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## **DYNAMIC ADJUSTMENT OF NON-PATHOLOGICAL RANGE OF BODY DATA VARIABILITY (BDV) THRESHOLD FOR SEIZURE DETECTION**

### **FIELD OF THE INVENTION**

[001] This disclosure relates to medical device systems and methods capable of detecting epileptic seizures.

### **SUMMARY OF THE INVENTION**

[002] In some embodiments, the present disclosure relates to a method of detecting an occurrence of a pathological state of a patient from body data of the patient, comprising: receiving a body signal of the patient; determining a current body data variability (BDV) value based upon the body signal; determining an activity level of the patient; determining a non-pathological BDV range based at least in part on the activity level; comparing the current BDV value to the non-pathological BDV range; detecting the occurrence of a pathological state in response to the current BDV value being outside the non-pathological BDV range.

[003] In some embodiments, the present disclosure relates to a method of detecting an occurrence of a pathological state of a patient from cardiac data of the patient, comprising: receiving a cardiac signal of the patient; determining an current heart rate variability (HRV) value based on the cardiac signal; determining an activity level of the patient; determining a non-pathological HRV range based at least in part on the activity level; comparing the current HRV value to the non-pathological HRV range; and detecting an occurrence of an epileptic seizure in response to the current HRV value being outside the non-pathological HRV range.

[004] In some embodiments, the present disclosure relates to a method of detecting an occurrence of a pathological state of a patient from body data of the patient, comprising: receiving a body signal of the patient; determining a current body data variability (BDV) based upon the body signal; comparing the current BDV to a non-pathological BDV range; and detecting the occurrence of a pathological state in response to the current BDV being outside the non-pathological BDV range. In one embodiment, the body data comprises one or more of autonomic data, neurologic data, metabolic data, endocrine data, or tissues stress factor data.

[005] In other embodiments, the present disclosure relates to a medical device system, comprising at least one sensor configured to collect a body signal from a patient; and a medical device, comprising: a body signal data module configured to determine a time series of body

signal values based upon the body signal; a body data variability module configured to determine at least a current body data variability (BDV) value based at least upon the time series of body signal values; a non-pathological body data range module configured to determine a non-pathological body data variability (BDV) range, based at least in part on the current body signal value; and a pathological state detection module configured to detect an occurrence of a pathological state, in response to the current BDV value being outside the non-pathological BDV range.

[006] In some embodiments, the present disclosure relates to a non-transitory computer readable program storage unit encoded with instructions that, when executed by a computer, perform a method as described above.

### **BRIEF DESCRIPTION OF THE DRAWINGS**

[007] The disclosure may be understood by reference to the following description taken in conjunction with the accompanying drawings, in which like reference numerals identify like elements, and in which:

[008] Figure 1 shows a schematic diagram of a medical device system, in accordance with some embodiments of the present disclosure;

[009] Figure 2 shows a schematic diagram of portions of a medical device system, in accordance with some embodiments of the present disclosure;

Figure 3 shows a schematic diagram of a body data variability (BDV) module, according to some embodiments of the present disclosure;

[0010] Figure 4 shows a dependence of a non-pathological BDV range (in this figure, heart rate variability (HRV)) on the value of the body data (in this figure, heart rate), according to some embodiments of the present disclosure;

[0011] Figure 5 shows a dependence of a non-pathological BDV range (in this figure, respiratory rate variability (RRV)) on the value of the body data (in this figure, respiratory rate), according to some embodiments of the present disclosure;

[0012] Figure 6 shows a work level lookup chart, indicating a work level range expected at various times of day, according to some embodiments of the present disclosure;

[0013] Figure 7 shows a flowchart depiction of a method, according to some embodiments of the present disclosure;

[0014] Figure 8 shows a flowchart depiction of a method, according to some embodiments of the present disclosure; and

[0015] Figure 9 shows a flowchart depiction of a method, according to some embodiments of the present disclosure.

[0016] While the disclosure is susceptible to various modifications and alternative forms, specific embodiments thereof have been shown by way of example in the drawings and are herein described in detail. It should be understood, however, that the description herein of specific embodiments is not intended to limit the disclosure to the particular forms disclosed, but on the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the disclosure as defined by the appended claims.

#### **DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS**

[0017] Illustrative embodiments of the disclosure are described herein. For clarity, not all features of an actual implementation are described. In the development of any actual embodiment, numerous implementation-specific decisions must be made to achieve design-specific goals, which will vary from one implementation to another. Such a development effort, while possibly complex and time-consuming, would nevertheless be a routine undertaking for persons of ordinary skill in the art having the benefit of this disclosure.

[0018] Embodiments disclosed herein provide for determining a body data variability (*e.g.*, heart rate variability, respiratory rate variability, O<sub>2</sub> saturation variability, blood pressure variability, etc.), as well as an activity level of a patient in order to determine a non-pathological range for the body data variability (BDV). A current BDV may then be compared to the non-pathological BDV range to perform a pathological state of a patient.

[0019] Figure 1 shows a schematic representation of a medical device system, according to some embodiments of the present disclosure. The medical device system 100 may comprise a medical device 200, body data sensor(s) 112, and lead(s) 111 coupling the sensor(s) 112 to the medical device 200. In one embodiment, body data sensor(s) 112 may each be configured to collect data from a patient relating to a time series of body data values. The body data may be selected from heart rate, heart rate pattern, blood pressure, respiratory rate, respiratory pattern, EKG morphology, dermal activity, pupillary activity, oxygen saturation, or kinetic activity, among others.

[0020] Various components of the medical device 200, such as controller 110, processor 115, memory 117, power supply 130, communication unit 140, warning unit 192, therapy unit 194, logging unit 196, and severity unit 198 have been described in other patent applications assigned to Flint Hills Scientific, LLC or Cyberonics, Inc., such as, USSN 12/896,525, filed October 1, 2010; USSN 13/288,886, filed November 3, 2011; USSN 13/449,166, filed April 17, 2012; and USSN 13/678,339, filed November 15, 2012. Each of the patent applications identified in this paragraph is hereby incorporated herein by reference.

[0021] The medical device 200 may comprise a body data module 150 configured to obtain a time series of body data from the collected data. The body data module 150 may also be configured to determine one or a time series of body data values or body index values based upon the time series. Such a time series of body index values may comprise at least one of an instantaneous heart rate (HR), an instantaneous respiratory rate (RR), an instantaneous blood pressure (BP), or an instantaneous blood oxygen saturation (O2S) value, among others.

[0022] The medical device 200 may comprise a body data variability module 165 configured to determine at least a body data variability (BDV) of a body signal. The body data variability module 165 may be configured to determine at least one body data variability selected from a heart rate variability (HRV), a respiratory rate variability (RRV), a blood pressure (BPV), a respiratory pattern variability, an EKG (electrocardiogram) morphology variability, a heart rate pattern variability, an electrodermal variability, a pupillary variability (hippus), a blood oxygen saturation variability, or a kinetic (rate, amplitude, direction or force of movement) rate variability.

[0023] The medical device 200 may comprise a non-pathological body data range module 160 configured to determine a non-pathological body data variability (BDV) range, based at least in part on a body data value. In some embodiments, the non-pathological body data variability (BDV) range may comprise at least one of a non-pathological HRV range, a non-pathological RRV range, a non-pathological BPV range, a non-pathological respiratory pattern variability range, a non-pathological EKG morphology variability range, a non-pathological heart rate pattern variability range, a non-pathological electrodermal variability range, a non-pathological pupillary variability range, a non-pathological blood oxygen saturation variability range, or a non-pathological kinetic rate variability range.

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