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AMBULATORY MEDICAL DEVICE HAVING SENSORS WITH LOCALIZED DRIVEN GROUNDS

Abstract

An ambulatory cardiac device for improving a signal to noise profile of an electrocardiogram (ECG) signal of a patient is provided. The ambulatory cardiac device includes a plurality of active ECG electrodes disposed in a plurality of locations about a patient. Each active electrode can include an ECG electrode substrate configured to be in physical contact with skin of the patient, a local biasing substrate proximate to the ECG electrode substrate and configured to be in physical contact with the skin of the patient, and local biasing circuitry configured to provide a local biasing signal into a body of the patient via the local biasing substrate.

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Background/Summary

RELATED APPLICATION [0001] This is a continuation of U.S. patent application Ser. No. 17/692,967 (filed 11 Mar. 2022), which claims the benefit of U.S. Provisional Patent Application 63/159,704 (filed 11 Mar. 2021). Each of these priority applications is hereby incorporated herein by reference in its entirety.

BACKGROUND

[0002] The present disclosure is directed to sensors incorporated within a medical device for a variety of monitoring, diagnostic, and treatment purposes.

[0003] Heart failure, if left untreated, can lead to certain life-threatening arrhythmias. Both atrial and ventricular arrhythmias are common in patients with heart failure. One of the deadliest cardiac arrhythmias is ventricular fibrillation, which occurs when normal, regular electrical impulses are replaced by irregular and rapid impulses, causing the heart muscle to stop normal contractions. Because the victim has no perceptible warning of the impending fibrillation, death often occurs before the necessary medical assistance can arrive. Other cardiac arrhythmias can include excessively slow heart rates known as bradycardia or excessively fast heart rates known as tachycardia. Cardiac arrest can occur when a patient in which various arrhythmias of the heart, such as ventricular fibrillation, ventricular tachycardia, pulseless electrical activity (PEA), and asystole (heart stops all electrical activity), result in the heart providing insufficient levels of blood flow to the brain and other vital organs for the support of life. It is generally useful to monitor heart failure patients to assess heart failure symptoms early and provide interventional therapies as soon as possible.

[0004] Patients who are at risk, have been hospitalized for, or otherwise are suffering from, adverse heart conditions can be prescribed a wearable cardiac monitoring and/or treatment device. In addition to the wearable device, the patient can also be given a battery charger and a set of rechargeable batteries. As the wearable device is generally prescribed for continuous or near-continuous use (e.g., only to be removed when bathing), the patient wears the device during all daily activities such as walking, sitting, climbing stairs, resting or sleeping, and other similar daily activities. Maintaining continuous or near-continuous use of the device as prescribed can be important for monitoring patient progress as well as providing treatment to the patient if needed.

SUMMARY

[0005] In at least one example, an ambulatory cardiac device for improving a signal to noise profile of an electrocardiogram (ECG) signal of a patient is provided. The ambulatory cardiac device includes a plurality of active ECG electrodes disposed in a plurality of locations about a patient. Each active electrode can include an ECG electrode substrate configured to be in physical contact with skin of the patient, a local biasing substrate proximate to the ECG electrode substrate and configured to be in physical contact with the skin of the patient, and local biasing circuitry configured to provide a local biasing signal into a body of the patient via the local biasing substrate.

[0006] Implementations of the ambulatory cardiac device for improving a signal to noise profile of an ECG signal of a patient can include one or more of the following features.

[0007] In examples, the ambulatory cardiac device can further include ECG sensing circuitry configured to sense a surface electrical signal from the ECG electrode substrate, the surface electrical signal including at least a portion of the local biasing signal. In some examples, the ambulatory cardiac device can further include a processor operably connected to the ECG sensing

circuitry and configured to receive the surface electrical signals from the ECG sensing circuitries of the corresponding first and second ECG electrodes and determine an ECG signal of the patient based on the received surface electrical signals.

[0008] In examples of the ambulatory cardiac device, the local biasing circuitry can be configured to apply a constant biasing signal to the body of the patient. In some examples, the constant biasing signal has a voltage of one of about 0.5 V, about 1.0 V, about 1.5 V, about 2.0 V, about 2.5 V, about 3.0 V, about 3.5 V, about 4.0 V, or about 4.5 V. In some examples, each of the plurality of active ECG electrodes can include a housing disposed proximate to the ECG electrode substrate for housing the ECG electrode substrate, the local biasing substrate, and the local biasing circuitry, the housing rated as IP67 in accordance with standard EN 60529. In some examples, the ambulatory cardiac device can include a plurality of therapy electrodes for delivering one or more therapeutic pulses to the patient. In some examples, the ambulatory cardiac device can include an ECG acquisition box including a processor for determining the ECG signal of the patient based on a received surface electrical signal.

[0009] In some examples, the ambulatory cardiac device can include a controller operably coupled to each of the plurality of active ECG electrodes, the controller configured to determine an arrhythmia condition based on the ECG signal of the patient. In some examples, the controller is configured to control delivery one or more therapeutic pulses to the patient based on the determined arrhythmia condition. In some examples, the ambulatory cardiac device can further include at least one patient response button operably coupled to the controller. In some examples, the controller can be configured to control the delivery of the one or more therapeutic pulses to the patient if a patient response is not received via the at least one patient response button. In some examples, the ambulatory cardiac device can include a garment configured to be worn about a torso of the patient, and wherein plurality of active ECG electrodes are disposed within the garment.

[0010] In examples of the ambulatory cardiac device, the local biasing circuitry can be configured to apply a time-varying biasing signal based upon at least a portion of a surface electrical signal. In some examples, the time-varying biasing signal includes at least one of a time-varied current or a time-varied voltage. In some examples, the at least a portion of the surface electrical signal includes noise. In some examples, each of the plurality of active ECG electrodes include signal processing circuitry configured to determine the noise included in a surface electrical signal. In some examples, the time-varying biasing signal is based upon the determined noise included in the surface electrical signal. In some examples, the signal processing circuitry can be configured to cancel the noise from the surface electrical signal prior to a processor determining the ECG signal of the patient. In some examples, the signal processing circuitry can include a filter and amplifier circuit to process the surface electrical signal to isolate the noise. In some examples, each of the plurality of active ECG electrodes include a housing disposed proximate to the ECG electrode substrate for housing the ECG electrode substrate, the local biasing substrate, and the local biasing circuitry, the housing rated as IP67 in accordance with standard EN 60529. In some examples, the ambulatory cardiac device can include a plurality of therapy electrodes for delivering one or more therapeutic pulses to the patient. In some examples, the ambulatory cardiac device can include an ECG acquisition box including a processor for determining the ECG signal of the patient based on a received surface electrical signal. In some examples, the ambulatory cardiac device can include a controller operably coupled to each of the plurality of active ECG electrodes, the controller configured to determine an arrhythmia condition based on the ECG signal of the patient. In some examples, the controller is configured to control delivery one or more therapeutic pulses to the patient based on the determined arrhythmia condition. In some examples, the ambulatory cardiac device can include at least one patient response button operably coupled to the controller. In some examples, the controller is configured to control delivery of one or more therapeutic pulses to the patient if a patient response is not received via the at least one patient response button. In some examples, the ambulatory cardiac device can include a garment configured to be worn about a torso

of the patient, and wherein plurality of active ECG electrodes are disposed within the garment.

[0011] In examples of the ambulatory cardiac device, the local biasing signal can be configured to provide a grounding signal to the body of the patient to reduce noise in a surface electrical signal.

[0012] In examples of the ambulatory cardiac device, one or both of the ECG electrode substrate and the local biasing substrate can include a fabric material. In some examples, each of the plurality of active ECG electrodes includes a housing disposed proximate to the ECG electrode substrate for housing the ECG electrode substrate, the local biasing substrate, and the local biasing circuitry, the housing rated as IP67 in accordance with standard EN 60529. In some examples, the ambulatory cardiac device can include a plurality of therapy electrodes for delivering one or more therapeutic pulses to the patient. In some examples, the ambulatory cardiac device can include an ECG acquisition box including a processor for determining the ECG signal of the patient based on a received surface electrical signal. In some examples, the ambulatory cardiac device can include a controller operably coupled to each of the plurality of active ECG electrodes, the controller configured to determine an arrhythmia condition based on the ECG signal of the patient. In some examples, the controller is configured to control delivery one or more therapeutic pulses to the patient based on the determined arrhythmia condition. In some examples, the ambulatory cardiac device can include at least one patient response button operably coupled to with the controller. In some examples, the controller is configured to control delivery of one or more therapeutic pulses to the patient if a patient response is not received via the at least one patient response button. In some examples, the ambulatory cardiac device can include a garment configured to be worn about a torso of the patient, and wherein plurality of active ECG electrodes are disposed within the garment. In some examples, the fabric material includes one or more flexible conductive fibers configured to provide an electrical contact with the patient.

[0013] In examples of the ambulatory cardiac device, each of the plurality of active ECG electrodes further can include an analog-to-digital converter operably coupled to the ECG electrode substrate and configured to convert at least a portion of a surface electrical signal to a digital surface electrical signal for transmitting to a processor.

[0014] In examples of the ambulatory cardiac device, each of the plurality of active ECG electrodes can include dry ECG electrodes. In some examples, each of the plurality of active ECG electrodes can include a housing disposed proximate to the ECG electrode substrate for housing the ECG electrode substrate, the local biasing substrate, and the local biasing circuitry, the housing rated as IP67 in accordance with standard EN 60529. In some examples, the ambulatory cardiac device can include a plurality of therapy electrodes for delivering one or more therapeutic pulses to the patient. In some examples, the ambulatory cardiac device can include an ECG acquisition box including a processor for determining the ECG signal of the patient based on a received surface electrical signal. In some examples, the ambulatory cardiac device can include a controller operably coupled to each of the plurality of active ECG electrodes, the controller configured to determine an arrhythmia condition based on the ECG signal of the patient. In some examples, the controller is configured to control delivery one or more therapeutic pulses to the patient based on the determined arrhythmia condition. In some examples, the ambulatory cardiac device can include at least one patient response button operably coupled to the controller. In some examples, the controller is configured to control delivery of one or more therapeutic pulses to the patient if a patient response is not received via the at least one patient response button. In some examples, the ambulatory cardiac device can include a garment configured to be worn about a torso of the patient, and wherein the plurality of active ECG electrodes are disposed within the garment.

[0015] In examples of the ambulatory cardiac device, the local biasing substrate being proximate to the ECG electrode substrate includes the local biasing substrate substantially surrounding the ECG electrode substrate. In some examples, each of the plurality of active ECG electrodes includes a housing disposed proximate to the ECG electrode substrate for housing the ECG electrode substrate, the local biasing substrate, and the local biasing circuitry, the housing rated as IP67 in

accordance with standard EN 60529. In some examples, the ambulatory cardiac device can include a plurality of therapy electrodes for delivering one or more therapeutic pulses to the patient. In some examples, the ambulatory cardiac device can include an ECG acquisition box including a processor for determining the ECG signal of the patient based on a received surface electrical signal. In some examples, the ambulatory cardiac device can include a controller operably coupled to each of the plurality of active ECG electrodes, the controller configured to determine an arrhythmia condition based on the ECG signal of the patient. In some examples, the controller is configured to control delivery one or more therapeutic pulses to the patient based on the determined arrhythmia condition. In some examples, the ambulatory cardiac device can include at least one patient response button operably coupled to the controller. In some examples, the controller can be configured to control delivery of one or more therapeutic pulses to the patient if a patient response is not received via the at least one patient response button. In some examples, the ambulatory cardiac device can include a garment configured to be worn about a torso of the patient, and wherein the plurality of active ECG electrodes are disposed within the garment.

[0016] In examples of the ambulatory cardiac device, the local biasing substrate being proximate to the ECG electrode substrate can include the local biasing substrate being disposed adjacent the ECG electrode substrate on a fabric material.

[0017] In examples, the ambulatory cardiac device can include a shared driven ground electrode configured to aggregate surface electrical signals to derive a common mode rejection signal and inject the common mode rejection signal into the body of the patient. In some examples, each of the plurality of active ECG electrodes includes a housing disposed proximate to the ECG electrode substrate for housing the ECG electrode substrate, the local biasing substrate, and the local biasing circuitry, the housing rated as IP67 in accordance with standard EN 60529. In some examples, the ambulatory cardiac device can include a plurality of therapy electrodes for delivering one or more therapeutic pulses to the patient. In some examples, the ambulatory cardiac device can include an ECG acquisition box including a processor for determining the ECG signal of the patient based on a received surface electrical signal. In some examples, the ambulatory cardiac device can include a controller operably coupled to each of the plurality of active ECG electrodes, the controller configured to determine an arrhythmia condition based on the ECG signal of the patient. In some examples, the controller is configured to control delivery one or more therapeutic pulses to the patient based on the determined arrhythmia condition. In some examples, the ambulatory cardiac device can include at least one patient response button operably coupled to the controller. In some examples, the controller is configured to control delivery of one or more therapeutic pulses to the patient if a patient response is not received via the at least one patient response button. In some examples, the ambulatory cardiac device can include a garment configured to be worn about a torso of the patient, and wherein the plurality of active ECG electrodes are disposed within the garment.

[0018] In examples, the ambulatory cardiac device can include a feedback loop circuit coupled between the ECG electrode substrate and the local biasing substrate. In some examples, the feedback loop circuit includes an inverting integrator circuit. In some examples, the ambulatory cardiac device can include an amplifier configured to output an amplified surface electrical signal. In some examples, the ambulatory cardiac device can include an amplifier configured to output an amplified surface electrical signal and a feedback loop circuit configured to receive the amplified surface electrical signal, invert the amplified surface electrical signal, integrate the inverted amplified surface electrical signal, and output the integrated signal to the local bias substrate. In some examples, each of the plurality of active ECG electrodes includes a housing disposed proximate to the ECG electrode substrate for housing the ECG electrode substrate, the local biasing substrate, and the local biasing circuitry, the housing rated as IP67 in accordance with standard EN 60529. In some examples, the ambulatory cardiac device can include a plurality of therapy electrodes for delivering one or more therapeutic pulses to the patient. In some examples, the ambulatory cardiac device can include an ECG acquisition box including a processor for

determining the ECG signal of the patient based on the received surface electrical signals. In some examples, the ambulatory cardiac device can include a controller operably coupled to each of the plurality of active ECG electrodes, the controller configured to determine an arrhythmia condition based on the ECG signal of the patient. In some examples, the controller is configured to control delivery one or more therapeutic pulses to the patient based on the determined arrhythmia condition. In some examples, the ambulatory cardiac device can include at least one patient response button operably coupled to the controller. In some examples, the controller is configured to control delivery of one or more therapeutic pulses to the patient if a patient response is not received via the at least one patient response button. In some examples, the ambulatory cardiac device can include a garment configured to be worn about a torso of the patient, and wherein the plurality of active ECG electrodes are disposed within the garment.

[0019] In another example, an ambulatory cardiac device having active ECG electrodes with local electronics for improving a signal to noise profile of an ECG signal of a patient is provided. The ambulatory cardiac device includes a first active ECG electrode, the first active ECG electrode including a first ECG electrode with associated first local electronics, a second active ECG electrode, the second active ECG electrode including a second ECG electrode with associated second local electronics, and a processor operably connected to the first and second active ECG electrodes. Each one of first and second active ECG electrodes includes an ECG electrode substrate configured to be in physical contact with skin of the patient, a local biasing substrate proximate to the ECG electrode substrate and configured to be in physical contact with the skin of the patient, and circuitry operably coupled to the ECG electrode substrate and the local biasing substrate. The circuitry includes local biasing circuitry configured to provide a local biasing signal into a body of the patient via the local biasing substrate and ECG sensing circuitry configured to sense a surface electrical signal from the ECG electrode substrate, the surface electrical signal including at least a portion of the local biasing signal. The processor is configured to receive the surface electrical signals from the ECG sensing circuitries of the corresponding first and second ECG electrodes and determine an ECG signal of the patient based on the received surface electrical signals.

[0020] Implementations of the ambulatory cardiac device having active ECG electrodes with local electronics for improving a signal to noise profile of an ECG signal of a patient can include one or more of the following features.

[0021] In examples, the ambulatory cardiac device can include third and fourth ECG electrode assemblies.

[0022] In examples of the ambulatory cardiac device, the circuitry is integrated into a printed circuit assembly.

[0023] In examples of the ambulatory cardiac device, the local biasing circuitry is configured to apply a constant biasing signal to the body of the patient. In some examples, the constant biasing signal has a voltage of one of about 0.5 V, about 1.0 V, about 1.5 V, about 2.0 V, about 2.5 V, about 3.0 V, about 3.5 V, about 4.0 V, or about 4.5 V.

[0024] In examples of the ambulatory cardiac device, each of the first and second active ECG electrodes include a housing disposed proximate to the ECG electrode substrate for housing the first local electronics and the second local electronics, the housing rated as IP67 in accordance with standard EN 60529.

[0025] In examples, the ambulatory cardiac device can include a plurality of therapy electrodes for delivering one or more therapeutic pulses to the patient.

[0026] In examples, the ambulatory cardiac device can include an ECG acquisition box including the processor for determining the ECG signal of the patient based on the received surface electrical signals.

[0027] In examples, the ambulatory cardiac device can include a controller operably coupled to the processor, the controller configured to determine an arrhythmia condition based on the ECG signal of the patient. In some examples, the controller is configured to control delivery one or more

therapeutic pulses to the patient based on the determined arrhythmia condition. In some examples, the ambulatory cardiac device can include at least one patient response button operably coupled to the controller. In some examples, the controller is configured to control the delivery of the one or more therapeutic pulses to the patient if a patient response is not received via the at least one patient response button. In some examples, the ambulatory cardiac device can include a garment configured to be worn about a torso of the patient, and wherein the first and second ECG electrodes and associated first and second local electronics are disposed within the garment.

[0028] In examples of the ambulatory cardiac device, the local biasing circuitry can be configured to apply a time-varying biasing signal based upon at least a portion of the surface electrical signal. In some examples, the time-varying biasing signal includes at least one of a time-varied current or a time-varied voltage. In some examples, the at least a portion of the surface electrical signal includes noise. In some examples, each of the first and second local electronics include signal processing circuitry configured to determine the noise included in the surface electrical signals. In some examples, the time-varying biasing signal is based upon the determined noise included in the surface electrical signals. In some examples, the signal processing circuitry is configured to cancel the noise from the surface electrical signal prior to the processor determining the ECG signal of the patient. In some examples, the signal processing circuitry of each of the first and second active ECG electrodes includes a filter and amplifier circuit to process the surface electrical signal to isolate the noise. In some examples, each of the first and second active ECG electrodes include a housing disposed proximate to the ECG electrode substrate for housing the first local electronics and the second local electronics, the housing rated as IP67 in accordance with standard EN 60529. In some examples, the ambulatory cardiac device can include a plurality of therapy electrodes for delivering one or more therapeutic pulses to the patient. In some examples, the ambulatory cardiac device can include an ECG acquisition box including the processor for determining the ECG signal of the patient based on the received surface electrical signals. In some examples, the ambulatory cardiac device can include a controller operably coupled to the processor, the controller configured to determine an arrhythmia condition based on the ECG signal of the patient. In some examples, the controller can be configured to control delivery one or more therapeutic pulses to the patient based on the determined arrhythmia condition. In some examples, the ambulatory cardiac device can include at least one patient response button operably coupled to the controller. In some examples, the controller can be configured to control the delivery of the one or more therapeutic pulses to the patient if a patient response is not received via the at least one patient response button. In some examples, the ambulatory cardiac device can include a garment configured to be worn about a torso of the patient, and wherein the first and second ECG electrodes and associated first and second local electronics are disposed within the garment.

[0029] In examples of the ambulatory cardiac device, the local biasing signal is configured to provide a grounding signal to the body of the patient to reduce noise in the surface electrical signal.

[0030] In examples of the ambulatory medical device, one or both of the ECG electrode substrate and the local biasing substrate includes a fabric material. In some examples, each of the first and second active ECG electrodes include a housing disposed proximate to the ECG electrode substrate for housing the first local electronics and the second local electronics, the housing rated as IP67 in accordance with standard EN 60529. In some examples, the ambulatory cardiac device can include a plurality of therapy electrodes for delivering one or more therapeutic pulses to the patient. In some examples, the ambulatory cardiac device can include an ECG acquisition box including the processor for determining the ECG signal of the patient based on the received surface electrical signals. In some examples, the ambulatory cardiac device can include a controller operably coupled to the processor, the controller configured to determine an arrhythmia condition based on the ECG signal of the patient. In some examples, the controller is configured to control delivery one or more therapeutic pulses to the patient based on the determined arrhythmia condition. In some examples, the ambulatory cardiac device can include at least one patient response button operably coupled to

the controller. In some examples, the controller is configured to control the delivery of the one or more therapeutic pulses to the patient if a patient response is not received via the at least one patient response button. In some examples, the ambulatory cardiac device can include a garment configured to be worn about a torso of the patient, and wherein the first and second ECG electrodes and associated first and second local electronics are disposed within the garment. In some examples, the fabric material includes one or more flexible conductive fibers configured to provide an electrical contact with the patient.

[0031] In examples of the ambulatory cardiac device, each of the first and second local electronics further includes an analog-to-digital converter operably coupled to the ECG sensing circuitry and configured to convert at least a portion of the surface electrical signal to a digital surface electrical signal for transmitting to the processor.

[0032] In examples of the ambulatory cardiac device, the first and second ECG electrodes include dry ECG electrodes. In some examples, each of the first and second active ECG electrodes include a housing disposed proximate to the ECG electrode substrate for housing the first local electronics and the second local electronics, the housing rated as IP67 in accordance with standard EN 60529. In some examples, the ambulatory cardiac device can include a plurality of therapy electrodes for delivering one or more therapeutic pulses to the patient. In some examples, the ambulatory cardiac device can include an ECG acquisition box including the processor for determining the ECG signal of the patient based on the received surface electrical signals. In some examples, the ambulatory cardiac device can include a controller operably coupled to the processor, the controller configured to determine an arrhythmia condition based on the ECG signal of the patient. In some examples, the controller is configured to control delivery one or more therapeutic pulses to the patient based on the determined arrhythmia condition. In some examples, the ambulatory cardiac device can include at least one patient response button operably coupled to the controller. In some examples, the controller is configured to control the delivery of the one or more therapeutic pulses to the patient if a patient response is not received via the at least one patient response button. In some examples, the ambulatory cardiac device can include a garment configured to be worn about a torso of the patient, and wherein the first and second ECG electrodes and associated first and second local electronics are disposed within the garment.

[0033] In examples of the ambulatory cardiac device, the local biasing substrate being proximate to the ECG electrode substrate can include the local biasing substrate substantially surrounding the ECG electrode substrate. In some examples, each of the first and second active ECG electrodes include a housing disposed proximate to the ECG electrode substrate for housing the first local electronics and the second local electronics, the housing rated as IP67 in accordance with standard EN 60529. In some examples, the ambulatory cardiac device can include a plurality of therapy electrodes for delivering one or more therapeutic pulses to the patient.

[0034] In some examples, the ambulatory cardiac device can include an ECG acquisition box including the processor for determining the ECG signal of the patient based on the received surface electrical signals. In some examples, the ambulatory cardiac device can include a controller operably coupled to the processor, the controller configured to determine an arrhythmia condition based on the ECG signal of the patient. In some examples, the controller is configured to control delivery one or more therapeutic pulses to the patient based on the determined arrhythmia condition. In some examples, the ambulatory cardiac device can include at least one patient response button operably coupled to the controller. In some examples, the controller is configured to control the delivery of the one or more therapeutic pulses to the patient if a patient response is not received via the at least one patient response button. In some examples, the ambulatory cardiac device can include a garment configured to be worn about a torso of the patient, and wherein the first and second ECG electrodes and associated first and second local electronics are disposed within the garment.

[0035] In examples of the ambulatory cardiac device, the local biasing substrate being proximate to

the ECG electrode substrate can include the local biasing substrate being disposed adjacent the ECG electrode substrate on a fabric material.

[0036] In examples, the ambulatory cardiac device can include a shared driven ground electrode configured to aggregate the surface electrical signals to derive a common mode rejection signal and inject the common mode rejection signal into the body of the patient. In some examples, each of the first and second active ECG electrodes include a housing disposed proximate to the ECG electrode substrate for housing the first local electronics and the second local electronics, the housing rated as IP67 in accordance with standard EN 60529. In some examples, the ambulatory cardiac device can include a plurality of therapy electrodes for delivering one or more therapeutic pulses to the patient. In some examples, the ambulatory cardiac device can include an ECG acquisition box including the processor for determining the ECG signal of the patient based on the received surface electrical signals. In some examples, the ambulatory cardiac device can include a controller operably coupled to the processor, the controller configured to determine an arrhythmia condition based on the ECG signal of the patient. In some examples, the controller is configured to control delivery one or more therapeutic pulses to the patient based on the determined arrhythmia condition. In some examples, the ambulatory cardiac device can include at least one patient response button operably coupled to the controller. In some examples, the controller can be configured to control the delivery of the one or more therapeutic pulses to the patient if a patient response is not received via the at least one patient response button. In some examples, the ambulatory cardiac device can include a garment configured to be worn about a torso of the patient, and wherein the first and second ECG electrodes and associated first and second local electronics are disposed within the garment.

[0037] In examples, the ambulatory cardiac device can include a feedback loop circuit coupled between the ECG electrode substrate and the local biasing substrate. In some examples, the feedback loop circuit includes an inverting integrator circuit. In some examples, the ambulatory cardiac device can include an amplifier configured to output an amplified surface electrical signal. In some examples, the ambulatory cardiac device can include an amplifier configured to output an amplified surface electrical signal and a feedback loop circuit configured to receive the amplified surface electrical signal, invert the amplified surface electrical signal, integrate the inverted amplified surface electrical signal, and output the integrated signal to the local bias substrate. In some examples, each of the first and second active ECG electrodes includes a housing disposed proximate to the ECG electrode substrate for housing the first local electronics and the second local electronics, the housing rated as IP67 in accordance with standard EN 60529. In some examples, the ambulatory cardiac device can include a plurality of therapy electrodes for delivering one or more therapeutic pulses to the patient. In some examples, the ambulatory cardiac device can include an ECG acquisition box including the processor for determining the ECG signal of the patient based on the received surface electrical signals. In some examples, the ambulatory cardiac device can include a controller operably coupled to the processor, the controller configured to determine an arrhythmia condition based on the ECG signal of the patient. In some examples, the controller is configured to control delivery one or more therapeutic pulses to the patient based on the determined arrhythmia condition. In some examples, the ambulatory cardiac device can include at least one patient response button operably coupled to the controller. In some examples, the controller is configured to control the delivery of the one or more therapeutic pulses to the patient if a patient response is not received via the at least one patient response button. In some examples, the ambulatory cardiac device can include a garment configured to be worn about a torso of the patient, and wherein the first and second ECG electrodes and associated first and second local electronics are disposed within the garment.

[0038] In examples, the ambulatory cardiac device can include a main printed circuit assembly operably coupled to the printed circuit assemblies of the first and second local electronics, the main printed circuit assembly configured to receive analog surface electrical signals from the printed

circuit assemblies of the first and second local electronics, convert the analog surface electrical signals into digitized surface electrical signals, and provide the digitized surface electrical signals to the processor.

[0039] In examples, the ambulatory cardiac device can include an array of ECG electrodes and associated local electronics, the array including the first and second ECG electrodes and associated first and second local electronics, wherein the processor is configured to selectively power two or more ECG electrodes of the array of ECG electrodes for use in determining the ECG signal of the patient. In some examples, each of the first and second active ECG electrodes include a housing disposed proximate to the ECG electrode substrate for housing the first local electronics and the second local electronics, the housing rated as IP67 in accordance with standard EN 60529. In some examples, the ambulatory cardiac device can include a plurality of therapy electrodes for delivering one or more therapeutic pulses to the patient. In some examples, the ambulatory cardiac device can include an ECG acquisition box including the processor for determining the ECG signal of the patient based on the received surface electrical signals. In some examples, the ambulatory cardiac device can include a controller operably coupled to the processor, the controller configured to determine an arrhythmia condition based on the ECG signal of the patient. In some examples, the controller is configured to control delivery one or more therapeutic pulses to the patient based on the determined arrhythmia condition. In some examples, the ambulatory cardiac device can include at least one patient response button operably coupled to the controller. In some examples, the controller is configured to control the delivery of the one or more therapeutic pulses to the patient if a patient response is not received via the at least one patient response button. In some examples, the ambulatory cardiac device can include a garment configured to be worn about a torso of the patient, and wherein the first and second ECG electrodes and associated first and second local electronics are disposed within the garment.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0040] Various aspects of at least one example are discussed below with reference to the accompanying figures, which are not intended to be drawn to scale. The figures are included to provide an illustration and a further understanding of the various aspects and examples and are incorporated in and constitute a part of this specification but are not intended to limit the scope of the disclosure. The drawings, together with the remainder of the specification, serve to explain principles and operations of the described and claimed aspects and examples. In the figures, each identical or nearly identical component that is illustrated in various figures is represented by a like numeral. For purposes of clarity, not every component may be labeled in every figure.

[0041] FIGS. 1A and 1B illustrate sample sensor arrangements in accordance with an example of the present disclosure.

[0042] FIG. 2 illustrates a sample wearable cardiac device including sensors having local driven grounds in accordance with an example of the present disclosure.

[0043] FIG. 3A and 3B illustrates a sample sensor assembly including a steady local driven ground in accordance with an example of the present disclosure.

[0044] FIG. 4A and 4B illustrates a sample sensor assembly including a variable local driven ground in accordance with an example of the present disclosure.

[0045] FIG. 5 illustrates a sample arrangement including multiple sensor assemblies having local driven grounds in accordance with an example of the present disclosure.

[0046] FIG. 6 illustrates a schematic view of a sample controller for a wearable medical device, in accordance with an example of the present disclosure.

[0047] FIG. 7 illustrates a sample system for determining sensor leads in accordance with an

example of the present disclosure.

[0048] FIG. 8 illustrates a sample process flow for determining sensor leads in accordance with an example of the present disclosure.

[0049] FIG. 9 illustrates a sample system for controlling active sensors in accordance with an example of the present disclosure.

[0050] FIG. 10 illustrates a sample process flow for controlling active sensors in accordance with an example of the present disclosure.

[0051] FIGS. 11A and 11B illustrate sample component diagrams of a first arrangement of a sensor having a local driven ground in accordance with an example of the present disclosure.

[0052] FIGS. 12A and 12B illustrate sample component diagrams of additional arrangements of sensors having a local driven ground in accordance with an example of the present disclosure.

[0053] FIGS. 13A and 13B illustrate sample component diagrams of a sensor including one or more fabric sensing components in accordance with an example of the present disclosure.

[0054] FIGS. 14A-14D illustrate sample ambulatory medical devices that may be prescribed to a heart failure patient in accordance with an example of the present disclosure.

DETAILED DESCRIPTION

[0055] As summarized above, example wearable ECG monitoring systems disclosed herein are directed to active ECG sensing electrode assemblies that include a localized driven ground implemented as, for example, a local biasing signal. By implementing a localized driven ground at each individual active ECG sensing electrode, noise and other similar signal degrading components can be reduced due to close proximity between a local biasing substrate that is configured to output the driven ground signal and an ECG substrate that is configured to detect at least a portion of the driven ground signal.

[0056] High-performance ECG monitoring systems can include a Right Leg Drive (RLD) or driven ground electrode that serves various functions. For example, the driven ground electrode acts to ground the patient to the medical device to reduce noise on signals obtained by the device such as skin surface electrical signals that are analyzed by the device to determine one or more ECG metrics for the patient. Additionally, the driven ground electrode helps to improve common mode rejection, which is important for 60 Hz noise rejection, which is an IEC60601-2-47 standard requirement. As such, by providing a common driven ground electrode, ECG monitoring systems act to reduce overall noise and provide a universal common mode rejection signal for processing of the skin surface electrical signals as obtained by the monitoring device.

[0057] In wearable ECG monitoring systems, noise and similar signal characteristics can degrade overall signal quality. Further, wires that connect the ECG electrodes to RLD and/or common mode rejection circuitry have associated lengths that result in relatively long driven ground loops that cause an unwanted increase in noise. For example, such wires have a length and associated impedance that can affect the driven ground signal. Similarly, for example, as flexible conductors such as fabric-based conductors that electrically connect the active ECG electrodes with RLD and/or common mode rejection circuitry can stretch and cause impedance changes and noise injection resulting from motion during use of the monitoring device. Such effects are another source of motion artifact that can affect the overall signal quality of the signals obtained by the wearable ECG monitoring device. Additionally, when considering the path of the common mode signal through the patient's body, the total length of the driven ground loop can exceed several feet, thereby increasing the potential for unwanted noise affecting the overall signal quality of the signals obtained by the wearable ECG monitoring device.

[0058] In some example wearable ECG monitoring systems as described herein, disadvantages associated with wires coupling ECG electrodes to RLD and/or common mode rejection circuitry are reduced as a result of the localized driven ground signals. As the size of the ground signal loop for each individual sensing electrode is reduced, so too is the noise that accumulates on the signal between transmission into the patient's body and detection of the signal by the sensing electrode.

For example, the arrangement as shown in FIG. 2 and described below can provide for reduced sized ground signal loops. To implement such an arrangement, examples as described herein include sensing electrodes that are configured to both generate a local biasing signal, transmit the local biasing signal into the patient via a biasing substrate, detect surface electrical signals of the patient by a ECG substrate positioned proximate to a debiasing substrate, and process the surface electrical signals wherein the surface electrical signals include at least a portion of the local biasing signal.

[0059] In some examples, the local biasing signal is a steady-state signal that is continually output by the biasing substrate. The steady-state biasing signal can be generated or otherwise output such that the surface electrical signals are centered about a particular voltage range of interest. In other examples, the local biasing signal can be a variable signal that is continually output by the biasing substrate. The variable signal can be generated or otherwise output based upon at least a portion of the surface electrical signals as detected by the ECG substrate.

[0060] In some examples, the biasing substrate and the ECG substrate can be integrated into a single electrode component. For example, the biasing substrate can be formed as an outer ring configured to surround the inner ECG substrate. In other examples, one or more of the biasing substrate and the ECG substrate can be manufactured from a flexible material such as a fabric electrode including, for example, a conductive thread woven or otherwise arranged into a particular pattern. Independent of the design and positioning of the individual substrates, however, the close proximity of the biasing substrate and the ECG substrate can provide for reduced noise in the resulting sensed surface electrical signal as detected or otherwise received by the ECG substrate.

[0061] These examples, and various other similar examples that benefit from the techniques, processes, and approaches as provided herein, are described in additional detail below.

[0062] A patient having an elevated risk of sudden cardiac death, unexplained syncope, prior symptoms of heart failure, an ejection fraction of less than 45%, less than 35%, or other such threshold deemed of concern by a physician, and other similar patients in a state of degraded cardiac health can be prescribed specialized cardiac monitoring and treatment devices, such as a mobile cardiac telemetry (MCT) device, a wearable cardioverter-defibrillator (WCD), and/or an hospital wearable defibrillator (HWD). As described above, such medical devices can benefit from the incorporation of, or interoperation with, an adjustable garment.

[0063] FIGS. 1A and 1B illustrate various examples of a patient **100** wearing medical devices that include one or more sensors (e.g., sensing electrodes, accelerometers, audio and/or vibrational sensors, radio frequency (RF) sensors, stretch or pressure sensors). As shown in FIG. 1A, the patient **100** can be prescribed an ambulatory medical device such as a WCD (or, for an in-hospital patient, an HWD). The WCD can include a controller **102** that is operably connected to one or more sensing electrodes **104** and therapy electrodes **106**. Additional details of examples of the controller **102**, sensing electrodes **104**, and the therapy electrodes **106** can be found in the discussion of FIG. 6 below.

[0064] The WCD can also include one or more accelerometers or other motion sensors. As shown in FIG. 1A, the WCD can include three accelerometers **108a**, **108b**, and **108c** (collectively referred to as accelerometers **108**) positioned at various places on the body of patient **100**. For example, accelerometer **108a** can be positioned on the front of the chest of the patient **100**, the accelerometer **108b** can be positioned on the back of the patient **100**, and the accelerometer **108c** can be integrated into the controller **102**. Each of the accelerometers **108** can be configured to measure movement associated with the patient **100** and to output an electrical signal indicating a direction and magnitude of the movement of the patient **100**.

[0065] It should be noted that the number and arrangement of the accelerometers **108** as shown in FIG. 1A is by way of example only. In certain implementations, the number and position of the accelerometers **108** can vary. Additionally, when included in a device such as a WCD, one or more of the accelerometers **108** can be integrated into components of the WCD. For example, as noted

above, the accelerometer **108c** can be integrated into the controller **102** of the WCD. Similarly, one or more of accelerometers **108a** and **108b** can be integrated into one or more components of the WCD. For example, the front accelerometer **108a** can be integrated into the therapy electrode **106**, which is operably connected to the controller **102** and configured to provide a therapeutic shock to the patient **100**. In some implementations, the accelerometer **108a** can be integrated into one of the sensing electrodes **104**, which are configured to measure electrical signals produced by the patient **100** that are indicative of cardiac activity of the patient **100**. Similarly, accelerometer **108b** can be integrated into one or more components of the WCD such as a connection node, at least one sensing electrode **104**, the therapy electrode **106**, and other similar components of the WCD as described herein. Alternatively or additionally, the one or more accelerometers **108** can be distinct components of the WCD.

[0066] In HWD implementations, the accelerometers can be integrated into one or more adhesive ECG sensing and/or therapy electrode patches. For example, a first accelerometer can be integrated into a first adhesive ECG sensing and/or therapy electrode patch and a second accelerometer can be integrated into a second adhesive ECG sensing and/or therapy electrode patch. Additional accelerometers can be disposed within a controller (similar to the controller **102** of a WCD) associated with the HWD.

[0067] In addition to accelerometers associated with a WCD as described above in regard to FIG. **1A**, a patient such as the patient **100** can also wear additional sensors. As shown in FIG. **1B**, the patient **100** can wear a vibrational sensor **110** that is configured to record bio-vibrational signals of the patient **100**. For example, the vibrational sensor **110** can be configured to detect vibrations of the patient **100** that are associated with, for example, heart and lung activity. In certain implementations, the vibrational sensor **110** can be configured to detect cardiovibrational values including any one or all of **S1**, **S2**, **S3**, and **S4**. From these cardiovibrational values, certain heart vibration metrics or combinational metrics may be calculated, including any one or more of electromechanical activation time (EMAT), left ventricular systolic time (LVST), or percentage of left ventricular systolic time (% LVST). In some examples, the vibrational sensor **110** can be configured to detect vibrations from the cardiac system of the patient **100** and provide an output signal responsive to the detected cardiovibrational values. The vibrational sensor **110** can also include a multi-channel accelerometer, for example, a three-channel accelerometer configured to sense movement in each of three orthogonal axes such that patient movement/body position can be detected and correlated to detected cardiovibrational values. The vibrational sensor **110** can transmit information descriptive of the cardiovibrational values to, for example, a sensor interface for subsequent analysis as described below.

[0068] Additionally, the patient **100** can wear an RF sensor **112**. For example, the RF sensor **112** can be configured to use RF-based techniques to assess fluid levels and accumulation in body tissue of the patient **100**. For instance, the RF sensor **112** can be configured to measure fluid content in the lungs, typically for diagnosis and follow-up of pulmonary edema or lung congestion in heart failure patients. Similarly, the RF sensor can be configured to measure thoracic fluid content for the patient **100**. In certain implementations, the RF sensor **112** can include one or more antennas configured to direct radio frequency waves through tissue of the patient **100** and measure output radio frequency signals in response to the waves that have passed through the tissue. In certain implementations, the output radio frequency signals include parameters indicative of a fluid level in the tissue. The RF sensor **112** can transmit information descriptive of the tissue fluid levels to a sensor interface for subsequent analysis as described below.

[0069] It should be noted that the placement and number of sensors as shown in FIGS. **1A** and **1B** are shown by way of example only. In actual implementation of the medical devices as described herein, the number and position of the sensors can vary based upon the type of patient monitoring and/or treatment to be performed and other various factors.

[0070] FIG. **2** illustrates system **200** including the components of a wearable medical device

including, for example, a WCD as described herein. As shown in FIG. 2, the components of the wearable medical device can be operably connected to a node **202** including, for example, a belt node or other similar node configured to both receive signals from and transmit signals to the components of the wearable medical device. For example, as shown in FIG. 2, belt node **202** can be operably connected to a set of sensing electrodes **204a-204d**. In certain implementations, if the wearable medical device includes treatment functionality, a set of therapy electrodes **206a-206c** can also be operably coupled to the belt node **202**. In some examples, the belt node **202** can be further coupled to a controller or another processing device configured to receive signals from the belt node **202**, process the signals received from the belt node **202**, and send control signals back to the belt node **202**. As such, the belt node **202** can be configured to operate as an ECG acquisition node or box that is configured to determine an ECG signal of the patient based on a received surface electrical signal as received from each of the sensing electrodes **204a-204d** as described herein.

[0071] As further shown in FIG. 2, and as taught herein, each of the sensing electrodes **204a-204d** can be configured to include circuitry to generate and output a localized driven ground signal. As described herein, by providing each individual sensing electrode with the circuitry to generate and output a localized driven ground signal, overall system noise can be reduced as the individual ground loop size for each sensing electrode is reduced. Additionally, the multiple localized driven ground signals provide redundancy in the system as sensing electrodes can further detect localized driven ground signals from other sensing electrodes in the event of a malfunction of an individual electrode's ability to generate a localized driven ground signal. In other examples, the sensing electrodes can include sensed localized driven ground signals from other sensing electrodes when generating a common mode noise signal and, as a result of the combined common mode noise signal, reduce or otherwise eliminate system noise more efficiently and accurately.

[0072] More specifically, as shown in FIG. 2 and described in greater detail in the discussion of FIGS. 3A and 3B, each of the sensing electrodes **204a-204d** can include an ECG electrode substrate configured to be in physical contact with the skin of the patient and sense, detect, or otherwise receive one or more surface electrical signals from the patient. Additionally, each of the sensing electrodes **204a-204d** can further include a local biasing substrate proximate to the ECG electrode substrate and also configured to be in physical contact with the skin of the patient. The local biasing substrate can be configured to provide a local biasing signal to the patient's body, the local biasing signal acting as a localized driven ground signal as described herein. For example, as shown in FIG. 2, sensing electrode **204a** can be configured to transmit and receive localized driven ground signal **208a**. Similarly, sensing electrode **204b** can be configured to transmit and receive localized driven ground signal **208b**, sensing electrode **204c** can be configured to transmit and receive localized driven ground signal **208c**, and sensing electrode **204d** can be configured to transmit and receive localized driven ground signal **208d**.

[0073] FIG. 3A illustrates system **300** including a more detailed schematic view of a sensing electrode such as one of sensing electrodes **204a-204d** as shown in FIG. 2 and described above. For example, as shown in FIG. 3A, an ECG assembly **302** can include an ECG substrate **304** and a biasing substrate **306**. In some examples, the ECG substrate **304** can be a dry substrate, e.g., a substrate that is not attached to the patient's skin by an adhesive or where contact is mediated by conductive gel. In an example scenario, a dry ECG substrate is placed directly on the skin and, as a result of the contact between the electrode and the skin, perspiration can accumulate on the electrode surface to provide an electrolytic connection with the patient. A dry ECG substrate can be constructed from a housing configured to hold various circuit components and a treated, anodized metal surface configured to contact the patient's skin. For example, the treated, anodized metal surface can be treated with a tantalum pentoxide coating.

[0074] Depending on the design, a dry ECG substrate can be configured to have a wide range of input impedances when in contact with a patient's skin. For example, the impedance as seen by the ECG substrate when in contact with the patient's skin can be in excess of 400 Ω , typically in the

range of tens to hundreds of megaohms. In certain implementations, the dry ECG substrate can have an impedance range of 400 Ω to 10 M Ω . In some examples, a dry ECG substrate can be a high impedance electrode having an impedance range of 10 M Ω to 100 M Ω , 100 M Ω to 1.0 G Ω , and 1.0 G Ω to 10 G Ω .

[0075] As described herein, the ECG substrate **304** can be configured to be in physical contact with the skin of the patient. Similarly, the biasing substrate **306** can also be configured to be in physical contact with the skin of the patient and positioned proximate to the ECG substrate **304** such that any signal transmitted or otherwise output by the biasing substrate **306** is detected and received by the ECG substrate **304**. Additionally, the ECG assembly **302** can include a circuitry **308**. The circuitry **308** can be configured to receive signals from the ECG substrate **304**, process the received signals, and output one or more signals to the biasing substrate **306**. In certain implementations, the circuitry **308** can be implemented as a printed circuit assembly manufactured in or otherwise printed on a dedicated circuit board.

[0076] As further shown in FIG. 3A, the circuitry **308** can include an ECG sensing circuitry **310**. The ECG sensing circuitry **310** can be electrically coupled to the ECG electrode substrate **304** and configured to receive one or more surface electrical signals as sensed or otherwise received by the ECG substrate **304**. Similarly, the circuitry **308** can include a biasing circuitry **312**. The biasing circuitry **312** can be electrically coupled to the biasing substrate **306** and configured to provide a local biasing signal to the biasing substrate **306** for transmission into the patient's body. In certain implementations, the biasing circuitry **312** can include one or more biasing elements **314** configured to condition the local biasing signal. For example, the biasing elements **314** can include one or more circuit elements such as resistors, capacitors, inductors, operational amplifiers, diodes, ground signals, voltage inputs, and other similar circuit elements.

[0077] As further shown in FIG. 3A, the biasing substrate **306** can be configured to output a local biasing signal **316** to the skin of the patient. The ECG substrate **304** can be configured to receive or otherwise sense a surface electrical signal **318**. In some examples, the surface electrical signal **318** can include electrical signals generated by the body of the patient including, for example, signals indicative of cardiac activity of the patient as well as at least a portion of the local biasing signal **316** as output by the biasing substrate **306**. Based upon the close proximity of the ECG substrate **304** and the biasing substrate **306**, noise introduced into the surface electrical signal **318** as a result of the distance travelled by the local biasing signal **316** is reduced, thereby increasing the signal-to-noise ratio of the surface electrical signal **318** and the overall signal quality of the surface electrical signal **318**.

[0078] In certain implementations, the biasing signal as output by the biasing substrate can be configured to be a steady-state signal. For example, the biasing circuitry can be configured to condition a steady voltage input and output a steady-state biasing signal. FIG. 3B illustrates a more detailed view of system **300** including particular circuit elements configured to process the surface electrical signal **318** as sensed or otherwise received by the ECG substrate **304**, as well as to condition a steady-state biasing signal for output by the biasing substrate **306** as the local biasing signal **316**.

[0079] More specifically, as shown in FIG. 3B, the ECG sensing circuitry **310** can include various circuit elements configured to condition the surface electrical signal **318** as sensed or otherwise received by the ECG substrate **304**. For example, the ECG sensing circuitry **310** can include a resistor **R1** sized appropriately to condition the surface electrical signal **318** and to provide patient isolation from the components of the ECG circuitry **310**. In an example, **R1** can have a resistance between about 50 k Ω and 500 k Ω . Additionally, the ECG sensing circuitry **310** can include an inductor **L1** and capacitor **C1** also sized appropriately to condition the surface electrical signal **318** and provide for a high frequency lowpass filter. For example, **L1** can have an inductance of about 10 nH to about 10 μ H and **C1** can have a capacitance of about 10 pF to about 1000 pF. The ECG sensing circuitry **310** can also include at least one operational amplifier **320**. In certain

implementations, the operational amplifier **320** can be configured to produce a high-gain output based upon the conditioned surface electrical signal **318**. For example, based upon the input and circuit components used to condition the inputs of the operational amplifier **320**, the operational amplifier **320** can be configured to output a signal approximately equal to the patient's measured ECG signal (e.g., about 100 μV to about 5.0 mV) plus any noise as well as a DC voltage that is approximately equal to the biasing signal plus any offsets related to the skin/electrode interface (e.g., between about 100 mV to 1000 mV). The output of the operational amplifier **320** can be passed to, for example, a processor for further analysis and processing of the conditioned surface electrical signal **318** as described herein.

[0080] As further shown in FIG. 3B, the biasing circuitry **312** can also include various circuit elements configured to produce a steady-state biasing signal to be output as the local biasing signal **316**. For example, the biasing circuitry **312** can include various resistors **R5**, **R6**, and **R10** sized appropriately to condition an input steady voltage signal V_s such as, for example, a 5.0 V input. In an example, resistors **R5** and **R6** can have a resistance of between about 1.0 k Ω and about 1.0 M Ω . The combination of resistors **R5** and **R6** can form a voltage divider used to generate a localized bias voltage from the local supply voltage $V_{\text{sub.s}}$. Resistor **R10** can be included to protect circuitry from voltage caused by, for example, a defibrillation or other treatment event. Resistor **R10** can have a resistance between about 1.0 k Ω and about 100 k Ω . In some examples, the resistor **R10** can be replaced with a high-voltage switch configured to protect components of the biasing circuitry **312**.

[0081] Additionally, the biasing circuitry can include at least one capacitor **C3** sized appropriately to filter the localized bias voltage. In an example, **C3** can have a capacitance of about 1.0 μF to about 50.0 μF . The biasing circuitry **312** can also include an operational amplifier **322** configured to produce a high-gain output based upon the localized bias voltage. In certain implementations, the operational amplifier **322** can be configured to produce a voltage equal to half of the supply voltage V_s as well as the electrode half-cell potential for, for example, a silver/silver chloride electrode. For a dry electrode, the operational amplifier **322** can be configured to produce a signal between about 2.0 V and 5.0 V to account for variation in electrode offset during wear.

[0082] It should be noted that the input voltages as shown in FIG. 3B as included in the biasing circuitry **312** are shown by way of example only. In implementation, the input voltages can be selected or otherwise chosen based upon the expected voltage range of the surface electrical signals **318** as sensed or otherwise received by the ECG substrate **304**. For example, if the desired voltage range of the surface electrical signals **318** is 0.0 V to 5.0 V, the input voltage can be selected such that the local biasing signal **316** is approximately half of the expected voltage range, in this example, 2.5 V. By providing a local biasing signal **316** that is approximately half of the expected voltage range of the surface electrical signal **318**, the local biasing signal **316** can act to center the surface electrical signal **318** about the appropriate and expected voltage range.

[0083] It should be noted that the 2.5 V is selected as the voltage of the output local biasing signal by way of example only. In implementations, the voltage of the output local biasing signal can vary accordingly and include, for example, voltages including, but not limited to, 0.5 V, 1.0 V, 1.5 V, 2.0 V, 2.5 V, 3.0 V, 3.5 V, 4.0 V, and 4.5 V. More generally, any voltage between 0 V and the chosen supply voltage can be output as the local biasing signal as described herein.

[0084] In the arrangement as shown in FIGS. 3A and 3B, the bias substrate can drive a constant and steady-state bias voltage into the patient's body in close proximity to the ECG substrate. Such an approach can be implemented with active electrodes that include a digital front end including, for example, additional circuitry such as an analog-to-digital converter and microcontroller. For active electrodes, several feet of cable length can be omitted, thereby avoiding a source of signal noise that degrades or otherwise impacts the quality of the sensed ECG signals.

[0085] In addition to providing a steady-state local biasing signal, a sensor assembly as described herein can be configured to produce a variable local biasing signal using, for example, an inverting

integrator circuit. For example, the biasing circuitry can use a conditioned version of the sensed surface electrical signals as an input rather than a fixed voltage input as shown in FIG. 3B and described above.

[0086] For example, FIG. 4A illustrates system **400** including a detailed schematic view of a sensing electrode assembly that includes a variable local biasing signal. For example, as shown in FIG. 4A, an ECG assembly **402** can include an ECG substrate **404** and a biasing substrate **406**. As described herein, the ECG substrate **404** can be configured to be in physical contact with the skin of the patient. Similarly, the biasing substrate **406** can also be configured to be in physical contact with the skin of the patient and positioned proximate to the ECG substrate **404** such that any signal transmitted or otherwise output by the biasing substrate **406** is detected and received by the ECG substrate **404**. Additionally, the ECG assembly **402** can include circuitry **408**. The circuitry **408** can be configured to receive signals from the ECG substrate **404**, process the received signals, and output one or more signals to the biasing substrate **406**. In certain implementations, the circuitry **408** can be implemented as a printed circuit assembly manufactured in or otherwise printed on a dedicated circuit board.

[0087] As further shown in FIG. 4A, the circuitry **408** can include an ECG sensing circuitry **410**. The ECG sensing circuitry **410** can be electrically coupled to ECG electrode substrate **404** and configured to receive one or more surface electrical signals as sensed or otherwise received by the ECG substrate **404**. Similarly, the circuitry **408** can include a biasing circuitry **412**. The biasing circuitry **412** can be electrically coupled to the biasing substrate **406** and configured to provide a local biasing signal to the biasing substrate **406** for transmission into the patient's body. In certain implementations, the biasing circuitry **412** can include one or more biasing elements **414** configured to condition the local biasing signal. For example, the biasing elements **414** can include one or more circuit elements such as resistors, capacitors, inductors, operational amplifiers, diodes, ground signals, voltage inputs, and other similar circuit elements. Additionally, as shown in FIG. 4A, the biasing circuitry **412** can be operably connected to the ECG sensing circuitry **410** and configured to receive one or more signals from the ECG sensing circuitry **410**.

[0088] As further shown in FIG. 4A, the biasing substrate **406** is configured to output a local biasing signal **416** to the skin of the patient. The ECG substrate **404** can be configured to receive or otherwise sense a surface electrical signal **418**. In some examples, the surface electrical signal **418** includes electrical signals generated by the body of the patient including, for example, signals indicative of cardiac activity of the patient as well as at least a portion of the local biasing signal **416** as output by the biasing substrate **406**. Based upon the close proximity of the ECG substrate **404** and the biasing substrate **406**, noise introduced into the surface electrical signal **418** as a result of the distance travelled by the local biasing signal **416** is reduced, thereby increasing the signal-to-noise ratio of the surface electrical signal **418** and the overall signal quality of the surface electrical signal **418**.

[0089] In some examples, as further shown in FIG. 4A, the output of the ECG sensing circuitry can also be directed to an analog-to-digital converter **420**. The converter **420** can be configured to receive the output of the ECG sensing circuitry **410** and convert the signal to a digital signal. The digital output of the converter **420** can be output to a processor **422**. The processor **422** can be configured to generate a local biasing input signal based upon the digital signal and output the local biasing input signal to the biasing circuitry **412**. In some examples, the output of the processor **422** can be a filtered pulse-width modulated signal. In some other examples, the processor can be configured to control a digital-to-analog converter to adjust the input to, for example, an operational amplifier as described below.

[0090] In certain implementations, the biasing signal as output by the biasing substrate can be configured to be a variable signal. For example, the biasing circuitry can be configured to condition a varying input received from the ECG sensing circuitry and to condition and output a variable biasing signal. FIG. 4B illustrates a more detailed view of the system **400** including particular

circuit elements configured to process the surface electrical signal **418** as sensed or otherwise received by the ECG substrate **404**, as well as to condition a variable biasing signal for output by the biasing substrate **406** as the local biasing signal **416**.

[0091] More specifically, as shown in FIG. **4B**, the ECG sensing circuitry **410** can include various circuit elements configured to condition the surface electrical signal **418** as sensed or otherwise received by the ECG substrate **404**. For example, the ECG sensing circuitry **410** can include a resistor **R11** sized appropriately to condition the surface electrical signal **418** and to provide patient isolation from the components of the ECG circuitry **410**. In an example, **R11** can have a resistance between about 50 k Ω and 500 k Ω . Additionally, the ECG sensing circuitry **410** can include an inductor **L2** and capacitor **C5** also sized appropriately to condition the surface electrical signal **418** and provide for a high frequency lowpass filter. For example, **L2** can have an inductance of about 10 nH to about 10 μ H and **C5** can have a capacitance of about 10 pF to about 1000 pF. The ECG sensing circuitry **410** can also include at least one operational amplifier **424**. In certain implementations, the operational amplifier **424** can be configured to produce a high-gain output based upon the conditioned surface electrical signal **418**. For example, based upon the input and circuit components used to condition the inputs of the operational amplifier **424**, the operational amplifier **424** can be configured to output a signal approximately equal to the patient's measured ECG signal (e.g., about 100 μ V to about 5.0 mV) plus any noise as well as a DC voltage that is approximately equal to the biasing signal plus any offsets related to the skin/electrode interface (e.g., between about 100 mV to 1000 mV). The output of the operational amplifier **424** can be passed to, for example, a processor for further analysis and processing of the conditioned surface electrical signal **418** as described herein.

[0092] As further shown in FIG. **4B**, the output of the operational amplifier **424** can be passed to the biasing circuitry **412**. The biasing circuitry **412** can include various circuit elements configured to produce a variable biasing signal based upon the output of the operational amplifier to be output as the local biasing signal **416**. For example, the biasing circuitry **412** can include various resistors **R15**, **R16**, and **R17** sized appropriately to condition an input steady voltage signal $V_{sub.s/2}$ such as, for example, a 2.5 V input. In an example, resistors **R15** and **R16** can have a resistance of between about 1.0 k Ω and about 1.0 M Ω . The combination of resistors **R15** and **R16** can form a voltage divider used to generate a localized bias voltage from the local supply voltage $V_{sub.s/2}$. Resistor **R17** can be included to protect circuitry from voltage caused by, for example, a defibrillation or other treatment event. Resistor **R17** can have a resistance between about 1.0 k Ω and about 100 k Ω . In some examples, the resistor **R17** can be replaced with a high-voltage switch configured to protect components of the biasing circuitry **412**.

[0093] Additionally, the biasing circuitry can include at least one capacitor **C7** sized appropriately to filter the localized bias voltage. In an example, **C7** can have a capacitance of about 1.0 μ F to about 50.0 μ F. The biasing circuitry **412** can also include an operational amplifier **426** configured to produce a high-gain output based upon the localized bias voltage. In certain implementations, the operational amplifier **426** can be configured to produce a voltage equal to the supply voltage $V_{sub.s/2}$ as well as the electrode half-cell potential for, for example, a silver/silver chloride electrode. For a dry electrode, the operational amplifier **426** can be configured to produce a signal between about 2.0 V and 5.0 V to account for variation in electrode offset during wear.

[0094] Additionally, as shown in FIG. **4B**, the circuitry can include several switches **S1**, **S2**, and **S3**. Depending upon the state of each individual switch, the type of input signal and resulting output local bias signal **416** can be controlled. For example, if each of switches **S1**, **S2**, and **S3** are open, this results in a stable constant DC bias applied to the biasing substrate **406** for output as the local biasing signal **416**. In another example, if switches **S1** and **S2** are closed, and switch **S3** is open, the output of the ECG sensing circuitry **410** is integrated into the local biasing signal **416**. In another example, if switches **S1** and **S2** are open, and switch **S3** is closed, a local processor (such as processor **422** as shown in FIG. **4A** and described above) can control the input signal to the

biasing circuitry **412** and the resulting local biasing signal **416** output by the biasing substrate **416** as described above. For example, as noted above, the local processor can be configured to output a filtered pulse-width modulated signal or to control a digital-to-analog converter to adjust the input to, for example, the operational amplifier **426** described herein.

[0095] The arrangement as shown in FIG. **4B** provides for a variable biasing signal that varies in response to changes in the surface electrical signals as well as to potential input signals from a local processor. Such an arrangement provides for a feedback loop implemented as an inverting integrator. The integrator circuit inverts the output of the operational amplifier **424**, integrates the signal, and sends back out to the biasing substrate as the variable biasing signal. Such an approach can cancel slow drifts in ECG electrode offset over time that can naturally occur through wear, after cleaning the sensing electrodes, applying lotion, and other similar patient activities that may impact the quality of the skin-interface connection. This approach can also help to avoid amplifier saturation or signal clipping that may otherwise occur at certain gain settings.

[0096] It should be noted that the variable biasing signal as discussed with regard to FIGS. **4A** and **4B** above is shown as a variable voltage signal by way of example only. In actual implementation, the variable biasing signal can be implemented as a time-varying signal that includes one of a variable current signal or a variable voltage signal as described above.

[0097] In certain examples, multiple sensor assemblies can be arranged into leads or sensor pairs, the outputs of which are used by a processor to determine one or more ECG metrics and an associated cardiac activity for a patient. For example, FIG. **5** illustrates a system **500** including two ECG assemblies as described herein. A first ECG assembly **502** can include a first ECG substrate **504** and a first biasing substrate **506**. The first ECG assembly **502** can also include a first circuitry **508**. The first circuitry **508** can include a first ECG sensing circuitry **510** as well as a first biasing circuitry **512**. The first circuitry **508** can be configured to process and analyze signals received from the first ECG substrate **504** as well as to generate and condition a biasing signal for output by the first biasing substrate **506**. For example, the first circuitry **508** can be configured to generate a steady-state biasing signal as described above, for example, in the discussion of FIG. **3B** or a variable biasing signal as described above, for example, in the discussion of FIG. **4B**.

[0098] As further shown in FIG. **5**, the first biasing substrate **506** of first ECG assembly **502** can be configured to output a first local biasing signal **514**. Additionally, the first ECG substrate **504** can be configured to sense or otherwise receive a first electrical signal **516** from the patient. In certain implementations, the first surface electrical signal **516** includes at least a portion of the first local biasing signal **514** as output by the first biasing substrate **506**. Based upon the first electrical signal **516**, the first circuitry **508** can be configured to output a conditioned and processed first surface electrical signal **518**.

[0099] FIG. **5** further illustrates a second ECG assembly **522**. The second ECG assembly **522** can include a second ECG substrate **524** and a second biasing substrate **526**. The second ECG assembly **522** can also include a second circuitry **528**. The second circuitry **528** can include second ECG sensing circuitry **530** as well as a second biasing circuitry **532**. The second circuitry **528** can be configured to process and analyze signals received from the second ECG substrate **524** as well as to generate and condition a biasing signal for output by the second biasing substrate **526**. For example, the second circuitry **528** can be configured to generate a steady-state biasing signal as described above in the discussion of FIG. **3B** or a variable biasing signal as described above in the discussion of FIG. **4B**.

[0100] As further shown in FIG. **5**, the second biasing substrate **526** of the second ECG assembly **522** can be configured to output a second local biasing signal **534**. Additionally, the second ECG substrate **524** can be configured to sense or otherwise receive a second electrical signal **536** from the patient. In certain implementations, the second surface electrical signal **536** includes at least a portion of the second local biasing signal **534** as output by the second biasing substrate **526**. Based upon the second electrical signal **536**, the second circuitry **528** can be configured to output a

conditioned and processed second surface electrical signal **538**.

[0101] As further shown in FIG. 5, a processor **540** can be configured to receive both the processed first surface electrical signal **518** and the processed second surface electrical signal **538**. The processor **540** can be configured to further condition and process the received signals an output a patient ECG signal **542** for further analysis by, for example, a medical device controller as described herein. In certain implementations, the processor **540** can be integrated into a node such as belt node **202** as described herein above. In some examples, the processor **540** can be integrated into the medical device controller as described herein below. In other examples, an ECG assembly can be implemented as an active electrode that includes a local processor for conditioning the surface electrical signals directly at the sensing electrode. In such an example, the active electrode can be configured to output a signal similar to the patient ECG signal **542** for further processing by a medical device controller as described herein.

[0102] FIG. 6 illustrates an example of a medical device controller **600** that is configured to control components of the medical devices described herein as well as process signals received from, for example, one or more sensing electrodes as described herein. A brief introduction applicable to medical controllers in general will now be provided with reference to FIG. 6. A more detailed description of some of the components of the medical device controller **600** is provided for additional context in a sample medical device discussion further below.

[0103] More specifically, FIG. 6 illustrates an example component-level view of the medical device controller **600** included in, for example, a wearable medical device such as a WCD or an HWD as described herein. As shown in FIG. 6, the medical device controller **600** can include a housing **601**. The housing **601** can house a therapy delivery circuitry **602** configured to provide one or more therapeutic shocks to a patient via at least two therapy electrodes **620** (e.g., therapy electrode **106** and therapy electrodes **206a-206c** as described above), a data storage **604**, a network interface **606**, a user interface **608**, and at least one rechargeable battery **610** (e.g., within a battery chamber configured for such purpose). The housing **601** can be further configured to house a sensor interface **612** (e.g., to interface with both ECG sensing electrodes **622** (e.g., sensing electrodes **104** and sensing electrodes **204a-204d** as described above) and non-ECG physiological sensors **623** such as vibrational sensors (e.g., vibrational sensor **110**), lung fluid sensors (e.g., RF sensor **112**), infrared and near-infrared-based pulse oximetry sensor, and blood pressure sensors, among others), a cardiac event detector **616**, and at least one processor **618**.

[0104] In some examples, the patient monitoring medical device can include a medical device controller that includes like components as those described above but that does not include the therapy delivery circuitry **602** and the therapy electrodes **620** (shown in dotted lines). That is, in certain implementations, the medical device can include only ECG monitoring components and not provide therapy to the patient. In such implementations, which may be referred to as MCT devices, the construction of the patient monitoring medical device is similar in many respects to the medical device controller **600** but need not include the therapy delivery circuitry **602** and associated therapy electrodes **620**.

[0105] In addition to providing a localized driven ground signal as described herein, the concepts as described can further be used to provide for selective lead forming and power management of an array of active electrodes. For example, FIG. 7 illustrates a system **700** that can be used to dynamically select sensing electrode leads. More specifically, as shown in FIG. 7, the system **700** can include a set of sensing electrodes **702a, 702b, 702c**, through **702n**. Each of the sensing electrodes can be operably coupled to a lead select switch **704**. The lead select switch **704** can be configured to receive the output of the sensing electrodes and determine one or more electrode pairs based upon an analysis of the output. The lead select switch **704** can be further configured to output signals received from the sensing electrodes to one or more amplifiers **706a** through **706x**. For example, the amplifiers **706a** through **706x** can be implemented as operational amplifiers or instrumentation amplifiers. The amplifiers **706a** through **706x** can be configured to amplify and

filter the signals to form one or more lead outputs for each sensing electrode lead as output by the lead select switch. The outputs of the amplifiers **706a**, **706b**, through **706x** can be transferred to one or more analog-to-digital converters **708** for processing and conversion to a digital output for transmission to, and processing by, a processor **710**.

[0106] For example, based upon an analysis of the output of each sensing electrode, a processing device operably coupled to the lead select switch **704** can determine that sensing electrode **702a** and sensing electrode **702b** are to be coupled as a sensing electrode lead. As such, lead select switch **704** can be configured to output signals received from electrode **702a** and sensing electrode **702b** to the amplifier **706a**. The amplifier **706a** can be configured to condition and filter the signal and output an electrode lead signal to the analog-to-digital converter **708** for processing and conversion to a single digital signal for further processing by processor **710**.

[0107] FIG. **8** illustrates a sample process **800** that can be used by a processor, such as a processor like the processor **618** has shown in FIG. **6** and discussed above, to analyze sensing electrode signals to determine electrode leads using, for example, the system **700** as shown in FIG. **7** and described above. The processor can receive **802** the outputs of the sensing electrodes. The processor can analyze and process the sensing electrode outputs to determine **804** one or more signal characteristics for each of the sensing electrode outputs. Based upon an analysis of the determined signal characteristics, the processor can determine **806** one or more signal leads for the sensing electrodes. For example, the processor can determine a pair of sensing electrodes that have outputs with similar signal characteristics that would match or otherwise combine to produce a high quality sensing electrode lead.

[0108] As further shown in FIG. **8**, once the sensing electrode leads are determined, the processor can perform **808** signal conditioning using, for example, one or more operational amplifiers as shown in FIG. **7** and described above. The processor can further convert **810** the conditioned signals using, for example, an analog to digital converter and output **812** the digital signals for further processing.

[0109] It should be noted that process **800** includes outputting **812** the digital signals for further processing by way of example only. In certain implementations, the processor performing process **800** can further process the converted signals without outputting to an additional processing device.

[0110] In another example, by monitoring the noise and signal quality at each individual sensing electrode, power to an individual sensing electrode can be reduced or turned off, thereby providing for active power management and power conservation. For example, FIG. **9** illustrates system **900** that includes a power management arrangement for a series of active sensing electrodes as described herein. As shown, a processor **902** can be configured to monitor signal quality and noise for multiple sensing electrodes **908a** through **908n**. Based upon the signal quality and noise levels of each of the sensing electrodes **908a** through **908n**, the processor **902** can provide a control signal to one or more individual switches **906a** through **906n** within a power select switch array **904**, thereby turning on or turning off power to one or more of the sensing electrodes **908a** through **908n**.

[0111] For example, as shown in FIG. **9**, the processor **902** can determine that the sensing electrode **908b** and the sensing electrode **908c** are producing high-quality output signals with minimal noise. Similarly, the processor **902** can determine that the sensing electrode **908a** and the sensing electrode **908n** are producing lower quality output signals with high levels of noise. As such, the processor **902** can control the power select switch array **904** such that: the switch **906a** is open, thereby turning off power to the sensing electrode **908a**; the switch **906b** is closed, thereby providing power to the sensing electrode **908b**; the switch **906c** is closed, thereby providing power to sensing electrode **908c**; and the switch **906n** is open, thereby turning off power to sensing electrode **908n**.

[0112] FIG. **10** illustrates a sample process **1000** that can be implemented by, for example, a processor such as processor **902** as shown in FIG. **9** and described above. More specifically,

process **1000** includes the processor receiving **1002** sensor outputs from each of the sensing electrodes. The processor can determine **1004** signal characteristics for each of the sensor outputs and determine which individual sensing electrodes are producing a high-quality and reliable output signal. For example, the processor can determine a signal-to-noise ratio for each sensor output as received from each sensing electrode. Based upon the determined signal characteristics, the processor can determine **1006** which active sensing electrodes to provide power to and which active sensing electrodes to turn off the power to. For example, the processor can compare the determined signal-to-noise ratio for each sensor output against a threshold value, e.g., a 5:1 signal-to-noise ratio. In certain implementations, the processor can perform a fast Fourier transform-based analysis to look for excess noise (e.g., 60 Hz noise) to determine the suitability of a given sensing electrode. For example, for an output signal that satisfies the threshold and/or further analysis, the processor can determine **1006** to provide power. Conversely, for each output signal that fails to satisfy the threshold, the processor can determine **1006** to turn the power off. Based upon this determination **1006**, the processor can update **1008** the power select switch array such that power is delivered to each of the active sensing electrodes appropriately.

[0113] It should be noted that analyzing signal-to-noise ratio as described above is provided by way of example only and other signal characteristics can be determined and analyzed. For example, the processor can determine whether a sensor output is indicative of an electrode falloff condition, e.g. that a sensing electrode has lost contact with the patient's body. In such an example, a sensing electrode that has lost contact can be powered off accordingly. In another example, the processor can detect amplifier saturation in the output signal of a sensing electrode. If the output signal is at one of the extremes of an amplifier associated with the sensing electrode, the processor can determine that the amplifier is saturated and that the output signal is not likely useful. In such an example, the processor can turn off power to that sensing electrode.

[0114] It should be noted that the system **700** as shown in FIG. 7 and the system **900** as shown in FIG. 9 are provided by way of example only and are intended to show additional functionality that can be achieved using the localized driven ground signals as described herein. Similarly, it should be noted that process **800** as shown in FIG. 8 and process **1000** as shown in FIG. 10 are provided by way of example only to show a set of sample process steps that can be implemented by one or more processors to execute the processes as described herein as related to the systems **700** and **900** as described above.

[0115] As described herein, the position of the ECG substrate and the local biasing substrate can vary depending upon the implementation and design of the sensing electrode. FIGS. **11A** through **13B** describe various implementations and arrangements for a sensing electrode including both an ECG substrate and a biasing substrate as described herein.

[0116] For example, as shown in FIGS. **11A** and **11B**, the ECG substrate and the biasing substrate can be arranged such that one substrate encircles or otherwise surrounds the other substrate. FIG. **11A** illustrates a side view of sensing electrode assembly **1100**. As shown in FIG. **11A**, the sensing electrode can be connected to a substrate such as a portion of a garment **1102**. The assembly **1100** can further include a housing **1104** of the sensing electrode that can be removably attached to the garment **1102**. The housing **1104** can also be configured to enclose circuitry **1106**. As described herein, the circuitry **1106** can include both ECG sensing circuitry and biasing circuitry as shown, for example, in FIG. 3A as described above. In some examples, the housing **1104** can include a specific ingress protection (IP) rating that classifies the degree of protection the housing provides as defined by standard EN 60529. For example, the housing **1104** can include an IP rating of at least IP67 which indicates the housing **1104** is dust tight and protected against immersion in water for 30 minutes at depths between 0.15 meters and 1.0 meter. In some examples, the housing **1104** can include an IP rating of at least IP68 which indicates the housing **1104** is dust tight and protected against complete and continuous submersion in water over 1.0 meter in depth.

[0117] As further shown in FIG. **11A**, the assembly **1100** can further include a first electrode

substrate **1108** and a second electrode substrate **1110**. In certain implementations, the first electrode substrate **1108** can be configured to function as the ECG substrate as described herein and the second electrode substrate **1110** can be configured to function as the biasing substrate as described herein. In other examples, the first electrode substrate **1108** can be configured to function as the biasing substrate as described herein and the second electrode substrate **1110** can be configured to function as the ECG substrate as described herein.

[0118] FIG. **11B** illustrates a front view of assembly **1100**. For example, as shown in FIG. **11B**, the first electrode substrate **1108** is configured to be outside of and to encircle or otherwise surround the second electrode substrate **1110**. As further shown in FIG. **11B**, an insulating layer **1112** can be positioned between the first electrode substrate **1108** and the second electrode substrate **1110** to provide electrical isolation between the two electrode substrates. For example, the first electrode substrate **1108** can be configured to function as the ECG substrate and can be manufactured from, for example, silver/silver chloride or an oxidized material coated with, for example, a tantalum-oxide coating. The second electrode substrate **1110** can be configured to function as the biasing substrate and can be manufactured from, for example, stainless steel. In such an example, the insulating layer **1112** can be made from a non-conductive material such as rubber, plastic, or another similar insulating material that is sized and configured to electrically isolate the first electrode substrate **1108** from the second electrode substrate **1110**. For example, the insulating layer **1112** may be configured and positioned such that the first electrode substrate **1108** and the second electrode substrate **1110** are about 0.01 inches apart, about 0.10 inches apart, about 0.25 inches apart, or about 0.50 inches apart.

[0119] FIGS. **12A** and **12B** illustrate alternative arrangements for a sensing electrode including both an ECG substrate and a biasing substrate as described herein. For example, FIG. **12A** illustrates sensor assembly **1200** including a sensor mounted on a portion of a garment **1202**. As shown in assembly **1200**, the sensing electrode includes a first electrode substrate **1204** and a second electrode substrate **1206**. Rather than being arranged in concentric circles as shown in FIGS. **11A** and **11B**, the electrode substrates can be arranged in additional patterns and/or arrangements. For example, as shown in FIG. **12A**, the second electrode substrate **1206** can be positioned on one side of the first electrode substrate **1204**. As noted above, depending upon the materials used for the first electrode substrate **1204** and the second electrode substrate **1206**, the assembly **1200** can further include an insulated layer **1208**.

[0120] Additionally, rather than surround one electrode substrate with another, the two electrode substrates as described herein can be positioned adjacent to each other. For example, as shown in FIG. **12B**, electrode assembly **1210** includes a sensing electrode mounted on a garment **1212**. As further shown, the assembly includes a first electrode substrate **1214** positioned adjacent to a second electrode substrate **1216**. As further shown, the assembly **1210** can include an insulating layer **1218** positioned between the two electrode substrates and configured to electrically isolate the first electrode substrate **1214** from the second electrode substrate **1216**. However, it should be noted that the insulating layer **1218** is shown by way of example only. In certain implementations, the first electrode substrate **1214** and the second electrode substrate **1216** can be spaced apart such that no additional insulating layer is needed to electrically isolate the two electrode substrates. Additionally, it should be noted that the first electrode substrate **1214** and the second electrode substrate **1216** are shown as the same size by way of example only. In implementation, the sizes of the first electrode substrate **1214** and the second electrode substrate **1216** can vary based upon what functionality the electrode substrate is configured to perform. For example, the electrode substrate configured to function as the ECG substrate can have a larger surface area than the electrode substrate configured to function as the biasing substrate.

[0121] In certain examples, one or more of the electrode substrates as described herein can be integrated directly into a portion of a garment as a fabric electrode. For example, one or more of the electrode substrates can be integrated as a series of conductive fibers woven into a portion of the

garment at a particular location such that, when the garment is worn, the fabric substrates are positioned proximate to the patient's skin.

[0122] For example, FIG. 13A illustrates a sensor assembly **1300** including components of a sensing electrode mounted on a portion of a garment **1302**. In certain implementations, a first electrode substrate **1304** can be implemented as a metal or otherwise solid electrode substrate removably affixed to the garment **1302**. The assembly **1300** can further include a second electrode substrate **1306** that is implemented as a fabric electrode constructed from a conductible fabric material such as a conductive thread woven into a particular pattern on or within the garment **1302**. In some examples, the first electrode substrate **1304** can be configured to operate as the ECG substrate. In such an example, the first electrode substrate **1304** can be made from a material such as silver/silver chloride and the second substrate **1306**, configured to operate as the biasing substrate, can be made from a material such as a stainless steel thread woven into a particular pattern in or on the garment **1302**. In another example, the first substrate **1304** can be configured to operate as the biasing substrate. In such an example, the first electrode substrate **1304** can be implemented as a metal or otherwise solid electrode substrate removably affixed to the garment **1302** and the second substrate **1306**, configured to operate as the ECG substrate, can be made from a material such as a silver/silver chloride thread woven into a particular pattern in garment **1302**.

[0123] In another example, both the ECG substrate and the biasing substrate in an electrode assembly can be made from conductive fabric materials. For example, FIG. 13B illustrates a sensor assembly **1310** including components of a sensing electrode mounted on a portion of a garment **1312**. For example, a first electrode substrate **1314** can be implemented as a fabric electrode constructed from a conductible fabric material such as a conductive thread woven into a particular pattern on garment **1312**. Similarly, the assembly **1310** can further include a second electrode substrate **1316** that is implemented as a fabric electrode constructed from a conductible fabric material such as a conductive thread woven into a particular pattern on garment **1312**. In some examples, the first electrode substrate **1314** can be configured to operate as the ECG substrate. In such an example, the first electrode substrate **1314** can be made from a material such as a silver/silver chloride thread woven into a particular pattern on the garment **1312**. The second substrate **1316**, which is configured to operate as the biasing substrate, can be made from a material such as a stainless steel thread woven into a particular pattern in the garment **1312**.

[0124] In some examples, the first electrode substrate **1314** and the second electrode substrate **1316** can be spaced apart such that the substrates are insulated from each other. For example, the first electrode substrate **1314** and the second electrode substrate **1316** can be spaced apart by about 0.1 inches, 0.25 inches, 0.5 inches, 0.75 inches, 1.0 inch, 1.25 inches, 1.50 inches, or other similar distances.

[0125] It should be noted that the position, size, and shape of the electrode substrates as shown in FIGS. 13A and 13B and described above is provided by way of example only. In actual implementation, each of the electrode substrates as described above can be positioned, sized, and shaped based upon an overall design of a wearable medical device garment.

[0126] The teachings of the present disclosure can be generally applied to external medical monitoring and/or treatment devices that include one or more sensors as described herein. Such external medical devices can include, for example, ambulatory medical devices as described herein that are capable of and designed for moving with the patient as the patient goes about his or her daily routine. An example ambulatory medical device can be a wearable medical device such as a WCD, a wearable cardiac monitoring device, an in-hospital device such as an HWD, a short-term wearable cardiac monitoring and/or therapeutic device, mobile cardiac event monitoring devices, and other similar wearable medical devices.

[0127] The wearable medical device can be capable of continuous use by the patient. In some implementations, the continuous use can be substantially or nearly continuous in nature. That is, the wearable medical device can be continuously used, except for sporadic periods during which

the use temporarily ceases (e.g., while the patient bathes, while the patient is refit with a new and/or a different garment, while the battery is charged/changed, while the garment is laundered, etc.). Such substantially or nearly continuous use as described herein may nonetheless be considered continuous use. For example, the wearable medical device can be configured to be worn by a patient for as many as **24** hours a day. In some implementations, the patient can remove the wearable medical device for a short portion of the day (e.g., for half an hour to bathe). In such an example, nearly continuous can include **23.5** hours a day of wear with a half hour removal period. [0128] Further, the wearable medical device can be configured as a long term or extended use medical device. Such devices can be configured to be used by the patient for an extended period of several days, weeks, months, or even years. In some examples, the wearable medical device can be used by a patient for an extended period of at least one week. In some examples, the wearable medical device can be used by a patient for an extended period of at least **30** days. In some examples, the wearable medical device can be used by a patient for an extended period of at least one month. In some examples, the wearable medical device can be used by a patient for an extended period of at least two months. In some examples, the wearable medical device can be used by a patient for an extended period of at least three months. In some examples, the wearable medical device can be used by a patient for an extended period of at least six months. In some examples, the wearable medical device can be used by a patient for an extended period of at least one year. In some implementations, the extended use can be uninterrupted until a physician or other healthcare provider (HCP) provides specific instruction to the patient to stop use of the wearable medical device.

[0129] Regardless of the extended period of wear, the use of the wearable medical device can include continuous or nearly continuous wear by the patient as described above. For example, the continuous use can include continuous wear or attachment of the wearable medical device to the patient, e.g., through one or more of the electrodes as described herein, during both periods of monitoring and periods when the device may not be monitoring the patient but is otherwise still worn by or otherwise attached to the patient. The wearable medical device can be configured to continuously monitor the patient for cardiac-related information (e.g., ECG information, including arrhythmia information, cardio-vibrations, etc.) and/or non-cardiac information (e.g., blood oxygen, the patient's temperature, glucose levels, tissue fluid levels, and/or lung vibrations). The wearable medical device can carry out its monitoring in periodic or aperiodic time intervals or times. For example, the monitoring during intervals or times can be triggered by a user action or another event.

[0130] As noted above, the wearable medical device can be configured to monitor other non-ECG physiologic parameters of the patient in addition to cardiac related parameters. For example, the wearable medical device can be configured to monitor, for example, pulmonary-vibrations (e.g., using microphones and/or accelerometers), breath vibrations, sleep related parameters (e.g., snoring, sleep apnea), tissue fluids (e.g., using radio-frequency transmitters and sensors), among others.

[0131] Other example wearable medical devices include automated cardiac monitors and/or defibrillators for use in certain specialized conditions and/or environments such as in combat zones or within emergency vehicles. Such devices can be configured so that they can be used immediately (or substantially immediately) in a life-saving emergency. In some examples, the ambulatory medical devices described herein can be pacing-enabled, e.g., capable of providing therapeutic pacing pulses to the patient. In some examples, the ambulatory medical devices can be configured to monitor for and/or measure ECG metrics including, for example, heart rate (such as average, median, mode, or other statistical measure of the heart rate, and/or maximum, minimum, resting, pre-exercise, and post-exercise heart rate values and/or ranges), heart rate variability metrics, premature ventricular contraction (PVC) burden or counts, atrial fibrillation burden metrics, pauses, heart rate turbulence, QRS height, QRS width, changes in a size or shape of

morphology of the ECG information, cosine R-T, artificial pacing, QT interval, QT variability, T wave width, T wave alternans, T-wave variability, and ST segment changes.

[0132] As noted above, FIG. 6 illustrates an example component-level view of a medical device controller **600** included in, for example, a wearable medical device. As further shown in FIG. 6, the therapy delivery circuitry **602** can be coupled to one or more electrodes **620** configured to provide therapy to the patient. For example, the therapy delivery circuitry **602** can include, or be operably connected to, circuitry components that are configured to generate and provide an electrical therapeutic shock. The circuitry components can include, for example, resistors, capacitors, relays and/or switches, electrical bridges such as an h-bridge (e.g., including a plurality of insulated gate bipolar transistors or IGBTs), voltage and/or current measuring components, and other similar circuitry components arranged and connected such that the circuitry components work in concert with the therapy delivery circuitry and under control of one or more processors (e.g., processor **618**) to provide, for example, at least one therapeutic shock to the patient including one or more pacing, cardioversion, or defibrillation therapeutic pulses.

[0133] Pacing pulses can be used to treat cardiac arrhythmia conditions such as bradycardia (e.g., less than 30 beats per minute) and tachycardia (e.g., more than 150 beats per minute) using, for example, fixed rate pacing, demand pacing, anti-tachycardia pacing, and the like. Defibrillation pulses can be used to treat ventricular tachycardia and/or ventricular fibrillation.

[0134] The capacitors can include a parallel-connected capacitor bank consisting of a plurality of capacitors (e.g., two, three, four or more capacitors). In some examples, the capacitors can include a single film or electrolytic capacitor as a series connected device including a bank of the same capacitors. These capacitors can be switched into a series connection during discharge for a defibrillation pulse. For example, a single capacitor of approximately 140 μF or larger, or four capacitors of approximately 650 μF can be used. The capacitors can have a 1600 VDC or higher rating for a single capacitor, or a surge rating between approximately 350 VDC to 500 VDC for paralleled capacitors and can be charged in approximately 15 seconds to 30 seconds from a battery pack.

[0135] For example, each defibrillation pulse can deliver between 60 J to 180 J of energy. In some implementations, the defibrillating pulse can be a biphasic truncated exponential waveform, whereby the signal can switch between a positive and a negative portion (e.g., charge directions). This type of waveform can be effective at defibrillating patients at lower energy levels when compared to other types of defibrillation pulses (e.g., such as monophasic pulses). For example, an amplitude and a width of the two phases of the energy waveform can be automatically adjusted to deliver a precise energy amount (e.g., 150 J) regardless of the patient's body impedance. The therapy delivery circuitry **602** can be configured to perform the switching and pulse delivery operations, e.g., under control of the processor **618**. As the energy is delivered to the patient, the amount of energy being delivered can be tracked. For example, the amount of energy can be kept to a predetermined constant value even as the pulse waveform is dynamically controlled based on factors such as the patient's body impedance while the pulse is being delivered.

[0136] In certain examples, the therapy delivery circuitry **602** can be configured to deliver a set of cardioversion pulses to correct, for example, an improperly beating heart. When compared to defibrillation as described above, cardioversion typically includes a less powerful shock that is delivered at a certain frequency to mimic a heart's normal rhythm.

[0137] The data storage **604** can include one or more of non-transitory computer-readable media, such as flash memory, solid state memory, magnetic memory, optical memory, cache memory, combinations thereof, and others. The data storage **604** can be configured to store executable instructions and data used for operation of the medical device controller **600**. In certain examples, the data storage can include executable instructions that, when executed, are configured to cause the processor **618** to perform one or more operations. In some examples, the data storage **604** can be configured to store information such as ECG data as received from, for example, the sensing

electrode interface.

[0138] In some examples, the network interface **606** can facilitate the communication of information between the medical device controller **600** and one or more other devices or entities over a communications network. For example, where the medical device controller **600** is included in an ambulatory medical device, the network interface **606** can be configured to communicate with a remote computing device such as a remote server or other similar computing device. The network interface **606** can include communications circuitry for transmitting data in accordance with a Bluetooth® wireless standard for exchanging such data over short distances to an intermediary device. For example, such an intermediary device can be configured as a base station, a “hotspot” device, a smartphone, a tablet, a portable computing device, and/or other devices in proximity of the wearable medical device including the medical device controller **600**. The intermediary device(s) may in turn communicate the data to a remote server over a broadband cellular network communications link. The communications link may implement broadband cellular technology (e.g., 2.5G, 2.75G, 3G, 4G, 5G cellular standards) and/or Long-Term Evolution (LTE) technology or GSM/EDGE and UMTS/HSPA technologies for high-speed wireless communication. In some implementations, the intermediary device(s) may communicate with a remote server over a WI-FI communications link based on the IEEE 802.11 standard.

[0139] In certain examples, the user interface **608** can include one or more physical interface devices such as input devices, output devices, and combination input/output devices and a software stack configured to drive operation of the devices. These user interface elements can render visual, audio, and/or tactile content. Thus, the user interface **608** can receive input or provide output, thereby enabling a user to interact with the medical device controller **600**.

[0140] The medical device controller **600** can also include at least one rechargeable battery **610** configured to provide power to one or more components integrated in the medical device controller **600**. The rechargeable battery **610** can include a rechargeable multi-cell battery pack. In one example implementation, the rechargeable battery **610** can include three or more **2200** mA.h lithium ion cells that provide electrical power to the other device components within the medical device controller **600**. For example, the rechargeable battery **610** can provide its power output in a range of between 20 mA to 1000 mA (e.g., 40 mA) output and can support 24 hours, 48 hours, 72 hours, or more, of runtime between charges. In certain implementations, the battery capacity, runtime, and type (e.g., lithium ion, nickel-cadmium, or nickel-metal hydride) can be changed to best fit the specific application of the medical device controller **600**.

[0141] The sensor interface **612** can include physiological signal circuitry that is coupled to one or more sensors configured to monitor one or more physiological parameters of the patient. As shown, the sensors can be coupled to the medical device controller **600** via a wired or wireless connection. The sensors can include one or more ECG sensing electrodes **622**, and non-ECG physiological sensors **623** such as vibration sensor **624**, tissue fluid monitors **626** (e.g., based on ultra-wide band RF devices), and motion sensors (e.g., accelerometers, gyroscopes, and/or magnetometers). In some implementations, the sensors can include a plurality of conventional ECG sensing electrodes in addition to digital sensing electrodes.

[0142] The sensing electrodes **622** can be configured to monitor a patient's ECG information. For example, by design, the digital sensing electrodes **622** can include skin-contacting electrode surfaces that may be deemed polarizable or non-polarizable depending on a variety of factors including the metals and/or coatings used in constructing the electrode surface. All such electrodes can be used with the principles, techniques, devices and systems described herein. For example, the electrode surfaces can be based on stainless steel, noble metals such as platinum, or Ag-AgCl.

[0143] In some examples, the electrodes **622** can be used with an electrolytic gel dispersed between the electrode surface and the patient's skin. In certain implementations, the electrodes **622** can be dry electrodes that do not need an electrolytic material. As an example, such a dry electrode can be based on tantalum metal and having a tantalum pentoxide coating as is described above. Such dry

electrodes can be more comfortable for long term monitoring applications.

[0144] Referring back to FIG. 6, the vibration sensors **624** can be configured to detect cardiac or pulmonary vibration information. For example, the vibration sensors **624** can detect a patient's heart valve vibration information. For example, the vibration sensors **624** can be configured to detect cardio-vibrational signal values including any one or all of S1, S2, S3, and S4. From these cardio-vibrational signal values or heart vibration values, certain heart vibration metrics may be calculated, including any one or more of electromechanical activation time (EMAT), average EMAT, percentage of EMAT (% EMAT), systolic dysfunction index (SDI), and left ventricular systolic time (LVST). The vibration sensors **624** can also be configured to detect heart wall motion, for instance, by placement of the sensor in the region of the apical beat. The vibration sensors **624** can include a vibrational sensor configured to detect vibrations from a patient's cardiac and pulmonary system and provide an output signal responsive to the detected vibrations of a targeted organ, for example, being able to detect vibrations generated in the trachea or lungs due to the flow of air during breathing. In certain implementations, additional physiological information can be determined from pulmonary-vibrational signals such as, for example, lung vibration characteristics based on sounds produced within the lungs (e.g., stridor, crackle, etc.). The vibration sensors **624** can also include a multi-channel accelerometer, for example, a three-channel accelerometer configured to sense movement in each of three orthogonal axes such that patient movement/body position can be detected and correlated to detected cardio-vibrations information. The vibration sensors **624** can transmit information descriptive of the cardio-vibrations information to the sensor interface **612** for subsequent analysis.

[0145] The tissue fluid monitors **626** can use RF based techniques to assess fluid levels and accumulation in a patient's body tissue. For example, the tissue fluid monitors **626** can be configured to measure fluid content in the lungs, typically for diagnosis and follow-up of pulmonary edema or lung congestion in heart failure patients. The tissue fluid monitors **626** can include one or more antennas configured to direct RF waves through a patient's tissue and measure output RF signals in response to the waves that have passed through the tissue. In certain implementations, the output RF signals include parameters indicative of a fluid level in the patient's tissue. The tissue fluid monitors **626** can transmit information descriptive of the tissue fluid levels to the sensor interface **612** for subsequent analysis.

[0146] As further shown in FIG. 6, the controller **600** can further include an accelerometer interface **630** and a set of accelerometers **632**. The accelerometer interface **630** can be operably coupled to each of the accelerometers **632** and configured to receive one or more outputs from the accelerometers. The accelerometer interface **630** can be further configured to condition the output signals by, for example, converting analog accelerometer signals to digital signals (if using an analog accelerometer), filtering the output signals, combining the output signals into a combined directional signal (e.g., combining each x-axis signal into a composite x-axis signal, combining each y-axis signal into a composite y-axis signal, and combining each z-axis signal into a composite z-axis signal). In some examples, the accelerometer interface **630** can be configured to filter the signals using a high-pass or band-pass filter to isolate the acceleration of the patient due to movement from the component of the acceleration due to gravity.

[0147] Additionally, the accelerometer interface **630** can configure the output for further processing. For example, the accelerometer interface **630** can be configured to arrange the output of an individual accelerometer **632** as a vector expressing the acceleration components of the x-axis, the y-axis, and the z-axis as received from each accelerometer. The accelerometer interface **630** can be operably coupled to the processor **618** and configured to transfer the output signals from the accelerometers **632** to the processor for further processing and analysis.

[0148] As described above, one or more of the accelerometers **632** (e.g., accelerometers **108** as described above) can be integrated into one or more components of a medical device. For example, as shown in FIG. 6, an accelerometer **632** (e.g., accelerometer **108c** as described above) can be

integrated into the controller **600**. In some examples, an accelerometer **632** can be integrated into one or more of a therapy electrode **620**, a sensing electrode **622**, a physiological sensor **623**, and into other components of a medical device. When controller **600** is included in an HWD, an accelerometer can be integrated into an adhesive ECG sensing and/or therapy electrode patch. [0149] In certain implementations, the cardiac event detector **616** can be configured to monitor a patient's ECG signal for an occurrence of a cardiac event such as an arrhythmia or other similar cardiac event. The cardiac event detector can be configured to operate in concert with the processor **618** to execute one or more methods that process received ECG signals from, for example, the sensing electrodes **622** and determine the likelihood that a patient is experiencing a cardiac event. The cardiac event detector **616** can be implemented using hardware or a combination of hardware and software. For instance, in some examples, cardiac event detector **616** can be implemented as a software component that is stored within the data storage **604** and executed by the processor **618**. In this example, the instructions included in the cardiac event detector **616** can cause the processor **618** to perform one or more methods for analyzing a received ECG signal to determine whether an adverse cardiac event is occurring. In other examples, the cardiac event detector **616** can be an application-specific integrated circuit (ASIC) that is coupled to the processor **618** and configured to monitor ECG signals for adverse cardiac event occurrences. Thus, examples of the cardiac event detector **616** are not limited to a particular hardware or software implementation.

[0150] In some implementations, the processor **618** includes one or more processors (or one or more processor cores) that each are configured to perform a series of instructions that result in manipulated data and/or control the operation of the other components of the medical device controller **600**. In some implementations, when executing a specific process (e.g., cardiac monitoring), the processor **618** can be configured to make specific logic-based determinations based on input data received and be further configured to provide one or more outputs that can be used to control or otherwise inform subsequent processing to be carried out by the processor **618** and/or other processors or circuitry with which processor **618** is communicatively coupled. Thus, the processor **618** reacts to specific input stimulus in a specific way and generates a corresponding output based on that input stimulus. In some example cases, the processor **618** can proceed through a sequence of logical transitions in which various internal register states and/or other bit cell states internal or external to the processor **618** can be set to logic high or logic low. As referred to herein, the processor **618** can be configured to execute a function where software is stored in a data store coupled to the processor **618**, the software being configured to cause the processor **618** to proceed through a sequence of various logic decisions that result in the function being executed. The various components that are described herein as being executable by the processor **618** can be implemented in various forms of specialized hardware, software, or a combination thereof. For example, the processor **618** can be a digital signal processor (DSP) such as a 24-bit DSP. The processor **618** can be a multi-core processor, e.g., having two or more processing cores. The processor **618** can be an Advanced RISC Machine (ARM) processor such as a 32-bit ARM processor or a 64-bit ARM processor. The processor **618** can execute an embedded operating system, and include services provided by the operating system that can be used for file system manipulation, display & audio generation, basic networking, firewalling, data encryption and communications.

[0151] As noted above, an ambulatory medical device such as a WCD can be designed to include a digital front-end where analog signals sensed by skin-contacting electrode surfaces of a set of digital sensing electrodes are converted to digital signals for processing. Typical ambulatory medical devices with analog front-end configurations use circuitry to accommodate a signal from a high source impedance from the sensing electrode (e.g., having an internal impedance range from approximately 100 k Ω to one or more M Ω). This high source impedance signal is processed and transmitted to a monitoring device such as processor **618** of the controller **600** as described above for further processing. In certain implementations, the monitoring device, or another similar

processor such as a microprocessor or another dedicated processor operably coupled to the sensing electrodes, can be configured to receive a common noise signal from each of the sensing electrodes, sum the common noise signals, invert the summed common noise signals and feed the inverted signal back into the patient as a driven ground using, for example, a driven right leg circuit to cancel out common mode signals.

[0152] FIG. 14A illustrates an example medical device **1400** that is external, ambulatory, and wearable by a patient **1402**, and configured to implement one or more configurations described herein. For example, the medical device **1400** can be a non-invasive medical device configured to be located substantially external to the patient. Such a medical device **1400** can be, for example, an ambulatory medical device that is capable of and designed for moving with the patient as the patient goes about his or her daily routine. For example, the medical device **1400** as described herein can be bodily-attached to the patient such as the LifeVest® wearable cardioverter defibrillator available from ZOLL® Medical Corporation. Such wearable defibrillators typically are worn nearly continuously or substantially continuously for two to three months at a time. During the period of time in which they are worn by the patient, the wearable defibrillator can be configured to continuously or substantially continuously monitor the vital signs of the patient and, upon determination that treatment is required, can be configured to deliver one or more therapeutic electrical pulses to the patient. For example, such therapeutic shocks can be pacing, defibrillation, or transcutaneous electrical nerve stimulation (TENS) pulses.

[0153] The medical device **1400** can include one or more of the following: a garment **1410**, one or more ECG sensing electrodes **1412**, one or more non-ECG physiological sensors **1413**, one or more therapy electrodes **1414a** and **1414b** (collectively referred to herein as therapy electrodes **1414**), a medical device controller **1420** (e.g., controller **600** as described above in the discussion of FIG. 6), a connection pod **1430**, a patient interface pod **1440**, a belt **1450**, or any combination of these. In some examples, at least some of the components of the medical device **1400** can be configured to be affixed to the garment **1410** (or in some examples, permanently integrated into the garment **1410**), which can be worn about the patient's torso.

[0154] The medical device controller **1420** can be operatively coupled to the sensing electrodes **1412**, which can be affixed to the garment **1410**, e.g., assembled into the garment **1410** or removably attached to the garment, e.g., using hook and loop fasteners. In some implementations, the sensing electrodes **1412** can be permanently integrated into the garment **1410**. The medical device controller **1420** can be operatively coupled to the therapy electrodes **1414**. For example, the therapy electrodes **1414** can also be assembled into the garment **1410**, or, in some implementations, the therapy electrodes **1414** can be permanently integrated into the garment **1410**. In an example, the medical device controller **1420** includes a patient user interface **1460** to allow a patient interface with the externally-worn device. For example, the patient can use the patient user interface **1460** to respond to activity related questions, prompts, and surveys as described herein.

[0155] Component configurations other than those shown in FIG. 14A are possible. For example, the sensing electrodes **1412** can be configured to be attached at various positions about the body of the patient **1402**. The sensing electrodes **1412** can be operatively coupled to the medical device controller **1420** through the connection pod **1430**. In some implementations, the sensing electrodes **1412** can be adhesively attached to the patient **1402**. In some implementations, the sensing electrodes **1412** and at least one of the therapy electrodes **1414** can be included on a single integrated patch and adhesively applied to the patient's body.

[0156] The sensing electrodes **1412** can be configured to detect one or more cardiac signals. Examples of such signals include ECG signals and/or other sensed cardiac physiological signals from the patient. In certain examples, as described herein, the non-ECG physiological sensors **1413** include sensors such as accelerometers, vibrational sensors, RF-based sensors, and other measuring devices for recording additional non-ECG physiological parameters. For example, as described above, the such non-ECG physiological sensors are configured to detect other types of patient

physiological parameters and acoustic signals, such as tissue fluid levels, cardio-vibrations, lung vibrations, respiration vibrations, patient movement, etc.

[0157] In some examples, the therapy electrodes **1414** can also be configured to include sensors configured to detect ECG signals as well as other physiological signals of the patient. The connection pod **1430** can, in some examples, include a signal processor configured to amplify, filter, and digitize these cardiac signals prior to transmitting the cardiac signals to the medical device controller **1420**. One or more of the therapy electrodes **1414** can be configured to deliver one or more therapeutic defibrillating shocks to the body of the patient **1402** when the medical device **1400** determines that such treatment is warranted based on the signals detected by the sensing electrodes **1412** and processed by the medical device controller **1420**. Example therapy electrodes **1414** can include metal electrodes such as stainless-steel electrodes that include one or more conductive gel deployment devices configured to deliver conductive gel to the metal electrode prior to delivery of a therapeutic shock.

[0158] In some implementations, medical devices as described herein can be configured to switch between a therapeutic medical device and a monitoring medical device that is configured to only monitor a patient (e.g., not provide or perform any therapeutic functions). For example, therapeutic components such as the therapy electrodes **1414** and associated circuitry can be optionally decoupled from (or coupled to) or switched out of (or switched in to) the medical device. For example, a medical device can have optional therapeutic elements (e.g., defibrillation and/or pacing electrodes, components, and associated circuitry) that are configured to operate in a therapeutic mode. The optional therapeutic elements can be physically decoupled from the medical device to convert the therapeutic medical device into a monitoring medical device for a specific use (e.g., for operating in a monitoring-only mode) or a patient. Alternatively, the optional therapeutic elements can be deactivated (e.g., via a physical or a software switch), essentially rendering the therapeutic medical device as a monitoring medical device for a specific physiologic purpose or a particular patient. As an example of a software switch, an authorized person can access a protected user interface of the medical device and select a preconfigured option or perform some other user action via the user interface to deactivate the therapeutic elements of the medical device.

[0159] FIG. **14B** illustrates a hospital wearable defibrillator **1400A** that is external, ambulatory, and wearable by a patient **1402**. Hospital wearable defibrillator **1400A** can be configured in some implementations to provide pacing therapy, e.g., to treat bradycardia, tachycardia, and asystole conditions. The hospital wearable defibrillator **1400A** can include one or more ECG sensing electrodes **1412a**, one or more therapy electrodes **1414a** and **1414b**, a medical device controller **1420** and a connection pod **1430**. For example, each of these components can be structured and function as like number components of the medical device **1400**. For example, the electrodes **1412a**, **1414a**, **1414b** can include disposable adhesive electrodes. For example, the electrodes can include sensing and therapy components disposed on separate sensing and therapy electrode adhesive patches. In some implementations, both sensing and therapy components can be integrated and disposed on a same electrode adhesive patch that is then attached to the patient. For example, the front adhesively attachable therapy electrode **1414a** attaches to the front of the patient's torso to deliver pacing or defibrillating therapy. Similarly, the back adhesively attachable therapy electrode **1414b** attaches to the back of the patient's torso. In an example scenario, at least three ECG adhesively attachable sensing electrodes **1412a** can be attached to at least above the patient's chest near the right arm, above the patient's chest near the left arm, and towards the bottom of the patient's chest in a manner prescribed by a trained professional.

[0160] A patient being monitored by a hospital wearable defibrillator and/or pacing device may be confined to a hospital bed or room for a significant amount of time (e.g., 75% or more of the patient's stay in the hospital). As a result, a user interface **1460a** can be configured to interact with a user other than the patient, e.g., a nurse, for device-related functions such as initial device baselining, setting and adjusting patient parameters, and changing the device batteries.

[0161] In some examples, the hospital wearable defibrillator **1400A** can further include one or more motion sensors such as accelerometers. For example, an accelerometer can be integrated into one or more of a sensing electrode **1412a** (e.g., integrated into the same patch as the sensing electrode), a therapy electrode **1414a** (e.g., integrated into the same patch as the therapy electrode), the medical device controller **1420**, the connection pod **1430**, and various other components of the hospital wearable defibrillator **1400A**.

[0162] In some implementations, an example of a therapeutic medical device that includes a digital front-end in accordance with the systems and methods described herein can include a short-term defibrillator and/or pacing device. For example, such a short-term device can be prescribed by a physician for patients presenting with syncope. A wearable defibrillator can be configured to monitor patients presenting with syncope by, e.g., analyzing the patient's physiological and cardiac activity for aberrant patterns that can indicate abnormal physiological function. For example, such aberrant patterns can occur prior to, during, or after the onset of syncope. In such an example implementation of the short-term wearable defibrillator, the electrode assembly can be adhesively attached to the patient's skin and have a similar configuration as the hospital wearable defibrillator described above in connection with FIG. **14A**.

[0163] FIGS. **14C** and **14D** illustrate example wearable patient monitoring devices with no treatment or therapy functions. For example, such devices are configured to monitor one or more physiological parameters of a patient, e.g., for remotely monitoring and/or diagnosing a condition of the patient. For example, such physiological parameters can include a patient's ECG information, tissue (e.g., lung) fluid levels, cardio-vibrations (e.g., using accelerometers or microphones), and other related cardiac information. A cardiac monitoring device is a portable device that the patient can carry around as he or she goes about their daily routine.

[0164] Referring to FIG. **14C**, an example wearable patient monitoring device **1400C** can include tissue fluid monitors **1465** that use RF based techniques to assess fluid levels and accumulation in a patient's body tissue. Such tissue fluid monitors **1465** can be configured to measure fluid content in the lungs, typically for diagnosis and follow-up of pulmonary edema or lung congestion in heart failure patients. The tissue fluid monitors **1465** can include one or more antennas configured to direct RF waves through a patient's tissue and measure output RF signals in response to the waves that have passed through the tissue. In certain implementations, the output RF signals include parameters indicative of a fluid level in the patient's tissue. In examples, device **1400C** may be a cardiac monitoring device that also includes digital sensing electrodes **1470** for sensing ECG activity of the patient. Device **1400C** can pre-process the ECG signals via one or more ECG processing and/or conditioning circuits such as an ADC, operational amplifiers, digital filters, signal amplifiers under control of a microprocessor. Device **1400C** can transmit information descriptive of the ECG activity and/or tissue fluid levels via a network interface to a remote server for analysis. Additionally, in certain implementations, the device **1400C** can include one or accelerometers for measuring motion signals as described herein.

[0165] Referring to FIG. **14D**, another example wearable cardiac monitoring device **1400D** can be attached to a patient via at least three adhesive digital cardiac sensing electrodes **1475** disposed about the patient's torso. Additionally, in certain implementations, the device **1400D** can include one or accelerometers integrated into, for example, one or more of the digital sensing electrodes for measuring motion signals as described herein.

[0166] Cardiac devices **1400C** and **1400D** are used in cardiac monitoring and telemetry and/or continuous cardiac event monitoring applications, e.g., in patient populations reporting irregular cardiac symptoms and/or conditions. These devices can transmit information descriptive of the ECG activity and/or tissue fluid levels via a network interface to a remote server for analysis. Example cardiac conditions that can be monitored include atrial fibrillation (AF), bradycardia, tachycardia, atrio-ventricular block, Lown-Ganong- Levine syndrome, atrial flutter, sinoatrial node dysfunction, cerebral ischemia, pause(s), and/or heart palpitations. For example, such patients may

be prescribed a cardiac monitoring for an extended period of time, e.g., 10 days to 30 days, or more. In some ambulatory cardiac monitoring and/or telemetry applications, a portable cardiac monitoring device can be configured to substantially continuously monitor the patient for a cardiac anomaly, and when such an anomaly is detected, the monitor can automatically send data relating to the anomaly to a remote server. The remote server may be located within a 24-hour manned monitoring center, where the data is interpreted by qualified, cardiac-trained reviewers and/or HCPs, and feedback provided to the patient and/or a designated HCP via detailed periodic or event-triggered reports. In certain cardiac event monitoring applications, the cardiac monitoring device is configured to allow the patient to manually press a button on the cardiac monitoring device to report a symptom. For example, a patient can report symptoms such as a skipped beat, shortness of breath, light headedness, racing heart rate, fatigue, fainting, chest discomfort, weakness, dizziness, and/or giddiness. The cardiac monitoring device can record predetermined physiologic parameters of the patient (e.g., ECG information) for a predetermined amount of time (e.g., 1 minute to 30 minutes before and 1 minute to 30 minutes after a reported symptom). As noted above, the cardiac monitoring device can be configured to monitor physiologic parameters of the patient other than cardiac related parameters. For example, the cardiac monitoring device can be configured to monitor, for example, cardio-vibrational signals (e.g., using accelerometers or microphones), pulmonary-vibrational signals, breath vibrations, sleep related parameters (e.g., snoring, sleep apnea), tissue fluids, among others.

[0167] In some examples, the devices described herein (e.g., FIGS. 14A-14D) can communicate with a remote server via an intermediary or gateway device 1480 such as that shown in FIG. 14D. For instance, devices such as shown in FIGS. 14A-D can be configured to include a network interface communications capability as described herein in reference to, for example, FIG. 6.

[0168] Although the subject matter contained herein has been described in detail for the purpose of illustration, it is to be understood that such detail is solely for that purpose and that the present disclosure is not limited to the disclosed embodiments, but, on the contrary, is intended to cover modifications and equivalent arrangements that are within the scope of the appended claims. For example, it is to be understood that the present disclosure contemplates that, to the extent possible, one or more features of any embodiment can be combined with one or more features of any other embodiment.

[0169] Other examples are within the scope of the description and claims. Additionally, certain functions described above can be implemented using software, hardware, firmware, hardwiring, or combinations of any of these. Features implementing functions can also be physically located at various positions, including being distributed such that portions of functions are implemented at different physical locations.

Claims

1-80. (canceled)

81. An ambulatory cardiac device having active electrocardiogram (ECG) electrodes with local electronics for improving a signal to noise profile of an ECG signal of a patient, the ambulatory cardiac device comprising: a first active ECG electrode, the first active ECG electrode comprising a first ECG electrode with associated first local electronics, a second active ECG electrode, the second active ECG electrode comprising a second ECG electrode with associated second local electronics, wherein each one of first and second active ECG electrodes comprises an ECG electrode substrate configured to be in physical contact with skin of the patient; a local biasing substrate proximate to the ECG electrode substrate and configured to be in physical contact with the skin of the patient; and circuitry operably coupled to the ECG electrode substrate and the local biasing substrate, the circuitry comprising local biasing circuitry configured to provide a local biasing signal into a body of the patient via the local biasing substrate, and ECG sensing circuitry

configured to sense a surface electrical signal from the ECG electrode substrate, the surface electrical signal including at least a portion of the local biasing signal; and a processor operably connected to the first and second active ECG electrodes, the processor configured to receive the surface electrical signals from the ECG sensing circuitries of the corresponding first and second ECG electrodes; and determine an ECG signal of the patient based on the received surface electrical signals.

82-83. (canceled)

84. The ambulatory cardiac device of claim 81, wherein the local biasing circuitry is configured to apply a constant biasing signal to the body of the patient.

85. The ambulatory cardiac device of claim 84, wherein the constant biasing signal has a voltage of one of about 0.5 V, about 1.0 V, about 1.5 V, about 2.0 V, about 2.5 V, about 3.0 V, about 3.5 V, about 4.0 V, or about 4.5 V.

86. The ambulatory cardiac device of claim 81, wherein each of the first and second active ECG electrodes comprise a housing disposed proximate to the ECG electrode substrate for housing the first local electronics and the second local electronics, the housing rated as IP67 in accordance with standard EN 60529.

87-88. (canceled)

89. The ambulatory cardiac device of claim 81, further comprising a controller operably coupled to the processor, the controller configured to determine an arrhythmia condition based on the ECG signal of the patient.

90. The ambulatory cardiac device of claim 89, wherein the controller is configured to control delivery one or more therapeutic pulses to the patient based on the determined arrhythmia condition.

91. The ambulatory cardiac device of claim 90, further comprising at least one patient response button operably coupled to the controller.

92. The ambulatory cardiac device of claim 91, wherein the controller is configured to control the delivery of the one or more therapeutic pulses to the patient if a patient response is not received via the at least one patient response button.

93. The ambulatory cardiac device of claim 92, further comprising a garment configured to be worn about a torso of the patient, and wherein the first and second ECG electrodes and associated first and second local electronics are disposed within the garment.

94. The ambulatory cardiac device of claim 81, wherein the local biasing circuitry is configured to apply a time-varying biasing signal based upon at least a portion of the surface electrical signal.

95-108. (canceled)

109. The ambulatory cardiac device of claim 81, wherein the local biasing signal is configured to provide a grounding signal to the body of the patient to reduce noise in the surface electrical signal.

110. The ambulatory cardiac device of claim 81, wherein one or both of the ECG electrode substrate and the local biasing substrate comprises a fabric material.

111-118. (canceled)

119. The ambulatory cardiac device of claim 110, wherein the fabric material comprises one or more flexible conductive fibers configured to provide an electrical contact with the patient.

120. The ambulatory cardiac device of claim 81, wherein each of the first and second local electronics further comprises an analog-to-digital converter operably coupled to the ECG sensing circuitry and configured to convert at least a portion of the surface electrical signal to a digital surface electrical signal for transmitting to the processor.

121-129. (canceled)

130. The ambulatory cardiac device of claim 81, wherein the local biasing substrate being proximate to the ECG electrode substrate comprises the local biasing substrate substantially surrounding the ECG electrode substrate.

131-138. (canceled)

139. The ambulatory cardiac device of claim 81, wherein the local biasing substrate being proximate to the ECG electrode substrate comprises the local biasing substrate being disposed adjacent the ECG electrode substrate on a fabric material.

140. The ambulatory cardiac device of claim 81, further comprises a shared driven ground electrode configured to aggregate the surface electrical signals to derive a common mode rejection signal and inject the common mode rejection signal into the body of the patient.

141-148. (canceled)

149. The ambulatory cardiac device of claim 81, further comprising a feedback loop circuit coupled between the ECG electrode substrate and the local biasing substrate.

150-160. (canceled)

161. The ambulatory cardiac device of claim 81, further comprising a main printed circuit assembly operably coupled to the printed circuit assemblies of the first and second local electronics, the main printed circuit assembly configured to receive analog surface electrical signals from the printed circuit assemblies of the first and second local electronics, convert the analog surface electrical signals into digitized surface electrical signals, and provide the digitized surface electrical signals to the processor.

162. The ambulatory cardiac device of claim 81, comprising an array of ECG electrodes and associated local electronics, the array including the first and second ECG electrodes and associated first and second local electronics, wherein the processor is configured to selectively power two or more ECG electrodes of the array of ECG electrodes for use in determining the ECG signal of the patient.

163-170. (canceled)
