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(54) **METHODS FOR DATA RETENTION IN AN IMPLANTABLE MEDICAL DEVICE**

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A61B 5/04 (2006.01)

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CPC . A61N 1/3702; A61N 1/37252; A61B 5/0031
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(56) **References Cited**

U.S. PATENT DOCUMENTS

3,958,563 A 5/1976 Fernandez
4,228,806 A 10/1980 Lidlow
(Continued)

FOREIGN PATENT DOCUMENTS

EP 0554208 8/1993
EP 1269911 1/2003
WO 2004023983 3/2004

OTHER PUBLICATIONS

International Preliminary Report on Patentability for related Application No. PCT/US205/040193 dated Jan. 15, 2007, 7 pages.

(Continued)

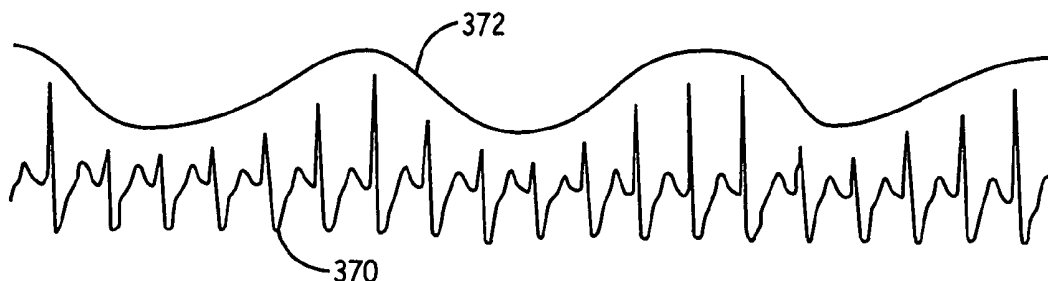
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(57) **ABSTRACT**

Methods for storing data records associated with a medical monitoring event in a data structure. An implanted device obtains data and stores the data in the data record in a first data structure that is age-based. Before an oldest data record is lost, the oldest data record may be stored in a second data structure that is priority index-based. The priority index may be determined by a severity level and may be further determined by associated factors. The implanted device may organize, off-load, report, and/or display a plurality of data records based on an associated priority index. Additionally, the implanted device may select a subset or composite of physiologic channels from the available physiologic channels based on a selection criterion.

27 Claims, 20 Drawing Sheets



(51)	Int. Cl.		5,722,999 A	3/1998	Snell	
	<i>A61N 1/372</i>	(2006.01)	5,726,898 A *	3/1998	Jacobs	700/231
	<i>G06F 19/00</i>	(2018.01)	5,732,708 A	3/1998	Nau	
	<i>G06F 17/30</i>	(2006.01)	5,752,976 A	5/1998	Duffin	
	<i>A61B 5/0205</i>	(2006.01)	5,776,168 A	7/1998	Gunderson	
	<i>A61B 5/0402</i>	(2006.01)	5,782,891 A	7/1998	Hassler	
	<i>A61B 5/0476</i>	(2006.01)	5,790,427 A	8/1998	Greer	
	<i>A61B 5/11</i>	(2006.01)	5,891,043 A	4/1999	Ericksen	
	<i>A61B 5/16</i>	(2006.01)	5,899,866 A	5/1999	Cyrus	
	<i>G16H 10/60</i>	(2018.01)	5,908,392 A	6/1999	Wilson	
	<i>A61N 1/36</i>	(2006.01)	5,944,745 A	8/1999	Rueter	
	<i>A61N 1/365</i>	(2006.01)	5,987,352 A	11/1999	Klein	
	<i>A61N 1/37</i>	(2006.01)	5,995,868 A	11/1999	Dorfmeister	
	<i>A61B 5/021</i>	(2006.01)	5,995,874 A	11/1999	Borza	
	<i>A61B 5/024</i>	(2006.01)	6,016,449 A	1/2000	Fischell	
	<i>A61B 5/03</i>	(2006.01)	6,061,593 A	5/2000	Fischell	
	<i>A61B 5/08</i>	(2006.01)	6,067,473 A	5/2000	Greeninger	
	<i>G16H 40/63</i>	(2018.01)	6,128,538 A	10/2000	Fischell	
(52)	U.S. Cl.		6,134,474 A	10/2000	Fischell	
	CPC		6,161,043 A	12/2000	McClure	
	<i>A61B 5/02055</i> (2013.01); <i>A61B 5/04001</i>		6,200,265 B1	3/2001	Walsh	
	(2013.01); <i>A61B 5/0402</i> (2013.01); <i>A61B</i>		6,227,203 B1	5/2001	Rise	
	<i>5/04012</i> (2013.01); <i>A61B 5/0476</i> (2013.01);		6,329,139 B1	12/2001	Nova	
	<i>A61B 5/1118</i> (2013.01); <i>A61B 5/165</i>		6,360,122 B1	3/2002	Fischell	
	(2013.01); <i>A61B 5/4082</i> (2013.01); <i>A61B</i>		6,364,834 B1	4/2002	Reuss et al.	
	<i>5/686</i> (2013.01); <i>A61B 5/7282</i> (2013.01);		6,405,086 B1	6/2002	Conley	
	<i>A61N 1/36135</i> (2013.01); <i>A61N 1/37252</i>		6,427,086 B1	7/2002	Fischell	
	(2013.01); <i>G06F 17/30336</i> (2013.01); <i>G06F</i>		6,438,649 B1	8/2002	Tanaka	
	<i>19/3418</i> (2013.01); <i>G16H 10/60</i> (2018.01);		6,456,887 B1	9/2002	Dudding et al.	
	<i>A61B 5/021</i> (2013.01); <i>A61B 5/024</i> (2013.01);		6,496,715 B1	12/2002	Lee	
	<i>A61B 5/031</i> (2013.01); <i>A61B 5/0816</i>		6,505,067 B1	1/2003	Lee	
	(2013.01); <i>A61B 5/7232</i> (2013.01); <i>A61N</i>		6,512,940 B1	1/2003	Brabec	
	<i>1/36132</i> (2013.01); <i>A61N 1/36521</i> (2013.01);		6,522,915 B1	2/2003	Ceballos	
	<i>A61N 1/36585</i> (2013.01); <i>A61N 1/3702</i>		6,526,314 B1	2/2003	Eberle et al.	
	(2013.01); <i>A61N 1/37282</i> (2013.01); <i>G16H</i>		6,549,804 B1	4/2003	Osorio	
	<i>40/63</i> (2018.01)		6,557,901 B1	6/2003	Thompson	
(58)	Field of Classification Search		6,589,187 B1 *	7/2003	Dirnberger et al.	600/508
	USPC	607/5, 27, 59; 600/508, 509, 513, 523	6,599,242 B1	7/2003	Splett	
	See application file for complete search history.		6,611,714 B1	8/2003	Mo	
(56)	References Cited		6,628,985 B2	9/2003	Sweeney	
	U.S. PATENT DOCUMENTS		6,647,296 B2	11/2003	Fischell	
	4,374,382 A	2/1983 Markowitz	6,662,049 B1	12/2003	Miller	
	4,485,813 A	12/1984 Anderson	6,664,729 B2	12/2003	Elledge	
	4,556,063 A	12/1985 Thompson	6,684,106 B2	1/2004	Herbst	
	4,567,892 A	2/1986 Plicchi	6,700,869 B1 *	3/2004	Falco et al.	370/230
	4,583,553 A	4/1986 Shah	6,704,595 B2	3/2004	Bardy	
	4,596,251 A	6/1986 Plicchi	6,721,490 B1 *	4/2004	Yao et al.	386/351
	4,903,701 A	2/1990 Moore	6,803,798 B1	10/2004	Wei	
	4,920,489 A	4/1990 Hubelbank	6,823,210 B2	11/2004	Eberle	
	4,945,477 A *	7/1990 Edwards	6,904,311 B2	6/2005	Freeberg	
	5,007,431 A	4/1991 Donehoo, III	6,907,289 B2	6/2005	Stahmann	
	5,012,411 A	4/1991 Policastro	7,079,977 B2	7/2006	Osorio et al.	
	5,052,388 A	10/1991 Sivula	7,089,056 B2	8/2006	Koshiol	
	5,078,134 A	1/1992 Heilman	7,130,678 B2	10/2006	Ritscher et al.	
	5,127,404 A	7/1992 Wyborny	7,212,858 B2	5/2007	Schaldach	
	5,168,759 A	12/1992 Bowman	7,280,867 B2	10/2007	Frei	
	5,215,086 A	6/1993 Terry, Jr.	7,285,090 B2	10/2007	Stivorice	
	5,269,302 A	12/1993 Swartz	7,313,440 B2	12/2007	Miesel	
	5,285,792 A	2/1994 Sjoquist	7,392,090 B2	6/2008	Sweeney	
	5,312,446 A	5/1994 Holschbach	7,450,743 B2	11/2008	Sundar	
	5,336,244 A	8/1994 Weijand	7,460,904 B2	12/2008	Deadwyler	
	5,354,318 A	10/1994 Taepke	7,496,403 B2	2/2009	Cao	
	5,409,009 A	4/1995 Olson	7,515,961 B2	4/2009	Germanson	
	5,431,691 A	7/1995 Snell	7,668,591 B2	2/2010	Lee	
	5,439,481 A	8/1995 Adams	7,756,573 B2	7/2010	Shen et al.	
	5,518,001 A	5/1996 Snell	7,917,199 B2	3/2011	Drew	
	5,554,177 A	9/1996 Kieval	8,024,029 B2	9/2011	Drew	
	5,645,068 A	7/1997 Mezack et al.	8,108,033 B2	1/2012	Drew et al.	
	5,659,614 A *	8/1997 Bailey, III	8,224,431 B2	7/2012	Drew et al.	
			8,478,417 B2	7/2013	Drew	
			8,565,864 B2	10/2013	Drew et al.	
			8,768,446 B2	7/2014	Drew	
			8,798,728 B2	8/2014	Drew et al.	
			2001/0051787 A1	12/2001	Haller et al.	
			2001/0051819 A1	12/2001	Fischell	
			2002/0013614 A1	1/2002	Thompson	
			2002/0077563 A1	6/2002	Sweeney	
			2002/0099303 A1	7/2002	Bardy	
			2002/0198473 A1 *	12/2002	Kumar et al.	600/595

(56)

References Cited

U.S. PATENT DOCUMENTS

2003/0074033 A1 4/2003 Pless et al.
 2003/0174069 A1 9/2003 Goetz et al.
 2003/0187365 A1 10/2003 Eberle
 2004/0059391 A1 3/2004 Sweeney
 2004/0077563 A1 4/2004 Lau
 2004/0122296 A1 6/2004 Hatlestad et al.
 2004/0122331 A1 6/2004 Freeberg
 2004/0122706 A1 6/2004 Walker et al.
 2004/0127945 A1 7/2004 Collins et al.
 2004/0133390 A1 7/2004 Osorio
 2004/0138536 A1 7/2004 Frei
 2004/0138579 A1 7/2004 Deadwyler et al.
 2004/0152957 A1 8/2004 Stivoric
 2004/0183579 A1 9/2004 Wei
 2004/0215270 A1 10/2004 Ritscher
 2005/0027324 A1 2/2005 Schaldach
 2005/0081847 A1 4/2005 Lee et al.
 2005/0203366 A1 9/2005 Donoghue et al.
 2005/0203385 A1 9/2005 Sundar
 2005/0209524 A1 9/2005 Donaldson
 2005/0222631 A1 10/2005 Dalal
 2006/0095092 A1 5/2006 Drew
 2006/0247706 A1 11/2006 Germanson
 2007/0049982 A1 3/2007 Cao
 2007/0208232 A1 9/2007 Kovacs
 2007/0255151 A1 11/2007 Struble
 2012/0116183 A1 5/2012 Osorio

OTHER PUBLICATIONS

International Search Report and Written Opinion for Application PCT/US2005/040193 dated May 8, 2006.
 International Search Report and Written Opinion for Application PCT/US2005/040192 dated Apr. 25, 2006, 9 pages.
 International Preliminary Report on Patentability for Application No. PCT/US2005/040192 dated Jan. 19, 2007, 8 pages.
 International Preliminary Report on Patentability for Application No. PCT/US2005/039857 dated Jan. 19, 2007, 8 pages.
 International Search Report and Written Opinion for Application No. PCT/US2005/039857 dated Apr. 25, 2006, 10 pages.
 International Preliminary Report on Patentability and Written Opinion for Application No. PCT/US2005/040190 dated May 8, 2007, 6 pages.
 Corrected International Search Report and Written Opinion for Application No. PCT/US2005/040190 dated May 2, 2006, 12 pages.
 International Preliminary Report on Patentability for Application No. PCT/US2005/039478 dated May 18, 2007, 4 pages.
 International Search Report and Written Opinion for Application No. PCT/US2005/039478 dated Apr. 3, 2006, 10 pages.
 International Preliminary Report on Patentability for Application No. PCT/US2005/040194 dated May 18, 2007, 6 pages.
 International Search Report and Written Opinion for Application No. PCT/US2005/040194 dated May 4, 2006, 5 pages.
 Office Action from U.S. Appl. No. 11/264,045, dated Aug. 26, 2010.
 Patent Application No. 13803462—Final Office Action—dated Oct. 23, 2015.
 Patent Application No. 13803462—Response—Feb. 23, 2016.

* cited by examiner

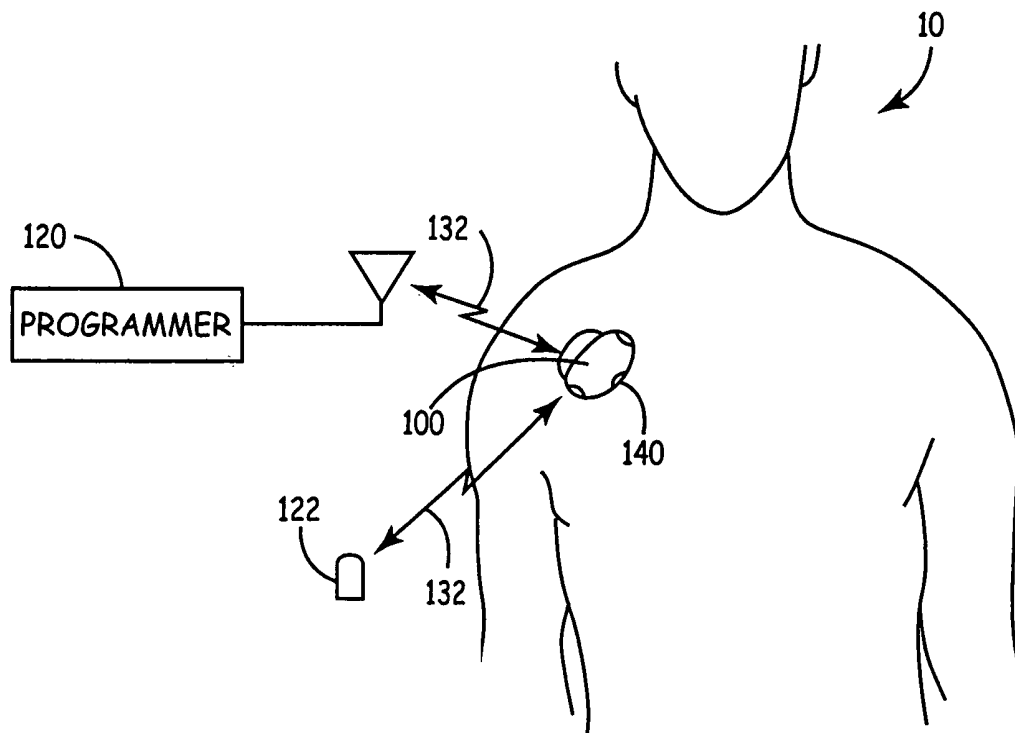


FIG. 1

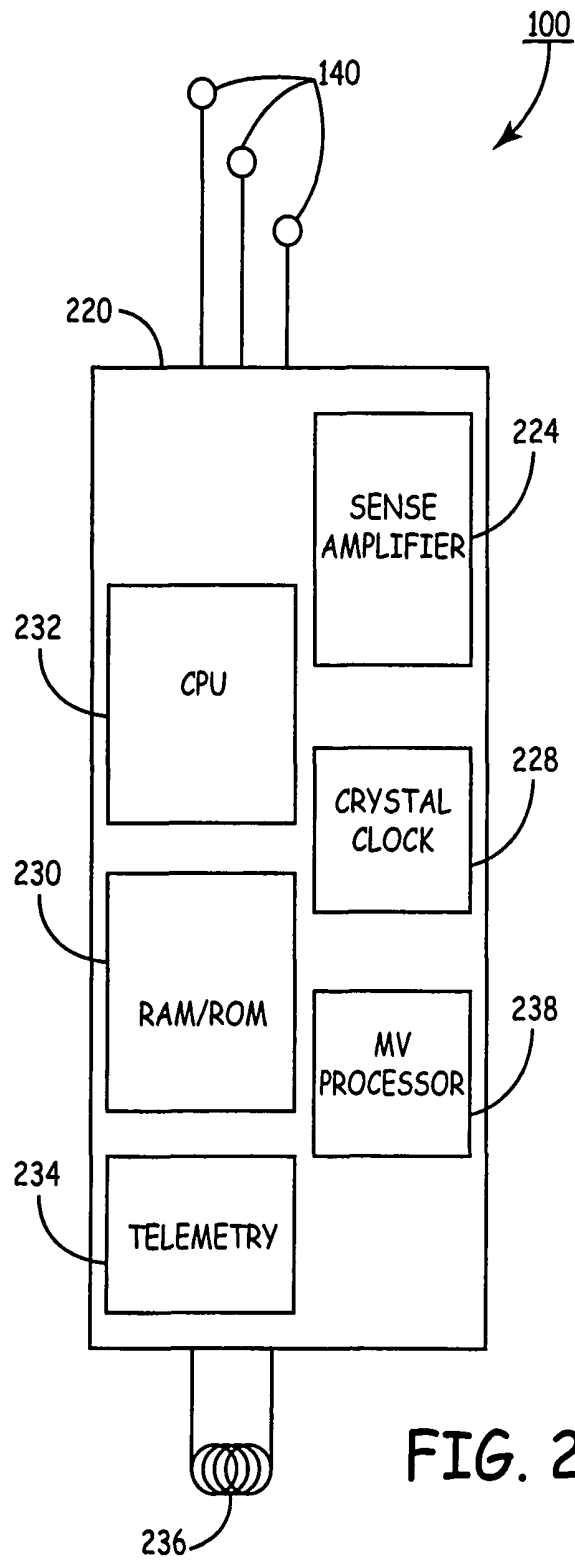


FIG. 2

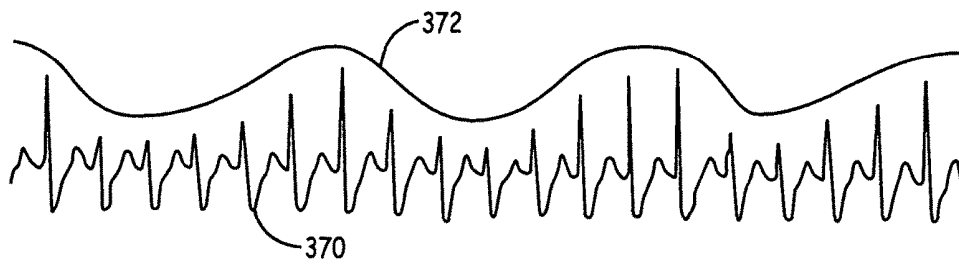


FIG. 3

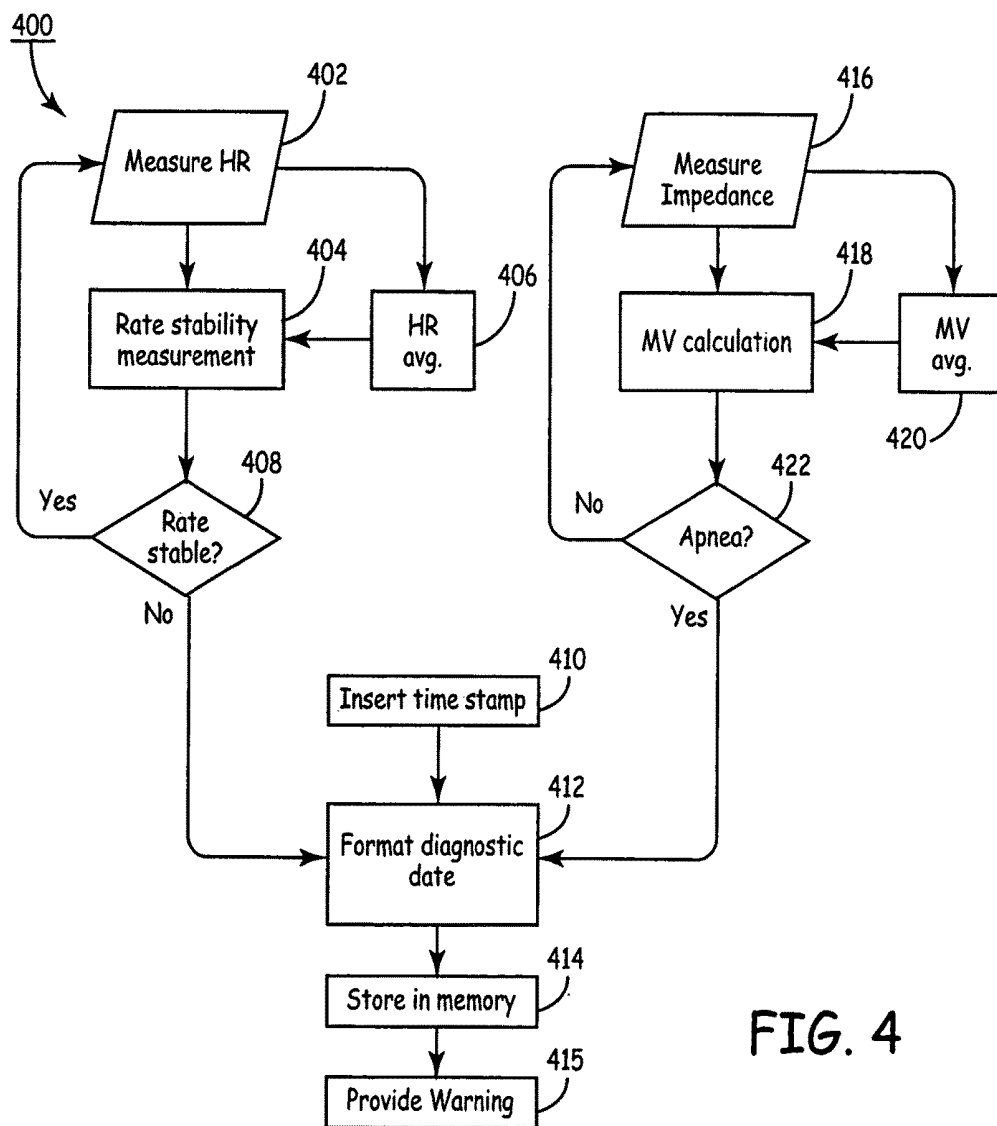


FIG. 4

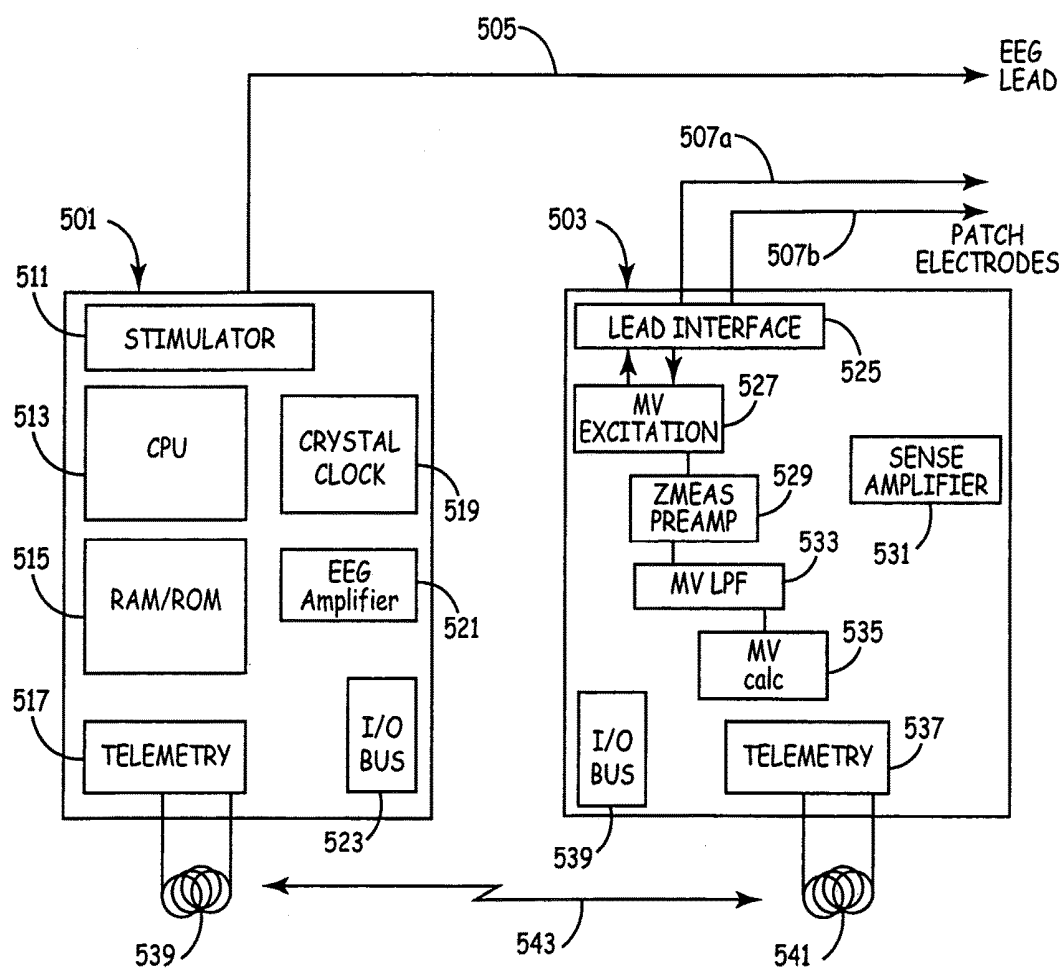


FIG. 5

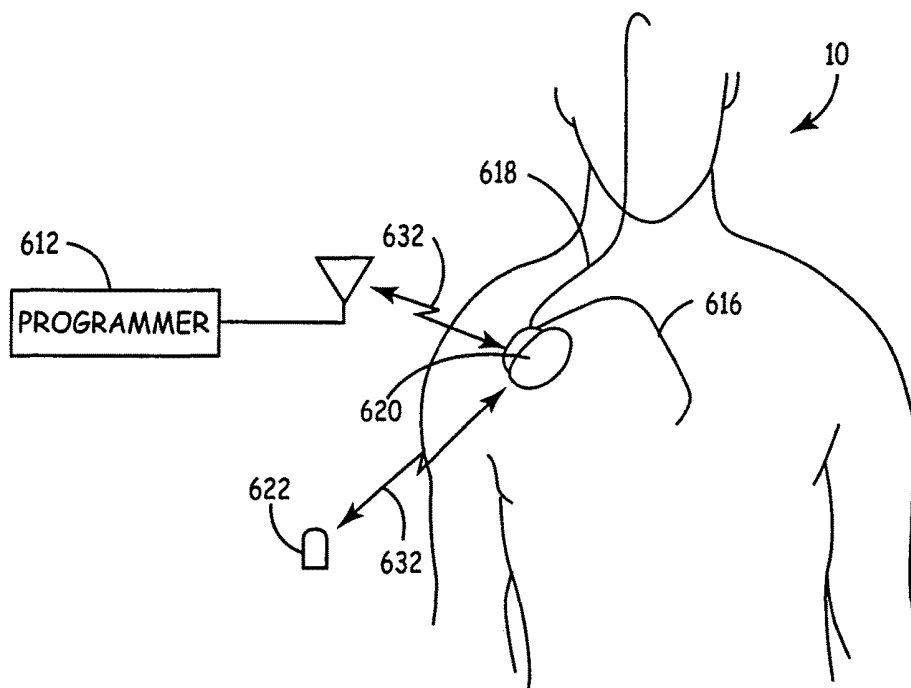


FIG. 6

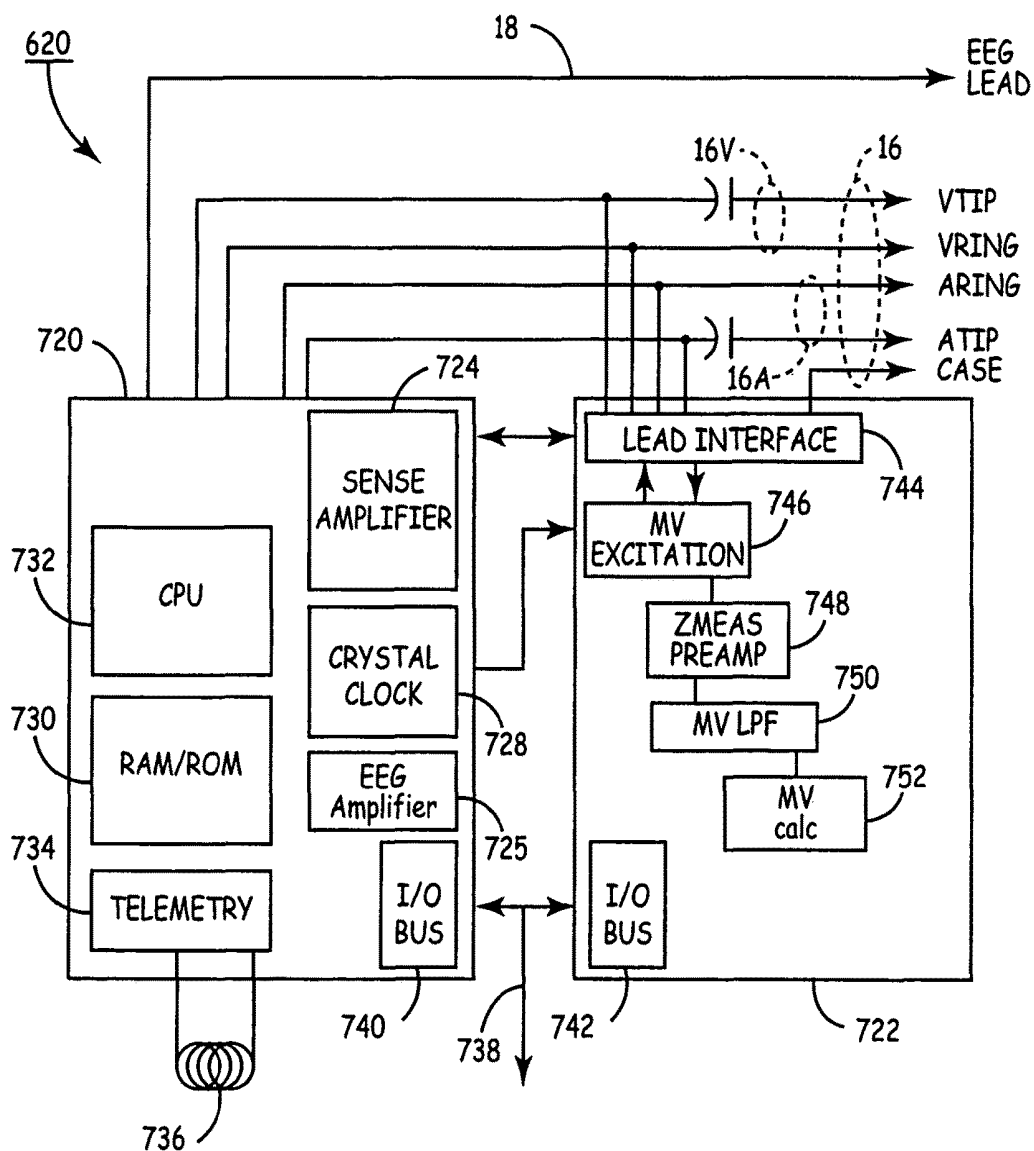


FIG. 7

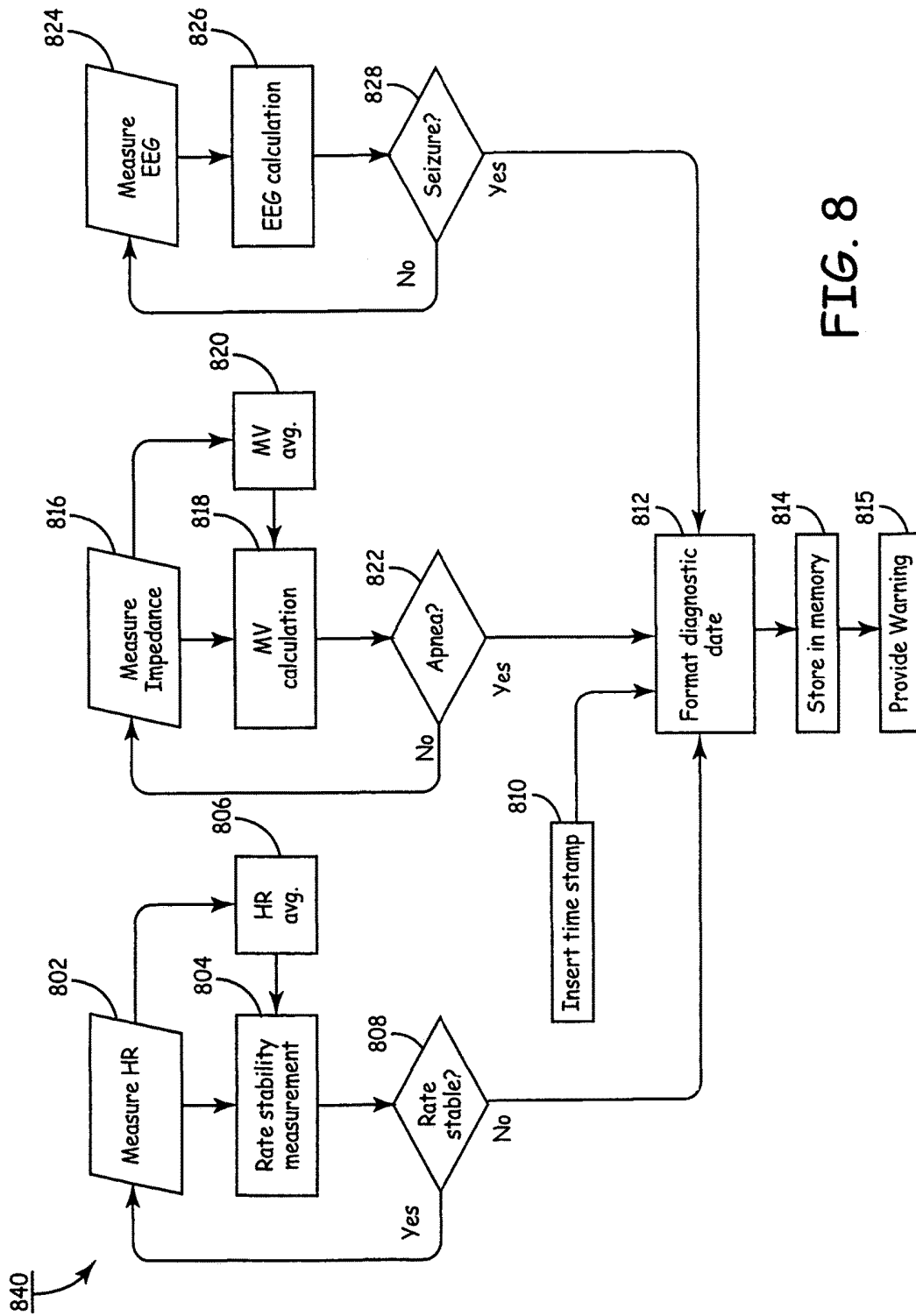


FIG. 8

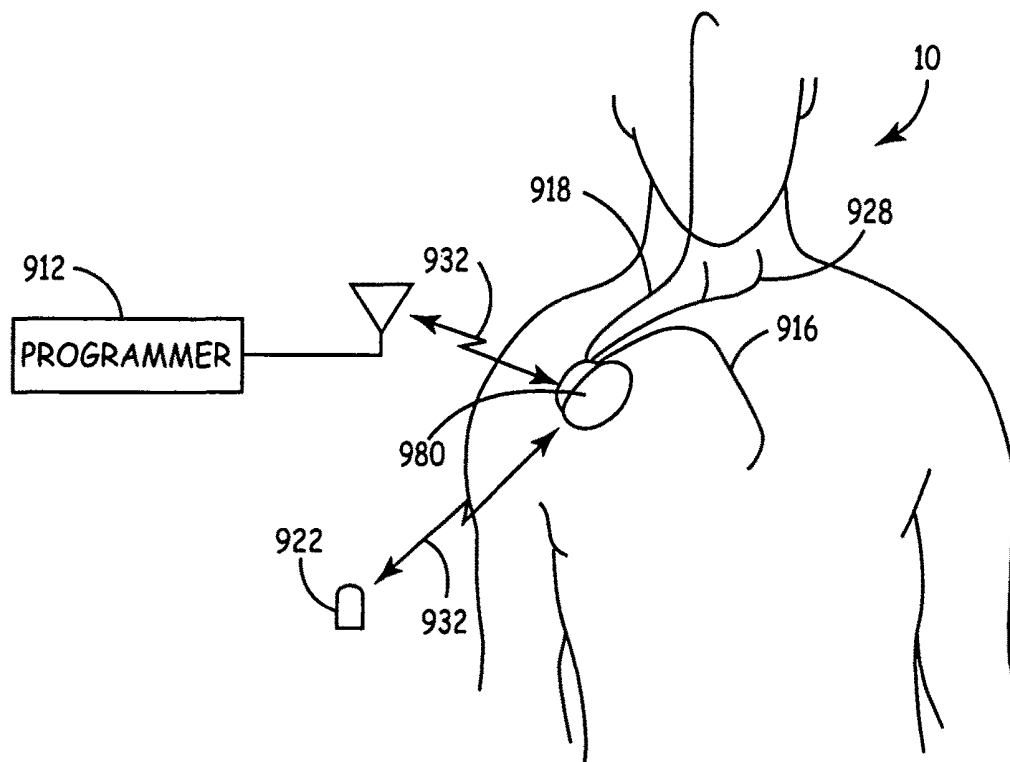


FIG. 9

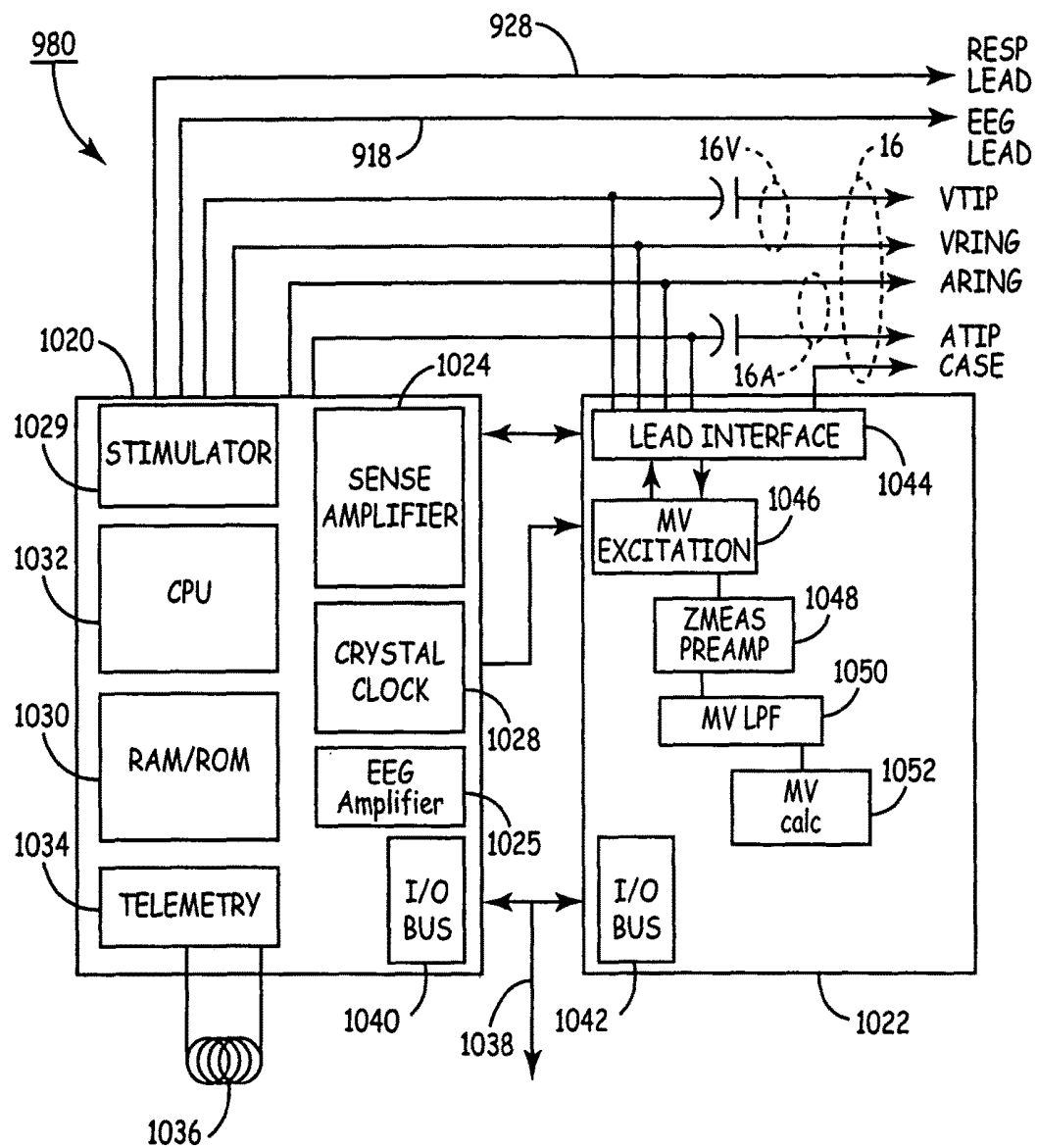
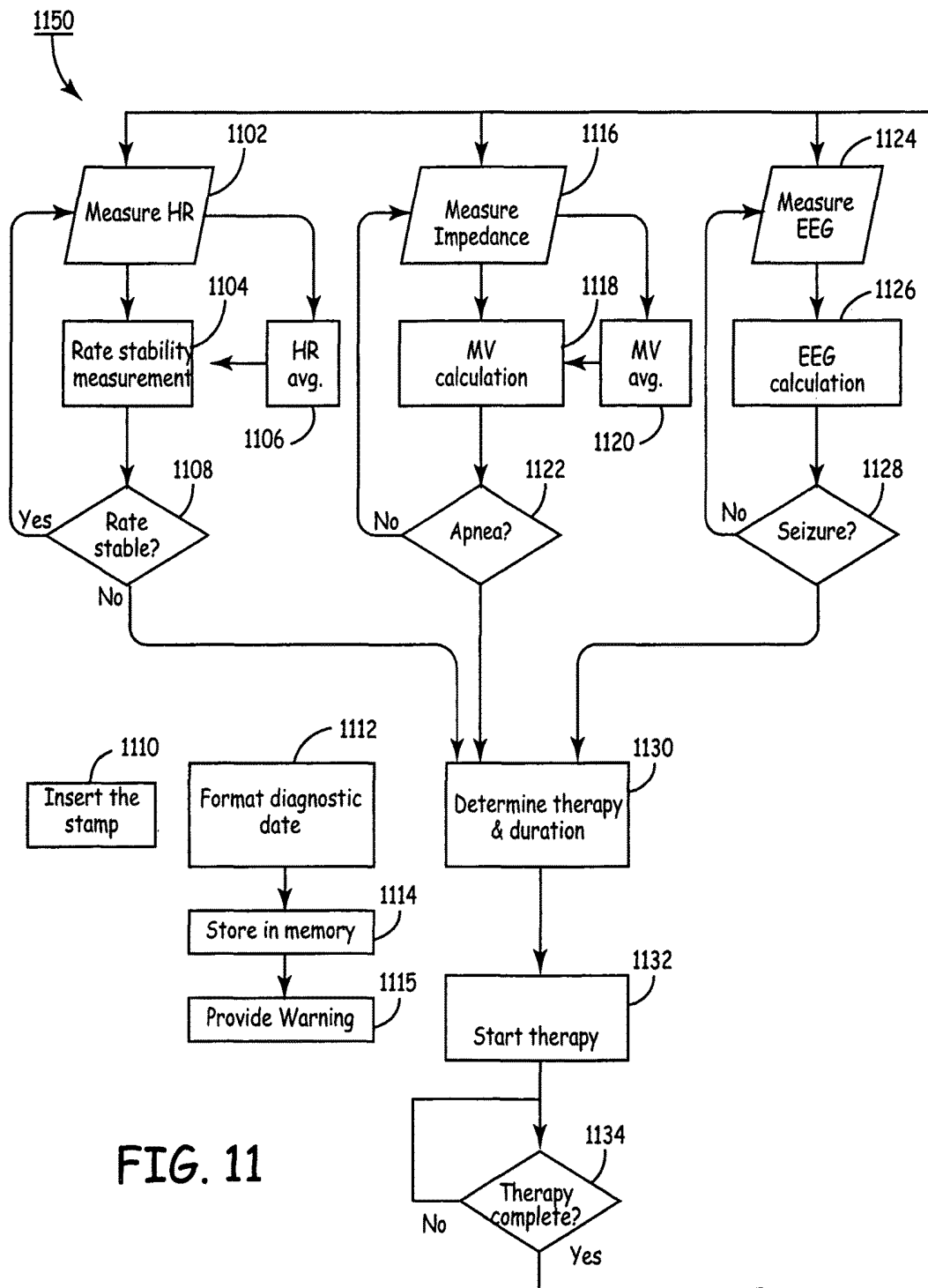


FIG. 10



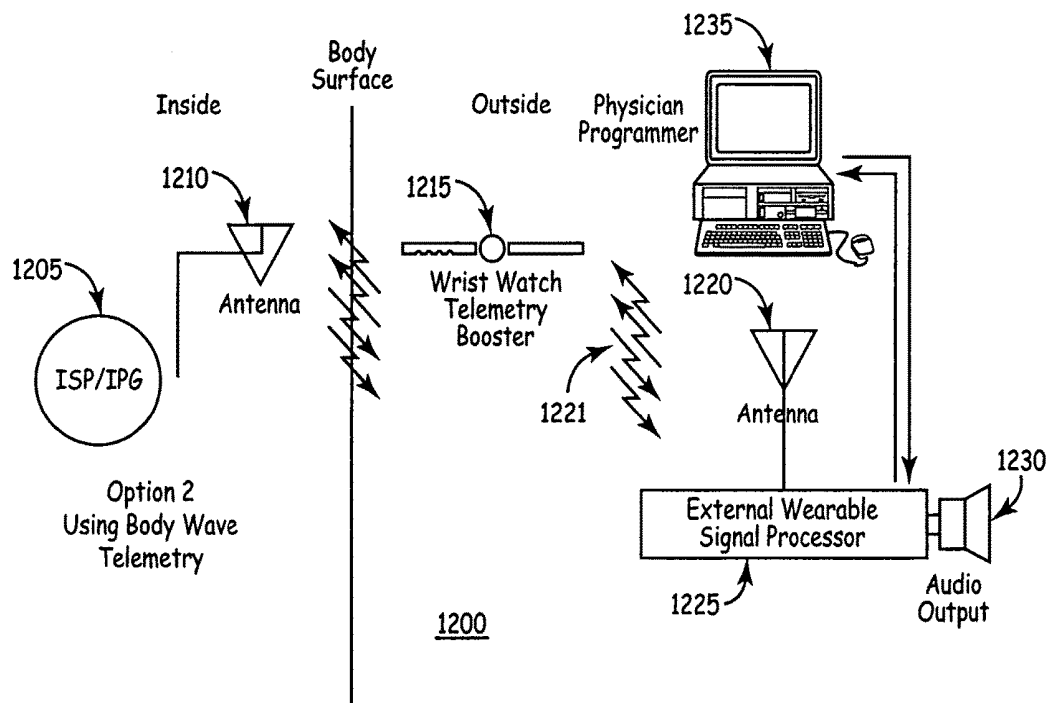


FIG. 12

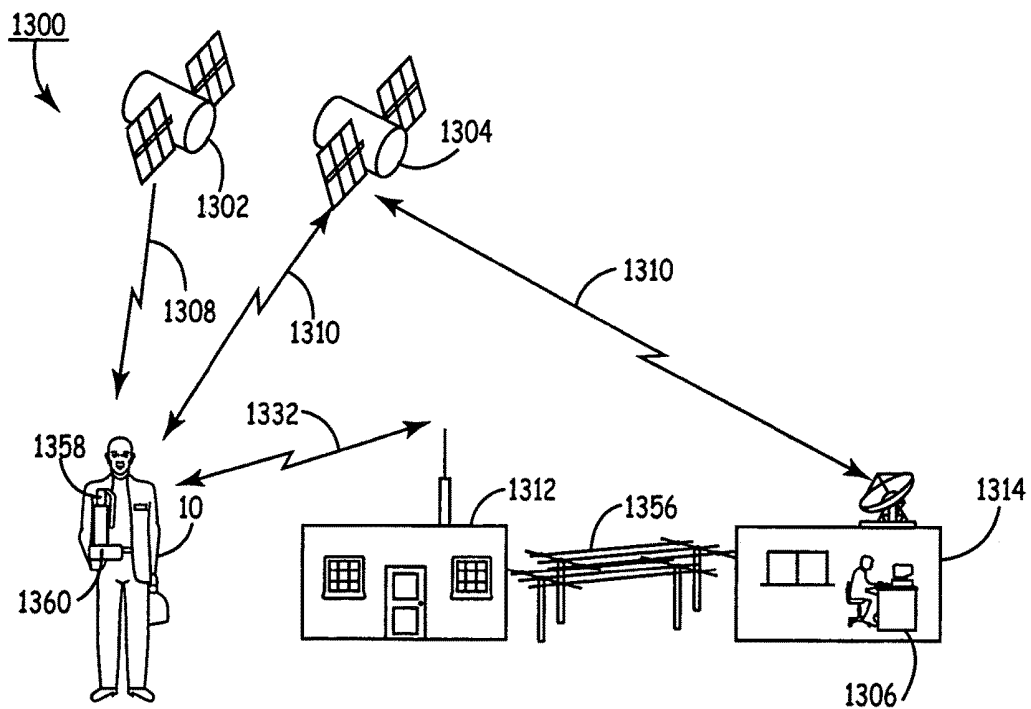


FIG. 13

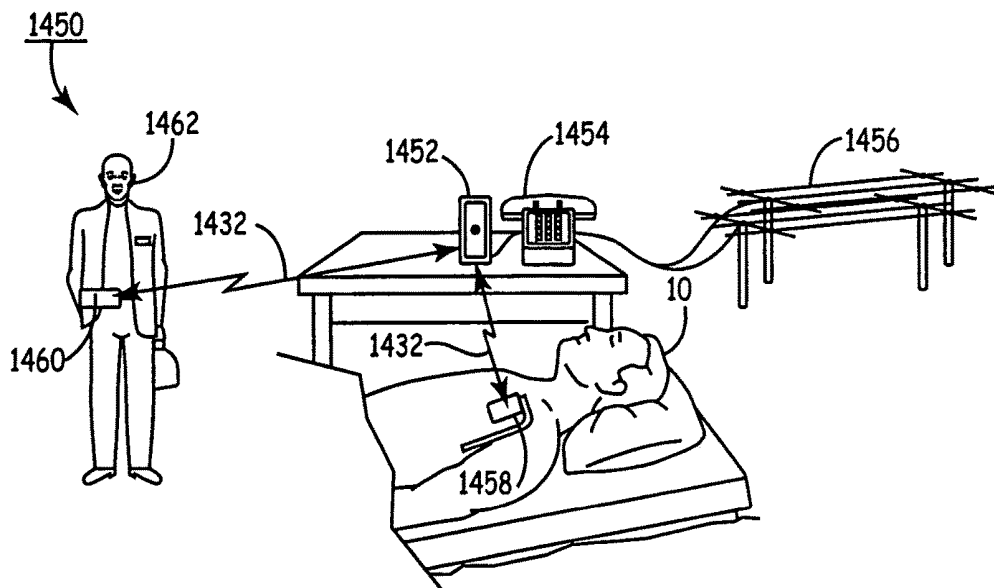
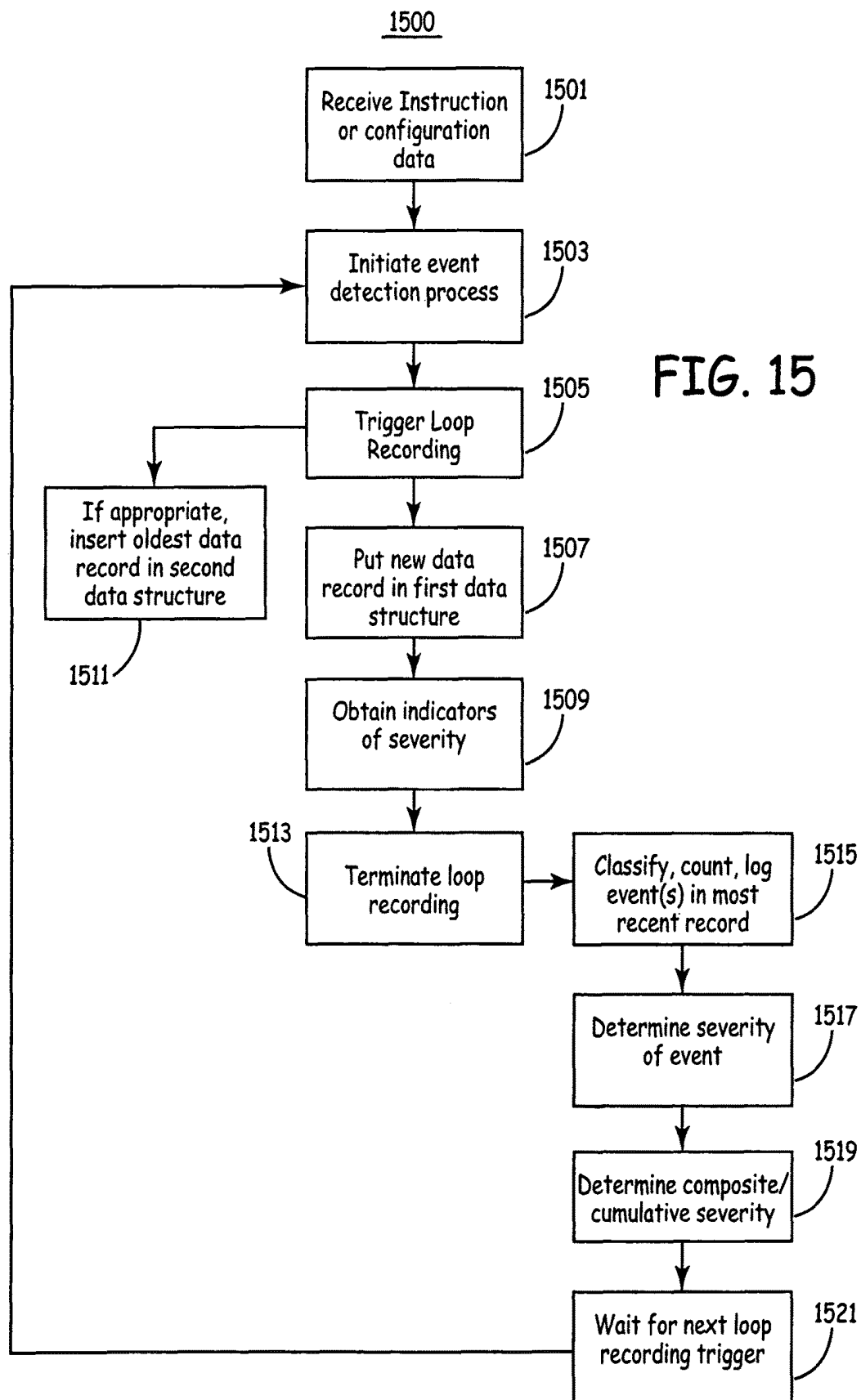


FIG. 14



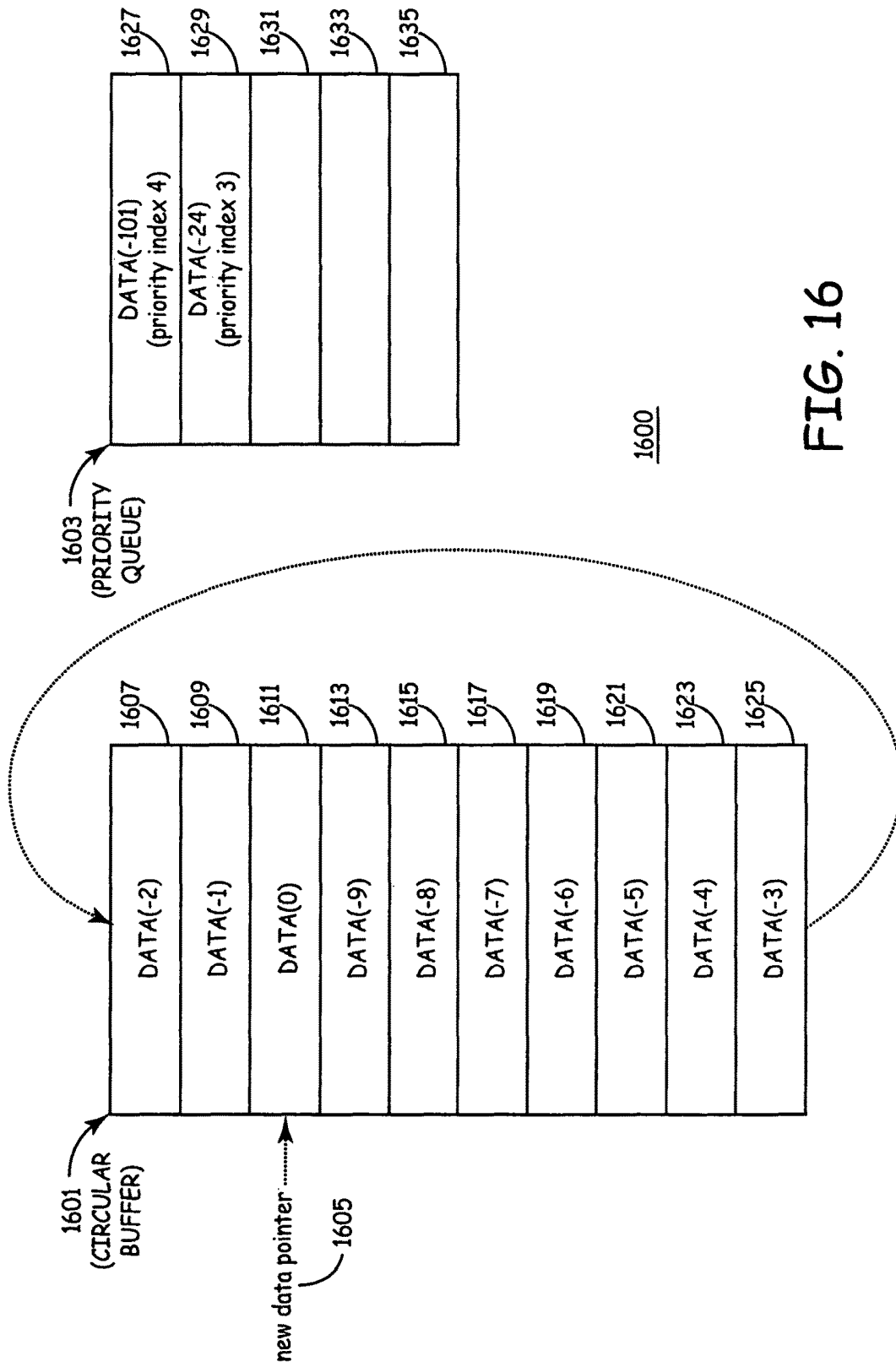


FIG. 16

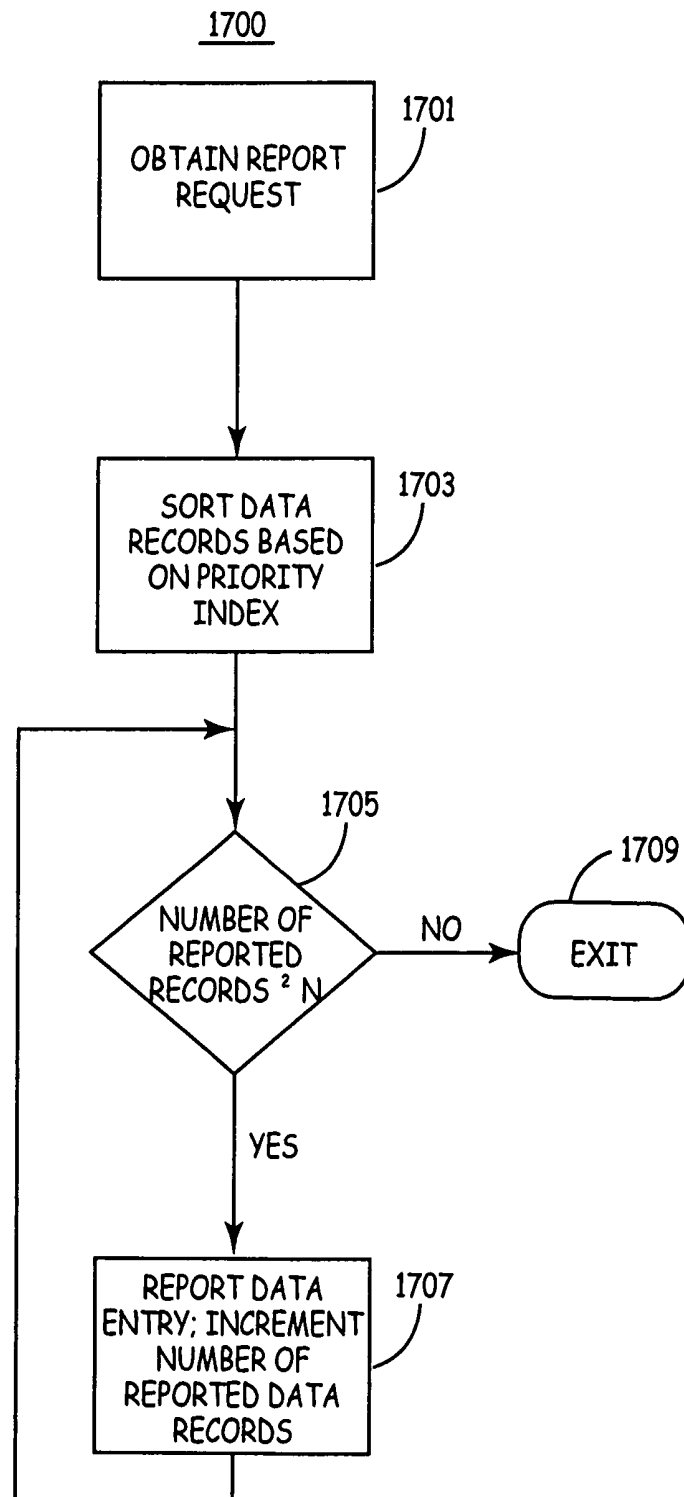


FIG. 17

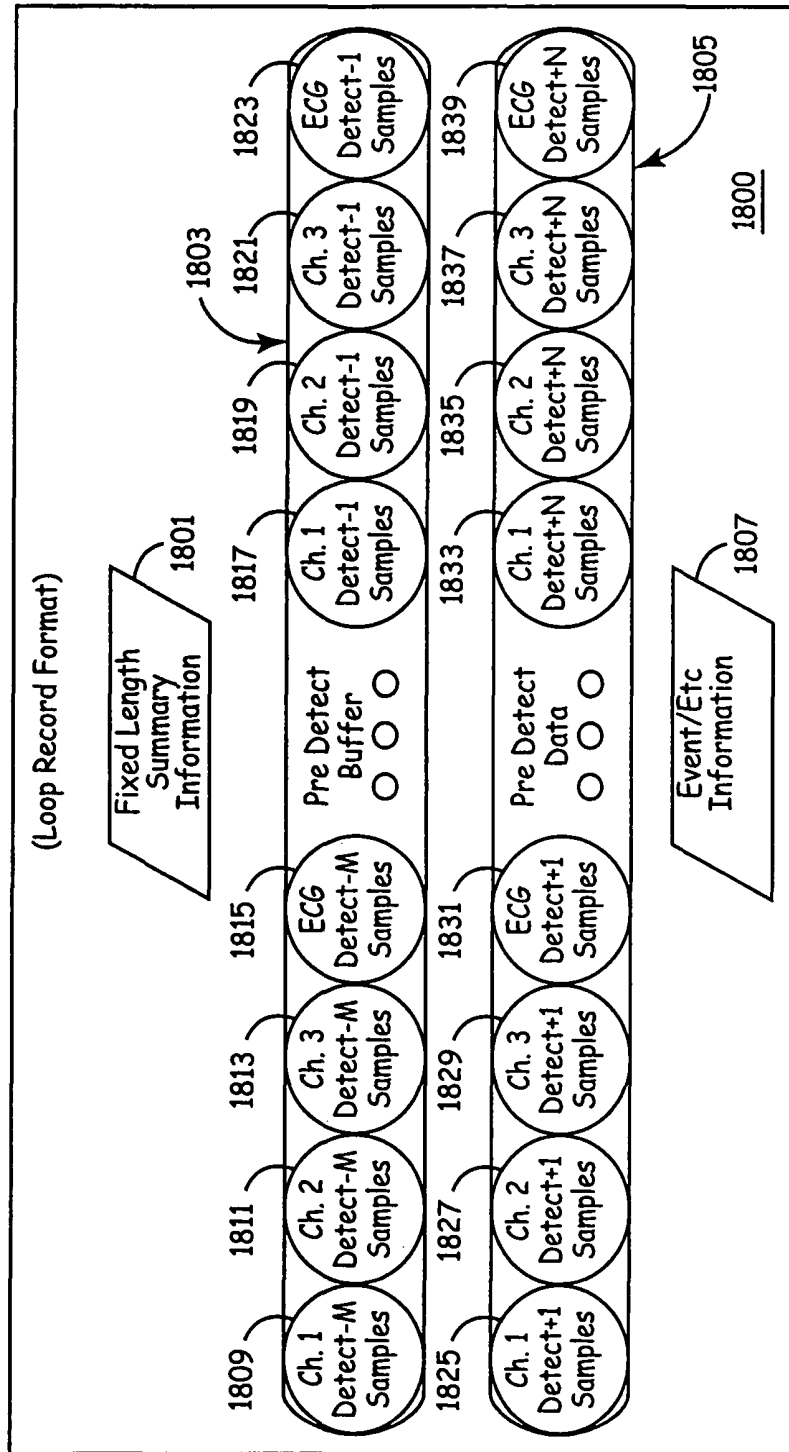


FIG. 18

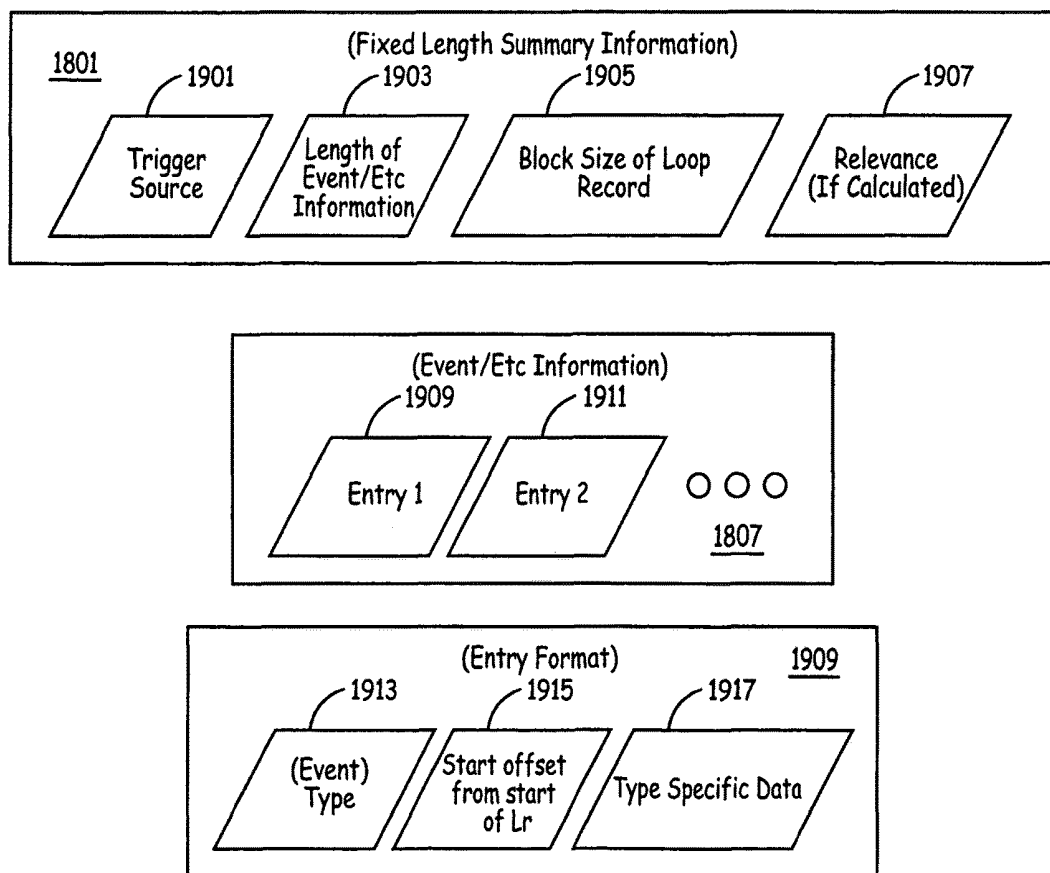


FIG. 19

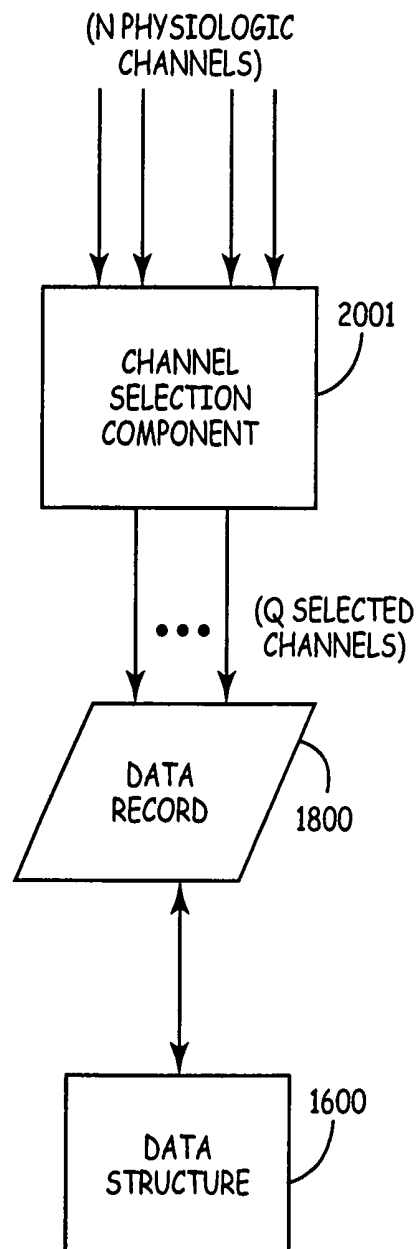


FIG. 20

METHODS FOR DATA RETENTION IN AN IMPLANTABLE MEDICAL DEVICE

This patent application claims priority to U.S. Provisional Application Ser. No. 60/624,232 filed Nov. 2, 2004, which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

The invention relates to techniques for selecting, storing and reporting data associated with physiologic signals that may be further associated with a neurological event.

BACKGROUND OF THE INVENTION

Nervous system disorders affect millions of people, causing death and a degradation of life. Nervous system disorders include disorders of the central nervous system, peripheral nervous system, and mental health and psychiatric disorders. Such disorders include, for example without limitation, epilepsy, Parkinson's disease, essential tremor, dystonia, headache, and multiple sclerosis (MS). Additionally, nervous system disorders include mental health disorders and psychiatric disorders which also affect millions of individuals and include, but are not limited to, anxiety (such as general anxiety disorder, panic disorder, phobias, post traumatic stress disorder (PTSD), and obsessive compulsive disorder (OCD)), mood disorders (such as major depression, bipolar depression, and dysthymic disorder), sleep disorders (narcolepsy), obesity, and anorexia.

As an example, epilepsy is the most prevalent serious neurological disease across all ages. Epilepsy is a group of neurological conditions in which a person has or is predisposed to recurrent seizures. A seizure is a clinical manifestation resulting from excessive, hypersynchronous, abnormal electrical or neuronal activity in the brain. (A neurological event is an activity that is indicative of a nervous system disorder. A seizure is a type of a neurological event.) This electrical excitability of the brain may be likened to an intermittent electrical overload that manifests with sudden, recurrent, and transient changes of mental function, sensations, perceptions, and/or involuntary body movement. Because the seizures are unpredictable, epilepsy affects a person's employability, psychosocial life, and ability to operate vehicles or power equipment. It is a disorder that occurs in all age groups, socioeconomic classes, cultures, and countries. In developed countries, the age-adjusted incidence of recurrent unprovoked seizures ranges from 24/100,000 to 53/100,000 person-years and may be even higher in developing countries. In developed countries, age specific incidence is highest during the first few months of life and again after age 70. The age-adjusted prevalence of epilepsy is 5 to 8 per 1,000 (0.5% to 0.8%) in countries where statistics are available. In the United States alone, epilepsy and seizures affect 2.3 million Americans, with approximately 181,000 new cases occurring each year. It is estimated that 10% of Americans will experience a seizure in their lifetimes, and 3% will develop epilepsy by age 75.

There are various approaches in treating nervous system disorders. Treatment therapies can include any number of possible modalities alone or in combination including, for example, electrical stimulation, magnetic stimulation, drug infusion, and/or brain temperature control. Each of these treatment modalities can be operated using closed-loop feedback control. Such closed-loop feedback control techniques receive from a monitoring element a neurological signal that carries information about a symptom or a con-

dition or a nervous system disorder. Such a neurological signal can include, for example, electrical signals (such as EEG, ECoG, and/or EKG), chemical signals, other biological signals (such as change in quantity of neurotransmitters), temperature signals, pressure signals (such as blood pressure, intracranial pressure or cardiac pressure), respiration signals, heart rate signals, pH-level signals, and peripheral nerve signals (cuff electrodes on a peripheral nerve). Monitoring elements can include, for example, recording electrodes or various types of sensors.

For example, U.S. Pat. No. 5,995,868 discloses a system for the prediction, rapid detection, warning, prevention, or control of changes in activity states in the brain of a patient. Use of such a closed-loop feed back system for treatment of a nervous system disorder may provide significant advantages in that treatment can be delivered before the onset of the symptoms of the nervous system disorder.

During the operation of a medical device system, the patient is likely to experience multiple detections of the nervous system disorder. For example, in the case of seizures, the patient may have thousands of seizures over the course of a time period, but only a few will have behavioral manifestations. The other seizure episodes that don't exhibit behavioral manifestations are considered sub-clinical or electrographic seizures. When the medical device system monitors for seizure occurrences, however, the medical device system will detect many seizure events although only some of these events will spread to other parts of the brain such that the patient will exhibit it (e.g., convulsions, unconsciousness, etc.).

In order to effectively provide treatment therapy, an implanted device may be required to record physiologic data that is related to the disorder. However, an implanted device is typically limited by memory capacity and by battery capacity. Thus, the implanted device is limited in the amount of data that can be stored and reported.

An implanted device often stores physiologic data in a data structure and manages memory allocation for the data structure. However, the memory allocation management supported by the implanted device may have deficiencies. For example, with a FIFO memory buffer if the amount of collected physiologic data exceeds the available memory space, the oldest physiologic data is lost regardless of the importance of the lost data.

It is therefore desirable to selectively store physiologic data in a limited memory space of an implanted device. The implanted device can report the most relevant data from the stored data so that the implanted device can be configured to provide efficacious treatment.

BRIEF SUMMARY

The following represents a simplified summary of some embodiments of the invention in order to provide a basic understanding of various aspects of the invention. This summary is not an extensive overview of the invention nor is it intended to identify key or critical elements of the invention or to delineate the scope of the invention. Its sole purpose is to present some embodiments of the invention in simplified form as a prelude to the more detailed description that is presented thereafter.

In accordance with an aspect of the invention, data records associated with a physiologic event, e.g., a neurological event, are stored in memory that includes a first data structure and a second structure. An implanted device obtains acquired data and stores a data record associated with the data in a selected data entry of the first data structure

(e.g., an age buffer such as circular buffer). Before an older data record in the first data structure is replaced (completely or partially) with a new data record, the older data record may be stored in the second data structure if the associated priority index exceeds a threshold criterion (e.g., exceeds a predetermined threshold value and/or is larger than a corresponding priority index of any data record that is currently stored in the second data structure). With another embodiment of the invention, the older data record may be stored in a min-max heap in accordance with the associated priority index.

In accordance with another aspect of the invention, the priority index that is associated with a data record may be determined by the severity level of a physiologic event and may be further determined by associated factors that may include associated physiologic events.

In accordance with another aspect of the invention, in response to an instruction from a clinician, an implanted device organizes stored physiologic data according to the associated priority index and reports a predetermined number of data records that are deemed as having a higher priority index than the other stored data records.

In accordance with another aspect of the invention, a subset or a composite of physiologic channels is selected from the available physiologic channels based on a selection criterion.

The subset of physiologic channels may be processed and/or stored by an implanted device.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a simplified schematic view of a thoracic cavity leadless medical device implanted in a patient that monitors cardiac and respiratory parameters in accordance with an embodiment of the invention.

FIG. 2 is a simplified block diagram of a core monitor as shown in FIG. 1.

FIG. 3 is a graphical representation of the signals sensed by core monitor as shown in FIG. 1 above.

FIG. 4 is a flow diagram showing operation of a core monitor as shown in FIG. 1 above.

FIG. 5 shows a first apparatus for collecting physiologic data that can be retained in accordance with an embodiment of the invention;

FIG. 6 is a simplified schematic view of an alternative embodiment of a thoracic and cranial leadless medical device implanted in a patient that monitors cardiac, respiratory and brain parameters in accordance with an embodiment of the invention.

FIG. 7 is a simplified block diagram of a full monitor as shown in FIG. 6 above.

FIG. 8 is a flow diagram showing operation of a full monitor as shown in FIG. 6 above.

FIG. 9 is a simplified schematic view of another embodiment of a cardiac, cranial and phrenic nerve leadless medical device implanted in a patient that monitors cardiac, respiratory and brain parameters and provides brain, respiration, and cardiac treatment thereof in accordance with an embodiment of the invention.

FIG. 10 is a simplified block diagram of a full monitor with brain, respiration and cardiac stimulation therapy as shown in FIG. 9 above.

FIG. 11 is a flow diagram showing operation of a full monitor with therapy (including brain, respiration and/or cardiac stimulation therapy) as shown in FIG. 9 above.

FIG. 12 shows apparatus that supports reporting neurological data in accordance with an embodiment of the invention;

FIG. 13 is a schematic diagram of a system utilizing any of the above-described embodiments and allowing remote monitoring and diagnostic evaluation of at risk patients.

FIG. 14 is a schematic diagram of an alternative system utilizing any of the above-described embodiments and allowing remote monitoring and diagnostic evaluation of at risk patients.

FIG. 15 shows a scenario for storing neurological data in accordance with an embodiment of the invention;

FIG. 16 shows a data structure for storing neurological data in accordance with an embodiment of the invention;

FIG. 17 shows a flow diagram for reporting neurological data in accordance with an embodiment of the invention;

FIG. 18 shows an exemplary data entry that contains physiologic data and that may be retained in memory of an implantable medical device;

FIG. 19 shows components of the exemplary data entry as shown in FIG. 18; and

FIG. 20 shows the selection of channel data for retention in a data structure.

DETAILED DESCRIPTION OF THE INVENTION

The following description discloses techniques for selecting, storing and reporting data associated with physiologic signals that may be further associated with a neurological event.

These techniques are suitable for use within any implantable medical device system including, but not limited to, a core monitoring device, a full monitoring device, and/or a combination monitoring and treatment device (e.g., involving brain, respiration, and/or cardiac physiologic signals, discussed below). For example, a core monitor system may consist of ECG and respiratory inputs, a full monitor system may consist of ECG, respiratory and EEG inputs, a monitor/treatment system may include brain, cardiac inputs and phrenic nerve stimulation in various combinations.

In an embodiment, the invention is implemented within an implantable neurostimulator system, however, as already discussed, those skilled in the art will appreciate that the techniques disclosed herein may be implemented generally within any implantable medical device system having monitoring capabilities of physiological conditions of the patient including, but not limited to, implantable drug delivery systems, implantable systems providing stimulation and drug delivery, pacemaker systems, defibrillator systems, cochlear implant systems, and implantable diagnostic system for detecting bodily conditions, including those in organs like the brain and/or the heart. The implantable medical device may provide therapeutic treatment to neural tissue in any number of locations in the body including, for example, the brain (which includes the brain stem), the vagus nerve, the spinal cord, peripheral nerves, etc. The treatment therapies can include any number of possible modalities alone or in combination including, for example, electrical stimulation, magnetic stimulation, drug infusion, brain temperature control, and/or any combination thereof.

In addition, the invention may be embodied in various forms to analyze and treat nervous system and other disorders, namely disorders of the central nervous system, peripheral nervous system, and mental health and psychiatric disorders. Such disorders include, for example without limitation, epilepsy, Sudden Unexpected Death in Epilepsy

Patients (SUDEP), Parkinson's disease, essential tremor, dystonia, multiple sclerosis (MS), anxiety (such as general anxiety, panic, phobias, post traumatic stress disorder (PTSD), and obsessive compulsive disorder (OCD)), mood disorders (such as major depression, bipolar depression, and dysthymic disorder), sleep disorders (narcolepsy), obesity, tinnitus, stroke, traumatic brain injury, Alzheimer's, and anorexia.

The physiologic signals that are selected, stored and reported in accordance with various aspects of the invention may include any number of sensed signals. Such physiological signals can include, for example, electrical signals (such as EEG, ECoG and/or EKG), chemical signals, biological signals (such as change in quantity of neurotransmitters), temperature signals, pressure signals (such as blood pressure, intracranial pressure or cardiac pressure), respiration signals, heart rate signals, pH-level signals, activity signals (e.g., detected by an accelerometer), and/or peripheral nerve signals (cuff electrodes on a peripheral nerve). Such physiological signals may be recorded using one or more monitoring elements such as monitoring electrodes or sensors. For example, U.S. Pat. No. 6,227,203 provides examples of various types of sensors that may be used to detect a symptom or a condition or a nervous system disorder and responsively generate a neurological signal. In addition, various types of physiologic activities may be sensing including, for example, brain, heart and/or respiration.

As discussed, the techniques disclosed herein are suitable for use within any implantable medical device system including, but not limited to, a core monitoring device, a full monitoring device, and/or a combination monitoring and treatment device. Each of these medical device implementations are discussed in further detail below. In general, however, each of these embodiments utilize one or more monitoring elements that receive signals associated with the physiological conditions being sensed, a memory component that contains multiple data structures (for example, at least one that is age-based and at least one other that is priority-based), and a processing component (logic or software) that stores data records in the data structures as disclosed herein (utilizing, for example, severity and priority determinations for the data).

Core Monitor

In an embodiment, a Core Monitor device monitors cardiac (ECG) and respiration signals and records these signals as discussed herein. Real-time analysis of the ECG signal evaluates rate disturbances (e.g., bradycardia; tachycardia; asystole) as well as any indications of cardiac ischemia (e.g., ST segment changes; T wave inversion, etc.). Real-time analysis of the respiration signal evaluates respiration disturbances (e.g., respiration rate, minute ventilation, apnea, prolonged pauses, etc.). Abnormalities detected during real-time analysis may lead to an immediate patient alert, which can be audible (beeps, buzzers, tones, spoken voice, etc.), light, tactile, or other means. Manual indication of a seizure may be achieved through an external activator device 22. The patient (or caregiver) may push a button on the external device, while communicating with the implanted device. This will provide a marker and will initiate a recording, as discussed herein, of the sensed data (for example, in the event the patient is experiencing a neurological event).

In treating SUDEP, for example, prolonged ECG recordings may be possible (e.g., recording all data during sleep since the incidence of SUDEP is highest in patients during sleep). Post-processing of the signal can occur in the implanted device, the patient's external device and/or in the

clinician external device. Intermittently (e.g., every morning, once/week, following a seizure), the patient may download data from the implantable device to the patient external device (as will be discussed further herein), which may then be analyzed by the external device (and/or sent through a network to the physician) to assess any ECG abnormalities. If an abnormality is detected, the device may notify the patient/caregiver. At that time, the patient/caregiver may inform the healthcare provider of the alert to allow a full assessment of the abnormality. The clinician external device may also be capable of obtaining the data from the implanted device and conducting an analysis of the stored signals. If a potentially life-threatening abnormality is detected, the appropriate medical treatment may be prescribed (e.g., cardiac abnormality: a pacemaker, an implantable defibrillator, or a heart resynchronization device may be indicated or respiration abnormality: CPAP, patient positioning, or stimulation of respiration may be indicated).

FIG. 1 is a simplified schematic view of a core monitor 100 implanted in a patient 10. monitor 100 continuously senses and monitors one or more physiological conditions of the patient via monitoring elements 140 (in the embodiment, the physiological conditions are cardiac and respiration functions of patient 10 and the monitoring elements 140 are subcutaneous electrodes). Stored diagnostic data is uplinked and evaluated by an external computing device 120 (e.g., a patient's physician utilizing programmer) via a 2-way telemetry link 132. An external patient activator 122 may optionally allow the patient 10, or other care provider (not shown), to manually activate the recording of diagnostic data.

In the embodiment, monitor 100 encompasses monitoring elements 140 that are several subcutaneous spiral electrodes and may be embedded individually into three or four recessed casings placed in a compliant surround that is attached to the perimeter of implanted monitor 100 as substantially described in U.S. Pat. Nos. 6,512,940 and 6,522,915. These electrodes are electrically connected to the circuitry of the implanted monitor 100 to allow the detection of cardiac depolarization waveforms (as substantially described in U.S. Pat. No. 6,505,067) that may be further processed to detect cardiac electrical characteristics (e.g., heart rate, heart rate variability, arrhythmias, cardiac arrest, sinus arrest and sinus tachycardia). Further processing of the cardiac signals signal amplitudes may be used to detect respiration characteristics (e.g., respiration rate, minute ventilation, and apnea). To aid in the implantation of monitor 100 in a proper position and orientation, an implant aid may be used to allow the implanting physician to determine the proper location/orientation as substantially described in U.S. Pat. No. 6,496,715.

FIG. 2 depicts a block diagram of the electronic circuitry of the core monitor 100 of FIG. 1 in accordance with an embodiment of the invention. Monitor 100 comprises a primary control circuit 220 and may be similar in design to that disclosed in U.S. Pat. No. 5,052,388. Primary control circuit 220 includes sense amplifier circuitry 224, a crystal clock 228, a random-access memory and read-only memory (RAM/ROM) unit 230, a central processing unit (CPU) 232, a MV Processor circuit 238 and a telemetry circuit 234, all of which are generally known in the art.

Monitor 100 may include internal telemetry circuit 234 so that it is capable of being programmed by means of external programmer/control unit 120 via a 2-way telemetry link 132 (shown in FIG. 1). External programmer/control unit 120 communicates via telemetry with the monitor 100 so that the programmer can transmit control commands and operational parameter values to be received by the implanted device, and

so that the implanted device can communicate diagnostic and operational data to the programmer 120. For example, programmer 120 may be Models 9790 and CareLink® programmers, commercially available from Medtronic, Inc., Minneapolis, Minn. Various telemetry systems for providing the necessary communications channels between an external programming unit and an implanted device have been developed and are well known in the art. Suitable telemetry systems are disclosed, for example, in U.S. Pat. Nos. 5,127,404; 4,374,382; and 4,556,063.

Typically, telemetry systems such as those described in the above referenced patents are employed in conjunction with an external programming/processing unit. Most commonly, telemetry systems for implantable medical devices employ a radio-frequency (RF) transmitter and receiver in the device, and a corresponding RF transmitter and receiver in the external programming unit. Within the implantable device, the transmitter and receiver utilize a wire coil as an antenna for receiving downlink telemetry signals and for radiating RF signals for uplink telemetry. The system is modeled as an air-core coupled transformer. An example of such a telemetry system is shown in U.S. Pat. No. 4,556,063.

In order to communicate digital data using RF telemetry, a digital encoding scheme such as is described in U.S. Pat. No. 5,127,404 can be used. In particular, a pulse interval modulation scheme may be employed for downlink telemetry, wherein the external programmer transmits a series of short RF “bursts” or pulses in which the interval between successive pulses (e.g., the interval from the trailing edge of one pulse to the trailing edge of the next) is modulated according to the data to be transmitted. For example, a shorter interval may encode a digital “0” bit while a longer interval encodes a digital “1” bit. For uplink telemetry, a pulse position modulation scheme may be employed to encode uplink telemetry data. For pulse position modulation, a plurality of time slots are defined in a data frame, and the presence or absence of pulses transmitted during each time slot encodes the data. For example, a sixteen-position data frame may be defined, wherein a pulse in one of the time slots represents a unique four-bit portion of data.

Programming units such as the above-referenced Medtronic Models 9790 and CareLink® programmers typically interface with the implanted device through the use of a programming head or programming paddle, a handheld unit adapted to be placed on the patient’s body over the implant site of the patient’s implanted device. A magnet in the programming head effects reed switch closure in the implanted device to initiate a telemetry session. Thereafter, uplink and downlink communication takes place between the implanted device’s transmitter and receiver and a receiver and transmitter disposed within the programming head.

As previously noted, primary control circuit 220 includes central processing unit 232 which may be an off-the-shelf programmable microprocessor or microcontroller, but in an embodiment of the invention is a custom integrated circuit. Although specific connections between CPU 232 and other components of primary control circuit 220 are not shown in FIG. 2, it will be apparent to those of ordinary skill in the art that CPU 232 functions to control the timed operation of sense amplifier circuit 224 under control of programming stored in RAM/ROM unit 230. Those of ordinary skill in the art will be familiar with such an operative arrangement.

With continued reference to FIG. 2, crystal oscillator circuit 228, in an embodiment, is a 32,768-Hz crystal controlled oscillator, provides main timing clock signals to primary control circuit 220. The various components of

monitor 100 are powered by means of a battery (not shown), which is contained within the hermetic enclosure of monitor 100. For the sake of clarity in the figures, the battery and the connections between it and the other components of monitor 100 are not shown. Sense amplifier 224 is coupled to monitoring elements 140. Where cardiac intrinsic signals are sensed, they may be sensed by sense amplifier 224 as substantially described in U.S. Pat. No. 6,505,067.

Processing by CPU 232 allows the detection of cardiac electrical characteristics and anomalies (e.g., heart rate, heart rate variability, arrhythmias, cardiac arrest, sinus arrest and sinus tachycardia). Further processing of the cardiac signals signal amplitudes may be used to detect respiration characteristics/anomalies (e.g., respiration rate, tidal volume, minute ventilation, and apnea) in MV Processor 238.

FIG. 3 shows the intracardiac signals 370 presented to sense amplifier 224 from monitoring elements 140. Note the amplitude variation of cardiac signals caused by the change in thoracic cavity pressure due to respiration (i.e., inspiration and expiration). By low pass filtering the cardiac signals 370, a signal representing minute ventilation may be obtained as depicted in waveform 372. This respiration signal may further be examined to detect respiration rate and reduced or absence of inspiration and expiration (central apnea) by CPU 232 and software resident in RAM/ROM 230.

Upon detection of either a cardiac or respiration anomaly, CPU 232, under control of firmware resident in RAM/ROM 230, will initiate recording of the appropriate diagnostic information into RAM of RAM/ROM 230 (discussed further herein), initiate a warning or alert to the patient, patient caregiver, or remote monitoring location.

FIG. 4 is a flow diagram 400 showing operation of a core monitor sensing/monitoring cardiac and respiration parameters for the detection of a neurological event as shown and described in FIG. 1 above. Beginning at block 402, the interval between sensed cardiac signals are measured. At block 404, a rate stability measurement is made on each cardiac interval utilizing a heart rate average from block 406. At block 408, a rate stable decision is made based upon preprogrammed parameters. If YES, the flow diagram returns to the HR Measurement block 402. If NO, the rate stability information is provided to Format Diagnostic Data block 412.

At block 416, thoracic impedance is continuously measured in a sampling operation. At block 418, a Mv and respiration rate calculation is made. At block 422, a pulmonary apnea decision is made based upon preprogrammed criteria. If NO, the flow diagram returns to MV Measurement block 416. If YES, the occurrence of apnea and MV information is provided to Format Diagnostic Data block 412. Format Diagnostic Data block 412 formats the data from the cardiac and respiration monitoring channels, adds a time stamp (i.e., date and time) and provides the data to block 414 where the data is stored in RAM, SRAM or MRAM memory for later retrieval by a clinician via telemetry (using the techniques discussed herein). Optionally, block 412 may add examples of intrinsic ECG and/or respiration signals recorded during a sensed neurological event. Additionally, optionally, block 415 may initiate a warning or alert to the patient, patient caregiver, or remote monitoring location (as described in U.S. Pat. No. 5,752,976).

It will be appreciated that alternative embodiments of the core monitor device may also be utilized. As discussed above, core monitor 100 may sense any number of physiologic conditions of the patient for purposes of detecting,

and storing data relating to, any number of the neurological events. For example, cardiac lead(s) may be used to facilitate detection of a neurological event and the recording of data and signals pre and post event. Cardiac leads may consist of any typical lead configuration as is known in the art, such as, without limitation, right ventricular (RV) pacing or defibrillation leads, right atrial (RA) pacing or defibrillation leads, single pass RA/RV pacing or defibrillation leads, coronary sinus (CS) pacing or defibrillation leads, left ventricular pacing or defibrillation leads, pacing or defibrillation epicardial leads, subcutaneous defibrillation leads, unipolar or bipolar lead configurations, or any combinations of the above lead systems.

In another embodiment, an electrode located distally on a sensor stub may be used to facilitate detection of a neurological event and the recording of data and signals pre and post event. The sensor stub is inserted subcutaneously in a thoracic area of the patient. The monitor **100** may sense cardiac signals between an electrode on the distal end of the sensor stub and the monitor case as described in conjunction with the embodiment shown in FIG. in U.S. Pat. No. 5,987,352. The monitor **100** may also sense respiration parameters such as respiration rate, minute ventilation and apnea via measuring and analyzing the impedance variations measured from the implanted monitor **100** case to the electrode located distally on the sensor stub lead as substantially described in U.S. Pat. Nos. 4,567,892 and 4,596,251.

In yet another embodiment, an external wearable device such as a wearable patch, a wristwatch, or a wearable computing device may be used may be used to continuously sense and monitor cardiac and respiration function of patient **10**. Optionally, a button on the external wearable device may be activated by the patient **10** (or a caregiver) to manually activate data recording (for example, in the event the patient is experiencing a neurological event). The external wearable device may comprise an amplifier, memory, microprocessor, receiver, transmitter and other electronic components as substantially described in U.S. Pat. No. 6,200,265. In the embodiment of a wearable patch, the device may consist of a resilient substrate affixed to the patient's skin with the use of an adhesive. The substrate flexes in a complimentary manner in response to a patient's body movements providing patient comfort and wearability. The low profile patch is preferably similar in size and shape to a standard bandage, and may be attached to the patient's skin in an inconspicuous location.

FIG. **5** shows an apparatus **500** for collecting physiologic data that can be retained in accordance with an embodiment of the invention. Apparatus comprises implanted device **501** and external device **503**. In the embodiment, implanted device **501** collects physiological data through EEG lead **505**, which is coupled to an electrode. The embodiment may support a plurality of electrodes that may collect physiological data from desired locations in the brain or other neural tissue within the body. With respect to sensing of the brain, the embodiment may support electrodes that are positioned in the brain, positioned on the scalp, or a combination. EEG amplifier **521** processes neurological signals from EEG lead **505**, while stimulator **511** forms appropriate electrical waveforms to stimulate electrodes that are coupled to EEG lead **505**. CPU **513** controls the circuitry in internal device **501** and is clocked by crystal clock **519**. CPU **513** obtains instructions from and stores neurological data to RAM/ROM **515**. Communication within internal device between components is transported on I/O bus **523**.

External device **503** collects other physiologic data through patch leads **507a** and **507b**, which are coupled to

patch electrodes. External device **503** is typically worn by the patient. In the embodiment, the patch electrodes monitor and stimulate the respiration of the patient in concert with monitoring neurological data. Respiratory data is collected from the patch electrodes through lead interface **525**. Minute Ventilation (Mv) module **527** excites the patch electrodes (if necessary) while respiratory data (indicative of the minute ventilation) is obtained through sense amplifier **531**. (Minute or total ventilation is the product of respiratory rate and tidal volume.) Additionally, impedance module **529**, MV low pass filter **533**, and MV calibration module **535** calibrate MV excitation module **527**. Data communication within external device **503** is transported on I/O bus **539**.

Internal device **501** and external device **503** communicate with each other over telemetry channel **543** through telemetry interfaces **517** and **537** and antennas **539** and **541**. However, internal device **501** and external device **503** may communicate using an alternative communications path. For example, I/O bus **523** and I/O bus **539** may be electrically connected through a wired channel.

While the embodiment shown in FIG. **5** collects and retains physiological data and respiratory data, other physiologic data may be collected and retained. For example, apparatus **500** may collect cardiac data and motor coordination data. The embodiment may further correlate the neurological data with the physiological data.

Full Monitor

The full monitor is capable of monitoring cardiopulmonary parameters as in the core monitor described above, and additionally an EEG from an intracranially implanted lead system. This will allow the full monitor to collect cardiovascular, respiratory and neurologic signals in close proximity to detected neurologic events as well as notifying the patient/caregiver of a prolonged event (and/or status epilepticus). Like the core monitor, cardiovascular and respiratory monitoring may occur around a neurologic event (peri-ictal). The full monitor device may detect the neurological event and analyze the peri-ictal signals and initiate loop recording. The addition of the neurologic monitor allows shorter loop-recording durations since the beginning of the neurological event may be known with greater certainty. In addition, the EEG monitoring may be programmed to provide alerts when a neurologic event has exceeded a pre-determined duration or severity.

FIG. **6** is a simplified schematic view of a full monitor **620** implanted in a patient **10**. Monitor **620** continuously senses and monitors cardiac, brain and respiration function of patient **10** via several subcutaneous electrodes **616** and a brain lead **618** to allow detection of neurological events and the recording of data and signals pre and post event. Stored diagnostic data is uplinked and evaluated by the patient's physician utilizing programmer **612** via a 2-way telemetry link **632**. An external patient activator **622** may optionally allow the patient **10**, or other care provider (not shown), to manually activate the recording of diagnostic data. An implant aid may be used with monitor **620** to ensure a proper position and orientation during implant as described above in connection with the system of FIG. **1**.

FIG. **7** is a block diagram of the electronic circuitry that makes up full monitor **620** with brain lead **618** and cardiac leads **616** (which includes leads **616A** and **616V**) of FIG. **6** in accordance with the disclosed alternative embodiment of the invention. Cardiac leads **616V** represent the grouping of VTIP and VRING. Cardiac leads **616A** represent the grouping of ATIP and ARING. Monitor **620** comprises a primary control circuit **720** and MV circuit **722** that are described herein above in conjunction with FIG. **2**. In addition, the full

Monitor **620** also includes an amplifier **725** to amplify and sense EEG signals from a cranially implanted lead **618**. The CPU **732**, in conjunction with a software program resident in RAM/ROM **730**, integrates the information from the sensed cardiac, respiration and EEG signals, detects the onset of cerebral, cardiac and/or respiratory anomalies, formats and stores diagnostic data for later retrieval by the patient's clinician and, optionally, may warn or alert the patient, patient caregiver or remote monitoring location. Sense amplifier circuit **724** is like sense amplifier circuit **224** in FIG. 2. Crystal clock **728** is like crystal clock **519** in FIG. 5. Telemetry interface **734** is like telemetry interface **517** in FIG. 5. Antenna **736** is like antenna **519** in FIG. 5. I/O bus **740** is like I/O bus **523** in FIG. 5. I/O bus **742** is like I/O bus **539** in FIG. 5. MV calibration module **752** is like MV calibration module **535** in FIG. 5. MV low pass filter **750** is like MV low pass filter **533** in FIG. 5. Impedance module **748** is like impedance module **529** in FIG. 5. MV excitation module **746** is like MV excitation module **527** in FIG. 5. Lead interface **744** is like lead interface **525** in FIG. 5. Communication link **738** connects additional I/O buses or other devices.

FIG. 8 is a flow diagram **840** showing operation of a full monitor sensing and monitoring cardiac, respiration and electroencephalogram parameters for the detection of a neurological event as shown and described in embodiment in FIG. 6 above. Beginning at block **802**, the interval between sensed cardiac signals are measured. At block **804**, a rate stability measurement is made on each cardiac interval utilizing a heart rate average from block **806**. At block **808**, a rate stable decision is made based upon preprogrammed parameters. If YES, the flow diagram returns to the HR Measurement block **802**. If NO, the rate stability information is provided to Format Diagnostic Data block **812**.

At block **816**, thoracic impedance is continuously measured in a sampling operation. At block **818**, a MV and respiration rate calculation is made. At block **822**, a pulmonary apnea decision is made based upon preprogrammed criteria. If NO, the flow diagram returns to MV Measurement block **816**. If YES, the occurrence of apnea and MV information is provided to Format Diagnostic Data block **812**.

At block **824**, the electroencephalogram is sensed and measured. An EEG seizure determination is performed at block **826** as described in U.S. patent application serial no. 2004/0138536. At block **828**, a seizure cluster episode is determined. If NO, the flow diagram returns to EEG Measurement block **824**. If YES, the occurrence of a seizure cluster is provided to Format Diagnostic Data block **812**. Format Diagnostic Data block **812** formats the data from the cardiac, respiration and EEG monitoring channels, adds a time stamp (ie, date and time) and provides the data to block **814** where the data is stored in RAM memory for later retrieval by a clinician via telemetry (using techniques discussed herein). Optionally, block **812** may add examples of intrinsic ECG, respiration and/or EEG signals recorded during a sensed episode/seizure. Additionally, optionally, block **815** may initiate a warning or alert to the patient, patient caregiver, or remote monitoring location (as described in U.S. Pat. No. 5,752,976).

Again, it will be appreciated that alternative embodiments of the full monitor device may also be utilized. For example, cardiac lead(s), a sensor stub, and/or a wearable patch may be used to facilitate detection of a neurologic event and the recording of data and signals pre and post event. An integrated electrode may also be used that senses ECG signals as described in U.S. Pat. No. 5,987,352 and respiration

signals as described in U.S. Pat. Nos. 4,567,892 and 4,596,251. Optionally, the monitor may warn/alert the patient **10** via buzzes, tones, beeps or spoken voice (as substantially described in U.S. Pat. No. 6,067,473) via a piezo-electric transducer incorporated in the housing of monitor and transmitting sound to the patient's inner ear.

In another embodiment, the monitor may be implanted cranially in the patient **10**. In such an embodiment, the monitor may be constructed as substantially described in U.S. Pat. Nos. 5,782,891 and 6,427,086. EEG sensing may be accomplished by the use of integrated electrodes in the housing of the monitor, cranially implanted leads, and or leadless EEG sensing.

Alternatively, ECG rate and asystole may be inferred using a variety of technologies. For example, ECG rate and asystole may be inferred (along with a blood pressure signal) from a capacitive dynamic pressure signal (i.e., dP/dt) as substantially described in U.S. Pat. No. 4,485,813. Similarly, an acoustic signal (i.e., sound) may be used as substantially described in U.S. Pat. No. 5,554,177 (the sensed acoustic signal is low pass filtered to limit ECG signals to 0.5-3 Hz while filtering out speech, swallowing and chewing sounds). As another example, ECG rate and asystole may be inferred (along with a blood saturation measurement) by monitoring a reflectance oximetry signal (i.e., O₂sat) as substantially described in U.S. Pat. No. 4,903,701. As yet another example, a blood temperature signal (i.e., dT/dt) may be used as substantially described in U.S. Pat. No. 5,336,244. As still another example, ECG rate and asystole may be inferred (along with an arterial flow measurement) by monitoring a blood flow signal (from an adjacent vein via impedance plethysmography, piezoelectric sensor or Doppler ultrasound) as substantially described in U.S. Pat. No. 5,409,009. As another example, ECG rate and asystole may be inferred (along with a blood pressure measurement) by monitoring a blood pressure signal utilizing a strain gauge substantially described in U.S. Pat. No. 5,168,759. As another example, ECG rate and asystole may be inferred by monitoring a blood parameter sensor (such as oxygen, pulse or flow) located on a V-shaped lead as substantially described in U.S. Pat. No. 5,354,318.

Monitor and Treat

As exemplified above, any number of implantable medical device systems are envisioned that may incorporate the recording and retention techniques discussed herein. For example, the monitoring may be achieved using any of the above techniques in conjunction with treatment by delivery of treatment therapy (e.g., electrical stimulation) to the brain, cardiac or respiration.

FIG. 9 is a simplified schematic view of a full Monitor/Brain, Respiration and Cardiac Therapy unit **980** implanted in a patient **10**. Monitor/Brain, Respiration and Cardiac Therapy unit **980** continuously senses and monitors cardiac, brain and/or respiration function of patient **10** via cardiac lead(s) **916** and a brain lead **918** to allow detection of epileptic neurological events, the recording of data and signals pre and post event, and the delivery of therapy via brain lead **918**, cardiac lead(s) **916** and phrenic nerve lead **928**. Stored diagnostic data is uplinked and evaluated by the patient's physician utilizing programmer **912** via a 2-way telemetry link **932**. An external patient activator **922** may optionally allow the patient **10**, or other care provider (not shown), to manually activate the recording of diagnostic data and delivery of therapy. Optionally, lead **928** may connect to the diaphragm to provide direct diaphragmatic stimulation. As discussed any combination of monitoring and any combination of treatment may be implemented.

FIG. 10 is a block diagram of the electronic circuitry that makes up full Monitor/Brain, Respiration and Cardiac Therapy device 980 of FIG. 9. Monitor/Brain, Respiration and Cardiac Therapy device 980 comprises a primary control circuit 1020 and MV circuit 1022 whose function was described herein above in conjunction with FIG. 2. In addition the Monitor/Brain, Respiration and Cardiac Therapy device of FIG. 10 also includes an amplifier 1025 to amplify and sense EEG signals from a cranially implanted lead 918 and an output stimulator 1029 to provide brain stimulation via cranially implanted lead 918 and phrenic nerve stimulation via respiration lead 928. The CPU 1032, in conjunction with software program in RAM/ROM 1030, integrates the information from the sensed cardiac, respiration and EEG signals, detects the onset of cerebral, cardiac and/or respiratory anomalies, provides preprogrammed stimulation therapy to the patient's brain via lead 918, stimulation of the patient's phrenic nerve via respiration lead 928 and stimulation of the patient's heart via cardiac leads 916 (which includes leads 916A and 916V), formats and stores diagnostic data for later retrieval by the patient's clinician and, optionally, may warn or alert the patient, patient caregiver or remote monitoring location. Cardiac leads 916V represent the grouping of VTIP and VRING. Cardiac leads 916A represent the grouping of ATIP and ARING. Optionally, lead 928 may connect to the diaphragm to provide direct diaphragmatic stimulation. Sense amplifier circuit 1024 is like sense amplifier circuit 224 in FIG. 2. Crystal clock 1028 is like crystal clock 519 in FIG. 5. Telemetry interface 1034 is like telemetry interface 517 in FIG. 5. Antenna 1036 is like antenna 519 in FIG. 5. I/O bus 1040 is like I/O bus 523 in FIG. 5. I/O bus 1042 is like I/O bus 539 in FIG. 5. MV calibration module 1052 is like MV calibration module 535 in FIG. 5. MV low pass filter 1050 is like MV low pass filter 533 in FIG. 5. Impedance module 1048 is like impedance module 529 in FIG. 5. MV excitation module 1046 is like MV excitation module 527 in FIG. 5. Lead interface 1044 is like lead interface 525 in FIG. 5. Communication link 1038 connects additional I/O buses or other devices.

FIG. 11 is a flow diagram 1150 showing operation of a full monitor/therapy sensing and monitoring cardiac, respiration and electroencephalogram parameters as shown and described in FIG. 9 above. Beginning at block 1102, the interval between sensed cardiac signals are measured. At block 1104, a rate stability measurement is made on each cardiac interval utilizing a heart rate average from block 1106. At block 1108, a rate stable decision is made based upon preprogrammed parameters. If YES, the flow diagram returns to the HR Measurement block 1102. If NO, the rate stability information is provided to Determine Therapy and Duration block 1130.

At block 1116, thoracic impedance is continuously measured in a sampling operation. At block 1118, a MV and respiration rate calculation is made. At block 1122, a pulmonary apnea decision is made based upon preprogrammed criteria. If NO, the flow diagram returns to MV Measurement block 1116. If YES, the occurrence of apnea and MV information is provided to Determine Therapy and Duration block 1130.

At block 1124, the electroencephalogram is sensed and measured. An EEG calculation is performed at block 1126. At block 1128, a seizure episode is determined. If NO, the flow diagram returns to EEG Measurement block 1124. If YES, the occurrence of a seizure is provided to Determine Therapy and Duration block 1130.

Based upon the data presented to it, Determine Therapy and Duration block 1130 determines the type of therapy and the duration to block 1132, which controls the start of the therapy by evaluating the severity and ranking of each event (i.e., maximum ratio, duration of seizure detection, spread, number of clusters per unit time, number of detections per cluster, duration of an event cluster, duration of a detection, and inter-seizure interval). Block 1134 monitors the completion of the determined therapy. If the therapy is not complete, block returns to block 1134. If the therapy is determined to be complete, block 1134 returns the flow diagram to blocks 1102 (Measure HR), 1116 (Measure Impedance) and 1124 (Measure EEG) to continue the monitoring of cardiac, respiratory and brain signal parameters. Therapy may consist of neural stimulation, cardiac pacing, cardioversion/defibrillation, and drug delivery via a pump or any combination of therapies.

When block 1130 determines that a therapy is to be initiated Format Diagnostic Data block 1112 formats the data from the cardiac, respiration and EEG monitoring channels, adds a time stamp (e.g., date and time) 1110, type and duration of therapy and provides the data to block 1114 where the data is stored in RAM memory for later retrieval by a clinician via telemetry (using techniques discussed herein). Optionally, block 1112 may add examples of intrinsic ECG, respiration and/or EEG signals recorded during a sensed episode/seizure. Block 1115 is like block 415 in FIG. 4. Block 1120 is like block 420 in FIG. 4.

The above embodiments illustrate that the disclosed techniques may be implemented within any number of medical device systems (drug delivery, electrical stimulation, pace-making, defibrillating, cochlear implant, and/or diagnostic) but configured to retain sensed data records in accordance with the teachings disclosed herein. In general, the implanted medical component utilizes one or more monitoring elements (e.g., electrodes or other sensors), a memory component having a plurality of data structures (and/or data structure types), a processing component (such as a CPU) to process received data for storage in memory as disclosed herein, and a telemetry component.

Data Reporting and Remote Monitoring

FIG. 12 shows apparatus 1200 that supports reporting physiological data in accordance with an embodiment of the invention. With apparatus 1200, the implanted component 1205 of the medical device system communicates with the relaying module 1215 via telemetry antenna 1210. Similarly, the external component 1225 communicates with the relaying module 1215 via antenna 1220. In the embodiment, a telemetry link 1221 between relaying module 1215 and antenna 1220 comprises a 3 MHz body wave telemetry link. To avoid interference, the relaying module 1215 may communicate with the external and implanted components using differing communication schemes. In some embodiments, the reverse direction and the forward direction of telemetry link 1221 may be associated with different frequency spectra. The relaying module 1215 thereby provides a greater range of communications between components of medical device system. For example, in the embodiment of an implanted system, an external programmer may communicate with an implanted device from a more remote location. The external programmer may be across the room and still be in communication via the relaying module 1215. With the telemetry booster stage, the use of an implanted system is more convenient to the patient, in particular at night while sleeping or when taking a shower, eliminating the need for an external device to be worn on the body. In an embodi-

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ment, relating module **1215** may also have the features and functionality of external device **503** as shown in FIG. **5**.

As shown in FIG. **13**, in an embodiment, the system allows the residential, hospital or ambulatory monitoring of at-risk patients and their implanted medical devices at any time and anywhere in the world. Medical support staff **1306** at a remote medical support center **1314** may interrogate and read telemetry from the implanted medical device and reprogram its operation while the patient **10** is at very remote or even unknown locations anywhere in the world. Two-way voice communications **1310** via satellite **1304**, cellular via link **1332** or land lines **1356** with the patient **10** and data/programming communications with the implanted medical device **1358** via a belt worn transponder **1360** may be initiated by the patient **10** or the medical support staff **1306**. The location of the patient **10** and the implanted medical device **1358** may be determined via GPS **1302** and link **1308** and communicated to the medical support network in an emergency. Emergency response teams can be dispatched to the determined patient location with the necessary information to prepare for treatment and provide support after arrival on the scene. See for example, U.S. Pat. No. 5,752,976.

An alternative or addition to the remote monitoring system as described above in conjunction with FIG. **13** is shown in the system **1450** of FIG. **14**, which shows a patient **10** sleeping with an implantable Monitor **1458** and/or optional therapy device as described above in connection with the above-described systems. The implantable device **1458**, upon detection of a neurologic event may alert a remote monitoring location via local remote box **1452** (as described in U.S. Pat. No. 5,752,976), telephone **1454** and phone lines **1456** or the patient's care provider via an RF link **1432** to a pager-sized remote monitor **1460** placed in other locations in the house or carried (i.e., belt worn) by the care provider **1462**. The remote caregiver monitor **1460** may include audible buzzes/tones/beeps, vocal, light and/or vibration to alert the caregiver **1462** of patient's monitor in an alarm/alert condition. The RF link may include RF portable phone frequencies, power line RF links, HomeRF, Bluetooth, Zig-Bee, WIFI, MICS band (medical implant communications service), or any other interconnect methods as appropriate.

Each of the above embodiments utilized graphical user interfaces that are suitable for displaying data records that have been retrieved from the implantable medical device. Data Retention and Recording Techniques

Discussed herein are techniques for selecting and storing sensed physiological data in an implanted medical device for subsequent reporting to an external device. As used herein, the term data record encompasses the sensed physiological data, summary information, or simply a pointer that references a location in memory where the sensed physiological data is stored. Thus, the concept of storage of data records in first and second data structures envisions possibilities of storage of the sensed physiological data and the storage of their associated pointers. As an example, summary information data may be stored in the first and second data structures wherein the more detailed and more space consuming waveform data (pre-detection data, post-detection data, etc.) may be stored, and pointed to, in an associated memory (such as a loop record buffer).

Mapping from entries in the first and second data structures to the waveform physiological data that is stored in the associated memory may be achieved with pointers. Each entry in the event log may point to its corresponding waveform data, or each waveform data may point to its corresponding data in the event log. Alternatively, multi-

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directional pointers in an "allocation table" or "allocation data structure" may be pointed to by the priority structures. Thus, when a data record is overwritten or replaced as discussed herein, both the data record itself and its mapping to the event log may be changed/removed in the allocation structure.

FIG. **15** shows process **1500** for storing physiological data in accordance with an embodiment of the invention. Again, the techniques disclosed herein may be implemented in any of the implantable medical device systems discussed above and may be performed in conjunction with the flow diagrams of FIGS. **4**, **8**, and **11** above. The process described therein may be implemented by computer executable instructions performed by a processor or dedicated hardware in the form of digital logic gates (also referred as hardware rather than software/firmware) in the implanted device. (Process **1500** may be performed by a logic component that may include a processor and/or digital logic such as an ASIC.) The process described herein discusses the storage of data records within one or more data structures and the moving of those data records. It will be appreciated, however, that these processes may be implemented by storage and movement of pointers, wherein each pointer points to data that is stored in memory, and/or the storage and movement of the sensed physiological data.

The technique for storing data records may begin with step **1501**, wherein an implanted device receives an instruction or configuration data from a clinician, typically via telemetry. For example, the clinician or patient may activate loop recording to store data collected for a specified neurological event between a specified time and having a minimum severity level (as will be discussed). In step **1503**, an implanted device initiates a detection process for a neurological event. This detection process may implement an event detection algorithm to process the sensed physiological data and determine the possible onset of a neurological event. The neurological event may be associated with a nervous system disorder (e.g., an epileptic seizure) having a severity level and a time duration. The neurological event may also be a cardiac event. For example, a patient's heart rate may increase with an occurrence of an epileptic seizure. Accordingly, the implanted device may initiate loop recording upon determination of a neurological event by processing of sensed physiologic signals or upon determination of any number of other criteria.

By way of example only, the system may monitor one set of physiological signals (e.g., EEG) and trigger loop recording of those same signals upon detection of a neurological event. As another example, the system may monitor any combination of a plurality of physiological signals (including EEG, respiratory, and cardiac) and trigger loop recording of only a subset of those physiological signals based on predetermined criteria being satisfied with respect to one or more of the other physiological signals.

In an embodiment, the implantable medical device may have a set of monitoring elements sensing brain activity and another set of monitoring element that sense a physiological activity other than the brain (e.g., heart activity such as a heart arrhythmia and/or respiratory activity). The device may then implement a detection algorithm to determine the possible onset of a possible neurological event (e.g., a seizure) based on the sensed signals from either the first or second monitoring elements. Once a neurological event is detected, data records associated with the first and second monitoring elements may be stored in memory in accordance with the teachings herein.

Alternatively or additionally, the device may initiate loop recording upon indication to do so by the patient based, for example, on a patient detecting a neurological event. In the event the patient initiates loop recording based on detection of a neurological event (wherein, however, the detection process of the implanted device has not detected the neurological event), the priority index (discussed below) for such data may be set at a higher level such that the data is stored in a memory. In the situation where the patient experiences a neurological event but the medical device has not detected the event, the physiological sensed data may be particularly important for storage and subsequent evaluation. In an embodiment, once activated by a patient, loop recording may save the data for 30 seconds before the indicated seizure and 3 minutes after the seizure. However, to allow for the fact that the patient may not mark the seizure until the seizure has ended, the ECG loop recording may begin 3 to 5 minutes before the patient mark. This time period may be programmable. As discussed below, a subset or a composite of physiologic channels is selected from the available physiologic channels based on a selection criterion.

Referring still to FIG. 15, if the detected neurological event meets the criterion provided by the clinician, the system triggers loop recording in step 1505. In step 1507, the implanted device stores a data record associated with the sensed physiological data in a first data structure (in an embodiment, a circular buffer as will be discussed in greater detail in FIG. 16). Again, the data record may either be a pointer or the physiological data. An exemplary data entry is discussed below in relation to FIGS. 18 and 19. In an embodiment, the circular buffer stores chronologically sequenced data records in sequential memory locations. When the last location in the circular buffer is reached, the next data record is entered in the first memory location of the circular buffer. Although the embodiment of FIG. 15 and the corresponding discussion herein is with respect to a circular buffer, it will be appreciated that the circular buffer may be any memory device or structure and the data records may be stored and replaced according to an associated priority index (discussed below). When the memory device is full, any new data may replace data in the memory device having the lowest associated priority index. Alternatively, as discussed below, the data may be automatically transferred out once the priority index is calculated.

With the storage of neurological data in step 1507, the implanted device may also obtain and retain indicators of severity when the neurological event occurs in step 1509. Examples of retained indicators include a maximum value of foreground ictal severity and heart rate during the neurological event. Indicators of severity are discussed further below and may be used to determine a priority index.

If the first data structure becomes full, a new data record replaces either the oldest data record or the existing data record having the lowest associated priority index. However, in step 1511, if the associated priority index of the data record being replaced by the new data record is sufficiently large, the data record being replaced may be stored in a priority buffer instead of being permanently removed. It will be appreciated, that the data records may vary in size. Accordingly, for a new data record having a sufficiently large size, the system may require multiple old data record to be removed. Alternatively, only the least important portions of the data record would need to be removed from the first data structure.

The priority index of a data entry, discussed next, is determined in steps 1515, 1517, and 1519 in concert with

clinician input and information obtained by the implanted device. In the embodiment of the invention, steps 1507, 1509, and 1511 are executed in a parallel manner. In step 1513, the recording of neurological and other physiological data in the circular buffer is completed. In an alternative embodiment, the data entry may be transferred from the first data structure (such as the circular buffer) to the second data structure (priority buffer) upon the priority index of the data entry being determined. In such an embodiment, the second data structure may begin to be populated with data records without requiring for the first data structure to become full and start replacing older data entries. Since the stored data entry is promptly removed to the second data structure, the circular buffer may vary in size.

One embodiment for determining the priority index of a data record is as follows. In step 1515, the most recent data record is classified. For example, the neurological event may be classified as an epileptic seizure. In step 1517, a priority index of the neurological event is determined. The priority index may be dependent on a severity level. In an embodiment, the severity level is a function of at least one characteristic of the neurological event, including the duration, spread, and measure of ictal content (e.g., peak ratio of algorithmically derived foreground to background ictal score) of the neurological event. Moreover, the embodiment may utilize other derivative indicators for determining the severity level. For example, a binary evidence count may be determined in which each new sample is compared to a criterion (e.g., a threshold determined by the product of a background value and a configured threshold value). If the criterion is met, a value of "1" is inserted into a data structure that contains Y previous Boolean values. Otherwise, if unmet, a value of "0" is inserted into the data structure. Upon insertion, a second value is removed from the data structure to ensure that the data structure retains a size of Y bits. The Boolean value of the first sample is then compared to the Boolean value of the second sample. The difference is used to maintain a separate counter value which reflects how many Boolean values in the data structure (e.g., Y-bit buffer) are "1". In this way, the evidence count reflects the number of samples out of the last Y samples which met the threshold criterion, and therefore ranges from 0 to Y.

As another example, a slew-rate limited output of an associated physiologic channel may be determined by incrementing the slew-rate limited output by a small amount if the sample is greater than the current value of the slew-rate limited output. Otherwise, the slew-rate limited output is decremented by the small amount. The severity level may be determined from the maximum value of the evidence count or the slew-rate limited output associated with the set of physiologic channels contained in a data record.

In addition, the priority index of the neurological event may be dependent on an associated event, e.g., a cardiac event or a user signal in the form of telemetry, presence of a medical magnet, and so forth. In an embodiment, the priority index is stored in a data field in the data record. However, another embodiment of the invention may store the priority index in an associated data structure or may be calculated when it is needed.

In step 1519, a composite severity measure of a group of neurological events, which includes the current neurological event, is determined. The composite severity measure may be a function of determined severity levels of individual events and the relative chronological occurrence of events. For example, a group of epileptic seizures that occur within a short period time may be indicative of a more significant cumulative event than a single epileptic seizure.

While the embodiment illustrated in FIG. 15 shows a sequential ordering of steps, it will be appreciated (as discussed above) that the process may execute the steps in a different order or may execute some of the steps in a parallel fashion.

The priority index may be dependent on the severity level, which may be expressed as a function $f(x_1, x_2, \dots, x_n)$, and/or on associated factors, which may be expressed as a function $g(y_1, y_2, \dots, y_m)$. Variable x_i corresponds to a characteristic of a physiologic event (e.g., a neurological event), and variable y_j is an associated factor. For example, characteristics of a neurological event may include a duration of a neurological cluster, a spread of a neurological cluster (which may be measured by the number of electrodes detecting the cluster), a statistic of an associated neurological signal, and an event class. A statistic may be a computed quantity characteristic of a physiologic signal or an ensemble of physiologic signals. An event class may include a most-severe seizure (potentially correlating to status epilepticus), a severe seizure, a sub-clinical seizure, a least severe seizure (potentially correlating to what is more likely to be an erroneous detection), a brady event, a tachy event, arrhythmia, and a detection on each electrode channel.

An associated event may include external event information and associated physiologic information that are correlated to a neurological event. For example, the associated physiologic information may be the age of the event. As another example, an external event may be a cardiac event, a chemical event, a scheduling event, a patient-initiated event (through a physical interface, e.g., a magnet interface or a telemetry interface), a caregiver-initiated event (e.g., through a telemetry channel), and a device-based event. Associated physiologic information may include heart rate, blood pressure, breathing rate, and glucose level. Moreover, an external event may not be associated with a neurological event. For example, a physician may instruct, through a programmer, that physiologic data for a designated time be stored and reported.

The priority index may be expressed as a mathematical combination of the severity level function $f(x_1, x_2, \dots, x_n)$ and the associated factor function $g(y_1, y_2, \dots, y_m)$. For example, the priority level may be expressed as:

$$\text{priority index} = f(x_1, x_2, \dots, x_n) + g(y_1, y_2, \dots, y_m) \quad (\text{EQ. 1A})$$

Either $f(x_1, x_2, \dots, x_n)$ or $g(y_1, y_2, \dots, y_m)$ may be a continuous function, a discrete-value function, a Boolean function, or a combination of the above function types. As another example, the priority level may be expressed as:

$$\text{priority index} = f(x_1, x_2, \dots, x_n) \cdot g(y_1, y_2, \dots, y_m) \quad (\text{EQ. 1B})$$

The priority index may be more generally expressed as a function $h(z_1, z_2)$, where

$$\text{priority index} = h(f(x_1, x_2, \dots, x_n), g(y_1, y_2, \dots, y_m)) \quad (\text{EQ. 1C})$$

FIG. 16 shows data structure 1600 for storing physiologic data in accordance with an embodiment of the invention. In this embodiment, data structure 1600 includes circular buffer 1601 and priority queue 1603. (Another embodiment of the invention may implement circular buffer 1601 and/or priority queue 1603 as a different type of data structure.) Circular buffer 1601 stores the most recent ten data records (DATA(-2) to DATA(-3)) corresponding to data entries 1607-1625. (An exemplary record is discussed with FIG. 18.) However, the embodiment may store a different number of data records, depending on the allocated memory for circular buffer 1601. In the example shown, circular buffer 1601 currently stores data records that have been acquired

between the previous nine time units (corresponding to data record DATA(-9)) and the current time (corresponding to data record DATA(0)). New data pointer 1605 points to a data entry in circular buffer 1601. At the current time, new data pointer 1605 points to the data entry where new data is stored. Previous to storing data record DATA(0), data entry 1611 stored data record DATA(-10), which was previously acquired 10 time units ago. The new data record may be associated with physiologic signals and may be further associated with a neurological event. With the next subsequent data acquisition, new data pointer 1605 will point to the next data entry that currently stores data record (DATA(-9)). In the embodiment, the new data record is stored in the data entry that stores the oldest data record. When last data entry 1625 (currently corresponding to data record DATA(-3)) of circular buffer 1601 is reached, the subsequent data acquisition is stored in data entry 1607 currently storing data record DATA(-2).

As discussed, the data record may be the sensed physiological data or a pointer that references a location in memory where the sensed physiological data is stored. Thus, the concept of storage of data records in first and second data structures envisions both possibilities of storage of the sensed physiological data and the storage of their associated pointers. Also as discussed, circular buffer 1601 may be in the form of any other data structure. In such an alternative embodiment, physiological data may be stored in a memory device such that when a new data record is to replace an existing data record, the data record with the lowest priority index is replaced. Alternatively, the data entries being replaced may vary depending on the relative sizes of the new and old data entries.

When a data record has been overwritten by the new data record, a portion of the old data record (which may be the entire data record) is stored in priority queue 1603 if the corresponding priority index is sufficiently large or exceeding a threshold criterion. In one embodiment, the more significant the corresponding physiologic event, the larger the corresponding priority index. However, in another embodiment the priority level may decrease with the significance of the physiologic event. Priority queue 1603 is capable of storing data records in data entries 1627-1635; however, as shown in the example, priority queue 1603 currently stores two data records. The remaining data entries 1631, 1633, and 1635 are empty and may store subsequent data acquisition. Data entry 1627 is currently storing data record DATA(-101), which was acquired 101 time units ago, and data entry 1629 is currently storing data record DATA(-24), which was acquired 24 time units ago. For example, the priority index must have a value of 3 or higher in order to be stored in priority queue 1603 when the corresponding data record is overwritten in circular buffer 1601. In the event that the priority queue 1603 is also filled, the system may determine that a data record shall be retained in priority queue 1603 only if the priority index of the removed data record from circular buffer 1601 has a larger priority index than any of the stored data entries in priority queue 1603. In other embodiments, the system may utilize a combination of the above retention strategies or other strategies.

In an embodiment of the invention, a data record (stored in data entries 1607, 1609, 1611, 1613, 1615, 1617, 1619, 1621, 1623, and 1625) in circular buffer 1601 may contain a different amount of data than a data record (stored in data entries 1627, 1629, 1631, 1633, and 1635) in priority queue 1603. For example, data may be discarded to reduce the

precision or to discard physiologic data that is not directly associated with a neurological event (e.g., cardiac data).

In an embodiment of the invention, stored data (either stored in circular buffer **1601**, or priority queue **1603**, or both) may be selected in accordance with a retention policy in order to support intelligent data loss (data triage) or offloading (e.g., to an external device) and to conserve memory usage and reduce/bound the time required to transfer the data. For example, an implanted device may store data in data structure **1600** for sensor channels fulfilling a predetermined criteria, may discard waveform data while retaining statistics, summary data, or burden information, enable or disable or prioritize sensor channels based on algorithm criteria, sensor location, or sensor type, or override the retention policy when a clinician provides instructions over a telemetry channel. Moreover, the embodiment may further use data compression if the data is compressible to compress the data content of the new or old record.

Reporting Physiological Data

In accordance with another aspect of the invention, in response to an instruction from a clinician, an implanted device organizes stored physiological data according to the associated priority index and reports a predetermined number of data records that are deemed as having a higher priority index than the other stored data records. Such structures for reporting stored physiological data are disclosed in FIGS. **12-14**.

FIG. **17** shows flow diagram **1700** for reporting physiological data in accordance with an embodiment of the invention. Step **1701** corresponds to an implanted device receiving a request (e.g., through a telemetry communications channel). In step **1703**, the data records (both in circular buffer **1601** and priority queue **1603**) are sorted according to the associated priority index if the associated priority index is sufficiently large (e.g., three or higher). Step **1705** determines if the number of reported data records is less than or equal to N. N can be, for example, the number of records that the user wishes to retrieve. If so, the physiological data associated with the data record is reported to a clinician's workstation over the telemetry communications channel and the number of reported data is incremented in step **1707**. Step **1705** is then repeated. If the number of records is greater than N, the reporting of neurological data is terminated in step **1709**, and procedure **1700** is completed.

A physician may request physiological data associated with N data records that are stored in circular buffer **1601** and priority queue **1603** and having a minimum priority index to be reported to, for example, a physician programmer over a telemetry link. The physician programmer may thereby display the requested physiological data or at least those where the priority index is above a threshold. When so instructed, implanted device sorts the physiological data associated with the data records in circular buffer **1601** and priority queue **1603** and reports physiological data associated with the N data records having at least the minimum priority index. Once the data is reported, the implanted device may release the memory space previously allocated to the identified data records, mark that memory space for deletion, and/or delete the data records. If more than N data records have the minimum priority index, the implanted device may select N data records based on a temporal criterion (e.g., the most recent or the oldest), being greater than a predetermined priority index, or a priority index that is dependent on an external event. Moreover, system may select a data record so that each occurring event type is included in the reported data records. Because the invention may be implanted within any implantable medical device

system, however, it will be appreciated that the external components may vary in configuration, components and/or features.

Data Format

FIG. **18** shows exemplary physiological data **1800** that can be retained in implanted medical device. The physiological data **1800** comprises summary information data **1801**, pre-detection data **1803**, post-detection data **1805**, and event/etc information data **1807**. Pre-detection data **1803** contains sampled data **1811**, **1813**, **1815**, **1817**, **1819**, **1821**, and **1823** that is collected before a detected physiologic event such as an epileptic seizure. Post-detection data **1805** contains sampled data **1825**, **1827**, **1829**, **1831**, **1833**, **1835**, **1837**, and **1839** after the detected physiologic event. In the exemplary data shown in FIG. **18**, pre-detection data **1803** includes sampled data **1809** and **1817** that are obtained from neurological channel **1**, sampled data **1811** and **1819** that are obtained from neurological channel **2**, sampled data **1813** and **1821** that are obtained from neurological channel **3**, and sampled ECG data **1815** and **1823** that are obtained from the ECG channel. Post-detection data **1805** includes sampled data **1825** and **1833** that are obtained from neurological channel **1**, sampled data **1827** and **1835** that are obtained from neurological channel **2**, sampled data **1829** and **1837** that are obtained from neurological channel **3**, and sampled data **1831** and **1839** that are obtained from the ECG channel. While the physiologic channels sampled before and after the physiologic event are same in exemplary record **1800**, different physiologic channels may be sampled before and after the physiologic event. Additionally, summary information data **1801** contains summary information about record **1800**. The embodiment of the invention supports physiological data that has a fixed length or that has a variable length. Event/Etc information data **1807** includes information about the associated physiologic event type and other associated information. Although depicted as data from different channels interleaved together, such data may also be stored in a non-interleaved fashion. For example, ECG may be stored separately from the other channels, etc.

FIG. **19** shows components of the exemplary physiological data as shown in FIG. **18**. Summary information data **1801** includes trigger source data **1901**, length of event/etc information data **1903**, size of loop record **1905**, and relevance information **1907**. Trigger source data **1901** identifies what triggered recording (e.g., a neurological channel number). Length of event/etc information data **1903** is indicative of the length of event/etc data **1807**, size of loop record **1905** contains the length of record **1800**, and relevance data **1907** indicates the relevance level of each sampled channel as will be later discussed. Event/Etc information **1807** contains entries **1909** and **1911**. Each entry includes event type **1913** that is indicative of an event associated with record **1800**, start offset data **1915** includes the offset of record **1800** from the start of the loop recording, and type specific field **1917** includes specific data that is associated with the event. (However, in an embodiment of the invention, a data entry may store a pointer to physiologic data rather than store the physiologic data itself.) Record **1800** may be associated with a plurality of event types, each being indicated in separate entries, e.g., entries **1909** and **1911**.

Data structure **1600** (as shown in FIG. **16**) typically can store 1 to 16 Mbytes of data. Record **1800** may contain anywhere from approximately 5 Kbytes to approximately 1 Mbyte. Typically, a record contains 30-90 Kbytes per record. The embodiment supports both fixed size records (e.g., 60 Kbytes) or variable size records. With variable size records

the retention scheme, as previously discussed, may require that a plurality of records or only portions of records be removed from circular buffer 201 in order to store a new record. Also, different parts of a record may be stored in physically different memory components (e.g., summary/header information data 601 in one place (a log) and sampled data 1803 and 1805 in another (waveform memory) with a pointer in the header/summary information indicating where the start of the data is and how much data is there).

As discussed, in an embodiment of the invention, a data record may be a pointer to physiologic data rather than store the physiologic data itself. Thus, for example, summary information data 1801 and/or event/etc information data 1807 may be stored in the first and second data structures wherein some or all of the entries may be mapped, via pointers, to more detailed and more space consuming waveform data (pre-detection data 1803, post-detection data 1805) in an associated memory (such as a loop record buffer).

Selective Storage of Data Channels

The embodiment supports the generation of records at different rates. The record rate will vary widely with an implanted device's configuration and with the patient. For example, a clinician may desire to record every detected seizure over a time period. There are some patients that have 1 seizure every 6 months, but there are some that have 500 seizures a day. A typical patient may have 2 unique events (seizure, button press, etc) per day.

While FIG. 18 shows an exemplary configuration with three neurological channels and an ECG channel, an embodiment of the invention supports a variable number of neurological channels so that the memory of an implanted device can store necessary information over a desired period of time. The channels may be adjusted either in quasi-static manner or in a dynamic manner. In an embodiment, the implanted medical device contains a channel selection component, which may be software or hardware logic for performing a process of selecting the one or more channels for data storage as described herein. An evaluation processing component may thereby obtain the selected channel data and process the channel data also in accordance with the techniques described herein.

For applications like the detection of epileptic seizures and the subsequent recording of data, it is advantageous, from a quality and resource stand-point, to be able to select a subset (which may include all physiologic channels) of the sensed input channels for detection processing and/or loop-recording. While this can be done manually prior to the availability of relevant data by defining the selected channels, manual configuration is less flexible and less desirable than allowing the closed-loop, real-time, quasi-real-time, periodic, or otherwise automated selection of physiologic channels.

With implantable detection algorithms and applications, there are typically a multitude of input sense channels. The degree of interest for each of these sense channels is often discernable while an implanted device is collecting data and storing the data in a memory component, e.g., a memory structure. As each sample is processed or stored as a short recording of samples, an application specific method may be employed to identify the most interesting (relevant) physiologic channels. Samples from selected physiologic channels may be utilized. Detection processing is typically resource intensive such that all physiologic channels may be utilized. Data recording in a loop-recording rapidly fills memory and then later prolongs telemetry. In order to

effectively process and store the samples, judicious selection of physiologic channels may be desired.

With a detection algorithm operating on physiological signals, it is likely that simply obtained information may reveal which channels to retain or continue processing. Often, physicians/users may be interested in examining, using, and retaining data from the physiologic channels in which an indication of an event is present. For example, if a seizure is detected on two of eight detection channels of data being recorded from the brain, only those two neurological channels need be retained. In this example, the savings in storage may be significant since only two channels are kept and six neurological channels are discarded, corresponding to a 4 to 1 sample compression.

Sample compression may be important if memory of an implanted device is limited. In the above example, one needs to decide which two channels should be kept. The decision may be based upon a number of factors including, independently-calculated channel severity (e.g., save the most severe), channel event onset time (e.g., save the first to detect), and seizure burden indication on the physiologic channel. In such a scenario, the flow diagram of FIG. 15 may be modified such that a severity calculation is performed prior to actual storage of the data in the first data structure. Or stored data records may be automatically removed from those data channels that are determined that the data is not important. Similarly, this approach may be extended to different and mixed physiologic signals. For example, if the multiple EEG channels are being polled, one may keep only those EEG channels where the neurological event data is most important (e.g., based on a severity scoring). If both cardiac, intra-cranial pressure (ICP) and EEG channels are being polled, one may keep only the signal types that deviated from norm. If the intra-cranial pressure rises significantly, one may keep samples from the ICP channel. If the previous scenario occurs while there is a tachycardia event, one may further keep samples from the ECG channel. Furthermore, if a seizure occurs near the same time, one may keep samples from all three channels.

The above approach may be extended to include the retention of more than one channel from a channel list sorted by relevancy as determined by a function of various factors (e.g., onset time, presence and severity of an event) as previously discussed. One may keep the most relevant physiologic channels of the channel list. For example, one may keep the three most relevant ("interesting") physiologic channels of five physiologic channels. Keeping the two or most relevant physiologic channels is referred to as the "multi-max" of the channel list.

Alternatively, the system may retain a composite signal, which may be, for example, the sum of a plurality of channels. Other embodiments of the invention may utilize other derivatives. Furthermore, the channels themselves may be down-sampled or precision-reduced so that, for example, the least relevant samples are kept at 16 times less precision in amplitude and 2 times lower sampling rate resulting in about 4 times smaller data size.

Furthermore, with seizure detection and many other neurological applications the most interesting physiologic channels may be identified as those physiologic channels that are associated with the maximum energy value, normalized energy value, severity, or energy approximated value in the applications seizure frequency domain. For seizure detection, the seizure frequency domain may be 5-70 Hz (more narrowly this is typically 5-45 Hz) or (for fast ripple detections) at very high frequency (approximately 200 Hz or more). The energy value may often be sampled as the

“rectified” (absolute value, square, etc.) of the samples taken directly from the filtered EEG signal. While this data may constantly be higher in some neurological locations, it is useful to normalize the data across the physiologic channels with manual or automatic gain control. Automatic gain control may be implemented as the daily comparison of running 1-pole filters and with the appropriate adjustment in response or in some other manner. For example, the gain of each physiologic channel may be adjusted so that the associated background signals are similar (to each other and/or to a target value), which may be referred to as background normalization. Because short signals may appear similar to interesting material over the short term, it is useful to smooth or reject outliers from the energy signals before comparison. Smoothing may be done, for example, using 1-pole filters, voting schemes, running or block percentile filters, percentile tracking technologies or slew-rate limiters to eliminate or mitigate, for example, the effect of epileptiform discharges (ED’s) and sleep-spindles.

The embodiment supports different criteria for selecting channels for retention from a set of N physiologic channels. Different selection criteria include Max, MultiMax, MaxDeviationRetention, and Time-Distributed Max, MultiMax or MaxDeviation criterion. With the Max criterion, the physiologic channel with the highest energy is selected. With the MultiMax criterion, the M of N physiologic channels with the highest energy signals are selected. The selection may be implemented in a number of approaches, including multiple passes and sorting techniques. With the MaxDeviationRetention criterion, the physiologic channel with the highest energy is selected (as with the Max criterion). Moreover, P additional physiologic channels are selected that have an energy value greater than a determined fraction of the highest energy value. Variations of the above three criteria (Max, MultiMax, and MaxDeviation) may be formed by selecting instantaneous values or by processing the physiologic channels with a window function. When determining a processed value, a physiologic channel may be selected based on a configurable long to very short-term running window. The window may be based on any number of criteria including without limitation one or more of the following: median (or other percentile) of the window; mean of the window; running 1-pole value (e.g., one for each physiologic channel in which an associated time constant defines the width of an “effective” window); and accumulated absolute differences sum/accumulation (i.e., line-length). The accumulated difference criterion accumulates the difference of all channels with respect to a selected zero-channel. If there are accumulations greater than zero, the largest of those physiologic channels is selected.

With an embodiment of the invention, the selection of physiologic channels may occur after filtering (e.g., band-pass, notch, FIR, and IIR) the physiologic channels. For example, an EEG signal may be filtered in the 10-60 Hz range to remove the bulk of the EEG energy content that may otherwise mask the ictal content. As another example, the physiologic channels may be filtered in the 180-250 Hz range in order to study “fast-ripple” events.

The above channel selection process is applicable both for records stored in circular buffer **1601** and priority queue **1603**. Moreover, the channel selection criterion for circular buffer **1601** may be different from the channel selection criterion for priority queue **1603**.

In an embodiment of the invention, a “channel compositing” process is supported. A physiologic data sample is obtained from each of a subset of physiologic channels at an approximate time instance. For example, an implanted

device may interface with N physiologic channels. A first subset of physiologic channels may include the first N/2 physiologic channels, a second subset may include the next N/2-1 physiologic channels, and a third subset may include the last physiologic channel. (A subset of physiologic channels may include all physiologic channels, one physiologic channel, or some number of physiologic channels in between.) Physiologic channels may be grouped into subsets in accordance different criterion, including the proximity of electrodes and the associated physiological functionality. A composite data may be determined from the sampled data of each subset of physiological data and stored in a data record. For example, the composite data may be the median value of the sampled data for the associated subset of physiologic channels. The embodiment may determine the composite data by other ways. For example, the minimum value, the maximum value, or the variation among the associated physiologic channels may be used. Also, the composite data may include a mixture of a plurality of physiologic data samples in a subset, e.g., a sum of selected physiologic data samples or a ratio of the largest physiologic data sample to the smallest physiologic data sample. Composite data is stored in a data record for each subset of physiologic channels.

FIG. **20** shows the selection of channel data for retention in data structure **1600**. In the embodiment, channel selection component **2001** and data structure **1600** are supported by an implanted component. Channel selection component **2001** obtains N physiologic channels from various sensors that may include neurological signals, EEG signals, and a mixture of physiologic signals. Channel selection component **2001** selects a subset of physiologic channels from the N physiologic channels using a selection criterion as previously discussed. Data from the selected physiologic channels is included in record **1800**. Moreover, the selected physiologic channels may be processed by the implanted device and/or stored into memory. The embodiment, as shown in FIG. **20**, stores record **1800** into data structure **1600** as previously discussed. Similarly, the above approach may be extended to different and mixed physiological signals.

In the embodiment, channel selection component **2001** includes a channel processor that selects a subset of physiological channels using the selection criterion. The channel processor may be implemented with a microprocessor, a signal processor, or other processor means.

As can be appreciated by one skilled in the art, a computer system with an associated computer-readable medium containing instructions for controlling the computer system can be utilized to implement the exemplary embodiments that are disclosed herein. The computer system may include at least one computer such as a microprocessor, digital signal processor, and associated peripheral electronic circuitry.

Thus, embodiments of the invention are disclosed. One skilled in the art will appreciate that the above teachings can be practiced with embodiments other than those disclosed. The disclosed embodiments are presented for purposes of illustration and not limitation, and the inventions are limited only by the claims that follow.

What is claimed is:

1. A method for retaining physiologic data in an implantable medical device, wherein the physiologic data comprises an old data record being stored in a first data structure and having an old priority index, the method comprising:
 - sensing a physiologic signal at the implantable medical device with a sensor and converting the physiological signal to physiologic data;

- (A) receiving a new data record that includes physiologic data obtained for an event;
 - (B) determining a new priority index of the new data record;
 - (C) replacing at least a portion of the old data record with at least a portion of the new data record in the first data structure;
 - (D) if the old priority index exceeds a threshold criterion, storing at least a portion of the old data record in a second data structure, wherein the threshold criterion is pre-determined relative to creation of the old and new data records so as to be determined independently from determining which priority indexes to associate to the old and new data records of the first and second data structures, wherein the first data structure comprises a new data pointer configured to point to one of a plurality of data entries, and, after a data record is stored in the one of a plurality of data entries, point to another data entry where the next incoming data record is to be stored in the first data structure, and wherein the second data structure is distinct from the first data structure;
 - (E) determining the old priority index by determining an old severity level that is associated with the old data record;
 - (F) determining a new severity level that is associated with the new data record, a new priority index of the new data record based on the new severity level;
 - (G) evaluating the new severity level by a processing device of the medical device to control a start of therapy; and
 - (H) using a therapy device of the medical device to provide the therapy.
2. The method of claim 1, wherein (A) further comprises:
 - (i) selecting at least a first physiologic channel from a plurality of physiologic channels; and (ii) including at least one data sample from the at least first physiologic channel into the new data record.
 3. The method of claim 2, wherein the first physiologic channel corresponds to a highest clinical relevance of the plurality of physiologic channels.
 4. The method of claim 3, further comprising: (iii) selecting another physiologic channel from the plurality of physiologic channels, wherein the other physiologic channel corresponds to the next highest clinical relevance of the plurality of physiologic channels.
 5. The method of claim 3, further comprising: (iii) selecting another physiologic channel from the plurality of physiologic channels, wherein the other physiologic channel corresponds to a predetermined fraction of the highest clinical relevance.
 6. The method of claim 3, further comprising: (iii) processing each physiologic channel of the plurality of physiologic channels with a window function.
 7. The method of claim 6, wherein the first physiologic channel corresponds to a highest clinical relevance.
 8. The method of claim 7, further comprising: (iv) selecting an other physiologic channel from the plurality of physiologic channels, wherein the other physiologic channel corresponds to a next highest clinical relevance.
 9. The method of claim 7, further comprising: (iv) selecting another physiologic channel from the plurality of physiologic channels, wherein the other physiologic channel corresponds to a predetermined fraction of the highest clinical relevance.

10. The method of claim 2, wherein (i) comprises sorting the plurality of physiologic channels by relevancy and keeping a selected number of physiologic channels that have a largest degree of relevancy.

11. The method of claim 10, wherein the relevancy is associated with a function, and wherein factors of the function are selected from the group consisting of an onset time, presence of a physiologic event, and a severity measure of the physiologic event.

12. The method of claim 1, further comprising:

(I) deleting selected data from at least one data record.

13. The method of claim 12, wherein (I) comprises reducing data precision of a portion of the at least one data record.

14. The method of claim 12, wherein (I) comprises eliminating an attribute of the at least one data record.

15. The method of claim 1, further comprising: (i) obtaining information of at least one external event; and (ii) determining the old priority index as a function of the information and the old severity level.

16. The method of claim 15, wherein the at least one external event is selected from the group consisting of a cardiac event, a chemical event, a scheduling event, a patient-initiated event, a physician-initiated event, and a device-based event.

17. The method of claim 1, wherein (D) is performed only if the old priority index is greater than another priority index of another data record in the second data structure, and wherein the other data record is deleted.

18. The method of claim 1, wherein (E) further comprises: (i) determining an age of the old data record; and (ii) determining the old priority index as a function of the age and the old severity level.

19. The method of claim 1, wherein the old severity level is determined from at least one neurological signal characteristic selected from the group consisting of a duration of a neurological cluster, a spread of the neurological cluster, and a statistic of the neurological signal.

20. The method of claim 1, further comprising: (i) determining an event class of a corresponding event is associated with the physiologic data; and (ii) determining the old priority index as a function of the event class and the old severity level.

21. The method of claim 1, wherein the second data structure does not contain available memory and wherein (D) comprises removing at least a portion of another data record from the second data structure, wherein the removed portion of the other data record occupies memory space.

22. The method of claim 1, wherein (D) is performed only if the old priority index is greater than another priority index of another data record in the second data structure, and wherein the other data record is marked for deletion.

23. The method of claim 1, wherein (D) is performed only if the old priority index is greater than another priority index of another data record in the second data structure, and wherein the other data record is off-loaded to an external device.

24. The method of claim 1, wherein (D) is performed only if the old priority index is greater than another priority index of another data record in the second data structure, and wherein the other data record is overwritten.

25. The method of claim 1, wherein (C) comprises storing the portion of the new data record in the first data record, wherein the portion of the new data record is a pointer to new data; and wherein the portion of the old data record that is replaced in (C) and potentially stored in (D) is a pointer to old data.

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26. The method of claim 1, wherein (A) comprises receiving an indication from a patient to initiate recording.

27. The method of claim 1, wherein (D) comprises compressing at least a portion of the old data record that is stored in the second data structure.

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专利名称(译)	用于植入式医疗设备中的数据保留的方法		
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摘要(译)

用于在数据结构中存储与医学监测事件相关联的数据记录的方法。植入设备获得数据并将数据存储在基于年龄的第一数据结构中的数据记录中。在丢失最旧的数据记录之前,最旧的数据记录可以存储在基于优先级索引的第二数据结构中。优先级指数可以由严重性级别确定,并且可以由关联因素进一步确定。植入设备可以基于相关联的优先级索引来组织,卸载,报告和/或显示多个数据记录。另外,植入设备可以基于选择标准从可用生理通道中选择生理通道的子集或复合。

