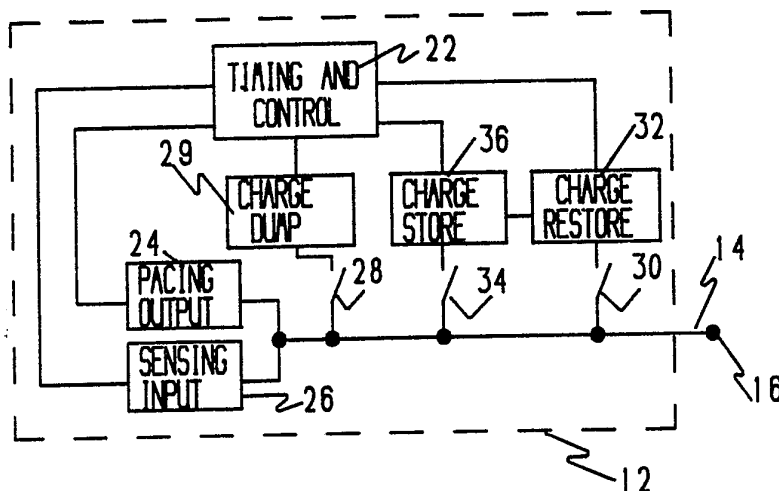




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<p>(21) International Application Number: PCT/US92/00502</p> <p>(22) International Filing Date: 21 January 1992 (21.01.92)</p> <p>(30) Priority data: 696,160 6 May 1991 (06.05.91) US</p> <p>(71) Applicant: INTERMEDICS, INC. [US/US]; 4000 Technology Drive, Angleton, TX 77515 (US).</p> <p>(72) Inventor: SCHROEPEL, Edward, A. ; 215 Dewberry Drive, Lake Jackson, TX 77566 (US).</p> <p>(74) Agents: ROBINSON, Richard, L. et al.; Intermedics, Inc., 4000 Technology Drive, Angleton, TX 77515 (US).</p>		<p>(81) Designated States: AT (European patent), BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), MC (European patent), NL (European patent), SE (European patent).</p> <p>Published <i>With international search report.</i></p>

(54) Title: APPARATUS AND METHOD FOR AN IMPLANTED CARDIAC PACEMAKER WITH MULTISE ELECTRODE WITH POTENTIAL RESTORATION



(57) Abstract

An apparatus for measuring an electrical potential in a human body by sampling the potential during a selected interval and storing the value of that potential at the end of the interval. The stored value of the potential will be restored as an initial value at the end of a second interval. The apparatus includes a timing circuit to identify appropriate intervals. Means are provided for sampling and storing the value of the electric potential at a given time and for restoring the measured potential to an electrode at a second selected time.

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**APPARATUS AND METHOD FOR AN IMPLANTED CARDIAC PACEMAKER
WITH MULTIUSE ELECTRODE WITH POTENTIAL RESTORATION**

TECHNICAL FIELD

My invention relates to implantable therapeutic devices having electrodes carried on leads, and in particular to implantable cardiac pacemakers. More specifically, my invention relates to a cardiac pacemaker having an electrode on an implanted lead adapted to perform multiple functions through the same electrode;
5 for example, the function of pacing the heart and the function of measuring a parameter indicative of the physiologic condition of the patient or the patient's heart.

BACKGROUND ART

Many therapeutic devices use electrodes to measure electrical potentials at selected locations in a human body. Electrodes have been used to measure electric
10 signals relating to chemical concentrations, nerve activity, respiration rate, or cardiac rhythms, as examples. Cardiac pacemakers, for example, stimulate the heart with electrical impulses to induce a heartbeat. Pacemakers may also sense the condition of the heart so that stimuli may be applied in an appropriate manner. Electrodes on a lead of a cardiac pacemaker may be used to measure features of the intracardiac
15 electrogram, lead or tissue impedance, pH of the blood and other parameters. In addition to the desired, information carrying signals, the electrode may detect unwanted signals such as remote or far field signals, noise, muscle activity potentials and so on. The sense electrode or another electrode may be used to stimulate a physiological mechanism by an appropriate signal; for example, stimulating the heart
20 to induce a heartbeat. Such a stimulation can result in a residual polarization voltage which masks the desired signal.

Accurate signal detection through an implanted electrode continues to present difficulties for the designer of an implanted therapeutic device. In some applications, it may be desired to detect one or more input signals and to apply one
25 or more stimulating or output signals. At the same time, it may be inadvisable to

employ a dedicated electrode for each operation. The desired size of a lead may limit the number of conducting wires which can practically be connected to separate electrodes or the number of electrodes themselves may be limited. Moreover, interelectrode cross-talk between separate electrodes may limit the usefulness of
5 separate electrodes.

To solve these problems, time multiplexing of an electrode has heretofore been employed. The same electrode used to output a stimulating pulse during a first interval may be employed to sense cardiac signals during another interval and noise or some other parameter during yet another interval. Bandpass filtering has
10 been used to discriminate between desirable signals and noise. These methods, however, are not effective in all cases. Unwanted signals may mask desired signals in certain applications. In other applications, a signal of interest may mask another signal of interest, requiring the rejection of the first signal in order to detect the second.

With the foregoing in mind, it is an object of my invention, therefore, to
15 provide an apparatus and method for an implanted therapeutic device having an electrode which can be used for multiple functions.

It is also an object of my invention to provide an apparatus and electrode which can be used for both input and output functions.

Another object of my invention is to provide an implanted apparatus which
20 can extract information from a background signal during a selected interval despite the presence of a primary signal which tends, during another time interval, to influence the electrode potential to destroy the electrode's ability to sense the background signal.

DISCLOSURE OF INVENTION

25 I have invented an apparatus which measures an electrical potential characteristic of a parameter during a selected interval and stores the value of that potential at the end of the interval. During a successive interval, an intervening

event may occur to seriously disrupt the potential. This intervening event may be either an intrinsic potential caused by the human body or an external stimulation; for example, a stimulus from a pacemaker. If such an intervening event occurred during the second time interval, the stored value of the measured potential will be restored as an initial value at the end of the second interval.

Apparatus, according to my invention, includes a timing circuit to identify appropriate intervals. Control circuitry or software is provided to determine if conditions have occurred which require potential restoration. Means are provided for sampling and storing the value of the electric potential at a given time and for restoring the measured potential to an electrode at a second selected time. The means may include electrical circuitry or software and may employ either analog circuitry or analog to digital conversion with digital registers or memory circuitry. Algorithms to establish appropriate responses to detected noise or other classes of signals may also be provided.

My invention may be employed with electrodes generally, including physiological, chemical, physical, or other electrodes. It may also be used to set the initial potential conditions of one electrode with reference to a detected condition at another electrode.

These and other objects and features of my invention will be apparent to those skilled in the art from the following detailed description of my preferred embodiment, made with reference to the accompanying drawings.

BRIEF DESCRIPTION OF DRAWINGS

FIG. 1 is perspective view of a cardiac pacemaker system according to my present invention with a cardiac pacemaker and a lead, showing placement of the lead in a cutaway section of a human heart.

FIG. 2 is a block diagram of a heart pacemaker employing apparatus according to my invention.

FIG. 3 is a logic diagram for describing timing of switches according to my present invention.

FIG. 4 is a graph of a potential varying over time.

FIG. 5 is the potential of FIG. 4 sampled at selected intervals.

5 FIG. 6 is a graph of a sampling of the potential of FIG. 4 with the potential forced to zero at the beginning of each interval.

FIG. 7 is a sampling of the potential of FIG. 4 with the terminal conditions of each sampled interval imposed on the succeeding sample interval as initial conditions.

10 FIG. 8 is a graph of an electric potential comprising a potential similar to that shown in FIG. 4 combined with an intrinsic cardiac depolarization signal.

FIG. 9 is a graph of the potential of FIG. 8 combined with stimulating cardiac pacing pulses.

15 FIG. 10 is a potential including the potential of FIG. 9 combined with restoration of initial conditions according to my present invention.

FIG. 11 is the potential of FIG. 10 with the cardiac pulses and stimulating pulses eliminated.

BEST MODE FOR CARRYING OUT THE INVENTION

20 I will now describe my preferred embodiment of my invention. In referring to the accompanying figures, like numerals will be used to refer to like parts throughout this description. Although I have chosen to describe my invention in terms of a implanted cardiac pacemaker, those skilled in the art will recognize that my invention can be applied to measure electric potentials in many applications.

In FIG. 1, a perspective view of a cardiac pacemaker system, generally designated 10, is shown in perspective view. A cardiac pacemaker 12 is provided having the capacity to sense electrical artifacts at sense electrodes within a heart. A lead 14 is shown connected to the pacemaker 12. In the illustrated embodiment, the lead is illustrated as having a distal electrode 16 at a distal end of the lead. As is known in the art, fixation means should generally be provided. I have illustrated tines 21. The distal electrode 16 may be used for both sensing and stimulating the heart in accordance with my present invention. An additional ring electrode 18 is shown within the atrium of the heart. The ring electrode 18 may also be used for multiple purposes and employed with the apparatus of my present invention. It will be apparent that the number of electrodes employing the invention is not limited.

FIG. 2 illustrates a block diagram of the cardiac pacemaker 12 showing the apparatus of my present invention. The lead 14 and the distal tip 16 are illustrated. Additional connections may be provided for additional electrodes, such as electrode 18. Timing and control circuitry 22 control pacing output circuitry 24 to provide stimulating pulses to the heart and, at appropriate times, receive signals from sensing input circuitry 26 from the heart. Multiplexing between pacing and sensing are known in the pacemaker art and need not be described in greater detail herein. Sensed signals may comprise the heart's QRS complexes, polarization potentials on the electrode 16, noise from electromagnetic sources or from muscles of the body, or various physiological parameters such as respiration, pH and so on. Timing and control circuitry 22 may be implemented by those skilled in the art in either electrical hardware or a combination of hardware and software.

Under the control of the timing and control circuit 22, a first switch 28 closes briefly after an output pulse is delivered from the pacing output 24. Closing of the first switch 28 connects the electrode 16 to ground or charge dump 29. The timing and control circuitry 22 may then begin to time out a physiological parameter sampling interval for a predetermined length of time. At the beginning of the sampling interval, the timing and controlling circuit closes a restore switch 30 which connects a charge restore circuit 32 to the electrode 16. The charge restore circuit 32 is effective to restore the electrical condition of the electrode to the condition of

that electrode at the end of the last preceding sampling interval. The charge control circuit 32 may be implemented by a storage capacitor and analog circuitry or by digital circuitry with a digital to analog converter.

5 The timing and control circuitry 32 then activates the sensing input 26 to measure the desired electrical potential at the electrode 16 during the sampling interval. At the end of the sampling interval, the timing and control circuit 22 briefly closes a charge store switch 34 and stores the value of the potential of the electrode 16 in charge store means 36. As with the charge restore means 32, the charge store means may comprise analog or digital circuitry. Any anticipated losses to the
10 electrode potential occurring in either potential measurement, charge storage or restoration are compensated in transferring the charge storage means 36 to the charge restore means 32.

Control of the switches 28, 30 and 34 can also be understood with reference to the logic diagram of FIG. 3. Under the control of the timing in control circuit 22,
15 all switches are normally open 38. Before attempting to restore the electrical condition of the electrode 16, as, for example, after a stimulating pulse from the pacing output 24, first switch 28 closes 40, connecting the electrode to ground and then quickly reopens. Just before the sampling interval and after switch 28 has been closed, the charge restore switch 30 closes 42, allowing charge restore
20 circuitry 32 to charge the electrode 16 to the predetermined electrical condition. The electrical condition of the electrode is relatively quickly restored and then switch 30 again reopens. Just before the end of the sampling interval, the charge store switch 34 is closed 44 connecting the charge store means 36 to the electrode. The electrical condition of the electrode is rapidly sampled over a very short interval and
25 the switch 34 is again opened.

I will now explain the operation of my invention with reference to the graphs of FIGS. 4 through 11. FIG. 4 illustrates an exemplary electrical potential 46 which varies in amplitude over time. The electrical potential is the signal which is to be measured or detected by an electrode. This does not imply, however, that the
30 potential 46 is the only electrical signal present. There may be other signals,

extraneous noise, or, in the case of a heart pacemaker, output signals or stimulating pulses which mask or make the measurement of the potential 46 more difficult.

FIG. 5 shows an idealized measurement of the potential 46 by a multiplexed electrode. As the electrode 16 is multiplexed to its sensing function, potential segments 48 are sensed during selected intervals 50. In the desired situation, the potential segments 48 closely approximate the potential 46 and meaningful information about the potential 46 can be extracted from the potential segments 48. With uncompensated multiplexing alone, however, the wave form of FIG. 5 is seldom if ever retrieved. This is because the initial conditions of the segments 48 in reality do not correspond to the initial conditions of each segment as shown in FIG. 5. Rather, each segment begins at some other value and only approaches the true value for the segment. Such a condition is illustrated in FIG. 6. At the beginning of each time segment 50 the value of the measured potential is constrained to be zero. Such a condition might occur if the electrode were grounded immediately before the beginning of the time segment 50. Those skilled in the art will recognize, of course, that the zero initial condition is chosen only as an example because of its simplicity and clarity. Any other initial condition, constant or varying, which was not related to the desired signal 46, would have the same negative affect. Because of the inherent time constants of the system, during each measurement 50 a measured segment of potential 52 will only begin to approximate the true value of the potential 46. A great deal of information about the potential 46 could be lost, resulting in potentially erroneous responses by an implanted device such as a cardiac pacemaker.

In a device with apparatus and methods according to my invention, the wave form of FIG. 7 would be recovered. During each time segment 50, the magnitude of the measured potential would more closely approximate the true potential 46. At the end 56 of a potential segment 54, the magnitude or other parameter of the potential would be stored. At a beginning 58 of the next succeeding segment 54, the ending value at 56 would be restored to the electrode. Measurement would then begin and the potential on the electrode would begin to approach the true value of the potential 46, constrained by the inherent time constants of the particular

system. Since it is likely, however, that the value at the end of the last measurir.
period more closely approximates the true value at the beginning of the nex
succeeding period than would an arbitrary value such as zero, the measurement of
potential, as shown in FIG. 7, would more closely approximate the idealized
5 measurements of FIG. 5 and thus be a better representation of the true potential
shown in FIG. 4.

FIGS. 8 through 11 illustrate an application of my invention in the field of
cardiac pacing. FIG. 8 shows a signal 60 similar to the potential 46 of FIG. 4 but
with the addition of an intrinsic intracardiac QRS complex 62 at periodic intervals.
10 Such a signal 62 would be detected on an electrode in the right ventricle of a typical
healthy heart. The intrinsic QRS signals 62 are essentially added to the underlying
baseline potential 46 shown in FIG. 4. To extract the baseline potential a low pass
filter or sampling method analogous to that illustrated in FIG. 5 might be employed.
Under such circumstances filtering and sampling would be adequate to extract the
15 desired information.

If a cardiac pacemaker is present, however, additional complications are
introduced. FIG. 9 illustrates the result of cardiac pacing on a prior art bandpass
and sampling electrode. A pacing pulse 64 and resulting depolarization disrupts the
measurement of the signal 60. Charge dumping, a known technique used to reduce
20 lead polarization potential, tends to force the voltage at the electrode to zero after
each pulse. The sampling of the underlying baseline potential occurs during the
intervals between pulses. Because of the pacing, the sampling intervals 50 may
tend to occur irregularly over time, being associated with a delay after the pacing
pulse. Moreover, charge dumping removes the baseline information and distorts the
25 sample values. Over time, of course, the baseline will return to its natural value but
during the time period surrounding a series of pacer pulses, significant amounts of
information will be lost.

Employing my invention, however, tends to restore the information regarding
the baseline 60. As seen in FIG. 10, the ending condition of one segment is
30 restored at 66 to the next time segment. The baseline can be much more closely

approximated. FIG. 11 extracts an approximation 61 of the baseline information from FIG. 10 and omits the pacer pulses and intrinsic QRS waves. A comparison between this waveform and the waveform of FIG. 8 or FIG. 4 illustrates that a closer approximation of the baseline potential can be expected.

5 It will be apparent to those skilled in the art that my invention can be embodied in other configurations without departing from the teachings or essential characteristics thereof. The foregoing description is, therefore, to be considered illustrative and not restrictive and the scope of my invention is to be defined by the following claims. All changes or variations that would come within the equivalency
10 of the claims are intended to be incorporated therein.

CLAIMS

1. An apparatus for measuring an electrical potential comprising an electrode capable of sampling said electrical potential; and characterized by:
timing means for timing a series of first and second intervals;
5 means for measuring said electrical potential during said first intervals;
means for storing the value of said electrical potential at the end of said first intervals; and
means for restoring the stored value of said electrical potential at the end of said second intervals.
2. The apparatus according to claim 1 further comprising means for compensating for expected losses in restoring the stored value of said electrical potential.
3. The apparatus according to claim 2 further comprising means for connecting the electrode to ground prior to restoring the stored value of the electrical potential.
4. The apparatus according to claim 3 wherein the storing means, the restoring means, and the ground connecting means each comprise switch means for selectively connecting and disconnecting the respective means to said electrode and wherein said timing means further comprises means for controlling said switches.
5. The apparatus according to claim 4 wherein the switches are normally open thereby disconnecting the storing means, the restoring means and the ground connecting means from the electrode except when the respective means are functional.
6. The apparatus according to claim 5 further comprising means for delivering an electrical output through said electrode during at least some of said second intervals.
7. A heart pacemaker comprising

means for sensing an electrical potential in the heart, said sensing means comprising

timing means for timing a series of first and second intervals;

5

means for measuring said electrical potential during said first intervals;

means for storing the value of said electrical potential at the end of said first intervals; and

means for restoring the stored value of said electrical potential at the end of said second intervals; and

10

means responsive to said electrical potential sensing means for pacing the heart as a function of said electrical potential.

8. The heart pacemaker according to claim 7 further comprising means for compensating for expected losses in restoring the stored value of said electrical potential.

9. The heart pacemaker according to claim 8 further comprising means for connecting the sensing means to ground prior to restoring the stored value of the electrical potential.

10. The heart pacemaker according to claim 9 wherein the storing means, the restoring means, and the ground connecting means each comprise switch means for selectively connecting and disconnecting the respective means to an electrode carried on a lead and wherein said timing means further comprises means for
5 controlling said switches.

11. The heart pacemaker according to claim 10 wherein the switches are normally open thereby disconnecting the storing means, the restoring means and the ground connecting means from the electrode except when the respective means are functional.

12. The heart pacemaker according to claim 11 wherein said pacing means further comprises means for delivering an electrical output through said electrode during at least some of said second intervals.

13. A method for measuring an electrical potential comprising the steps of
sampling said electrical potential;
timing a series of first and second intervals;
measuring said electrical potential during said first intervals;
5 storing the value of said electrical potential at the end of said first intervals;
and
restoring the stored value of said electrical potential at the end of said second
intervals.
14. The method according to claim 13 further comprising compensating for
expected losses in restoring the stored value of said electrical potential.
15. The method according to claim 14 further comprising connecting a sampling
electrode to ground prior to restoring the stored value of the electrical potential.
16. The method according to claim 15 further comprising selectively connecting
and disconnecting storing means, restoring means, and ground connecting means
to said electrode.
17. A method for pacing a human heart comprising the steps of
sensing an electrical potential in the heart, said sensing step comprising
timing a series of first and second intervals;
measuring said electrical potential during said first intervals;
5 storing the value of said electrical potential at the end of said first
intervals; and
restoring the stored value of said electrical potential at the end of said
second intervals; and
pacing the heart as a function of said electrical potential.
18. The method for pacing a human heart according to claim 17 further
comprising compensating for expected losses in restoring the stored value of said
electrical potential.

19. The method for pacing a human heart according to claim 18 further comprising connecting sensing means to ground prior to restoring the stored value of the electrical potential.

20. The method for pacing a human heart according to claim 19 further comprising selectively connecting and disconnecting storing means, restoring means, and ground connecting means to an electrode carried on a lead.

21. The method for pacing a human heart according to claim 20 wherein said pacing step further comprises delivering an electrical output through said electrode during at least some of said second intervals.

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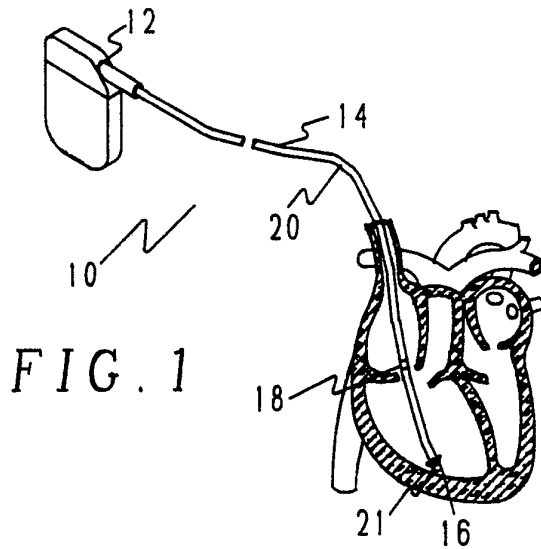


FIG. 1

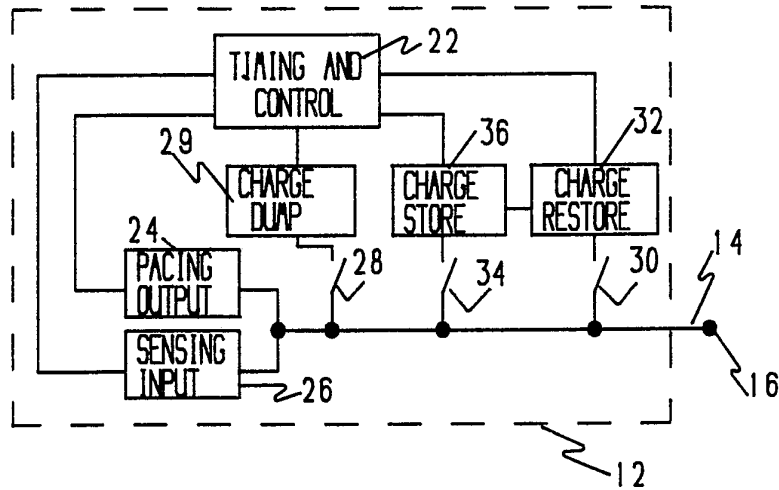


FIG. 2

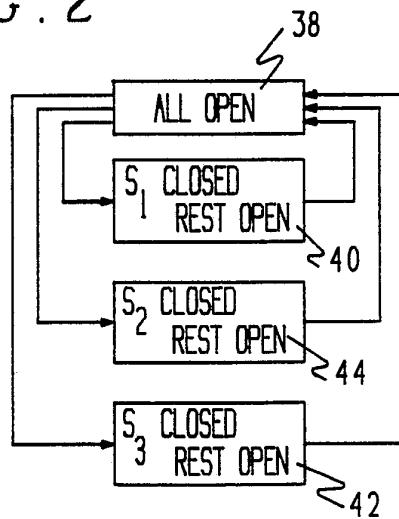


FIG. 3

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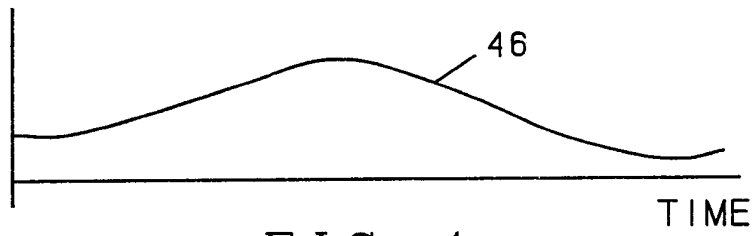


FIG. 4

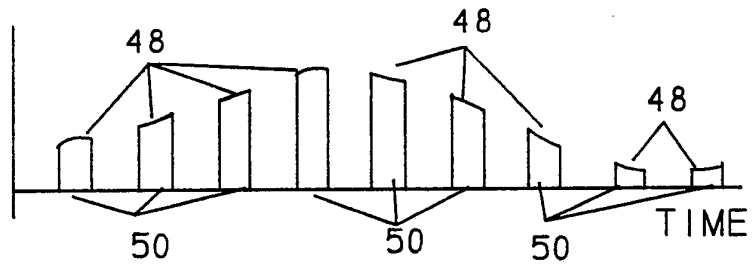


FIG. 5

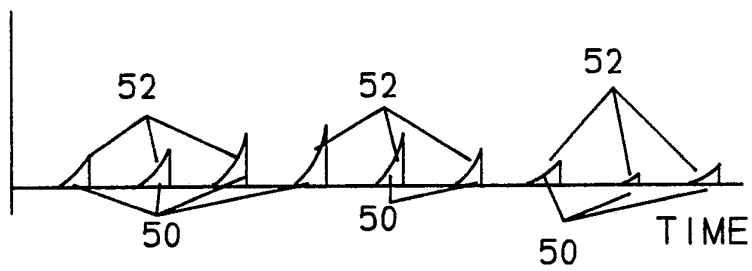


FIG. 6

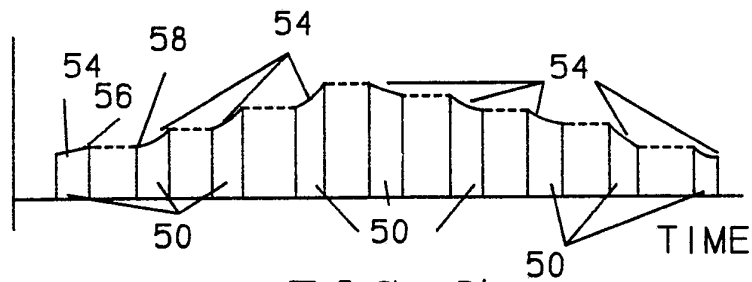


FIG. 7

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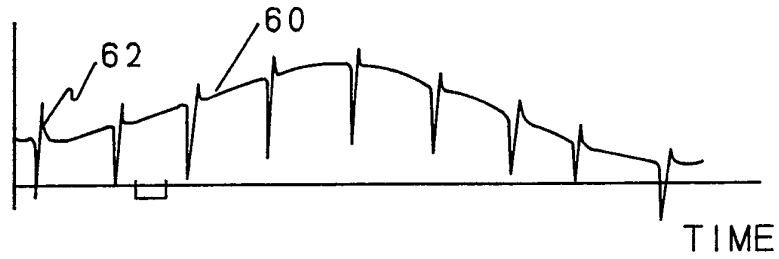


FIG. 8

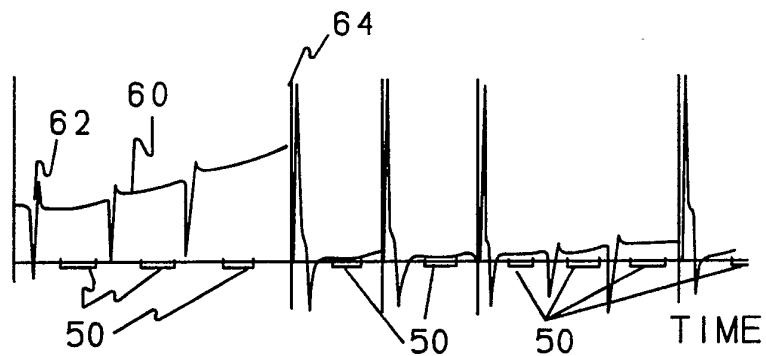


FIG. 9

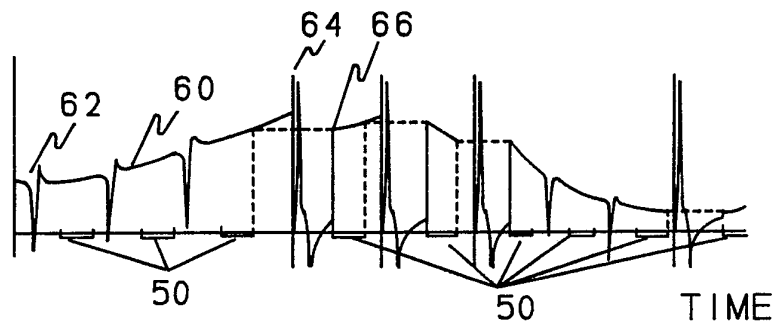


FIG. 10

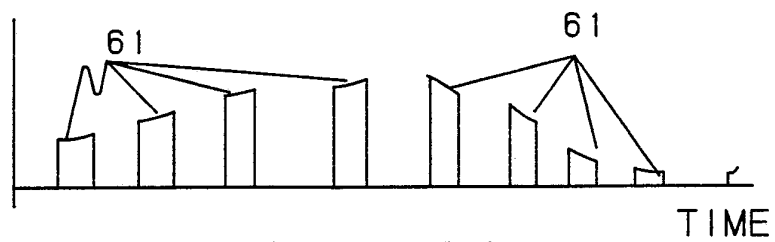


FIG. 11

INTERNATIONAL SEARCH REPORT

PCT/US 92/00502

International Application No

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC Int.Cl. 5 A61N1/37		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
Int.Cl. 5	A61N ; G01R ; H03F ; A61B	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
Y	EP,A,0 246 908 (COVENTRY CITY COUNCIL) 25 November 1987 see the whole document ---	1, 3, 4, 7, 9, 10, 12, 13, 15-17, 19-21
Y	WO,A,8 909 514 (ARZCO MEDICAL ELECTRONICS) 5 October 1989 see abstract see page 6, line 1 - page 7, line 33 see page 13, column 10 - page 15, line 9 see page 16, line 9 - line 34; figures 5,7 ---	1, 3, 4, 7, 9, 10, 12, 13, 15-17, 19-21
A	EP,A,0 043 690 (STIMTECH, INC.) 13 January 1982 see the whole document ---	1,7
<p>¹⁰ Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
04 JUNE 1992	15. 06. 92	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	FERRIGNO A. <i>A Ferrigno</i>	

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category °	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
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A	GB,A,2 193 101 (TELECTRONICS N.V.) 3 February 1988 see the whole document ---	1,7
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**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

US 9200502
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This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on
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