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BIOCHEMICAL SENSING FOR HEART FAILURE MANAGEMENT

Abstract

This disclosure is directed to devices, systems, and techniques for determining when to deploy sensors. Processing circuitry of an example medical device system is configured to receive first sensor data. The processing circuitry is configured to determine, based on the first sensor data, a likelihood that a heart failure decompensation event of a patient is impending. The processing circuitry is configured to compare the likelihood to a first threshold. The processing circuitry is configured to, based on the likelihood satisfying the first threshold, at least one of a) generate a first instruction for output to a user to deploy one or more biochemical or bacterial sensors, or b) control an implantable medical device to automatically deploy one or more biochemical or bacterial sensors.

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Background/Summary

[0001] This application claims the benefit of U.S. Provisional Patent Application Ser. No. 63/363,456, filed Apr. 22, 2022, the entire content of which is incorporated herein by reference.

TECHNICAL FIELD
[0002] The disclosure relates generally to medical devices and, more particularly, medical devices configured to monitor patient parameters.
BACKGROUND
[0003] Some types of medical devices may be used to monitor one or more physiological parameters of a patient. Such medical devices may include, or may be part of a system that includes, sensors that detect signals associated with such physiological parameters. Values determined based on such signals may be used to assist in detecting changes in patient conditions, in evaluating the efficacy of a therapy, or in generally evaluating patient health.
SUMMARY
[0004] Acute decompensated heart failure is a manifestation of worsening of heart failure (or broadly chronic illness) symptoms that may require heart failure hospital admission to relieve such patients of congestion and/or shortness of breath symptoms. A system configured for continuous (e.g., on a periodic or triggered basis without human intervention) ambulatory heart failure monitoring may be used to potentially predict worsening heart failure prior to development of severe symptoms requiring heart failure hospitalizations and provide clinicians with an opportunity to proactively treat the patient to avoid the heart failure hospital admission. Remote monitoring of some physiological parameters, such as thoracic impedance, e.g., via OptiVol™ available from Medtronic, Inc. of Minneapolis, Minnesota, or pulmonary artery pressure, is available. However, clinicians are often reluctant to make treatment decisions in the absence of information provided by all or a portion of a Basic Metabolic Panel (BMP) (e.g., sodium, chloride, potassium, bicarbonate, BUN, creatinine, glucose, etc.) or an International Normalized Ration (INR), a measure of clotting time, or in the absence of information regarding an infection status of the patient. Such measures provide a more complete picture of a patient's health status. Biochemical parameters, such as those of the BMP, are usually measured by a blood draw and a laboratory analysis, a finger stick point of care test, or by short-term (measured in days) percutaneous sensors.
[0005] In general, this disclosure is directed to techniques for using a medical device system to monitor physiological parameters of a patient, such as a heart failure patient. Sensors may be located on one or more implantable medical devices (IMDs), wearable devices, point of care finger

stick devices, and/or other external devices, for sensing physiological parameters of a patient. Processing circuitry of the medical device system may execute an algorithm (e.g., TriageHF™ available from Medtronic, Inc. or a similar algorithm) to determine a likelihood of an impending heart failure decompensation event based on these sensed physiological parameters. As used herein "impending" may mean within less than 30 days, and in some examples within 7-10 days.

[0006] Many sensors for sensing physiological parameters relevant to heart failure have much longer lifespans than biochemical sensors which may be used to determine biochemical parameters, such as those of a BMP, or bacterial sensors which may be used to determine bacterial parameters. Because such biochemical and bacterial sensors may have a much shorter lifespan than other sensors and because clinicians are reluctant to hospitalize a heart failure patient without a recent BMP or a known bacterial infection, it may be desirable to deploy such sensors when an impending heart failure decompensation event is detected. Data sensed by such sensors may be further input into the algorithm to increase the accuracy of the initial assessment of the likelihood that there may be an impending heart failure decompensation event.

[0007] According to the techniques of this disclosure, a machine learning model or other algorithm configured to determine a likelihood of an impending heart failure decompensation event may be implemented in an implantable medical device (IMD), in a wearable device, such as a smart watch, in a smart phone that the patient may carry with them, on one or more servers, in a cloud computing environment, or the like. The device may execute the algorithm and may generate an instruction for output to a patient, caregiver or healthcare monitoring system, when the device determines that the likelihood of an impending heart failure decompensation event, based on sensed physiological parameters, meets a threshold. This instruction may automatically prescribe for the patient or caregiver to conduct a fingerstick measure, insert a percutaneous sensor, or insert an implantable sensor. Alternatively, or additionally, if the IMD includes one or more biochemical sensors or one or more bacterial sensors on or near the surface of the IMD, the device executing the algorithm could activate one or more biochemical sensors or one or more bacterial sensors, based on determining that the likelihood of an impending heart failure decompensation event meets a threshold. Such sensed biochemical parameters and/or bacterial parameters may be utilized by the device executing the algorithm to provide further precision in a determination of whether the patient should seek admission to a hospital or emergency room and/or whether a change in treatment is desirable.

[0008] Additionally, in the absence of a trigger from an indication of an impending heart failure decompensation, any one of these techniques for biochemical sensing or bacterial sensing, or a combination of these techniques, may be used to establish a baseline measure and trends over time. The frequency of such measurements could be predetermined, programmed and/or remotely activated by a clinician, be based on the patient's pattern of change in sensed biochemical parameters, bacterial parameters, and/or physiological parameters over time, or be determined by a machine learning model. A clinician may use such baseline measure and trends over time to monitor the cardiac health or comorbidities of the patient which may facilitate earlier detection of medical conditions requiring treatment, or to guide selection of medications, dosages or the like when treating the patient.

[0009] Because physicians are often reluctant to make treatment decisions in the absence of information provided by BMP or INR or in the absence of information regarding an infection status of a patient, it may be desirable to provide for the remote monitoring of such parameters. Because biochemical and/or bacterial sensors may have a shorter lifespan when in use than other types of sensors which may be used to sense physiological parameters of a patient, such as sensors of an implantable medical device, it may be desirable only to deploy biochemical and/or bacterial sensors when any physiological parameters that may be monitored, indicate that there is a likely impending heart failure decompensation event of the patient. Additionally, it may be desirable to deploy the biochemical and/or bacterial sensor(s) for a patient remotely from their clinician so that the patient

does not need to make an office visit to deploy such sensor(s). Data collected by the biochemical and/or bacterial sensor(s) may be used to improve or verify the data collected by other sensors, so as to better predict an impending heart failure decompensation event, improve patient outcomes, and increase hospital efficiency. The techniques of this disclosure may address these issues by providing for at least one of generating an instruction for output to a user to deploy at least one of one or more biochemical sensors or one or more bacterial sensors, or controlling an implantable medical device to automatically deploy at least one of one or more biochemical sensors or one or more bacterial sensors when a likelihood that a heart failure decompensation event, determined based on other sensor data, meets a threshold.

[0010] Systems including one or more IMDs that incorporate such sensors and may be implanted in a patient over months or years and perform numerous operations per second on the data to enable the systems herein to determine varying risk levels of heart failure decompensation. Using techniques of this disclosure with an IMD may be advantageous when a physician cannot be continuously present with the patient over weeks or months to evaluate the physiological parameters and/or where performing the operations on the data described herein (e.g., application of a machine learning model) could not practically be performed in the mind of a physician. Using the techniques of this disclosure with autonomously/continuously operating IMDs and computing devices may provide a clinical advantage in timely detecting changes in a patient's condition and providing timely alerts to the patient and/or caregiver.

[0011] In some examples, the techniques and systems of this disclosure may use a machine learning model, e.g., a Bayesian probability model, to more accurately determine a risk level of a heart failure event based on physiological data collected by an IMD. In some examples, the machine learning model is trained with a set of training instances, where one or more of the training instances comprise data that indicate relationships between various sets of input data and risk level outputs, e.g., heart failure event likelihoods or probabilities. Because the machine learning model is trained with potentially thousands or millions of training instances, the machine learning model may reduce the amount of error in determining heart failure event risk. Reducing errors using the techniques of this disclosure may provide one or more technical and clinical advantages, such as increasing reliability of another device, user, and/or clinician on the accuracy of determining a patient's condition and improve resulting treatment of the patient and patient outcomes.

[0012] In some examples, a medical device system includes: memory configured to store first sensor data; and processing circuitry communicatively coupled to the memory, the processing circuitry being configured to: receive the first sensor data; determine, based on the first sensor data, a likelihood that a heart failure decompensation event of a patient is impending; compare the likelihood to a first threshold; and based on the likelihood satisfying the first threshold, at least one of a) generate a first instruction for output to a user to deploy at least one of one or more biochemical sensors or one or more bacterial sensors, or b) control an implantable medical device to automatically deploy at least one of one or more biochemical sensors or one or more bacterial sensors.

[0013] In some examples, a method includes receiving, by processing circuitry, first sensor data; determining, by the processing circuitry and based on the first sensor data, a likelihood that a heart failure decompensation event of a patient is impending; comparing, by the processing circuitry, the likelihood to a first threshold; based on the likelihood satisfying the first threshold, at least one of a) generating, by the processing circuitry, a first instruction for output to a user to deploy at least one of one or more biochemical sensors or one or more bacterial sensors, or b) controlling an implantable medical device, by the processing circuitry, to deploy at least one of one or more biochemical sensors or one or more bacterial sensors.

[0014] In some examples, a non-transitory computer-readable medium includes instructions, which when executed, cause processing circuitry to: receive first sensor data; determine, based on the first

sensor data, a likelihood that a heart failure decompensation event of a patient is impending; compare the likelihood to a first threshold; based on the likelihood satisfying the first threshold, at least one of a) generate a first instruction for output to a user to deploy at least one of one or more biochemical sensors or one or more bacterial sensors, or b) control an implantable medical device to automatically deploy at least one of one or more biochemical sensors or one or more bacterial sensors.

[0015] This summary is intended to provide an overview of the subject matter described in this disclosure. It is not intended to provide an exclusive or exhaustive explanation of the systems, device, and methods described in detail within the accompanying drawings and description below. Further details of one or more examples of this disclosure are set forth in the accompanying drawings and in the description below. Other features, objects, and advantages will be apparent from the description and drawings, and from the claims.

Description

BRIEF DESCRIPTION OF DRAWINGS

[0016] FIG. **1** illustrates the environment of an example medical device system in conjunction with a patient, in accordance with one or more techniques of this disclosure.

[0017] FIG. **2** is a conceptual drawing illustrating an example configuration of the implantable medical device (IMD) of the medical device system of FIG. **1**, in accordance with one or more techniques described herein.

[0018] FIG. **3** is a functional block diagram illustrating an example configuration of the IMD of FIGS. **1** and **2**, in accordance with one or more techniques described herein.

[0019] FIGS. **4**A and **4**B are block diagrams illustrating two additional example IMDs that may be substantially similar to the IMD of FIGS. **1**-**3**, but which may include one or more additional features, in accordance with one or more techniques described herein.

[0020] FIG. **5** is a block diagram illustrating an example configuration of components of the external device of FIG. **1**, in accordance with one or more techniques of this disclosure.

[0021] FIG. **6** is a conceptual diagram illustrating an example sensor system which may be deployed by a patient or caregiver according to the techniques of this disclosure.

[0022] FIG. **7** is a conceptual diagram illustrating another example sensor system which may be deployed by a patient or caregiver according to the techniques of this disclosure.

[0023] FIG. **8** is a block diagram illustrating an example system that includes an access point, a network, external computing devices, such as a server, and one or more other computing devices, which may be coupled to the IMD of FIGS. **1**-**4**, an external device, and processing circuitry via a network, in accordance with one or more techniques described herein.

[0024] FIG. **9** is a flow diagram illustrating an example of techniques to determine when to deploy biochemical sensors or bacterial sensors according to one or more aspects of this disclosure.

[0025] FIG. **10** is a conceptual diagram illustrating an example machine learning model configured to determine an extent to which data of a patient indicates a heart failure event.

[0026] FIG. **11** is a conceptual diagram illustrating an example training process for an artificial intelligence model, in accordance with examples of the current disclosure.

[0027] Like reference characters denote like elements throughout the description and figures.

DETAILED DESCRIPTION

[0028] This disclosure describes techniques for determining when to deploy biochemical sensors or bacterial sensors in a heart failure or other patient. Data from such sensors may be used to improve the accuracy of a determined likelihood that heart failure decompensation event is impending. By improving the accuracy of the determined likelihood that a heart failure decompensation event is impending, the techniques of this disclosure may improve hospital resource usage, and may lead to

early, more effective treatment. Data from such sensors may also be used to establish baseline biochemical and/or bacterial parameters for a patient and to track the patient health over time.

[0029] The techniques of this disclosure may facilitate the remote, ambulatory, monitoring and management of a heart failure patient, peripheral vascular disease patient, diabetes patient, patient at risk of deep vein thrombosis, and/or other cardiac patient. By providing for the remote and ambulatory monitoring of potential impending heart failure decompensation events, including improving the accuracy thereof by using data from deployed biochemical and/or bacterial sensors, the techniques of this disclosure may facilitate early intervention by a clinician during deteriorating conditions of the patient, faster detection of actionable events, reduced hospitalization, better management of medications, such as heart failure medications, which may improve patient outcomes and patient quality of life.

[0030] FIG. **1** illustrates the environment of an example medical device system **2** in conjunction with a patient **4**, in accordance with one or more techniques of this disclosure. While the techniques described herein are generally described in the context of an insertable cardiac monitor and/or an external device, the techniques of this disclosure may be implemented in any implantable medical device or external device or combination thereof, such as a pacemaker, a defibrillator, a cardiac resynchronization therapy device, an implantable pulse generator, an intra-cardiac pressure measuring device, a ventricular assist device, a pulmonary artery pressure device, a subcutaneous blood pressure device, or an external device having a telemetry system and weight sensors, blood pressure sensors, pulse oximeters, activity sensors, patch systems, implantable biochemical sensor or bacterial sensors, implantable bacterial sensors, percutaneous biochemical sensor or bacterial sensors, percutaneous bacterial sensors, wearable biochemical sensor or bacterial sensors, wearable bacterial sensors, point of care finger stick sensors, or the like, configured to sense physiological parameters of a patient. The example techniques may be used with an IMD **10**, which may be in wireless communication with at least one of external device **12** and other devices not pictured in FIG. **1**. Processing circuitry **14** is conceptually illustrated in FIG. **1** as separate from IMD **10** and external device **12**, but may be processing circuitry of IMD **10** and/or processing circuitry of external device **12**. In general, the techniques of this disclosure may be performed by processing circuitry **14** of one or more devices of a system, such as one or more devices that include sensors that provide signals, or processing circuitry of one or more devices that do not include sensors, but nevertheless analyze signals using the techniques described herein. For example, another external device (not pictured in FIG. **1**) may include at least a portion of processing circuitry **14**, the other external device configured for remote communication with IMD **10** and/or external device **12** via a network.

[0031] In some examples, IMD **10** is implanted outside of a thoracic cavity of patient **4** (e.g., subcutaneously in the pectoral location illustrated in FIG. **1**). IMD **10** may be positioned near the sternum near or just below the level of patient **4**'s heart, e.g., at least partially within the cardiac silhouette. For other medical conditions, IMD **10** may be implanted in other appropriate locations, such as the interstitial space, abdomen, back of arm, wrist, etc. In some examples, IMD **10** takes the form of a Reveal LINQ™ or LINQ II™ Insertable Cardiac Monitor (ICM), available from Medtronic, Inc.

[0032] Clinicians sometimes diagnose patients with medical conditions based on one or more observed physiological signals collected by physiological sensors, such as electrodes, optical sensors, chemical sensors, temperature sensors, acoustic sensors, and motion sensors. In some cases, clinicians apply non-invasive sensors to patients in order to sense one or more physiological signals while a patient is in a clinic for a medical appointment. However, in some examples, physiological markers (e.g., arrhythmia, etc.) of a patient condition are rare or are difficult to observe over a relatively short period of time. As such, in these examples, a clinician may be unable to observe the physiological markers needed to diagnose a patient with a medical condition or effectively treat the patient while monitoring one or more physiological signals of the patient

during a medical appointment. Moreover, an impending heart failure decomposition event may be difficult to diagnose during a medical appointment. In the example illustrated in FIG. **1**, IMD **10** is implanted within patient **4** to continuously record one or more physiological signals, such as an electrocardiogram (ECG), electromyogram (EMG), impedance, respiration, activity, posture, blood oxygen saturation, or other physiological signals, of patient **4** over an extended period of time.

[0033] In some examples, IMD **10** includes a plurality of electrodes. The plurality of electrodes is configured to detect signals that enable processing circuitry **14**, e.g., of IMD **10**, to monitor and/or record physiological parameters of patient **4**. For example, the plurality of electrodes may be configured to sense an ECG, EMG, impedance, or the like, of patient **4**. IMD **10** may additionally or alternatively include one or more optical sensors, accelerometers, temperature sensors, chemical sensors, light sensors, pressure sensors, in some examples. Such sensors may detect one or more physiological parameters indicative of a patient condition. The physiological parameters may include impedance, such as interstitial or other impedance indicative of fluid accumulation analyzed according to the OptiVol™ algorithm or another algorithm that determines a fluid index based on impedance, patient activity, anti-tachycardia/anti-fibrillation burden, ventricular rate during anti-tachycardia/anti-fibrillation, percentage of ventricular pacing, shocks, treated ventricular tachycardia/ventricular fibrillation, night ventricular rate, heart rate variability, heart sounds, lung sounds, and/or other physiological parameters. In some examples, additional sensors may be located on other devices (not shown in FIG. **1**) which may also sense physiological parameters of patient **4**.

[0034] Sensor data may be collected by various devices such as implantable therapy devices, implantable monitoring devices, wearable devices, point of care devices, and noncontact sensors in the home or vehicle or other area frequented by the patient or a combination of such sensor platforms. The sensor data collected may be relevant to the disease state (e.g., heart failure) or comorbidities (e.g., chronic obstructive pulmonary disease (COPD), kidney disease, etc.) or for diagnosing a suspected comorbidity. For patients with multiple comorbidities, it may be possible to perform a differential diagnosis between different sources of a problem, e.g., heart failure decompensation, COPD exacerbation, pneumonia, etc. This would permit a clinician to prescribe appropriate therapies to address the patient's condition, such as diuretics, antibiotics, encourage fluids, etc.

[0035] Processing circuitry **14** may process the sensed physiological parameters (whether sensed by IMD **10**, another device(s), or any combination thereof). For example, processing circuitry **14** may execute an algorithm (such as TriageHF™ or a similar algorithm) configured to determine a likelihood of an impending heart failure decompensation event based on sensed physiological parameters of patient **4**.

[0036] This likelihood may be a percentage chance that patient **4** may have an impending heart failure decompensation event, a rating (e.g., high, medium, low), a score (e.g., on a scale of 1-10) or the like. Processing circuitry **14** may monitor such sensed physiological parameters as impedance (e.g., using a fluid index algorithm), patient activity, atrial tachycardia (AT)/atrial fibrillation (AF) burden, ventricular rate during AT/AF. percentage of ventricular pacing, shocks, treated ventricular tachycardia/ventricular fibrillation, night ventricular rate, heart rate variability, heart sounds, lung sounds, and/or other physiological parameters. In some examples, processing circuitry **14** may compare each of the sensed physiological parameters used by the algorithm to parameter-specific thresholds and processing circuitry **14** may apply a Bayesian probabilistic model (e.g., a Bayesian Belief Network) to results of the comparisons to determine a likelihood that patient **4** may have an impending heart failure decompensation event. Further details on how to determine a likelihood that a heart failure decomposition event is impending may be found in commonly-assigned U.S. Patent Publication 2020-0187864 A1 published on Jun. 18, 2020, and U.S. Patent Publication 2021-0093254 A1, the entire contents of which are hereby incorporated by reference.

[0037] For example, processing circuitry **14** may derive features (such as a fluid index) from aggregated data. Raw data, aggregated data, and determined physiological features may be combined in the cloud using machine learning algorithms or deep learning models to generate clinically actionable insights. In some examples, the sensed physiological parameters may be collected and processed to provide an index or score of patient **4**'s health. There are several examples of such scoring systems that are in clinical use today. One example is the APACHE (Acute Physiology and Chronic Health Evaluation) IV scoring system. In some examples, processing circuitry **14** may continuously calculate such a score, or a similar score. Processing circuitry **14** may attempt to determine any source of changes in patient **4**'s health based on such sensed physiological parameters and, when appropriate, send an indication to a clinician regarding the change in the score and the source of the changes in the patient's health status with suggested treatment options. Processing circuitry **14** may also provide to patient **4** or a caregiver of patient **4** any prescription changes in medications or directions to use a biochemical sensor or bacterial sensor. These scores and directions could be provided via external device **12**. Such a biochemical sensor may include a multianalyte sensor that is configured to sense BMP parameters, a multianalyte sensor that is configured to sense other biochemical parameters, a multianalyte sensor that is configured to sense some BMP parameters, a multianalyte sensor that is configured to sense some BMP parameters and some other biochemical parameters, or a single analyte sensor. Such a bacterial sensor may include an antigen sensor configured to sense an antigen present on a membrane of a bacterium, a byproduct sensor configured to sense a biproduct particular to a bacterium, a sensor configured to sense something that normally is not present in a human body, or the like.

[0038] Processing circuitry **14** may receive sensor data. For example, processing circuitry **14** may receive sensor data from IMD **10** or other sensors in or about patient **4**. Processing circuitry may determine, based on the sensor data, a likelihood that a heart failure decompensation event is impending. Processing circuitry **14** may compare the likelihood to a first threshold. For example, if the likelihood meets the first threshold it may indicate that a heart failure decompensation event is likely to occur within the next 30 days. Based on the likelihood satisfying the first threshold, processing circuitry **14** may generate an instruction for output to deploy one or more biochemical or bacterial sensors, for example, via external device **12** to patient **4** or a caregiver of patient **4**. In some examples, processing circuitry **14** may also generate an indication for output for review by a clinician, e.g., via external device **12**. Such an indication may include a heart failure score, sensed physiological parameters, or the like. In some examples, processing circuitry **14** may generate further instructions or messages for patient **4** or a caregiver regarding when patient **4** or the caregiver should replace the biochemical sensor or bacterial sensor and/or when it is no longer necessary to replace the biochemical sensor or bacterial sensor.

[0039] In some examples, IMD **10** may include one or more biochemical sensors and/or one or more bacterial sensors which may be disposed on a surface or near the surface of IMD **10**. Such sensors may be covered by welds, doors, or the like to keep the biochemical sensor(s) and/or bacterial sensor(s) inactive to preserve their life. In such a case, processing circuitry **14** may control IMD **10** to deploy one or more biochemical sensors or bacterial sensors based on the likelihood that a heart failure decompensation event of patient **4** is impending meeting the threshold. This may be performed alone or together with generating the instructions for output to patient **4** or a caregiver of patient **4** as described above.

[0040] For example, processing circuitry **14** may control IMD **10** to release, perforate, dissolve, or otherwise open the weld or door of one or more of the biochemical sensors or bacterial sensors. In some examples, the door or weld may include a thin gold foil which IMD **10** may electro-perforate or electro-vaporize to deploy a given biochemical or bacterial sensor.

[0041] In some examples, regardless of the determined likelihood of an impending heart failure decompensation event meeting the threshold, a clinician may desire to periodically monitor

biochemical parameters and/or bacterial parameters of patient **4**, for example to determine a baseline or monitor trends over time in the cardiac health of patient **4**. In such cases, the clinician via external device **12** may provide patient **4** or a caregiver of patient **4** with instructions to deploy one or more biochemical sensor or bacterial sensors. Additionally, or alternatively, the clinician may trigger the opening of the weld or door of one or more biochemical sensor or bacterial sensors of IMD **10**. This triggering may be performed by programming IMD **10**, via external device **12**, to open the weld or door of the one or more biochemical sensor or bacterial sensors at a programed time, at a programmed time interval, or in real-time based on a command sent be the clinician via external device **12**. In some examples, the times with which IMD **10** may open a weld or door or with which external device **12** provides patient **4** or a caregiver of patient **4** with instructions to deploy one or more biochemical sensor or bacterial sensors may be predetermined.

[0042] In some examples, IMD **10**, external device **12**, and/or processing circuitry **14** may apply a machine learning model to determine when to trigger the deployment, either by patient **4** or a caregiver, or by IMD **10**, of one or more biochemical sensors and/or one or more bacterial sensors. The machine learning model may be trained, for example, on particular physiological parameters, biochemical parameters, bacterial parameters, disease states, comorbidities, activities, postures, family history, age, or the like of patient **4**, or of a population of a plurality of patients.

[0043] Potential machine learning models may be configured as Bayesian algorithms, clustering algorithms, decision-tree algorithms, regularization algorithms, regression algorithms (e.g., linear or logistic), instance-based algorithms, artificial neural network algorithms, deep learning algorithms, random forest algorithms, support vector machines, dimensionality reduction algorithms and the like. Various examples of specific algorithms include Naïve Bayes, Bayesian Linear Regression, Boosted Decision Tree Regression, and Neural Network Regression, Back Propagation Neural Networks, Convolution Neural Networks (CNN), Long Short Term Networks (LSTM), the Apriori algorithm, K-Means Clustering, k-Nearest Neighbour (kNN), Learning Vector Quantization (LVQ), Self-Organizing Map (SOM), Locally Weighted Learning (LWL), Ridge Regression, Least Absolute Shrinkage and Selection Operator (LASSO), Elastic Net, and Least-Angle Regression (LARS), Principal Component Analysis (PCA) and Principal Component Regression (PCR).

[0044] For example, a k-means clustering model may be used having two clusters: one for deploying the one or more biochemical sensor and one for not deploying the one or more biochemical sensor. Each time the model is run may be associated with a vector that includes variables for, e.g., particular physiological parameters, biochemical parameters, disease states, comorbidities, activities, postures, family history, age, of patient **4**, how many biochemical sensors remain on IMD **10** or within the possession of patient **4** or a caregiver, or the like. The location of the vector in a given one of the clusters may be indicative of whether IMD **10**, patient **4** or a caregiver should deploy one or more biochemical sensors. For example, if the vector falls within the deploy the one or more biometric sensor cluster, IMD **10** may deploy the one or more biochemical sensor and/or external device **12** may inform patient **4** or a caregiver to deploy one or more biochemical sensors. In some examples, a more complicated model may be used with additional clusters for different types of biochemical sensors, such that the deployment of different types of biochemical sensors may be determined through the machine learning model. A similar model may be used to determine when to deploy one or more bacterial sensor.

[0045] External device **12** may be a hand-held computing device with a display viewable by the user and an interface for providing input to external device **12** (i.e., a user input mechanism). For example, external device **12** may include a small display screen (e.g., a liquid crystal display (LCD) or a light emitting diode (LED) display) that presents information to the user, such as instructions to deploy one or more biochemical sensor or bacterial sensors. In addition, external device **12** may include a touch screen display, keypad, buttons, a peripheral pointing device, voice activation, or another input mechanism that allows the user to navigate through the user interface of

external device **12** and provide input. If external device **12** includes buttons and a keypad, the buttons may be dedicated to performing a certain function, e.g., a power button, the buttons and the keypad may be soft keys that change in function depending upon the section of the user interface currently viewed by the user, or any combination thereof.

[0046] In other examples, external device **12** may be a larger workstation or a separate application within another multi-function device, rather than a dedicated computing device. For example, the multi-function device may be a notebook computer, tablet computer, workstation, one or more servers, cellular phone, personal digital assistant, or another computing device that may run an application that enables the computing device to operate as a secure device.

[0047] When external device **12** is configured for use by the clinician, external device **12** may be used to transmit instructions to IMD **10** and to receive measurements, such sensed physiological parameters, sensed biochemical parameters, sensed bacterial parameters, heart failure scores, indications of the determined likelihood of an impending heart failure decompensation event, or the like. Example instructions may include requests to set electrode combinations for sensing and any other information that may be useful for programming into IMD **10**, such as when to deploy one or more biochemical sensors and/or one or more bacterial sensors. The clinician may also configure and store operational parameters for IMD **10** within IMD **10** with the aid of external device **12**. In some examples, external device **12** assists the clinician in the configuration of IMD **10** by providing a system for identifying potentially beneficial operational parameter values.

[0048] Whether external device **12** is configured for clinician or patient use, external device **12** is configured to communicate with IMD **10** and, optionally, another computing device (not illustrated in FIG. **1**), via wireless communication. External device **12**, for example, may communicate via near-field communication technologies (e.g., inductive coupling, NFC or other communication technologies operable at ranges less than 10-20 cm) and far-field communication technologies (e.g., RF telemetry according to the 802.11 or Bluetooth® specification sets, or other communication technologies operable at ranges greater than near-field communication technologies).

[0049] Processing circuitry **14**, in some examples, may include one or more processors that are configured to implement functionality and/or process instructions for execution within IMD **10** and/or external device **12**. For example, processing circuitry **14** may be capable of processing instructions stored in a storage device. Processing circuitry **14** may include, for example, microprocessors, digital signal processors (DSPs), application specific integrated circuits (ASICs), field-programmable gate arrays (FPGAs), or equivalent discrete or integrated logic circuitry, or a combination of any of the foregoing devices or circuitry. Accordingly, processing circuitry **14** may include any suitable structure, whether in hardware, software, firmware, or any combination thereof, to perform the functions ascribed herein to processing circuitry **14**.

[0050] Processing circuitry **14** may represent processing circuitry located within any combination of IMD **10** and/or external device **12**. In some examples, processing circuitry **14** may be entirely located within a housing of IMD **10**. In other examples, processing circuitry **14** may be entirely located within a housing of external device **12**. In other examples, processing circuitry **14** may be located within any combination of IMD **10**, external device **12**, and another device or group of devices that are not illustrated in FIG. **1**. As such, techniques and capabilities attributed herein to processing circuitry **14** may be attributed to any combination of IMD **10**, external device **12**, and other devices that are not illustrated in FIG. **1**.

[0051] In some examples, IMD **10** includes one or more motion sensors, such as accelerometers. An accelerometer of IMD **10** may collect an accelerometer signal which reflects a measurement of a motion of patient **4**. In some cases, the accelerometer may collect a three-axis accelerometer signal indicative of patient **4**'s movements within a three-dimensional Cartesian space. For example, the accelerometer signal may include a vertical axis accelerometer signal vector, a lateral axis accelerometer signal vector, and a frontal axis accelerometer signal vector. The vertical axis

accelerometer signal vector may represent an acceleration of patient **4** along a vertical axis, the lateral axis accelerometer signal vector may represent an acceleration of patient **4** along a lateral axis, and the frontal axis accelerometer signal vector may represent an acceleration of patient **4** along a frontal axis. In some cases, the vertical axis substantially extends along a torso of patient **4** when patient **4** from a neck of patient **4** to a waist of patient **4**, the lateral axis extends across a chest of patient **4** perpendicular to the vertical axis, and the frontal axis extends outward from and through the chest of patient **4**, the frontal axis being perpendicular to the vertical axis and the lateral axis. In some examples, processing circuitry **14** may be configured to identify, based on one of more accelerometer signals, a posture or activity of patient **4**. In some examples, the sensed physiological parameters by IMD **10** may include the posture and/or activity of patient **4**. Such postures and/or activities of patient **4** may be used when determining the likelihood of an impending heart failure decompensation event.

[0052] Although in one example IMD **10** takes the form of an ICM, in other examples, IMD **10** takes the form of any one or more of an ICM, a pacemaker, a defibrillator, a cardiac resynchronization therapy device, an implantable pulse generator, an intra-cardiac pressure measuring device, a ventricular assist device, a pulmonary artery pressure device, a subcutaneous blood pressure device, or the like. The physiological parameters, the biochemical parameters, and/or the bacterial parameters may be sensed or determined using one or more of the aforementioned devices, as well as external devices such as external device **12**.

[0053] FIG. **2** is a conceptual drawing illustrating an example configuration of IMD **10** of the medical device system **2** of FIG. **1**, in accordance with one or more techniques described herein. In the example shown in FIG. **2**, IMD **10** may be a leadless, subcutaneously- or vascularly-implantable monitoring device having housing **15**, proximal electrode **16**A, and distal electrode **16**B. Housing **15** may further include first major surface **18**, second major surface **20**, proximal end **22**, and distal end **24**. In some examples, IMD **10** may include one or more additional electrodes **16**C. **16**D positioned on one or both of major surfaces **18**, **20** of IMD **10**. Housing **15** encloses electronic circuitry located inside the IMD **10**, and protects the circuitry contained therein from fluids such as body fluids (e.g., blood). In some examples, electrical feedthroughs provide electrical connection of electrodes **16**A-**16**D, and antenna **26**, to circuitry within housing **15**. In some examples, electrode **16**B may be formed from an uninsulated portion of conductive housing **15**.

[0054] In the example shown in FIG. **2**, IMD **10** is defined by a length L, a width W. and thickness or depth D. In this example, IMD **10** is in the form of an elongated rectangular prism in which length L is significantly greater than width W, and in which width W is greater than depth D. However, other configurations of IMD **10** are contemplated, such as those in which the relative proportions of length L, width W, and depth D vary from those described and shown in FIG. **2**. In some examples, the geometry of the IMD **10**, such as the width W being greater than the depth D, may be selected to allow IMD **10** to be inserted under the skin of the patient using a minimally invasive procedure and to remain in the desired orientation during insertion. In addition, IMD **10** may include radial asymmetries (e.g., the rectangular shape) along a longitudinal axis of IMD **10**, which may help maintain the device in a desired orientation following implantation.

[0055] In some examples, a spacing between proximal electrode **16**A and distal electrode **16**B may range from about 30-55 mm, about 35-55 mm, or about 40-55 mm, or more generally from about 25-60 mm. Overall, IMD **10** may have a length L of about 20-30 mm, about 40-60 mm, or about 45-60 mm. In some examples, the width W of major surface **18** may range from about 3-10 mm, and may be any single width or range of widths between about 3-10 mm. In some examples, a depth D of IMD **10** may range from about 2-9 mm. In other examples, the depth D of IMD **10** may range from about 2-5 mm, and may be any single or range of depths from about 2-9 mm. In any such examples, IMD **10** is sufficiently compact to be implanted within the subcutaneous space of patient **4** in the region of a pectoral muscle.

[0056] IMD **10**, according to an example of the present disclosure, may have a geometry and size

designed for ease of implant and patient comfort. Examples of IMD **10** described in this disclosure may have a volume of 3 cubic centimeters (cm.sup.3) or less, 1.5 cm.sup.3 or less, or any volume therebetween. In addition, in the example shown in FIG. **2**, proximal end **22** and distal end **24** are rounded to reduce discomfort and irritation to surrounding tissue once implanted under the skin of patient **4**.

[0057] In the example shown in FIG. **2**, first major surface **18** of IMD **10** faces outward towards the skin, when IMD **10** is inserted within patient **4**, whereas second major surface **20** is faces inward toward musculature of patient **4**. Thus, first and second major surfaces **18**, **20** may face in directions along a sagittal axis of patient **4** (see FIG. **1**), and this orientation may be generally maintained upon implantation due to the dimensions of IMD **10**.

[0058] Proximal electrode **16**A and distal electrode **16**B may be used to sense cardiac EGM signals (e.g., ECG signals) when IMD **10** is implanted subcutaneously in patient **4**. In some examples, processing circuitry of IMD **10** also may determine whether cardiac ECG signals of patient **4** are indicative of arrhythmia or other abnormalities, which processing circuitry of IMD **10** may evaluate in determining whether a medical condition (e.g., heart failure, sleep apnea, or COPD) of patient **4** has changed. The cardiac ECG signals may be stored in a memory of IMD **10**, and data derived from the cardiac ECG signals and/or other sensor signals, such as an impending heart failure decompensation event may be transmitted via integrated antenna **26** to another device, such as external device **12**. Additionally, in some examples, electrodes **16**A, **16**B may be used by communication circuitry of IMD **10** for tissue conductance communication (TCC) communication with external device **12** or another device.

[0059] In the example shown in FIG. **2**, proximal electrode **16**A is in close proximity to proximal end **22**, and distal electrode **16**B is in close proximity to distal end **24** of IMD **10**. In this example, distal electrode **16**B is not limited to a flattened, outward facing surface, but may extend from first major surface **18**, around rounded edges **28** or end surface **30**, and onto the second major surface **20** in a three-dimensional curved configuration. As illustrated, proximal electrode **16**A is located on first major surface **18** and is substantially flat and outward facing. However, in other examples not shown here, proximal electrode **16**A and distal electrode **16**B both may be configured like proximal electrode **16**A shown in FIG. **2**, or both may be configured like distal electrode **16**B shown in FIG. **2**. In some examples, additional electrodes **16**C and **16**D may be positioned on one or both of first major surface **18** and second major surface **20**, such that a total of four electrodes are included on IMD **10**. Any of electrodes **16**A-**16**D may be formed of a biocompatible conductive material. For example, any of electrodes **16**A-**16**D may be formed from any of stainless steel, titanium, platinum, iridium, or alloys thereof. In addition, electrodes of IMD **10** may be coated with a material such as titanium nitride or fractal titanium nitride, although other suitable materials and coatings for such electrodes may be used.

[0060] In the example shown in FIG. **2**, proximal end **22** of IMD **10** includes header assembly **32** having one or more of proximal electrode **16**A, integrated antenna **26**, anti-migration projections **34**, and suture hole **36**. Integrated antenna **26** is located on the same major surface (e.g., first major surface **18**) as proximal electrode **16**A, and may be an integral part of header assembly **32**. In other examples, integrated antenna **26** may be formed on the major surface opposite from proximal electrode **16**A, or, in still other examples, may be incorporated within housing **15** of IMD **10**. Antenna **26** may be configured to transmit or receive electromagnetic signals for communication. For example, antenna **26** may be configured to transmit to or receive signals from a programmer via inductive coupling, electromagnetic coupling, tissue conductance, Near Field Communication (NFC), Radio Frequency Identification (RFID), Bluetooth®, WiFi®, or other proprietary or non-proprietary wireless telemetry communication schemes. Antenna **26** may be coupled to communication circuitry of IMD **10**, which may drive antenna **26** to transmit signals to external device **12**, and may transmit signals received from external device **12** to processing circuitry of IMD **10** via communication circuitry.

[0061] In some examples, IMD **10** may include several features for retaining IMD **10** in position once subcutaneously implanted in patient **4**, so as to decrease the chance that IMD **10** migrates in the body of patient **4**. For example, as shown in FIG. **2**, housing **15** may include anti-migration projections **34** positioned adjacent integrated antenna **26**. Anti-migration projections **34** may include a plurality of bumps or protrusions extending away from first major surface **18**, and may help prevent longitudinal movement of IMD **10** after implantation in patient **4**. In other examples, anti-migration projections **34** may be located on the opposite major surface as proximal electrode **16**A and/or integrated antenna **26**. In addition, in the example shown in FIG. **2** header assembly **32** includes suture hole **36**, which provides another means of securing IMD **10** to the patient to prevent movement following insertion. In the example shown, suture hole **36** is located adjacent to proximal electrode **16**A. In some examples, header assembly **32** may include a molded header assembly made from a polymeric or plastic material, which may be integrated or separable from the main portion of IMD **10**.

[0062] In the example of FIG. **2**, IMD **10** includes sensors **44**. Sensors **44** may include one or more biochemical sensor and/or one or more bacterial sensors. Such biochemical sensor or bacterial sensors may be arranged in an array. Each biochemical sensor or bacterial sensor may be covered by a weld or door (not shown in FIG. **2**) which may shield each biochemical sensor or bacterial sensor from exposure to the surrounding tissue of patient **4**. When a particular biochemical sensor or bacterial sensor is to be deployed, IMD **10** may dissolve, perforate, or otherwise open the door to expose the biochemical sensor or bacterial sensor to the surrounding tissue of patient **4**. In some examples, IMD **10** includes treatment **45**. Treatment **45** may include one or more boluses of anti-biotic medication. Such boluses of anti-biotics may also each be covered by a weld or door which IMD **10** may dissolve, perforate, or otherwise open to release the bolus into patient **4**. In some examples, IMD **10** may release a bolus of antibiotic medication based on a bacterial sensor signal indicating that there is an infection in patient **4**.

[0063] In the example shown in FIG. **2**, IMD **10** includes a light emitter **38**, a proximal light detector **40**A, and a distal light detector **40**B positioned on housing **15** of IMD **10**. Light detector **40**A may be positioned at a distance S from light emitter **38**, and a distal light detector **40**B positioned at a distance S+N from light emitter **38**. In other examples, IMD **10** may include only one of light detectors **40**A, **40**B, or may include additional light emitters and/or additional light detectors. Although light emitter **38** and light detectors **40**A, **40**B are described herein as being positioned on housing **15** of IMD **10**, in other examples, one or more of light emitter **38** and light detectors **40**A, **40**B may be positioned, on a housing of another type of IMD within patient **4**, such as a transvenous, subcutaneous, or extravascular pacemaker or ICD, or connected to such a device via a lead.

[0064] As shown in FIG. **2**, light emitter **38** may be positioned on header assembly **32**, although, in other examples, one or both of light detectors **40**A, **40**B may additionally or alternatively be positioned on header assembly **32**. In some examples, light emitter **38** may be positioned on a medial section of IMD **10**, such as part way between proximal end **22** and distal end **24**. Although light emitter **38**, light detectors **40**A, **40**B, and sensors **44** are illustrated as being positioned on first major surface **18**, light emitter **38**, light detectors **40**A, **40**B, and sensors **44** alternatively may be positioned on second major surface **20**. In some examples, IMD may be implanted such that light emitter **38** and light detectors **40**A, **40**B face inward when IMD **10** is implanted, toward the muscle of patient **4**, which may help minimize interference from background light coming from outside the body of patient **4**. Light detectors **40**A, **40**B may include a glass or sapphire window, such as described below with respect to FIG. **4**B, or may be positioned beneath a portion of housing **15** of IMD **10** that is made of glass or sapphire, or otherwise transparent or translucent.

[0065] In some examples, IMD **10** may include one or more additional sensors, such as one or more motion sensors (not shown in FIG. **2**). Such motion sensors may be 3D accelerometers configured to generate signals indicative of one or more types of movement of the patient, such as

gross body movement (e.g., motion) of the patient, patient posture, movements associated with the beating of the heart, or coughing, rales, or other respiration abnormalities, or the movement of IMD **10** within the body of patient **4**. One or more of the parameters monitored by IMD **10** (e.g., bio impedance, EGM) may fluctuate in response to changes in one or more such types of movement. For example, changes in parameter values sometimes may be attributable to increased patient motion (e.g., exercise or other physical motion as compared to immobility) or to changes in patient posture, and not necessarily to changes in a medical condition. Thus, in some methods of identifying or tracking a medical condition of patient **4**, it may be advantageous to account for such fluctuations when determining whether a change in a parameter is indicative of a change in a medical condition or when determining the likelihood of an impending heart failure decompensation event.

[0066] FIG. **3** is a functional block diagram illustrating an example configuration of IMD **10** of FIGS. **1** and **2**, in accordance with one or more techniques described herein. In the illustrated example, IMD **10** includes electrodes **16**, antenna **26**, processing circuitry **50**, sensing circuitry **52**, communication circuitry **54**, storage device **56**, switching circuitry **58**, sensors **62** including motion sensor(s) **42** (which may include an accelerometer) and a plurality of other sensors (e.g., first sensor **44**A-Nth sensor **44**N, collectively "sensors **44**), treatment **45**, and power source **64**. Sensors **44** may include one or more biochemical sensor and/or one or more bacterial sensors which may be disposed on or near a surface of IMD **10**. Each of biochemical sensors or bacterial sensors of sensors **44** may be covered by a weld or door so as to not expose the biochemical sensors or bacterial sensors to surrounding tissue of patient **4** until each biochemical sensor or bacterial sensor is deployed via dissolving, perforating, or otherwise opening the weld or door. In some examples, the one or more biochemical sensors and/or the one or more bacterial sensors may be arranged in an array.

[0067] Processing circuitry **50** may include fixed function circuitry and/or programmable processing circuitry. Processing circuitry **50** may include any one or more of a microprocessor, a controller, a DSP, an ASIC, an FPGA, or equivalent discrete or analog logic circuitry. In some examples, processing circuitry **50** may include multiple components, such as any combination of one or more microprocessors, one or more controllers, one or more DSPs, one or more ASICs, or one or more FPGAs, as well as other discrete or integrated logic circuitry. The functions attributed to processing circuitry **50** herein may be embodied as software, firmware, hardware or any combination thereof. In some examples, one or more techniques of this disclosure may be performed by processing circuitry **50**.

[0068] Sensing circuitry **52** and communication circuitry **54** may be selectively coupled to electrodes **16**A-**16**D via switching circuitry **58**, as controlled by processing circuitry **50**. Sensing circuitry **52** may monitor signals from electrodes **16**A-**16**D in order to monitor electrical activity of heart (e.g., to produce an ECG). Sensing circuitry **52** also may monitor signals from sensors **62**, which may include motion sensor(s) **42** (which may include an accelerometer) and sensors **44**. In some examples, sensing circuitry **52** may include one or more filters and amplifiers for filtering and amplifying signals received from one or more of electrodes **16**A-**16**D, motion sensor(s) **42**, and/or sensors **44**.

[0069] Communication circuitry **54** may include any suitable hardware, firmware, software or any combination thereof for communicating with another device, such as external device **12** or another IMD or sensor, such as a pressure sensing device. Under the control of processing circuitry **50**, communication circuitry **54** may receive downlink telemetry from, as well as send uplink telemetry to, external device **12** or another device with the aid of an internal or external antenna, e.g., antenna **26**. In addition, processing circuitry **50** may communicate with a networked computing device via an external device (e.g., external device **12**) and a computer network, such as the Medtronic CareLink® Network developed by Medtronic, Inc.

[0070] A clinician or other user may retrieve data from IMD **10** using external device **12**, or by

using another local or networked computing device configured to communicate with processing circuitry **50** via communication circuitry **54**. The clinician may also program parameters of IMD **10** using external device **12** or another local or networked computing device.

[0071] In some examples, storage device **56** includes computer-readable instructions that, when executed by processing circuitry **50**, cause IMD **10** and processing circuitry **50** to perform various functions attributed to IMD **10** and processing circuitry **50** herein. Storage device **56** may include any volatile, non-volatile, magnetic, optical, or electrical media, such as a random access memory (RAM), ferroelectric RAM (FRAM) read-only memory (ROM), non-volatile RAM (NVRAM), electrically-erasable programmable ROM (EEPROM), flash memory, or any other digital media.

[0072] Storage device **56** may also store machine learning model **46**. In some examples, machine learning model **46** may be used by processing circuitry **50** to determine when to deploy one or more biochemical sensors and/or one or more bacterial sensors of sensors **44** and/or to instruct patient **4** or a caregiver to deploy one or more biochemical sensors and/or one or more bacterial sensors as discussed above. In some examples, processing circuitry **50** may employ machine learning model **46** or another machine learning model to determine a risk of a heart failure event based on data determined from sensors **44**, and in some cases other values of other parameters, e.g., sensed via sensing circuitry **52** or sensors as described herein.

[0073] Power source **64** is configured to deliver operating power to the components of IMD **10**. Power source **64** may include a battery and a power generation circuit to produce the operating power. In some examples, the battery is rechargeable to allow extended operation. In some examples, recharging is accomplished through proximal inductive interaction between an external charger and an inductive charging coil within external device **12**. Power source **64** may include any one or more of a plurality of different battery types, such as nickel cadmium batteries and lithium ion batteries. A non-rechargeable battery may be selected to last for several years, while a rechargeable battery may be inductively charged from an external device, e.g., on a daily or weekly basis.

[0074] FIGS. **4**A and **4**B illustrate two additional example IMDs that may be substantially similar to IMD **10** of FIGS. **1-3**, but which may include one or more additional features, in accordance with one or more techniques described herein. The components of FIGS. **4**A and **4**B may not necessarily be drawn to scale, but instead may be enlarged to show detail. FIG. **4**A is a block diagram of a top view of an example configuration of an IMD **10**A. FIG. **4**B is a block diagram of a side view of example IMD **10**B, which may include an insulative layer as described below.

[0075] FIG. **4**A is a conceptual drawing illustrating another example IMD **10**A that may be substantially similar to IMD **10** of FIG. **1**. In addition to the components illustrated in FIGS. **1-3**, the example of IMD **10** illustrated in FIG. **4**A also may include a body portion **72**, an attachment plate **74**, and treatment **45**. Attachment plate **74** may be configured to mechanically couple header assembly **32** to body portion **72** of IMD **10**A. Body portion **72** of IMD **10**A may be configured to house one or more of the internal components of IMD **10** illustrated in FIG. **3**, such as one or more of processing circuitry **50**, sensing circuitry **52**, communication circuitry **54**, storage device **56**, switching circuitry **58**, internal components of sensors **62**, and power source **64**. In some examples, body portion **72** may be formed of one or more of titanium, ceramic, or any other suitable biocompatible materials. Treatment **45** may include one or more boluses of anti-biotics for treating an infection of patient **4**. Treatment **45** may be disposed on or near the surface of IMD **10**A, each of which may be behind a weld or door similar to those covering sensors **44**. When a bacterial infection is detected by IMD **10**A, IMD **10**A may open the weld or door covering one or more of the boluses of anti-biotic medication to release anti-biotic medication into the body of patient **4**.

[0076] FIG. **4**B is a conceptual drawing illustrating another example IMD **10**B that may include components substantially similar to IMD **10** of FIG. **1**. In addition to the components illustrated in FIGS. **1-3**, the example of IMD **10**B illustrated in FIG. **4**B also may include a wafer-scale insulative cover **76**, which may help insulate electrical signals passing between electrodes **16**A-

16D, light detectors **40**A, **40**B on housing **15**B and processing circuitry **50**. In some examples, insulative cover **76** may be positioned over an open housing **15** to form the housing for the components of IMD **10**B. One or more components of IMD **10**B (e.g., antenna **26**, light emitter **38**, light detectors **40**A, **40**B, processing circuitry **50**, sensing circuitry **52**, communication circuitry **54**, switching circuitry **58**, and/or power source **64**) may be formed on a bottom side of insulative cover **76**, such as by using flip-chip technology. Insulative cover **76** may be flipped onto a housing **15**B. When flipped and placed onto housing **15**B, the components of IMD **10**B formed on the bottom side of insulative cover **76** may be positioned in a gap **78** defined by housing **15**B.

[0077] Insulative cover **76** may be configured so as not to interfere with the operation of IMD **10**B. For example, insulative cover may include one or more gaps or holes to permit sensors **44** and/or treatment **45** to be exposed to the surrounding tissue of patient **4** when welds or doors **48** are opened. Each of welds or doors **48** may be configured to prevent or limit the exposure of one or more of sensors **44** and/or treatment **45** from the surrounding tissue of patient **4**. Additionally, one or more of electrodes **16**A-**16**D may be formed or placed above or on top of insulative cover **76**, and electrically connected to switching circuitry **58** through one or more vias (not shown) formed through insulative cover **76**. Insulative cover **76** may be formed of sapphire (i.e., corundum), glass, parylene, and/or any other suitable insulating material. Sapphire may be greater than 80% transmissive for wavelengths in the range of about 300 nm to about 4000 nm, and may have a relatively flat profile. In the case of variation, different transmissions at different wavelengths may be compensated for, such as by using a ratiometric approach. In some examples, insulative cover **76** may have a thickness of about 300 micrometers to about 600 micrometers. Housing **15**B may be formed from titanium or any other suitable material (e.g., a biocompatible material), and may have a thickness of about 200 micrometers to about 500 micrometers. These materials and dimensions are examples only, and other materials and other thicknesses are possible for devices of this disclosure.

[0078] FIG. **5** is a block diagram illustrating an example configuration of components of external device **12**, in accordance with one or more techniques of this disclosure. In the example of FIG. **5**, external device **12** includes processing circuitry **80**, communication circuitry **82**, storage device **84**, user interface **86**, and power source **88**.

[0079] Processing circuitry **80**, in one example, may include one or more processors that are configured to implement functionality and/or process instructions for execution within external device **12**. For example, processing circuitry **80** may be capable of processing instructions stored in storage device **84**. Processing circuitry **80** may include, for example, microprocessors, DSPs, ASICs, FPGAs, or equivalent discrete or integrated logic circuitry, or a combination of any of the foregoing devices or circuitry. Accordingly, processing circuitry **80** may include any suitable structure, whether in hardware, software, firmware, or any combination thereof, to perform the functions ascribed herein to processing circuitry **80**. In some examples, processing circuitry **80** may perform one or more of the techniques of this disclosure.

[0080] Communication circuitry **82** may include any suitable hardware, firmware, software or any combination thereof for communicating with another device, such as IMD **10**. Under the control of processing circuitry **80**, communication circuitry **82** may receive downlink telemetry from, as well as send uplink telemetry to, IMD **10**, or another device.

[0081] Storage device **84** may be configured to store information within external device **12** during operation. Storage device **84** may include a computer-readable storage medium or computer-readable storage device. In some examples, storage device **84** includes one or more of a short-term memory or a long-term memory. Storage device **84** may include, for example, RAM, dynamic random access memories (DRAM), static random access memories (SRAM), magnetic discs, optical discs, flash memories, or forms of electrically programmable memories (EPROM) or EEPROM. In some examples, storage device **84** is used to store data indicative of instructions for execution by processing circuitry **80**. Storage device **84** may be used by software or applications

running on external device **12** to temporarily store information during program execution.

[0082] Storage device **84** may also store machine learning model **79**. In some examples, machine learning model **79** may be used by processing circuitry **80** to determine when to deploy one or more of sensors **44** and/or to instruct patient **4** or a caregiver to deploy one or more biometric sensors as discussed above. In the example where machine learning model **79** is located in storage device **84**, external device **12** may generate an instruction for transmission to IMD **10** to deploy one or more biochemical sensors and/or one or more bacterial sensors of sensors **44** and/or output an instruction to patient **4** or a caregiver via user interface **86** to deploy one or more biochemical sensors and/or one or more bacterial sensors.

[0083] Data exchanged between external device **12** and IMD **10** may include operational parameters. External device **12** may transmit data including computer readable instructions which, when implemented by IMD **10**, may control IMD **10** to change one or more operational parameters (such as to deploy one or more of sensors **44**) and/or export collected data. For example, processing circuitry **80** may transmit an instruction to IMD **10** which requests IMD **10** to export collected data (e.g., data corresponding to one or more of optical sensor signals, an accelerometer signal, or other collected data) to external device **12**. In turn, external device **12** may receive the collected data from IMD **10** and store the collected data in storage device **84**. Additionally, or alternatively, processing circuitry **80** may export instructions to IMD **10** requesting IMD **10** to update one or more operational parameters of IMD **10**.

[0084] A user, such as a clinician, patient **4**, or a caregiver, may interact with external device **12** through user interface **86**. User interface **86** includes a display (not shown), such as an LCD or LED display or other type of screen, with which processing circuitry **80** may present information related to IMD **10** (e.g., sensed physiological, biochemical parameters, and/or bacterial parameters). In addition, user interface **86** may include an input mechanism to receive input from the user. The input mechanisms may include, for example, any one or more of buttons, a keypad (e.g., an alphanumeric keypad), a peripheral pointing device, a touch screen, or another input mechanism that allows the user to navigate through user interfaces presented by processing circuitry **80** of external device **12** and provide input. In other examples, user interface **86** also includes audio circuitry for providing audible notifications, instructions or other sounds to patient **4**, receiving voice commands from patient **4**, or both. Storage device **84** may include instructions for operating user interface **86** and for managing power source **88**.

[0085] Power source **88** is configured to deliver operating power to the components of external device **12**. Power source **88** may include a battery and a power generation circuit to produce the operating power. In some examples, the battery is rechargeable to allow extended operation. Recharging may be accomplished by electrically coupling power source **88** to a cradle or plug that is connected to an alternating current (AC) outlet. In addition, recharging may be accomplished through proximal inductive interaction between an external charger and an inductive charging coil within external device **12**. In other examples, traditional batteries (e.g., nickel cadmium or lithium ion batteries) may be used. In addition, external device **12** may be directly coupled to an alternating current outlet to operate.

[0086] FIG. **6** is a conceptual diagram illustrating an example sensor system which may be deployed by a patient or caregiver according to the techniques of this disclosure. Sensor system **100** may include sensor **102** and communication circuitry **104**. In some examples, sensor system **100** may include other components, such as processing circuitry, memory configured to store the sensed signals, additional sensors, or the like. Sensor system **100** may be configured to be injected into patient **4** via a hypodermic needle, a pen device similar to an epi-pen, or any other device configured to deliver sensor system **100** into a body of patient **4**. Sensor system **100** may be generally shaped and sized like a grain of rice. For example, sensor system **100** may be 0.5 mm wide and between 3 mm and 5 mm long.

[0087] In some examples, sensor **102** may be a biochemical sensor configured to sense one or more

biochemical parameters of patient **4**. In some examples, sensor **102** may be a bacterial sensor configured to sense one or more bacterial parameters of patient **4**. Communication circuitry **104** may be configured to transmit the sensed one or more biochemical parameters or the sensed one or more bacterial parameters of patient **4** to IMD **10** and/or external device **12**.

[0088] FIG. **7** is a conceptual diagram illustrating another example sensor system which may be deployed by a patient or caregiver according to the techniques of this disclosure. Sensor system **108** may include sensor **110**, wire **114**, and external device **112**. In some examples, external device may be an example of external device **12**. Sensor **110** may be a biochemical sensor or bacterial sensor configured to sense one or more biochemical or one or more bacterial parameters of patient **4**. Sensor **110** may be communicatively coupled to external device **112** via wire **114** (which may be a pintail) which may remain at least partially external to patient when sensor **110** is inserted into patient **4**. Sensor **110** may be similarly sized or smaller than sensor system **100** of FIG. **6**. Sensor **110** may be configured to be injected into patient **4** via a hypodermic needle, a pen device similar to an epi-pen, or any other device configured to deliver sensor **110** into a body of patient **4**. Sensor signals may travel from sensor **110** over wire **114** to external device **112**.

[0089] FIG. **8** is a block diagram illustrating an example system that includes an access point **90**, a network **92**, external computing devices, such as a server **94**, and one or more other computing devices **100**A-**100**N, which may be coupled to IMD **10**, external device **12**, and processing circuitry **14** via network **92**, in accordance with one or more techniques described herein. In this example, IMD **10** may use communication circuitry **54** to communicate with external device **12** via a first wireless connection, and to communication with an access point **90** via a second wireless connection. In the example of FIG. **8**, access point **90**, external device **12**, server **94**, and computing devices **100**A-**100**N are interconnected and may communicate with each other through network **92**.

[0090] Access point **90** may include a device that connects to network **92** via any of a variety of connections, such as telephone dial-up, digital subscriber line (DSL), fiber optic, or cable modem connections. In other examples, access point **90** may be coupled to network **92** through different forms of connections, including wired or wireless connections. In some examples, access point **90** may be a user device, such as a tablet or smartphone, that may be co-located with the patient. As discussed above, IMD **10** may be configured to transmit data, such an indication that a heart failure decompensation event is impending, biochemical sensor or bacterial sensor signals, optical sensor signals, an accelerometer signal, or other data collected by IMD **10** to external device **12**. In addition, access point **90** may interrogate IMD **10**, such as periodically or in response to a command from the patient or network **92**, in order to retrieve parameter values determined by processing circuitry **50** of IMD **10**, or other operational or patient data from IMD **10**. Access point **90** may then communicate the retrieved data to server **94** via network **92**.

[0091] In some cases, server **94** may be configured to provide a secure storage site for data that has been collected from IMD **10**, and/or external device **12**, such as physiological parameters and/or biochemical parameters of patient **4**. In some cases, server **94** may assemble data in web pages or other documents for viewing by trained professionals, such as clinicians, via computing devices **100**A-**100**N. One or more aspects of the illustrated system of FIG. **8** may be implemented with general network technology and functionality, which may be similar to that provided by the Medtronic CareLink® Network developed by Medtronic, Inc.

[0092] Server **94** may include processing circuitry **96**. Processing circuitry **96** may include fixed function circuitry and/or programmable processing circuitry. Processing circuitry **96** may include any one or more of a microprocessor, a controller, a DSP, an ASIC, an FPGA, or equivalent discrete or analog logic circuitry. In some examples, processing circuitry **96** may include multiple components, such as any combination of one or more microprocessors, one or more controllers, one or more DSPs, one or more ASICs, or one or more FPGAs, as well as other discrete or integrated logic circuitry. The functions attributed to processing circuitry **96** herein may be embodied as software, firmware, hardware or any combination thereof. In some examples,

processing circuitry **96** may perform one or more techniques described herein, e.g., application of a machine learning model to patient parameter data to determine when IMD **10** should activate sensor(s) **44** and/or to determine a risk level of a heart failure event.

[0093] Server **94** may include memory **98**. Memory **98** includes computer-readable instructions that, when executed by processing circuitry **96**, cause IMD **10** and processing circuitry **96** to perform various functions attributed to IMD **10** and processing circuitry **96** herein. Memory **98** may include any volatile, non-volatile, magnetic, optical, or electrical media, such as RAM, ROM, NVRAM, EEPROM, flash memory, or any other digital media. Memory **98** may store a machine learning model.

[0094] In some examples, one or more of computing devices **100**A-**100**N (e.g., device **100**A) may be a tablet or other smart device located with a clinician, by which the clinician may program, receive alerts from, and/or interrogate IMD **10**. For example, the clinician may access data corresponding to physiological parameters, biochemical parameters, and/or bacterial parameters of patient **4** determined by IMD **10**, external device **12**, processing circuitry **14**, or server **94** through device **100**A, such as when patient **4** is in between clinician visits, to check on a status of a medical condition, such as heart failure. In some examples, the clinician may enter instructions for a medical intervention for patient **4** into an app in device **100**A, such as based on a status of a patient condition determined by IMD **10**, external device **12**, processing circuitry **14**, or any combination thereof, or based on other patient data known to the clinician. Device **100**A then may transmit the instructions for medical intervention to another of computing devices **100**A-**100**N (e.g., device **100**B) located with patient **4** or a caregiver of patient **4**. For example, such instructions for medical intervention may include an instruction to change a drug dosage, timing, or selection, to schedule a visit with the clinician, or to seek medical attention. In further examples, device **100**B may generate an indication for output, such as an alert to patient **4** based on a status of a medical condition of patient **4** determined by IMD **10**, which may enable patient **4** proactively to seek medical attention prior to receiving instructions for a medical intervention. In this manner, patient **4** may be empowered to take action, as needed, to address his or her medical status, which may help improve clinical outcomes for patient **4**.

[0095] FIG. **9** is a flow diagram illustrating an example of biochemical sensor or bacterial sensor deployment techniques according to one or more aspects of this disclosure. The example of FIG. **9** is discussed with respect to IMD **10** of FIG. **3**, but these techniques may be implemented in any combination of devices of system **2** (FIG. **1**) or of FIG. **8**.

[0096] Processing circuitry **50** may receive first sensor data (**200**). For example, medical device system **2** may include one or more sensors (e.g., sensing circuitry **52** and/or sensors **62**) configured to generate the first sensor data. Processing circuitry **50** may receive sensor data from sensing circuitry **52** and/or sensors **62**. The first sensor data may include physiological parameters such as impedance (e.g., OptiVol™ fluid index), patient activity, tachycardia/fibrillation burden, ventricular rate during tachycardia/fibrillation, percentage of ventricular pacing, shocks, treated ventricular tachycardia/ventricular fibrillation, night ventricular rate, heart rate variability, and/or other physiological parameters.

[0097] Processing circuitry **50** may determine, based on the first sensor data, a likelihood that a heart failure decompensation event of patient **4** is impending (**202**). For example, processing circuitry **50** may execute an algorithm that is configured to calculate a likelihood that a heart failure decompensation event of patient **4** is impending based on the first sensor data.

[0098] Processing circuitry **50** may compare the likelihood to a first threshold (**204**). For example, processing circuitry may retrieve the first threshold from thresholds **47** and compare the likelihood to the first threshold. Based on the likelihood satisfying the first threshold, processing circuitry **50** may at least one of a) generating a first instruction for output to a user to deploy at least one of one or more biochemical sensors or one or more bacterial sensors, or b) control IMD **10** to deploy at least one of one or more biochemical or one or more bacterial sensors (**206**). For example,

processing circuitry **50** may generate a first instruction for output to patient **4** or a caregiver of patient **4** to deploy one or more biochemical sensors, one or more bacterial sensors, or both one or more biochemical sensors and one or more bacterial sensors. Such an instruction may be output to external device **12** for review by a user, such as patient **4** or a caregiver of patient **4**. In some examples, the instruction may be displayed on external device **12**. Alternatively, or additionally, processing circuitry **50** may control IMD **10** to deploy one or more biochemical sensors, one or more bacterial sensors, or both one or more biochemical sensors and one or more bacterial sensors.

[0099] In some examples, processing circuitry **50** may receive at least one of biochemical sensor data from the one or more biochemical sensors or bacterial sensor data from the one or more bacterial sensors and update the likelihood that a heart failure decompensation event is impending based on at least one of the biochemical sensor data or the bacterial sensor data. In some examples, processing circuitry **50** may compare the updated likelihood to a second threshold and generate, based on the updated likelihood that the heart failure decompensation event is impending meeting the second threshold, a first indication for output to a user (e.g., a clinician, patient **4**, or a caregiver of patient **4**). In some examples, the first indication includes at least one of an indication to seek medical attention, an indication of the updated likelihood that the heart failure decompensation event is impending, or a proposed treatment of the patient. In some examples, processing circuitry **50** may output the first indication to the user. For example, processing circuitry **50** may control communication circuitry **54** to transmit the first indication to external device **12** for review by patient **4**, a caregiver of patient **4**, or a clinician. External device **12** may, for example, display the first indication on user interface **86** (FIG. **5**).

[0100] In some examples, IMD **10** includes an insertable cardiac monitor. In some examples, the one or more biochemical sensors or the one or more bacterial sensors are disposed on IMD **10**. In some examples, IMD **10** includes one or more boluses of anti-biotic medication disposed on IMD **10** and processing circuitry **50** determines that the bacterial sensor data indicates a bacterial infection and controls IMD **10** to release at least one of the one or more boluses of anti-biotic medication based on the determination that the bacterial sensor data indicates the bacterial infection.

[0101] In some examples, at least one of the one or more biochemical sensors or at least one of the one or more bacterial sensors are insertable into the patient by the patient or a caregiver. In some examples, processing circuitry **50** may at least one of generate a second instruction for output to a user to deploy one or more biochemical or bacterial sensors according to a schedule, or control IMD **10** to deploy one or more biochemical or bacterial sensors according to the schedule. In some examples, the schedule is at least one of: predetermined; programmed by a clinician; based on a change in pattern of at least one of sensed biochemical parameters, bacterial parameters, or physiological parameters over time; or determined by the processing circuitry executing a machine learning model.

[0102] In some examples, processing circuitry **50** may receive at least one of biochemical sensor data from the one or more biochemical sensors or bacterial sensor data from the one or more bacterial sensors and generate a second indication for output to a clinician, the second indication comprising at least one of the biochemical sensor data or the bacterial sensor data.

[0103] In some examples, processing circuitry **50** may generate a score based on at least one of the first sensor data, the biochemical sensor data, or the bacterial sensor data and output the score to a clinician. For example, processing circuitry **50** may control communication circuitry **54** to output the score to external device **12**. External device **12** may, for example, display the score on user interface **86** (FIG. **5**). In some examples, processing circuitry **50** may compare the score to a previous score and determine that the score is different than the previous score. In some examples, processing circuitry **50** may output a third indication to the clinician, the third indication including at least one or information relating to the change in the score from the previous score, a source of the change in the score from the previous score, or suggested treatment options.

[0104] In some examples, the first sensor data comprises a plurality of sensed physiological parameters and to determine the likelihood that a heart failure decompensation event of a patient is impending, processing circuitry **50** compares each of the plurality of sensed physiological parameters to parameter specific thresholds and applies a Bayesian probabilistic model to results of the comparisons. In some examples, the plurality of sensed physiological parameters comprise at least two of a fluid index, patient activity, atrial tachycardia (AT)/atrial fibrillation (AF) burden, ventricular rate during AT/AF, percentage of ventricular pacing, shocks, treated ventricular tachycardia/ventricular fibrillation, night ventricular rate, heart rate variability, heart sounds, or lung sounds,

[0105] FIG. **10** is a conceptual diagram illustrating an example machine learning model **300** configured to determine one or more output values based on patient parameter data as described herein. Machine learning model **300** may correspond to machine learning models **46** and **79**. Machine learning model **300** is an example of a deep learning model, or deep learning algorithm, trained to determine whether a particular set of patient parameter data indicates a condition of the patient meriting a system communication as described herein. One or more of IMD **10**, external device **12**, or server **94** may train, store, and/or utilize machine learning model **300**, but other devices may apply inputs associated with a particular patient to machine learning model **300** in other examples. Some non-limiting examples of machine learning techniques include Bayesian probability models, Support Vector Machines, K-Nearest Neighbor algorithms, and Multi-layer Perceptron.

[0106] As shown in the example of FIG. **10**, machine learning model **300** may include three layers. These three layers include input layer **302**, hidden layer **304**, and output layer **306**. Output layer **306** comprises the output from the transfer function **305** of output layer **306**. Input layer **302** represents each of the input values X1 through X4 provided to machine learning model **300**. The number of inputs may be less than or greater than 4, including much greater than 4, e.g., hundreds or thousands. In some examples, the input values may any of the of values input into a machine learning model, as described above. In some examples, input values may include parameter values described herein, e.g., impedance or fluid index, night heart rate, heart rate variability, and arrhythmia metrics. In addition, in some examples input values of machine learning model **300** may include additional data, such as analyte or bacteria values.

[0107] Each of the input values for each node in the input layer **302** is provided to each node of hidden layer **304**. In the example of FIG. **10**, hidden layers **304** include two layers, one layer having four nodes and the other layer having three nodes, but fewer or greater number of nodes may be used in other examples. Each input from input layer **302** is multiplied by a weight and then summed at each node of hidden layers **304**. During training of machine learning model **300**, the weights for each input are adjusted to establish the relationship between the inputs determining whether a particular set of inputs represents a health event and/or determining a score indicative of whether a set of inputs may be representative of a health event, e.g., a risk level of heart failure decompensation. In some examples, one hidden layer may be incorporated into machine learning model **300**, or three or more hidden layers may be incorporated into machine learning model **300**, where each layer includes the same or different number of nodes.

[0108] The result of each node within hidden layers **304** is applied to the transfer function of output layer **306**. The transfer function may be liner or non-linear, depending on the number of layers within machine learning model **300**. Example non-linear transfer functions may be a sigmoid function or a rectifier function. The output **307** of the transfer function may be or a score indicative of a risk level (e.g., likelihood or probability) of heart failure decompensation. By applying the patient parameter data to a machine learning model, such as machine learning model **300**, processing circuitry of system **2** is able to determine a patient is experiencing or will soon experience a health event, such as heart failure decompensation, with great accuracy, specificity, and sensitivity. This may facilitate activation of sensors, alerts, or other actions as described herein.

[0109] FIG. **11** is an example of a machine learning model **300** being trained using supervised and/or reinforcement learning techniques. Machine learning model **300** may be implemented using any number of models for supervised and/or reinforcement learning, such as but not limited to, an artificial neural network, a decision tree, naïve Bayes network, support vector machine, or k-nearest neighbor model, to name only a few of the examples discussed above. In some examples, processing circuitry one or more of IMD **10**, external device **12**, and/or server **94** initially trains the machine learning model **300** based on training set data **400** including numerous instances of input data corresponding to health events, such as heart failure decompensation, and non-health events, e.g., as labeled by an expert. A prediction or classification by the machine learning model **300** may be compared **404** to the target output **403**, e.g., as determined based on the label. Based on an error signal representing the comparison, the processing circuitry implementing a learning/training function **405** may send or apply a modification to weights of machine learning model **300** or otherwise modify/update the machine learning model **300**. For example, one or more of IMD **10**, external device **12**, and/or server **94** may, for each training instance in the training set **400**, modify machine learning model **300** to change a score generated by the machine learning model **300** in response to data applied to the machine learning model **300**.

[0110] The techniques described in this disclosure may be implemented, at least in part, in hardware, software, firmware, or any combination thereof. For example, various aspects of the techniques may be implemented within one or more microprocessors, DSPs, ASICS, FPGAs, or any other equivalent integrated or discrete logic QRS circuitry, as well as any combinations of such components, embodied in external devices, such as clinician or patient programmers, stimulators, or other devices. The terms "processor" and "processing circuitry" may generally refer to any of the foregoing logic circuitry, alone or in combination with other logic circuitry, or any other equivalent circuitry, and alone or in combination with other digital or analog circuitry.

[0111] For aspects implemented in software, at least some of the functionality ascribed to the systems and devices described in this disclosure may be embodied as instructions on a computer-readable storage medium such as RAM, FRAM, DRAM, SRAM, magnetic discs, optical discs, flash memories, or forms of EPROM or EEPROM. The instructions may be executed to support one or more aspects of the functionality described in this disclosure.

[0112] In addition, in some aspects, the functionality described herein may be provided within dedicated hardware and/or software modules. Depiction of different features as modules or units is intended to highlight different functional aspects and does not necessarily imply that such modules or units must be realized by separate hardware or software components. Rather, functionality associated with one or more modules or units may be performed by separate hardware or software components, or integrated within common or separate hardware or software components. Also, the techniques could be fully implemented in one or more circuits or logic elements. The techniques of this disclosure may be implemented in a wide variety of devices or apparatuses, including an IMD, an external programmer, a combination of an IMD and external programmer, an integrated circuit (IC) or a set of ICs, and/or discrete electrical circuitry, residing in an IMD and/or external programmer.

[0113] This disclosure includes the following non-limiting examples.

[0114] Example 1. A medical device system comprising: memory configured to store first sensor data; and processing circuitry communicatively coupled to the memory, the processing circuitry being configured to: receive the first sensor data; determine, based on the first sensor data, a likelihood that a heart failure decompensation event of a patient is impending; compare the likelihood to a first threshold; and based on the likelihood satisfying the first threshold, at least one of a) generate a first instruction for output to a user to deploy at least one of one or more biochemical sensors or one or more bacterial sensors, or b) control an implantable medical device to automatically deploy at least one of one or more biochemical sensors or one or more bacterial sensors.

[0115] Example 2. The medical device system of example 1, wherein the processing circuitry is further configured to output the first instruction to the user.

[0116] Example 3. The medical device system of example 1 or 2, wherein the processing circuitry is further configured to: receive at least one of biochemical sensor data from the one or more biochemical sensors or bacterial sensor data from the one or more bacterial sensors; and update the likelihood that a heart failure decompensation event is impending based on at least one of the biochemical sensor data or the bacterial sensor data.

[0117] Example 4. The medical device system of example 3, wherein the processing circuitry is further configured to: compare the updated likelihood to a second threshold; and based on the updated likelihood meeting the second threshold, generate a first indication for output to a user.

[0118] Example 5. The medical device system of example 4, wherein the first indication comprises at least one of: an indication to seek medical attention; an indication of the updated likelihood that the heart failure decompensation event is impending; or a proposed treatment of the patient.

[0119] Example 6. The medical device system of example 4 or 5, wherein the processing circuitry is further configured to output the first indication to the user.

[0120] Example 7. The medical device system of any of examples 1-6, wherein the medical device system comprises an insertable cardiac monitor.

[0121] Example 8. The medical device system of any of examples 1-7, wherein the one or more biochemical sensors or the one or more bacterial sensors are disposed on the implantable medical device.

[0122] Example 9. The medical device system of **8**, further comprising one or more boluses of antibiotic medication disposed on the implantable medical device, wherein the one or more bacterial sensors are configured to generate bacterial sensor data, and wherein the processing circuitry is further configured to: determine that the bacterial sensor data indicates a bacterial infection; and control the implantable medical device to release at least one of the one or more boluses of antibiotic medication based on the determination that the bacterial sensor data indicates the bacterial infection.

[0123] Example 10. The medical device system of any of examples 1-9, wherein at least one of the one or more biochemical sensors or at least one of the one or more bacterial sensors are insertable into the patient by the patient or a caregiver.

[0124] Example 11. The medical device system of any of examples 1-10, further comprising one or more first sensors, the one or more first sensors being configured to generate the first sensor data.

[0125] Example 12. The medical device system of any of examples 1-11, wherein the first sensor data comprises physiological parameters.

[0126] Example 13. The medical device system of any of examples 1-12, wherein the processing circuitry is further configured to at least one of: generate a second instruction for output to a user to deploy one or more biochemical or bacterial sensors according to a schedule, or control the implantable medical device to deploy one or more biochemical or bacterial sensors according to the schedule.

[0127] Example 14. The medical device system of example 13, wherein the schedule is at least one of: predetermined; programmed by a clinician; based on a change in pattern of at least one of sensed biochemical parameters, bacterial parameters, or physiological parameters over time; or determined by the processing circuitry executing a machine learning model.

[0128] Example 15. The medical device system of example 13 or example 14, wherein the processing circuitry is further configured to: receive at least one of biochemical sensor data from the one or more biochemical sensors or bacterial sensor data from the one or more bacterial sensors; and generate a second indication for output to a clinician, the second indication comprising at least one of the biochemical sensor data or the bacterial sensor data.

[0129] Example 16. The medical device system of any of examples 1-15, wherein the processing circuitry is further configured to: generate a score based on at least one of the first sensor data, the

biochemical sensor data, or the bacterial sensor data; and output the score to a clinician.

[0130] Example 17. The medical device system of example 16, wherein the processing circuitry is further configured to: compare the score to a previous score; determine that the score is different than the previous score; and output a third indication for review by the clinician, the third indication comprising at least one or information relating to the change in the score from the previous score, a source of the change in the score from the previous score, or suggested treatment options.

[0131] Example 18. The medical device of any of examples 1-17, wherein the first sensor data comprises a plurality of sensed physiological parameters and wherein as part of determining the likelihood that a heart failure decompensation event of a patient is impending, the processing circuitry is configured to: compare each of the plurality of sensed physiological parameters to parameter specific thresholds; and apply a Bayesian probabilistic model to results of the comparisons.

[0132] Example 19. The medical device of example 18, wherein the plurality of sensed physiological parameters comprise at least two of a fluid index, patient activity, atrial tachycardia (AT)/atrial fibrillation (AF) burden, ventricular rate during AT/AF, percentage of ventricular pacing, shocks, treated ventricular tachycardia/ventricular fibrillation, night ventricular rate, heart rate variability, heart sounds, or lung sounds.

[0133] Example 20. A method comprising: receiving, by processing circuitry, first sensor data; determining, by the processing circuitry and based on the first sensor data, a likelihood that a heart failure decompensation event of a patient is impending; comparing, by the processing circuitry, the likelihood to a first threshold; and based on the likelihood satisfying the first threshold, at least one of a) generating, by the processing circuitry, a first instruction for output to a user to deploy at least one of one or more biochemical sensors or one or more bacterial sensors, or b) controlling an implantable medical device, by the processing circuitry, to deploy at least one of one or more biochemical sensors or one or more bacterial sensors.

[0134] Example 21. The method of example 20, further comprising outputting the first instruction to the user.

[0135] Example 22. The method of example 20 or 21, further comprising: receiving, by the processing circuitry, at least one of biochemical sensor data from the one or more biochemical sensors or bacterial sensor data from the one or more bacterial sensors; and updating, by the processing circuitry, the likelihood that a heart failure decompensation event is impending based on at least one of the biochemical sensor data or the bacterial sensor data.

[0136] Example 23. The method of example 22, further comprising: comparing, by the processing circuitry, the updated likelihood to a second threshold; and generating, by the processing circuitry and based on the updated likelihood meeting the second threshold, a first indication for output to a user.

[0137] Example 24. The method of example 23, wherein the first indication comprises at least one of: an indication to seek medical attention; an indication of the updated likelihood that the heart failure decompensation event is impending; or a proposed treatment of the patient.

[0138] Example 25. The method of example 23 or 24, further comprising outputting the first indication to the user.

[0139] Example 26. The method of any of examples 20-25, wherein the implantable medical device comprises an insertable cardiac monitor.

[0140] Example 27. The method of any of examples 20-26, wherein the one or more biochemical sensors or the one or more bacterial sensors are disposed on the implantable medical device.

[0141] Example 28. The method of 27, wherein the implantable medical device comprises one or more boluses of anti-biotic medication disposed on the implantable medical device and the one or more bacterial sensors are configured to generate bacterial sensor data, the method further comprising: determining, by the processing circuitry, that the bacterial sensor data indicates a

bacterial infection; and controlling, by the processing circuitry, the implantable medical device to release at least one of the one or more boluses of anti-biotic medication based on the determination that the bacterial sensor data indicates the bacterial infection.

[0142] Example 29. The method of any of examples 20-28, wherein at least one of the one or more biochemical sensors or at least one of the one or more bacterial sensors are insertable into the patient by the patient or a caregiver.

[0143] Example 30. The method of any of examples 20-29, wherein the first sensor data comprises physiological parameters.

[0144] Example 31. The method of any of examples 20-30, further comprising at least one of: generating, by the processing circuitry, a second instruction for output to a user to deploy one or more biochemical or bacterial sensors according to a schedule; or controlling, by the processing circuitry, the implantable medical device to deploy one or more biochemical or bacterial sensors according to the schedule.

[0145] Example 32. The method of example 30, wherein the schedule is at least one of: predetermined; programmed by a clinician; based on a change in pattern of at least one of sensed biochemical parameters, bacterial parameters, or physiological parameters over time; or determined by the processing circuitry executing a machine learning model.

[0146] Example 33. The method of example 31 or example 32, further comprising: receiving, by the processing circuitry, at least one of biochemical sensor data from the one or more biochemical sensors or bacterial sensor data from the one or more bacterial sensors; and generating, by the processing circuitry, a second indication for output to a clinician, the second indication comprising at least one of the biochemical sensor data or the bacterial sensor data.

[0147] Example 34. The method of any of examples 20-33, further comprising: generating, by the processing circuitry, a score based on at least one of the first sensor data, the biochemical sensor data, or the bacterial sensor data; and outputting, by the processing circuitry, the score to a clinician.

[0148] Example 35. The method of example 34, further comprising: comparing the score to a previous score; determining that the score is different than the previous score; and outputting a third indication for review by the clinician, the third indication comprising at least one or information relating to the change in the score from the previous score, a source of the change in the score from the previous score, or suggested treatment options.

[0149] Example 36. The method of any of examples 20-35, wherein the first sensor data comprises a plurality of sensed physiological parameters and wherein determining the likelihood that a heart failure decompensation event of a patient is impending comprises:

[0150] comparing each of the plurality of sensed physiological parameters to parameter specific thresholds; and applying a Bayesian probabilistic model to results of the comparisons.

[0151] Example 37. The method of example 36, wherein the plurality of sensed physiological parameters comprise at least two of a fluid index, patient activity, atrial tachycardia (AT)/atrial fibrillation (AF) burden, ventricular rate during AT/AF, percentage of ventricular pacing, shocks, treated ventricular tachycardia/ventricular fibrillation, night ventricular rate, heart rate variability, heart sounds, or lung sounds.

[0152] Example 38. A non-transitory computer-readable storage medium storing instructions, which when executed, cause processing circuitry to: receive first sensor data; determine, based on the first sensor data, a likelihood that a heart failure decompensation event of a patient is impending; compare the likelihood to a first threshold; and based on the likelihood satisfying the first threshold, at least one of a) generate a first instruction for output to a user to deploy at least one of one or more biochemical sensors or one or more bacterial sensors, or b) control an implantable medical device to automatically deploy at least one of one or more biochemical sensors or one or more bacterial sensors.

[0153] Various examples have been described. These and other examples are within the scope of the following claims.

Claims

1. A medical device system comprising: an implantable medical device configured to sense one or more physiological signals and determine first sensor data based on the one or more physiological signals; and processing circuitry configured to: receive the first sensor data; determine, based on the first sensor data, a likelihood that a heart failure decompensation event of a patient is impending; compare the likelihood to a first threshold; and based on the likelihood satisfying the first threshold, at least one of a) generate a first instruction for output to a user to deploy at least one of one or more biochemical sensors or one or more bacterial sensors, or b) control the implantable medical device or another implantable medical device to automatically deploy at least one of one or more biochemical sensors or one or more bacterial sensors.

2. The medical device system of claim 1, wherein the processing circuitry is further configured to output the first instruction to the user.

3. The medical device system of claim 1, wherein the processing circuitry is further configured to: receive at least one of biochemical sensor data from the one or more biochemical sensors or bacterial sensor data from the one or more bacterial sensors; and update the likelihood that a heart failure decompensation event is impending based on at least one of the biochemical sensor data or the bacterial sensor data.

4. The medical device system of claim 3, wherein the processing circuitry is further configured to: compare the updated likelihood to a second threshold; and based on the updated likelihood meeting the second threshold, generate a first indication for output to a user.

5. The medical device system of claim 4, wherein the first indication comprises at least one of: an indication to seek medical attention; an indication of the updated likelihood that the heart failure decompensation event is impending; or a proposed treatment of the patient.

6. The medical device system of claim 4 or 5, wherein the processing circuitry is further configured to output the first indication to the user.

7. The medical device system of claim 1, wherein the implantable medical device comprises an insertable cardiac monitor.

8. The medical device system of claim 7, wherein the insertable cardiac monitor comprises: a housing configured for subcutaneous implantation in a patient, the housing having a length between 40 millimeters (mm) and 60 mm between a first end and a second end, a width less than the length, and a depth less than the width; a first electrode at or proximate to the first end; and a second electrode at or proximate to the second end, wherein the insertable cardiac monitor is configured to sense at least one of the one or more physiological signals via the first electrode and the second electrode.

9. The medical device system of claim 1, further comprising one or more boluses of anti-biotic medication disposed on the implantable medical device, wherein the one or more bacterial sensors are configured to generate bacterial sensor data, and wherein the processing circuitry is further configured to: determine that the bacterial sensor data indicates a bacterial infection; and control the implantable medical device to release at least one of the one or more boluses of anti-biotic medication based on the determination that the bacterial sensor data indicates the bacterial infection.

10. The medical device system of claim 1, wherein at least one of the one or more biochemical sensors or at least one of the one or more bacterial sensors are insertable into the patient by the patient or a caregiver.

11. The medical device system of claim 1, wherein the processing circuitry is further configured to at least one of: generate a second instruction for output to a user to deploy one or more biochemical

or bacterial sensors according to a schedule, or control the implantable medical device to deploy one or more biochemical or bacterial sensors according to the schedule.

12. The medical device system of claim 11, wherein the schedule is at least one of: predetermined; programmed by a clinician; based on a change in pattern of at least one of sensed biochemical parameters, bacterial parameters, or physiological parameters over time; or determined by the processing circuitry executing a machine learning model.

13. The medical device system of claim 11, wherein the processing circuitry is further configured to: receive at least one of biochemical sensor data from the one or more biochemical sensors or bacterial sensor data from the one or more bacterial sensors; and generate a second indication for output to a clinician, the second indication comprising at least one of the biochemical sensor data or the bacterial sensor data.

14. The medical device system of claim 1, wherein the processing circuitry is further configured to: generate a score based on at least one of first sensor data, biochemical sensor data, or bacterial sensor data; and output the score to a clinician.

15. The medical device system of claim 14, wherein the processing circuitry is further configured to: compare the score to a previous score; determine that the score is different than the previous score; and output a third indication for review by the clinician, the third indication comprising at least one of information relating to a change in the score from the previous score, a source of the change in the score from the previous score, or suggested treatment options.

16. The medical device of claim 1, wherein the first sensor data comprises a plurality of sensed physiological parameters and wherein as part of determining the likelihood that a heart failure decompensation event of a patient is impending, the processing circuitry is configured to: compare each of the plurality of sensed physiological parameters to parameter specific thresholds; and apply a Bayesian probabilistic model to results of the comparisons.

17. The medical device of claim 16, wherein the plurality of sensed physiological parameters comprise at least two of a fluid index, patient activity, atrial tachycardia (AT)/atrial fibrillation (AF) burden, ventricular rate during AT/AF, percentage of ventricular pacing, shocks, treated ventricular tachycardia/ventricular fibrillation, night ventricular rate, heart rate variability, heart sounds, or lung sounds.

18. A method comprising: receiving, by processing circuitry, first sensor data; determining, by the processing circuitry and based on the first sensor data, a likelihood that a heart failure decompensation event of a patient is impending; comparing, by the processing circuitry, the likelihood to a first threshold; and based on the likelihood satisfying the first threshold, at least one of a) generating, by the processing circuitry, a first instruction for output to a user to deploy at least one of one or more biochemical sensors or one or more bacterial sensors, or b) controlling an implantable medical device, by the processing circuitry, to deploy at least one of one or more biochemical sensors or one or more bacterial sensors.

19. The method of claim 18, further comprising outputting, by the processing circuitry, the first instruction to the user.

20. Non-transitory computer-readable storage media storing instructions, which when executed, cause processing circuitry to: receive first sensor data; determine, based on the first sensor data, a likelihood that a heart failure decompensation event of a patient is impending; compare the likelihood to a first threshold; and based on the likelihood satisfying the first threshold, at least one of a) generate a first instruction for output to a user to deploy at least one of one or more biochemical sensors or one or more bacterial sensors, or b) control an implantable medical device to automatically deploy at least one of one or more biochemical sensors or one or more bacterial sensors.