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(54) **SEIZURE DETECTION USING COORDINATE DATA**

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See application file for complete search history.

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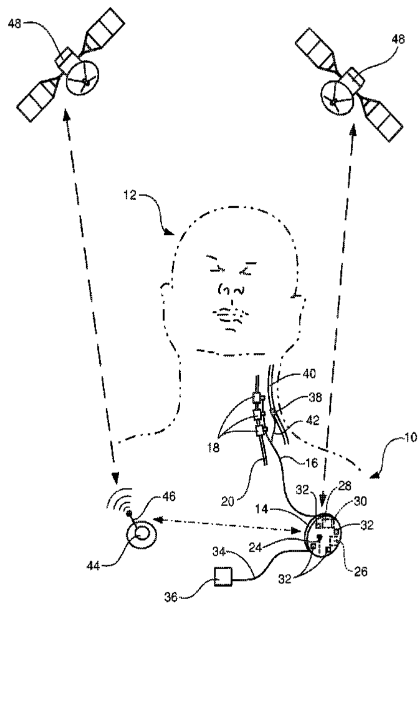
(57) **ABSTRACT**

A seizure detection device includes a coordinate data interface configured to receive coordinate data for a human, a memory to store coordinate data for a defined location of the human, and a seizure detector configured to identify a seizure event responsive to the coordinate data.

20 Claims, 5 Drawing Sheets



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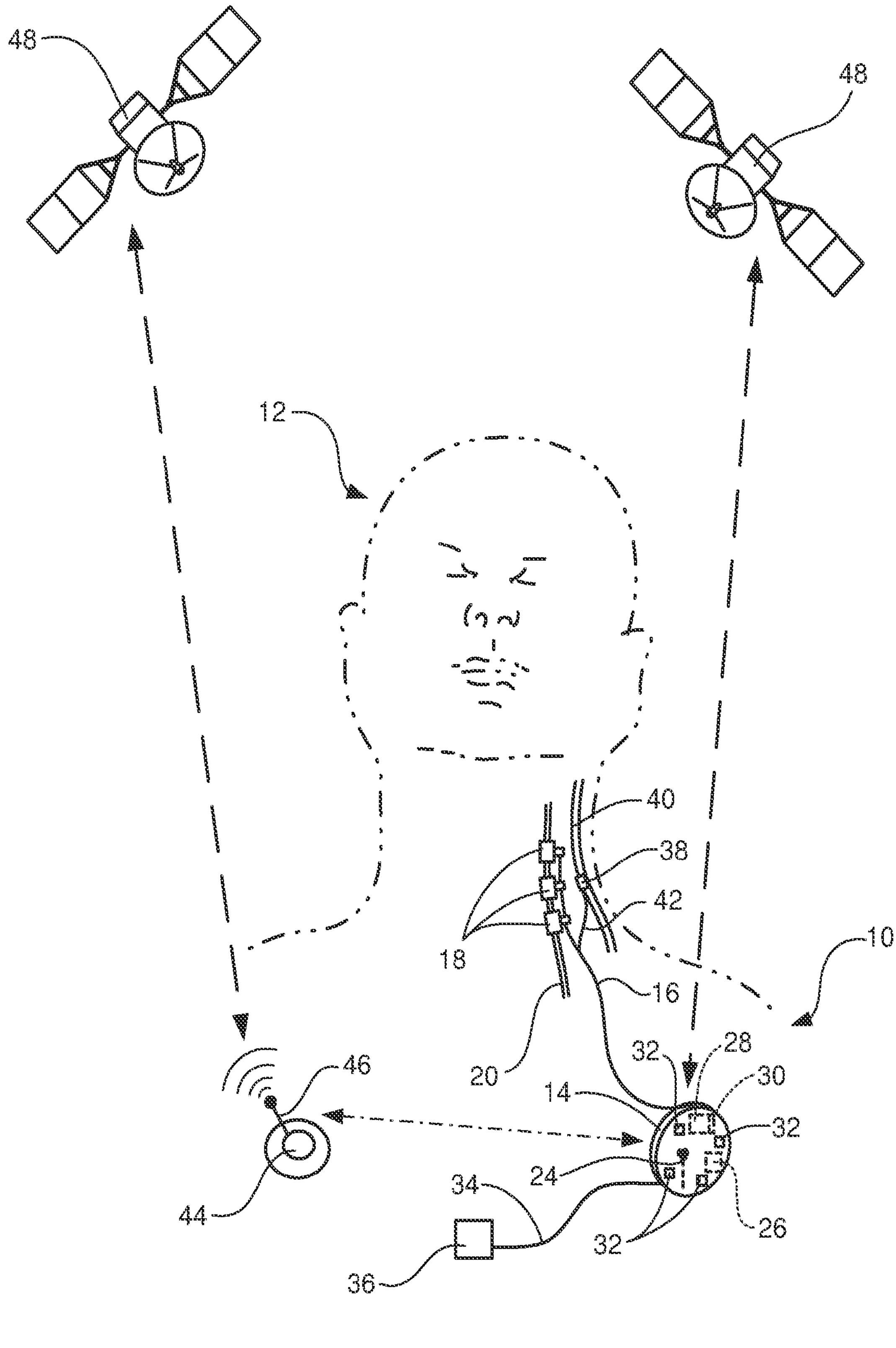


FIG. 1

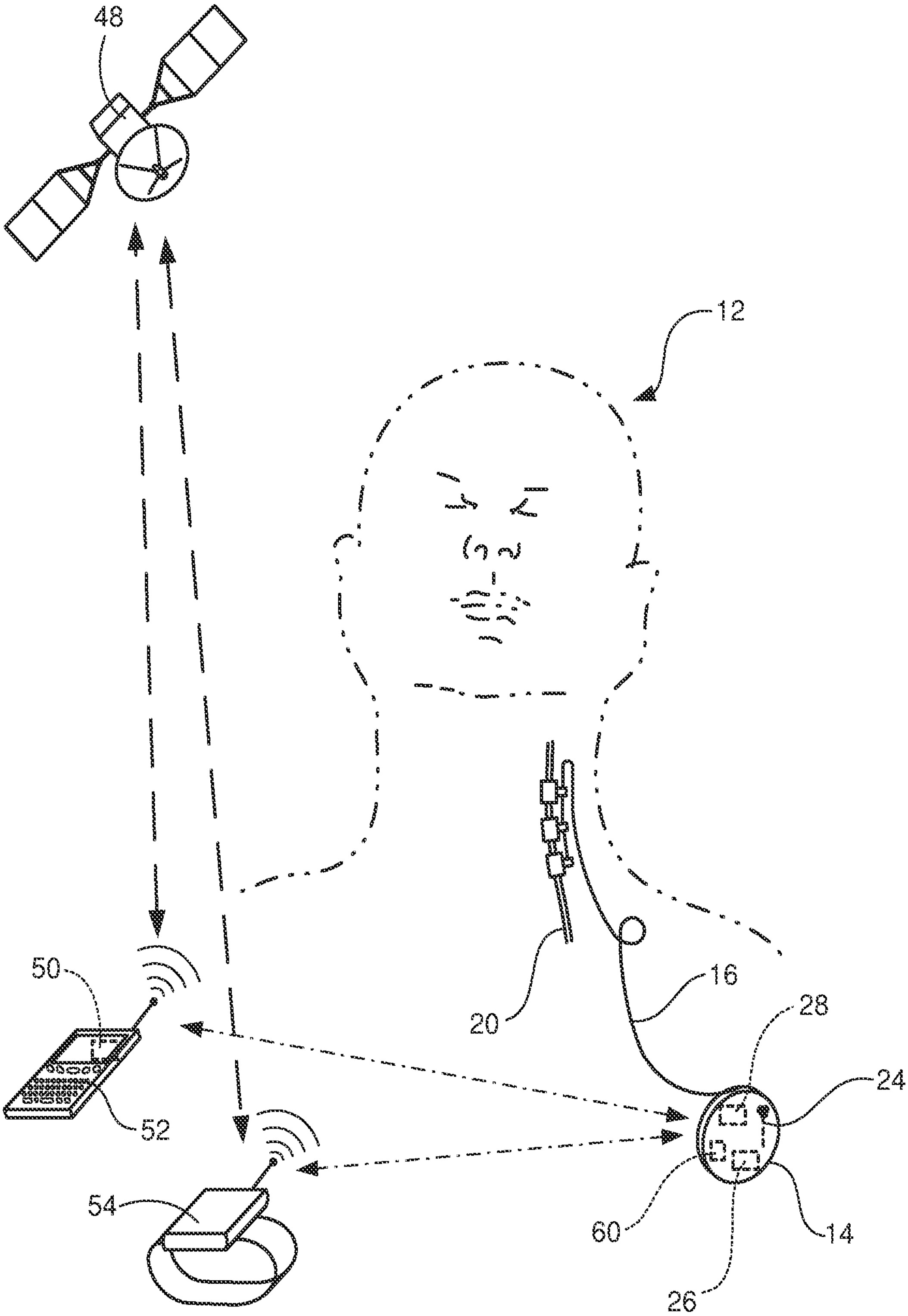


FIG. 2

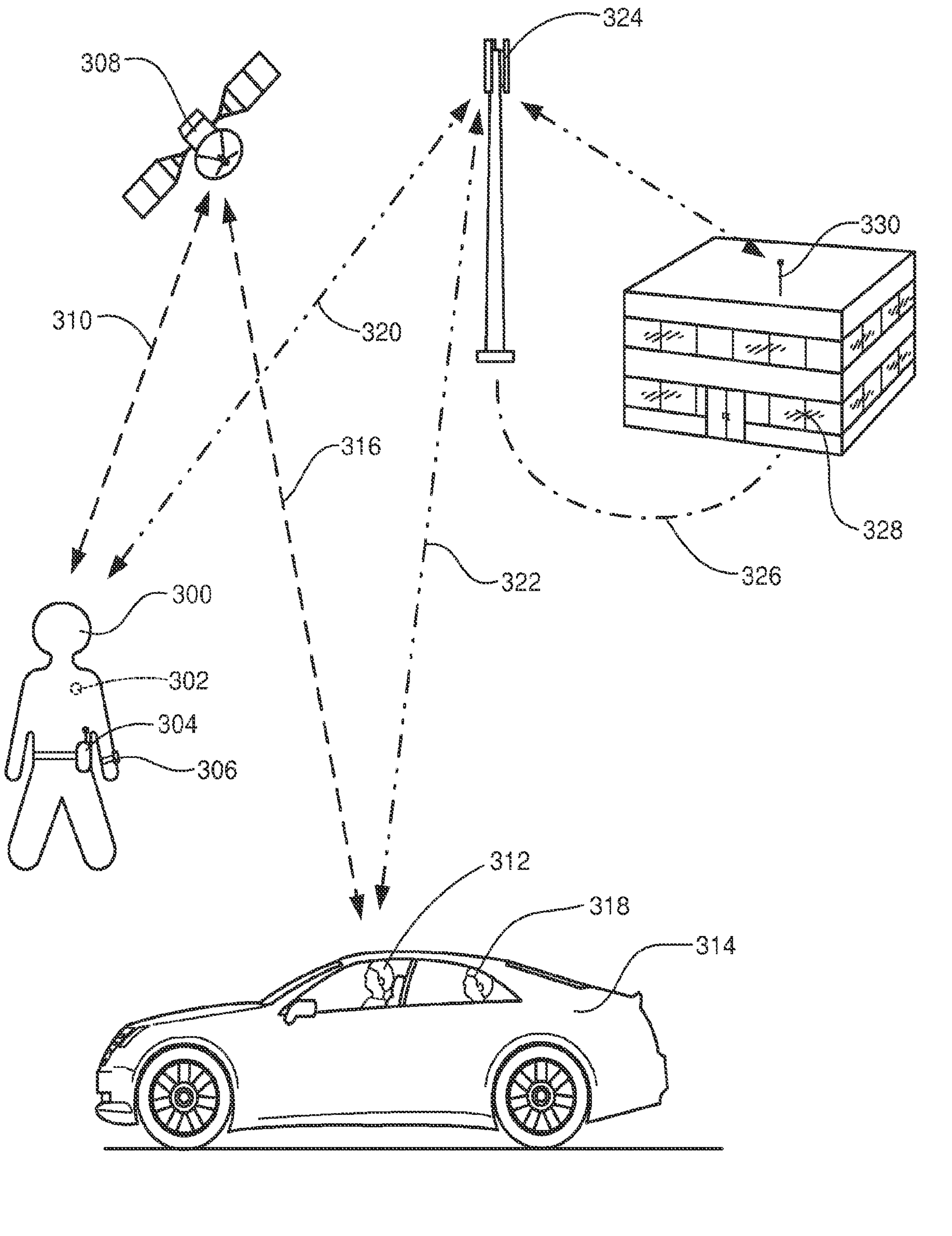
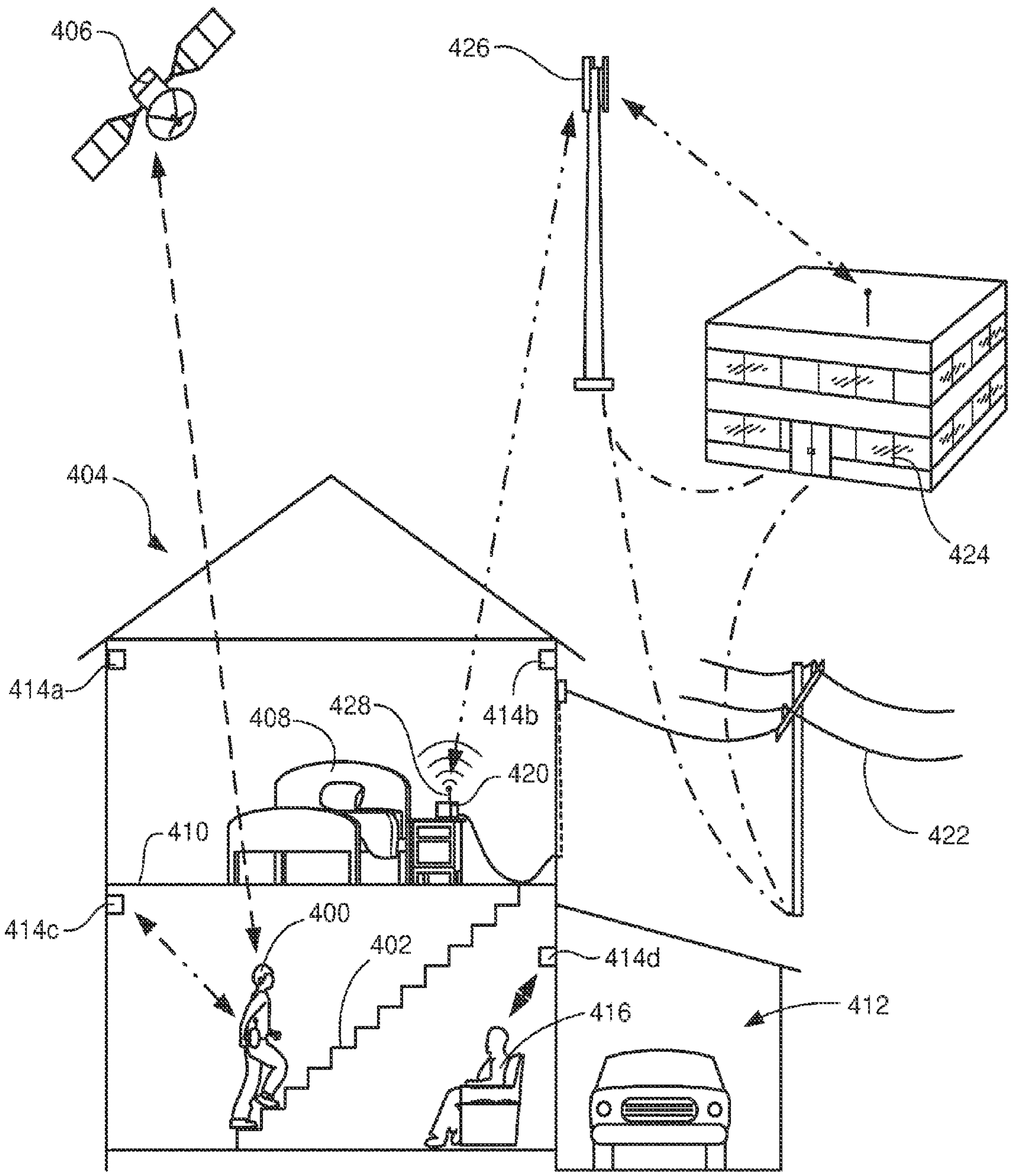


FIG. 3


406
426
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414b
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414c
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402
414d
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412

FIG. 4

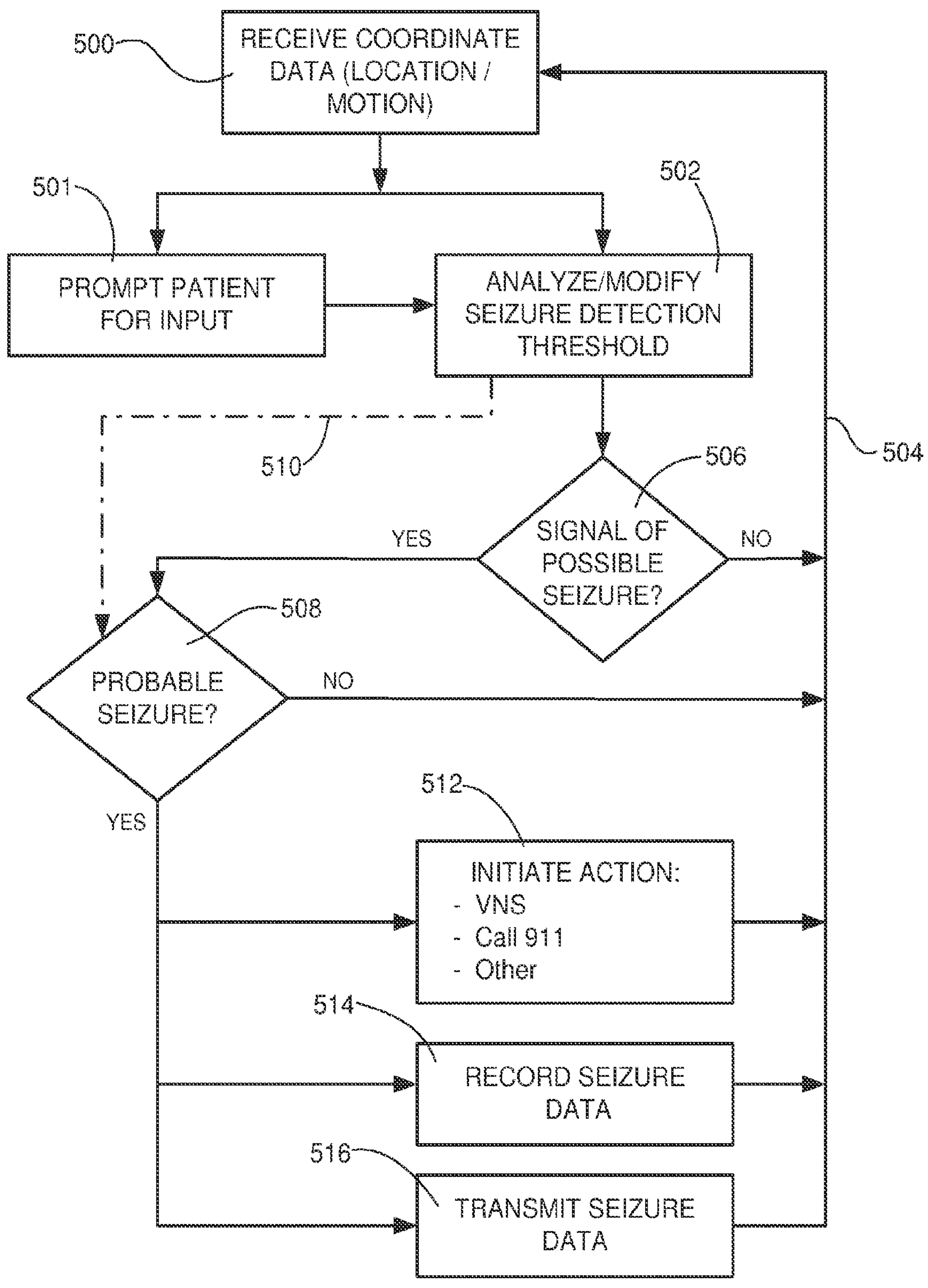
500
RECEIVE COORDINATE DATA (LOCATION / MOTION)
501
PROMPT PATIENT FOR INPUT
502
ANALYZE/MODIFY SEIZURE DETECTION THRESHOLD
510
504
506
SIGNAL OF POSSIBLE SEIZURE?
YES
NO
508
PROBABLE SEIZURE?
NO
YES
512
INITIATE ACTION:
- VNS
- Call 911
- Other
514
RECORD SEIZURE DATA
516
TRANSMIT SEIZURE DATA

FIG. 5

SEIZURE DETECTION USING COORDINATE DATA

FIELD OF THE INVENTION

The present disclosure generally relates to systems and methods for detecting, predicting or logging seizures in a human patient and, optionally, providing a therapy in response thereto. More particularly, the present disclosure relates to a system and methods for detecting physiological changes indicative of a seizure in a patient having an implanted seizure control device, and using coordinate data, such as GPS, to improve seizure detection algorithm specificity.

DESCRIPTION OF THE RELATED ART

Implantable devices have been developed for delivering targeted nervous stimulation at preprogrammed intervals as a therapy for neurological disorders, such as epileptic seizures. It has been shown that measurable parameters of cardiac activity correlate with epileptic seizure events. Consequently, methods have been developed for recognizing a seizure event by measuring changes in heart rate. One challenge to this methodology is that many reasons exist that can cause a heart rate change, such as physical exertion. Thus, heart rate changes alone can give a misleading indication of a seizure event if the heart rate changes are precipitated by other causes. The present disclosure is directed to overcoming, or at least reducing the effects, of one or more of the issues set forth above.

SUMMARY OF THE INVENTION

It has been recognized that it would be desirable to discriminate heart rate changes associated with a seizure from heart rate changes precipitated by other causes, when determining whether to trigger nervous stimulation for seizure control.

It has also been recognized that information regarding activity or location or position of an individual can help distinguish heart rate changes that accompany a seizure from those that relate to other causes.

In accordance with one aspect thereof, the present disclosure provides a seizure detection device, including a coordinate data interface configured to receive coordinate data for a human, a memory to store coordinate data for a defined location where the human has previously been, and a seizure detector configured to identify a seizure event responsive to the coordinate data.

In accordance with another aspect thereof, the present disclosure provides a system for nerve stimulation, including a pulse generator device suitable for subcutaneous implantation into a human body, and a coordinate data interface configured to receive coordinate data for the human body. A memory is also provided to store coordinate data for a defined location where the human has previously been, and an activation device is configured to activate the pulse generation device responsive to the coordinate data.

In accordance with yet another aspect thereof, the disclosure provides a method for detecting seizures, including the steps of receiving coordinate data for a human body, determining a seizure threshold responsive to the coordinate data, and identifying a seizure event responsive to the seizure threshold.

These and other embodiments of the present application will be discussed more fully in the description. The features, functions, and advantages can be achieved independently in various embodiments of the claimed invention, or may be combined in yet other embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic representation of a human subject implanted with an embodiment of a subcutaneous vagus nerve stimulation system, including apparatus for receiving coordinate data of the human subject and identifying a seizure event responsive to the coordinate data.

FIG. **2** is a schematic representation of a human subject implanted with another embodiment of a subcutaneous vagus nerve stimulation system, including apparatus for identifying a seizure episode based upon coordinate data associated with a human subject.

FIG. **3** is a schematic representation of another embodiment of a system for identifying a seizure episode based upon coordinate data associated with a human subject.

FIG. **4** is a schematic representation of another embodiment of a system for identifying a seizure episode based upon coordinate data associated with a human subject, where the coordinate data can be obtained from devices other than a GPS system.

FIG. **5** is a block diagram outlining the steps in an embodiment of a method for determining a seizure threshold and identifying a seizure episode responsive to coordinate data.

While the disclosure is susceptible to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and will be described in detail herein. However, it should be understood that the disclosure is not intended to be limited to the particular forms disclosed. Rather, the intention is to cover all modifications, equivalents and alternatives falling within the spirit and scope as defined by the appended claims.

DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

Illustrative embodiments are described below as they might be employed in a system for seizure detection using coordinate data. In the interest of clarity, not all features of an actual implementation are described in this specification. It will of course be appreciated that in the development of any such actual embodiment, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which will vary from one implementation to another. Moreover, it will be appreciated that such a development effort might be complex and time-consuming, but would nevertheless be a routine undertaking for those of ordinary skill in the art having the benefit of this disclosure.

Further aspects and advantages of the various embodiments will become apparent from consideration of the following description and drawings. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and it is to be understood that modifications to the various disclosed embodiments may be made, and other embodiments may be utilized, without departing from the spirit and scope of the present invention. The following detailed description is, therefore, not to be taken in a limiting sense.

As used herein, the term "implantable" means a device that can be completely implanted into a human or animal body, with no portions of the apparatus extending outside the body after implantation.

As used herein, the terms "implantable device" and "implantable medical device" or "IMD" mean any type of electrical device that is implantable into a human or animal body, and is configured to monitor or affect a function of the body. Examples of implantable medical devices include cardiac pacemakers, nerve stimulation devices, and implantable drug delivery devices.

There are a variety of implantable devices that can be used for monitoring and affecting physiological or biological function of a human body. Such devices include cardiac pacemakers, implantable drug delivery systems and nerve stimulation devices. Among the latter are implantable devices for nerve stimulation, such as vagus nerve stimulation (VNS). VNS was approved by the FDA in 1998 as an adjunctive therapy for epilepsy with partial onset seizures. VNS is achieved through an implanted pulse generator that delivers a bipolar, biphasic pulse to the vagus nerve. The implant procedure is very similar to the implantation of a pacemaker. The generator is implanted subcutaneously, typically in the upper left pectoral region. An electric lead is connected between the pulse generator and one or more electrodes that are attached to the vagus nerve.

Shown in FIG. **1** is a schematic diagram of one embodiment of an implantable vagus nerve stimulation system, indicated generally at **10**, implanted into a patient **12**. The system includes a pulse generator **14**, and a tether or lead **16** that has one or more electrodes **18** at its distal end. The tether and electrodes are collectively referred to as the lead, and the lead provides an interface between the pulse generator **14** and the electrodes **18**. The electrodes **18** are attachable to the vagus nerve **20**. An implantable VNS system of this type and having these basic features is known to those of skill in the art, and is commercially available, such as from Cyberonics, Inc. of Houston, Tex.

The implantable VNS system **10** can also include an antenna **24**, a GPS receiver **26**, and a microprocessor **28** with digital memory **30**. These elements can be included within the housing of the pulse generation device **14**. It will be appreciated by those of skill in the art that the pulse generation device can also include other elements that are not shown in FIG. **1**, such as a rechargeable battery, etc. for providing electrical power to the device through periodic inductive recharging of the battery. The antenna **24** is a common element for an implantable pulse generation device, and is often provided to send and/or receive data and programming and control instructions from an external communications device, such as a heart monitor patch **44**. This allows the implanted device to receive programming and control instructions from the external communications device, and to transmit data regarding operation of the pulse generation device. Communications and control with implanted devices is well known and widely used. Devices such as pacemakers and the like are routinely programmed and/or controlled via wireless communication methods, such as the Medical Information Communication System protocol (MICS), which uses radio waves to transmit information to and from implanted devices.

The pulse generator **14** can be a multi-programmable device, which allows a physician to set various parameters of operation of the device. The programmable parameters can include signal amplitude (e.g., 0-3.5 mA), frequency (e.g., 1-30 Hz), pulse width (e.g., 130-1000 μs), signal ON time (e.g., 7-60 sec) and signal OFF time (e.g., 0.2-180 min). It is to be appreciated that these pulse parameters are only exemplary, and that other parameters can also be used. The pulses can be delivered at the specified amplitude and frequency over the course of the ON time, and then during the OFF time, no stimulation takes place. This type of device typically does not stimulate continuously because it has been found that the antiepileptic effect tends to last much longer than the actual time of stimulation. In one embodiment, pulse settings can be 2 mA, at 15 Hz frequency, 250 μs pulse width, with a 30 sec ON time, and 5 min OFF time. The variability in parameters allows the physician to adjust for greater efficacy or less severe side effects, depending on the patient.

The implantable nerve stimulation device can also include programming and structure to allow adjustment of its operation in real-time based upon detected physiological conditions of the patient in whom it is implanted. Of particular interest in this disclosure, a seizure detector can be provided in conjunction with an implanted device, such as the pulse generation device **14**, to identify a seizure event based upon at least one body parameter and coordinate data indicating position or motion of the patient. In one embodiment, the pulse generation device **14** can include a device for detecting the cardiac cycle, as one example of a body parameter or physiological condition of the human subject. There are many different ways to detect cardiac cycles, and several of these are shown in FIG. **1**. For example, the implanted pulse generation device **14** can include multiple electrodes **32** on its outer surface or casing (but electrically insulated from the casing), the electrodes being in contact with bodily fluids and thereby detecting a change in electrical potential, which gives an ECG (Electro-CardioGram) signal indicative of the patient's cardiac cycle. As another alternative, another lead **34** can extend from the pulse generation device **14** to a separate implanted heart monitoring device **36**, which includes a group of spaced electrodes (not shown) that measure ECG. Such an implanted device can be anchored to a rib or other anatomical structure. As another alternative, a lead with electrodes attached directly to the heart (not shown) can also be used.

As another alternative for monitoring the cardiac cycle of the subject **12**, a pressure transducer **38** can be placed next to an artery, such as the carotid artery **40**. It is to be appreciated that in the case of vagus nerve stimulation, the carotid artery **40** is relatively close to the vagus nerve **20** in the neck region. Thus, a surgeon could extend a branch **42** of the lead **16** toward the carotid artery during implantation of the nerve stimulation electrodes **18**, and implant the pressure transducer **38**. This pressure transducer detects changes in pressure adjacent to the artery, which are indicative of the cardiac cycle of the subject.

While the heart monitoring devices discussed above involve implanted structure, it is also to be appreciated that external devices can also be used for monitoring the subject's heart. For example, another method for detecting cardiac cycles can include the use of an external patch **44** which can be adhered to the skin of the chest of the subject **12** and can be similar to current Holter monitors. The patch can include a group of spaced electrodes (not shown), which detect the subject's ECG, in the same manner as implanted electrodes. The use of external adhesive electrodes for measuring the cardiac cycle is widely known in the medical arts. The patch **44** can include internal circuitry and a power source (not shown) and an antenna **46**, so that the cardiac cycle information can be wirelessly transmitted to the pulse generation device **14**. It is to be understood that, while the patch **44** is shown having an external antenna **46**, this is for illustrative purposes only, and does not necessarily represent actual physical structure. It will be appreciated that the antenna can be an internal part of the patch device itself. This sort of patch can be a disposable device, which the subject can wear for a period of time and then replace with a new one whenever desired. The external patch is thus one example of an external communication device that can collect and/or receive seizure event data and threshold parameters associated with physical coordinates of the patient (e.g., GPS data).

It is to be appreciated that other heart monitoring devices, whether implanted or external, can be used in a seizure detection system as disclosed herein. For example, the discussion of the external patch **44** above applies equally to Holter monitors, which come in many varieties and sizes (e.g., simple strap versions commonly used during exercise or a larger "pager style" connected to multiple adhesive electrode patches). Whatever method is used for detecting the subject's cardiac cycle, data regarding the heart rate, heart rate variability, etc. of the subject are continuously transmitted back to the microprocessor **28** of the pulse generator **14**. This allows the pulse generation device to be programmed to adjust nerve stimulation based upon the events detected from the cardiac cycle of the subject.

It is known that measurable parameters of cardiac activity correlate with epileptic seizure events. For example, an accelerated heart rate (tachycardia) often accompanies the onset of a seizure event. As used herein, the term "tachycardia" is used in a broader sense than that customarily used by cardiologists—it is used to generally refer to any increase in heart rate. When tachycardia is detected by the microprocessor **28**, its programming can cause the pulse generation device to initiate nervous stimulation to treat the seizure. The microprocessor can include activation circuitry that is programmed and configured to activate the implantable device in response to at least one of the coordinate data and the body parameter or body signal data. In this way, the microprocessor **28** of the pulse generation device operates as an activation device for initiating nervous stimulation via the pulse generator. It is believed that nervous stimulation upon detection of a possible seizure can shorten the duration or lessen the severity of a seizure event. Moreover, it is believed that timely nervous stimulation upon first detection of seizure precursor symptoms can even prevent a seizure from fully developing. It is to be understood that to say that the seizure detector merely detects tachycardia can be a simplification. The algorithm for analyzing the cardiac cycle can do more than merely detect an elevated heart rate. Specifically, the algorithm may use matching techniques to identify tachycardia typical of seizures, use accelerometer or other data to confirm or deny seizure detections, or use linear or non-linear properties of heart rate variability (and it's derivatives) to detect or categorize seizure events.

One challenge to this methodology is that there are many possible causes for heart rate and cardiac cycle changes, such as physical exertion. The inventor has recognized that it is desirable to discriminate between the causes of cardiac cycle change when determining whether a seizure event has begun, and whether to trigger nerve stimulation for seizure control. The inventor has determined that information regarding an individual's activity or location can help distinguish cardiac cycle changes or other detectable physiological parameters that accompany a seizure from those that relate to other causes. Advantageously, the inventor has developed systems and methods disclosed herein for obtaining and using coordinate data related to the location of the human subject for more accurately identifying seizure events, and for determining a seizure threshold responsive to the coordinate data. In particular, in various embodiments, the apparatus and methods disclosed herein involve the use of GPS (Global Positioning System satellite data) or other coordinate measurement systems for seizure detection and logging specificity improvement.

GPS transceivers have become a common part of many electrical devices. For example, laptop computers, personal digital assistants (PDA's) and many or most smart phones now incorporate a GPS transceiver. The implanted vagus nerve stimulation system shown in FIG. **1** also includes a GPS transceiver **26**, which is interconnected to the antenna **24** and the microprocessor **28** and memory **30**. The GPS transceiver is one type of coordinate data interface, and is configured to receive coordinate data for the human patient. With these elements, the microprocessor can periodically or continuously determine the subject's location using the publically-accessible GPS satellite system. The coordinate data can then be stored in the memory **30**. This data can represent a defined location for the patient. This can be a user-defined location or a previously designated location, for example. The location can also be a mobile location. It is to be appreciated that the defined location is not limited to locations where the patient has been. For example, it can be advantageous to be able to program in, for example, a beach, hunting camp or other area where the patient has not been but intends to go, and where a seizure would present elevated risks of injury to self or others. As is well known, the GPS system allows tracking of latitude, longitude and altitude of the transceiver at any given time, based upon the position of the transceiver **26** relative to multiple GPS satellites **48**, and also provides very accurate time data. Moreover, receiving data regarding changes in position over time allows the system (e.g., the microprocessor **28**) to also determine velocity and direction of motion of the subject at any time. In other words, the microprocessor can be programmed as a movement calculator, which can determine movement in response to coordinate data over time.

While the GPS transceiver **26** is shown incorporated into the implanted pulse generation device in FIG. **1**, the GPS transceiver can be placed in other locations associated with the patient's body, such as an external communications device. An external communications device can thus provide the coordinate data interface discussed above, and can function as an activation device for the implanted device. The external communications device can include activation circuitry and programming for activating the implantable device (e.g. via wireless signals) in response to the coordinate data and the body parameter or body signal data. A variety of types of external devices can be used. Some of these are shown in FIG. **2**. For example, a GPS transceiver **50** can be incorporated into a smart phone **52** or similar device that is substantially constantly kept in the possession of the person. Alternatively, a wristwatch or wristwatch-like device **54** or other wearable device can include a GPS transceiver which receives locational information and transmits this information wirelessly to the pulse generation device **14**. Other wearable or external communication devices can also be used. The smart phone **52** and wristwatch device **54** are shown in FIG. **2** with antennas, which are intended to represent the wireless communications capability of the devices, rather than the shape or position of an actual antenna structure. The antenna allows the external device to receive GPS signals from the satellites **48**, and transmit the received GPS data to the pulse generation device **14** using Bluetooth or some other wireless transmission protocol, for example. The wireless external device can be a cellular device, and can house the coordinate data interface and the activation device for the pulse generator. In this way coordinate signals from a wireless external communication device can be transmitted to the pulse generation device. It is recognized that the accuracy of seizure detection can be affected if the GPS device is not kept upon the person of the epileptic patient.

Having the GPS transceiver included within a device other than the pulse generation device **14** can be desirable for power conservation. It will be apparent that power consumption of a GPS transceiver that is in substantially constant communication with the GPS satellite system and a microprocessor that analyzes the positional information can use significant power, which is at a premium with implanted devices. Thus, having an external GPS device can reduce the power demands of the implanted device. Since the external device and the implanted device are presumably kept in relatively close proximity (both upon the person of the epileptic patient), wireless transmission between these devices can be at a much lower power than communication with the GPS system or some other wireless system, thus reducing the power demands upon the implanted device.

Additionally, microprocessing tasks and analysis can be transferred to an external device, rather than being performed by the microprocessor **28** of the pulse generation device, with the results of those microprocessing tasks transmitted to the implanted device. This can also conserve power for the implanted device. For example, the microprocessor associated with a smart phone **52** or wristwatch device **54** or some other external device can be programmed to receive cardiac cycle information (e.g, from an external heart monitoring device or transmitted from the pulse generator **14** or some other implanted device) as well as locational information (GPS, etc.), and perform the analysis discussed herein to distinguish seizure related tachycardia from other causes. The external device can then transmit operational commands or other information to the pulse generation device **14** that can affect its operation, when a seizure event is detected.

Having a GPS transceiver on or associated with the subject **12**, along with an implanted or external seizure detector, such as a heart monitoring device, as shown in FIG. **1**, allows the system to use location and motion information in conjunction with seizure detection (e.g. heart rate) information to increase confidence in a seizure detection determination. For example, if a heart rate increase accompanies a change in velocity to a fairly constant 3-7 mph, then the system can reduce seizure declaration likelihood (i.e., increase an adaptive threshold), because the change in velocity indicates that the change in heart rate likely results from the person walking or jogging. On the other hand, if no contemporary change in velocity is detected in association with the other seizure detection sensors, then the system can increase the seizure detection likelihood (i.e. reduce the adaptive threshold), so that this heart rate event is considered more likely to accompany a seizure event. This is the basic analytical method for detecting seizures using coordinate data. In this way the seizure detection system is programmed with a threshold evaluator or threshold determining element (i.e. threshold determining logic), which can determine a dynamic seizure detection threshold in response to the coordinate data (representing location and/or motion). Threshold parameters associated with various physical locations or coordinates can be stored in the memory of the seizure detection device (e.g. the implanted device or external communications device).

A flowchart outlining the basic steps in this method is provided in FIG. **5**. The system first receives the coordinate data (step **500**), which can be GPS data or some other data. Coordinate data also includes data regarding motion, which can involve time-based analysis of GPS or other positional information in order to determine velocity. In either case, the positional or velocity-related data is referred to herein as coordinate data. Based upon this data, the system analyzes or modifies a seizure detection threshold (step **502**) with reference to the patient's location or motion. As shown by return arrow **504**, so long as no signal indicating a possible seizure is received by the associated heart monitoring device (step **506**), the system simply returns to step **500** and continues to monitor and receive the coordinate data, and periodically adjust the seizure detection threshold as needed (step **502**).

However, if a signal indicating a possible seizure (e.g., tachycardia or other signal) is received (at step **506**), the system then determines whether a seizure is probably occurring (step **508**). This analysis is based upon the modified seizure detection threshold that is part of a seizure detection algorithm, which was determined at step **502**, as represented by dashed arrow **510**. The difference between analytical steps **506** and **508** is the difference between possible and probable. Step **506** merely determines that a seizure is possible, based upon the received signal. At step **508**, it is determined whether a seizure is probable or not, based upon the modified seizure detection threshold. As noted above, once the system has determined, from the coordinate data, how to adjust the seizure detection threshold, its ability to selectively identify a probable seizure is improved. If, in view of the modified seizure detection threshold, it is determined that the detected signal indicating a possible seizure is not likely to be indicative of a seizure, the system can again return to step **500** and continue to monitor and receive the coordinate data, and periodically adjust the seizure detection threshold (step **502**). However, if a seizure is detected in view of the modified seizure detection threshold, one or more of various actions can be initiated, as indicated in boxes **512**, **514** and **516**. These are discussed in more detail below.

The configuration described above allows the system to be used in a variety of ways, some of which are illustrated in FIG. **3**. Shown in FIG. **3** is a patient **300** having an implanted VNS device **302**, and a smart phone **304** and wristwatch device **306**. These external devices are intended to be indicative of any external GPS and/or microprocessor device. It is to be understood that the operational capabilities illustrated in FIG. **3** can be applied whether the implanted device is associated with a coordinate data system like that of FIG. **1** or FIG. **2**, or other embodiments. The depiction of the patient **300** is intended to represent the person in any common condition—such as standing, walking, running, etc. Whether through the implanted device **302** or an external device **304**, **306** (depending on which device includes a GPS transceiver), the person's position is continually monitored via the GPS satellite system **308**, as indicated by dashed line **310**. By tracking the person's position over time, the microprocessor that receives the GPS information (like the GPS transceiver, the microprocessor can be part of the implanted pulse generation device **302** or part of an external device **304**, **306**) can determine the velocity of the person in three dimensions at any time.

Similarly, the microprocessor can incorporate automotive travel logic into the seizure detection algorithm to account for instances when the defined location of the person is mobile. Shown in FIG. **3** is a person **312** in an automobile **314**. Though not shown, this person also has a GPS based seizure detection system, like the person **300**, and this system is in communication with the satellite based GPS system, as indicated at **316**. The microprocessor associated with the seizure detection system can be programmed so that patterns of velocity indicative of automotive travel are recognized and used to modify the seizure detection threshold. Patterns of velocity indicative of automotive travel can include motion at anything above a running speed (e.g., 20 mph), for example. When automotive travel is recognized, the system can adjust (either increase or decrease) the seizure declaration likelihood. On one hand, the system can reduce the adaptive threshold in the circumstance of probable automotive travel because (1) there is less risk of harm from a seizure when traveling as a passenger in a motor vehicle, and (2) there is less likelihood of exertional tachycardia while traveling in a car or bus.

The seizure detection threshold can also vary depending upon the person's relationship to the vehicle—i.e. whether a driver or passenger. For example, tachycardia can be considered more likely for a driver **312**, especially in crowded or difficult traffic conditions, than for a passenger **318**, as shown in FIG. **3**. This sort of factor can come into play in other situations, too. Thus, the seizure detection system disclosed herein can include another feature shown in FIG. **5**. In addition to receiving coordinate data (step **500**) and modifying the seizure detection threshold based on that information (step **502**), the system can also prompt a patient to input relevant locational or conditional information (step **501**). For example, when the system detects velocity data indicative of automotive travel, the patient's smart phone or other external device (**52** in FIG. **2**) can prompt the user with a question such as "Are you traveling in a motor vehicle?" The patient can then enter the appropriate answer to confirm their condition. The system can then ask a follow-up question such as "Are you driving or are you a passenger?"

In this way the coordinate data interface prompts the user to provide information that can identify their location, thus allowing any location to become a user-defined or designated location. In one embodiment, the coordinate data interface can display a predetermined list of location types, from which the user can select to identify the location. For example, the display may list "home", "work", "shopping" and "vehicle" as possible location choices. Multiple nested lists can be involved. When the user selects one, the system can then store the coordinate data of that location in conjunction with the identifier. In another embodiment, the coordinate data interface can be configured to receive an identifying name for the defined location via input of the user or a caretaker or medical personnel, for example. The named location can also have a location type associated with it, such as via a predetermined list of location types, in the manner discussed above.

The system can also prompt for risk factor inputs. These risk factor inputs can then be associated with physical coordinates of a defined location, and can be used to determine the seizure threshold responsive to the risk factor inputs and the coordinate data. The seizure detection algorithm's thresholds can be lowered to be more sensitive to possible seizures when the user is in a risky location. The risk of harm to the user increases in locations such as the gym, swimming pool, bath tub, driver's seat of a vehicle, kitchen, staircase, on a bicycle, and so forth. Each location can have a corresponding risk factor associated with it or the user can input the risk factor necessary for a certain location. The risk factor input can simply be the coordinate data and modify the risk factor dynamically as the user, for example, moves through the house from the bed, to the bath tub, to the kitchen, to the dining room, and then to the vehicle. The user can also input the risk factor by defining a location (e.g., a bicycle) as the user arrives at the location. The user can also input a risk factor without defining the location by, for example, setting a high risk factor when rock climbing and then input a low risk factor when the user eats a picnic lunch near the rock he climbed.

After the user has been prompted to enter relevant information, the system can then adjust the seizure detection threshold. In one embodiment, if a person is a passenger, the seizure detection algorithm can operate normally, but if the person is a driver, the algorithm can become more aggressive (e.g., lowering a threshold) to act upon every possible seizure, for example. Alternatively, the system can use the knowledge that the patient is the driver to separate out tachycardia induced by the stress of driving from tachycardia (or other cardiac cycle events) resulting from seizures.

While much of the above discussion has considered seizure detection based upon sensing tachycardia and cardiac cycles, it is to be understood that this is only one example of a body parameter or physiological condition that can be indicative of a possible seizure event. It is to be appreciated that seizure detection can be accomplished using any one or more of a wide variety of body parameters, in addition to cardiac cycles. For example, seizure detection data can be obtained from cardiovascular signals, respiratory signals, skin signals, pupillary signals, temperature signals, peristaltic signals, brain signals, cranial nerve signals, spinal cord signals, peripheral nerve signals, autonomic nerve or ganglia signals, biomedical presence or concentration signals (i.e. detection of a particular chemical species), body kinetic, position and force signals, and others. Additionally or alternatively, neurological signals, such as those generated by the brain or cranial nerves can be used for detecting a seizure. Exemplary body parameter sensor(s) can include electrocardiography (EKG) devices, accelerometers, inclinometers, pupillometers, face or body temperature monitors, skin resistance monitors, and/or sound and pressure sensors, among others. Those of skill in the art will be aware that sensor(s) to detect these and other body parameters are commercially available, and can be placed in, on, or near a particular organ, tissue, nerve, or blood vessel of the patient, or outside the patient's body, such as on the patient's skin or in the patient's environment.

Referring back to FIG. **3**, the system can be configured with additional functionality. As shown by dashed lines **320** and **322**, the seizure detection system can incorporate mobile communications technology that allows wireless communication with a cellular phone system (represented by a cell tower **324**), which can further connect into the publicly switched telephone system (PSTN) **326**. This allows the seizure detection system to communicate with a base station, medical professional, hospital or the like, as represented by building **328**, when a seizure is detected. Such remote communications can be desirable for many possible reasons, such as for health monitoring, emergency medical assistance, transmitting seizure related data, providing notifications or programming updates for an implanted device, etc. Various options for action upon detection of a seizure are indicated in FIG. **5**, and these can include options that involve remote communications. For example, as indicated in box **512**, upon detection of a seizure the system can actuate an implanted nerve stimulation device (**14** in FIG. **1**) to initiate nervous stimulation. In certain circumstances and certain locations the system can dial 911 to request emergency medical aid. Other actions related to the patient can also be taken.

Additionally, upon detection of a seizure the seizure detection system can begin recording data of the patient and other conditions, perhaps at a faster rate than normally. For example, if the system normally checks position and motion at a rate of once every 4 seconds when no seizure is detected, detection of a seizure could initiate electronic recording of the person's location, movement, heart rate, blood pressure, and other possible factors at a much higher refresh rate—e.g. every 1 second—during the seizure event. This information can be recorded or logged by the microprocessor (step **514**) and/or transmitted to a remote location (step **516**) if desired. A remote monitoring location or facility can also include its own wireless communication capability, as indicated by antenna **330**, to allow direct communications with seizure detection systems, as opposed to or in addition to communications through the PSTN **326**.

It is also to be appreciated that the seizure detection system can be used when there is no implanted nerve stimulation device. That is, for purposes of studying seizures, it may be desirable to provide a patient with heart monitoring devices, as discussed above, and an external device of some kind to detect and transmit data regarding seizures, even in the absence of any mechanism for treating them. This approach can be suitable for some patients and desirable from a research standpoint to gather seizure information.

The system can also be configured for other functions and for operation in other conditions, as shown in FIG. **4**. The seizure detection system disclosed herein can incorporate stair-climbing logic to help prevent false seizure indications from exertion that results from stair climbing. For example, shown in FIG. **4** is a person **400** climbing a flight of stairs **402** in a building **404**. In a situation like this, the seizure detection system can detect a pattern of velocity and altitude change that is indicative of stair-climbing. Since this sort of action is likely to raise one's heart rate, the adaptive seizure detection threshold can be reduced in a manner specific to stair-climbing. That is, since stair climbing presents a more extreme case of exertion, it is therefore more likely to induce an accelerated heart rate that is not associated with a seizure event.

The system can also incorporate neural network self-programming, so that the adaptive thresholds "learn" to match a particular patient's pattern of how speed and altitude changes result in heart rate changes. Over time, the adaptive threshold can be "trained" to follow an expected pattern of exertion versus resulting heart rate (or other autonomic) change. A seizure detection declaration is made to be more likely when the pattern of cardiac cycle deviates from the cardiac cycle that would have normally been expected given contemporary velocity data.

In addition to adjusting an adaptive heart rate threshold in conjunction with data regarding velocity or motion of the individual, the system can also use GPS positional or coordinate data to modify the seizure detection threshold based on specific coordinate locations. That is, the system can use a logical neural network self-programming and learning for recognizing specific positional patterns. For example, using data from a GPS satellite system **406**, the system can logically determine that the patient is in a position of a bed **408** (e.g. on an upper floor **410** of a known residential building **404**, in a substantially constant position for several continuous hours each day). If a 'bed' locational determination is made, adaptive thresholds can be adjusted to attempt to discriminate from patterns of normal sleep behaviors. Where the system determines this type of location, sudden tachycardia can be indicative either of a seizure event, or of waking and rising. To distinguish between sudden heart rate change due to a seizure and sudden heart rate change upon getting out of bed, the system can be programmed to recognize that a heart rate jump upon arising from bed is likely to occur after a change in body position. Consequently, GPS or other signals that detect body or positional changes can screen this out.

Similarly, logical determination that the patient is in a position of a car's normal patterned parking space (i.e., within a garage **412** of a residence **404**) can trigger corresponding logical conclusions. If a 'car' locational determination is made, adaptive thresholds can be adjusted to 'automotive travel' mode immediately, rather than having to wait for a pattern of velocity that indicates automotive travel.

Relevant data can also be obtained from devices in addition to a GPS transceiver. For example, as shown in FIG. **2**, the pulse generation device can also include an accelerometer **60** that is interconnected to the microprocessor **28**. There are a wide variety of low cost, miniature accelerometers that are commercially available, and can be incorporated into an implantable device, or an external device, such a smart phone **52**, wristwatch **54**, etc. For example, many cardiac pacemakers currently include accelerometers to detect exercise, and can adjust pacing accordingly. Such an accelerometer device can accurately detect acceleration along three axes (up-down, forward-back, left-right), allowing the microprocessor **28** to detect the onset of motion of the patient in any direction. An inclinometer (not shown) can similarly be used to give an indication of the patient's posture, such as lying down, reclining, standing, etc. A neural network logical self-programming pattern recognition algorithm can be incorporated into the programming of the microprocessor to correlate patterns of data from the accelerometer, inclinometer, etc. with data from the GPS receiver.

As noted above, receiving GPS signals generally requires a line of sight to GPS satellites. However, there are many locations, such as inside a building, etc., where it may be difficult or impossible to obtain a GPS signal. Such a situation is suggested in FIG. **4**. Correlating the accelerometer data with the most recently obtained GPS data allows adaptive threshold adjustment in the absence of a GPS signal. The accelerometer data can represent an 'activity level' in a way that is derived from the GPS data that indicates 'activity level' based on velocity changes. Thus, after a learning period of sufficient simultaneous GPS and accelerometry recording, the pattern recognition learning algorithm can have the ability to adjust seizure declaration thresholds in the absence of a GPS signal, which may be the case for many indoor locations.

Additionally, other position-finding technologies can also be used to determine location when a GPS signal is limited, such as at certain indoor locations. Other position-finding technologies that can be used can include local positioning systems, RFID systems, toll tag technologies, cell phone positional methodologies, internal radio positional networks, proximity sensors, motion sensors, and acoustic broadcasts and sensors (especially those tuned to inaudible frequencies) which can determine the location and/or motion of a patient in many locations. These types of systems can provide a local coordinate system that can provide local coordinate data regarding the position or motion of the patient. One of these types of systems is suggested in FIG. **4**. It is possible that GPS detection can work within a building, as indicated by the communication line between the satellite **406** and the person **400**. However, the home **404** may prevent the reception of GPS signals in many instances. Consequently, this building is equipped with a plurality of detection devices **414***a*-*d*, which can allow local detection of the position and motion of a patient inside the building.

These detection devices **414** can be sensors which actually sense position and/or motion (e.g. motion detectors), or they can be broadcast devices that broadcast a signal (e.g. a radio signal), and then sense reflected information. For example, the detection devices **414** can provide signals (e.g. proximity signals) to an IMD or external device upon the person of the patient, and the IMD or external device can then interpret the proximity data to independently determine the position and motion of the patient to detect the patient **400** climbing a flight of stairs **402**, for example, even if the GPS system is not able to detect it. Similarly, the detection devices can detect when the person is sitting relatively still, as at **416**, or in or near the bed **408**. The detection devices **414** for this type of application can be cell phone positional sensors, an internal radio positional network, proximity sensors, motion sensors, or others. Thus, for example, viewing FIG. **4**, detection device **414***a* can be a radio-frequency transmitter, detection device **414***b* can be a motion sensor, detection device **414***c* can be a proximity sensor, and detection device **414***d* can be an acoustic broadcast sensor.

In an interior or other location where a GPS signal may not be available, the user can 'set up' the home or commonly visited place with detection devices of two or more types. One type of detection device can be used to indicate that the area is associated with a 'high risk'. Another type of detection device can be associated with a 'low risk' location. In instances when there is only one type of detection device present, the default programming can consider decision making without the condition of 'high risk' or 'low risk' biasing the decision.

In the case of a tachycardia-based detection algorithm, one example of a high risk location can be the person's the bed **208**, since tachycardia when in one's bed should be rare except in the event of an actual seizure. As another example, a bathtub (not shown) can be considered a high risk location because, even though non-seizure tachycardia could happen in the bathtub, the consequences of an unattended seizure in the bathtub carry high risk. In high risk locations the propensity to declare an event and respond can be biased toward more vigilance. On the other hand, an example of a low risk location could be a stairway **402**. It is highly probable that tachycardia will be associated with exertion in a stairway. Consequently, the threshold for seizure responsive action in a stairway can be relaxed, since a tachycardia event experienced at the stairway is more likely to be due to exertion, rather than a seizure event.

The locational data that is collected when setting up the commonly visited locations can also be presented for use in patient care. For example, medical professionals, caregivers, and/or patients can analyze the patient's sleeping habits, daily rituals, frequency of exposure to 'high risk' locations, the amount of time spent in particular locations of interest, and general activity levels. These types of factors can be referred to as lifestyle factors, and can be evaluated and considered in the seizure detection system disclosed herein. For example, this data can help determine the patient's quality of life or, among other things, behavioral patterns that may lead to changes in the prescribed therapy. The conglomerated and trended positional and body sensor data may be used to collaterally quantify and communicate lifestyle factors such as in the form of standard indices like Physical Activity Level (PAL)/Physical Activity Index (PAI), Total Energy Expenditure (TEE), and other existing standards used to quantify state of health. Such indices and their trends may themselves be used to adjust a seizure detection declaration threshold, reveal trends that may be predictive of seizure propensity, or simply for presenting a measure of health improvement or decline to the healthcare provider.

An additional feature of the seizure detection system shown in FIG. **4** is a bedside monitoring unit or base station **420**. This unit can operate in much the same way as other external devices disclosed above (such as the smart phone **52** in FIG. **2**). It can transmit and receive low power signals with an implanted nerve stimulation device, and can receive or be programmed with GPS or other positional data. Advantageously, the bedside unit **420** can be hard-wired into a communications system, such as the PSTN, represented by wires **422**, allowing rapid and reliable communications with a remote monitoring station **424** or other remote location. The base station can also include wireless capability, allowing it to communicate directly with a wireless telephone system, represented by cell tower **426**, or other wireless devices. The base station and other external devices allow some device other than an implanted device to do the "heavy lifting" of communications and analysis for seizure detection, so that power demands on the implanted device are minimized.

Alternatively, in an embodiment, similar to FIG. **2**, the seizure detection algorithm can be processed in either the IMD or the external device. The computational 'heavy lifting' can be performed on the external device whenever it is within range and operational, but when the external device is unavailable, the IMD can be programmed to perform the computational chores, even at the expense of battery use, so as not to lose functionality of the system as a whole.

It is to be appreciated that the system and method disclosed herein can also apply to cardiac pacemakers. That is, a pacemaker is an implantable device that can be provided with a coordinate data interface in the manner disclosed herein, and include programming to determine or adjust operational parameters based upon coordinate and/or motion data and a detected physiological condition, such as cardiac cycles.

The system and method disclosed herein can thus improve the accuracy of automated seizure detection devices and algorithms. This system has the greatest potential to improve specificity of automated seizure declarations. It can reduce battery consumption by an implanted nerve stimulation device by avoiding false alarms and incorrectly identified needs for therapy delivery. It can also reduce anxiety and disruption by avoiding false alarms for alerting-type systems. Additionally, this system and method can improve the tracking of disease progression by making seizure counts more accurate.

Although various embodiments have been shown and described, the invention is not so limited and will be understood to include all such modifications and variations as would be apparent to one skilled in the art. For example, equivalent elements may be substituted for those specifically shown and described, certain features may be used independently of other features, and the number and configuration of various vehicle components described above may be altered, all without departing from the spirit or scope of the invention as defined in the appended claims.

Such adaptations and modifications should and are intended to be comprehended within the meaning and range of equivalents of the disclosed exemplary embodiments. It is to be understood that the phraseology of terminology employed herein is for the purpose of description and not of limitation. Accordingly, the foregoing description of the exemplary embodiments of the invention, as set forth above, are intended to be illustrative, not limiting. Various changes, modifications, and/or adaptations may be made without departing from the spirit and scope of this invention.

What is claimed is:

1. A seizure detection device comprising:

a coordinate data interface configured to receive coordinate data indicating a coordinate location of a patient;

a memory configured to store the coordinate data associated with a defined location; and

a seizure detector configured to detect a seizure event in the patient based on the coordinate data and body parameter data corresponding to at least one body parameter.

2. The seizure detection device of claim **1**, wherein the coordinate data includes global positioning system data obtained from a global positioning system, local coordinate data obtained from a local coordinate system, or both.

3. The seizure detection device of claim **2**, wherein the coordinate data includes time data, and wherein the global positioning system data, the local coordinate data, or both, includes velocity data, acceleration data, or both.

4. The seizure detection device of claim 1, further comprising a motion detector configured to detect motion of the patient, wherein the seizure detector is responsive to the coordinate data and the motion of the patient.

5. The seizure detection device of claim 4, wherein the motion detector comprises an accelerometer.

6. The seizure detection device of claim 1, wherein the seizure detector is further configured to:

dynamically determine a seizure detection threshold based at least in part on the coordinate data; and

compare the body parameter data to the seizure detection threshold.

7. The seizure detection device of claim 1, further comprising a communication interface configured to communicate with an external communication device: the body parameter data, seizure event data, seizure detection threshold data, the coordinate data, or a combination thereof.

8. The seizure detection device of claim 1, wherein the coordinate data includes altitude data.

9. The seizure detection device of claim 1, further comprising a movement calculator configured to determine an amount of movement of the patient responsive to the coordinate data.

10. The seizure detection device of claim 1, wherein the body parameter data is determined based on a cardiovascular signal, a respiratory signal, a skin signal, a pupillary signal, a temperature signal, a peristaltic signal, a brain signal, a cranial nerve signal, a spinal cord signal, a peripheral nerve signal, an autonomic nerve signal, an autonomic ganglia signal, a biomedical presence signal, a biomedical concentration signal, a body kinetic signal, a body position signal, a body force signal, or a combination of two or more thereof.

11. The seizure detection device of claim 7, wherein the external communication device activates an implantable medical device based at least in part on the body parameter data, the coordinate data, or both.

12. The seizure detection device of claim 11, wherein the implantable medical device includes a pulse generation device for nerve stimulation to the patient.

13. A method comprising:

receiving coordinate data indicating a coordinate location of a patient;

determining a seizure threshold based at least in part on the coordinate data; and

detecting a seizure event in the patient based at least in part on the seizure threshold.

14. The method of claim 13, wherein receiving the coordinate data includes receiving global positioning system data from a global positioning system, receiving local coordinate system data from a local coordinate system, or both.

15. The method of claim 14, wherein receiving the coordinate data includes receiving time data, and wherein receiving the global positioning system data, the local coordinate system data, or both, includes receiving velocity data, acceleration data, or both.

16. The method of claim 13, further comprising determining an amount of movement of the patient based on the coordinate data, wherein the seizure event is detected in the patient based on the coordinate data and the amount of movement of the patient.

17. The method of claim 13, further comprising logging seizure event data associated with the coordinate data.

18. The method of claim 13, further comprising sending seizure event data associated with the coordinate data to an external communication device.

19. The method of claim 13, further comprising receiving input data indicating an activity being performed by the patient, wherein the seizure threshold is determined based on the input data.

20. The method of claim 19, wherein the input data further indicates a location where the activity is being performed.

* * * * *

patsnap

专利名称(译)	使用坐标数据检测癫痫发作		
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申请(专利权)人(译)	约翰·科尔伯恩		
当前申请(专利权)人(译)	Cyberonics公司，INC.		
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摘要(译)

癫痫发作检测装置包括：坐标数据接口，被配置为接收人的坐标数据;存储器，用于存储人的定义位置的坐标数据;以及癫痫发作检测器，被配置为响应于坐标数据识别癫痫发作事件。