used in conjunction with or as an alternative to the activity sensor 126 for verifying that the patient is at rest, in conjunction with measurement of long-term heart rate trends according to the present invention.

[0025] In another embodiment, IMD 120 is a pacing device including atrial lead 130 carrying electrodes 136 and 138. In this embodiment, the electrodes may be employed for sensing and pacing the patient's atrium. Additionally, lead 128 is a ventricular lead provided with electrodes 140 and 142 for monitoring and pacing right ventricular heart signals.

[0026] Figure 3 illustrates a subcutaneously implantable monitor of a type appropriate for use in practicing the present invention. The monitor shares the external con-

figuration of the Medtronic Reveal® implantable monitor, and is provided with a hermetically sealed enclosure 104 containing the electronic circuitry used for generating cardiac pacing pulses and for monitoring the patient's heart rhythm and which carries a molded plastic header 108. The enclosure 104 and the header 108 each carry an electrode 102 and 106, respectively for monitoring heart rhythm. Also mounted in the header 108 is an antenna 110 for use in communicating between the device and an external programmer. Illustrated in broken outline at 112 is an internal activity sensor, of the type typically employed in the context of rate responsive cardiac pacemakers, taking the form either of an accelerometer or a piezo-electric transducer. Heart signals are detected between the electrodes 102 and 106 and measurements of physical activity are detected by sensor 112 for use in storing and calculating heart rate trends and heart rate variability measurements according to the present invention.

[0027] Figure 4 is a plan view of an external programmer of a sort appropriate for use in conjunction with the practice of the present invention in conjunction with any of the devices of Figures 1 - 3. The programmer 420 is a microprocessor controlled device which is provided with a programming head 422 for communicating with an implanted device, a set of surface electrogram electrodes 459 for monitoring a patient's electrogram, a display 455 which is preferably a touch sensitive display, control buttons or keys 465, and a stylist 456 for use in conjunction with the touch sensitive screen 455. By means of the control keys 465 and the touch sensitive screen 455 and stylus 456, the physician may format commands for transmission to the implantable device. By means of the screen 455, the physician may observe information telemetered from the implantable device. The programmer is further provided with a printer 463 which allows for hard copy records of displays of signals received from the implanted device such as electrograms, stored parameters, programmed parameters and information as to heart rate trends according to the present invention. While not visible in this view, the device may also be provided with a floppy disk or CD ROM drive and/or a port for insertion of expansion cards such as P-ROM cartridges, to allow for software upgrades and modifications to the programmer 420.

[0028] In the context of the present invention, programmer 420 may serve simply as a display device, displaying information with regard to heart rate variability and heart rate trends as calculated by the implanted device or instead may receive uplinked raw data related to heart intervals and may calculate the heart rate trends and heart rate variability values according to the present invention. It is believed that it is preferable for the implanted device to perform the bulk of the computations necessary to practice the invention, and in particular that it is preferable for the implanted device to at least calculate average rate values, to reduce the storage requirements within the implanted device. However, allocation of functions between the implanted device and the programmer may differ from the preferred embodiments and still result in a workable system.

[0029] Figure 5 is a functional schematic diagram of an implantable pacemaker/cardioverter/defibrillator of the type illustrated in Figure 3, in which the present invention may usefully be practiced. This diagram should be taken as exemplary of one type of anti-tachyarrhythmia device in which the invention may be embodied, and not as limiting, as it is believed that the invention may usefully be practiced in a wide variety of device implementations, including devices providing therapies for treating atrial arrhythmias instead of or in addition to ventricular arrhythmias, cardioverters and defibrillators which do not provide anti-tachycardia pacing therapies, anti-tachycardia pacers which do not provide cardioversion or defibrillation, and devices which deliver different forms of anti-arrhythmia therapies such nerve stimulation or drug administration.

[0030] The device is provided with a lead system including electrodes, which may be as illustrated in Figure 1. Alternate lead systems may of course be substituted. If the electrode configuration of Figure 1 is employed, the correspondence to the illustrated electrodes is as follows. Electrode 311 corresponds to electrode 11, and is the uninsulated portion of the housing of the implantable pacemaker/cardioverter /defibrillator. Electrode 320 corresponds to electrode 20 and is a defibrillation electrode located in the right ventricle. Electrode 310 corresponds to electrode 8 and is a defibrillation electrode located in the coronary sinus. Electrode 318 corresponds to electrode 28 and is a defibrillation electrode located in the superior vena cava. Electrodes 324 and 326 correspond to electrodes 24 and 26, and are used for sensing and pacing in the ventricle. Electrodes 317 and 321 correspond to electrodes 19 and 21 and are used for pacing and sensing in the atrium.

[0031] Electrodes 310, 311, 318 and 320 are coupled to high voltage output circuit 234. Electrodes 324 and 326 are coupled to the R-wave amplifier 200, which preferably takes the form of an automatic gain controlled amplifier providing an adjustable sensing threshold as a function of the measured R-wave amplitude. A signal is generated on R-out line 202 whenever the signal sensed between electrodes 324 and 326 exceeds the present sensing threshold.

[0032] Electrodes 317 and 321 are coupled to the P-wave amplifier 204, which preferably also takes the form of an automatic gain controlled amplifier providing an adjustable sensing threshold as a function of the measured R-wave amplitude. A signal is generated on P-out line 206 whenever the signal sensed between electrodes 317 and 321 exceeds the present sensing threshold. The general operation of the R-wave and P-wave amplifiers 200 and 204 may correspond to that disclosed in U.S. Patent No. 5,117,824, by Keimel, et al., issued June 2, 1992, for an Apparatus for Monitoring Electrical Physiologic Signals.

[0033] However, any of the numerous prior art sense amplifiers employed in implantable cardiac pacemakers, defibrillators and monitors may also usefully be employed in conjunction with the present invention.

[0034] Switch matrix 208 is used to select which of the available electrodes are coupled to wide band amplifier 210 for use in digital signal analysis. Selection of electrodes is controlled by the microprocessor 224 via data/address bus 218, which selections may be varied as desired. Signals from the electrodes selected for coupling to bandpass amplifier 210 are provided to multiplexer 220, and thereafter converted to multi-bit digital signals by A/D converter 222, for storage in random access memory 226 under control of direct memory access circuit 228. Microprocessor 224 may employ digital signal analysis techniques to characterize the digitized signals stored in random access memory 226 to recognize and classify the patient's heart rhythm employing any of the numerous signal-processing methodologies known to the art.

[0035] Telemetry circuit 330 receives downlink telemetry from and sends uplink telemetry to the patient activator by means of antenna 332. Data to be uplinked to the activator and control signals for the telemetry circuit are provided by microprocessor 224 via address/data bus 218. Received telemetry is provided to microprocessor 224 via multiplexer 220. The atrial and ventricular sense amp circuits 200, 204 produce atrial and ventricular EGM signals, which also may be digitized, and uplink telemetered to an associated programmer on receipt of a suitable interrogation command. The device may also be capable of generating so-called marker codes indicative of different cardiac events that it detects. A pacemaker with marker-channel capability is described, for example, in U.S. Patent No. 4,374,382 to Markowitz.
The particular telemetry system employed is not critical to practicing the invention, and any of the numerous types of telemetry systems known for use in implantable devices may be used. In particular, the telemetry systems as disclosed in U.S. Patent No. 5,292,343 issued to Blanchette et al., U.S. Patent No. 5,314,450, issued to Thompson, U.S. Patent No. 5,354,319, issued to Wyborny et al. U.S. Patent No. 5,383,909, issued to Keimel, U.S. Patent No. 5,168,871, issued to Grevious, U.S. Patent No. 5,107,833 issued to Barsness or U.S. Patent No. 5,324,315, issued to Grevious, are suitable for use in conjunction with the present invention. However, the telemetry systems disclosed in the various other patents cited herein which are directed to programmable implanted devices, or similar systems may also be substituted. The telemetry circuit 330 is of course also employed for communication to and from an external programmer, as is conventional in implantable anti-arrhythmia devices.

[0036] The device of Figure 5 may additionally be provided with an activity sensor 344, mounted to the interior surface of the device housing or to the hybrid circuit within the device housing. The sensor 344 and sensor present in circuitry 342 may be employed in the conventional fashion described in U.S. Patent 4,428,378 issued to Anderson et al, to regulate the underlying pacing rate of the device in rate responsive pacing modes and also serves as in an indicator of the patient's activity level for use in conjunction with the measurement of heart rate at rest or during sleep, as discussed above and as discussed in more detail below in conjunction with Figures 10 and 12. In addition, the sensor 344 may be employed to track the functional status of the patient as in the above-cited application by Stone et al. In such case, the device may also store trend information with regard to the number of and/or durations of periods in which the patient's physical activity meets or exceeds a defined level. Comparisons of the stored trend of day and/or night heart rate with trend information related to sensor output may be especially valuable.

[0037] The remainder of the circuitry is dedicated to the provision of cardiac pacing, cardioversion and defibrillation therapies, and, for purposes of the present invention may correspond to circuitry known in the prior art An exemplary apparatus is disclosed for accomplishing pacing, cardioversion and defibrillation functions as follows. The pacer timing/control circuitry 212 includes programmable digital counters which control the basic time intervals associated with DDD, VVI, DVI, VDD, AAI, DDI, DDDR, VVIR, DVIR, VDDR, AAIR, DDIR and other modes of single and dual chamber pacing well known to the art. Circuitry 212 also controls escape intervals associated with anti-tachyarrhythmia pacing in both the atrium and the ventricle, employing, any anti-tachyarrhythmia pacing therapies known to the art.

[0038] Intervals defined by pacing circuitry 212 include atrial and ventricular pacing escape intervals, the refractory periods during which sensed P-waves and R-waves are ineffective to restart timing of the escape intervals and the pulse widths of the pacing pulses. The durations of these intervals are determined by microprocessor 224, in response to stored data in memory 226 and are communicated to the pacing circuitry 212 via address/data bus 218. Pacer circuitry 212 also determines the amplitude of the cardiac pacing pulses under control of microprocessor 224.

[0039] During pacing, the escape interval counters within pacer timing/control circuitry 212 are reset upon sensing of R-waves and P-waves as indicated by signals on lines 202 and 206, and in accordance with the selected mode of pacing on time-out trigger generation of pacing pulses by pacer output circuits 214 and 216, which are coupled to electrodes 317, 321, 324 and 326. The escape interval counters are also reset on generation of pacing pulses, and thereby control the basic timing of cardiac pacing functions, including anti-tachyarrhythmia pacing.

[0040] The durations of the intervals defined by the escape interval timers are determined by microprocessor 224, via data/address bus 218. The value of the count present in the escape interval counters when reset by sensed R-waves and P-waves may be used to measure the durations of R-R intervals, P-P intervals, PR intervals

and R-P intervals, which measurements are stored in memory 226 and are used in conjunction with the present invention to measure heart rate variability and heart rate trends and in conjunction with tachyarrhythmia detection functions.

[0041] Microprocessor 224 operates as an interrupt driven device, and is responsive to interrupts from pacer timing/control circuitry 212 corresponding to the occurrences of sensed P-waves and R-waves and corresponding to the generation of cardiac pacing pulses. These interrupts are provided via data/address bus 218. Any necessary mathematical calculations to be performed by microprocessor 224 and any updating of the values or intervals controlled by pacer timing/control circuitry 212 take place following such interrupts. Microprocessor 224 includes associated ROM in which the stored program controlling its operation as described below resides. A portion of the memory 226 (Figure 2) may be configured as a plurality of recirculating buffers, capable of holding series of measured intervals, which may be analyzed in response to the occurrence of a pace or sense interrupt to determine whether the patient's heart is presently exhibiting atrial or ventricular tachyarrhythmia.

[0042] The arrhythmia detection method of the present invention may include any of the numerous available prior art tachyarrhythmia detection algorithms. One preferred embodiment may employ all or a subset of the rule-based detection methods described in U.S. Patent No. 5,545,186 issued to Olson et al. or in U.S. Patent No. 5,755,736 issued to Gillberg et al.

However, any of the various other arrhythmia detection methodologies known to the art might also be employed.

[0043] In the event that an atrial or ventricular tachyarrhythmia is detected, and an anti-tachyanhythmia pacing regimen is desired, timing intervals for controlling generation of anti-tachyarrhythmia pacing therapies are loaded from microprocessor 224 into the pacer timing and control circuitry 212, to control the operation of the escape interval counters therein and to define refractory periods during which detection ofR-waves and P-waves is ineffective to restart the escape interval counters.

[0044] In the event that generation of a cardioversion or defibrillation pulse is required, microprocessor 224 employs the escape interval counter to control timing of such cardioversion and defibrillation pulses, as well as associated refractory periods.

In response to the detection of atrial or ventricular fibrillation or tachyarrhythmia requiring a cardioversion pulse, microprocessor 224 activates cardioversion/defibrillation control circuitry 230, which initiates charging of the high voltage capacitors 246, 248 via charging circuit 236, under control of high voltage charging control line 240. The voltage on the high voltage capacitors is monitored via VCAP line 244, which is passed through multiplexer 220 and in response to reaching a predetermined value set by microprocessor 224, results in generation of a logic signal on Cap Full (CF) line 254, terminating charging. Thereafter, timing of the delivery of the defibrillation or cardioversion pulse is controlled by pacer timing/control circuitry 212. Following delivery of the fibrillation or tachycardia therapy the microprocessor then returns the device to cardiac pacing and awaits the next successive interrupt due to pacing or the occurrence of a sensed atrial or ventricular depolarization. In the illustrated device, delivery of the cardioversion or defibrillation pulses is accomplished by output circuit 234, under control of control circuitry 230 via control bus 238. Output circuit 234 determines whether a monophasic or biphasic pulse is delivered, whether the housing 311 serves as cathode or anode and which electrodes are involved in delivery of the pulse.

[0045] Figure 6 is a functional schematic diagram of the pacemaker 120 illustrated in Figure 2. The pacemaker of Figures 2 and 6 is essentially a set of subcomponents of the implantable pacemaker/cardioverter/defibrillator illustrated in Figures 1 and 5. Like the device of Figure 5, the pacemaker is a microprocessor-controlled device with microprocessor 189 operating under control of programming stored in Read Only Memory (ROM) 191. In the device as illustrated, electrodes 136 and 138, intended for location in the atrium of the patient's heart are coupled to an atrial amplifier 181 which may correspond to atrial amplifier 204 in Figure 5. Similarly, ventricular electrodes 140 and 142 are coupled to ventricular amplifier 182, which may correspond to ventricular amplifier 200 in Figure 5. The outputs of atrial and ventricular amplifiers 181 and 182 are input into timing and control circuitry 183 which conforms generally to the pacer timing and control circuitry 212 of Figure 5, and which measures intervals between detected depolarizations and controls intervals between delivered pacing pulses as well as generating interrupts via data/address 192 to awake microprocessor 189 in response to delivery of a pacing pulse or sensing of a cardiac depolarization. Intervals between depolarizations measured by timing/control circuitry 183 are stored in Random Access Memory (RAM) 190 until processed by microprocessor 189 to derive average heart rate values. Atrial and ventricular pacing pulses delivered according to one or more of the standard pacing modes described in conjunction with Figure 5 are produced by atrial and ventricular pulse generator circuits 184 and 185 which may correspond to pulse generator circuits 215 ad 216 in Figure 5.

[0046] The sensor illustrated in Figure 6 may correspond to either an activity sensor 126 as described in conjunction with Figure 2 above, to a hemodynamic sensor 140, as described in conjunction with one embodiment of Figure 2, or to a respiration sensor. If the sensor is an activity sensor, then sensor-processing circuitry 186 may correspond to sensor processing circuitry 342 discussed in conjunction with Figure 5. However, if the sensor is a hemodynamic sensor, the sensor processing circuitry would correspond to the sort of processing circuitry typically associated with hemodynamic sensors. For purposes of the present invention, the hemodynamic sensor may be, for example, an oxygen saturation sensor in con-

junction with associated processing circuitry as described in U.S. Patent No. 6,125,290 issued to Miesel, a pressure sensor and associated sensor processing circuitry as described in U.S. Patent No. 6,024,704 issued to Meador et al., an impedance sensor and associated sensor processing circuitry as described in U.S. Patent No. 5,876,353 issued to Riff, or a temperature sensor and associated processing circuitry as described in U.S. Patent No. 5,957,961 issued to Maguire et al. or may correspond to other types of physiologic sensors, as may be appropriate. As discussed in more detail below, in the context of the present invention, the sensor 126, 140 is employed to determine when the patient is in a resting state, for purposes of controlling the gathering and storage of information related to long term heart rate trends. Telemetry circuitry 187 in conjunction with antenna 188 serves to transmit information to and receive information from an external programmer precisely as described above in conjunction with the device of Figure 5, including information related to stored median interval values and heart rate variability measurements in RAM 190, as calculated by microprocessor 189.

[0047] Figure 7 illustrates the functional organization of the subcutaneously implantable heart monitor 100 illustrated in Figure 3. This device consists essentially of a set of subcomponents of the more complex embodiment of the invention disclosed in Figure 5, and includes a sense amplifier 152 coupled to electrodes 102 and 106, illustrated in Figure 1. Sense amplifier 152 may correspond to sense amplifier 204 or 200 in Figure 5. Like the device of Figure 5, the implantable monitor may be a microprocessor control device operating under control microprocessor 156 with its functionality controlled primarily by software stored in the read only memory associated therein. In this context, amplifier 152 detects the occurrence of heart depolarizations, with timing/control circuitry 154 serving to measure the durations between the detected heart depolarizations and to generate interrupts awakening microprocessor 156 so that it may store, analyze and process the detected intervals. Random Access Memory (RAM) 158 serves to store measured and calculated parameters including the calculated average heart rate values for later telemetry to an external device. Like the device in Figure 5, timing and control circuitry communicates with the microprocessor and the remaining circuitry by means of the address/data bus 168. Telemetry system 162 may correspond to telemetry system 330 in Figure 5 and, via antenna 110 transmits and receives information from the external programmer, including transmitting information with regard to the calculated median rate values and heart variability values stored in RAM 158. Sensor 112 may correspond to sensor 344 in Figure 5 and it may be a physical activity sensor as discussed above. The output of sensor 112 is passed through sensor processing circuitry 166 which may correspond to sensor processing circuitry 342 in Figure 5.

[0048] Figure 8 is a functional schematic of a programmer as illustrated in Figure 4 appropriate for use in conjunction with the invention. Programmer 420 is a personal computer type, microprocessor-based device incorporating a central processing unit 450, which may be, for example, an Intel 80386 or 80486 or Pentium microprocessor or the like. A system bus 451 interconnects CPU 450 with a hard disk drive 452 storing operational programs and data and with a graphics circuit 453 and an interface controller module 454. A floppy disk drive 466 or a CD ROM drive is also coupled to bus 451 and is accessible via a disk insertion slot within the housing of the programmer 420. Programmer 420 further comprises an interface module 457, which includes digital circuit 458, non-isolated analog circuit 459, and isolated analog circuit 460. Digital circuit 448 enables interface module 457 to communicate with interface controller module 454.

[0049] In order for the physician or other caregiver or user to communicate with the programmer 420, control buttons 465 or optionally a keyboard coupled to CPU 50 are provided. However the primary communication mode is through graphics display screen 455 of the well-known "touch sensitive" type controlled by graphics circuit 453. A user of programmer 420 may interact therewith through the use of a stylus 456, also coupled to graphics circuit 453, which is used to point to various locations on screen 455, which display menu choices for selection by the user or an alphanumeric keyboard for entering text or numbers and other symbols.

[0050] Graphics display 455 also displays a variety of screens of telemetered out data or real time data including measurements of heart rate variability and heart rate trends according to the present invention. Programmer 420 is also provided with a strip chart printer 463 or the like coupled to interface controller module 454 so that a hard copy of a patient's ECG, EGM, marker channel or of graphics displayed on the display 455 can be generated.

[0051] As will be appreciated by those of ordinary skill in the art, it is often desirable to provide a means for programmer 20 to adapt its mode of operation depending upon the type or generation of implanted medical device to be programmed. Accordingly, it may be desirable to have an expansion cartridge containing EPROM's or the like for storing software programs to control programmer 420 to operate in a particular manner corresponding to a given type or generation of implantable medical device. In addition, in accordance with the present invention, it is desirable to provide the capability through the expansion cartridge or through the floppy disk drive 66 or CD ROM drive.

[0052] The non-isolated analog circuit 459 of interface module 457 is coupled to a programming head 422, which is used to establish the uplink and downlink telemetry links between the pacemaker 410 and programmer 420 as described above. Uplink telemetered EGM signals are received in programming head 422 and provided to non-isolated analog circuit 459. Non-isolated analog circuit 459, in turn, converts the digitized EGM signals to analog EGM signals and presents these signals on output lines

A EGM OUT and V EGM OUT. These output lines may then be applied to a strip-chart recorder 463 to provide a hard-copy printout of the A EGM or V EGM for viewing by the physician. Similarly, the markers received by programming head 422 are presented on the MARKER CHANNEL output line from non-isolated analog circuit 459.

[0053] Isolated analog circuit 460 in interface module 547 is provided to receive external ECG and electrophysiologic (EP) stimulation pulse signals. In particular, analog circuit 460 receives ECG signals from patient skin electrodes 459 and processes these signals before providing them to the remainder of the programmer system in a manner well known in the art. Circuit 460 further operates to receive the EP stimulation pulses from an external EP stimulator for the purposes of non-invasive EP studies, as is also known in the art.

[0054] In order to ensure proper positioning of programming head 422 over the antenna of the associated implanted device, feedback is provided to the physician that the programming head 422 is in satisfactory communication with and is receiving sufficiently strong RF signals. This feedback may be provided, for example, by means of a head position indicator, e.g. a light-emitting diode (LED) or the like that is lighted to indicate a stable telemetry channel.

[0055] Figure 9 illustrates a functional flow chart describing a first method of calculating average heart rates during predetermined time periods within the course of a day. For example, day-time and night-time heart rate averages may be calculated for use in determining heart rate trends that may then be displayed on an associated external programmer. In this context, the flow chart of Figure 9 starts from the assumption that the implanted device will collect the measured heart intervals and calculate and store the average heart interval values for day heart rate and/or night heart rate, with the calculated average day heart rate and night simply displayed on the external device associated with the implanted device. In this context, it should also be understood that all calculations and processing of the measured heart intervals is performed by the microprocessor within the implanted device. However, as noted above, alternate divisions of tasks between the implanted and external devices are still believed to be within the scope of the invention.

[0056] At 600, the device is initialized and thereafter sets SUMNN = 0 at 602. SUMNN is a running sum of the total duration of measured heart intervals retained for use in calculation of average heart rate according to the present invention. The device also sets the value of NN = 0 in 602. NN is the running total of measured heart intervals employed in calculation of average day or night heart rates according to the present invention. The device then waits until the time of day falls within the desired time window extending from a start time "A" to an end time "B" at 604. In the context of monitoring of average daily heart rate, the defined time range may extend between 8:00 a.m. and 8:00 p.m., for example. In the context of a device which measures average nightly heart rate, the defined range may extend between 12:00 a.m. and 4:00 a.m., for example. It should be also understood that the same device may make and store measurements of both average day heart rate and average night heart rate.

[0057] If the device determines that present time T is within the defined desired time range for heart range monitoring, in response to a sensed or paced depolarization at 606, the device at 608 stores the measured heart interval separating the sensed or paced depolarization 606 from the preceding paced or sensed depolarization, as measured in milliseconds. In one embodiment, all intervals within the desired time range are retained for purposes of calculating an average rate. In another embodiment, only intervals terminating in a sensed depolarization are retained. That is, in this alternative embodiment, only "sense-to-sense" intervals and "pace-to-sense" intervals are measured, with "sense-to-pace" and "pace-to-pace" intervals being discarded as not being indicative of a natural heart rate. Of course, if the invention is implemented within a hemodynamic monitoring device that does not provide pacing therapy, all intervals will be retained in both embodiments.

[0058] At 610, the device determines whether the measured heart interval is acceptable for use in determining average heart rate or should be rejected. The desirability of rejecting measured heart intervals will depend upon the condition of the patient and the type of device implanted. For example, in the case of a patient who is subject to atrial or ventricular tachycardia, wherein the device employing the present invention is an implantable pacemaker/cardioverter/defibrillator, it may be desirable to discard all measured heart intervals associated with detection and treatment of tachyarrhythmias. For example the device may reject all intervals which meet tachyarrhythmia detection criteria due to their relatively short duration, all intervals obtained during charging of the output capacitors of such a device prior to delivery of a cardioversion or defibrillation shock and all intervals sensed during delivery of anti-tachyarrhythmia therapies such as anti-tachycardia pacing, cardioversion and defibrillation. In contrast, if the invention is embodied in a simple VVI-type pacemaker, and the patient is not subject to tachyarrhythmias, there may be no need to discard any heart intervals ending on a sensed depolarization. In addition or as an alternative, in which the invention is embodied to include a dual chamber pacemaker capable of switching between various pacing modes in response to detected atrial tachyarrhythmias, it may be desirable to discard heart intervals measured during operation of the mode switch between pacing modes.

[0059] If the measured heart interval is not rejected, the value of the interval is added to SUMNN at 612, and the value of NN is incremented by one at 614. The device continues to increment the values of SUMNN and NN according to this mechanism until the present time T equals or exceeds the defined expiration time B for heart

rate monitoring. At 616, the device compares the total duration of measured and saved intervals to a desired total duration "X" which may reflect a predetermined proportion of the duration of the monitoring interval. For example, the value of SUMNN may have to exceed 20% of the defined monitoring period. In the event that the value of SUMNN is inadequate, the device stores an indication that no heart rate has been calculated for the monitoring period presently in effect at 620, and the device resets the values of SUMNN and NN to zero at 602, awaiting the next defined monitoring interval. If the value of SUMNN is adequate, the average heart rate HR in beats per minute is calculated by means of the equation HR = 60,000/(SUMNN/NN) at 622, and the value of HR, representing the average heart rate over the monitoring period is stored at 624 for later telemetry to the associated external device and for display by the associated external device. The method of operation illustrated in Figure 9 may be employed to collect and calculate average daily rates, average night heart rates, or both, for display on the associated external device.

[0060] Figure 10 illustrates an alternative embodiment of the present invention in which an associated activity sensor or other metabolic sensor is employed in order to assure that during the defined heart rate monitoring periods, only heart intervals indicative of the patient at rest are employed in calculating average heart rates. It should be noted that the method of operation illustrated in Figure 10 also permits the calculation of average resting heart rates over 24 hour periods, by simply designating the desired monitoring period as successive 24 hour periods rather than discreet periods within each 24 hour period.

[0061] After initialization at 700, the device sets SUMNN and NN to zero at 702, as discussed above in conjunction with Figure 9, and awaits the beginning of the defined monitoring period at 704. At 706, the device initiates the relatively shorter time period T1, over which the patient's physical activity or other metabolic indicator of demand for cardiac output is to be monitored. The values of INTCOUNT, indicative of the number of intervals counted during this shorter time interval T1 and INTSUM, reflective of the total duration of intervals stored during interval T1 are reset to zero at 706. The value of T1 is preferably fairly short, for example, in the range of a few minutes, for example, about two to five minutes. Thereafter, until expiration of the shorter period T1 at 712, each time a paced or sensed depolarization is occurs at 708, the heart interval separating the depolarization from the preceding depolarization is stored at 710, and the device determines whether the stored interval should be rejected at 726, in a fashion analogous to that described in conjunction with Figures 9 above. If the interval is saved, the value of INTCOUNT is incremented by one at 728 and the value of INTSUM is incremented by the duration of the stored heart interval at 730. This process continues until expiration of time period T1 at 712. Following expiration of T1 at 712, the device checks the output of the sensor over the preceding time period T1 and compares the output to a defined threshold to determine whether the patient is at rest at 714. For example, if the sensor output takes the form of successive numerical values (e.g. counts) generated over T1, the sum, mean, or median of the numerical values generated during TI may be calculated and analyzed, for example by comparison to a threshold value, to determine whether the patient was at rest during T1. If the sensor's output based on directly measured activity or other measured metabolic demand indicator indicates the patient was not at rest, the intervals collected during the preceding shorter T1 period are discarded, and the next T1 period is initiated at 706. If the activity sensor or other indicator of metabolic demand indicates that the patient was at rest during the preceding shorter time period T1, the value of NN is incremented by the value of INTCOUNT at 732 and the value of SUMNN is incremented by INTSUM at 734. This process continues until the device determines at 736 that the present time T is equal to or after the expiration point B of the defined monitoring period.

[0062] On expiration of the defined monitoring period, the device checks at 724 to determine whether the value of SUMNN exceeds a desired total duration, precisely as described above, in conjunction with Figure 9. If the total duration of stored heart intervals is less than the desired total, the device stores an indication that no measurement of average heart rate was stored for the monitoring period at 720. However, if the total duration of measured heart intervals is sufficiently great, the value of the average heart rate is calculated at 718 in the same fashion as discussed in conjunction with Figure 10 above, and the stored value of the average heart rate for the monitoring interval is stored at 716 for later telemetry to an associated external device for display thereon.

[0063] It may be noted that the time interval T1 may be selected as one or more hours long. Alternatively, T1 may be less than one hour long. If desired, T1 may be reduced to a value that approximates one heart interval so that the activity level of the patient is tracked on a beat-to-beat basis.

[0064] Figure 11 illustrates a functional flow chart describing an alternative embodiment of the present invention in which sensor outputs are monitored over daytime or nighttime periods, in a manner analogous to the collection of heart rate information as discussed in conjunction with Figure 9 and 10 above. The term "average" in the context of Figure 11 is the same as discussed above in conjunction with monitoring of heart rates. The sensor may be an activity sensor as described above or any of the various known physiologic sensors available for implant in the human body, including but not limited to sensors of metabolic demand for oxygenated blood, including oxygen saturation sensors, blood pressure sensors, blood temperature sensors, pH sensors, respiration sensors and the like.

[0065] Calculation of a daily sensor output and a night sensor output value may be used, for example, in constructing day sensor output trends and night sensor out-

put trends for display on the associated external programmer. In this context, the flow chart of Figure 11 starts from the assumption that the implanted device will collect the measured sensor output values and calculate and store average or total values for day sensor output and/or night sensor output, with the calculated average or total value displayed on the external device associated with the implanted device. In this context, it should also be understood that all calculations and processing of the measured sensor output values are performed by the microprocessor within the implanted device. However, as noted above, alternate divisions of tasks between the implanted and external devices are still believed to be within the scope of the invention.

[0066] At 800, the device is initialized and thereafter sets SUMSENS = 0 at 802. SUMSENS is a running sum of the total of measured sensor outputs retained for use in calculation of average or total sensor output according to the present invention. The device then waits until the time of day falls within the desired time window extending from a start time "A" to an end time "B". In the context of monitoring of daily sensor output, the defined time range may extend between 8:00 a.m. and 8:00 p.m., for example. In the context of a device that measures nightly sensor output, the defined range may extend between 12:00 a.m. and 4:00 a.m., for example. It should be also understood that the same device may make and store measurements of both day and night sensor outputs.

[0067] If the device determines that present time T is within the defined desired time range for heart range monitoring, in response to a new output sensor value at 806, the device at 808 stores the measured sensor output as a numerical value. The value of the sensor output (SO) is added to SUMSENS at 812. The device continues to increment the values of SUMSENS according to this mechanism until the present time T equals or exceeds the defined expiration time B for sensor output monitoring at 816. On expiration of the defined time for sensor output monitoring, the device either stores SUMSENS at 820 or optionally calculates and stores an average sensor output value at 822 and 824, for example calculated based on SUMSENS and the duration of the defined time for sensor output monitoring or based on SUMSENS and the total number of sensor outputs included in SUMSENS, in a fashion analogous to that employed to calculate heart rate averages according to the method illustrated in Figure 9.

[0068] According to one aspect of the invention, the physiologic sensor is an implanted impedance sensor employed to measure respiration rates, as may be provided by an implantable medical device such as that shown in Figure 2. Systems using impedance sensors to measure patient respiratory trends are disclosed in U.S. Patent No. 5,957,861 issued Combs et al, U.S. Patent No. 5,876,353 issued to Riff et al, or U.S. Patent No. 5,562,711 issued to Yerich et al.

[0069] As discussed above, respiration rates are often tracked using minute ventilation. Minute ventilation is defined as the total amount of gas that is moved into, and out of, the lungs in one minute. This measurement is generally obtained in a clinical setting using a flow meter positioned within a patient's mouth. However, the inventors have shown that minute ventilation can also be closely approximated by measuring the changes in tissue impedance that occur as the lungs expand and contract during breathing, as may be detected by an implanted impedance sensor.

[0070] The current invention provides a system for monitoring minute ventilation in a manner that extends beyond the clinical setting so that long-term trends in patient health may be more accurately evaluated. For example, the invention may be used to detect otherwise unrecognized acute disease or acute deterioration in the status of chronic disease. Early detection of otherwise unrecognized acute disease permits treatment that can potentially prevent, or minimize, further progression of the disease.

[0071] Many health conditions cause changes in minute ventilation rates. For example, elevated minute ventilation can be caused by acute heart failure, acute cardiac ischemia, renal failure, pneumonia, pulmonary congestion, pulmonary edema, pulmonary embolism, acute asthma, fever, sepsis, shock, and stroke. Additionally, minute ventilation trends that include a period of increased breathing rate followed by a significantly slowed breathing rate may indicate Cheyne-Stokes respiration or sleep apnea. Detection of Cheyne-Stokes respiration is particularly critical since this symptom is present in up to forty percent of all heart failure patients.

[0072] As stated above, the current invention provides a system for monitoring long-term trends in minute ventilation using impedance measurements. The inventors have determined that transthoracic impedance minute ventilation measurements have a good correlation to minute ventilation measurements obtained using an external gas flow meter. It may be noted, however, that the correlation between a minute ventilation measurement obtained using an impedance sensor and a measurement obtained using a flow meter may vary on a patient-to-patient basis. In other words, if two patients manifest a change in minute ventilation value measured using the impedance system described above, they may not exhibit an identical change in minute ventilation values measured using a flow meter. Therefore, for purposes of employing average values of measured minute ventilation as a diagnostic criterion, it is recommended that proportional, rather than absolute, changes in minute ventilation values be employed for diagnostic purposes. For example, it has been found that a percentage changes in minute ventilation measured using the impedance-based system correspond very well to the percentage changes in minute ventilation as measured by the flow meter.

[0073] According to one embodiment of the invention, displays of trend lines obtained using an impedance sensor may be formatted using a percentage of change scale as opposed to an absolute value of a ventilation scale.

In the context of the present invention it is anticipated that a programmer as described above may be used to display a trend line of the measured minute ventilation values, and that a particularly useful display might employ a baseline of average minute ventilation values obtained prior to the values displayed, with a vertical axis indicative of a percentage change from the baseline associated with each subsequent monitoring period. Similarly, changes in minute ventilation may be used as a means for triggering an indicator or an alarm, or for altering an operative parameter of the medical device so that a clinician may be alerted of a patient's changing condition. In this case as in the cases discussed above, it is suggested that the programmer or implanted device employ a percentage change in minute ventilation as a threshold for detection.

[0074] According to one embodiment of the invention, minute volume measurements are obtained only when the patient is at rest. As discussed above, this can be determined using an activity sensor or another sensor for measuring metabolic parameters. Preferably, impedance measurements indicative of minute ventilation are taken only after the patient has been inactive for at least several minutes. Limiting measurements to time periods when the patient is at rest eliminates the need to evaluate physical exertion, which will also affect minute ventilation.

[0075] In one embodiment of the invention, minute ventilation is only measured during predetermined time periods. For example, the time period employed to monitor respiration during night time hours may be limited to the vicinity of 12 o'clock midnight, and more preferably to a monitoring period between about 12:00. a.m. to about 2:00 a.m. Testing by the inventors has determined that minute ventilation measurements using impedance sensors as described in the above-cited patents show the greatest repeatability (least variability) over multiple measurement cycles when measured during this time period. As such, this particular time period provides the best opportunity for measuring changes in minute ventilation characteristics as reflective of a real change in the patient's underlying condition. Therefore, this offers the best opportunity for updating the base line value for use in an impedance sensor employed to measure minute ventilation. The inventors have also determined that in the context of a device which monitors respiration during daytime or evening hours, periods between approximately 12:00 p.m. to 2:00 p.m. and approximately 6:00 p.m. to 8:00 p.m. also provide relatively high levels of repeatability, and might also be useful for obtaining baseline values corresponding to minute ventilation.

[0076] During the selected monitoring periods, average minute ventilation values may be stored according to the mechanism discussed above in conjunction with Figure 11, and may be employed to generate minute ventilation trend line analysis for use by the physician in monitoring changes in the patient's underlying physical condition. In addition, the average minute ventilation value obtained during a defined monitoring period or periods may be employed as a baseline to regulate the relationship between measured minute ventilation values and pacing rate, according to the above-discussed Yerich patent.

[0077] Figure 12 is a functional flow chart illustrating a method of monitoring breathing trends, which may be employed in conjunction with the present invention. In step 830, an Abnormal Breathing Index (ABI) is set to zero. Then it is determined whether the current time "T" is between a predetermined start time "A" and a predetermined end time "B". This is shown in decision steps 832 and 834. When time "T" is between the predetermined start and end times, which in one embodiment of the invention may be 12:00 a.m. to 2:00 a.m., respectively, processing continues to step 836. In step 836, monitoring of minute ventilation is performed by collecting and storing impedance sensor data. The collection of data may be further pre-conditioned on a measurement that confirms the patient is inactive. Such a measurement may be provided by a posture sensor, an activity sensor, or a sensor for measuring a metabolic parameter. In the event the patient is not inactive during the time period, the measurement is not taken until inactivity is confirmed.

[0078] In one embodiment, collected data is processed in incremental time periods T_w to determine whether abnormal breathing has occurred, as shown in step 838. Abnormal breathing may be detected by determining that the minute ventilation is outside of predetermined "normal" limits for the particular time period. These limits may be different, for example, during night-time monitoring as compared to day-time monitoring when the patient is at rest. The number of breaths may also be used in conjunction with the volume of gas expelled as measured by minute ventilation to determine abnormal breathing patterns. For example, detection of greater than twenty-five breaths per minute may be used as an indicating of an abnormal breathing pattern.

[0079] The incremental time period T_w selected for use in the inventive process may be any time period shorter than the total monitoring time (B-A), and in one embodiment, is set to one minute. The calculation of minute ventilation over incremental time periods is useful in detecting irregular breathing patterns such Cheyne-Stokes respiration, or as breathing patterns caused by sleep apnea. As noted above, during Cheyne-Stokes respiration or when experiencing sleep apnea, a patient may exhibit a first time period of increased minute ventilation followed by a second time period of significantly reduced minute ventilation. This pattern is generally repeated multiple times in succession. Other types of conditions discussed above will also cause an increase or decrease in minute ventilation over short time periods.

[0080] If an abnormal breathing pattern is detected in decision step 840, the ABI is incremented, as illustrated in step 842, and monitoring continues as shown by arrow 844. Otherwise, if the breathing pattern is considered normal, monitoring continues as shown by arrow 846.

[0081] When the monitoring time period elapses such that current time "T" is greater than, or equal to time "B", the calculated ABI may be stored for use in determining long-range trends. If desired, the calculated ABI may be used to update a running average ABI value, as may be desirable to conserve memory within an Implantable Medical Device. This is shown in step 848. Processing then continues to step 830 and the method is repeated.

[0082] Figure 13 is a flowchart illustrating the use of heart rate and respiration trend data as is generated by use of the current invention. As noted above, heart rate and minute ventilation data may be temporarily stored in a storage device such as RAM 226 (Figure 5.) At predetermined times, this data may be retrieved from the storage device and transferred via a communication circuit such as telemetry circuit 330 to external programmer 420. This is shown in step 900 of Figure 13. Once the data is transferred, it may be further manipulated, and displayed for user analysis, as illustrated in step 902. The data may also be further processed for diagnostic purposes, as depicted by step 904. For example, minute ventilation data may be analyzed to determine whether a patient is likely undergoing Cheyne-Stokes respiration. If so, other patient data may be used in conjunction with this apparent respiration trend to determine whether the patient is experiencing the onset of a illness such as heart disease.

[0083] In some embodiments, patient therapy may be modified based on the diagnosis, as indicated by step 906. For example, assuming a patient has been provided with a bi-ventricular pacing device, bi-ventricular pacing could be initiated, or associated pacing parameters could be adjusted, based on the apparent progression of a heart failure condition. Such parameters could be transferred to the IMD via programmer 420 and telemetry circuit 330 for storage in RAM 226, for instance.

[0084] Variations and modifications to the present invention may be possible given the above disclosure. However, all such variations and modifications are intended to be within the scope of the invention claimed by this letters patent.

[0085] In conjunction with the above disclosure, we claim:

Claims

1. A monitoring device for implant in a patient's body, comprising:

an impedance sensor (140) to provide an impedance signal indicative of tissue impedance; and

a processing circuit (186) coupled to the impedance sensor to receive the signal indicative of tissue impedance, and to generate therefrom, numerical values indicative of trends in minute ventilation; **characterised by** further including a second sensor (126) to indicate when a patient is at rest coupled to the processing circuit, and whereby the numerical values indicative of trends in minute ventilation are generated only for an impedance signal measured when the patient is at rest.

2. The device according to claim 1, wherein the processing circuit includes a timing circuit (183) to define monitoring periods during which the processing circuit will use the signal indicative of tissue impedance to generate the numerical values indicative of trends in minute ventilation.

3. The device according to claim 2, wherein the timing circuit includes means to define the monitoring periods as occurring during successive nights substantially between 12:00 a.m. and 2:00 a.m.

4. The device according to claim 1, and further including a storage device (190, 191) coupled to the processing circuit to store the numerical values indicative of trends in minute ventilation.

5. The device according to claim 1, and further includes diagnostic means for utilizing the numerical values to diagnose long-term patient illness.

6. The device according to claim 1, and further including a pulse generator coupled to the processing circuit to generate electrical stimulation signals to be provided to the patient, and whereby the pulse generator is capable of modifying the electrical stimulation signals in response to the numerical values indicative of trends in minute ventilation.

7. The device according to claim 5, and further including a communication circuit (187) coupled to the processing circuit to transfer the numerical values indicative of trends in minute ventilation to a location external to the monitoring device.

8. The device according to claim 7, and further including a programmer (420) coupled to receive from the communication circuit the numerical values indicative of trends in minute ventilation, and wherein the programmer includes a display to display the numerical values indicative of trends in minute ventilation to a user.

9. The device according to claim 8, wherein at least a portion of the diagnostic means is provided by the programmer.

10. The device according to claim 9, wherein the diagnostic means includes means for diagnosing Cheyne-Stokes respiration.

11. The device according to claim 1, and further including an alarm coupled to the processing circuit to provide a notification that the numerical values indicative of trends in minute ventilation are indicative of one or more predetermined conditions.

12. The device according to claim 1, and further including a sensor to measure heart intervals, and wherein the processing circuit further includes means to generate from the measured heart intervals numerical values indicative of heart rate trends.

13. The device according to claim 12, wherein the processing circuit further includes means to discard any ones of the measured heart intervals that have a length outside of a predetermined interval range.

Patentansprüche

1. Überwachungsvorrichtung zur Implantation in den Körper eines Patienten mit:

einem Impedanzsensor (140) zum Bereitstellen eines Impedanzsignals, das die Gewebeimpedanz angibt, und
einer Verarbeitungsschaltung (186), die mit dem Impedanzsensor gekoppelt ist, um das die Gewebeimpedanz angebende Signal zu empfangen und um anhand dessen Zahlenwerte zu erzeugen, die Trends eines Atemminutenvolumens angeben,

dadurch gekennzeichnet, dass sie weiter aufweist:

einen zweiten Sensor (126) zum Angeben, wenn sich ein Patient in Ruhe befindet, der mit der Verarbeitungsschaltung gekoppelt ist, wobei die Trends eines Atemminutenvolumens angebenden Zahlenwerte nur für ein Impedanzsignal erzeugt werden, das gemessen wird, wenn sich der Patient in Ruhe befindet.

2. Vorrichtung nach Anspruch 1, wobei die Verarbeitungsschaltung eine Zeitgeberschaltung (183) zum Definieren von Überwachungszeiträumen, während derer die Verarbeitungsschaltung das die Gewebeimpedanz angebende Signal verwendet, um die Trends eines Atemminutenvolumens angebenden Zahlenwerte zu erzeugen, aufweist.

3. Vorrichtung nach Anspruch 2, wobei die Zeitgeberschaltung Mittel aufweist, um zu definieren, dass die Überwachungszeiträume während aufeinander folgender Nächte im Wesentlichen zwischen 12:00 Uhr nachts und 2:00 Uhr morgens auftreten.

4. Vorrichtung nach Anspruch 1, welche weiter eine Speichervorrichtung (190, 191) aufweist, die mit der Verarbeitungsschaltung gekoppelt ist, um die Trends eines Atemminutenvolumens angebenden Zahlenwerte zu speichern.

5. Vorrichtung nach Anspruch 1, welche weiter diagnostische Mittel zur Verwendung der Zahlenwerte, um einen langfristigen Krankheitszustand des Patienten zu diagnostizieren, aufweist.

6. Vorrichtung nach Anspruch 1, welche weiter einen Impulsgenerator aufweist, der mit der Verarbeitungsschaltung gekoppelt ist, um an den Patienten abzugebende elektrische Stimulationssignale zu erzeugen, wobei der Impulsgenerator in der Lage ist, die elektrischen Stimulationssignale ansprechend auf die Trends eines Atemminutenvolumens angebenden Zahlenwerte zu modifizieren.

7. Vorrichtung nach Anspruch 5, welche weiter eine Kommunikationsschaltung (187) aufweist, die mit der Verarbeitungsschaltung gekoppelt ist, um die Trends eines Atemminutenvolumens angebenden Zahlenwerte zu einem Ort außerhalb der Überwachungsvorrichtung zu übertragen.

8. Vorrichtung nach Anspruch 7, welche weiter ein Programmiergerät (420) aufweist, das gekoppelt ist, um von der Kommunikationsschaltung die Trends eines Atemminutenvolumens angebenden Zahlenwerte zu empfangen, wobei das Programmiergerät eine Anzeige aufweist, um die Trends eines Atemminutenvolumens angebenden Zahlenwerte einem Benutzer zu zeigen.

9. Vorrichtung nach Anspruch 8, wobei zumindest ein Teil der diagnostischen Mittel durch das Programmiergerät bereitgestellt ist.

10. Vorrichtung nach Anspruch 9, wobei die diagnostischen Mittel Mittel zum Diagnostizieren einer Cheyne-Stokes-Atmung aufweisen.

11. Vorrichtung nach Anspruch 1, welche weiter einen mit der Verarbeitungsschaltung gekoppelten Alarm aufweist, um darauf hinzuweisen, dass die Trends eines Atemminutenvolumens angebenden Zahlenwerte eine oder mehrere vorbestimmte Bedingungen angeben.

12. Vorrichtung nach Anspruch 1, welche weiter einen Sensor zum Messen von Herzintervallen aufweist, wobei die Verarbeitungsschaltung weiter Mittel aufweist, um anhand der gemessenen Herzintervalle Herzfrequenztrends angebende Zahlenwerte zu erzeugen.

13. Vorrichtung nach Anspruch 12, wobei die Verarbeitungsschaltung weiter Mittel aufweist, um alle gemessenen Herzintervalle zu verwerfen, deren Länge außerhalb eines vorbestimmten Intervallbereichs liegt.

Revendications

1. Dispositif de surveillance destiné à être implanté dans le corps d'un patient, comportant :

un capteur d'impédance (140) pour délivrer un signal d'impédance indicatif d'impédance de tissu ; et
un circuit de traitement (186) couplé au capteur d'impédance pour recevoir le signal indicatif d'impédance de tissu, et pour générer d'après celui-ci, des valeur numériques indicatives de tendances dans une ventilation minute ; **caractérisé en ce qu'**il inclut de plus un second capteur (126) pour indiquer lorsqu'un patient est au repos couplé au circuit de traitement, et de sorte que les valeurs numériques indicatives de tendances dans une ventilation minute sont générées seulement pour un signal d'impédance mesuré lorsque le patient est au repos.

2. Dispositif selon la revendication 1, dans lequel le circuit de traitement inclut un circuit de cadencement (183) pour définir des périodes de surveillance durant lesquelles le circuit de traitement utilisera le signal indicatif d'impédance de tissu pour générer les valeurs numériques indicatives de tendances dans une ventilation minute.

3. Dispositif selon la revendication 2, dans lequel le circuit de cadencement inclut des moyens pour définir les périodes de surveillance lorsqu'elles apparaissent durant des nuits successives essentiellement entre 12:00 a.m. et 2:00 a.m.

4. Dispositif selon la revendication 1, incluant de plus un dispositif de mémorisation (190, 191) couplé au circuit de traitement pour mémoriser les valeurs numériques indicatives de tendances dans une ventilation minute.

5. Dispositif selon la revendication 1, incluant de plus des moyens de diagnostic pour utiliser les valeurs numériques pour diagnostiquer une maladie chez un patient à long terme.

6. Dispositif selon la revendication 1, incluant de plus un générateur d'impulsions couplé au circuit de traitement pour générer des signaux de stimulation électrique à délivrer au patient, et de sorte que le générateur d'impulsions est capable de modifier les signaux de stimulation électrique en réaction aux valeurs numériques indicatives de tendances dans une ventilation minute.

7. Dispositif selon la revendication 5, incluant de plus un circuit de communication (187) couplé au circuit de traitement pour transférer les valeurs numériques indicatives de tendances dans une ventilation minute à un emplacement à l'extérieur du dispositif de surveillance.

8. Dispositif selon la revendication 7, incluant de plus un programmateur (420) couplé pour recevoir à partir du circuit de communication les valeurs numériques indicatives de tendances dans une ventilation minute, et dans lequel le programmateur inclut un afficheur pour afficher les valeurs numériques indicatives de tendances dans une ventilation minute à un utilisateur.

9. Dispositif selon la revendication 8, dans lequel au moins une partie des moyens de diagnostic est fournie par le programmateur.

10. Dispositif selon la revendication 9, dans lequel les moyens de diagnostic incluent des moyens pour diagnostiquer une respiration de Cheyne-Stokes.

11. Dispositif selon la revendication 1, incluant de plus une alarme couplée au circuit de traitement pour délivrer une notification que les valeurs numériques indicatives de tendances dans une ventilation minute sont indicatives d'un ou de plusieurs conditions prédéterminées.

12. Dispositif selon la revendication 1, incluant de plus un capteur pour mesurer des intervalles cardiaques, et dans lequel le circuit de traitement inclut de plus des moyens pour générer d'après les intervalles cardiaques mesurés des valeurs numériques indicatives de tendances de débit cardiaque.

13. Dispositif selon la revendication 12, dans lequel le circuit de traitement inclut de plus des moyens pour rejeter de quelconques intervalles parmi les intervalles cardiaques mesurés qui ont une longueur à l'extérieur d'une plage d'intervalles prédéterminée.

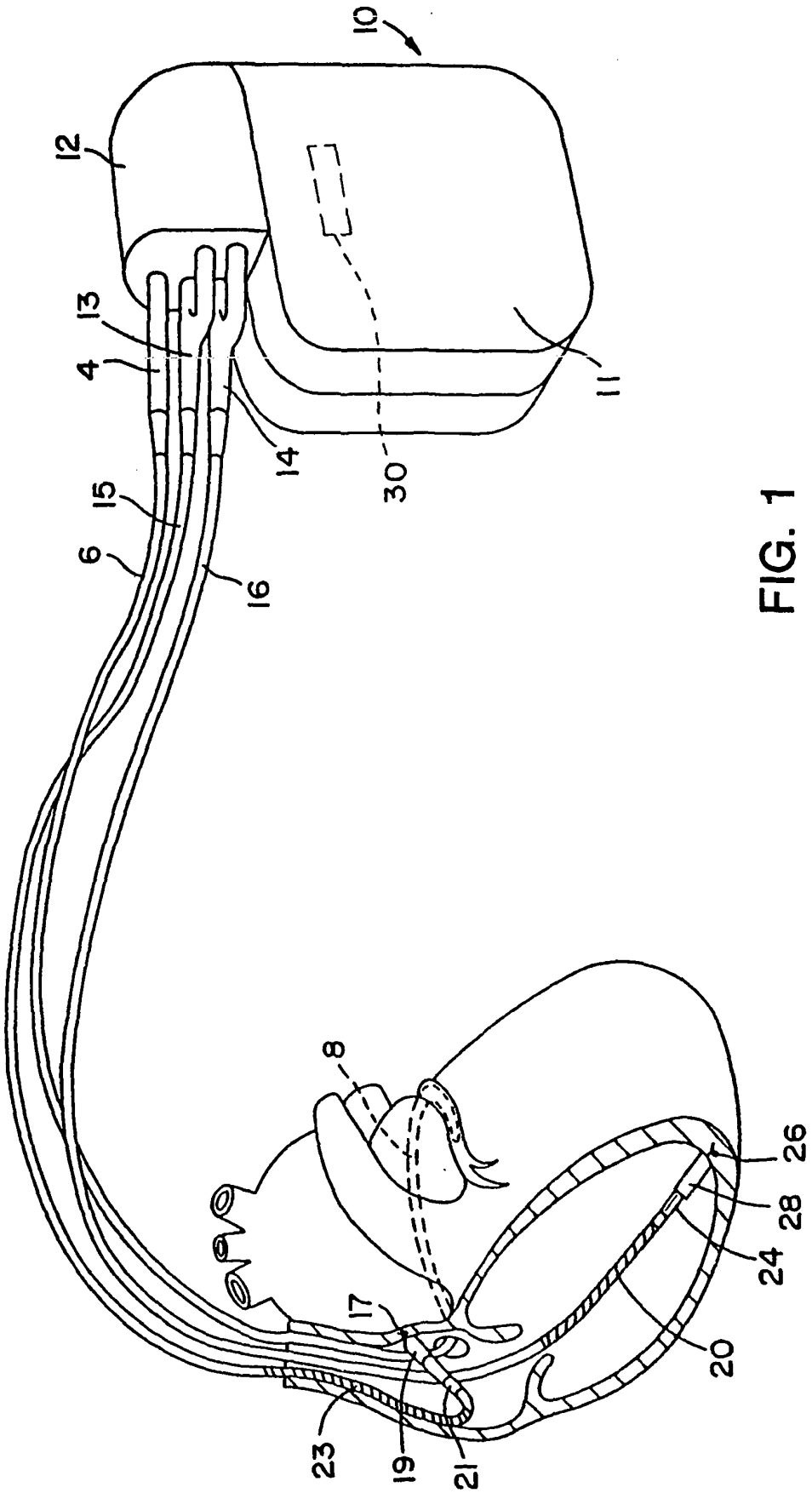

FIG. 1

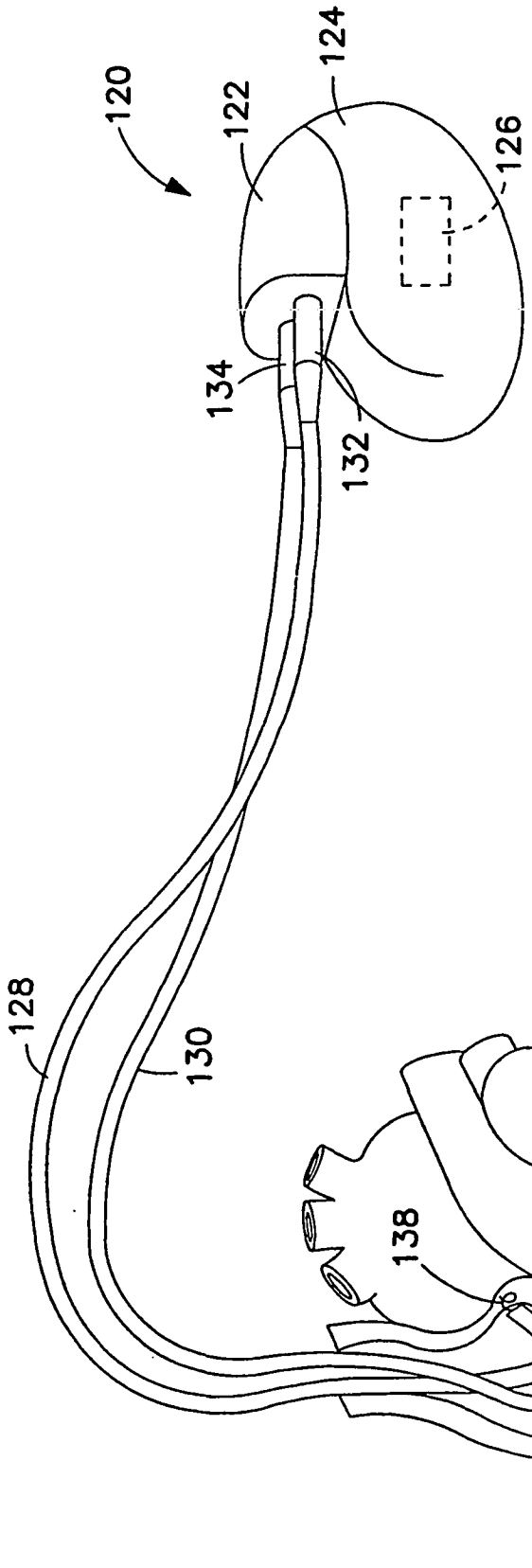
120
122
124
126
134
132
128
130
138
136
142
140
144

FIG. 2

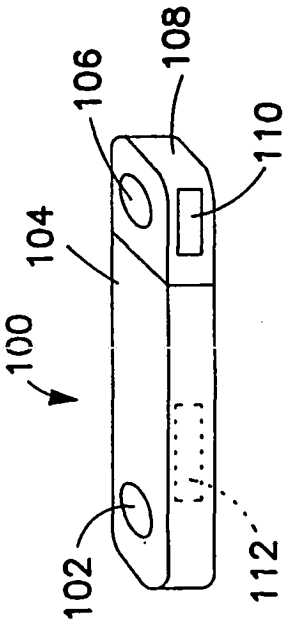
100
102
104
106
108
110
112

FIG. 3

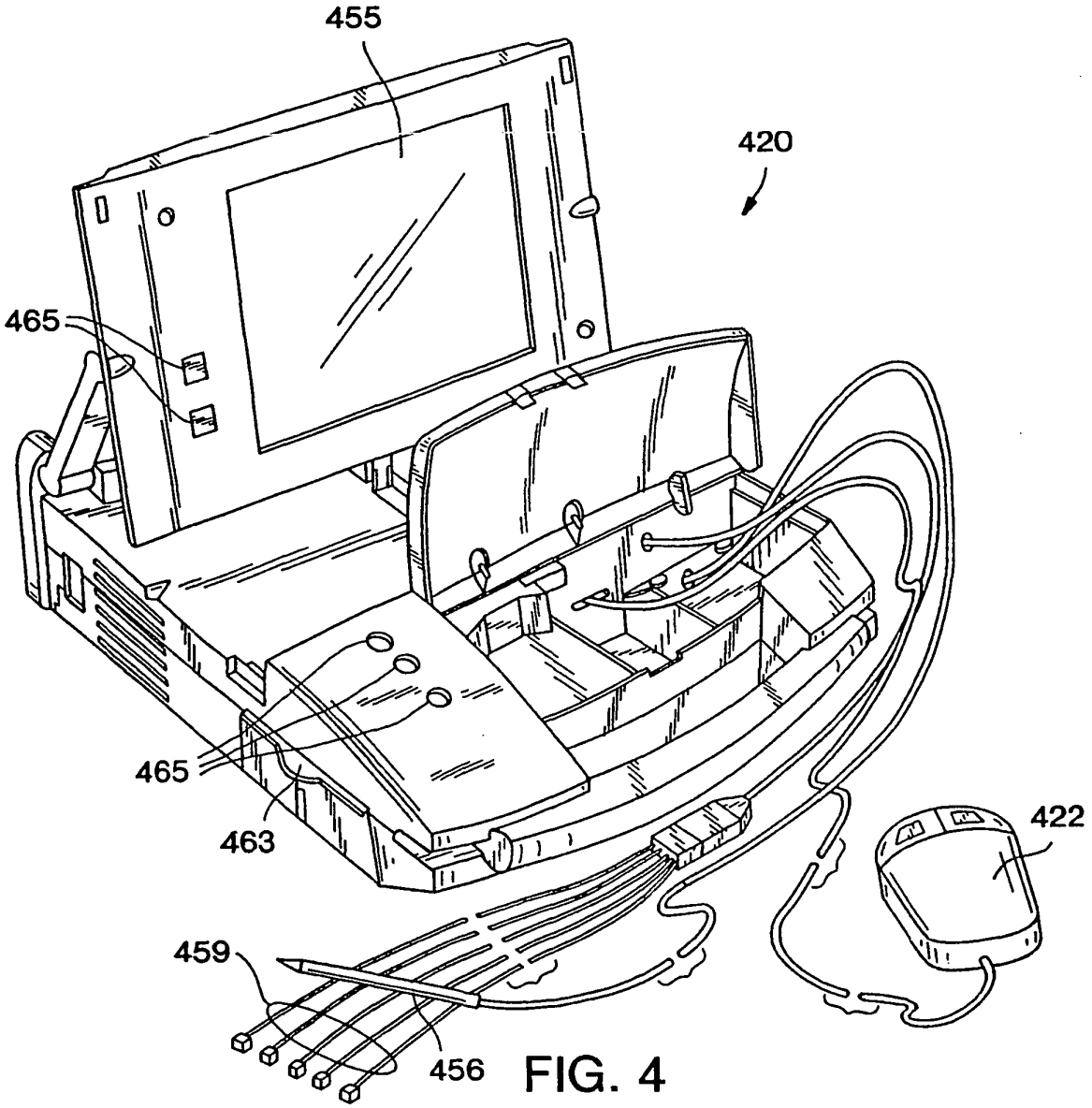

FIG. 4

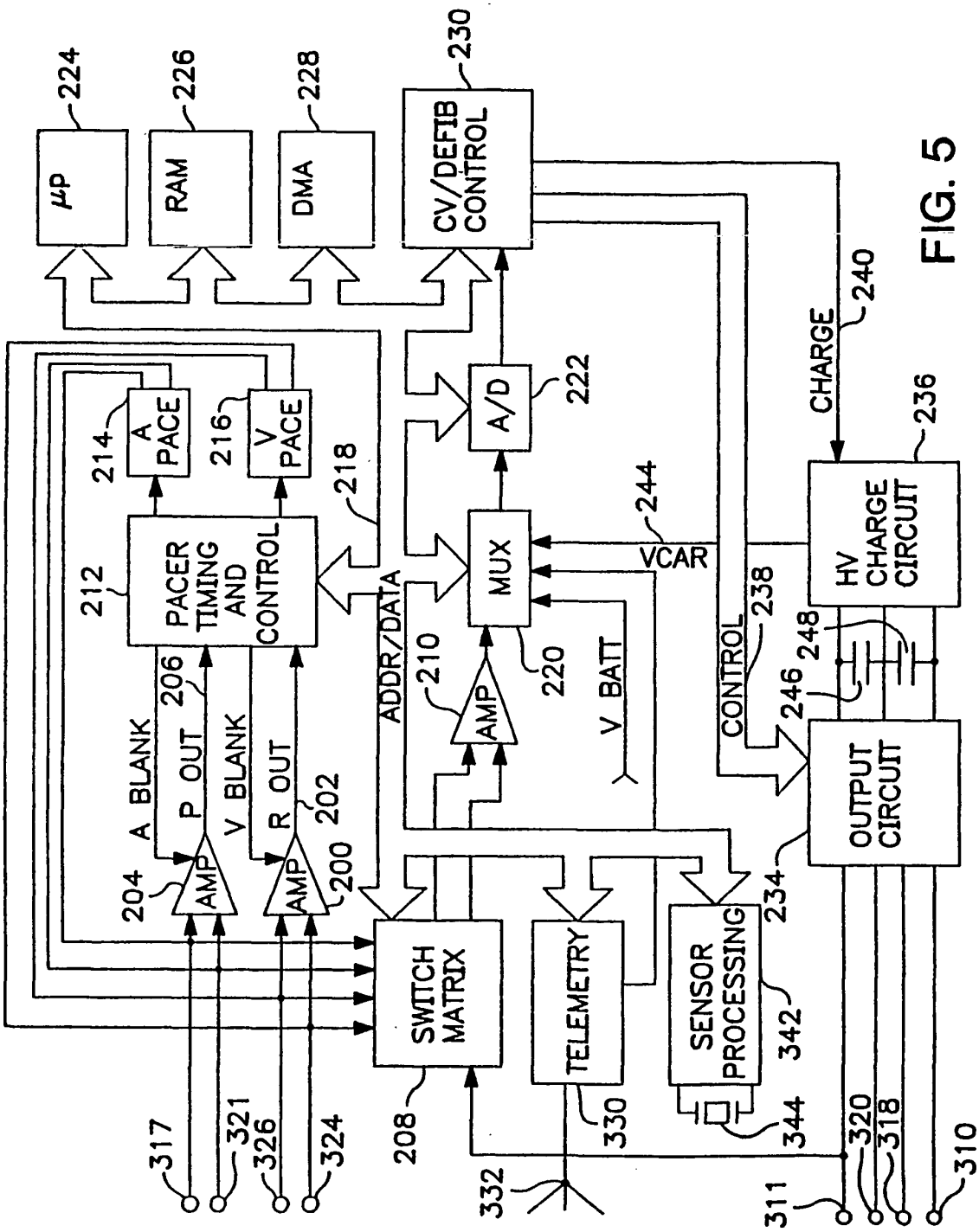
μP
224
RAM
226
DMA
228
CV/DEFIB CONTROL
230
A PACE
214
V PACE
216
218
PACER TIMING AND CONTROL
212
A/D
222
MUX
220
244
VCAR
CHARGE
240
HV CHARGE CIRCUIT
236
ADDR/DATA
210
AMP
V BATT
CONTROL
238
248
246
A BLANK
P OUT
206
V BLANK
R OUT
202
204
AMP
AMP
200
OUTPUT CIRCUIT
234
SWITCH MATRIX
TELEMETRY
SENSOR PROCESSING
342
208
330
344
317
321
326
324
332
311
320
318
310

FIG. 5

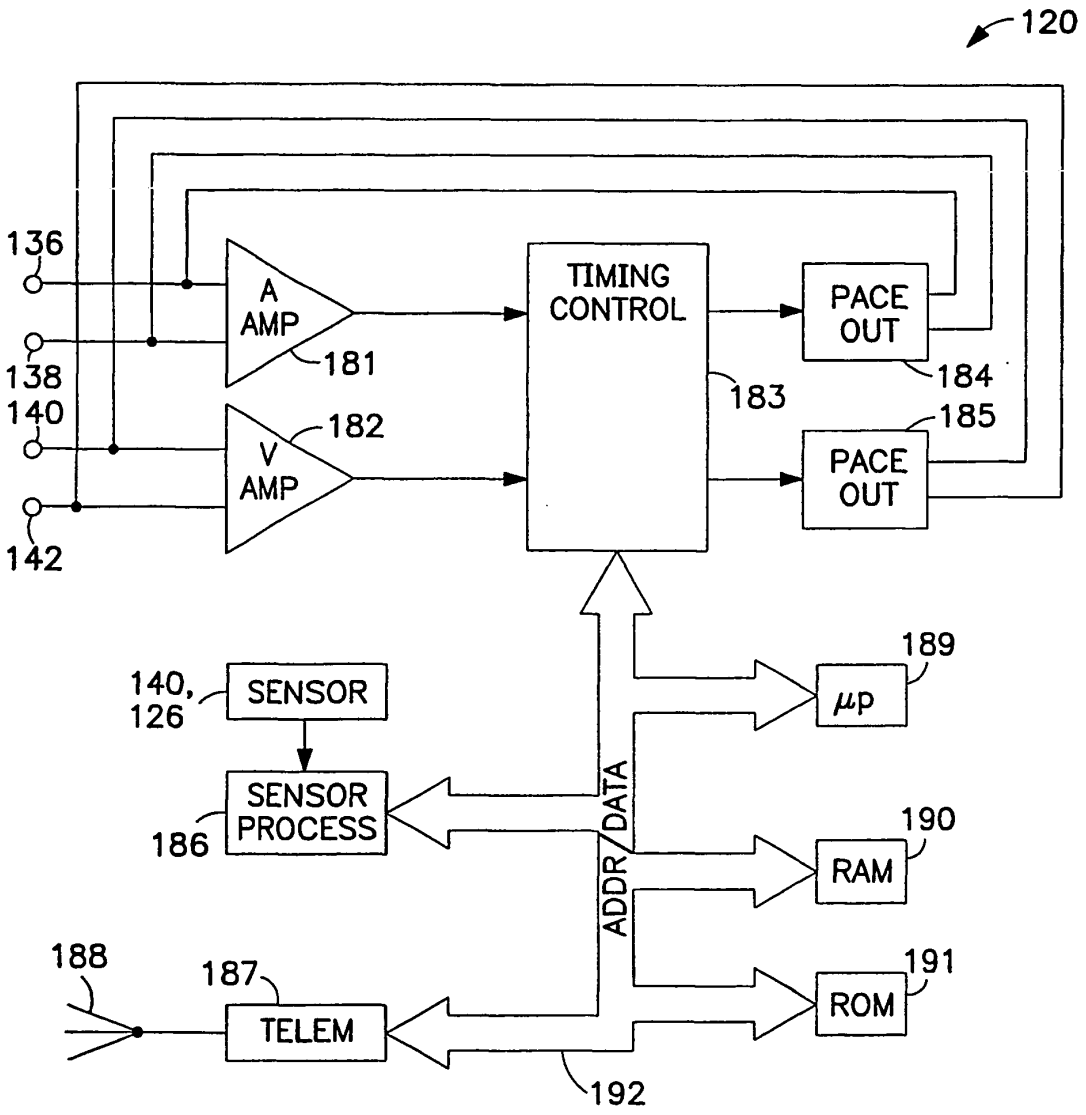
120
136
138
140
142
A AMP
181
V AMP
182
TIMING CONTROL
183
PACE OUT
184
PACE OUT
185
189
μp
140, 126
SENSOR
SENSOR PROCESS
186
DATA
ADDR
190
RAM
191
ROM
188
187
TELEM
192

FIG. 6

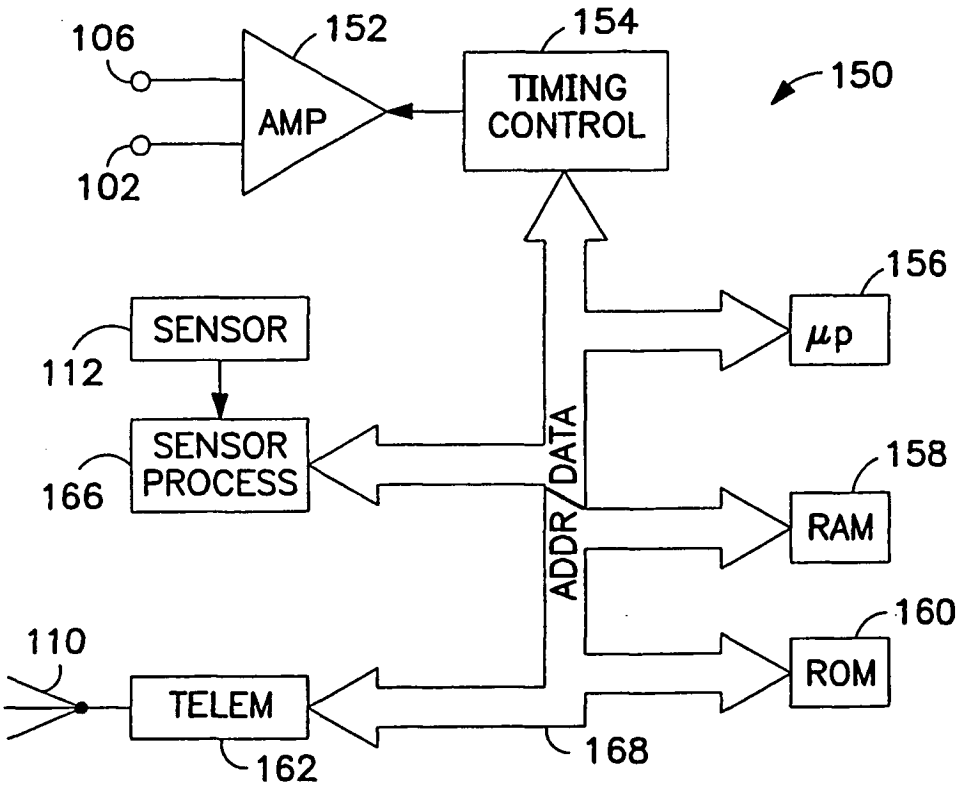
106
152
154
150
AMP
TIMING CONTROL
102
156
SENSOR
μp
112
SENSOR PROCESS
DATA
158
166
ADDR
RAM
160
110
ROM
TELEM
168
162

FIG. 7

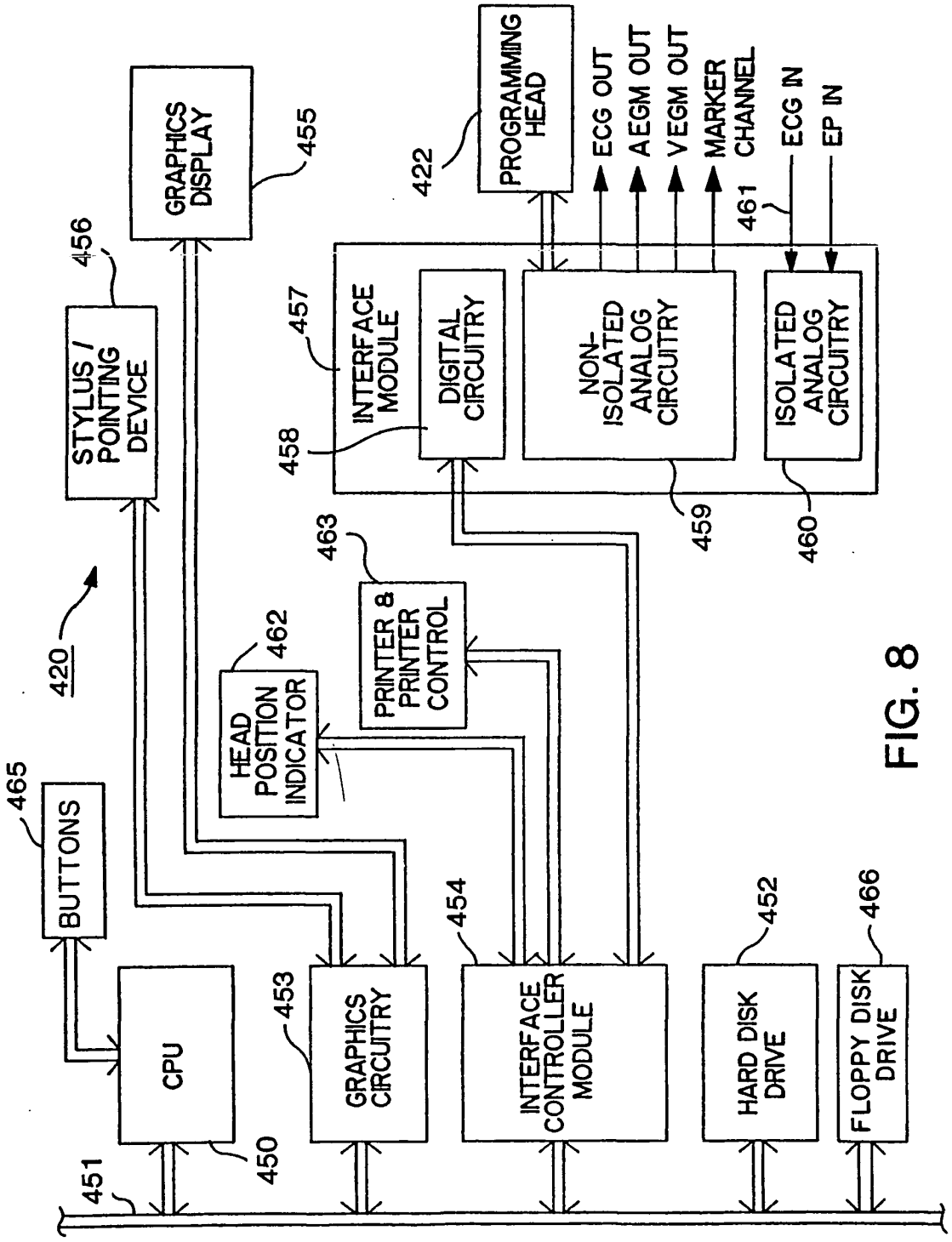
GRAPHICS DISPLAY
455
PROGRAMMING HEAD
422
ECG OUT
AEGM OUT
VEGM OUT
MARKER CHANNEL
ECG IN
EP IN
461
456
STYLUS / POINTING DEVICE
457
INTERFACE MODULE
DIGITAL CIRCUITRY
NON-ISOLATED ANALOG CIRCUITRY
ISOLATED ANALOG CIRCUITRY
458
459
460
463
PRINTER & PRINTER CONTROL
462
HEAD POSITION INDICATOR
420
465
BUTTONS
CPU
450
453
GRAPHICS CIRCUITRY
454
INTERFACE CONTROLLER MODULE
452
HARD DISK DRIVE
466
FLOPPY DISK DRIVE
451

FIG. 8

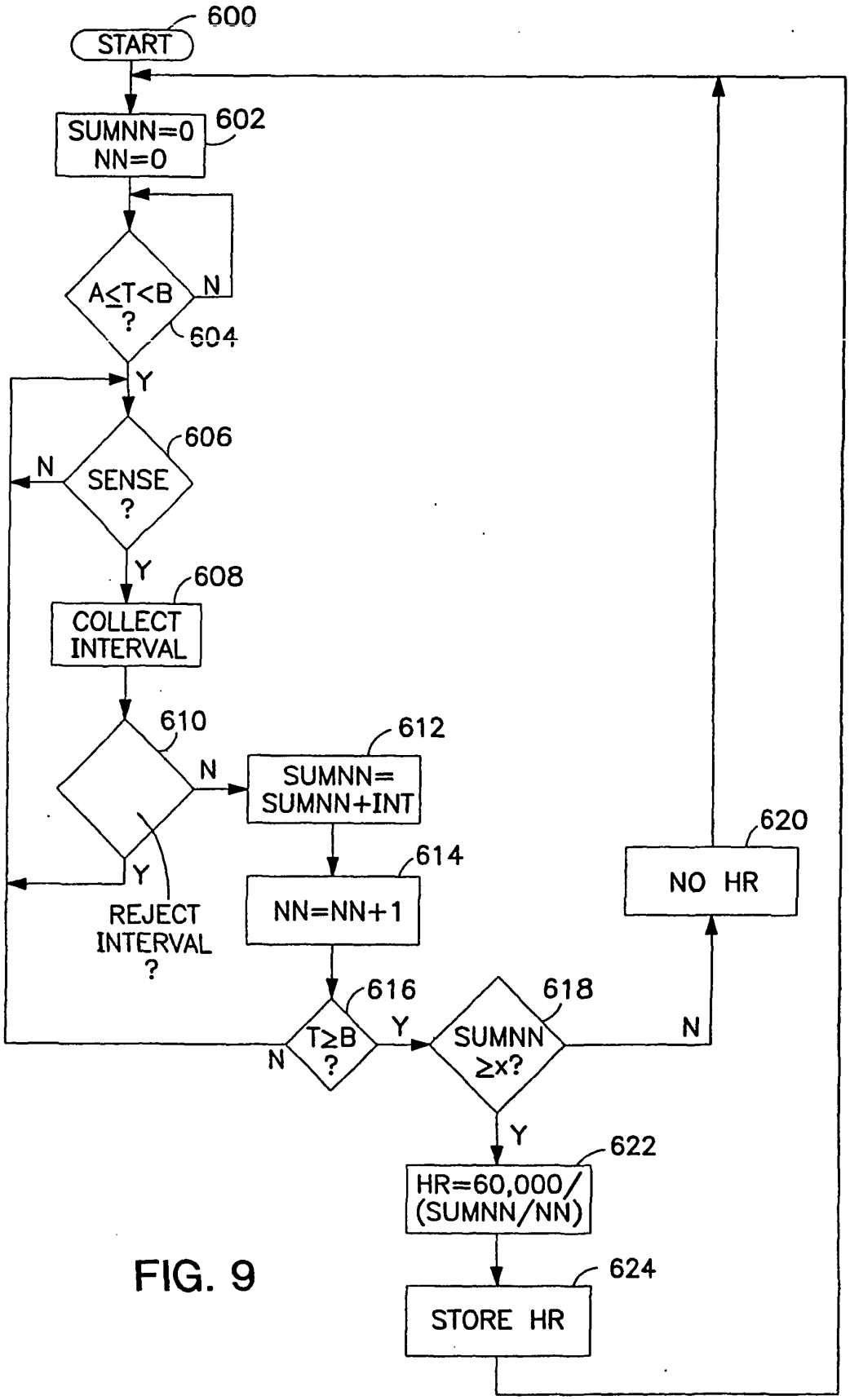
600
START
SUMNN=0
NN=0
602
A≤T<B
?
N
604
Y
606
SENSE
?
N
Y
608
COLLECT
INTERVAL
610
N
612
SUMNN=
SUMNN+INT
Y
REJECT
INTERVAL
?
614
NN=NN+1
616
T≥B
?
N
Y
618
SUMNN
≥x?
N
620
NO HR
Y
622
HR=60,000/
(SUMNN/NN)
624
STORE HR

FIG. 9

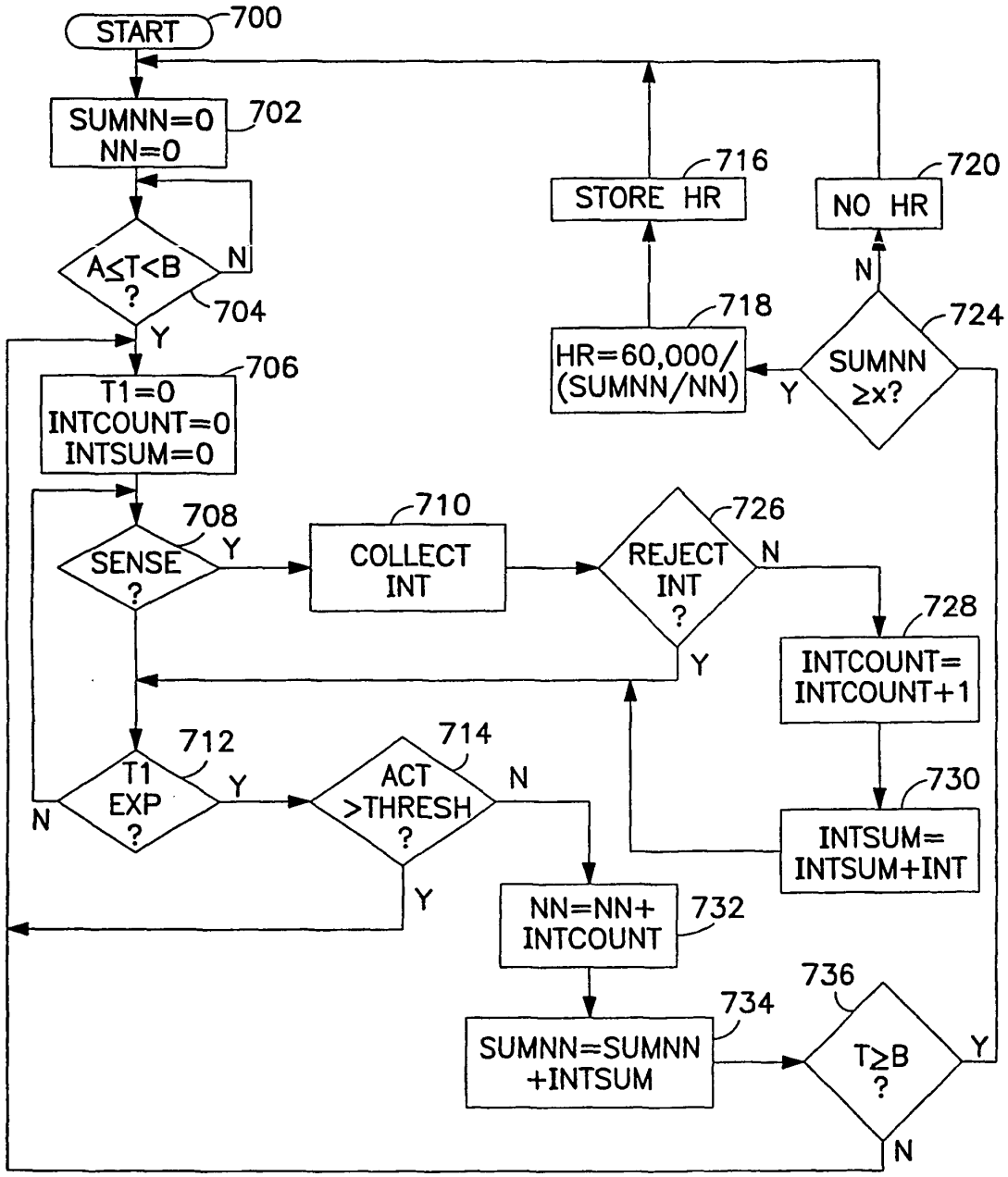
START
700
SUMNN=0
NN=0
702
A≤T<B
?
704
N
Y
T1=0
INTCOUNT=0
INTSUM=0
706
SENSE
?
708
Y
N
COLLECT
INT
710
REJECT
INT
?
726
N
Y
INTCOUNT=
INTCOUNT+1
728
T1
EXP
?
712
Y
N
ACT
>THRESH
?
714
N
Y
INTSUM=
INTSUM+INT
730
NN=NN+
INTCOUNT
732
SUMNN=SUMNN
+INTSUM
734
T≥B
?
736
Y
N
STORE HR
716
NO HR
720
HR=60,000/
(SUMNN/NN)
718
SUMNN
≥x?
724
Y
N

FIG. 10

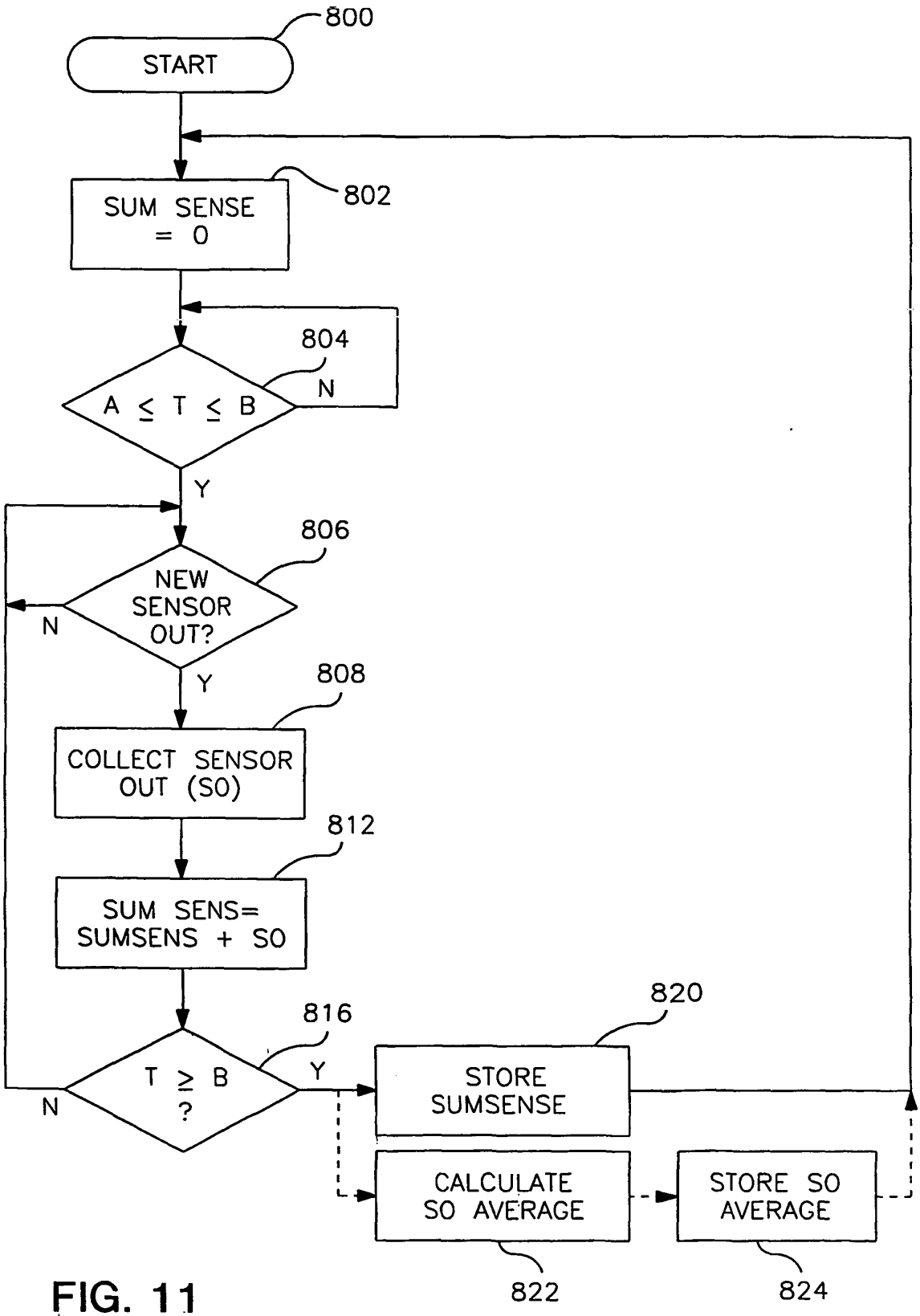
800
START
802
SUM SENSE = 0
804
A ≤ T ≤ B
N
Y
806
NEW SENSOR OUT?
N
Y
808
COLLECT SENSOR OUT (SO)
812
SUM SENS= SUMSENS + SO
816
T ≥ B ?
N
Y
820
STORE SUMSENSE
CALCULATE SO AVERAGE
STORE SO AVERAGE
822
824

FIG. 11

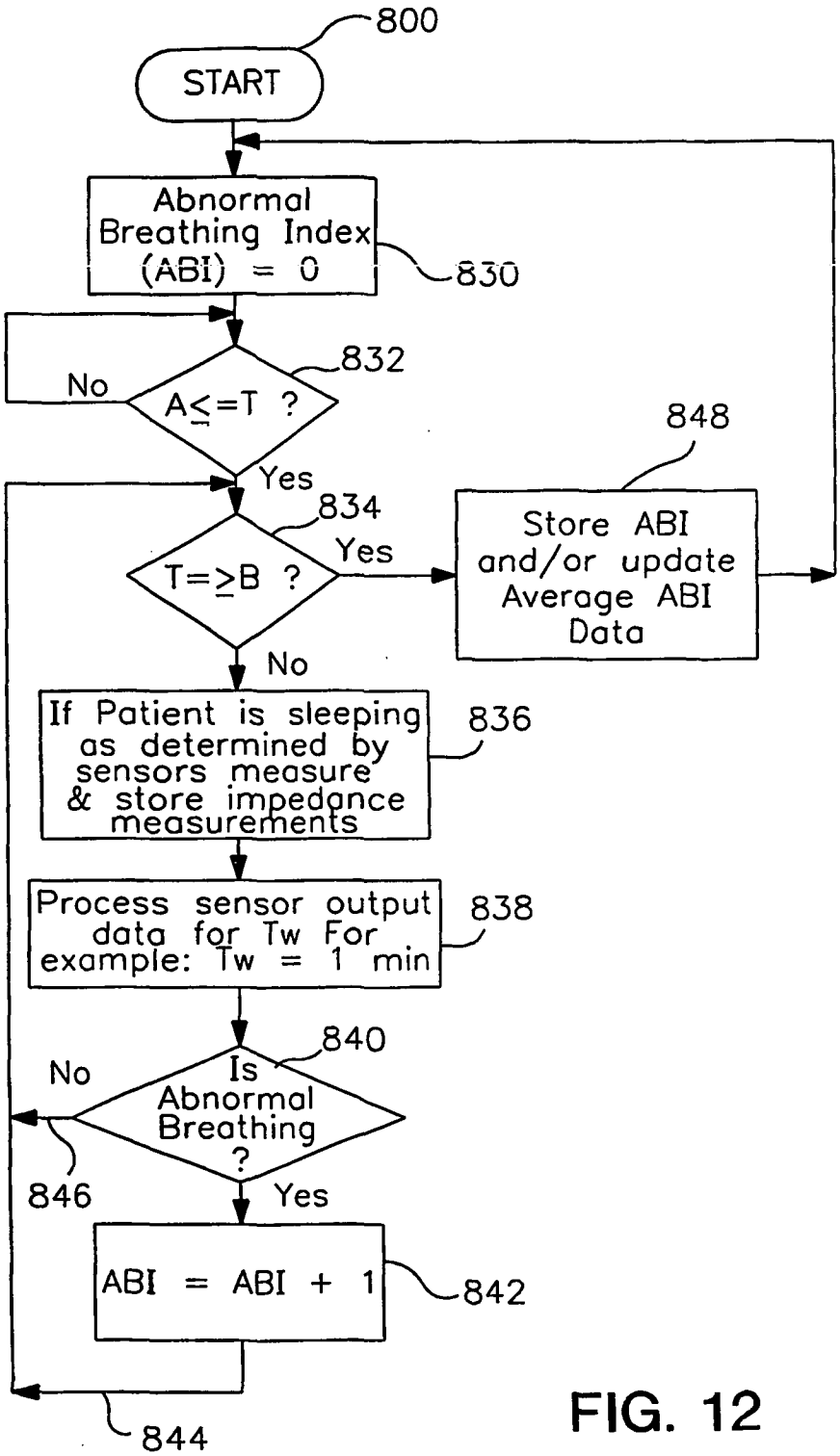
800
START
Abnormal Breathing Index (ABI) = 0
830
832
No
A≤=T ?
Yes
848
834
T=≥B ?
Yes
Store ABI and/or update Average ABI Data
No
If Patient is sleeping as determined by sensors measure & store impedance measurements
836
Process sensor output data for Tw For example: Tw = 1 min
838
840
No
Is Abnormal Breathing ?
846
Yes
ABI = ABI + 1
842
844

FIG. 12

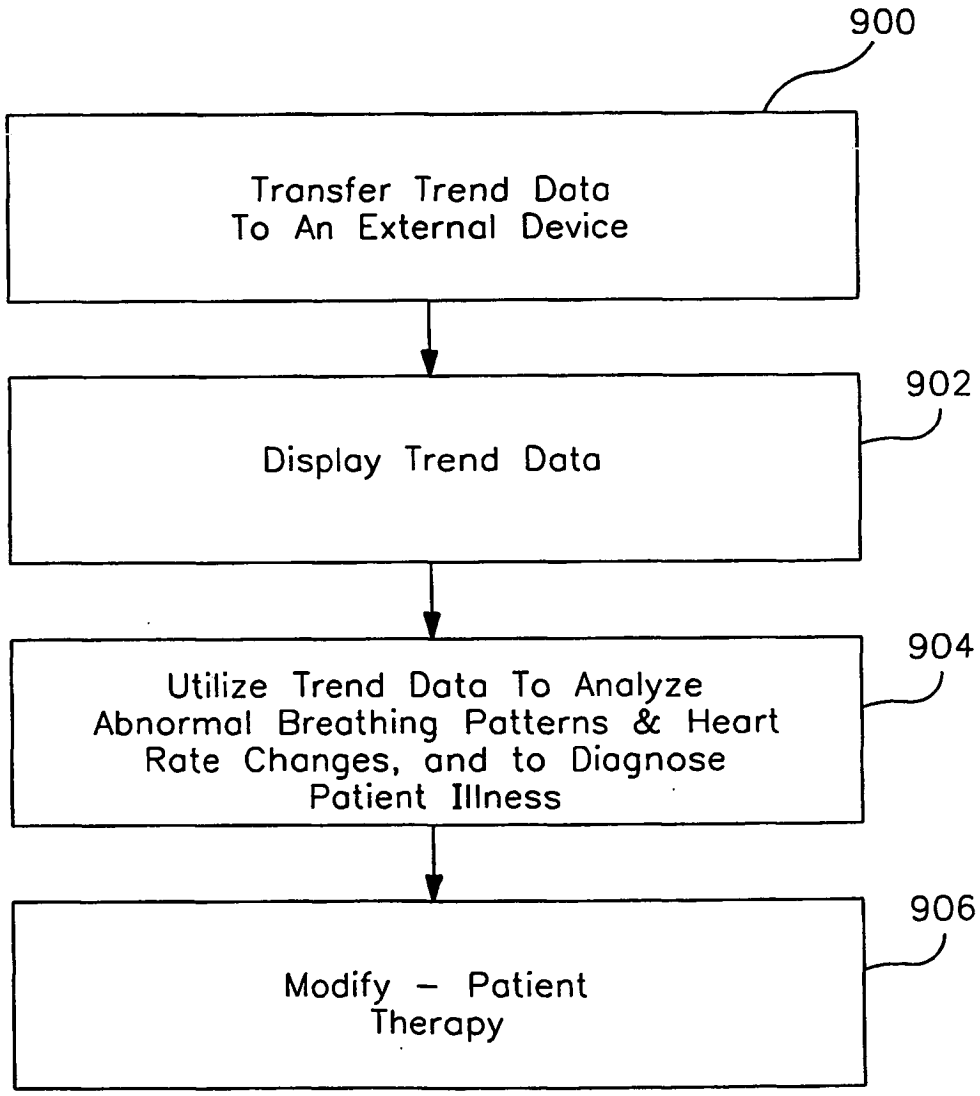
900
Transfer Trend Data To An External Device
902
Display Trend Data
904
Utilize Trend Data To Analyze Abnormal Breathing Patterns & Heart Rate Changes, and to Diagnose Patient Illness
906
Modify – Patient Therapy

FIG. 13

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	用于监测心率和异常呼吸的装置		
公开(公告)号	EP1337296B1	公开(公告)日	2007-07-25
申请号	EP2000982429	申请日	2000-12-05
[标]申请(专利权)人(译)	美敦力公司		
申请(专利权)人(译)	美敦力公司，INC.		
当前申请(专利权)人(译)	美敦力公司，INC.		
[标]发明人	JENSEN DONALD N RUETZ LINDA L CONDIE CATHERINE R CHO YONG KYUN STROBEL ULLA		
发明人	JENSEN, DONALD, N. RUETZ, LINDA, L. CONDIE, CATHERINE, R. CHO, YONG, KYUN STROBEL, ULLA		
IPC分类号	A61N1/365 A61B5/00 A61B5/05 A61B5/08 A61M16/00 A61N1/08		
CPC分类号	A61N1/36521		
优先权	09/715637 2000-11-17 US		
其他公开文献	EP1337296A1		
外部链接	Espacenet		

摘要(译)

公开了一种可植入装置，其具有增强的能力，用于在延长的时间段内监测患者的心率和呼吸趋势。由可植入设备（10）收集的信息可以被存储和遥测到相关的外部设备，例如用于显示和分析的无用编程器（420）。通过测量感测到的患者心脏腔室的去极化与先前感测的去极化或递送的起搏脉冲之间的时间间隔来测量心率。可以在患者心脏的心室和/或心房中测量间隔。根据本发明的另一方面，采用植入的阻抗传感器来监测每分钟通气。心率和每分通气量数据用于开发用于诊断目的的长期趋势数据。在本发明的一个实施例中，仅在患者休息的夜晚和/或白天的限定时间段期间进行心脏间隔和每分钟通气测量。诸如活动传感器或代谢速率传感器的传感器（30）可用于确认患者不活动。

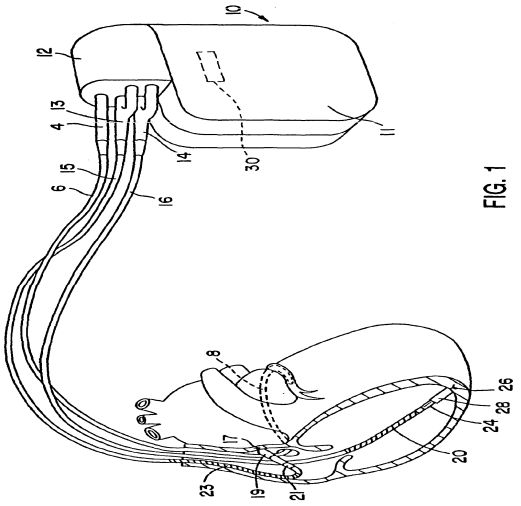

FIG. 1