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(54) **HISTOGRAM-BASED THORACIC IMPEDANCE MONITORING**

THORAX-IMPEDANZÜBERWACHUNG AUF HISTOGRAMM-BASIS

SURVEILLANCE DE L'IMPÉDANCE THORACIQUE FONDÉE SUR UN HISTOGRAMME

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Description

TECHNICAL FIELD

[0001] This patent document pertains generally to medical systems and methods. More particularly, but not by way of limitation, this patent document pertains to fluid monitoring systems and methods configured for using histogram-based information about one or more thoracic impedance-indicative signal values to compute and provide a lung fluid status indication.

BACKGROUND

[0002] Excess thoracic fluid retention can take various forms and can have different causes. As an example, eating salty foods can result in retaining excess fluid in the thorax and elsewhere. Another source of thoracic fluid accumulation is pulmonary edema, which involves a build-up of extravascular fluid in or around a subject's lungs.

[0003] One cause of pulmonary edema is congestive heart failure ("CHF"), sometimes referred to simply as "heart failure." Heart failure is a major health problem-it is estimated that 5 million people suffer heart failure in the United States alone and it is believed to be growing at an approximate rate of 550,000 new cases each year due to, among other things, overall demographic aging. CHF can be conceptualized as an enlarged weakened heart muscle. The impaired heart muscle results in poor cardiac output of blood. Consequently, pulmonary vascular pressures may be elevated to the point that fluid leaks from the pulmonary capillaries into the lungs, affecting normal oxygen exchange. For this reason, pulmonary edema can be an indicator of CHF.

[0004] Pulmonary edema can present a medical emergency that requires immediate care. The outlook for pulmonary edema patients can be good if detected early and treated promptly. If left undetected, and consequently untreated, pulmonary edema can lead to extensive hospitalization and even death.

[0005] US 2007/179389 A1 discloses a system comprising:

- an implantable medical device including: an electrical impedance measuring circuit configured to measure at least one thoracic impedance-indicating signal characteristic, including at least a fluid status component, using information about electrical energy injected between the same or different two or more electrodes; and a memory for storing measured values; and
- an external memory circuit including a histogram comprising a plurality of histogram bins, each bin representing a subrange of thoracic impedance-indicating signal characteristic values, the memory circuit configured for storing the at least one thoracic impedance-indicating signal characteristic into a histogram bin having a numerically inclusive subrange; and
- a processor circuit including an input to receive and use information about the at least one thoracic impedance-indicating signal characteristic to compute and provide a lung fluid status indication.

[0006] Further, EP-A-1 604 705 discloses a method of handling information relating to cardiac condition which includes selecting a cross-correlation frequency having an associated cross-correlation period, detecting and binning a heart rate in a heart rate bin, detecting an binning an activity state in an activity state bin, then repeating the detecting and binning a heart rate and the detecting and binning an activity state during a cross-correlation period. The products of the bin count of the heart rate bins and the bin count of the activity state bins are summed to provide a cross-correlation index for the cross-correlation period.

OVERVIEW

[0007] The present invention is defined by a system comprising the features of claim 1 and a method comprising the features of claim 10. Preferred embodiments of this system and method, respectively, are represented in the corresponding dependent claims.

[0008] The present inventors have recognized, among other things, that one problem presented by worsening heart failure is its timely detection and treatment. The present inventors have further recognized an unmet need for enhanced sensitivity or specificity of ongoing chronic monitoring for actual or impending excess fluid accumulation in the thoracic region of a subject, such as the subject's lungs, before the need for hospitalization arises.

[0009] According to the aspect of the present invention, a system comprises an implantable medical device, including an electrical impedance measurement circuit configured to measure at least one thoracic impedance-indicating signal characteristic, including at least a fluid status component, using information about electrical energy injected between two or more electrodes and a potential difference created thereby between the same or different two or more electrodes, and a memory circuit including a histogram comprising a plurality of histogram bins, each bin representing a subrange

of thoracic impedance-indicating signal characteristic values, the memory circuit being configured for storing a value representative of the at least one thoracic impedance indicating signal characteristic into one of the histogram bins having a numerically inclusive subrange, wherein each histogram bin includes a corresponding count indicative of a number of thoracic impedance-indicating signal characteristic values detected during a particular time period and falling within the subrange of the corresponding histogram bin, and wherein the memory circuit further includes a counter circuit configured to increment, for each thoracic impedance-indicating signal characteristic value stored in a particular histogram bin, the count for the corresponding histogram bin;

a comparator circuit configured to compute a deviation-using one or more histogram bins received from the memory circuit and one or more corresponding baseline histogram bins having substantially the same numerical subrange; and

a processor circuit including an input to receive and use information about the deviation to compute and provide a lung fluid status indication.

[0010] According to a preferred embodiment, the system comprises a trigger circuit to trigger a thoracic impedance-indicating signal measurement synchronized with a refractory portion of a subject's cardiac cycle, wherein the trigger circuit comprises at least one of a timing circuit or a cardiac sensor circuit.

[0011] According to another preferred embodiment, the system comprises a posture sensor configured to produce a posture signal indicative of a posture of a subject, the posture sensor configured to trigger a thoracic impedance-indicating signal measurement when the posture signal is indicative of a substantially upright orientation.

[0012] According to a further preferred embodiment, the system comprises a histogram-selective circuit configured to select one or more histogram bins representative of a reduced subrange of the histogram; and wherein the processor circuit is configured to use the reduced subrange of the histogram to compute and provide the lung fluid status indication, the reduced subrange representing an upper-percentile of the histogram or an intra-percentile range of the histogram.

[0013] According to a still further preferred embodiment the processor circuit is configured to compute a central tendency of one or more values stored in the selected one or more histogram bins, which are representative of the reduced subrange; and wherein the processor circuit is configured to use the central tendency of the reduced subrange of the histogram to compute and provide the lung fluid status indication.

[0014] According to a still further preferred embodiment the memory circuit is configured for storing a value of the at least one thoracic impedance-indicating signal characteristic into the histogram bin having a numerically inclusive subrange; and the comparator circuit is configured to compute, as the deviation,-a difference between an average of thoracic impedance-indicating signal characteristic value data of the one or more histogram bins previously received and the thoracic impedance-indicating signal characteristic value data of the one or more baseline histogram bins.

[0015] According to a still further preferred embodiment, the system comprises an external user-interface device communicatively coupled to the implantable medical device and including a user-detectable indication, the user-detectable indication configured to provide a display of at least one of received information about thoracic impedance-indicating signal characteristic data of one or more histogram bins, a trend over time of impedance summary information computed from one or more portions of the histogram, or the computed lung fluid status indication.

[0016] According to a still further preferred embodiment the computed and provided lung fluid status indication includes a pulmonary edema event indication.

[0017] According to a still further preferred embodiment the at least one thoracic impedance-indicating signal characteristic includes a respiration component.

[0018] According to another aspect of the present invention a method comprises: measuring, using an electrical impedance measurement circuit, at least one thoracic impedance-indicating signal characteristic including a fluid status component, the measuring using information about electrical energy injected between two or more electrodes and a potential difference created thereby between the same or different two or more electrodes;

storing in a histogram bin of a memory circuit that includes a histogram that includes a plurality of histogram bins representing corresponding subranges of thoracic impedance-indicating signal characteristic values, a count indicative of a number of thoracic impedance-indicating signal characteristic values detected during a particular time period and falling within the subrange of the histogram bin;

computing, using a comparator circuit, a deviation indicative of a difference in a number of counts between at least one histogram bin of a short-term histogram received from the memory circuit and at least one corresponding bin, having substantially the same numerical subrange, of a baseline histogram; and

providing, using a processor circuit, a lung fluid status indication using information about the deviation.

[0019] According to a preferred embodiment the method further comprises storing a value of the at least one thoracic impedance-indicating signal characteristic;

and

wherein providing the lung fluid status indication includes correlating a reduction over time in the central tendency of one or more values stored in the selected one or more histogram bins with an indication of present or impending fluid accumulation.

[0020] According to another preferred embodiment computing the lung fluid status indication further includes correlating

a reduction over time in the number of counts of one or more values stored in the selected one or more histogram bins with an indication of present or impending fluid accumulation.

[0021] The present systems and methods can enhance thoracic fluid monitoring by reducing data storage or signal processing needed. This can reduce implanted device size or increase its longevity. The foregoing can be made possible by, among other things, storing information about at least one thoracic impedance-indicating signal characteristic in one of a number of histogram bins. Each histogram bin can numerically represent a different subrange of thoracic impedance-indicating signal characteristic values from an expected range. Thoracic fluid monitoring complexity can be reduced by using information about a count of thoracic impedance signal characteristic values stored in one or more of the histogram bins to compute a lung fluid status indication. Thoracic fluid monitoring can also be made more accurate, such as by using information about a selected portion of a histogram array. For example, information about an upper-quartile portion or intra-quartile portion of the histogram array can be used to compute the lung fluid status indication. The patent is defined by the appended claims. Other examples, advantages, and features of the present fluid monitoring systems and methods will be set forth in part in following Detailed Description. This Overview is intended to provide an overview of subject matter of the present patent application. It is not intended to provide an exclusive or exhaustive explanation of the invention. The Detailed Description is included to provide further information about the present patent application.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] In the drawings, like numerals may be used to describe similar components throughout the several views. Like numerals having different letter suffixes may be used to represent different instances of similar components. The drawings illustrate generally, by way of example, but not by way of limitation, various embodiments discussed in the present document.

FIG. **1** is a block diagram illustrating examples of various causes and indications of pulmonary edema in a subject.

FIG. **2** is a schematic view of an example of a system configured for monitoring excess fluid accumulation in the thoracic region of a subject by computing and providing a lung fluid status indication, the indication found using information organized and stored in one or more histogram bins.

FIG. **3** is a schematic view illustrating an example implant site of portions of a system configured for monitoring excess fluid accumulation in the thoracic region of a subject by computing and providing a lung fluid status indication, the indication found using information organized and stored in one or more histogram bins.

FIG. **4** is a block diagram illustrating an example of an implantable memory circuit used by a fluid monitoring system to organize and store at least one thoracic impedance-indicating signal in one of a number of histogram bins.

FIGS. **5A-5B** are block diagrams illustrating portions of an example system configured for monitoring excess fluid accumulation in the thoracic region of a subject by computing and providing a lung fluid status indication, the indication found using information organized and stored in one or more histogram bins.

FIG. **6** is a graphical display illustrating an example of a histogram array stored in a memory circuit, information of which can be used by a fluid monitoring system to compute and provide a lung fluid status indication.

FIG. **7** is a graphical display illustrating an example of a trend over time of information stored in one or more portions of a histogram array, such trend indicative of present or impending fluid accumulation.

FIG. **8** is a block diagram illustrating an example of a regimen control circuit for use in the present system, the system being configured for monitoring excess fluid accumulation in the thoracic region of a subject using information organized and stored in one or more histogram bins.

FIG. **9** is a block diagram illustrating an example method of monitoring excess fluid accumulation in the thoracic region of a subject by computing and providing a lung fluid status indication, the indication found using information organized and stored in one or more histogram bins.

DETAILED DESCRIPTION

[0023] Excess fluid accumulation in a region of a subject is typically referred to simply as "edema." Edema can be conceptualized as a failure or decompensation of one or more homeostatic processes within the subject's body. The body normally prevents the accumulation of fluids therewithin by maintaining adequate pressures and concentrations of salts and proteins, and by actively removing excess fluid. If a disease affects any of these normal bodily mechanisms or if the normal bodily mechanisms are unable to keep up with the fluid accumulation, the result can be edema, such as pulmonary edema.

[0024] There are several conditions or diseases that can cause or affect pulmonary edema. As shown in FIG. 1, this

includes, among others, heart failure **102,** left-sided myocardial infarction **104,** high blood pressure **106,** altitude sickness **108,** emphysema **110,** cancers that affect the lymphatic system **112,** diseases that disrupt protein concentrations **114,** or epithelial pathologies **116,** such as those caused by inhalation of toxic chemicals, leading to flooding of the alveoli. While pulmonary edema **100** can be a sign of many conditions or diseases, the prospect that pulmonary edema **100** can be a sign of failing heart circulation **102** is often of first concern to caregivers (e.g., health care professionals) due to the severity of its nature. Unfortunately, the first indication that an attending caregiver typically has of an occurrence of pulmonary edema **100** is very late in the disease process, such as when it becomes physically manifested by swelling **118,** noticeable weight gain **120,** jugular venous distension **122,** or breathing difficulties **124** that are so overwhelming as to be noticed by the subject, who then proceeds to be examined by his or her caregiver. For a heart failure subject, hospitalization at such a physically apparent time will likely be required.

[0025] In an effort to timely and accurately detect impending edema, such as pulmonary edema, and avoid its associated hospitalizations, the present ambulatory fluid monitoring systems and methods compute and provide a lung fluid status indication using information about at least one thoracic impedance-indicating signal characteristic stored in one of a number of histogram bins. Each histogram bin represents a numerical subrange of an array of expected thoracic impedance-indicating signal characteristic values, and is configured to quantifiably store the occurrence of numerically inclusive thoracic impedance-indicating signal characteristics measured by an electrical impedance measurement circuit. For each thoracic impedance-indication signal characteristic value stored in a given histogram bin, a count of values for that bin is incremented. Thus, over a given time period, many measurements can be efficiently stored. This histogram-based information, upon storing, can thereafter be used to estimate the probability distribution or summary statistics of thoracic impedance-indicating values for the given time period. This can be used to compute and provide a lung fluid status indication having potentially enhanced sensitivity (e.g., effectively detect a condition that a user desired to detect or treat) or specificity (e.g., avoid erroneous or "false" detections of the condition that a user desires to detect or treat).

Examples:

[0026] FIG. **2** shows a heart **202** and lungs **204** (left), **206** (right) of a subject **208** (via a cut-away portion **210),** and an example of an ambulatory system **200** configured for monitoring excess fluid accumulation in a thoracic region, such as the lungs. The monitoring can use information about at least one thoracic impedance-indicating signal characteristic implantably stored in one of a plurality of histogram bins. In various examples, such monitoring can occur in the comfort of one's own home **280.** Each histogram bin represents a numerical subrange of a range of thoracic impedance-indicating signal characteristic values. Each histogram bin can be configured to quantifiably store the occurrence of numerically inclusive thoracic impedance-indicating signal characteristics, such as can be measured by an electrical impedance measurement circuit.

[0027] In FIG. **2,** the system **200** includes a pectorally-implanted medical device (IMD) **212,** which is coupled via one or more electrode-bearing leads **214** to the heart **202** of the subject **208.** In this example, the system **200** can also include one or more programmers, medical data storage systems **270,** or other external user-interface devices **216** (nearby), or **218** (distant) providing communications with the IMD **212,** such as by using telemetry **220** or another communication network **222.** As shown, the one or more external user-interface devices **216, 218** can include, among other things, a user-detectable indication **224,** a user input device **226,** and a processor circuit **230.** The user-detectable indication **224,** such as an LCD or LED or other display, can textually or graphically relay information collected by the IMD **212** or information about a lung fluid status indication computed by the processor circuit **230** using the IMD collected information. The user input device **226** is configured for receiving programming information from a user and communicating the programming information to the IMD **212.** A wearable device **228** can be used to extend the communications range between the IMD **212** and the nearby external user-interface device **216** or the communication network **222** without substantially increasing battery usage of the IMD **212.**

[0028] As shown, the IMD **212** can include a housing **232** that houses the electrical impedance measurement circuit **250** configured for measuring the at least one thoracic impedance-indicating signal characteristic and a memory circuit **252** configured for implantably storing the at least one thoracic impedance-indicating signal characteristic in one of a number of histogram bins having a numerically inclusive subrange. The IMD **212** can include a left ventricular port in a header **234** thereof for receiving a proximal end of an electrode-bearing left ventricular lead **214.** A distal end of the left ventricular lead **214** can be introduced into the venous system, down the superior vena cava, into the right atrium **236,** into a coronary sinus through an orifice **238,** and then further into a coronary vein, which runs epicardially over the left ventricle **240.**

[0029] In the example shown, the left ventricular lead **214** includes two electrodes **242, 244** that are electrically connected to respective conductors that run through the lead **214.** The conductors connect to conducting wires within the IMD **212** when the left ventricular lead **214** is received by the left ventricular lead port, thereby establishing electrical connections between the electrical impedance measurement circuit **250** and the electrodes **242,** 244. In this example, the electrode **242** can be referred to as a left ventricular proximal electrode, while electrode **244** can be referred to as

a left ventricular distal electrode, due to their relative positioning on the left ventricular lead **214.** While the left ventricular lead **214** shown in FIG. **2** is bipolar in nature, the lead **214** can optionally include additional or fewer electrodes and can further follow a different path through the heart **202** from that shown and described.

[0030] A housing electrode **254** on an exterior surface of the IMD housing **232** can be electrically connected to the electrical impedance measurement circuit **250** to complete a tripolar electrode configuration in which electrical energy (e.g., current) is injected between a lead electrode, such as the left ventricular distal electrode **244,** and the housing electrode **254,** and a potential difference (i.e., voltage) created by the injected energy can be measured between the other lead electrode-in this example, the left ventricular proximal electrode **242-** and the housing electrode **254.** The IMD **212** can optionally include a second housing or header electrode **256** to facilitate a tetrapolar electrode configuration in which electrical energy is injected, for example, between a the left ventricular distal electrode **244** and the housing electrode **254,** and a responsive potential difference created by the energy is measured between the left ventricular proximal electrode **242** and the header electrode **256.** Using information about the injected electrical energy and the resulting potential difference, an impedance calculator (e.g., within the electrical impedance measurement circuit **250)** can calculate a thoracic impedance-indicating signal characteristic such as by taking the ratio of measured voltage to injected current. An impedance-indicating signal characteristic, such as amplitude of the impedance signal, for example, can then be communicated to memory **252** for storing in the appropriate one of a number of histogram bins, such as by incrementing the count of the histogram bin representing an impedance range into which the measured impedance amplitude falls.

[0031] FIG. **3** illustrates that the IMD **212** can include not only a left ventricular port in the header **234** thereof for receiving the proximal end of the left ventricular lead **214,** but can also include a right atrial port for receiving a proximal end of an electrode-bearing right atrial lead **302.** A distal end of the right atrial lead **302** is shown in this example as being introduced into the venous system, down the superior vena cava, and into the right atrium **236.** In the example shown, the right atrial lead **302** includes two electrodes **304, 306** that are electrically connected to conductors that run through the lead **302.** The conductors connect to conducting wire within the IMD **212** when the right atrial lead **302** is received by the right atrial lead portion, thereby establishing electrical connections between the electrical impedance measurement circuit and the electrodes **304, 306.** In this example, the electrode **304** can be referred to as a right atrial proximal electrode, while electrode **306** can be referred to as a right atrial distal electrode, due to their relative positioning on the right atrial lead **302.** While the right atrial lead **302** shown in FIG. 3 is bipolar in nature, the lead **302** can optionally include additional or fewer electrodes and can follow a different path through the heart **202** from that shown.

[0032] Including the right atrial lead **302** in FIG. **3** provides a tetrapolar electrode configuration for measuring thoracic impedance-indicating signal characteristics. In such an example, electrical energy can be injected between the housing electrode **254** and the left ventricular distal electrode **244.** A potential difference created by the energy can be measured between left ventricular proximal electrode **242** and one of the right atrial proximal electrode **304** or the right atrial distal electrode **306.** In this example, should the left ventricular lead **214** not be available, thoracic impedance-indicating signal characteristics can still be measured, such as by injecting electrical energy between the housing electrode **254** and the right atrial distal electrode **306.** A potential difference created by the energy can be measured between the housing **254** or header **256** electrode and the right atrial proximal electrode **304.**

[0033] The human body includes a number of thoracic organs, tissues, and fluids. Measurement of thoracic impedance can include contributions from each. For example, resistivities of the heart muscle, lungs, pectoral muscle, pectoral fat, liver, kidneys, spleen, stomach, skeletal muscle, bone, cartilage, blood and other tissues and fluids each can contribute to a measurement of thoracic impedance. As such, changes in measured thoracic impedance can be caused by changes in the resistivities of these and other organs or tissues.

[0034] Thus, when measuring impedance, such as thoracic impedance, to detect or assess one or more pathologies or conditions, such as pulmonary edema, it can be desirable to measure the impedance-indicating signals using one or more electrode configurations that are more sensitive to a particular region(s) of interest. In the examples of FIGS. **2-3,** placement of the left ventricular lead **214** and the right atrial lead **302** near the left ventricle **240** and the right atrium **236** of the heart **202,** respectively, provide an example of a suitable location for measuring thoracic impedance, and more specifically heart and lung impedance, due to the proximity of the heart and lungs **204, 206** thereto. Although not shown, a right ventricular lead having right ventricular electrodes can also be used in one or more thoracic impedance measurement configurations.

[0035] In various examples, the electrical impedance measurement circuit **250** within the IMD **212,** in conjunction with the lead **214, 302,** header **256,** or housing **254** electrodes, measure thoracic impedance-indicating signal characteristics by injecting a relatively small amplitude electrical energy (e.g., a current) between at least two implanted electrodes and concurrently measuring an responsive induced potential difference (i.e., a voltage) between the same or different at least two implanted electrodes, such as discussed above. Because the magnitude of the injected electrical energy is typically specified, the measurement of the responsive potential difference allows for a thoracic impedance-indicating signal characteristic measurement to be determined, such as from Ohm's law (e.g., by taking a ratio of measured voltage to injected current).

[0036] In various examples, the thoracic impedance-indicating signal characteristic measured includes-listed in order from generally higher frequencies to generally lower frequencies-information about the subject's heart contractions (stroke component), the subject's breathing (respiration component), and the subject's edema (fluid status component). As fluid accumulates in the lungs due to pulmonary edema, such as from a low fluid level to a higher fluid level, the impedance-indicating signal decreases in value permitting pulmonary edema to be detected. Without being bound by theory, it is believed that the respiration component may also be affected by thoracic fluid accumulation.

[0037] The IMD **212** can include one or both of a timing or cardiac sensor circuit (see FIG. **5A**) to synchronize impedance sampling to occur at a particular portion of the subject's cardiac cycle, such as within a refractory portion of the subject's cardiac cycle. During such refractory periods, sense amplifiers for detecting the intrinsic electrical heart signals are "blanked" or otherwise configured to be less likely to detect intrinsic electrical depolarizations that are indicative of intrinsic heart contractions. This avoids the possibility of the delivered test current somehow being erroneously detected by such sense amplifiers as indicating an intrinsic electrical depolarization corresponding to an intrinsic heart contraction. Such an erroneous detection, in turn, could trigger delivery of inappropriate responsive therapy. Synchronizing thoracic impedance sampling to a refractory portion of a cardiac cycle is consistent with established techniques for thoracic impedance sampling, such as thoracic impedance determination of a minute ventilation signal for controlling pacing rate of a rate-responsive pacer. Because no analogous difficulties exist with respect to the respiration component of the thoracic impedance signal, the measured thoracic impedance signal need not be synchronized to a particular portion of the respiration cycle of the measured thoracic impedance signal. Therefore, the measured impedance signal generally can include at least a respiration component.

[0038] FIG. **4** is a block diagram illustrating one conceptual example of an implantable memory circuit **252** that can be used by the present fluid monitoring system **200.** A classification circuit **402** of the memory circuit **252** is configured to organize and store digitized thoracic impedance-indicating signal characteristic measurements in one of a number of bins collectively comprising a histogram. The histogram can be divided into a programmable number of bins (e.g., 255 bins). Each bin can represent a corresponding subrange of thoracic impedance-indicating signal characteristic amplitude values. Each bin can also include a corresponding count representing the number of samples detected during a particular time period that fell within the subrange of that bin. In certain examples, this count can be implemented as a memory location storing a count value. In certain examples, such bin count memory locations can be included in a counter circuit **404** that increments the appropriate bin's count of the number of impedance samples falling into that bin's subrange of values. Using the histogram approach, over a given time period many measurements can be efficiently stored in the histogram. The histogram, or portions thereof, can be used to estimate the probability distribution or summary statistics of the impedance values for the given time period.

[0039] In an example, the bins collectively form an intraday histogram. The intraday histogram can store part of a day's worth of thoracic impedance-indicating signal characteristic data. A new intraday histogram array can be acquired and populated with impedance signal measurements several times daily, if desired. In some examples, the IMD **212** (FIG. **2**) can store about 90 days worth of intraday histograms in a buffer, and after 90 days, can overwrite the oldest histograms with newly acquired histograms. A daily or other short-term histogram can also be computed in certain examples, such as directly or by aggregating that day's intraday histograms, for example. In various examples, an internal or external processor circuit includes an input to receive thoracic impedance histogram information, and is configured to use such information to compute and provide a lung fluid status indication, such as further discussed below.

[0040] FIGS. **5A-5B** are block diagrams illustrating generally, by way of example, but not by way of limitation, portions of an example system **200** configured for using thoracic impedance histogram information for monitoring fluid accumulation status in a subject's thoracic region, such as a subject's left **204** or right **206** lungs. In this example, the system **200** includes a hermetically sealed IMD **212** coupled to a subject's heart **202** such as by one or more electrode-bearing intravascular leads. The example of FIG. **5A** illustrates use of a left ventricular lead **214** having electrodes **242, 244** or a right atrial lead **302** having electrodes **304, 306.** As shown in FIG. **5B,** the system **200** can further include one or more programmers or other external user-interface devices **216** (nearby), **218** (distant). The IMD **212** includes circuitry for, among other things, measuring thoracic impedance-indicating signal characteristics, efficiently storing the impedance-indicating signals, and interfacing with external components.

[0041] In the example of FIG. **5A,** an electrical impedance measurement circuit **250** can include an injected electrical energy generator circuit **508,** a voltage measurement circuit **510,** an analog-to-digital (A/D) converter, and a calculation circuit **512** to compute and provide a thoracic impedance-indicating signal characteristic to a memory circuit **252** for efficient storage, as discussed above for FIG. **4.** The electrical energy generator circuit **508** can be configured to generate and inject a sub-stimulation current or other electrical energy between at least two electrodes, such as excitation electrodes (e.g., left ventricular distal electrode **244** and can electrode **254**). In one example, the injected current is AC in nature and has a frequency of about 4 KHz-100 KHz.

[0042] The injection current creates an electric field in a subject's body. Thus, a voltage potential appears between, for example, the left ventricular proximal electrode **242** and header electrode **256.** A voltage measurement circuit **510** is configured to then measure this voltage between electrodes **242** and **256,** for example. The voltage measurement

circuit **510** can include a demodulator. In various examples, the particular electrodes used to inject the energy and to measure the resulting potential difference can be selected by an electrode configuration switch circuit **516.**

[0043] The calculation circuit **512** receives, measures, or includes information on the magnitudes of both the injected current and the resulting measured voltage. An analog-to-digital (A/D) converter, within or outside of the calculation circuit **512,** can be used to translate the information. Other signal processing or frequency-selective filtering can (but need not) be performed. Once digitized, these values can be applied as inputs to the calculation circuit **512** for calculating a thoracic impedance-indicating signal characteristic, such as by dividing the measured voltage by the injected current. As body tissue fluid levels increase, the tissue impedance decreases. Thus, the impedance can be used to assess pulmonary edema, and a degree of pulmonary edema can be determined for the subject.

[0044] Information from one or more sensor circuits, such as a posture sensor circuit **520,** a cardiac sensor circuit **522,** or a respiration sensor circuit **524,** can be input to an internal processor circuit **514** and used to adjust the relationship (via a state correction circuit **526**) between the measured thoracic impedance-indicating signal characteristics and the degree of edema or ensure certain impedance sampling parameters are met. For instance, the posture sensor circuit **520** may provide subject orientation information to the state correction circuit **526.** This allows posture compensation to be included in the assessment of edema. Because organs and excess fluid in the thorax and lungs can shift with posture changes due to gravity, measured impedance may vary as a subject **208** (FIG. **2**) assumes different positions. For example, when a subject **208** lies on his/her right side, fluid and tissues in the left lung **204** may gravitate towards the mediastinum near the left ventricular lead electrodes **242, 244** resulting in lower measured impedance. Thus, based on posture sensor information, the relationship between the impedance-indicating signal measurement and the degree of edema may be adjusted to compensate. Similarly, that relationship may be inversely adjusted for a subject lying on his/her left side. One or more of several types of posture sensors could be used, including one or any combination of a mercury switch, a tilt switch, a single axis accelerometer, a multi-axis accelerometer, or piezoresistive or other devices.

[0045] A respiration sensor circuit **524,** such as a minute ventilation (MV) sensor, motion sensor, strain gauge on the diaphragm, or other activity sensor, can also provide information to the state correction circuit **526.** The respiration sensor circuit **524** can provide breathing cycle information to the state correction circuit **526.** This information can be used for verifying that an impedance sampling period is greater a corresponding respiration cycle, such as to ensure that one or more respiratory components are retained and included in the thoracic-impedance indicating signal, if desired.

[0046] The IMD **212** can further include a timing **550** or other circuit, such as the cardiac sensor circuit **522** that can detect cardiac rate or amplitude, such as to synchronize impedance sampling to a specified portion (e.g., a refractory portion) of the subject's cardiac cycle. This helps reduce the chance of the delivered impedance test current being erroneously detected as a heart depolarization by sense amplifiers for detecting intrinsic electrical heart signals. Any of the sensors **520, 522,** or **524** can optionally be excluded from the IMD **212.**

[0047] A communication circuit **506** within the IMD **212** can be configured for wirelessly communicating with a communication circuit of the nearby external user-interface device **216.** In certain examples, the communication circuit **506** is configured for wirelessly communicating with a communication circuit of a distant external user-interface device **218,** such as by using a nearby external communication repeater **570.** In one such example, the external communication repeater **570** is coupled to the distant external user-interface device **218** such as via an Internet or telephone communication network **222.** The Internet or telephone communication network **222,** in certain examples, allows the external communication repeater **570** to communicate with electronic medical data storage system **270.**

[0048] The external user-interface devices **216, 218** can include, among other things, an input **572** to receive thoracic impedance histogram information from the memory circuit **252** and an external processor circuit **230** to use such received information to compute and provide a lung fluid status indication. The external user-interface devices **216, 218** can further include a user-detectable indication **224,** such as for textually or graphically relaying information collected via input **572** or information about the lung fluid status indication computed by the processor circuit **230.** In addition, the external user-interface devices **216, 218** can include a user input device **226** for receiving programming information from a user and communicating the programming information to the IMD **212.**

[0049] To compute and provide the lung fluid status indication, the external processor circuit **230** can include a histogram-selective circuit **580,** a calculation circuit **582,** a comparator circuit **584,** and a fluid accumulation determination circuit **554.** The histogram-selective circuit **580** can be configured to select one or more histogram bins representative of certain histogram portion, such as an upper-quartile histogram portion, for use in computing the lung fluid status indication. The calculation circuit **582** can be configured to receive the selected one or more histogram bins to extract a signal count or compute a mean or median or other measure of central tendency of thoracic impedance-indication signal characteristic counts stored in such bins such as by using statistical analysis.

[0050] The count, mean, median or the like can then be output to the comparator circuit **584,** such as for comparison with a stored specified baseline threshold, algorithm, pattern, or histogram, each of which can be based on a subject in a non-edemic state. An initial stored baseline can be preprogrammed into the comparator **584,** and thereafter adjusted up and down using recently measured and stored thoracic impedance-indicating signal characteristic data. It can be determined whether the output data exhibits a characteristic of present or impending lung fluid accumulation, such as

an indication that a deviation between the output data and the baseline is beyond some programmed limit, for example. If the deviation extends beyond such limit, the resulting comparison can be forwarded to a fluid accumulation determination circuit **554.** The fluid accumulation determination circuit 554 can be configured to use such information to provide a lung fluid status indication, such as an indication of present or impending lung fluid accumulation.

[0051] In one example, the comparator circuit **584** is configured to compute a deviation between one or more portions of a daily histogram array and a baseline histogram array using the following equation:

$$\Delta z_n = \frac{1}{C_n} \sum_{i=1}^{I} z_i \left(c_{ni} - \frac{C_n}{B_n} b_{ni} \right) \qquad \textbf{[Equation 1]},$$

where c_{ni} represents the count in the ith histogram bin of the nth day's daily histogram array, b_{ni} represents the count in the ith bin of the baseline histogram array, C_n is the total number of the current day's daily histogram array counts, B_n is the total number of the baseline histogram array counts, I is the total number of histogram array bins, and z_i is the thoracic impedance-indication signal value corresponding to the ith bin. If the above equation yields a value below a specified threshold value, then the fluid accumulation determination circuit **554** declares an indication of fluid accumulation to exist. This indication of fluid accumulation can be the sole basis of issuing an alert to a user, or it can be combined or otherwise used with one or more other indications, referred to as "detection enhancements."

[0052] A first such "detection enhancement" integrates a negative difference between Δz_n and the specified threshold value, such as over a period of multiple days. If this integrated value exceeds a specified (different) threshold value, then an indication of fluid accumulation is declared.

[0053] In a second detection enhancement technique, one or more rules require m out of n of the most recent Δz_n samples to meet the specified threshold value before declaring the occurrence of a thoracic fluid accumulation event. In such a case, a single threshold crossing can be referred to as a "tentative event." No alert is provided until m out of the last n days meet the threshold, which is then deemed an actual fluid accumulation event. Multiple such m of n rules may be concurrently employed, e.g. three out of three, three out of four, three out of five, three out of six, four out of seven, etc.

[0054] The specified threshold value, to which Δz_n is compared, can be obtained using a Constant False Alarm Rate (CFAR) detection technique. At least one example of a suitable CFAR detection technique is described in commonly-owned Siejko et al., U.S. Patent Application Serial No. 11/276,735, entitled "PHYSIOLOGICAL EVENT DETECTION SYSTEMS AND METHODS". The caregiver specifies a maximum acceptable rate of false alarms (e.g., 1%) that the caregiver is willing to tolerate. If the baseline histogram has been acquired during a time period that is free of any fluid accumulation events, this baseline histogram can be used as a probability density function (PDF). The user-specified maximum acceptable rate of false alarms maps to a tail area under the PDF curve provided by the event-free baseline histogram. A boundary of the tail area corresponds to the specified threshold value, against which Δz_n is compared. Thoracic impedance-indicating signal characteristic values detected in the bins corresponding to the defined tail of the distribution represent evidence of fluid accumulation events. Since the baseline histogram can change over time, the specified threshold value can be periodically or recurrently re-computed. Such re-computation effectively provides an adaptive threshold that remains consistent with the user-specified maximum acceptable false alarm rate.

[0055] In addition to the fluid accumulation alert described above, the external processor circuit **230** can be capable of computing a representative fluid index value from the daily histogram data array received from the IMD **212.** A trend of the representative fluid index value (e.g., over several or many days) can be displayed for the subject, caregiver, or other user. Advantageously, by externally processing the histogram-stored thoracic impedance information, the IMD's **212** battery life may be prolonged. Notably, internal processing of the histogram-stored thoracic impedance information can also be found advantageous in certain situations, such as in situations where closed-loop systems for disease detection and responsive therapy are warranted and desired.

[0056] In various examples, the system **200** can include a regimen control circuit **552** configured for initiating or adjusting a regimen to a subject **208** (FIG. **2**) at least in part by using thoracic impedance histogram information or an indication of present or impending lung fluid accumulation (e.g., a lung fluid status indication) externally computed from such information and output by a fluid accumulation determination circuit **554.** In an example, such regimen includes electrical stimulation, such as cardiac pacing, resynchronization, cardioversion, or defibrillation stimulation, generated by a regimen pulse generator circuit **502** and delivered via one or more electrodes selected by the electrode configuration switch circuit **516.** The one or more electrodes can be selected individually or in combination to serve as an anode or a cathode in any unipolar, bipolar or multipolar configuration.

[0057] In another example, such regimen is provided elsewhere (e.g., communicated to the nearby external user-interface **216** or delivered via an implantable drug pump **504**) and includes, for example, a drug dose, a diet regimen, or a fluid intake regimen. In one example, the drug dose can include a set of one or more drug regimen instructions

communicated and displayed on the nearby external user-interface **216,** such as in the form of the user-detectable indication **224.** In certain examples, the set of drug regimen instructions includes a suggested daily intake schedule of one or more drugs, such as antiotension-converting enzyme (ACE) inhibitors, beta blockers, digitalis, diuretics, vasodilators, or the like. In certain examples, the drug dose can be automatically delivered per the suggested daily intake schedule via the implantable drug pump **504** or another drug dispensing device provided within the IMD **212** or implanted nearby and coupled thereto. In certain examples, the drug dose can be delivered per the suggested daily intake schedule via external (e.g., electronic) drug dispersing devices.

[0058] In a similar manner, the diet regimen and the fluid intake regimen can be communicated to the subject **208** via the user-detectable indication **224** of the nearby external user-interface **216.** In an example, the diet regimen can include a set of one or more dietary instructions to be followed by the subject **208,** such as restriction of sodium to 2 grams or less per day and no more than one alcoholic drink per day. In another example, the fluid intake regimen can include a set of one or more fluid intake instructions to be followed by the subject **208,** such as to avoid consuming an excess amount of fluid. **FIGS. 5A-5B** illustrate just one example of various circuits, devices, and interfaces of the system **200,** which are implemented either in hardware or as one or more sequences of steps carried out on a microprocessor or other controller. Such circuits, devices, and interfaces are illustrated separately for conceptual clarity; however, it is to be understood that the various circuits, devices, and interfaces of FIGS. **5A-5B** need not be separately embodied, but can be combined or otherwise implemented. As an example, an internal or an external processor circuit can include an input to receive thoracic impedance histogram information, and can be configured to use such information to internally or externally compute and provide a lung fluid status indication.

[0059] FIG. **6** is a graphical display illustrating a histogram **600,** such as an intraday histogram, stored in a memory circuit **252** (FIG. **2**). The horizontal axis of the histogram **600** lists the impedance bin subranges. The vertical axis indicates the relative number of signal counts present in each subrange. In this example, the histogram **600** includes eight histogram bins (bin #1, bin #2, . . . , bin #8). Each such bin represents a subrange of expected thoracic impedance-indicating signal characteristic amplitude values. Each such bin is configured to quantifiably store the occurrence of numerically inclusive thoracic impedance-indication signals measured by an electrical impedance measurement circuit **250** (FIG. **2**). For each thoracic impedance-indication signal value acquired that corresponds to the subrange of a given histogram bin, a count of values for that bin can be incremented. As shown in FIG. 6, bin #1 has a count of approximately C_1, bin #2 has a count of approximately C_3, bin #3 has a count of approximately C_5, bin #4 has a count of approximately C_7, bin #5 has a count of approximately C_7, bin #6 has a count of approximately C_4, bin #7 has a count of approximately C_2, and bin #8 has a count of approximately C_1. As discussed above, an external processor circuit **230** (FIG. **2**) is configured to receive and use such thoracic impedance histogram information to compute and provide a lung fluid status indication.

[0060] FIG. 7 is a graphical display illustrating a conceptualized (not real data) trend **700** over time of impedance summary information computed from one or more portions of a histogram array, such as an upper-quartile portion of the histogram array (see, e.g., bins #7 and #8 of FIG. **6**). In the example shown, the impedance summary information from the one or more portions of the histogram array has a decreasing trend over time. A decreasing trend in histogram-based impedance values can indicate present or impending fluid accumulation, such as pulmonary edema. The upper-quartile portion of the histogram array is representative of higher thoracic impedance-indicating signal characteristic values than the remaining quartiles of the histogram array. Thus, a reduction over time in the number of counts, mean, median or the like of the upper quartile portion of the impedance histogram can indicate a shift of the histogram toward lower impedance signal values. This can correlate to an indication of present or impending fluid accumulation in the lungs **204, 206** (FIG. **2**). Information about such a decrease can be used by the present system **200** (FIG. **2**) to further specify an indication of lung fluid status. The graphical display illustrating the trend **700** over time can be received and displayed on an external user-interface device **216, 218** (FIG. **2**), such as on an user-detectable indication screen **224.**

[0061] Without being bound by theory, the present inventors have recognized that an upper-quartile portion of a histogram may exhibit the largest diurnal variation when comparing thoracic fluid status levels between a healthy (baseline) subject to a fluid overload subject. This is because higher thoracic impedance signal values are typically measured two, three or more hours after a subject wakes from a supine sleep position. After awaking, the subject will often assume some sort of upright posture position in which fluid that has flowed toward the thoracic region during supine sleep slowly drains away from such region over time. For healthy subjects, the increase in thoracic impedance during such time is relatively large; however, for fluid overload subjects, the increase in thoracic impedance may less pronounced. Thus, it is believed that comparing a fluid overload subject's largest measured short-term thoracic impedance-indicating signal characteristic values (e.g., mean or median of the histogram's upper-quartile) or number of upper-quartile bin counts to that of a healthy baseline subject may provide a user with enhanced fluid accumulation status information, such as for determining the presence or absence of pulmonary edema. One or more of a sleep state detector circuit, an activity sensor circuit, or a posture sensor circuit **520** (FIG. **5A**) can be used to recognize sleep and awake subject states.

[0062] There are a variety of underlying conditions that may lead to thoracic fluid build-up, more specifically pulmonary edema, and a variety of regimen approaches targeting such conditions. The selection of the regimen approach, and the parameters of the particular regimen approach selected, can be a function of the underlying condition and a severity of

such condition. For this reason, the present system **200** (FIG. **2**) can include a regimen control circuit **550** to appropriately select a regimen given a subject's detected health status.

[0063] FIG. **8** is a block diagram illustrating an example of a regimen control circuit **552,** which can be used to trigger one or more regimens (e.g., therapies) to a subject **208** (FIG. **2**). A regimen can be triggered in response to thoracic impedance histogram information or a resulting indication of present or impending lung fluid accumulation status indication. The fluid status indication can be externally computed from such information and output by a fluid accumulation determination circuit **554.**

[0064] The regimen control circuit **552** can include an input that receives the indication of present or impending lung fluid accumulation output from the fluid accumulation determination circuit **552.** In an example, a scheduler **802** schedules the indications of present or impending lung fluid accumulation. A regimen decision circuit **804** decides whether some form of regimen is warranted. If a regimen is deemed to be warranted, a regimen selection circuit **806** selects one or more appropriate regimens. A control circuit **808** adjusts the selected regimen via an output to one or more of a regimen pulse generator circuit **502,** a nearby external user-interface **216,** or a drug pump **504,** for example.

[0065] The regimen control circuit **552** can include a regimen list **810,** which can relate the regimens of such list **810** to the highest contributor(s) to the indication of present or impending lung fluid accumulation. In an example, the regimen list **810** includes all possible disease state preventive regimens or secondarily related regimens that the present system **200** can deliver or communicate to the subject **208.** The regimen list **810** can be programmed into an IMD **212** (FIG. **2**) either in hardware, firmware, or software and stored in a memory **252** (FIG. **2**).

[0066] In another example, the regimen list **810** includes immediate, short-term, intermediate-term, or long-term fluid accumulation preventive therapies. Immediate fluid accumulation preventive therapies can include, by way of example, initiating or changing a drug dose administered to the subject via an implantable drug pump **504** or electrical stimulation administered to the subject **208** via the regimen pulse generator circuit **502.** Short-term fluid accumulation preventive regimens can include, by way of example, administering a continuous positive air pressure ("CPAP") dose to the subject **208** or notifying a caregiver to initiate or change the subject's drug dose treatment program. Intermediate-term fluid accumulation preventive regimens can include, by way of example, adjusting the subject's **208** lifestyle such as his or her diet or fluid intake regimen. Finally, long-term fluid accumulation preventive regimens can include, by way of example, notifying the subject **208** or caregiver to alter the drug which takes longer to affect the subject (e.g., beta blockers, ACE inhibitors) or administering CRT to the subject **208.**

[0067] Each member of the regimen list **810** can be associated with a corresponding time of action, which can include information about one or more of a time for the regimen to become effective or a time after which the regimen is no longer effective. In one example, only one member of the regimen list **810** is invoked at any particular time. In another example, one or more combinations of different regimens are provided at substantially the same time. The various subcircuits in the regimen control circuit **552** are illustrated as such for illustrative purposes only; however, these subcircuits can alternatively be incorporated in the fluid accumulation determination circuit **554** or elsewhere, such as being implemented as a set of programmed instructions performed by a general purpose controller or other circuit.

[0068] FIG. **9** is a block diagram **900** illustrating one example of a method of monitoring excess fluid accumulation in the thoracic region of a subject. This can involve monitoring one or both of a subject's lungs using thoracic impedance histogram information. Each histogram bin represents a subrange of expected thoracic impedance-indicating signal characteristic values. Each histogram bin can be configured to quantifiably store the occurrence of numerically inclusive thoracic impedance-indicating signal characteristic measurements measured by an electrical impedance measurement circuit. At **902,** one or more thoracic impedance-indicating signal characteristics including at least a respiration component and a fluid status component are measured. At **904,** a cardiac stroke component of the one or more thoracic impedance-indicating signal characteristics is optionally attenuated. In various examples, one or both of a timing circuit or a cardiac sensor circuit is used to synchronize the thoracic impedance-indicating signal characteristic measurements, such as to a refractory portion of a subject's cardiac cycle.

[0069] At **906,** the one or more thoracic impedance-indicating signal characteristic measurements are compared to histogram bin subranges to identify an appropriate histogram bin for the measurement. At **908,** a bin count of the appropriate histogram bin is optionally incremented, such as by incrementing a histogram bin counter or memory location stored count value. At **909,** a decision is made as to whether or not complete histogram information has been obtained. If not, the process returns to **902.** If it is determined that complete histogram information has been obtained, the process continues to **910.** At **910,** a first histogram is optionally overwritten with a later second histogram. In this way, newly acquired histograms can overwrite older histograms, such as to prolong battery life of a device associated with the memory storage device.

[0070] At **912,** one or more histogram bins representative of an upper-quartile histogram portion or an intra-quartile range are optionally selected and processed, such as via a processor circuit (see at **916**). At **914,** one or both of a short-term histogram or a baseline histogram is optionally updated using information about thoracic impedance-indicating signal characteristic measured over a period of time. The short-term and baseline histograms can be used to compute and provide a lung fluid status indication. In various examples, the lung fluid status indication provides an indication of

the presence or absence of a thoracic fluid accumulation event, such as a pulmonary edema event.

[0071] At **916,** the lung fluid status indication is internally or externally computed using thoracic impedance histogram information. In one example, histogram bin count information from a particular intraday histogram is used to compute the lung fluid status indication. In another example, a plurality of intraday histograms are aggregated and used to compute the lung fluid status indication. In yet another example, the lung fluid status indication is computed using a deviation between one or more histogram bins of a short-term histogram array and one or more corresponding histogram bins of a baseline histogram array.

[0072] At **918,** a subject is alerted to a detected presence of thoracic fluid accumulation if the computed lung fluid status indication is beyond some programmed limit. At **920,** a regimen for application to the subject is initiated or adjusted in response to the computed lung fluid status indication.

Conclusion:

[0073] Chronic diseases, such as heart failure, require close medical management to reduce hospitalizations, morbidity and mortality, as subjects with heart failure live in a delicate balance. Because such disease status evolves with time, frequent caregiver follow-up examinations are often necessary. This conventional approach of periodic follow-up is unsatisfactory for diseases like heart failure, in which acute, life-threatening exacerbations, such as pulmonary edema, can develop between follow-up examinations. Pulmonary edema is a serious medical condition in which an excess amount of fluid accumulates in or around a subject's lungs. This condition can, and often does, result from heart failure. Pulmonary edema can require immediate care. While it can sometimes prove fatal, the outlook for subjects possessing pulmonary edema can be good upon early detection and prompt treatment.

[0074] Advantageously, the present systems and methods may provide for enhanced thoracic fluid monitoring via less complex data processing and thus, may provide a timelier, more accurate, and potentially cheaper detection of pulmonary edema or other thoracic fluid accumulation than is currently available. In this way, caregivers and heart failure subjects can be provided with a better tool to manage pulmonary edema, and ultimately, heart failure. Such detection is made possible by, among other things, storing at least one thoracic impedance-indicating signal characteristic in one of a number of histogram bins, each histogram bin numerically representing a different subrange of thoracic impedance-indicating signal characteristic values from a range of expected signal values. In one example, thoracic fluid monitoring is made less complex by using information about a count of thoracic impedance signal values stored in one or more of the histogram bins to compute a lung fluid status indication. In another example, thoracic fluid monitoring is made more accurate by using information about a selected portion of a histogram array, such as information about an upper-quartile portion or intra-quartile portion of the histogram array, to compute the lung fluid status indication.

Closing Notes

[0075] The above Detailed Description includes references to the accompanying drawings, which form a part of the Detailed Description. The drawings show, by way of illustration, specific embodiments in which the invention can be practiced. These embodiments are also referred to herein as "examples."

[0076] In this document, the terms "a" or "an" are used, as is common in patent documents, to include one or more than one, independent of any other instances or usages of "at least one" or "one or more." In this document, the term "or" is used to refer to a nonexclusive or, such that "A or B" includes "A but not B," "B but not A," and "A and B," unless otherwise indicated. In this document, the phrase "implantable medical device" or simply "IMD" is used to include, but is not limited to, implantable cardiac rhythm management (CRM) systems such as pacemakers, cardioverters/defibrillators, pacemakers/defibrillators, biventricular or other multi-site resynchronization or coordination devices such as cardiac resynchronization therapy (CRT) device, subject monitoring systems, neural modulation systems, and drug delivery systems. In the appended claims, the terms "including" and "in which" are used as the plain-English equivalents of the respective terms "comprising" and "wherein." Also, in the following claims, the terms "including" and "comprising" are open-ended, that is, a system, device, article, or process that includes elements in addition to those listed after such a term in a claim are still deemed to fall within the scope of that claim. Moreover, in the following claims, the terms "first," "second," and "third," etc. are used merely as labels, and are not intended to impose numerical requirements on their objects.

[0077] Method examples described herein can be machine-implemented or computer-implemented at least in part. Some examples can include a computer-readable medium or machine-readable medium encoded with instructions operable to configure an electronic device to perform methods as described in the above examples. An implementation of such methods can include code, such as microcode, assembly language code, a higher-level language code, or the like. Such code can include computer readable instructions for performing various methods. The code may form portions of computer program products. Further, the code may be tangibly stored on one or more volatile or non-volatile computer-readable media during execution or at other times. These computer-readable media may include, but are not limited to,

hard disks, removable magnetic disks, removable optical disks (e.g., compact disks and digital video disks), magnetic cassettes, memory cards or sticks, random access memories (RAM's), read only memories (ROM's), and the like.

[0078] The above description is intended to be illustrative, and not restrictive. For example, the above-described examples (or one or more features thereof) may be used in combination with each other. Other embodiments can be used, such as by one of ordinary skill in the art upon reviewing the above description. Also, in the above Detailed Description, various features may be grouped together to streamline the disclosure. This should not be interpreted as intending that an unclaimed disclosed feature is essential to any claim. Rather, inventive subject matter may lie in less than all features of a particular disclosed embodiment. In addition, while the majority of this patent document discusses the monitoring of fluid in a thoracic region of a subject, the present systems and methods can be used in ways similar to those discussed herein to monitor fluid accumulation in other regions of a subject's body. Thus, the following claims are hereby incorporated into the Detailed Description, with each claim standing on its own as a separate embodiment. The scope of the invention should be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled.

[0079] The Abstract is provided to allow the reader to quickly ascertain the nature of the technical disclosure. It is submitted with the understanding that it will not be used to interpret or limit the scope or meaning of the claims.

Claims

1. A system (200) comprising:

an implantable medical device (212), including an electrical impedance measurement circuit (250) configured to measure at least one thoracic impedance-indicating signal characteristic, including at least a fluid status component, using information about electrical energy injected between two or more electrodes and a potential difference created thereby between the same or different two or more electrodes, and a memory circuit (252) including a histogram comprising a plurality of histogram bins, each bin representing a subrange of thoracic impedance-indicating signal characteristic values, the memory circuit (252) being configured for storing a value representative of the at least one thoracic impedance indicating signal characteristic into one of the histogram bins having a numerically inclusive subrange, wherein each histogram bin includes a corresponding count indicative of a number of thoracic impedance-indicating signal characteristic values detected during a particular time period and falling within the subrange of the corresponding histogram bin, and wherein the memory circuit (252) further includes a counter circuit (404) configured to increment, for each thoracic impedance-indicating signal characteristic value stored in a particular histogram bin, the count for the corresponding histogram bin;
a comparator circuit (584) configured to compute a deviation-using one or more histogram bins received from the memory circuit (252) and one or more corresponding baseline histogram bins having substantially the same numerical subrange; and
a processor circuit (230) including an input to receive and use information about the deviation to compute and provide a lung fluid status indication.

2. The system of claim 1, comprising a trigger circuit to trigger a thoracic impedance-indicating signal measurement synchronized with a refractory portion of a subject's cardiac cycle, wherein the trigger circuit comprises at least one of a timing circuit *(*550*)* or a cardiac sensor circuit (522).

3. The system of any of claims 1 or 2, comprising a posture sensor configured (520) to produce a posture signal indicative of a posture of a subject, the posture sensor configured to trigger a thoracic impedance-indicating signal measurement when the posture signal is indicative of a substantially upright orientation.

4. The system of any of claims 1-3, comprising a histogram-selective circuit (580) configured to select one or more histogram bins representative of a reduced subrange of the histogram; and wherein the processor circuit (230) is configured to use the reduced subrange of the histogram to compute and provide the lung fluid status indication, the reduced subrange representing an upper-percentile of the histogram or an intra-percentile range of the histogram.

5. The system of claim 4, wherein the processor circuit 230 is further configured to compute a central tendency of one or more values stored in the selected one or more histogram bins, which are representative of the reduced subrange; and wherein the processor circuit (230) is configured to use the central tendency of the reduced subrange of the histogram to compute and provide the lung fluid status indication.

6. The system of claim 1, wherein the memory circuit (252) is further configured for storing a value of the at least one

thoracic impedance-indicating signal characteristic into the histogram bin having a numerically inclusive subrange; and

wherein the comparator circuit (584) is further configured to compute, as the deviation,-a difference between an average of thoracic impedance-indicating signal characteristic value data of the one or more histogram bins previously received and the thoracic impedance-indicating signal characteristic value data of the one or more baseline histogram bins.

7. The system of any of claims 1-6, comprising an external user-interface device (216, 218) communicatively coupled to the implantable medical device (212) and including a user-detectable indication (224), the user-detectable indication (224) configured to provide a display of at least one of received information about thoracic impedance-indicating signal characteristic data of one or more histogram bins, a trend over time of impedance summary information computed from one or more portions of the histogram, or the computed lung fluid status indication.

8. The system of any of claims 1-7, wherein the computed and provided lung fluid status indication includes a pulmonary edema event indication.

9. The system of any of claims 1-8, wherein the at least one thoracic impedance-indicating signal characteristic includes a respiration component.

10. A method comprising:

measuring, using an electrical impedance measurement circuit (250), at least one thoracic impedance-indicating signal characteristic including a fluid status component, the measuring using information about electrical energy injected between two or more electrodes and a potential difference created thereby between the same or different two or more electrodes;

storing in a histogram bin of a memory circuit (252) that includes a histogram that comprises a plurality of histogram bins representing corresponding subranges of thoracic impedance-indicating signal characteristic values, a count indicative of a number of thoracic impedance-indicating signal characteristic values detected during a particular time period and falling within the subrange of the histogram bin;

computing, using a comparator circuit (584), a deviation indicative of a difference in a number of counts between at least one histogram bin of a short-term histogram received from the memory circuit (252) and at least one corresponding bin, having substantially the same numerical subrange, of a baseline histogram; and

providing, using a processor circuit (230), a lung fluid status indication using information about the deviation.

11. The method of claim 10, further comprising storing a value of the at least one thoracic impedance-indicating signal characteristic; and wherein providing the lung fluid status indication includes correlating a reduction over time in the central tendency of one or more values stored in the selected one or more histogram bins with an indication of present or impending fluid accumulation.

12. The method of any of claims 10 or 11, wherein computing the lung fluid status indication further includes correlating a reduction over time in the number of counts of one or more values stored in the selected one or more histogram bins with an indication of present or impending fluid accumulation.

Patentansprüche

1. System (200), welches aufweist:

eine implantierbare medizinische Vorrichtung (212), enthaltend eine elektrische Impedanzmessschaltung (250), die konfiguriert ist zum Messen von zumindest einer Charakteristik eines eine Thoraximpedanz anzeigenden Signals, das zumindest eine Fluidzustandskomponente enthält, unter Verwendung von Informationen über elektrische Energie, die zwischen zwei oder mehr Elektroden injiziert wird, und eine hierdurch geschaffene Potentialdifferenz zwischen denselben oder zwei oder mehr verschiedenen Elektroden, und eine Speicherschaltung (252), das ein Histogramm enthält, das mehrere Histogrammfächer aufweist, wobei jedes Fach einen Unterbereich von Charakteristikwerten eines eine Thoraximpedanz anzeigenden Signals darstellt, welche Speicherschaltung (252) konfiguriert ist zum Speichern eines Wertes, der repräsentativ ist für die zumindest eine Charakteristik des eine Thoraximpedanz anzeigenden Signals, in einem der Histogrammfächer mit einem numerisch inklusiven Unterbereich, wobei jedes Histogrammfach einen entsprechenden Zählwert enthält, der eine

Anzahl von Charakteristikwerten des eine Thoraximpedanz anzeigenden Signals anzeigt, die während einer bestimmten Zeitperiode erfasst wurden und in den Unterbereich des entsprechenden Histogrammfachs fällt, und wobei die Speicherschaltung (252) weiterhin eine Zählerschaltung (404) enthält, die konfiguriert ist zum Erhöhen des Zählwerts für das entsprechende Histogrammfach für jeden in einem bestimmten Histogrammfach gespeicherten Charakteristikwert eines eine Thoraximpedanz anzeigenden Signals;
eine Komparatorschaltung (584), die konfiguriert ist zum Berechnen einer Abweichung unter Verwendung eines oder mehrerer Histogrammfächer, die von der Speicherschaltung (252) empfangen wurden, und eines oder mehrerer entsprechender Basislinien-Histogrammfächer mit im Wesentlichen demselben numerischen Subbereich; und
eine Prozessorschaltung (230), enthaltend einen Eingang zum Empfangen und Verwenden von Informationen über die Abweichung, um eine Lungenfluid-Zustandsanzeige zu berechnen und bereitzustellen.

2. System nach Anspruch 1, aufweisend eine Triggerschaltung zum Auslösen der Messung eines eine Thoraximpedanz anzeigenden Signals, das mit einem Refraktärteil des Herzzyklus eines Subjekts synchronisiert ist, wobei die Triggerschaltung zumindest eine von einer Zeitgeberschaltung (550) oder einer Herzsensorschaltung (522) aufweist.

3. System nach einem der Ansprüche 1 oder 2, aufweisend einen Körperhaltungssensor (520), der konfiguriert ist zum Erzeugen eines eine Körperhaltung eines Subjekts anzeigenden Körperhaltungssignals, wobei der Körperhaltungssensor konfiguriert ist zum Auslösen der Messung eines eine Thoraximpedanz anzeigenden Signals, wenn das Körperhaltungssignal eine im Wesentlichen aufrechte Orientierung anzeigt.

4. System nach einem der Ansprüche 1 bis 3, aufweisend eine histogrammselektive Schaltung (580), die konfiguriert ist zum Auswählen eines oder mehrerer Histogrammfächer, die für einen reduzierten Unterbereich des Histogramms repräsentativ sind; und wobei die Prozessorschaltung (230) konfiguriert ist zum Verwenden des reduzierten Unterbereichs des Histogramms für die Berechnung und Bereitstellung der Lungenfluid-Zustandsanzeige, wobei der reduzierte Unterbereich ein oberes Perzentil des Histogramms oder einen Intra-Perzentilbereich des Histogramms darstellt.

5. System nach Anspruch 4, bei dem die Prozessorschaltung (230) weiterhin konfiguriert ist zum Berechnen einer mittleren Tendenz eines oder mehrerer Werte, die in den ausgewählten einem oder mehreren Histogrammfächern gespeichert sind, die repräsentativ sind für den reduzierten Subbereich; und wobei die Prozessorschaltung (230) konfiguriert ist zum Verwenden der mittleren Tendenz des reduzierten Subbereichs des Histogramms für die Berechnung und Bereitstellung der Lungenfluid-Zustandsanzeige.

6. System nach Anspruch 1, bei dem die Speicherschaltung (252) weiterhin konfiguriert ist zum Speichern eines Wertes der zumindest einen Charakteristik des eine Thoraximpedanz anzeigenden Signals in dem Histogrammfach mit einem numerisch inklusiven Unterbereich; und

bei dem die Komparatorschaltung (584) weiterhin konfiguriert ist zum Berechnen, als der Abweichung, einer Differenz zwischen einem Durchschnitt von Charakteristikwertdaten des eine Thoraximpedanz anzeigenden Signals des einen oder der mehreren Histogrammfächer, die vorher empfangen wurden, und den Charakteristikwertdaten des eine Thoraximpedanz anzeigenden Signals des einen oder der mehreren Basislinien-Histogrammfächer.

7. System nach einem der Ansprüche 1 bis 6, aufweisend eine externe Benutzerschnittstellenvorrichtung (216, 218), die kommunikativ mit der implantierbaren medizinischen Vorrichtung (212) gekoppelt ist und eine benutzererfassbare Anzeige (224) enthält, wobei die benutzererfassbare Anzeige (224) konfiguriert ist zum Liefern einer Anzeige von zumindest einer von empfangenen Informationen über Charakteristikdaten eines eine Thoraximpedanz anzeigenden Signals von einem oder mehreren Histogrammfächern, eines Trends über die Zeit von Impedanzzusammenfassungsinformationen, die anhand eines oder mehrerer Teile des Histogramms berechnet wurden, oder der berechneten Lungenfluid-Zustandsanzeige.

8. System nach einem der Ansprüche 1 bis 7, bei dem die berechnete und bereitgestellte Lungenfluid-Zustandsanzeige eine Lungenödem-Ereignisanzeige enthält.

9. System nach einem der Ansprüche 1 bis 8, bei dem die zumindest eine Charakteristik des eine Thoraximpedanz anzeigenden Signals eine Atmungskomponente enthält.

10. Verfahren, welches aufweist:

Messen, unter Verwendung einer elektrischen Impedanzmessschaltung (250), zumindest einer Charakteristik eines eine Thoraximpedanz anzeigenden Signals, enthaltend eine Fluidzustandskomponente, wobei das Messen Informationen über elektrische Energie, die zwischen zwei oder mehr Elektroden injiziert wurde, und eine Potentialdifferenz, die hierdurch zwischen denselben oder zwei oder mehr verschiedenen Elektroden geschaffen wurde, verwendet;
Speichern eines Zählwerts, der eine Anzahl von Charakteristikwerten eines eine Thoraximpedanz anzeigenden Signals anzeigt, die während einer bestimmten Zeitperiode erfasst wurden und in den Unterbereich des Histogrammfachs fallen, in einem Histogrammfach einer Speicherschaltung (252), die ein Histogramm enthält, das mehrere Histogrammfächer aufweist, die entsprechende Charakteristikwerte eines eine Thoraximpedanz anzeigenden Signals repräsentieren;
Berechnen, unter Verwendung einer Komparatorschaltung (584), einer Abweichung, die eine Differenz in einer Anzahl von Zählwerten zwischen zumindest einem Histogrammfach eines kurzfristigen Histogramms, das von der Speicherschaltung (252) empfangen wurde, und zumindest einem entsprechenden Fach, das im Wesentlichen demselben numerischen Unterbereich hat, eines Basislinien-Histogramms anzeigt; und
Bereitstellen einer Lungenfluid-Zustandsanzeige unter Verwendung von Informationen über die Abweichung durch Verwendung einer Prozessorschaltung (230).

11. Verfahren nach Anspruch 10, weiterhin aufweisend das Speichern eines Wertes der zumindest einen Charakteristik des eine Thoraximpedanz anzeigenden Signals; und

wobei das Bereitstellen der Lungenfluid-Zustandsanzeige das Korrelieren einer Reduktion über die Zeit in der mittleren Tendenz eines oder mehrerer Werte, die in dem einen oder den mehreren ausgewählten Histogrammfächern gespeichert sind, mit einer Anzeige von gegenwärtiger oder drohender Fluidansammlung enthält.

12. Verfahren nach einem der Ansprüche 10 oder 11, bei dem das Berechnen der Lungenfluid-Zustandsanzeige weiterhin das Korrelieren einer Reduktion über die Zeit in der Anzahl von Zählwerten eines oder mehrerer Werte, die in dem einen oder den mehreren ausgewählten Histogrammfächern gespeichert sind, mit einer Anzeige von gegenwärtiger oder drohender Fluidansammlung enthält.

Revendications

1. Système (200) comprenant :

un dispositif médical implantable (212), incluant un circuit de mesure d'impédance électrique (250) configuré de manière à mesurer au moins une caractéristique de signal indicateur d'impédance thoracique, incluant au moins une composante d'état de fluide, en utilisant une information concernant l'énergie électrique injectée entre deux électrodes ou plus et une différence de potentiel ainsi créée entre les mêmes deux électrodes ou plus ou entre deux électrodes ou plus différentes, et un circuit de mémoire (252) incluant un histogramme comprenant une pluralité de barres d'histogramme, chaque barre représentant une sous-plage de valeurs de caractéristique de signal indicateur d'impédance thoracique, le circuit de mémoire (252) étant configuré pour stocker une valeur représentative de l'au moins une caractéristique de signal indicateur d'impédance thoracique à l'intérieur de l'une des barres d'histogramme présentant une sous-plage numériquement inclusive, dans lequel chaque barre d'histogramme inclut un comptage correspondant indicatif d'un nombre de valeurs de caractéristique de signal indicateur d'impédance thoracique détectées pendant une période temporelle particulière et tombant à l'intérieur de la sous-plage de la barre d'histogramme correspondante, et dans lequel le circuit de mémoire (252) inclut en outre un circuit de compteur (404) configuré de manière à incrémenter, pour chaque valeur de caractéristique de signal indicateur d'impédance thoracique stockée dans une barre d'histogramme particulière, le comptage pour la barre d'histogramme correspondante ;
un circuit de comparateur (584) configuré de manière à calculer un écart en utilisant une ou plusieurs barre(s) d'histogramme reçue(s) depuis le circuit de mémoire (252) et une ou plusieurs barre(s) d'histogramme de ligne de base correspondante(s) présentant sensiblement la même sous-plage numérique ; et
un circuit de processeur (230) incluant une entrée pour recevoir et utiliser une information concernant l'écart afin de calculer et de fournir une indication d'état de fluide des poumons.

2. Système selon la revendication 1, comprenant un circuit de déclenchement pour déclencher une mesure de signal

indicateur d'impédance thoracique synchronisée avec une partie réfractaire du cycle cardiaque d'un sujet, dans lequel le circuit de déclenchement comprend au moins un circuit pris parmi un circuit de cadencement (550) et un circuit de capteur cardiaque (522).

3. Système selon l'une quelconque des revendications 1 ou 2, comprenant un capteur de posture (520) configuré de manière à produire un signal de posture indicatif d'une posture d'un sujet, le capteur de posture étant configuré de manière à déclencher une mesure de signal indicateur d'impédance thoracique lorsque le signal de posture est indicatif d'une orientation sensiblement verticale.

4. Système selon l'une quelconque des revendications 1-3, comprenant un circuit sélectif en histogramme (580) configuré de manière à sélectionner une ou plusieurs barre(s) d'histogramme représentative(s) d'une sous-plage réduite de l'histogramme ; et dans lequel le circuit de processeur (230) est configuré de manière à utiliser la sous-plage réduite de l'histogramme afin de calculer et de fournir l'indication d'état de fluide des poumons, la sous-plage réduite représentant un centile supérieur de l'histogramme ou une plage intra-centiles de l'histogramme.

5. Système selon la revendication 4, dans lequel le circuit de processeur (230) est en outre configuré de manière à calculer une tendance centrale d'une ou de plusieurs valeur(s) stockée(s) dans les une ou plusieurs barre(s) d'histogramme sélectionnée(s), lesquelles valeurs sont représentatives de la sous-plage réduite ; et dans lequel le circuit de processeur (230) est configuré de manière à utiliser la tendance centrale de la sous-plage réduite de l'histogramme afin de calculer et de fournir l'indication d'état de fluide des poumons.

6. Système selon la revendication 1, dans lequel :

le circuit de mémoire (252) est en outre configuré de manière à stocker une valeur de l'au moins une caractéristique de signal indicateur d'impédance thoracique à l'intérieur de la barre d'histogramme comportant une sous-plage numériquement inclusive ; et dans lequel :

le circuit de comparateur (584) est en outre configuré de manière à calculer, en tant qu'écart, une différence entre une moyenne de données de valeur de caractéristique de signal indicateur d'impédance thoracique des une ou plusieurs barre(s) d'histogramme précédemment reçues et les données de valeur de caractéristique de signal indicateur d'impédance thoracique des une ou plusieurs barre(s) d'histogramme de ligne de base.

7. Système selon l'une quelconque des revendications 1-6, comprenant un dispositif d'interface utilisateur externe (216, 218) couplé en communication au dispositif médical implantable (212) et incluant une indication détectable par utilisateur (224), l'indication détectable par utilisateur (224) étant configurée de manière à fournir un affichage d'au moins l'un d'éléments informationnels pris parmi une information reçue concernant des données de caractéristique de signal indicateur d'impédance thoracique d'une ou de plusieurs barre(s) d'histogramme, une tendance dans le temps d'une information de résumé d'impédance calculée à partir d'une ou de plusieurs partie(s) de l'histogramme, ou l'indication d'état de fluide des poumons calculée.

8. Système selon l'une quelconque des revendications 1-7, dans lequel l'indication d'état de fluide des poumons calculée et fournie inclut une indication d'événement d'oedème pulmonaire.

9. Système selon l'une quelconque des revendications 1-8, dans lequel l'au moins une caractéristique de signal indicateur d'impédance thoracique inclut une composante de respiration.

10. Procédé comprenant :

la mesure, en utilisant un circuit de mesure d'impédance électrique (250), d'au moins une caractéristique de signal indicateur d'impédance thoracique incluant une composante d'état de fluide, la mesure utilisant une information concernant l'énergie électrique injectée entre deux électrodes ou plus et une différence de potentiel ainsi créée entre les mêmes deux électrodes ou plus ou entre deux électrodes ou plus différentes ;
le stockage, dans une barre d'histogramme d'un circuit de mémoire (252) qui inclut un histogramme qui comprend une pluralité de barres d'histogramme représentant des sous-plages correspondantes de valeurs de caractéristique de signal indicateur d'impédance thoracique, d'un comptage indicatif d'un nombre de valeurs de caractéristique de signal indicateur d'impédance thoracique détectées pendant une période temporelle particulière et tombant à l'intérieur de la sous-plage de la barre d'histogramme ;

le calcul, en utilisant un circuit de comparateur (584), d'un écart indicatif d'une différence en termes de nombre de comptages entre au moins une barre d'histogramme d'un histogramme de court terme reçu depuis le circuit de mémoire (252) et au moins une barre correspondante, présentant sensiblement la même sous-plage numérique, d'un histogramme de ligne de base ; et

la fourniture, en utilisant un circuit de processeur (230), d'une indication d'état de fluide des poumons en utilisant une information concernant l'écart..

11. Procédé selon la revendication 10, comprenant en outre le stockage d'une valeur de l'au moins une caractéristique de signal indicateur d'impédance thoracique ; et dans lequel la fourniture de l'indication d'état de fluide des poumons inclut la corrélation d'une réduction dans le temps de la tendance centrale d'une ou de plusieurs valeur(s) stockée(s) dans les une ou plusieurs barre(s) d'histogramme sélectionnée(s) avec une indication d'accumulation de fluide présente ou imminente.

12. Procédé selon l'une quelconque des revendications 10 ou 11, dans lequel le calcul de l'indication d'état de fluide des poumons inclut en outre la corrélation d'une réduction dans le temps du nombre de comptages d'une ou de plusieurs valeur(s) stockée(s) dans les une ou plusieurs barre(s) d'histogramme sélectionnée(s) avec une indication d'accumulation de fluide présente ou imminente.

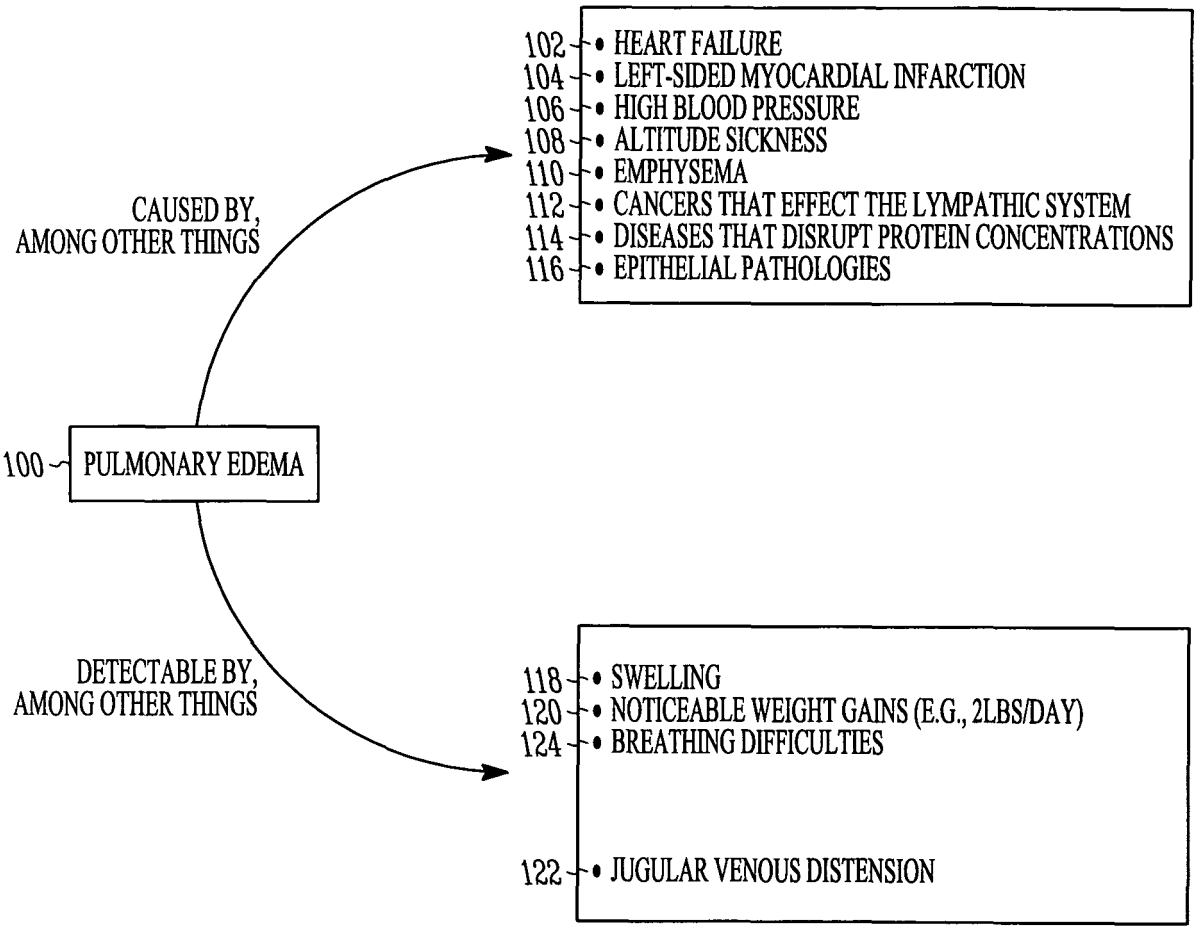
100
PULMONARY EDEMA
CAUSED BY,
AMONG OTHER THINGS
DETECTABLE BY,
AMONG OTHER THINGS
102 • HEART FAILURE
104 • LEFT-SIDED MYOCARDIAL INFARCTION
106 • HIGH BLOOD PRESSURE
108 • ALTITUDE SICKNESS
110 • EMPHYSEMA
112 • CANCERS THAT EFFECT THE LYMPATHIC SYSTEM
114 • DISEASES THAT DISRUPT PROTEIN CONCENTRATIONS
116 • EPITHELIAL PATHOLOGIES
118 • SWELLING
120 • NOTICEABLE WEIGHT GAINS (E.G., 2LBS/DAY)
124 • BREATHING DIFFICULTIES
122 • JUGULAR VENOUS DISTENSION

FIG. 1

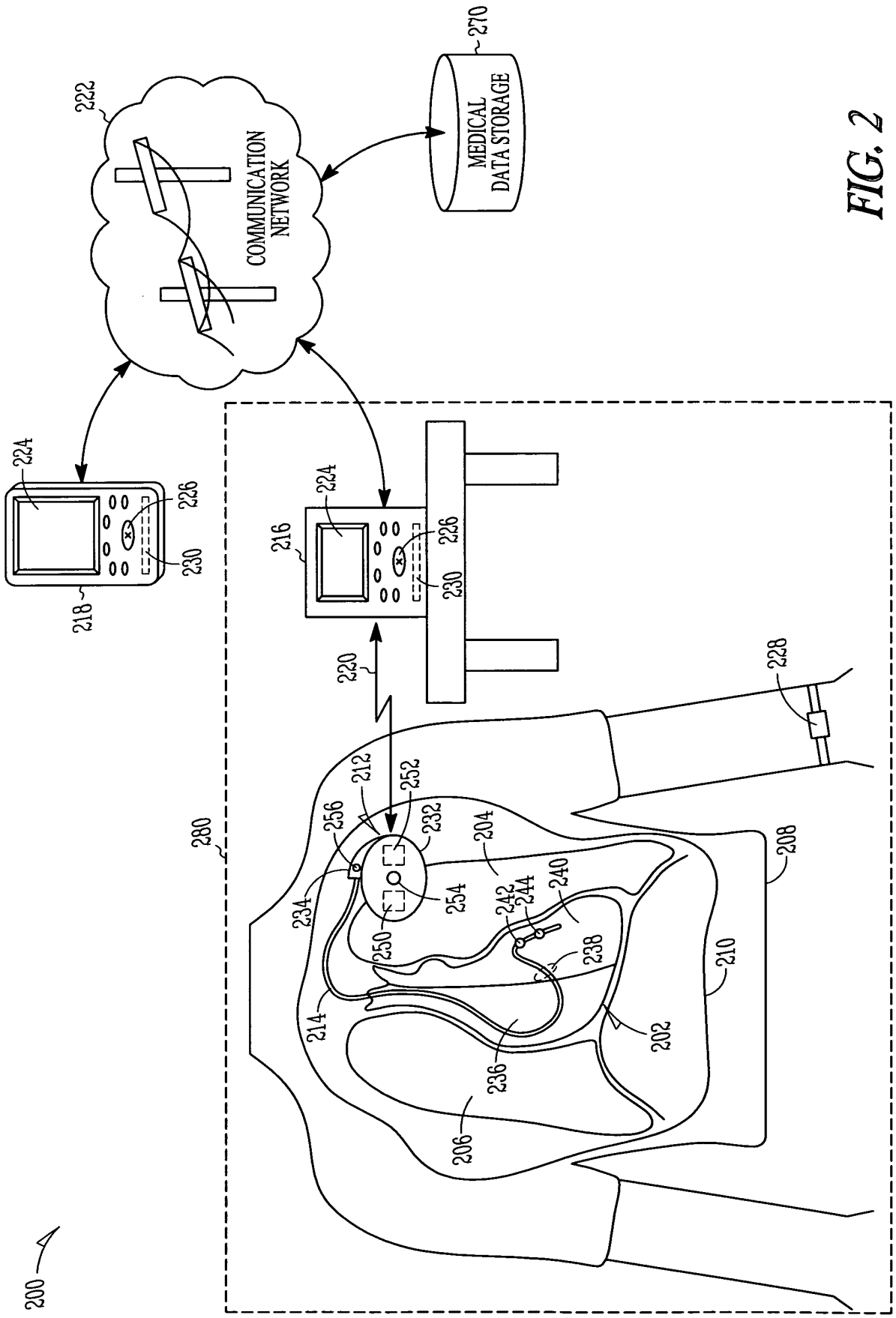
200
280
COMMUNICATION NETWORK
222
MEDICAL DATA STORAGE
270
224
226
230
218
216
220
228
212
252
256
232
204
208
234
254
242
244
240
250
238
210
214
202
236
206

FIG. 2

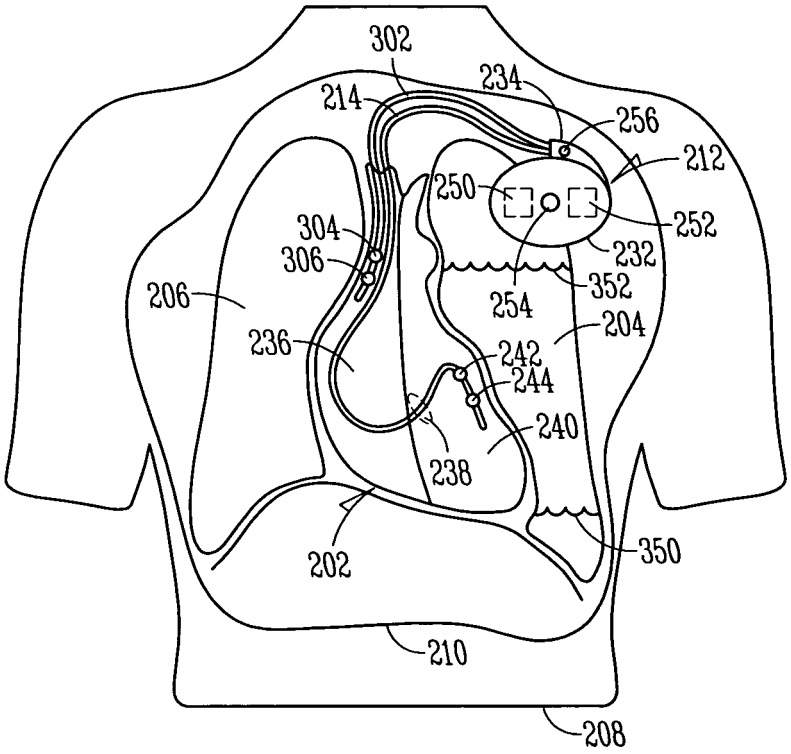
302
234
214
256
212
250
252
304
232
306
352
206
254
204
236
242
244
240
238
202
350
210
208

FIG. 3

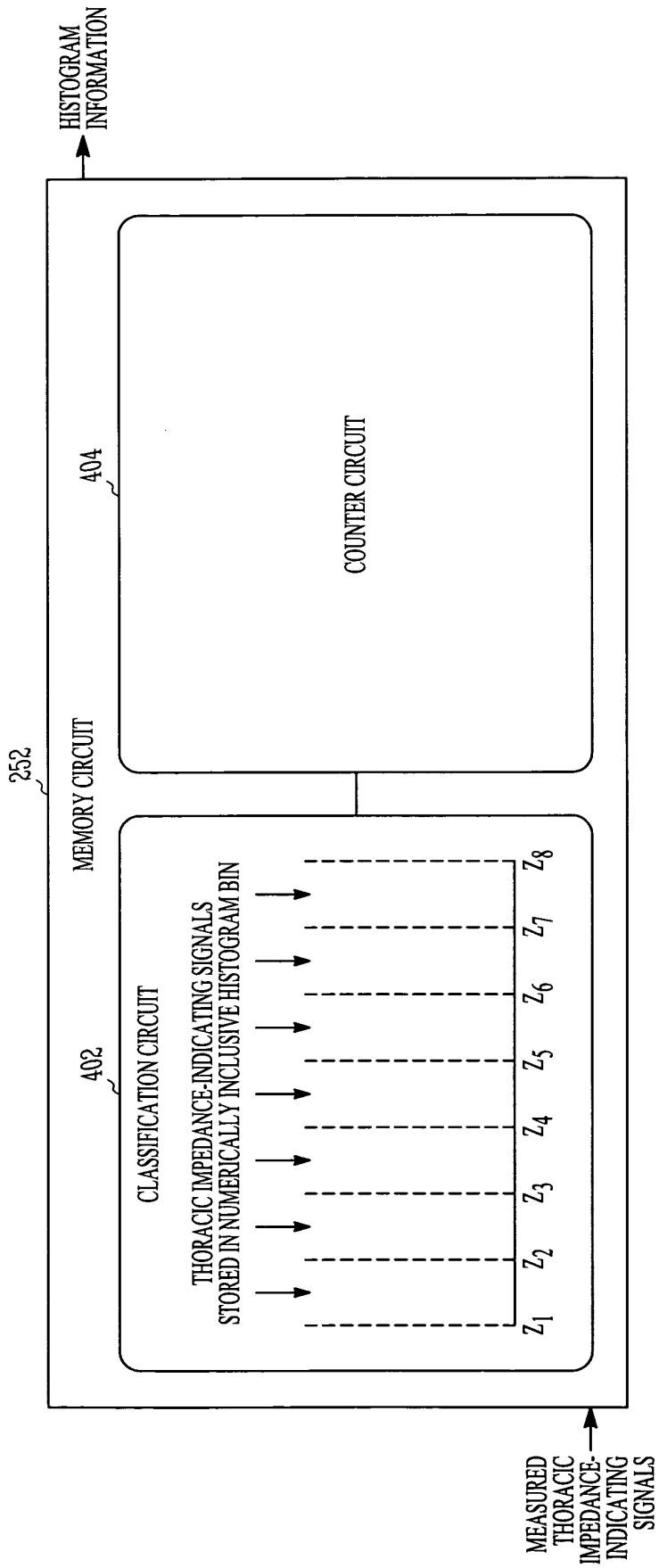
HISTOGRAM INFORMATION
252
MEMORY CIRCUIT
404
COUNTER CIRCUIT
402
CLASSIFICATION CIRCUIT
THORACIC IMPEDANCE-INDICATING SIGNALS STORED IN NUMERICALLY INCLUSIVE HISTOGRAM BIN
Z_1
Z_2
Z_3
Z_4
Z_5
Z_6
Z_7
Z_8
MEASURED THORACIC IMPEDANCE-INDICATING SIGNALS

FIG. 4

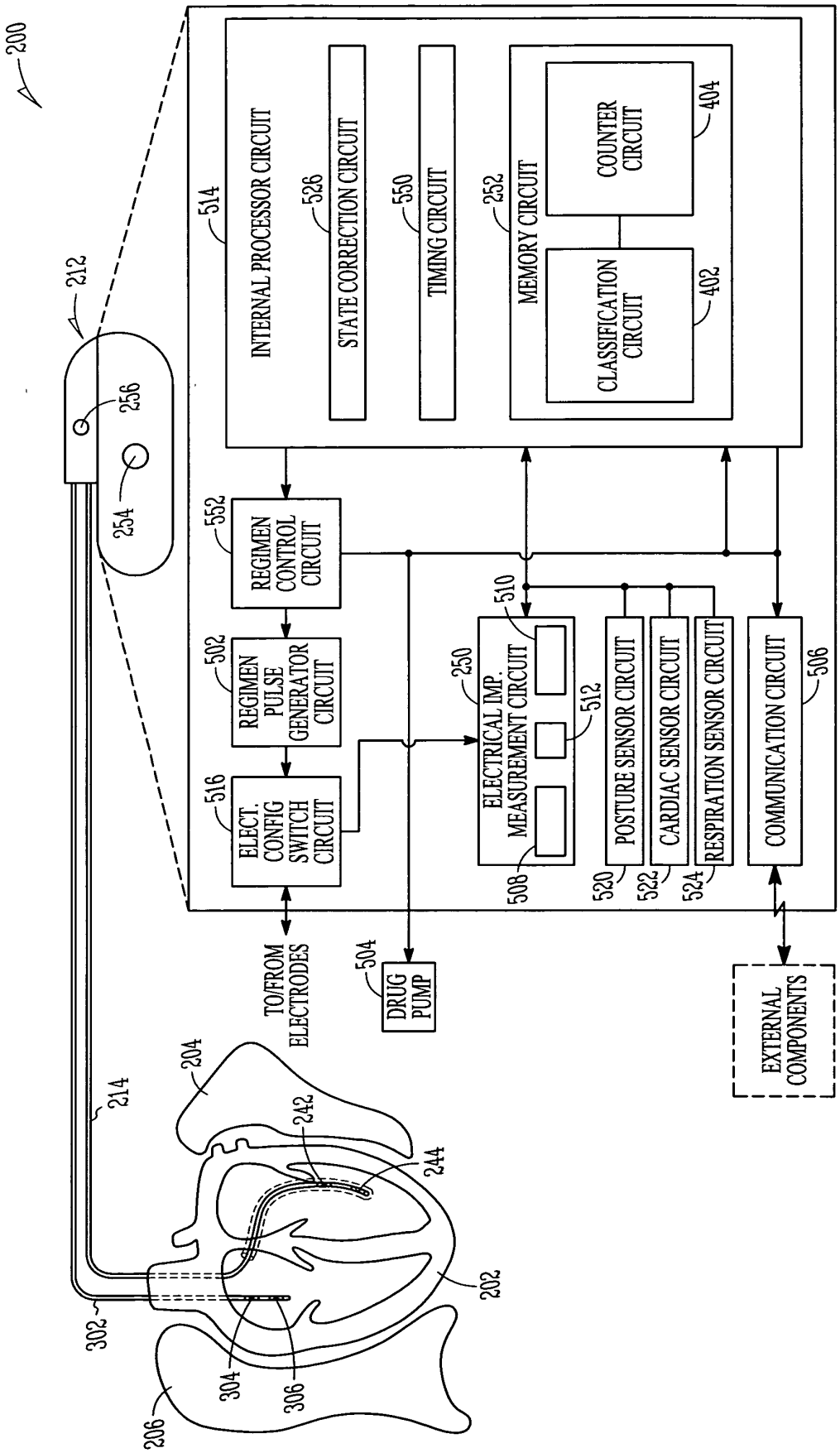
200
212
256
254
214
302
INTERNAL PROCESSOR CIRCUIT
514
STATE CORRECTION CIRCUIT
526
TIMING CIRCUIT
550
MEMORY CIRCUIT
252
COUNTER CIRCUIT
404
CLASSIFICATION CIRCUIT
402
REGIMEN CONTROL CIRCUIT
552
REGIMEN PULSE GENERATOR CIRCUIT
502
ELECT. CONFIG SWITCH CIRCUIT
516
ELECTRICAL IMP. MEASUREMENT CIRCUIT
250
510
512
508
POSTURE SENSOR CIRCUIT
520
CARDIAC SENSOR CIRCUIT
522
RESPIRATION SENSOR CIRCUIT
524
COMMUNICATION CIRCUIT
506
TO/FROM ELECTRODES
DRUG PUMP
504
EXTERNAL COMPONENTS
204
242
244
202
304
306
206

FIG. 5A

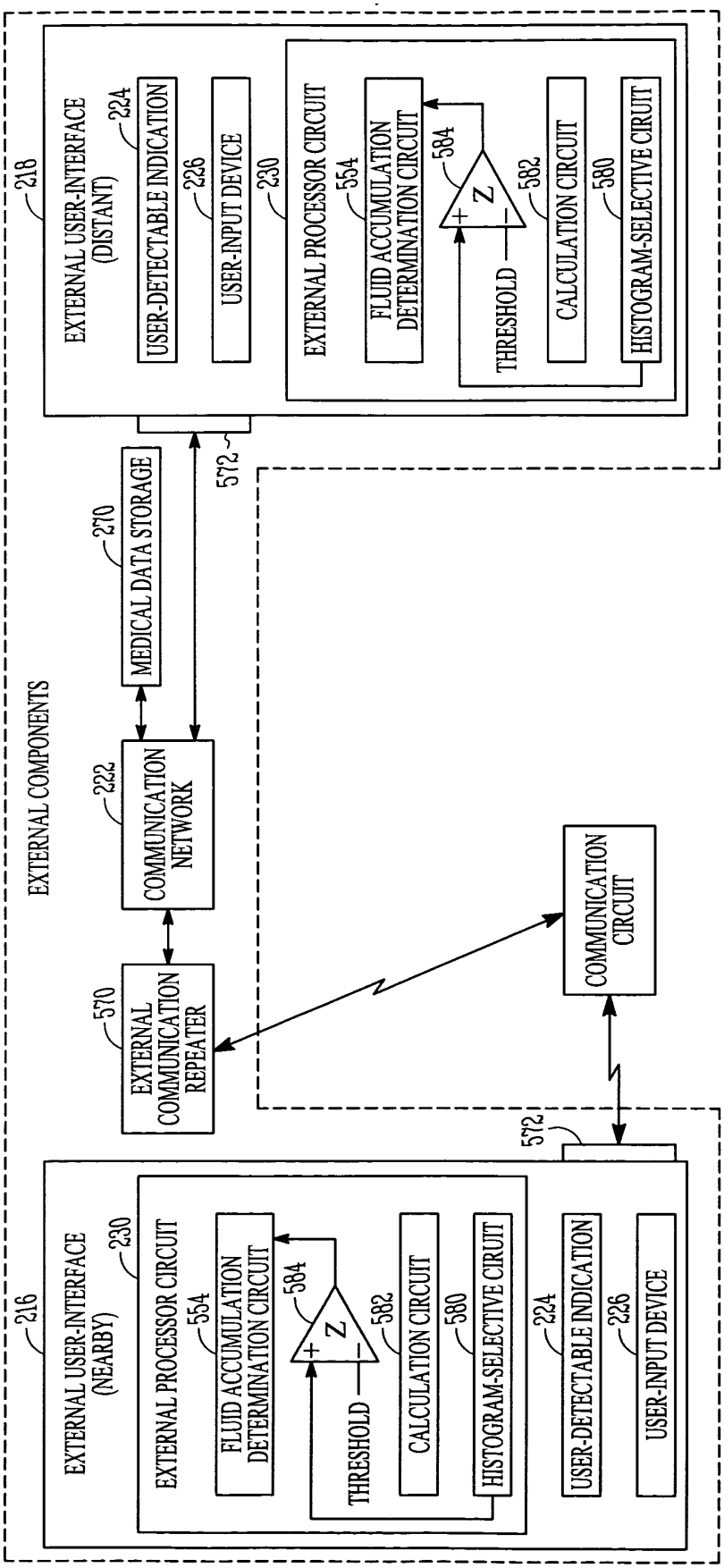
EXTERNAL COMPONENTS
218
EXTERNAL USER-INTERFACE (DISTANT)
224
USER-DETECTABLE INDICATION
226
USER-INPUT DEVICE
230
EXTERNAL PROCESSOR CIRCUIT
554
FLUID ACCUMULATION DETERMINATION CIRCUIT
584
Z
+
−
THRESHOLD
582
CALCULATION CIRCUIT
580
HISTOGRAM-SELECTIVE CIRUIT
572
270
MEDICAL DATA STORAGE
222
COMMUNICATION NETWORK
570
EXTERNAL COMMUNICATION REPEATER
COMMUNICATION CIRCUIT
216
EXTERNAL USER-INTERFACE (NEARBY)
230
EXTERNAL PROCESSOR CIRCUIT
554
FLUID ACCUMULATION DETERMINATION CIRCUIT
584
Z
+
−
THRESHOLD
582
CALCULATION CIRCUIT
580
HISTOGRAM-SELECTIVE CIRUIT
224
USER-DETECTABLE INDICATION
226
USER-INPUT DEVICE
572

FIG. 5B

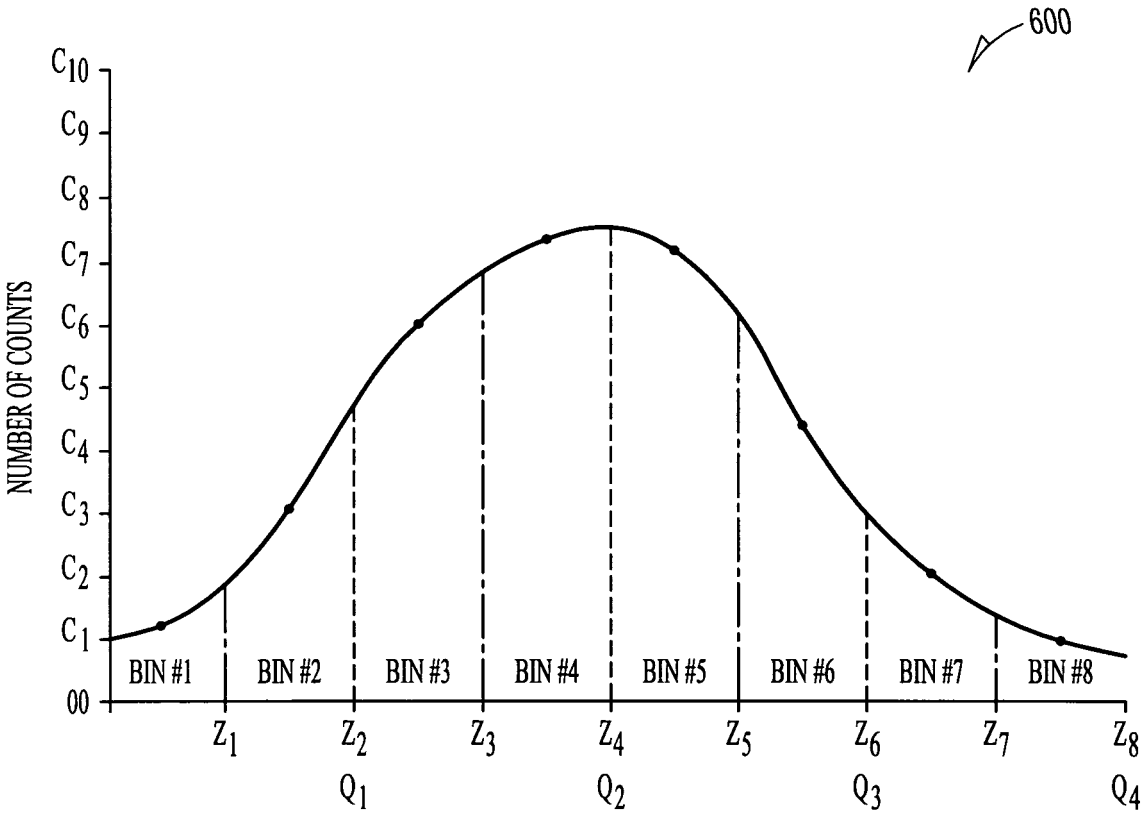
600
NUMBER OF COUNTS
C10
C9
C8
C7
C6
C5
C4
C3
C2
C1
00
BIN #1
BIN #2
BIN #3
BIN #4
BIN #5
BIN #6
BIN #7
BIN #8
Z1
Z2
Z3
Z4
Z5
Z6
Z7
Z8
Q1
Q2
Q3
Q4

FIG. 6

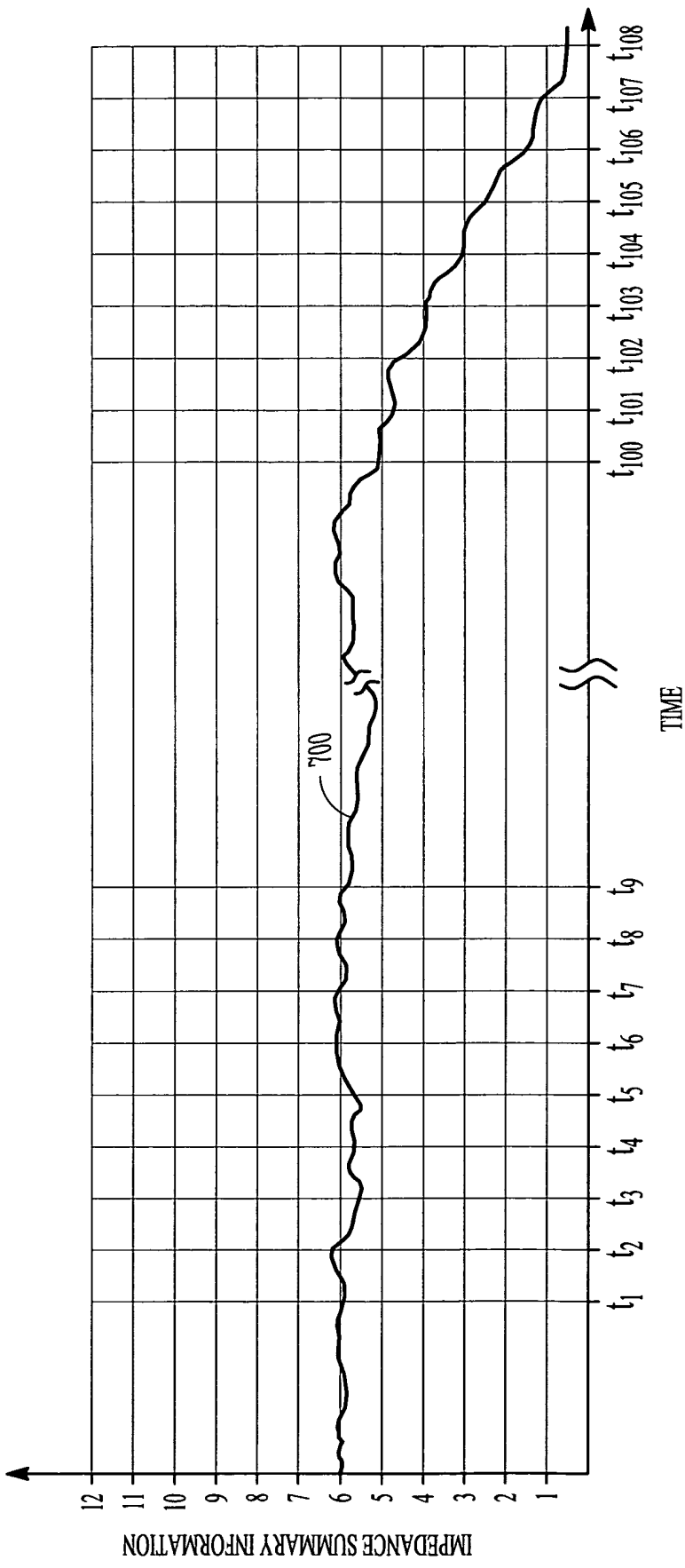
IMPEDANCE SUMMARY INFORMATION
12
11
10
9
8
7
6
5
4
3
2
1
700
TIME
t_1 t_2 t_3 t_4 t_5 t_6 t_7 t_8 t_9
t_{100} t_{101} t_{102} t_{103} t_{104} t_{105} t_{106} t_{107} t_{108}

FIG. 7

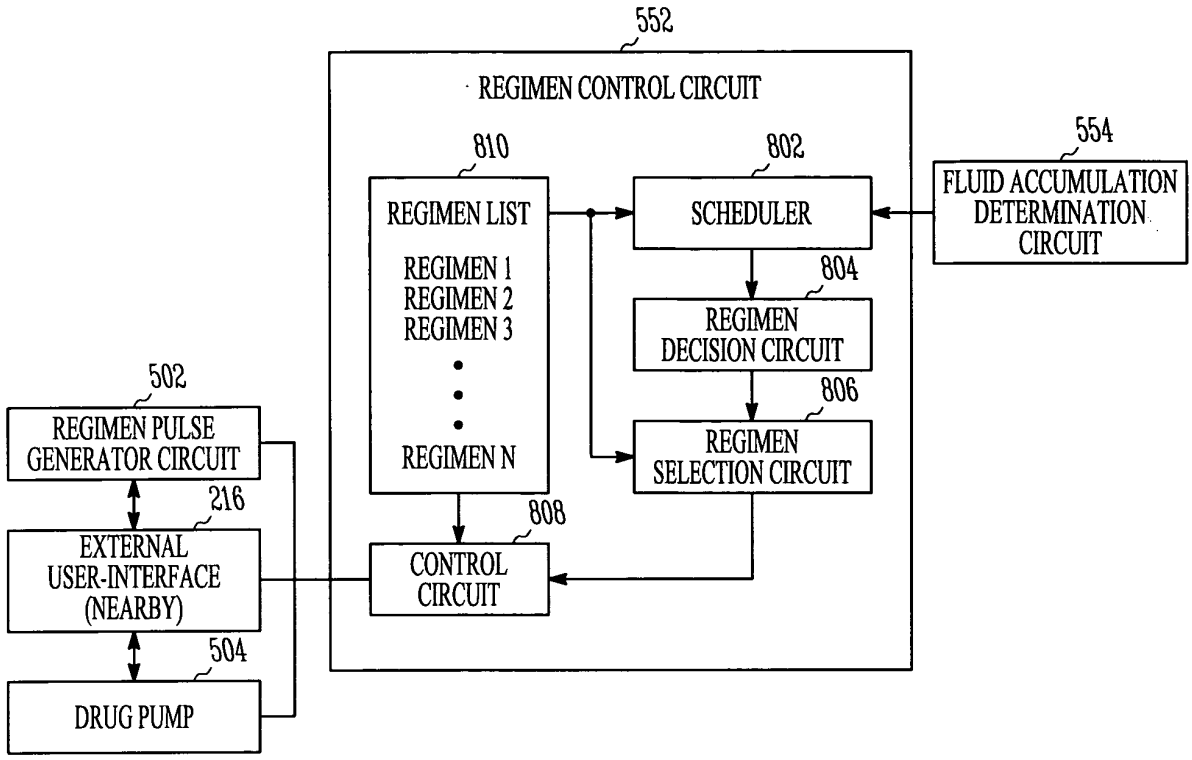
552
REGIMEN CONTROL CIRCUIT
810
REGIMEN LIST
REGIMEN 1
REGIMEN 2
REGIMEN 3
REGIMEN N
802
SCHEDULER
804
REGIMEN DECISION CIRCUIT
806
REGIMEN SELECTION CIRCUIT
808
CONTROL CIRCUIT
554
FLUID ACCUMULATION DETERMINATION CIRCUIT
502
REGIMEN PULSE GENERATOR CIRCUIT
216
EXTERNAL USER-INTERFACE (NEARBY)
504
DRUG PUMP

FIG. 8

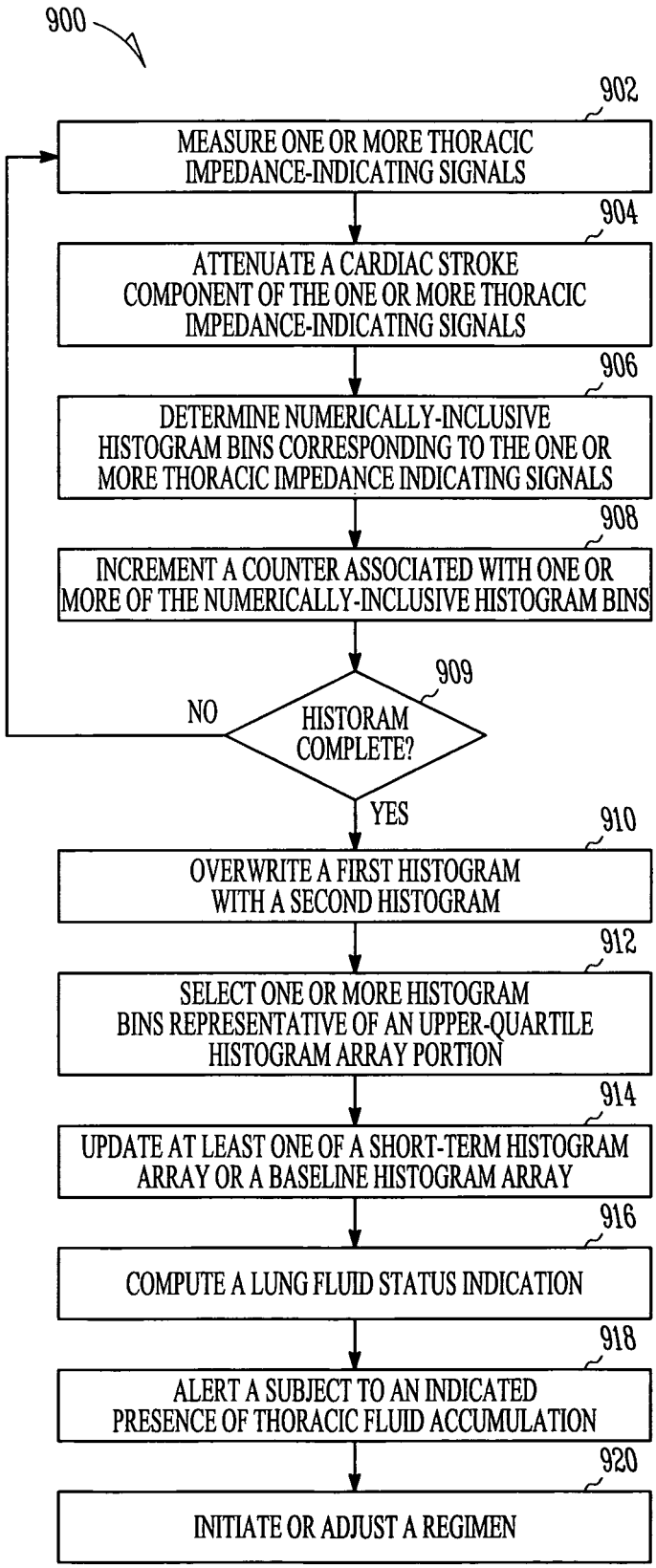
900
902
MEASURE ONE OR MORE THORACIC IMPEDANCE-INDICATING SIGNALS
904
ATTENUATE A CARDIAC STROKE COMPONENT OF THE ONE OR MORE THORACIC IMPEDANCE-INDICATING SIGNALS
906
DETERMINE NUMERICALLY-INCLUSIVE HISTOGRAM BINS CORRESPONDING TO THE ONE OR MORE THORACIC IMPEDANCE INDICATING SIGNALS
908
INCREMENT A COUNTER ASSOCIATED WITH ONE OR MORE OF THE NUMERICALLY-INCLUSIVE HISTOGRAM BINS
909
HISTORAM COMPLETE?
NO
YES
910
OVERWRITE A FIRST HISTOGRAM WITH A SECOND HISTOGRAM
912
SELECT ONE OR MORE HISTOGRAM BINS REPRESENTATIVE OF AN UPPER-QUARTILE HISTOGRAM ARRAY PORTION
914
UPDATE AT LEAST ONE OF A SHORT-TERM HISTOGRAM ARRAY OR A BASELINE HISTOGRAM ARRAY
916
COMPUTE A LUNG FLUID STATUS INDICATION
918
ALERT A SUBJECT TO AN INDICATED PRESENCE OF THORACIC FLUID ACCUMULATION
920
INITIATE OR ADJUST A REGIMEN

FIG. 9

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

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- EP 1604705 A **[0006]**
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专利名称(译)	基于直方图的胸阻抗监测		
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摘要(译)

用于监测受试者中的肺水肿或其他胸液状态的系统和方法使用胸阻抗直方图信息。内部或外部处理器电路接收胸阻抗直方图信息并使用它来计算并提供肺液状态指示。胸阻抗直方图信息可包括直方图区间内的直方图区间或区域的子范围的计数，平均值或中值。

$$\Delta z_n = \frac{1}{C_n} \sum_{i=1}^{I} z_i \left(c_{mi} - \frac{C_n}{B_n} b_{mi} \right) \quad \text{[Equation 1]},$$