

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
8 July 2004 (08.07.2004)

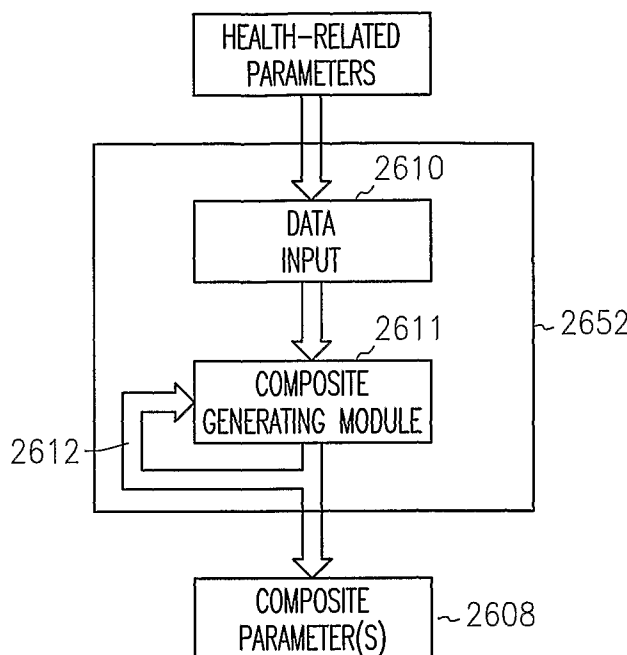
PCT

(10) International Publication Number
WO 2004/056266 A1

- (51) International Patent Classification⁷: A61B 5/00, 5/0205, G06F 17/00
- (74) Agents: STEFFEY, Charles, E. et al.; Schwegman, Lundberg, Woessner & Kluth, P.A., P.O. Box 2938, Minneapolis, MN 55402 (US).
- (21) International Application Number: PCT/US2003/040662
- (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.
- (22) International Filing Date: 16 December 2003 (16.12.2003)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data: 10/323,860 18 December 2002 (18.12.2002) US
- (84) Designated States (*regional*): ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- (71) Applicant: CARDIAC PACEMAKERS, INC. [US/US]; 4100 Hamline Avenue North, St. Paul, MN 55112 (US).
- (72) Inventors: HATLESTAD, John; 11117 Zebulon Pike Avenue, Burnsville, MN 55337 (US). STAHMANN, Jeffrey, E.; 4850 154th Lane NW, Ramsey, MN 55303 (US). ZHU, Qingsheng; 3025 Valento Lane, Little Canada, MN 55117 (US).
- Published:
— with international search report
— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

[Continued on next page]

(54) Title: ADVANCED PATIENT MANAGEMENT WITH COMPOSITE PARAMETER INDICES



(57) Abstract: Devices and methods for defining, identifying and utilizing composite parameter indices from health-related parameters are disclosed, wherein a first set of at least two health-related parameters is acquired and a first composite parameter is generated using the first set of at least two health-related parameters. One aspect is a programmable device having machine executable instructions for performing a method to assist with managing a patient's health. Other aspects and embodiments are provided herein.

WO 2004/056266 A1



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

ADVANCED PATIENT MANAGEMENT WITH COMPOSITE PARAMETER INDICES

Technical Field

5 This application relates generally to medical devices and, more particularly, to advanced patient management that defines, identifies and utilizes composite parameter indices.

Background

10 An Implantable Medical Device (IMD) is a medical device designed to be chronically implanted in a human or other organism. Some IMDs include sensors to monitor a patient's condition, and some IMDs have been used to treat a patient. Some examples of IMDs include implantable cardiac rhythm management (CRM) devices such as cardiac pacemakers and implantable cardioverter / defibrillators (ICDs). Other examples of IMDs include a number
15 of monitors or sensors, stimulators and delivery systems for both cardiac-related applications and non-cardiac-related applications.

 The sensed data from the IMD is capable of being wirelessly communicated to an external device, and the external device is capable of wirelessly programming the IMD. For example, data from an implantable CRM
20 is capable of being wirelessly communicated to a programmer device. Additionally, the programmer is capable of wirelessly communicating with the implantable CRM to program the CRM to perform a desired device function.

 Due to the potentially large amount of data capable of being sensed by one or more IMDs, it is desired to appropriately process the large amount of
25 sensed data to provide meaningful information. The sensed data alone may not be an accurate indication of the overall health of the patient because other factors can significantly influence the sensed data. Thus, it has been proposed to use patient data from other sources. However, this patient data can compound the problem of providing meaningful data, and still may not provide an accurate
30 indication of the overall health of the patient.

Summary

The above mentioned problems are addressed by the present subject matter and will be understood by reading and studying the following specification. The present subject matter provides for defining, identifying and
5 utilizing composite parameter indices generated from health-related parameters acquired from a variety of sources, including data provided by an implanted medical device (IMD) and from other sources.

One aspect is a programmable device having machine executable instructions for performing a method to assist with managing a patient's health.
10 In various embodiments, a first set of at least two health-related parameters is acquired. A first composite parameter is generated using the first set of at least two health-related parameters.

These and other aspects, embodiments, advantages, and features will become apparent from the following description and the referenced drawings.

15 Brief Description of the Drawings

Figure 1 illustrates an advanced patient management (APM) system according to various embodiments of the present subject matter.

Figure 2 illustrates an advanced patient management (APM) system according to various embodiments of the present subject matter.

20 Figure 3 illustrates an advanced patient management (APM) system having direct communication links according to various embodiments of the present subject matter.

Figure 4 illustrates an advanced patient management (APM) system having network communication links according to various embodiments of the
25 present subject matter.

Figure 5 illustrates an advanced patient management (APM) system having network communication links according to various embodiments of the present subject matter.

Figure 6 illustrates a perspective view of an advanced patient
30 management (APM) system that includes an IMD and a portable device such as a PDA.

Figure 7 illustrates a perspective view of an advanced patient management (APM) system that includes an IMD, a portable device such as a PDA, and another wellness monitoring device, such as a programmer for the IMD, networked to the PDA.

5 Figure 8 illustrates a perspective view of an advanced patient management (APM) system that includes an IMD, a portable device such as a PDA, and another wellness monitoring device, such as a programmer for the IMD, directly connected to the PDA.

10 Figure 9 illustrates a block diagram of an IMD according to various embodiments of the present subject matter.

Figure 10 illustrates a block diagram of a wellness monitoring device, such as a portable device, according to various embodiments of the present subject matter.

15 Figure 11 illustrates various embodiments of a wellness monitoring device (WMD) in the form of a general-purpose computing device.

Figure 12 illustrates a block diagram of an advanced patient management system for acquiring, trending and displaying multiple health-related parameters according to various embodiments of the present subject matter.

20 Figure 13 illustrates a block diagram of a wellness trending display generally illustrating parameter trends available for display according to various embodiments of the present subject matter.

Figure 14 illustrates a block diagram of a wellness trending display illustrating an arrangement for selecting and displaying parameter trends according to various embodiments of the present subject matter.

25 Figure 15 illustrates an example of a wellness trending display.

Figure 16 illustrates a block diagram according to various aspects of the present subject matter in which a diagnostic context is provided to assist with interpreting the health condition of the patient, and to appropriately adjust the device and/or medical therapy, accordingly.

Figure 17 illustrates a method for managing a patient's health by defining, detecting and using predetermined health-related events, according to various embodiments of the present subject matter.

Figure 18 illustrates a device (such as a WMD or IMD) for monitoring a patient's health condition that is capable of detecting predetermined health-related events, according to various embodiments of the present subject matter.

Figure 19 illustrates a wellness monitoring device (WMD) for monitoring a patient's health condition that is capable of detecting predetermined health-related events, according to various embodiments of the present subject matter.

Figure 20 illustrates a method for reporting multiple parameters related to a health condition of a patient, according to various embodiments of the present subject matter.

Figure 21 illustrates a device (such as a WMD or IMD) for monitoring a patient's health condition that is capable of prioritizing communication of health-related parameters, according to various embodiments of the present subject matter.

Figure 22 illustrates a device (such as a WMD or IMD) for monitoring a patient's health condition that is capable of synthesizing environmental parameters with IMD parameters, according to various embodiments of the present subject matter.

Figure 23 illustrates a device (such as a WMD or IMD) for monitoring a patient's health condition that is capable of correlating trended parameters, predetermined events, and alerts, according to various embodiments of the present subject matter.

Figure 24 illustrates a method to generate composite parameters for use in managing a patient's health, according to various embodiments of the present subject matter.

Figure 25 illustrates a method to generate composite parameters for use in managing a patient's health, according to various embodiments of the present subject matter.

Figure 26 illustrates a device (such as a WMD or IMD) for monitoring a patient's health condition that is capable of generating composite parameters, according to various embodiments of the present invention.

Figure 27 illustrates a method to triage predetermined events for use in
5 managing a patient's health, according to various embodiments of the present subject matter.

Figure 28 illustrates a device (such as a WMD or IMD) for monitoring a patient's health condition that is capable of classifying a number of predetermined events according to severity, and performing a system action
10 based on the classification, according to various embodiments of the present subject matter.

Detailed Description of the Invention

The following detailed description refers to the accompanying drawings which show, by way of illustration, specific aspects and embodiments in which
15 the present subject matter may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice the present subject matter. Other embodiments may be utilized and structural, logical, and electrical changes may be made without departing from the scope of the present subject matter. The various embodiments disclosed herein are not necessarily mutually
20 exclusive, as some disclosed embodiments can be combined with one or more other disclosed embodiments to form new embodiments. The following detailed description is, therefore, not to be taken in a limiting sense, and the scope of the present subject matter is defined only by the appended claims, along with the full scope of equivalents to which such claims are entitled.

25 The present subject matter provides a system to assist with monitoring the overall health of patients, and thus to assess and treat health conditions, by acquiring, trending and displaying a number of health-related parameters. In various embodiments, a clinician such as a physician monitors the patient's health. In various embodiments, the system includes an implantable medical
30 device (IMD) which is capable of sensing various health-related parameters (also referred to herein as internal health-related parameters) indicative of a health

condition. The IMD includes one or more IMD sensors to sense one or more desired internal health-related parameters. In various embodiments, the IMD is capable of providing therapy to treat the health condition. In various
5 other health-related parameters (also referred to herein as external health-related parameters). The external health-related parameters can influence the sensed internal health-related parameters. Thus, a combination of internal and external health-related parameters can provide a more accurate view of the patient's health.

10 In various embodiments, the system includes a user input to collect health-related information that is contributed voluntarily by a user (such as a patient, clinician or other user). This user-volunteered information is an example of external human-resource parameters and is able to be more subjective in nature (compared to the internal health-related parameters determined by sensors
15 or other external health-related parameters such as databases and external sensors), and thus is useful to identify other information that can influence the other health-related parameters. The present subject matter acquires internal and/or external health-related parameters from one or more of these sources, and generates composite parameter indices to assist with accurately assessing and
20 treating a patient's health condition. As such, the present subject matter is capable of providing a diagnostic context used to interpret the health condition of the patient, and to appropriately adjust the device and/or medical therapy, accordingly.

A large number of health-related parameters are capable of being
25 acquired, trended and displayed according to various embodiments of the present subject matter. For example, a non-exhaustive list of health-related parameters includes heart rate / rhythm including ventricular tachycardia and fibrillation, conduction intervals, ectopic density, atrial fibrillation (AF) / atrial tachycardia (AT) percent, heart rate variability (HRV), activity, lead position, concomitant
30 conditions, temperature, blood pressure, respiration rate / rhythm, pulmonary / peripheral edema, posture, blood gases, stroke volume contractility, filling time,

heart sounds, weight, ischemia, cardiac output, after load, medications, device indications, and electromyogram. Other examples of health-related parameters are provided throughout this disclosure.

These health-related parameters are capable of being acquired from a number of data sources. For example, a non-exhaustive list of data sources include IMDs, external device sensors, medication usage monitors, databases, and user inputs by a clinician and/or patient. An IMD, for example, is capable of providing health-related parameters for rhythms, conduction delays, respiration, activity, heart sounds, posture, and the like. External device measurements, for example, are capable of providing health-related parameters for weight, blood pressure, echo pulse oximetry, peripheral edema, and the like. Other examples of IMD health-related parameters and external health-related parameters are provided throughout this disclosure. A physician, for example, is capable of providing health-related parameters for lead positions, indications(s), medications, concomitant conditions, and the like. A medical database, for example, is capable of providing health-related parameters from external device measurements and physician input for medical tests and a large number and a large variety of other parameters. A patient, for example, is capable of providing health-related parameters for diet, medication usage, symptoms, blood pressure, and the like. As technology continues to improve, more and more health-related parameters will be automatically acquired using, for example, an IMD rather than using an external interactive system.

In various embodiments of the present subject matter, the APM system performs various methods related to managing a patient's health. The APM system includes a number of programmable devices with a machine-readable medium having machine-executable instructions. The programmable device(s) perform the machine-executable instructions to perform the method. In various embodiments, the programmable device includes a processor to perform the machine-executable instructions. In various embodiments, the machine-executable instructions are provided on one or more machine-readable mediums (or media).

Figure 1 illustrates an advanced patient management system according to various embodiments of the present subject matter. Various embodiments of the system 100 include less than all of the components shown in Figure 1, and various embodiments of the system 100 include other components than those
5 shown in Figure 1.

A patient 101 is illustrated with an implantable medical device (IMD) 102. Generally, the IMD includes one or more IMDs that provide internal therapy and/or acquire or sense internal data parameters. In various embodiments, the IMD is a CRM device that provides cardiac rhythm
10 management pulsing and also senses one or more physiological parameters of a heart. Other IMDs that sense parameters and/or provide therapy, including various electrical and drug therapy, are within the scope of the present subject matter.

In various embodiments, at least one IMD 102 provides internal data
15 such as heart rhythm, breathing, and activity. Other types of data derived from IMDs are also contemplated. For example, in one embodiment, a respiration sensor is implanted into patient and communicates with portable device. Data received from such IMDs may be perceived as involuntary, or passive, data since the patient has no control over the process of collecting and transmitting the data
20 from such sources. In various embodiments, IMD-provided data includes parameters sensed by the IMD and/or parameters provided by interrogating the IMD to obtain device performance status.

The illustrated system also includes one or more external data source(s) 103 that provide health-related parameters. The external health-related
25 parameters supplement the internal parameters and/or provide a diagnostic context to the internal health-related parameters. Examples of external source(s) of health data include: external sensing devices such as body temperature thermometers, blood pressure monitors, and the like; room temperature thermometers, light sensors and the like; databases such as patient history
30 databases that are found hospitals or clinics and that may include information such as medical test results and family history; a web server database (a database

accessible through a global communication network -- e.g. Internet) that may include information regarding environment, medication interaction, and the like; databases and/or user inputs regarding mental/emotional and diet parameter types; and other external data sources capable of providing health-related

5 parameters. One definition of the term mental is something that is of or relates to the mind. One definition of the term emotional is a strong feeling, aroused mental state, or intense state of drive or unrest, which may be directed toward a definite object and is evidenced in both behavior and in psychologic changes, with accompanying autonomic nervous system manifestations.

10 The illustrated system also includes a user input 104 through which a user is able to input additional health-related parameters for use by a wellness monitoring device (WMD) 105. In various embodiments, the user input 104 includes a touch screen on a PDA or other device, a keyboard and mouse on a computer, and the like. In various embodiments, a patient is able to input

15 additional health-related parameters for use by the wellness monitoring device. In various embodiments, a clinician is able to input additional health-related parameters for use by the WMD.

The WMD 105 is illustrated by dotted line, and includes one or more devices. In various embodiments, the at least one IMD 102 communicates

20 wirelessly with at least one WMD 105, as shown by communication link 106. In various embodiments that include multiple WMDs, the WMDs are able to communicate with each other, as shown via communication link 107. In various embodiments, the WMD(s) includes portable devices 108 that are external to the body of patient such as a PDA, (variously referred to as a personal digital, or

25 data, assistant), a portable telephone (including a cellular telephone or a cordless telephone), a pager (one way or two way), a handheld, palm-top, laptop, portable or notebook computer, or other such battery operated portable communication device. In various embodiments, the WMD(s) includes programmers. In various embodiments, the WMD(s) includes various non-portable devices such as larger

30 computers or computer enterprise systems.

In various embodiments of the present subject matter, the WMD 105 (which includes one or more devices) includes a display on which parameter trends are capable of being displayed. In various embodiments, the portable device 108 includes a touch-sensitive display screen for displaying information to a user or patient. Depending on the application executing on the portable device 108, the display screen may provide prompts, messages, questions, or other data designed to elicit an input from patient. Examples of such prompts are provided in the patent application entitled "Method and Apparatus for Establishing Context Among Events and Optimizing Implanted Medical Device Performance," Ser. No. 10/093,353, filed on March 6, 2002. Data received from such interactive prompts may be perceived as voluntary, or active, data since the cooperation and active input of the patient is part of the data collection process. In various embodiments, the user input data may be received from a user based on a prompt provided to the user, on an *ad hoc* basis as determined by the user, or as determined by a processor. The user may enter data using a menu based system, a graphical user interface (GUI), textual data or numerical data.

The WMD provides analysis of internal and external (both voluntary and involuntary) parameters. In various embodiments, the WMD includes computer and programming that conducts data analysis suitable for use in managing patient health and medical care.

Figure 2 illustrates an advanced patient management (APM) system according to various embodiments of the present subject matter. Various embodiments of the system 200 include all of the components shown in Figure 2, various embodiments of the system 200 include less than all of the components shown in Figure 2, and various embodiments of the system 200 include other components than those shown in Figure 2.

In the figure, the system 200 is shown to include an IMD 202. In various embodiments, the IMD includes an implantable cardiac device (ICD), cardiac rhythm management (CRM) device, pulse generator, or other implanted medical device that provides therapy to a patient or an organ of a patient, and/or that

provides data derived from measurements internal to a patient. In various embodiments, the IMD includes a device to provide drug therapy.

The illustrated system 200 includes at least one WMD 205 that includes at least one display for displaying trended parameters. In the illustrated system, the at least one WMD includes a portable device 208 (such as a PDA) and a programmer 209. The IMD 202 is shown coupled to the portable device 208 by communication link 210. The portable device is further coupled to the programmer by communication link 207. Various embodiments of the present subject matter do not include the portable device 208. In these embodiments, the IMD 202 is able to be coupled directly to the programmer 209 by a communication link (not shown).

At least one external data source 203 (such as web server(s), database(s), and sensor(s)) is coupled to the WMD(s) via at least one communication link. The external data source 203 provides external (with respect to the IMD in the patient) health-related parameters that supplement and/or provide context for the IMD parameters. In the illustrated system, a communication link 211 exists between the portable device 208 and the external data source 203, and a communication link 212 exists between the programmer 209 and the external data source 203. It is noted that various applications may not require both communication links 211 and 212. In the illustration, the system 200 includes at least one user input 204 to the at least one WMD 205. For example, a patient is able to provide health-care information using the portable device 208, and a health care provider is capable of providing health-care information using the programmer 209.

In various embodiments, the IMD also includes circuitry and programming adapted to monitor the condition and performance of the pulse generator or other IMD. For example, in various embodiments, the IMD provides data concerning the remaining battery condition for a power supply coupled to the IMD. Such data may include information regarding remaining battery capacity or life, battery internal resistance or other measurable parameters. In various embodiments, the data includes information regarding the

electrical therapy provided by the IMD. For example, in various embodiments, such data includes lead impedance, sense voltage levels, therapy history, and device therapy mode settings and parameter values. In various embodiments, the IMD provides data regarding dosage, timing and other functions regarding the delivery of a drug therapy or other therapy. For example, in various
5 embodiments, the IMD monitors blood sugar levels and the amount and timing of insulin delivered to the patient.

In various embodiments, the IMD includes a program executing on an internal processor that controls the operation of the IMD. The program
10 instructions reside in a memory accessible to the internal processor. By changing the program, or memory contents, the present system allows the operating program of the IMD to be dynamically tailored to a particular patient or condition. In various embodiments, the operating system, or memory contents of the IMD is changed using wireless communication.

15 In various embodiments, the IMD includes a wireless transceiver. The transceiver operates using radio frequency transmissions, electromagnetic transmissions, magnetic coupling, inductive coupling, optical coupling, or other means of communicating without need of a wire connection between the IMD and another transceiver.

20 In various embodiments, the IMD performs a data acquisition function. In various embodiments, the IMD is adapted to monitor a fluid pressure, such as blood or urine. In various embodiments, the detector is adapted to monitor respiration, stress level, or other measurable biometric parameter. In various embodiment, monitoring includes determining an absolute or relative value for a
25 particular biometric parameter. In various embodiments, internal memory within the IMD stores a comparison value which may then be compared with a measured value thereby determining the performance of the IMD or the health of the patient.

In various embodiments, the communication link includes a wireless
30 communication link between the IMD and portable device. The communication link allows communication in one or two directions.

In various embodiments, data from the IMD is communicated to portable device with no data transmitted from portable device to the IMD. In this manner, portable device functions as a data storage facility for the IMD. In various embodiments, data stored in portable device is accessed by a treating physician and used for diagnosis, therapy or other purposes. Programming and controlling the operation of the IMD is performed using a programmer adapted to transmit commands, data or code to the IMD. In various embodiments, portable device executes programming to analyze and process the data received from the IMD. In various embodiments, communication link precludes transfer of data from portable device to the IMD or precludes transfer of data from the IMD to portable device. For example, it may be desirable in certain circumstances to prevent the portable device from executing programming to automatically adjust the performance or operation of the IMD independent of a programmer.

In various embodiments, data is communicated from portable device to the IMD with no data transmitted from the IMD to portable device. In this manner, portable device functions as an interface to communicate commands, data or code to the IMD. In various embodiments, data is communicated from the IMD to the portable or external device with no data transferred from the device to the IMD.

In various embodiments, data is communicated bidirectionally between the IMD and the portable device. In various embodiments, the communication link between the IMD and the portable device entails a single bidirectional communication channel or includes multiple unidirectional communication channels which, when viewed as a whole, provide bidirectional communication. In various embodiments, a unidirectional communication channel operates using a particular frequency or communication protocol. For example, the link may include a wireless radio frequency link compatible with a transmitter and receiver that uses frequency hopping, spread spectrum technology.

In various embodiments, internal memory within the IMD provides storage for data related to the IMD-provided therapy (such as CRM therapy

provided to a heart). For example, the data can relate to the electrical, chemical or mechanical operation of the heart. In addition, the IMD includes memory for programming, comparison and other functions. In various embodiments, the contents of the memory regulates the operation of the IMD.

5 In various embodiments, the portable device 208 includes or otherwise is incorporated or in communication with a battery operated portable communicator having a processor, memory, and an output interface to communicate with a user and an input interface to receive user entered data. One suitable example of a portable communicator is that of a personal digital
10 assistant (PDA). PDA devices typically include a display screen for presenting visual information to a user and a writing surface for entry of data using a stylus. Data can be entered using a keyboard coupled to the portable communicator or by means of a wired or wireless communication link. Some portable
15 communicator models also include an audio transducer, or sound generator, adapted to produce sounds that are audible by a user. In various embodiment, data from the IMD or the programmer is displayed on a display or screen of the portable device.

 In various embodiments, the portable device 208 includes or otherwise is incorporated or in communication with a portable telephone (such as a cellular
20 telephone or a cordless telephone), a pager (one way or two way), or a computer (such as a handheld, palm-top, laptop, or notebook computer) or other such battery operated, processor based, portable communication device.

 In various embodiments, the portable device 208 includes data storage and includes programming and instructions to conduct data processing. In
25 various embodiments, the data storage capacity of the portable device 208 augments the data storage capacity of the IMD 202, thus enabling a clinician to access a greater amount of multi-related information regarding the medical condition of a user. For example, but not by way of limitation, the additional information may assist in discovering and understanding relationships among
30 different events.

In various embodiments, a wireless receiver is coupled to a portable device for purposes of receiving data from the IMD 202 through communication link 210. In various embodiments, a wireless transmitter is coupled to the portable device for purposes of transmitting data to the IMD. In various
5 embodiments, a wireless transceiver is coupled to the portable device for purposes of both transmitting data to, and receiving data from, the IMD. In various embodiments, the portable device includes telemetry to facilitate wireless communications.

In various embodiments, circuitry or programming allows the portable
10 device 208 to trigger an alarm under predetermined conditions. In various embodiments, for example, the portable device sounds an audible alarm or transmits an alarm signal if a biometric parameter exceeds a particular value or is outside a specified range of values. The alarm signal can be received by the programmer 209 or a designated physician.

15 Communication link 207 couples the portable device 208 with the programmer 209. In various embodiments, communication link 207 includes a wired or wireless link that allows data communication between portable device and the programmer. In various embodiments, data is exchanged between portable device and the programmer by means of a removable storage media.

20 In various embodiments, the programmer 209 includes a processor based apparatus that executes programming to communicate with the IMD 202, the portable device 208, or both. A clinician (e.g. physician) can operate the programmer to communicate with the IMD using 202 portable device as a data interface. In particular, various embodiments provide that data from the IMD
25 202 can be retrieved by accessing the memory of portable device 208. In various embodiments, the programmer 209 transmits data to the IMD 202 via the portable device 208.

In various embodiments, at least one of the WMDs includes a display. Figure 2 illustrates a system in which the portable device 208 includes a display
30 and the programmer 209 includes a display. According to various embodiments of the present subject matter, health-related parameters are displayed on the

display(s) of the wellness monitoring device(s). In various embodiments, these health-related parameters are acquired via an IMD and/or via an external source such as user input and/or external health data sources such as databases and the like. According to various embodiments of the present subject matter, trended
5 health-related parameters, predetermined events, alerts and/or other information provided in this disclosure are displayed on the wellness monitoring device(s).

Figure 3 illustrates an advanced patient management (APM) system having direct communication links according to various embodiments of the present subject matter. According to various embodiments of the system 300,
10 the communication links include wired links, wireless links or both wired and wireless links. Various embodiments include all of the components shown in Figure 3, various embodiments include less than all of the components shown in Figure 3, and various embodiments include other components than those shown in Figure 3.

15 The illustrated system 300 includes at least one IMD 302, at least one external source of health data 303, and at least one WMD 305 with a display 313. The illustrated system includes a user input 304 to communicate with the WMD. The illustrated system includes a communication link 314 between the IMD(s) 302 and the external source(s) of health-related data 303, a
20 communication link 315 between the external source(s) of health-related data 303 and the WMD(s) 305, and a communication link 316 between the IMD(s) 302 and the WMD(s) 305. It is noted that various embodiments include less than all of the communication links. For example, in various embodiments data from the external source(s) of health data is not communicated to IMD(s) through link
25 314, and in various embodiments data from the external source(s) of health data is communicated to the wellness monitor device(s) through the IMD(s) and links 314 and 316. Various embodiments implement various communication designs to achieve various data flow.

In various embodiments, the display 313 of the WMD(s) is used to
30 display trended parameters, such as internal parameters from the IMD(s) and external parameters for the external source(s) of health-related data. Other

information can be displayed, as is provided throughout the disclosure.

Furthermore, a user is able to input additional external health-related information via user input. In various embodiments, the WMD(s) include a portable device such as a PDA, laptop computer, cell phone, and the like. In various
5 embodiments, the WMD(s) include other external devices such as bedside monitors, desktop computers, IMD programmers, and the like.

Figure 4 illustrates an advanced patient management (APM) system having network communication links according to various embodiments of the present subject matter. According to various embodiments, the communication
10 links include wired links, wireless links or both wired and wireless links.

Various embodiments include all of the components shown in Figure 4, various embodiments include less than all of the components shown in Figure 4, and various embodiments include other components than those shown in Figure 4.

The illustrated system 400 includes at least one IMD 402, at least one
15 external source of health data 403, at least one WMD 405 with a display 413, and at least one network infrastructure through which the other devices (also referred to within this discussion as network devices) are capable of communicating. The illustrated system includes a user input 404 to communicate with the WMD 405. In various embodiments, the WMD(s)
20 includes a portable device such as a PDA, laptop computer, cell phone, and the like. In various embodiments, the wellness monitor device(s) include other external devices such as bedside monitors, desktop computers, IMD programmers, and the like. Examples of a network communication link includes, but is not limited to, one or more of the following: cellular telephone
25 coupled to a portable device via the Internet, a private area branch exchange (PABX, also known as a PBX); an intranet network; an ethernet connection or other remote communication means.

The illustrated system includes a communication link between the
IMD(s) 402 and the external source(s) of health-related data 403 via the network
30 417, a communication link between the external source(s) of health-related data 403 and the WMD(s) 405 via the network 417, and a communication link

between the IMD(s) and the WMD(s) 405 via the network 417. The illustrated system includes a network interface or adapter 418. The network adapter 418 wirelessly communicates with the IMD 402 via communication link 419, and communicates with network devices through network via communication link
5 420. Although not expressly, other network devices include a network interface.

Various embodiments include a direction communication link as illustrated in Figure 3 and a network communication link as illustrated in Figure 4. The display of the WMD(s) is used to display trended parameters, such as internal health-related parameters from the IMD(s) and external health-related
10 parameters for the external source(s) of health-related data. Furthermore, a user is able to input additional external health-related information via user input.

Figure 5 illustrates an advanced patient management (APM) system having network communication links according to various embodiments of the present subject matter. Various embodiments include all of the components
15 shown in Figure 5, various embodiments include less than all of the components shown in Figure 5, and various embodiments include other components than those shown in Figure 5.

The illustrated system 500 includes at least one IMD 502, at least one external source of health data 503, at least one WMD 505 with a display 513,
20 and at least one network infrastructure 517 through which the other devices (also referred to within this discussion as network devices) are capable of communicating. The illustrated system 500 also includes direct communication connections 521 between the IMD(s) 502 and the external source(s) of the health data 503, and between the WMD(s) 505 and the IMDS(s) 502. One of ordinary
25 skill in the art will understand, upon reading and comprehending this disclosure, that various embodiments include some direct communication connections between some components and include some network communication connections between some components.

The illustrated external source(s) of health data 503 include at least one
30 external sensing device 522 such as a body temperature or blood pressure monitor, at least one patient history database 523, at least one web server 524,

and other external sources 525. Various embodiments of the present subject matter include one or more of the illustrated external sources of health data. The illustrated WMD(s) includes a programmer 509 with a display, a portable device 508 (such as a PDA or laptop computer) with a display, or other WMD(s) 526
5 with a display. Various embodiments of the present subject matter include one or more of the illustrated WMDs.

Figure 6 illustrates a perspective view of an advanced patient management (APM) system that includes an IMD 602 and a portable device 608 such as a PDA. The illustrated portable device 608 includes a display screen
10 627, a plurality of user operable buttons 628, and an expansion port 629 which receives and is coupled to an expansion device 630 that is designed to communicate with the IMD 602. In various embodiments, a specially designed portable device is employed with an integrated communication subsystem. A stylus 631 can be used to manually enter data using screen. Link 606 is
15 illustrated as a bidirectional link and thus, data from IMD 602 is wirelessly telemetered to the portable device 608 through the expansion device 630. In addition, data, or programming from the portable device 608 is wirelessly telemetered from the expansion device 630 to the IMD 602.

According to various embodiments, the portable device (such as the
20 illustrated PDA) generates a prompt at various times calling for a response in the form of a user input. A user may enter data using any of a variety of means. For example, a response may be entered using stylus , buttons, or an external keyboard. In one embodiment, portable device responds to voice commands received from a user. A prompt may be visually displayed using screen or
25 audibly generated using an internal sound generator. Manually entered data received from a user, as well as data received from other inputs is stored using the portable device. The data stored in the portable device is available for processing, and to tailor the therapy.

In addition to data entry, the portable device 608 provides a user with
30 limited control over the operation of an IMD 602 in various embodiments. In

various embodiments, reasonable constraints on the authority to change the operation of IMD are established and implemented by a clinician.

Figure 7 illustrates a perspective view of an advanced patient management (APM) system that includes an IMD 702, a portable device 708
5 such as a PDA, and another WMD 732, such as a programmer for the IMD, networked to the PDA. The illustrated portable device includes a wireless communication antenna 733. In various embodiments, the portable device 708 is adapted for wireless access to Internet network using link 734. In various
10 embodiments, link 734 includes a radio frequency communication link. The programmer accesses the Internet via link 735. In various embodiments, 735 link includes a dial-up modem connection, a cable modem connection, a DSL connection, an ISDN line, or other channel providing access to the Internet.

A user is able to compile contextual information regarding IMD 702, as well as himself, using the portable device 708. In various embodiments, a
15 clinician using the programmer 732 is able to remotely access the data stored in the portable device 708 using link 735, Internet and link 734. In this manner, programmer 732 is able to wirelessly receive the data, process the data, and transmit data and code to change the future operation of the IMD 702.

Figure 8 illustrates a perspective view of an advanced patient
20 management (APM) system that includes an IMD 802, a portable device such as a PDA 808, and another WMD 832, such as a programmer for the IMD, directly connected to the PDA. The PDA is coupled to IMD by wireless link 836, and is further coupled to programmer by link 837 (illustrated as a communication
cable).

25 A clinician operating programmer 832 is able to exchange data or code with the PDA 808 using link 837. Connector is a multi-conductor connector providing access to data of the PDA. It will be appreciated that link may couple the PDA to a local area network or other communication network. For example, the PDA may be connected to a public switched telephone network (PSTN) link,
30 and thus, programmer may exchange data with portable communicator using a modem coupled to PSTN.

Figure 9 illustrates a block diagram of an IMD according to various embodiments of the present subject matter. The illustrated IMD 902 includes a processor 938, memory 939, an update module 940 and a transceiver 941. In operation, the processor governs the operation of IMD and executes programming stored in memory. In addition to the executable program, memory also includes data storage regarding the patient and IMD. The update module operates in conjunction with processor, memory and transceiver to receive, install, and execute new instructions for execution by processor.

Figure 10 illustrates a block diagram of a WMD, such as a portable device, a programmer and the like, according to various embodiments of the present subject matter. The illustrated WMD 1005 includes long term data storage 1042, an input/output 1043, a controller 1044, an IMD transceiver 1045, a communication interface 1046 and a display 1047. The long term data storage augments the data storage capacity of the memory of the IMD. In various embodiments, the storage is of a greater capacity than that of memory, is physically larger in size, and is less expensive and more robust than medical grade implantable memory.

The input/output, the IMD transceiver and the communication interface, in conjunction with the controller enables receipt and transmission of data from the IMD as well as data from other sources such as other WMDs, databases and the like. The IMD transceiver provides a wireless communication link between the IMD and the portable device. The display is used to, among other things, display parameters that have been acquired and trended by the system according to the present subject matter.

Figure 11 provides a brief, general description of a suitable computing environment in which the above embodiments may be implemented. The illustrated computing environment, or portions thereof, can be implemented in a WMD. Additionally, portions of the illustrated computing environment (such as the system memory and processor) can be implemented in IMDs.

Embodiments of the present subject matter can be described in the general context of computer-executable program modules containing instructions

executed by a computing device. The term module includes hardware, firmware, software, and various combinations thereof to perform task(s) described in this disclosure, as is understood by one of ordinary skill in the art upon reading and comprehending this disclosure. Program modules include routines, programs, 5 objects, components, data structures, etc. that perform particular tasks or implement particular abstract data types. Those skilled in the art will appreciate that the invention may be practiced with other computer-system configurations, including hand-held devices, multiprocessor systems, microprocessor-based programmable consumer electronics, network PCs, minicomputers, mainframe 10 computers, and the like which have multimedia capabilities. The invention may also be practiced in distributed computing environments where tasks are performed by remote processing devices linked through a communications network. In a distributed computing environment, program modules may be located in both local and remote memory storage devices.

15 Figure 11 illustrates various embodiments of a WMD in the form of a general-purpose computing device. One of ordinary skill in the art will understand, upon reading and comprehending this disclosure, how to implement the present subject matter using other WMDs and IMDs with some of the illustrated components or other components.

20 The illustrated computing device 1148 includes a processing unit 1149, a system memory 1150, and a system bus 1151 that couples the system memory and other system components to processing unit. The system bus may be any of several types, including a memory bus or memory controller, a peripheral bus, and a local bus, and may use any of a variety of bus structures. The system 25 memory includes read-only memory (ROM) and random-access memory (RAM). A basic input/output system (BIOS), stored in ROM, contains the basic routines that transfer information between components of personal computer. BIOS also contains start-up routines for the system. Various embodiments of the computing device further include a hard disk drive for reading from and writing 30 to a hard disk (not shown), a magnetic disk drive for reading from and writing to a removable magnetic disk, and an optical disk drive for reading from and

writing to a removable optical disk such as a CD-ROM or other optical medium. Hard disk drive, magnetic disk drive, and optical disk drive are connected to system bus by a hard-disk drive interface, a magnetic-disk drive interface, and an optical-drive interface, respectively. The drives and their associated computer-readable media provide nonvolatile storage of computer-readable instructions, data structures, program modules and other data for the computing device. Those skilled in the art will appreciate that other types of computer-readable media which can store data accessible by a computer may also be used.

Program modules can be stored on the hard disk, magnetic disk, optical disk, ROM and RAM. Program modules may include operating system, one or more application programs, other program modules, and program data. A user may enter commands and information into personal computer through input devices such as a keyboard and a pointing device. These and other input devices are often connected to the processing unit through a serial-port interface coupled to system bus; but they may be connected through other interfaces not shown in Figure 11, such as a parallel port or a universal serial bus (USB). A monitor or other display device also connects to system bus via an interface such as a video adapter. In addition to the monitor, personal computers typically include other peripheral output devices (not shown) such as speakers and printers. In one embodiment, one or more speakers or other audio output transducers are driven by sound adapter connected to system bus.

In various embodiments the computing device operates in a networked environment using logical connections to one or more remote devices such as remote computer. Examples of remote computers include a personal computer (PC), a server, a router, a network PC, a peer device, or other common network node. In various embodiments, the remote computer includes many or all of the components described above in connection with the computing device; however, only a storage device is illustrated in Figure 11 to simplify the disclosure. The logical connections depicted in Figure 11 include local-area network (LAN) and a wide-area network (WAN). Such networking environments exist in offices,

enterprise-wide computer networks, intranets and the Internet. The computing device connects to local network through a network interface or adapter in various embodiments, and to a WAN / Internet network through a modem or other means for establishing communications over network.

5 Various embodiments of the present subject matter are illustrated in Figures 12 - 27 and are discussed below. One of ordinary skill in the art will understand, upon reading and comprehending this disclosure, that these embodiments are not necessarily mutually exclusive as various embodiment can be combined or otherwise modified to create other embodiments. One of
10 ordinary skill in the art also will understand, upon reading and comprehending this disclosure, that various elements shown and described with respect to one or more of Figures 1 - 11 are capable of being combined with various elements shown and described with respect to one or more of Figures 12 - 27.

Acquisition, Trending and Displaying Health-Related Parameters

15 Figures 12 - 16 illustrate various embodiments of the present subject matter related to acquiring, trending and displaying health-related parameters. In various embodiments, an IMD acquires, trends and displays a variety of parameters pertinent to the health status of a patient.

Figure 12 illustrates a block diagram of a device for acquiring, trending
20 and displaying multiple health-related parameters according to various embodiments of the present subject matter. The device 1252 acquires available parameters from available sources. In various embodiments, the device 1252 includes a WMD such as a portable device, a programmer and the like. In various embodiments, the device 1252 includes an IMD. For example,
25 potentially available sources include an IMD parameter collection 1253 (internal health-related parameters such as internal physiological measurements, applied therapy, device performance, and the like), an external parameter collection 1254 (external parameters such as external physiological and environmental measurements, databases, and the like), and a user input parameter collection
30 1255 (voluntary data). User inputs can be considered to be an external health-related parameter. However, for purposes of the description with respect to

Figure 12, external parameter collection and user input parameter collection are considered separately.

In various embodiments, the IMD parameter collection 1253 includes at least one of a physical parameter type, a physiological / pathological parameter type, a mental / emotional parameter type, a diet parameter type, an environmental parameter type, a symptom parameter type, and a medical compliance type. In various embodiments, the IMD is gathers information from an external device or sensor in order to gather certain parameter types. Furthermore, the IMD is capable of acquiring medication compliance by monitoring a measurable parameter correlated to compliance. For example, blood pressure is monitored to verify that a patient is compliant with hypertensive medications. The IMD is also capable of acquiring environmental data, such as barometric pressure using an implanted pressure sensor and such as relative temperature changes using an implanted temperature sensor near the surface of the skin.

One definition of mental is of or relating to the mind. One definition of emotional is relating to or marked by an emotion (a strong feeling, aroused mental state, or intense state of drive or unrest, which may be directed toward a definite object and is evidenced in both behavior and in psychologic changes, with accompanying autonomic nervous system manifestations). One definition of physiological is normal, as opposed to pathologic. One definition of pathological is diseased. Other definitions can be used consistently with respect to these terms.

In various embodiments, the external parameter collection 1254 includes one or more of a mental / emotional parameter type, an environmental parameter type and a diet parameter type. In various embodiments, the external parameter collection 1254 includes a physical parameter type, a physiological / pathological parameter type, a symptom parameter type, and / or a medication compliance parameter type. The external parameter collection can include any one or any combination of the above parameter types according to embodiments of the present subject matter.

In various embodiments, the user input parameter collection 1255 includes one or more of a mental / emotional parameter type, an environmental parameter type and a diet parameter type. In various embodiments, the user input parameter collection 1255 includes a physical parameter type, a
5 physiological / pathological parameter type, a symptom parameter type, and / or a medication compliance parameter type. The user input parameter collection can include any one or any combination of the above parameter types according to embodiments of the present subject matter.

Examples of a physical parameter type include, but are not limited to,
10 parameters related to activity, posture, and sleep. Examples of a mental / emotional parameter type include, but are not limited to, parameters related to stress, excitement, anger, anxiety (such as may be detected via sighing), and depression. Examples of physiological / pathological parameter types include, but are not limited to, parameters related to blood pressure, respiration rate and
15 patterns, and medical test results. Examples of environmental parameter types include, but are not limited to, parameters related to altitude, temperature, air quality, pollen count, and humidity. Examples of diet parameter types include, but are not limited to, parameters related to sodium intake, fluid intake and lipid intake. Examples of symptom parameter types include, but are not limited to,
20 parameters related to pain, dyspnea and fatigue. In various embodiments, a symptom can be considered to be, for example, a patient -perceived condition based on frequency, severity and/or repetition. Examples of medication compliance parameter types include, but are not limited to, parameters related to drug administration such as drug type, dosage and time. Examples of drug type
25 includes insulin, beta-blockers, diuretics and the like.

Health-related parameters are acquired from various sources. In various embodiments, a number of parameters are acquired from IMD, and from external sources such as external parameter collections (programmer, web servers, patient databases, external sensors, etc.) and user input parameter collections (answered
30 questions, etc.). The parameter trends are displayed in a single display area of at least one of the WMDs.

In various embodiments, available parameters are acquired at module 1256. The acquired parameters are processed according to a procedure implemented in software. In various embodiments, the software automatically acquires those health-related parameters deemed to be useful based on a potential health condition. In various embodiments, the software instructions provide a procedure, when operated on by a processor, which automatically determines a potential health condition, and thus additional parameters to be acquired, from previously acquired parameters. Thus, the present subject matter is capable of automatically and intelligently acquiring additional parameters to confirm and/or dismiss an initial diagnosis.

In various embodiments, module 1257 includes software instructions that, when operated on by a processor, provide a procedure that automatically trends the acquired parameters. The trending procedure analyzes the parameters as a function of time or other measured parameter. In various embodiments, module 1258 allows a user to select parameter trends to be displayed in a single display area. Module 1259 is used to display representations in a single display area. In various embodiments in which device 1252 includes a WMD, module 1259 displays the representation on a display of the WMD. In various embodiments in which device 1259 includes an IMD, module 1259 transmits a signal for reception by a display device to display the representation on the display device.

In various embodiments, the acquired data and trends are analyzed to select an updated program or specify updated operational parameters for the IMD. The updated program or operational parameters are capable of being transferred and implemented by IMD.

Figure 13 illustrates a block diagram of a wellness trending display generally illustrating parameter trends available for display according to various embodiments of the present subject matter. In various embodiments of the display 1360, trends associated with at least one of a physical parameter type 1361, a physiological / pathological parameter type 1362, a mental / emotional parameter type 1363, an environmental parameter type 1364, a diet parameter

type 1365, a symptom parameter type 1366 and a medication compliance parameter type 1367 (and various combinations of a physical parameter type, a physiological / pathological parameter type, a mental / emotional parameter type, an environmental parameter type, a diet parameter type, a symptom parameter type and a medication compliance parameter type) are available to be displayed in a single wellness trending display area 1360.

In various embodiments, parameters available to be displayed that are associated with a physical parameter type include, but are not limited to, parameters related to activity, posture, and sleep. In various embodiments, parameters available to be displayed that are associated with a mental / emotional parameter type include, but are not limited to, parameters related to stress, anxiety (such as may be detected via sighing), excitement, anger and depression. In various embodiments, parameters available to be displayed that are associated with a physiological / pathological parameter type include, but are not limited to, parameters related to blood pressure, respiration rate and patterns, and medical test results. In various embodiments, parameters available to be displayed that are associated with a environmental parameter type include, but are not limited to, parameters related to altitude, temperature, air quality, pollen count and humidity. In various embodiments, parameters available to be displayed that are associated with a diet parameter type include, but are not limited to, parameters related to sodium intake, fluid intake and lipid intake.

Figure 14 illustrates a block diagram of a wellness trending display illustrating an arrangement for selecting and displaying parameter trends according to various embodiments of the present subject matter. In the illustrated embodiment, the screen display 1460 of the WMD includes a patient health trend area 1468A, a device trend area 1468B, and a trend display area 1468C. In various embodiments, the screen display includes a time indicator 1469 and an event identifier 1470. The event identifier is used to display predetermined events. In various embodiments, significant events include events that are clinically important in themselves, those events that may trigger clinically important changes, and/or those events that explain clinically

important changes. The illustrated screen display promotes the correlation of various parameter trends to various predetermined events. The correlation of various parameter trends is useful to diagnose and treat various health conditions.

5 In various embodiments, various trended parameters from the patient health trend area and from the device trend area are capable of being displayed in the trend display area. In various embodiments, a user is capable of selecting the displayed parameters and/or is capable of modifying the scale, arrangement and/or other display characteristic.

10 The illustrated patient health trend area 1468A includes a physical parameter type 1461, a physiological / pathological parameter type 1462, a mental / emotional parameter type 1463, an environmental parameter type 1464, a diet parameter type 1465, a symptom parameter type 1466 and a medication condition parameter type 1467. In various embodiments, selecting the parameter
15 type displays a second window for selecting a particular parameter associated with that parameter type. For example, selecting the physical parameter type button displays available physical parameters for display such as activity, posture and sleep. Other embodiments provide other ways for a user to select the parameters to be displayed.

20 The illustrated device trend area 1468C includes parameters associated with the device that can affect the sensed parameters or that otherwise provide context to the sensed parameters. In various embodiments of the present subject matter which include a pulse generator IMD, the device trend area includes battery impedance 1471, lead impedance 1472, and percent pacing 1473. One of
25 ordinary skill in the art will understand, upon reading and comprehending this disclosure, the significance of device trends such as battery impedance, lead impedance, percent pacing and the like. One of ordinary skill in the art will further understand, upon reading and comprehending this disclosure, the desirability of correlating device trends with the patient health trends.

30 A number of parameters trends, shown as trend 1, trend 2 . . . trend n, are capable of being displayed in the trend display area 1468B. The trends are

plotted as a function of time, which is illustrated at 1469. In various embodiments, and event identifier, represented at 1470, is also displayed in the trend display area. The event identifier displays predetermined events that occurred at various times, and assists with determining causes for changes in the displayed parameter trends..

Figure 15 illustrates an example of a wellness trending display. In the illustrated embodiment, the screen display of the wellness monitor device includes a patient health trend area 1566, a device trend area 1568, and a trend display area 1567.

In the illustrated embodiment, a number of patient health parameter trends are accessible in the patient health trend area, including mean resting heart rate trends, an activity trends, standard deviation of averaged normal-to-normal (SDANN) interval trends, percent atrial fibrillation (AF) trends, intrinsic PR interval trends (the period of time from the onset of the P wave (atrial depolarization) to the onset of the QRS complex (ventricular depolarization)), autonomic balance trends, and mean resting respiratory trends.

SDANN is a particular measure of heart rate variability (HRV) that is based on 24 hour recordings of heartbeats. SDANN is computed by determining average heart rate over a given interval (e.g. five (5) minute intervals), and taking the standard deviation of the heart rates. Preferably, the SDANN measure uses every interval during the day assuming that all of the intervals provide good recordings. For example, there are 288 5-minute periods during a day. If all of the intervals provide good recordings, the SDANN is the standard deviation of these 288 averages. However, since all of the recordings may not be good throughout the 24 hour day, the SDANN is computed from the good portions of the recording.

Upon reading and understanding this disclosure, those skilled in the art will readily understand the value of the heart rate, percent atrial fibrillation, autonomic balance, and respiratory trends in the context of patient wellness. The intrinsic PR interval is useful to determine optimal cardiac resynchronization therapy in heart failure patients.

In the illustrated embodiment, a number of device trends 1568 are accessible in the device trend area, including percent ventricular pacing trends, atrial lead impedance trends, RV lead impedance trends, LV lead impedance trends, atrial intrinsic amplitude trends, right ventricular amplitude trends, and left ventricular amplitude trends. Upon reading and comprehending this disclosure, those skilled in the art will readily understand the value of the parameters in assessing device functionality and thereby the ability of the device to deliver proper therapy.

Labels are provided in Figure 15 to illustrate the correlation between various parameter trends and various predetermined events. For example, programming the IMD, as indicated by the event identifier, resulted in a lower resting mean heart rate and an increased activity. U.S. Patent 6,021,351, issued to Kadhiresan et al. and entitled Method and Apparatus For Assessing Patient Well-Being, describes an example of an activity. U.S. Patent 6,021,351 is assigned to Applicant's assignee. The illustration also shows that a ventricular tachycardia (VT) shock therapy did not significantly affect the heart rate or activity, but that atrial fibrillation (AF>15%) significantly worsened the patient's health status as indicated by an increased resting mean heart rate and a decreased activity. One of ordinary skill in the art will understand, upon reading and comprehending this disclosure, that other parameters and predetermined events can be acquired and displayed to illustrate the correlation between various parameter trends and various predetermined events.

Figure 16 illustrates a block diagram according to various aspects of the present subject matter in which a diagnostic context is provided to assist with interpreting the health condition of the patient, and to appropriately adjust the device and/or medical therapy, accordingly. The patient diagnostics 1669 and the diagnostic context 1670 are capable of being acquired using a variety of IMD and external sources, such as those provided throughout this disclosure. A number of patient diagnostics and diagnostic contexts are provided in Figure 15, and will not be repeated in this specification.

In the illustrated embodiment, the diagnostic context 1670 is used as an input in forming the patient diagnosis 1669. The diagnostic context and the patient diagnostics provide inputs to titration algorithms 1671, which are used to determine an appropriate device therapy based on the diagnosis and the context of the diagnosis. The titrated settings for the device therapy are implemented by the device at 1672. At 1673, various trends, reports and/or alerts/alarms are determined based on the patient diagnostics. A physician 1674 receives these various trends, reports and/or alerts/alarms, along with other data 1675 such as clinical exams, clinical data, medical history and the like. Based on the available information, the physician is able to adjust (or titrate) the device therapy 1672 and/or the medical therapy 1676.

Defining, Identifying and Using Predetermined Health-Related Events

Figures 17 - 19 illustrate various embodiments of the present subject matter related to defining, identifying and using predetermined health-related events. In various embodiments, a device such as a WMD or IMD defines, identifies, displays and triggers actions based on a predetermined health-related event. In various embodiments, the predetermined events include significant events that are clinically important. Significant events includes those events that are clinically important in themselves (such as ventricular fibrillation), those events that trigger an important change (such as loss of ventricular pacing) or those events that explain a change (such as increased anxiety).

Figure 17 illustrates a method for managing a patient's health by defining, detecting and using predetermined health-related events, according to various embodiments of the present subject matter. At 1777, predetermined events are defined. In various embodiments, predetermined events are significant health-related events, such as events that are clinically important in themselves, events that trigger a change, and/or events that explain a change. Examples of predetermined events includes device (e.g. IMD) therapy changes initiated by the device and/or clinician, a drug therapy change initiated by the device and/or clinician, arrhythmic events, changes in trended parameters, and autonomously-identified parameter correlations.

At 1778, predetermined health-related events are detected based on health-related parameters. In various embodiments, the health-related parameters are acquire through IMD sensors, external sensors, external data sources such as patient databases, and/or manual data inputs. At 1779, the
5 detected event is recorded in a time log. In various embodiments, a time stamp is associated with the event to record the time to of the event.

At 1780, an action is triggered based on the detected events. In various embodiments, the triggered action includes a change in device therapy, an alarm and/or a display or report of the predetermined events along with trended health-
10 related parameters. In various embodiments, the triggered action includes initiating a signal for use within the device(s) that detected the events for transmission for use by other device(s).

Figure 18 illustrates a device (such as a WMD or IMD) for monitoring a patient's health condition that is capable of detecting predetermined health-
15 related events, according to various embodiments of the present subject matter. The illustrated device includes a parameter acquisition module 1881 to acquire health related parameters. These health-related parameters can include IMD parameters (whether sensed or device interrogated), and parameters from external data sources such as sensors and databases. Various embodiments
20 acquire various health-related parameters that are provided throughout this disclosure. The illustrated device 1852 further includes a predetermined event detection module in communication with the parameter acquisition module. The predetermined event detection module 1882 communicates with the parameter acquisition module 1881 to determine whether the health-related parameter(s)
25 correspond to at least one of the number of predetermined events. The illustrated device further includes an action trigger module 1883 to communicate with the predetermined event detection module and trigger at least one action appropriate for a detected predetermined event.

Figure 19 illustrates a wellness monitoring device (WMD) for monitoring
30 a patient's health condition that is capable of detecting predetermined health-related events, according to various embodiments of the present subject matter.

The illustrated device 1952 includes a communication module 1984, a parameter acquisition module 1981, an input module 1985, a predetermined event definition module 1986, a timer module 1987 and a predetermined event detection module 1982. In operation, the modules perform the functions as
5 described below.

The communication module 1984 receives at least one health-related parameter. The parameter acquisition module 1981 communicates with the communication module to acquire the at least one health-related parameter. The input module 1985 receives manual input data, such as data for defining
10 predetermined events and/or parameters to be acquired by the parameter acquisition module 1981 through a communication link. The predetermined event definition module 1986 communicates with the input module 1985 and/or a memory storage that contains a set of predetermined health-related events 1988 to define a number of predetermined events for the patient's health condition.
15 The predetermined event detection module 1982 communicates with the parameter acquisition module 1981 and the predetermined event definition module 1986 to determine that the health-related parameter(s) correspond to at least one of the number of predetermined events. The predetermined event detection module 1982 further communicates with the timer module 1987 to
20 associate a time with the at least one of the number of predetermined events.

Various embodiments of the present subject matter include an action trigger module 1983 in communication with the predetermined event detection module. The action trigger module 1983 is adapted to trigger a desired action based on a detected predetermined event. In various embodiments, the action
25 trigger is adapted to provide a signal to display the detected predetermined event along with a trend for the at least one health related parameter. In various embodiments, the device includes a display on which the predetermined event and the trend for the at least one health related parameter are displayed. In various embodiments, the signal is transmitted to another device with a display
30 on which the predetermined event and the trend for the at least one health related parameter are displayed. In various embodiments, the action trigger is adapted to

provide a signal to send an alarm in response to the detected predetermined event. Various embodiments of the present subject matter include an action trigger to provide a signal to change device therapy in response to the detected predetermined event.

5 The health-related parameters acquired by the parameter acquisition module 1981 are capable of including IMD parameters or health-related parameters from an external data source such as external sensors, patient history databases, databases accessible through a global computer network (e.g. Internet), and user inputs (e.g. manual inputs from a patient and/or clinician).

10 Reporting Multiple Health-Related Parameters

 Figures 20 - 21 illustrate various embodiments of the present subject matter related to reporting multiple health-related parameters. Various embodiments of the present subject matter provide a number of methods for transferring trended data, predetermined events and alerts to a clinician. In various embodiments, this type of information is capable of being displayed on a programmer screen or being otherwise used by a WMD and/or IMD within an advanced patient management system, such as those described within this disclosure, for example. This information is filtered in various embodiments of the present subject matter such that only the most relevant or clinically useful information is displayed or otherwise used.

 Figure 20 illustrates a method for reporting multiple parameters related to a health condition of a patient, according to various embodiments of the present subject matter. At 2088, a number of trended health-related parameters are acquired. In various embodiments, the trended health-related parameters include any of the various parameters described within this disclosure. In various embodiments, acquiring the trended health-related parameters includes acquiring parameters and trending the acquired parameters. At 2089, a number of predetermined events are acquired. In various embodiments, the predetermined events include events that are clinically important in themselves, events that trigger a change, or events that explain a change. In various embodiments, acquiring predetermined events include determining that the event is a

significant health-related event as provided elsewhere in this disclosure. At 2090, a number of alerts are acquired. In various embodiments, acquiring alerts includes determining alerts. Alerts in various embodiments of the present subject matter include device-initiated alerts, patient-initiated alerts, and
5 clinician-initiated alerts. Additionally, alerts in various embodiments of the present subject matter include alerts directed to the patient and alerts directed to a clinician.

At 2091, the present subject communicates at least one of the parameters, events and/or alerts. Various embodiments prioritize or characterize the
10 relevance of the parameters, events and/or alerts, and appropriately communicate the information according to the relevance of the information. In various embodiments, the parameters, events and/or alerts are communicated in a report-like manner. Various embodiments of the present subject matter communicate the parameters, events and/or alerts incorporating a variety of communication
15 technologies provided in this disclosure. In various embodiments, the communication displaying the parameters, events and/or alerts, providing an alarm signal with respect to the parameters, events and/or alerts, transmitting an e-mail, transmitting a telefax, placing a telephone call, and conducting wireless communication.

20 Figure 21 illustrates a wellness monitoring device (WMD) for monitoring a patient's health condition that is capable of prioritizing communication of health-related parameters, according to various embodiments of the present subject matter. The illustrated device 2152 includes a communication module 2184, a parameter acquisition module 2181, an input module 2185, a
25 predetermined event definition module 2186, a timer module 2187, a predetermined event detection/acquisition module 2182, and an alert acquisition module 2192. In operation, the modules perform the following functions. The communication module 2184 receives at least one health-related parameter. The parameter acquisition module 2181 communicates with the communication
30 module 2184 to acquire the at least one health-related parameter. The input module 2185 receives manual input data, such as data for defining predetermined

events and/or parameters acquired by the parameter acquisition module 2181 through a communication link. The predetermined event definition module 2186 communicates with the input module 2185 to define a number of predetermined events for the patient's health condition. The predetermined event
5 detection/acquisition module 2182 communicates with the parameter acquisition module 2181 and the predetermined event definition module 2186 to determine that the health-related parameter(s) correspond to at least one of the number of predetermined events. The predetermined event acquisition module 2182 further communicates with the timer module 2187 to associate a time with the at least
10 one of the number of predetermined events. The alert acquisition module 2192 communicates with the predetermined event acquisition module 2182 and with an alert definition module 2193 to determine alerts from, among other things, the acquired predetermined events.

Various embodiments of the present subject matter include an output
15 communication module 2194 in communication with the alert acquisition module 2192, the predetermined event acquisition module 2182 and the parameter acquisition module 2181. In various embodiments, the output communication module 2194 is in communication with a priority filter 2195 for characterizing or classifying the relevance of the parameter(s), event(s) and/or
20 alert(s). The output communication module 2194 is adapted to appropriately communicate the parameter(s), event(s) and/or alert(s) using various communication technologies based on their relevance.

One of ordinary skill in the art will understand, upon reading and comprehending this disclosure, how to acquired parameters, events and/or alerts
25 using an IMD, and transmitting a communication signal represented the acquired parameters, events and/or alerts from the IMD to assist with managing a patient's health.

Environmental Data

Figure 22 illustrates various embodiments of the present subject matter
30 related to reporting environmental data. Various embodiments of the present subject matter automatically acquire and present environmental data to the

attending physicians and/or patients for disease diagnosis and therapy decision making. For example, chronically ill patients can be very sensitive to the environment changes such as air quality and temperature. Patients who have respiratory disorders secondary to cardiovascular diseases (e.g. HF) may be
5 vulnerable to certain environmental conditions. For example, acute exacerbation sometimes can be attributed to environmental changes. In various embodiments, a device (such as an IMD and/or WMD) is able to automatically acquire environmental data and provide such information in correlation to other measurements of the patient conditions to the clinician and/or patient.

10 Figure 22 illustrates a device (such as a WMD or IMD) for monitoring a patient's health condition that is capable of synthesizing environmental parameters with implantable medical device (IMD) parameters, according to various embodiments of the present subject matter. Examples of environmental parameter types include, but are not limited to, parameters related to altitude,
15 temperature, air quality, pollen count, and humidity. The illustrated device 2252 includes a first communication module 2296 for receiving IMD parameters, and a second communication module 2297 for receiving environmental parameters from a source of environmental parameters (such as an external sensor or a database). The device includes a correlation module 2298 that receives the IMD
20 parameter(s) and the environmental parameter(s), and correlates the environmental parameters with the IMD parameters.

Various embodiments of the present subject matter include an action trigger module 2283 in communication with the correlation module 2298. The action trigger module 2283 is adapted to trigger a desired action based on the
25 IMD parameter(s) and the environmental parameter(s). In various embodiments, the action trigger module 2283 is adapted to provide a signal to display the correlation between the IMD parameter(s) and the environmental parameter(s).

In various embodiments, the device 2252 includes a display on which the correlation between the IMD parameter(s) and the environmental parameter(s) is
30 displayed. In various embodiments, the signal is transmitted to another device with a display on which the correlation between the IMD parameter(s) and the

environmental parameter(s) is displayed. In various embodiments, the action trigger is adapted to provide a signal to send an alarm in response to the correlation between the IMD parameter(s) and the environmental parameter(s). Various embodiments of the present subject matter include an action trigger
5 module 2283 to provide a signal to change device therapy in response to the correlation between the IMD parameter(s) and the environmental parameter(s).

In various embodiments, the device 2252 further includes a third communication module 2299 to receive IMD position parameters. Thus, for example, in an embodiment in which the second communication module is
10 accessing environmental parameter(s) from a database of regional environmental parameters, the present subject matter is capable of determining the appropriate region for which to retrieve environmental parameters. Additionally, in various embodiments, the IMD position parameters include parameters indicative of altitude. According to various embodiments, the IMD position parameters are
15 generated using cellular technology to determine a cell region, GPS technology, and manual data inputs.

Various embodiments of the present subject matter relate to an advanced patient management system. In various embodiments, the system includes at least one implantable medical device (IMD) to acquire at least one IMD
20 parameter indicative of patient wellness, means to acquire at least one environmental parameter from at least one external source, and means to factor in the at least one environmental parameter in the advanced patient management system. In various embodiments, the environmental parameter is factored in by adjusting the IMD parameter based on the at least one environmental parameter.
25 In various embodiments, the environmental parameter is factored in by adjusting a display of the IMD parameter. In various embodiments, the environmental parameter is factored in by adjusting IMD-provided therapy (such as electrical therapy, drug therapy, and the like). A number of environmental parameter types are acquired in various embodiments. Examples of these environmental types
30 include altitude, temperature, air quality, pollen counts, humidity, and pressure.

In various embodiments, the IMD parameter(s) and/or the environmental parameter(s) are trended and/or correlated, as provided in this disclosure.

Identifying, Displaying and Assisting in Correlating Health-Related Data

Figure 23 illustrates various embodiments of the present subject matter related to identifying, displaying and assisting in data correlation. One definition of correlation is a relation existing between phenomena or things or between mathematical or statistical variables which tend to vary, be associated, or occur together in a way not expected on the basis of chance alone. Correlating data involves showing a reciprocal, mutual, and/or causal relationship among the data.

Various embodiments of the present subject matter provide methods of correlating, or assisting in the correlation of, trended data, predetermined events and other actions taken by the system (such as an alert transmitted to the clinician). Various embodiments of the present subject matter autonomously identify correlations and display the identified correlations. For example, various embodiments determine correlations without human intervention. In various embodiments, the present subject matter assists the clinician in correlating the information by displaying the data in an appropriate manner. Cause and effect relationships that are suitable for use in treating patients can be established by correlating data items.

Figure 23 illustrates a device (such as a WMD or IMD) for monitoring a patient's health condition that is capable of correlating trended parameters, predetermined events, and alerts, according to various embodiments of the present subject matter. The illustrated device 2352 includes a first data input 2301 to receive trended health-related parameter(s), a second data input 2302 to receive predetermined event(s) associated with a patient's health, and a third data input 2303 to receive alert(s) associated with a patient's health. According to various embodiments of the present subject matter, the health-related parameters, the predetermined events, and the alerts include any of the health-related parameters, the predetermined events, and the alerts provided throughout this disclosure.

The device 2352 includes a correlation module 2304 in communication with the first data input 2301, the second data input 2302, and the third data input 2303. The correlation module 2304, which in uses various correlation algorithms 2305 in various embodiments, is adapted to correlate at least one of
5 one or more trended health-related parameters, one or more health-related predetermined events, and one or more health-related alerts. In various embodiments, the correlation module 2304 is adapted to trigger an action. In various embodiments, the action is automatically triggered based on the correlation. In various embodiments, the correlation module automatically
10 triggers an IMD therapy change based on the correlation. In various embodiments, the correlation module automatically displays the correlation. For example, a cursor or other indicator can be used to highlight the correlation.

Those versed in the art will understand, upon reading and comprehending this disclosure, how to incorporate various well known techniques for computing
15 correlations between two or more data sources. For example, in the case of providing correlations between two data sources, Pearson's product-moment correlations is one example of a type of correlation that may be computed. In the case of three or more data sources, multivariate correlation techniques may be employed.

20 According to various embodiments of the present subject matter, the choice of which data sources to correlate is based on knowledge of physiological coupling between the sources. According to various embodiments, the choice of which data sets to correlate and the time durations(s) over which the correlations are computed is determined at the start of monitoring, and is either the same for
25 each patient, or is tailored to individual patients based on the physicians' knowledge of the patient's condition. In various embodiments, the decisions of which parameters to correlate with each other may be dynamically selected based on ongoing IMD or WMD monitoring of the patient's physiology.

30

Composite Parameter Indices

Figures 24 - 26 illustrate various embodiments of the present subject matter related to defining, identifying and utilizing composite parameter indices. A composite parameter is a parameter created by combining two or more parameter inputs. For example an exercise conditioning composite parameter is generated by dividing a heart rate by an activity level. A lower exercise condition composite parameter indicates that a patient is in better condition. Various embodiments of the present subject matter provide composite parameters that function as trended parameters in various manner in which the trended parameters are used, as provided throughout this disclosure. A composite parameter is capable of being used in any way a raw parameter is used, such as displaying, correlating, defining predetermined events, defining alerts, and the like.

Figure 24 illustrates a method to generate composite parameters for use in managing a patient's health, according to various embodiments of the present subject matter. The method illustrates a first parameter 2406 and a second parameter 2407 being operated on to form a composite parameter 2408. One or ordinary skill in the art will understand, upon reading and comprehending this disclosure, that the operation denoted at 2409 can be any number of mathematical and/or logical operations. For example, the composite parameter 2408 can be formed by multiplying the first parameter 2406 and the second parameter 2407, or can be formed by dividing the second parameter 2407 into the first parameter 2406. More complex mathematical and/or logical operations can be used to generate the composite index.

Figure 25 illustrates a method to generate composite parameters for use in managing a patient's health, according to various embodiments of the present subject matter. The method illustrates a number of parameters (1, 2, P) and a number of composite parameters (1, 2, C) that are capable of being combined to form one or more composite parameters 2508. Thus, the present subject matter is capable of generating a composite parameter from any number of health-related parameters, from any number of previously-determined composite

parameters, or from any combination of one or more parameters and one or more composite parameters.

In various embodiments, the parameters include IMD-measured parameters and/or IMD-interrogated parameters. IMD-interrogated parameters include, for example, parameters related to a device status such as battery or lead impedance. In various embodiments, the parameters include user-inputted parameters provided by a patient, clinician or other person.

Various embodiments of the present subject matter combine two or more health-related parameters related to a body system to generate a composite parameter that is indicative of the health of the body system. For example, respiratory rate, tidal volume, maximum oxygen consumption (VO₂) and periodic breathing parameters relate to a respiratory system. These parameters can be used to generate a single composite parameter index that provides a health indication concerning the respiratory system. Another example uses an average heart rate and an activity parameter to generate a composite parameter index indicative of physical conditioning. Other examples use cardiac output and vascular pressures to measure vascular resistance. Another example measures respiration and heart rate to measure respiratory sinus arrhythmia.

In various embodiments, the composite index is displayed with trended health-related parameter(s), predetermined event(s) and/or alert(s). In various embodiments, the composite parameter is used to define a predetermined health-related event. In various embodiments, the composite parameter is used to define a clinician alert. In various embodiments, the composite parameter is used to modify device therapy.

Figure 26 illustrates a device (such as a WMD or IMD) for monitoring a patient's health condition that is capable of generating composite parameters, according to various embodiments of the present invention. The illustrated device 2652 includes a data input 2610 to receive two or more health-related parameters and a composite generating module 2611 in communication with the data input 2610. In operation, the composite generating module 2611 receives the health-related parameters and generates a composite parameter using the

health-related parameters. The composite generating module 2611 is capable of performing any number of mathematical and/or logical operations, such as that denoted at 2409 in Figure 24. In various embodiments, the composite generating module 2611 is capable of combining one or more composite parameters
 5 (represented by line 2612) with one or more health-related parameters to form other composite parameters.

Various embodiments provide various composite parameters. A number of these composite parameters are identified below. The identified composite parameters is not intended to be an exclusive list of the available composite
 10 parameters.

In a first example, a composite parameter indicative of systemic vascular resistance (SVR) is generated using an acquired cardiac output parameter (C.O.), a mean arterial pressure parameter (P_{ART}), and a mean right atrial pressure parameter (P_{RA}). In various embodiments, the SVR composite parameter is
 15 provided by:

$$SVR = \frac{\overline{P_{ART}} - \overline{P_{RA}}}{C.O.}$$

In a second example, a composite parameter indicative of pulmonary vascular resistance (PVR) is generated using an acquired cardiac output parameter (C.O.), a mean pulmonary artery pressure parameter (P_{PA}), and one of
 20 a mean pulmonary capillary wedge pressure parameter (P_{CW}) and a mean left atrial pressure parameter (P_{LA}). In various embodiments, the PVR composite parameter is provided by:

$$PVR = \frac{\overline{P_{PA}} - \overline{P_{CW}}}{C.O.}, \text{ or}$$

$$25 \quad PVR = \frac{\overline{P_{PA}} - \overline{P_{LA}}}{C.O.}$$

In a third example, a composite parameter indicative of respiratory sinus arrhythmia (RSA) is generated using an acquired heart rate parameter (P_{HR}) and a parameter related to instantaneous lung volume (P_{LV}). For example, a trans-thoracic sensor can be used in the acquisition. In various embodiments, the
 5 RSA composite parameter is provided by:

$$RSA = f(P_{HR}, P_{LV}).$$

In a fourth example, a composite parameter indicative of a degree of dyspnea (D) is generated using an acquired respiration rate parameter (P_{RR}) and a tidal volume parameter (P_{TV}). In various embodiments, the dyspnea composite
 10 parameter is provided by:

$$D = \frac{P_{RR}}{P_{TV}}.$$

Context may temporarily affect the physiological condition of a monitored patient. A patient context (or body-related concept), for example, may include posture, activity level, mental/emotional state and the like.
 15 Examples of patient contexts include sleeping or lying down, running, and driving. An environmental context (or external factor), for example, may include ambient temperature, sound level and the like. The concept of context has previously been discussed with respect to Figure 16.

In various embodiments, the context is correlated with the physiologic
 20 measurements. In various embodiments, measurements are taken only for certain contexts so as to provide a repeatable baseline. For example, it is preferred to measure some parameters when a patient is at rest or in a known position. Thus, repeatable composite parameters can be generated. This is useful to determine trends or deviations from normal values. Additionally,
 25 various embodiments determine the context to provide an appropriate therapy for a contextual situation.

The following commonly-assigned patent applications refer to the use of multiple parameters: "Implantable Cardiac Rhythm Management Device For Assessing Status of CHF Patients," Ser. No. 09/434,009, filed November 4,

1999, now U.S. Pat. 6,275,727; “Method and Apparatus For Determining Changes In Heart Failure Status,” Ser. No. 10/001,223, filed November 15, 2001; and “Cardiac Rhythm Management Systems and Methods Predicting Congestive Heart Failure Status,” Ser. No. 10/213,268, filed August 6, 2002. The following
5 commonly-assigned patent application refers to context: “Methods and Devices For Detection of Context When Addressing A Medical Condition of a Patient”, Ser. No. 10/269,611, filed October 11, 2002.

Triaging Health-Related Data

Figures 27 - 28 illustrates various embodiments of the present subject
10 matter related to triaging health-related data in an advanced patient management system. Various embodiments of the present subject matter provide one or more devices (such as IMD, WMD, programmer and the like) with the ability to rank the severity of predetermined events. This ranking is used to prioritize the processing of the predetermined events and respond in an appropriate manner.
15 For example, the system can be designed such that a modest increase in heart rate holds a lower priority and is related to the clinician at a next patient followup; whereas a sudden increases in weight (which may be associated with acute decompensation in a heart failure patient) may be assigned a higher priority and immediately be communicated to the clinician through various
20 communication means.

Figure 27 illustrates a method to triage predetermined events for use in managing a patient’s health, according to various embodiments of the present subject matter. At 2713, predetermined events are acquired. At 2714, the acquired predetermined events are classified, ranked, sorted or filtered according
25 to severity. At 2715, an action is triggered based on the severity of the predetermined event. According to various embodiments, the action includes one or more of displaying the predetermined event to a clinician at a patient followup visit 2716, alerting a clinician of the predetermined event at a patient followup visit 2717, initiating an alert for the patient 2718, altering device
30 therapy 2719, and initiating an alert (such as a prompt emergency alert) to the clinician using an advance patient management system 2720. In various

embodiments, the above-identified actions are performed for predetermined events that have been classified for increasing severity such that action 2716 is performed for a less severe event than action 2717, which is performed for a less severe event than action 2718, which is performed for a less severe event than action 2719, which is performed for a less severe event than action 2710. Other actions can be performed according to the severity of the predetermined event.

In various embodiments, the available actions to be performed are associated with various severity levels for predetermined events. This information is stored in a computer-readable memory such that a device is capable of performing an action that is associated with a detected predetermined event.

Figure 28 illustrates a device (such as a WMD or IMD) for monitoring a patient's health condition that is capable of classifying a number of predetermined events according to severity, and performing a system action based on the classification, according to various embodiments of the present subject matter. The illustrated device 2852 includes an input module 2821 and a triage module 2822.

In various embodiments, the input module 2821 acquires predetermined events. In various embodiments, the input module 2821 includes a predetermined event determination module 2823 to determine whether a predetermined event has occurred. In various embodiments, the input module 2821 includes a first communication module 2824 to acquire IMD parameters for use by the predetermined event determination module 2823. In various embodiments, the input module 2821 includes a second communication module 2825 to acquire database parameters for use by the predetermined event determination module.

The triage module 2822 receives the predetermined event(s) and ranks or otherwise classifies, the predetermined events according to severity. In various embodiments, the device 2852 includes a triggering module 2826 in communication with the triage module 2822. The triage module 2822 is adapted to automatically initiate a desired action by the triggering module 2826 based on

the severity of the predetermined event. In various embodiments, the action initiated is appropriate for the severity of the event. In various embodiments, a communication or report is initiated by the device when a predetermined event is classified as being more severe. For example, the communication can be an alarm or a prominently displayed message. In various embodiments, a communication or report is provided during a subsequent patient follow-up session when a predetermined event is classified as being less severe. In various embodiments, the device 2852 automatically performs a desired system action selected from a number of available system actions. The action is selected based on the severity of the predetermined event.

Although specific embodiments have been illustrated and described herein, it will be appreciated by those of ordinary skill in the art that any arrangement which is calculated to achieve the same purpose may be substituted for the specific embodiments shown. This application is intended to cover any adaptations or variations of the present subject matter. It is to be understood that the above description is intended to be illustrative, and not restrictive. Combinations of the above embodiments, and other embodiments will be apparent to those of skill in the art upon reviewing the above description. The scope of the present subject matter should be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled.

What is claimed is:

1. A device, comprising:
at least one data input to acquire a first set of at least two health-related
5 parameters and a second set of at least one health-related parameter; and
at least one composite generating module to generate a first composite
parameter using the first set of at least two health-related parameters, and to
generate a second composite parameter using the first composite parameter and
the second set of at least one health-related parameter.
10
2. The device according to claim 1, wherein the at least one data input
includes at least one data input to receive data from an implantable medical
device.
- 15 3. The device according to any of the preceding claims, wherein the at least
one data input includes at least one data input to receive user-inputted data.
4. The device according to any of the preceding claims, wherein the at least
one data input is configured to further acquire at least two health-related
20 parameters related to a body system.
5. The device according to any of the preceding claims, wherein the device
includes a wellness monitoring device within an advanced patient management
system.
25
6. The device according to any of the preceding claims, wherein at least one
of the health-related parameters includes at least one context-related parameter.
7. The device according to any of the preceding claims, wherein at least one
30 of the health-related parameters includes at least one of an environmental
parameter, a diet parameter, and a mental/emotional parameter.

8. The device according to any of the preceding claims, further comprising a module to trend at least one of:

one or more parameters in the first set of at least two health-related parameters;

5 one or more parameters in the second set of at least one health-related parameter;

the first composite parameter; and

the second composite parameter.

10 9. The device according to any of the preceding claims, further comprising an output module to provide a display signal representative of a display area containing at least one of the first composite parameter and the second composite parameter.

15 10. The device according to any of the preceding claims, further comprising a display to represent at least one of the first composite parameter and the second composite parameter.

11. A device, comprising:

20 at least one data input to acquire a first set of at least two health-related parameters, wherein the first set includes at least one of an environmental parameter, a diet parameter, and a mental/emotional parameter; and

at least one composite generating module to generate a first composite parameter using the first set of at least two health-related parameters.

25

12. The device according to claim 11, wherein the at least one data input is configured to further acquire a second set of at least one health-related parameter, the at least one composite generating module to generate a second composite parameter using the first composite parameter and the second set.

30

13. The device according to any of claims 11-12, wherein the device includes a wellness monitoring device within an advanced patient management system.
14. The device according to any of claims 11-13, wherein at least one of the
5 health-related parameters includes a context-related parameter.
15. The device according to any of claims 11-14, further comprising a trending module to trend at least one of:
one or more parameters in the first set of at least two health-related
10 parameters; and
the first composite parameter.
16. The device according to any of claims 11-15, wherein further comprising a display to represent the first composite parameter.
15
17. A device, comprising:
means to acquire a first set of at least two health-related parameters related to a body system;
means to generate a first composite parameter using the first set of at
20 least two health-related parameters; and
means to acquire a second set of at least one health-related parameter to provide a context for the first composite parameter.
18. The device according to claim 17, wherein the means to acquire a first set
25 of at least two health-related parameters includes at least one data input to receive data from an implantable medical device.
19. The device according to any of claims 17-18, further comprising means to acquire a second set of at least two health related parameters, and means to
30 generate a second composite parameter using the second set of at least two health-related parameters and the first composite parameter.

20. The device according to any of claims 17-19, further comprising means to trend at least one of:
one or more of the first set of at least two health-related parameters related to a body system;
- 5 the first composite parameter; and
the second set of the at least one health-related parameter to provide a context for the first composite parameter.
21. The device according to any of claims 17-20, further comprising means
10 to display the first set of at least two health-related parameters related to a body system, the first composite parameter, and the second set of the at least one health-related parameter to provide a context for the first composite parameter.
22. A programmable device having machine executable instructions for
15 performing a method to assist with managing a patient's health, the method comprising:
acquiring a first set of at least two health-related parameters and at least one context-related parameter for the at least two health-related parameters; and
generating a first composite parameter using the first set of at least two
20 health-related parameters based on the at least one context-related parameter.
23. The device according to claim 22, wherein acquiring a first set of at least two health-related parameters includes acquiring at least one parameter from an implantable medical device (IMD).
- 25
24. The device according to claim 23, wherein acquiring a first set of at least two health-related parameters includes acquiring at least one IMD-measured parameter.

25. The device according to any of claims 23-24, wherein acquiring a first set of at least two health-related parameters includes acquiring at least one IMD-interrogated parameter.
- 5 26. The device according to any of claims 22-25, wherein acquiring a first set of at least two health-related parameters includes acquiring at least one user inputted parameter.
27. The device according to any of claims 22-26, wherein the first set of at
10 least two health-related parameters includes a second composite parameter generated using a second set of at least two health-related parameters.
28. The device according to any of claims 22-27, wherein:
the first set of at least two health-related parameters include at least two
15 health-related parameters related to a body system; and
the first composite parameter is indicative of a health status of the body system.
29. The device according to claim 28, wherein:
20 the at least two health-related parameters related to a body system includes respiratory rate, tidal volume, maximum oxygen consumption (VO₂), and periodic viewing; and
the first composite parameter is indicative of a health status of the respiratory system.
- 25 30. The device according to claim 28, wherein:
the at least two health-related parameters related to a body system includes average heart rate parameter and an activity parameter; and
the first composite parameter is indicative of a health status of physical
30 conditioning.

31. The device according to any of claims 22-30, further comprising displaying the first composite parameter with at least one of one or more trended health-related parameters, one or more predetermined health-related events, and one or more health-related alerts.
- 5
32. The device according to any of claims 22-31, wherein the first composite parameter is used to define a health-related event.
33. The device according to any of claims 22-31, wherein the first composite
10 parameter is used to define a clinician alert.
34. The device according to any of claims 22-31, wherein the first composite parameter is used to modify device therapy.
- 15 35. The device according to any of claims 22-34, wherein the method performed by the machine executable instructions further includes trending at least one of:
- one or more of the first set of at least two health-related parameters; and
 - the at least one context-related parameter; and
 - 20 the first composite parameter.
36. The device according to any of claims 22-35, wherein the method performed by the machine executable instructions further includes displaying the first composite parameter.
- 25
37. The device according to claim 22, wherein in the method performed by the machine executable instructions,
- acquiring a first set of at least two health-related parameters and at least one context-related parameter for the at least two health-related parameters
 - 30 includes acquiring a cardiac output parameter, a mean arterial pressure parameter, and a mean right atrial pressure parameter; and

generating a first composite parameter using the first set of at least two health-related parameters based on the at least one context-related parameter includes generating a composite parameter indicative of systemic vascular resistance using the cardiac output parameter, the mean arterial pressure parameter, and the mean right atrial pressure parameter.

38. The device according to claim 22, wherein in the method performed by the machine executable instructions,

acquiring a first set of at least two health-related parameters and at least one context-related parameter for the at least two health-related parameters includes acquiring a cardiac output parameter, a mean pulmonary artery pressure parameter, and at least one of a mean pulmonary capillary wedge pressure parameter and a left atrial pressure parameter; and

generating a first composite parameter using the first set of at least two health-related parameters based on the at least one context-related parameter includes generating a composite parameter indicative of pulmonary vascular resistance using the cardiac output parameter, the mean pulmonary artery pressure parameter, and at least one of the mean pulmonary capillary wedge pressure parameter and the left atrial pressure parameter.

20

39. The device according to claim 22, wherein in the method performed by the machine executable instructions,

acquiring a first set of at least two health-related parameters and at least one context-related parameter for the at least two health-related parameters includes acquiring a heart rate parameter and a parameter related to instantaneous lung volume; and

generating a first composite parameter using the first set of at least two health-related parameters based on the at least one context-related parameter includes generating a composite parameter indicative of respiratory sinus arrhythmia using the heart rate parameter and the parameter related to instantaneous lung volume.

30

40. The device according to claim 22, wherein in the method performed by the machine executable instructions,
- acquiring a first set of at least two health-related parameters and at least
5 one context-related parameter for the at least two health-related parameters
includes acquiring a respiration rate parameter and a tidal volume parameter; and
generating a first composite parameter using the first set of at least two
health-related parameters based on the at least one context-related parameter
includes generating a composite parameter indicative of a degree of dyspnea
10 using the respiration rate parameter and the tidal volume parameter.
41. The device according to any of claim 37-40, wherein the device includes a wellness monitoring device within an advanced patient management system.

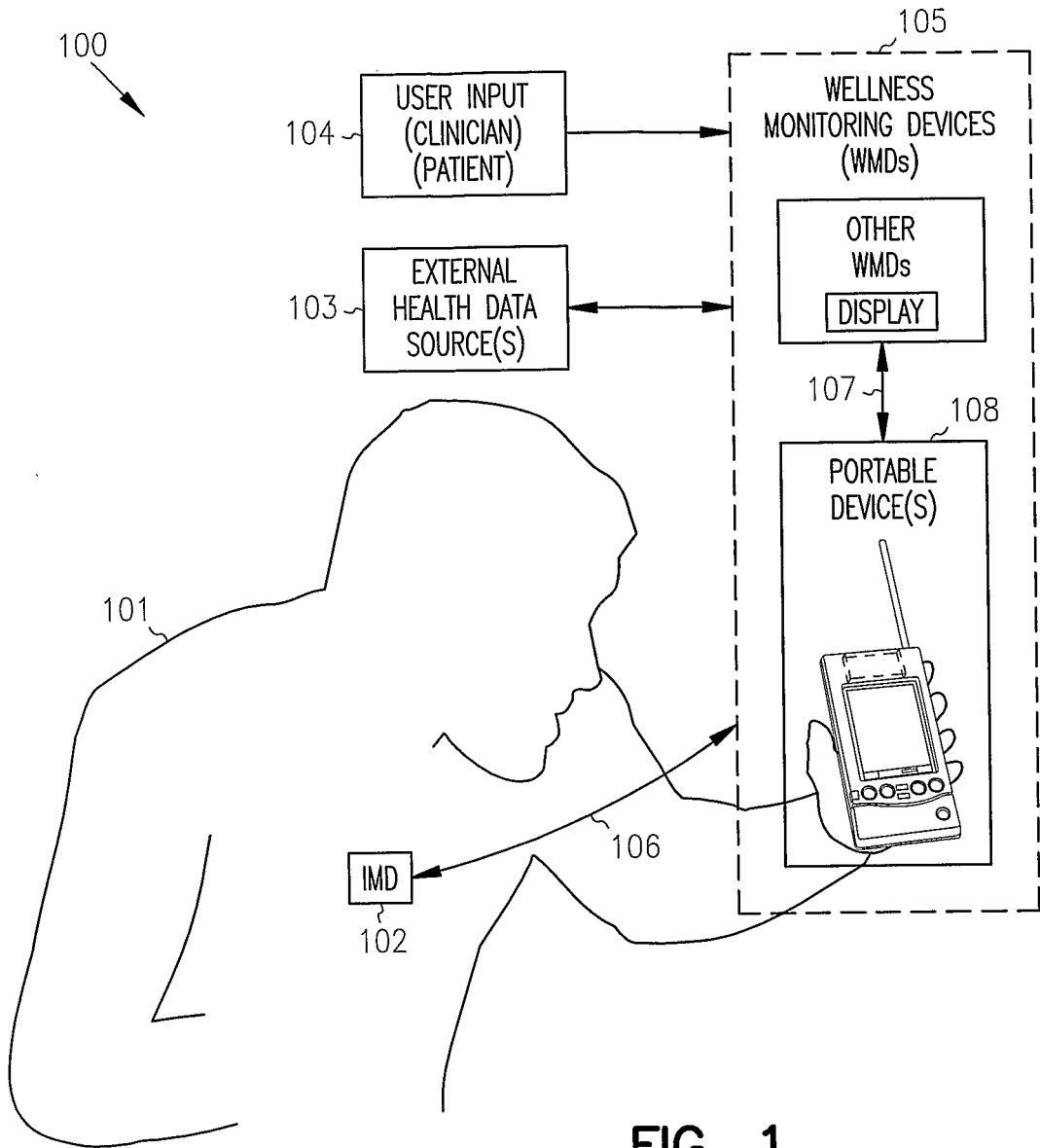


FIG. 1

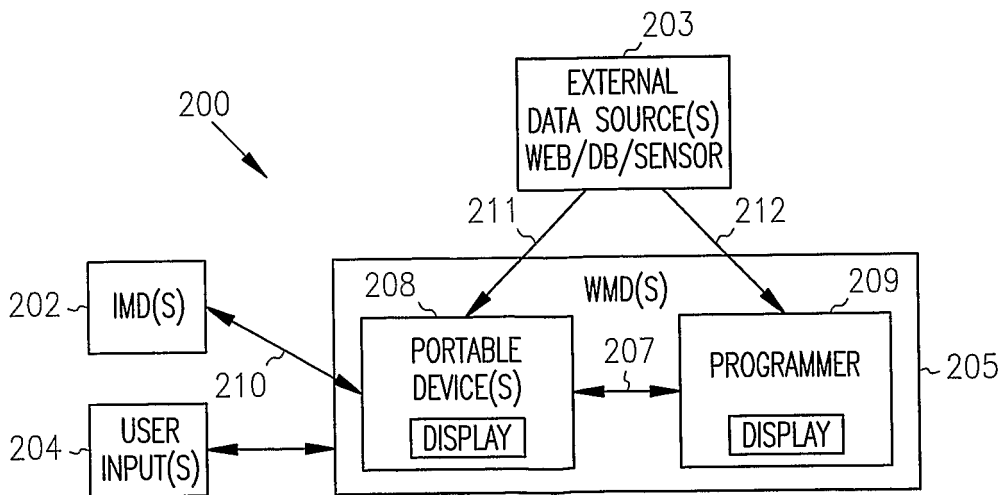


FIG. 2

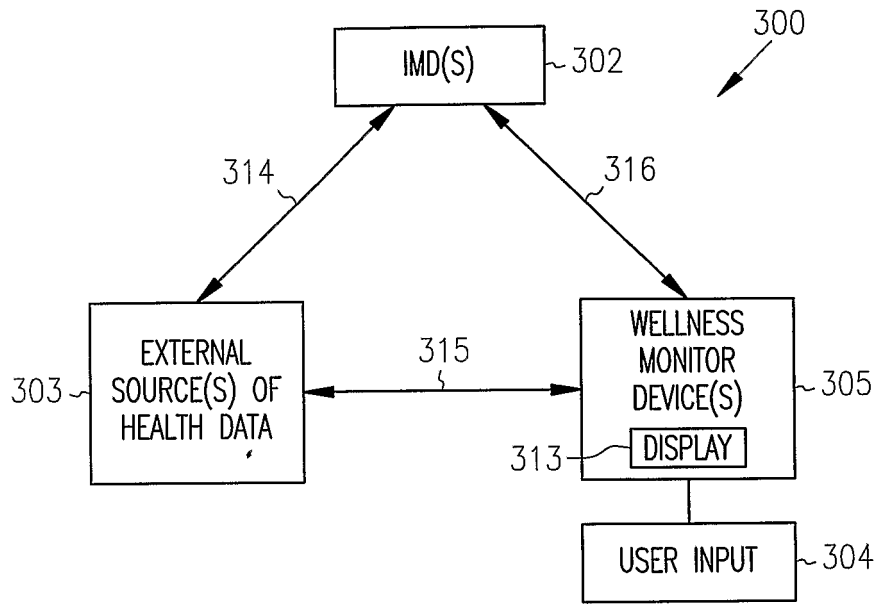


FIG. 3

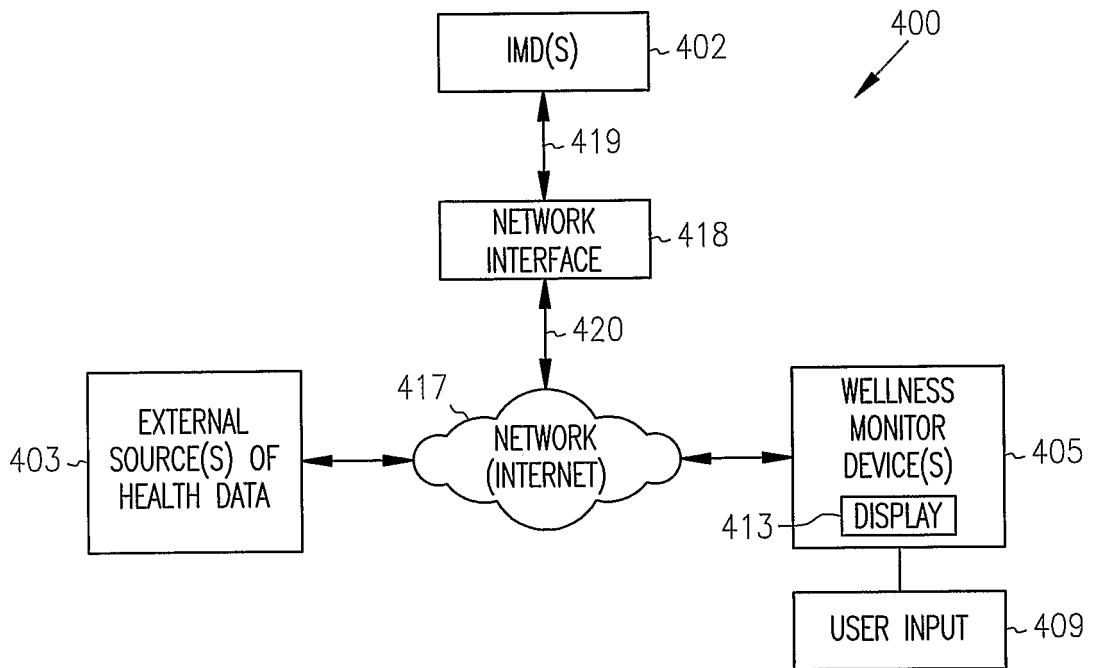


FIG. 4

3/21

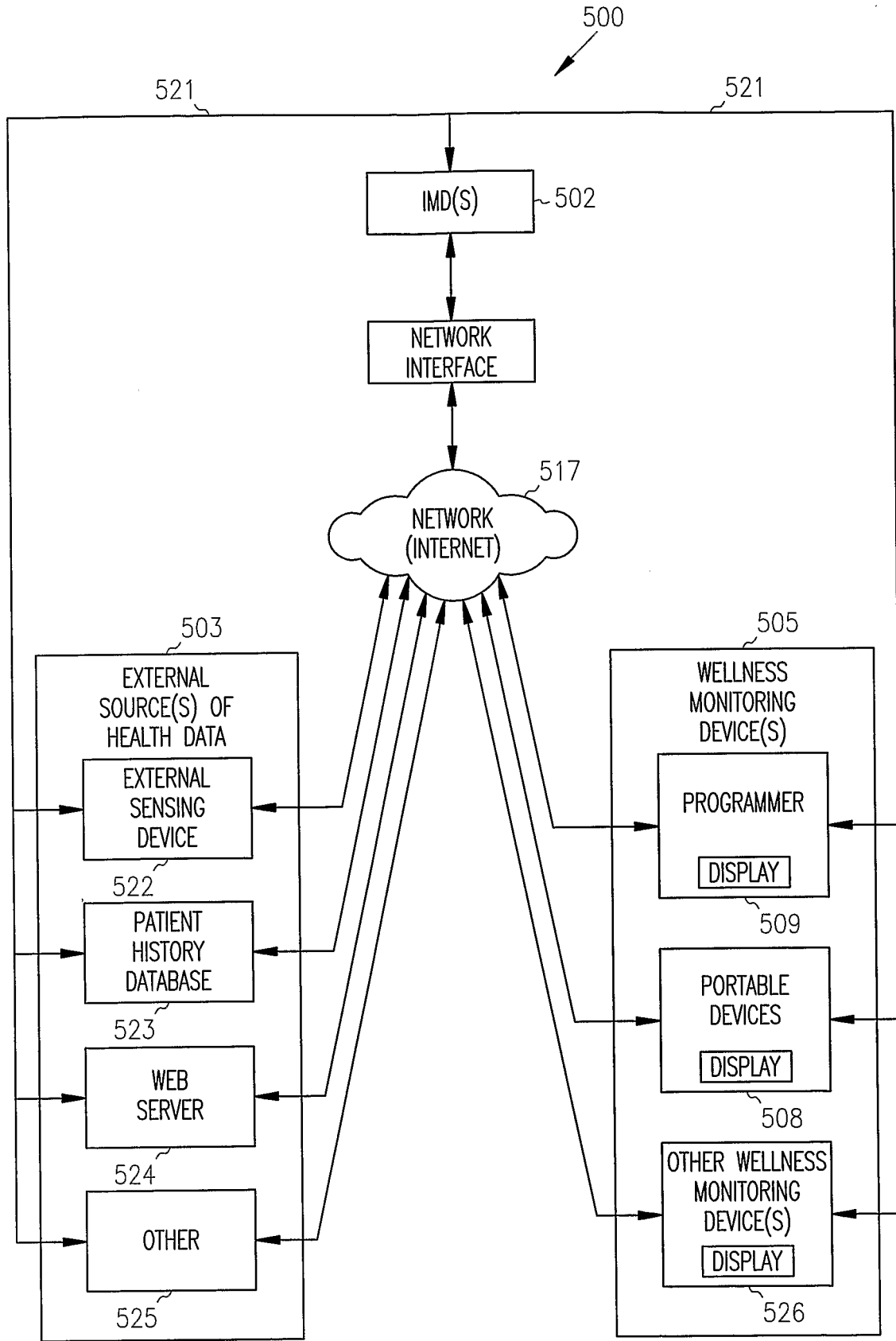


FIG. 5

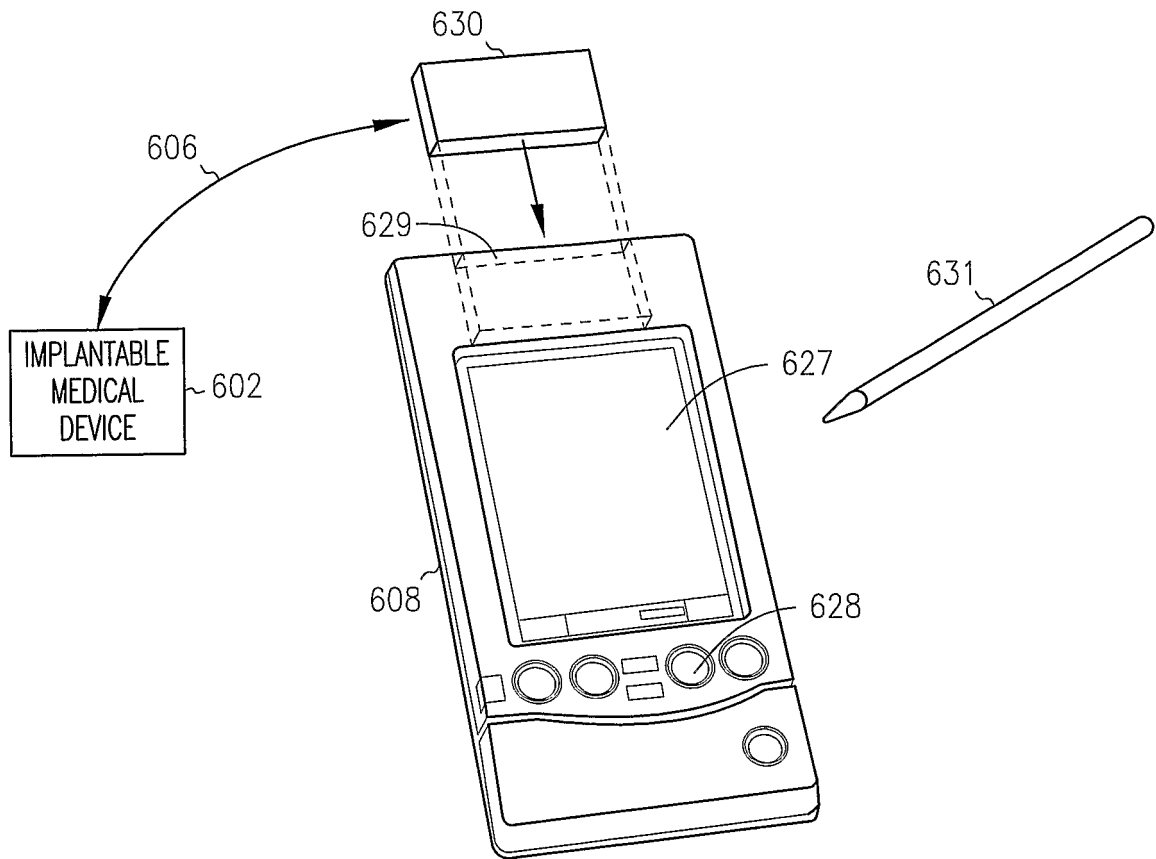


FIG. 6

5/21

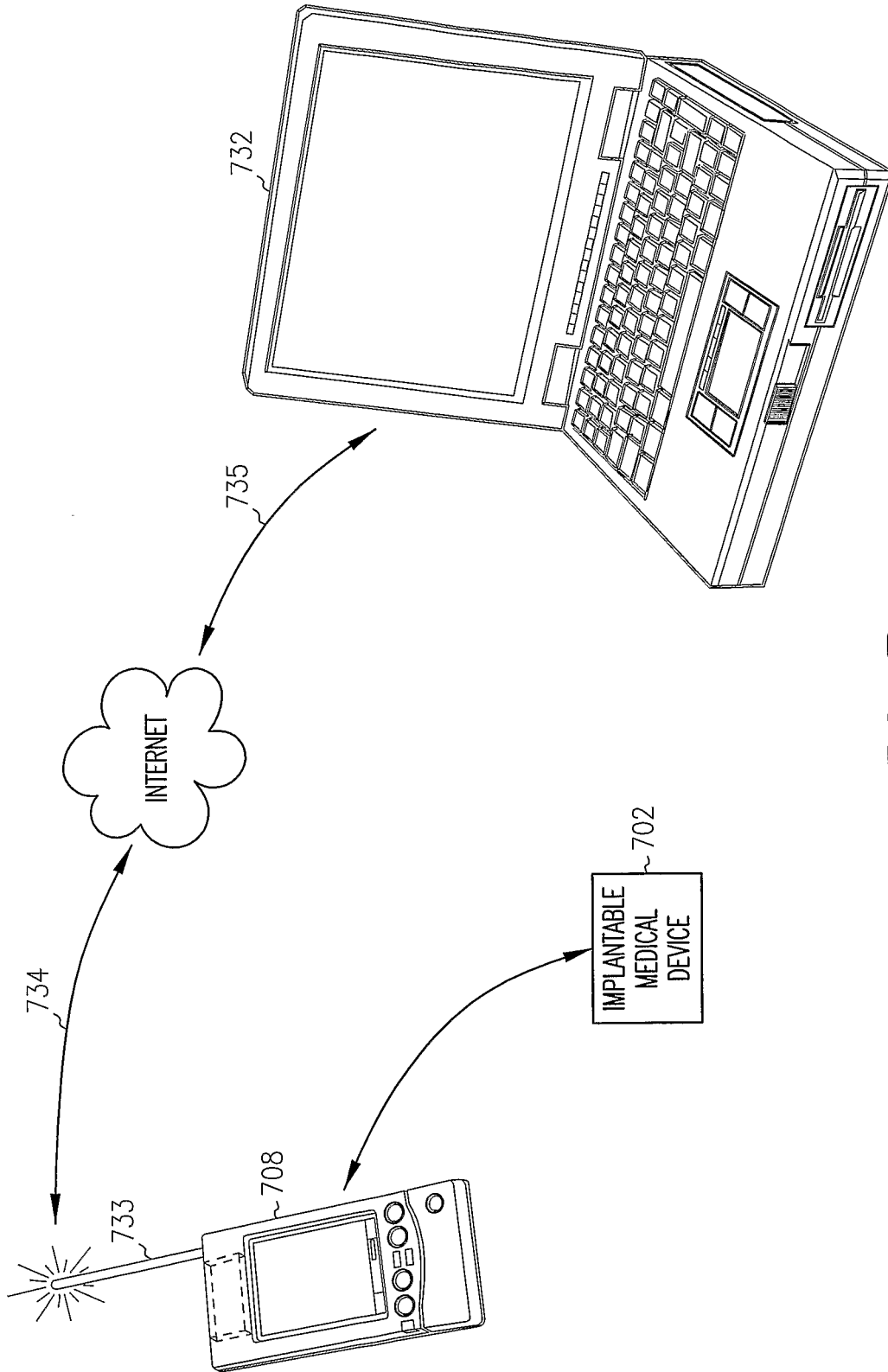


FIG. 7

6/21

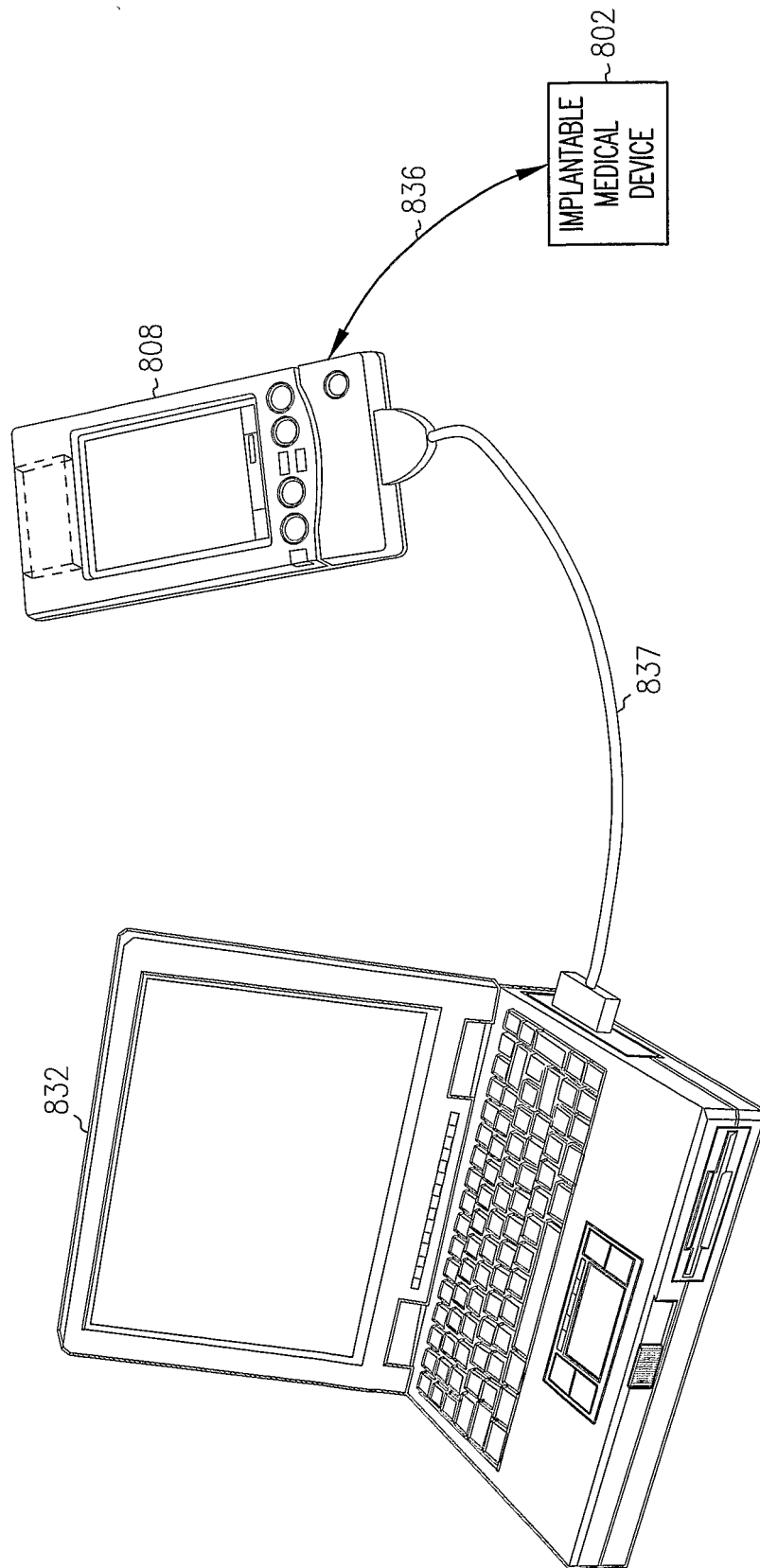


FIG. 8

7/21

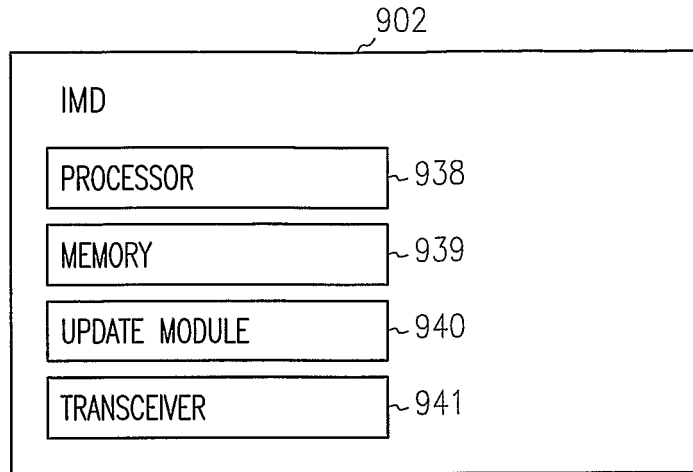


FIG. 9

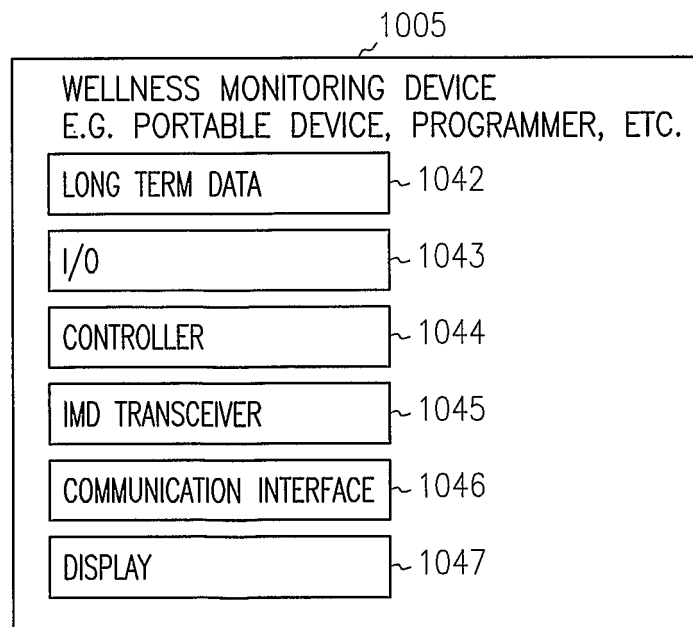


FIG. 10

8/21

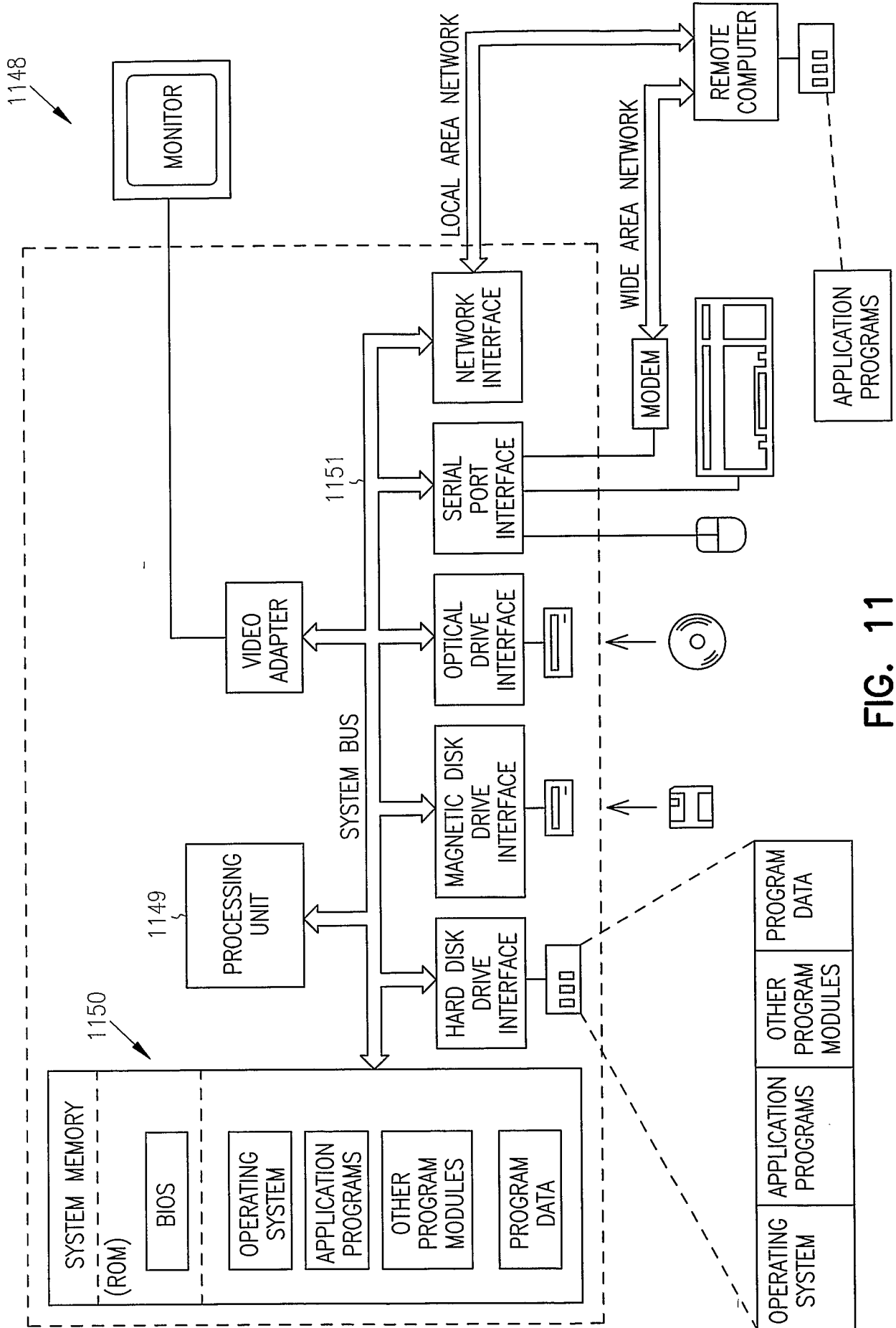


FIG. 11

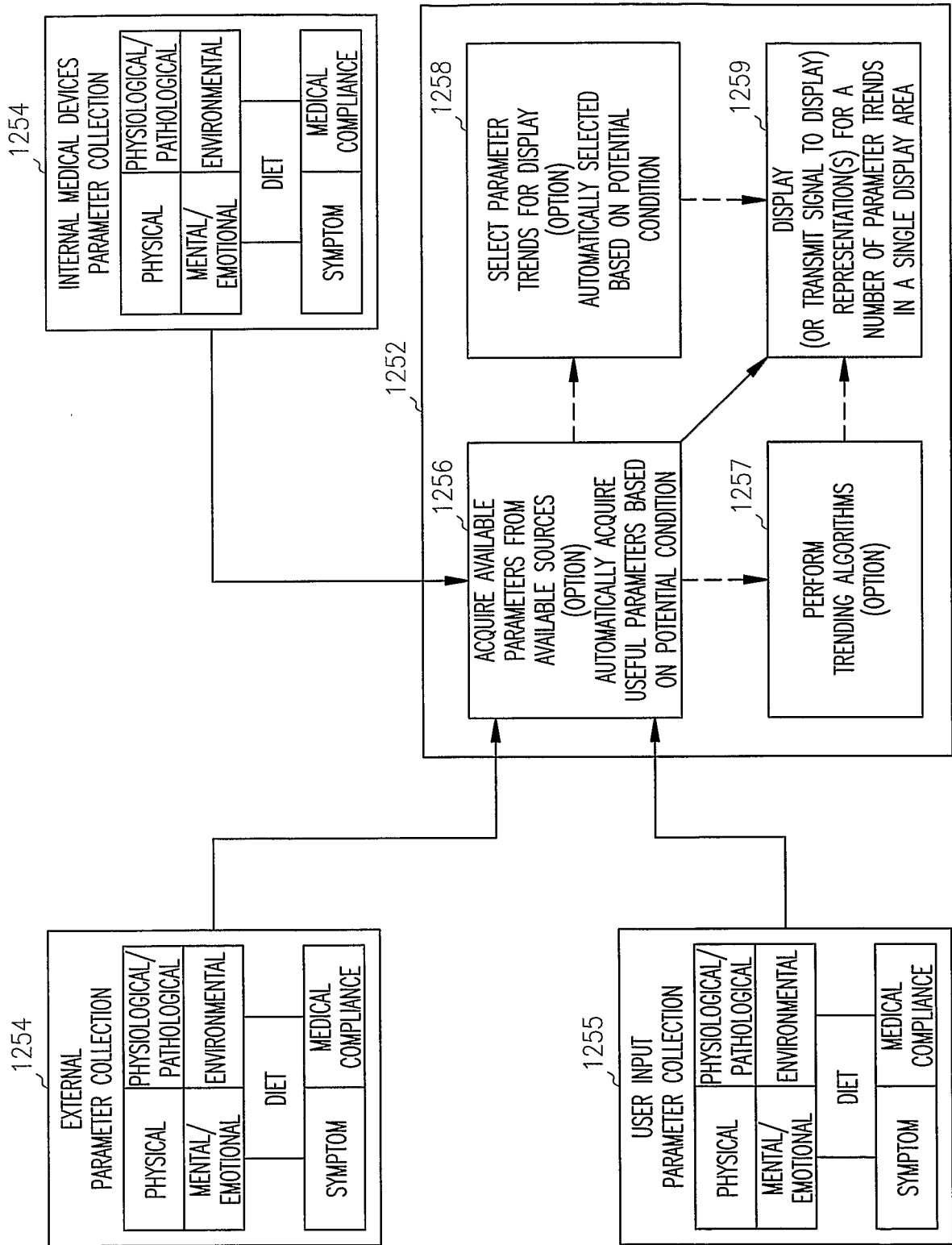


FIG. 12

10/21

1360

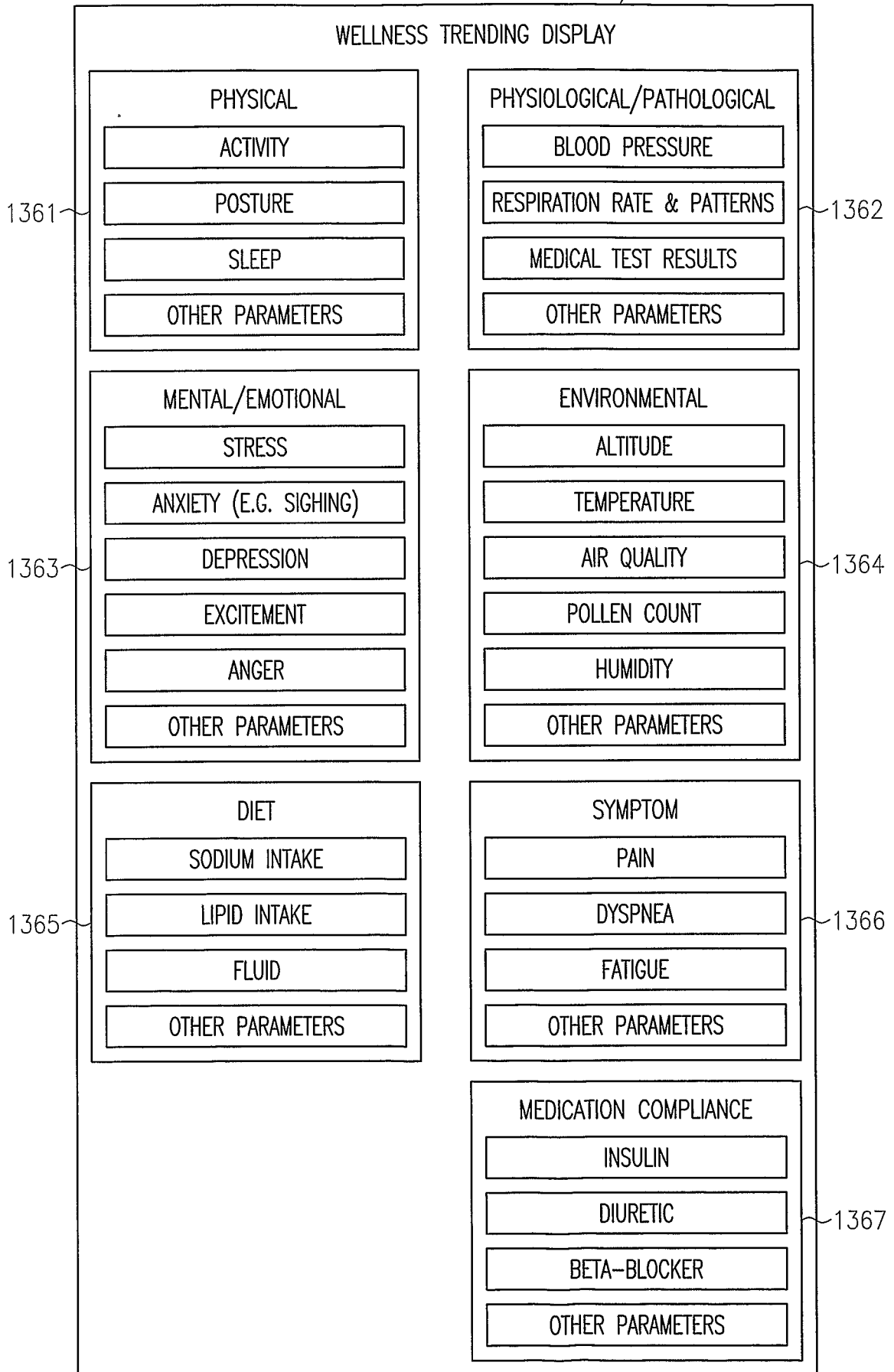


FIG. 13

11/21

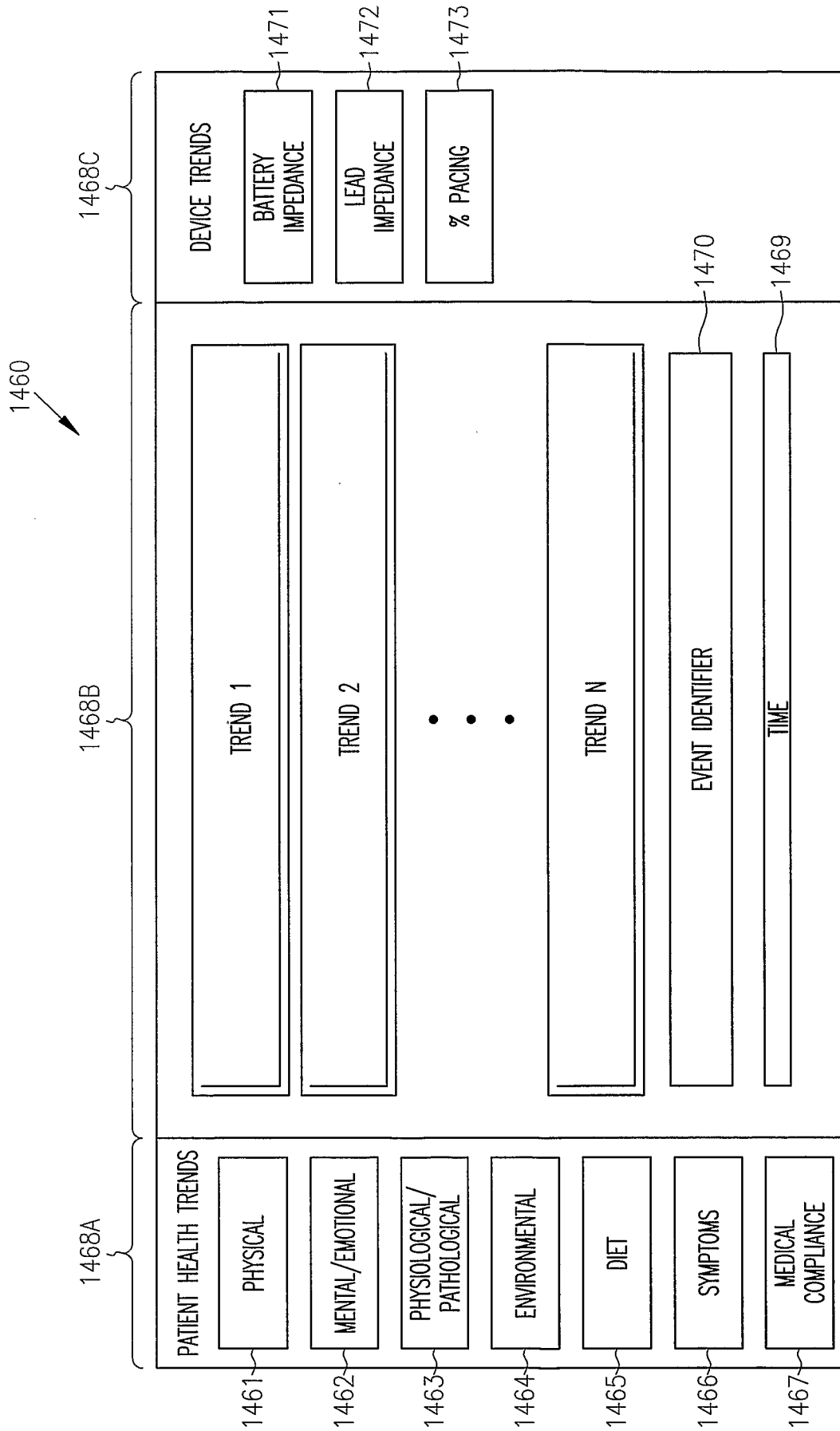


FIG. 14

12/21

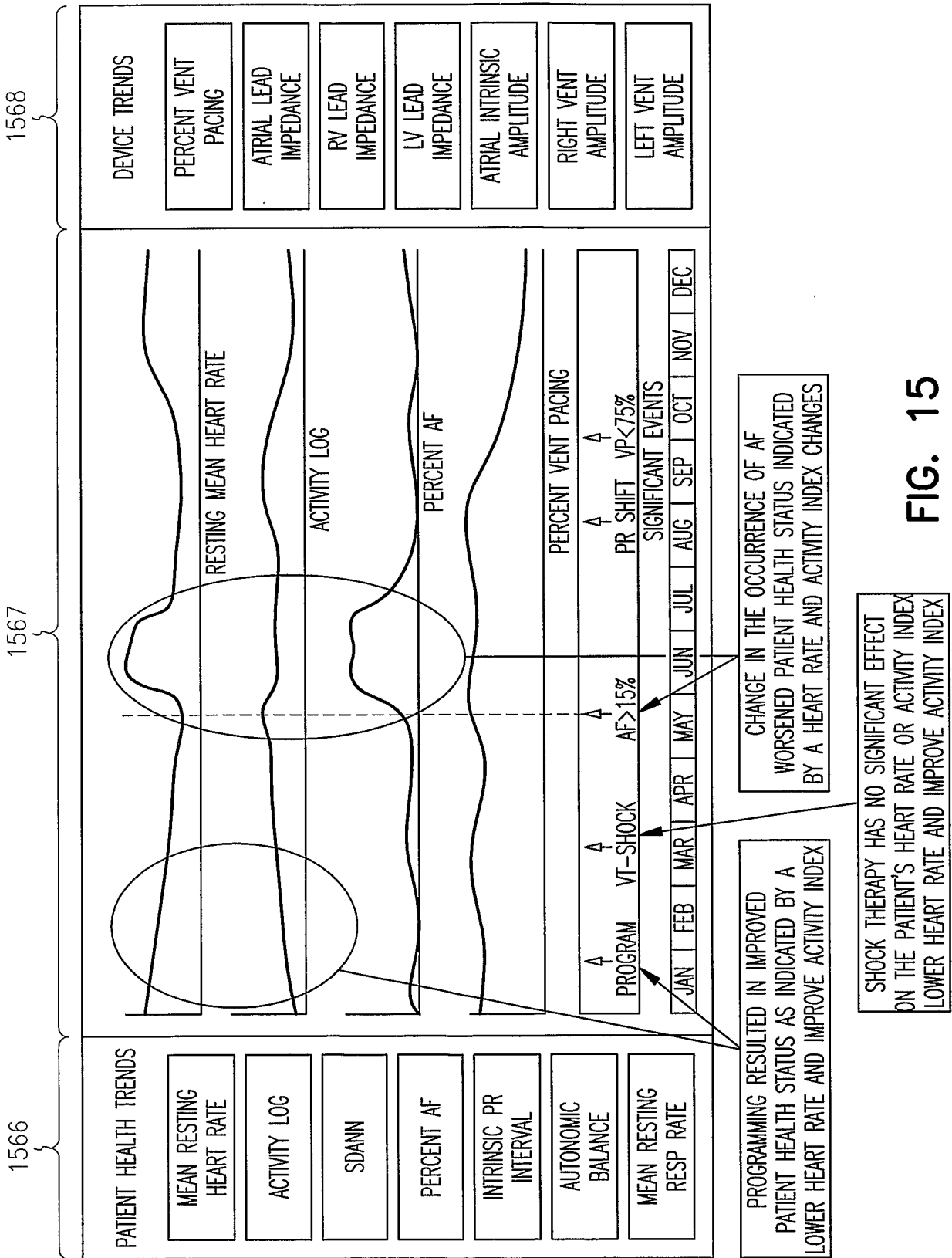


FIG. 15

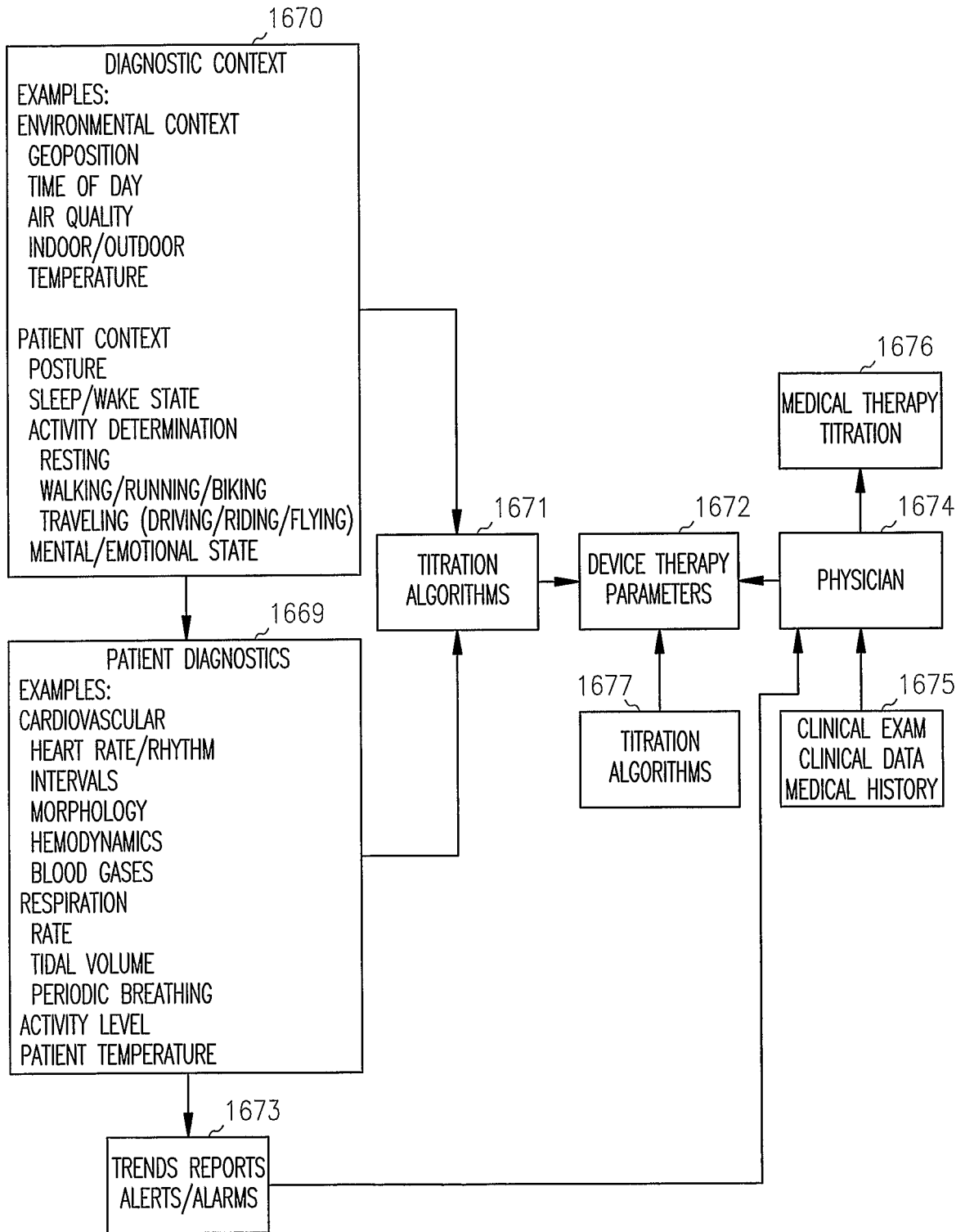


FIG. 16

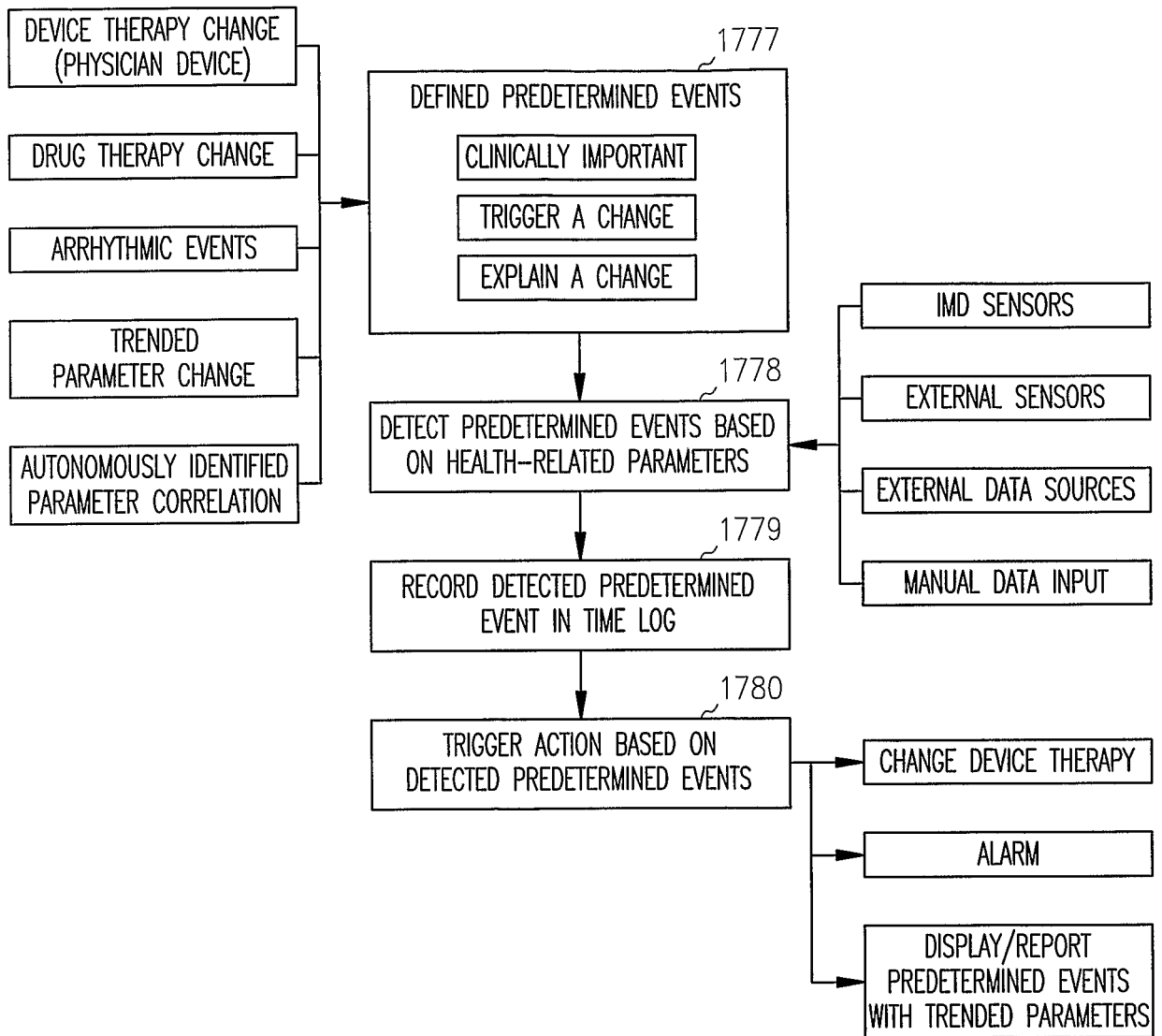


FIG. 17

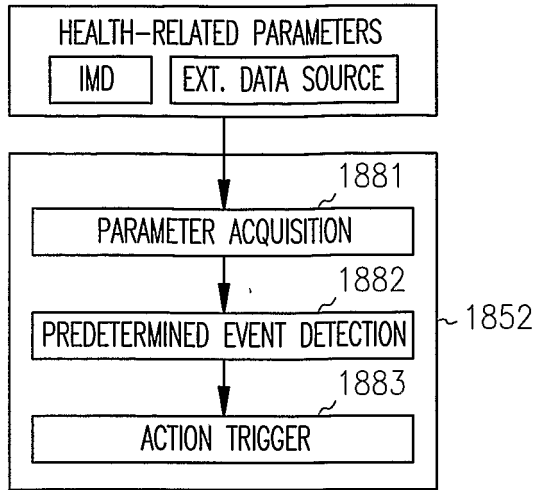


FIG. 18

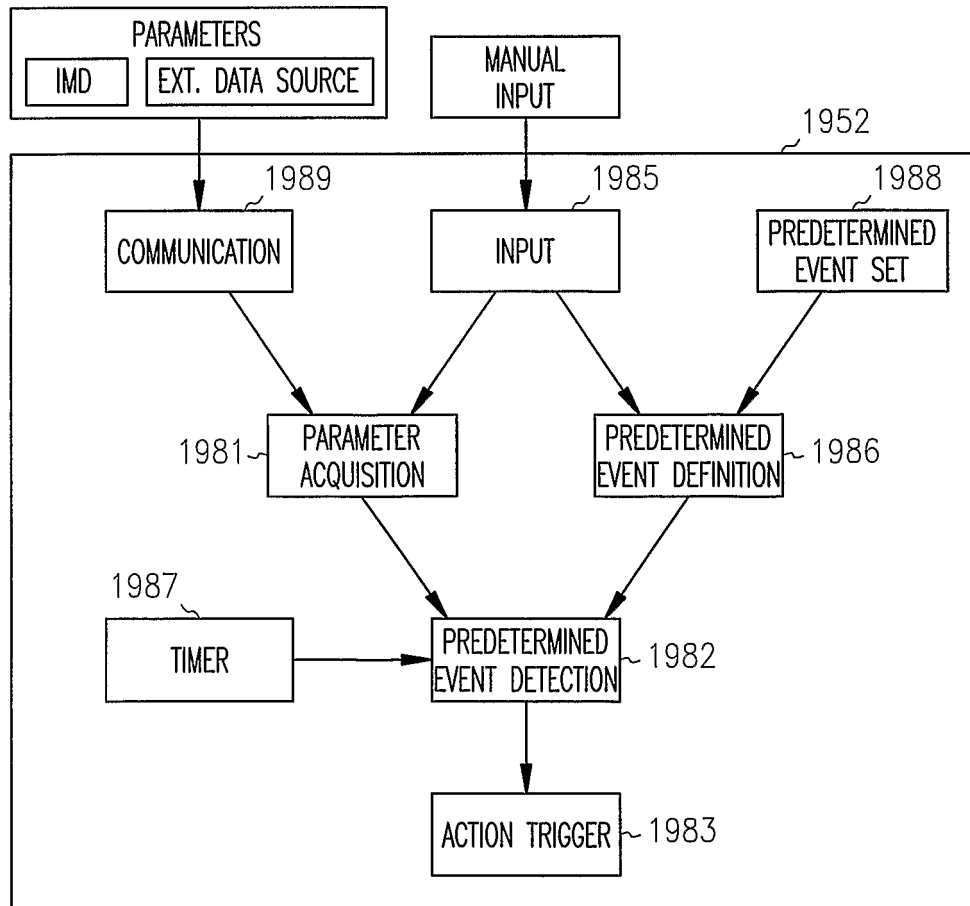


FIG. 19

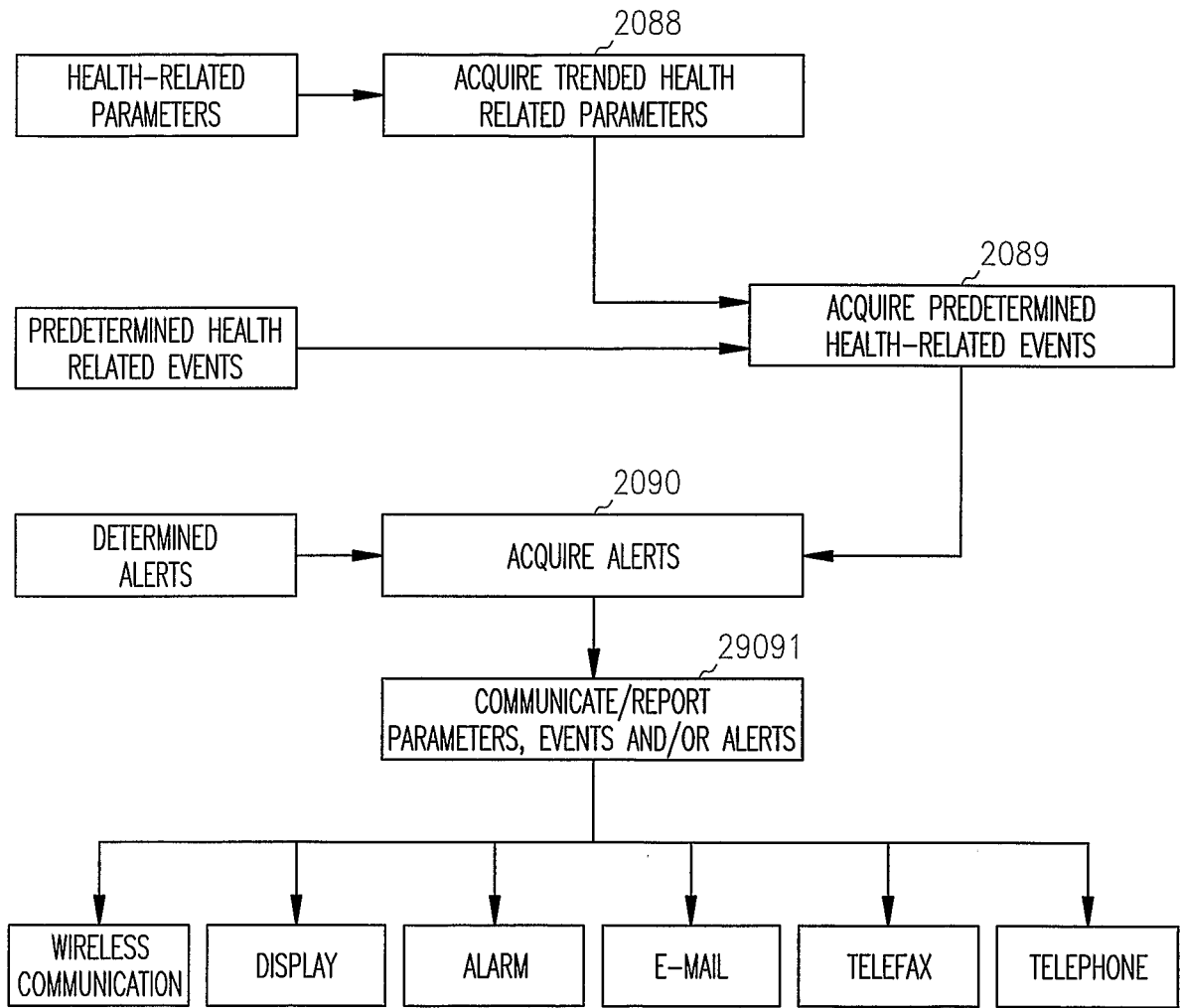


FIG. 20

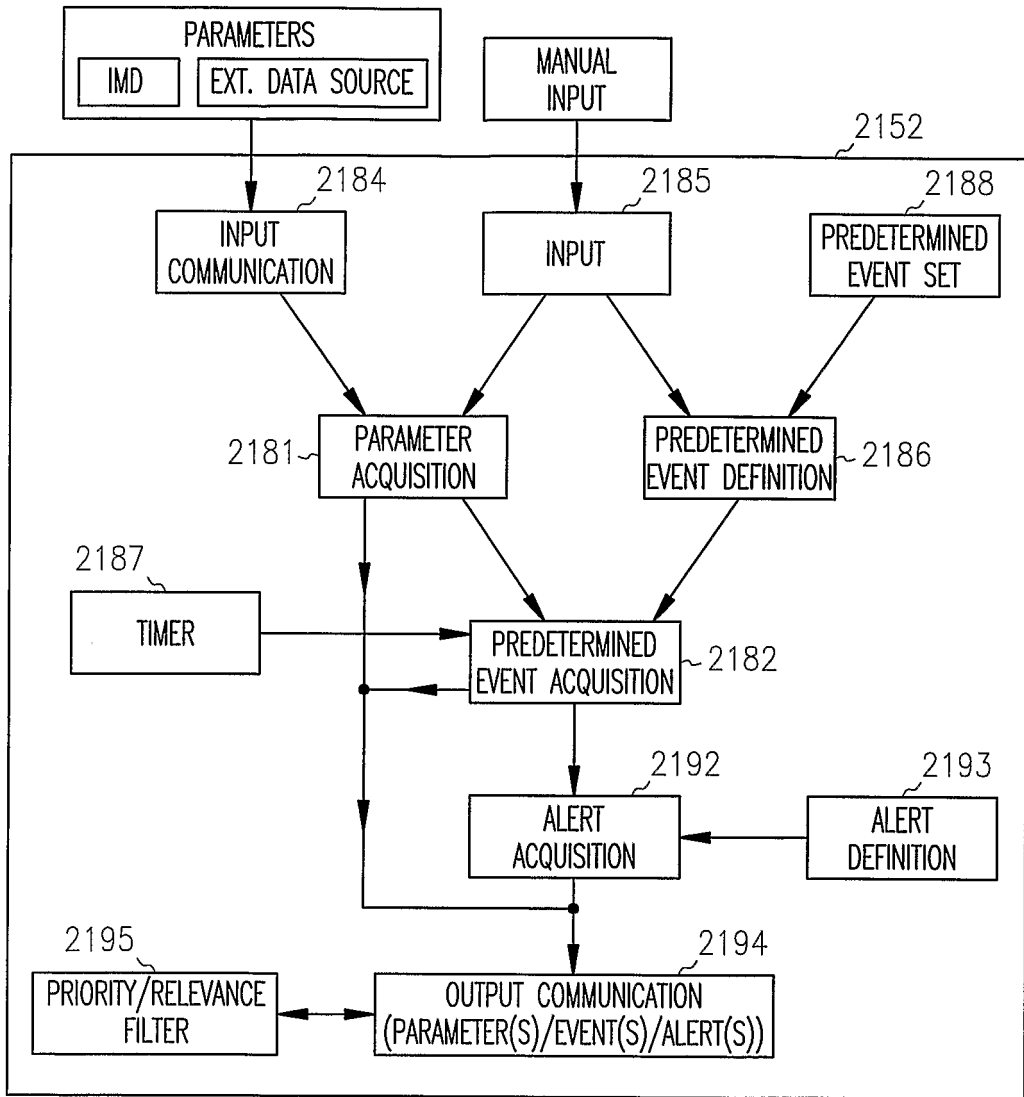


FIG. 21

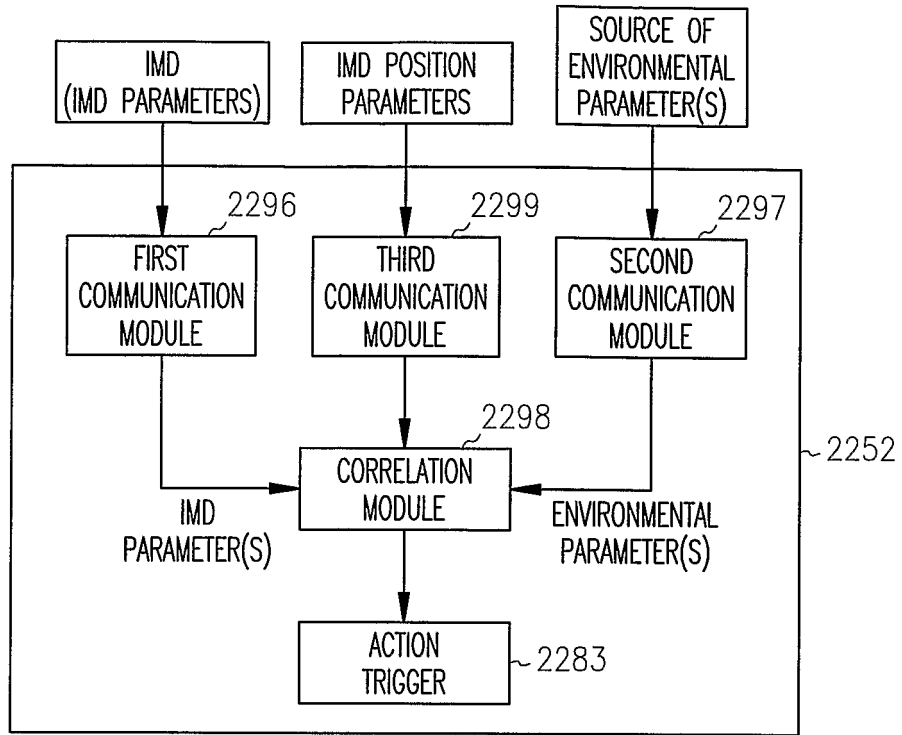


FIG. 22

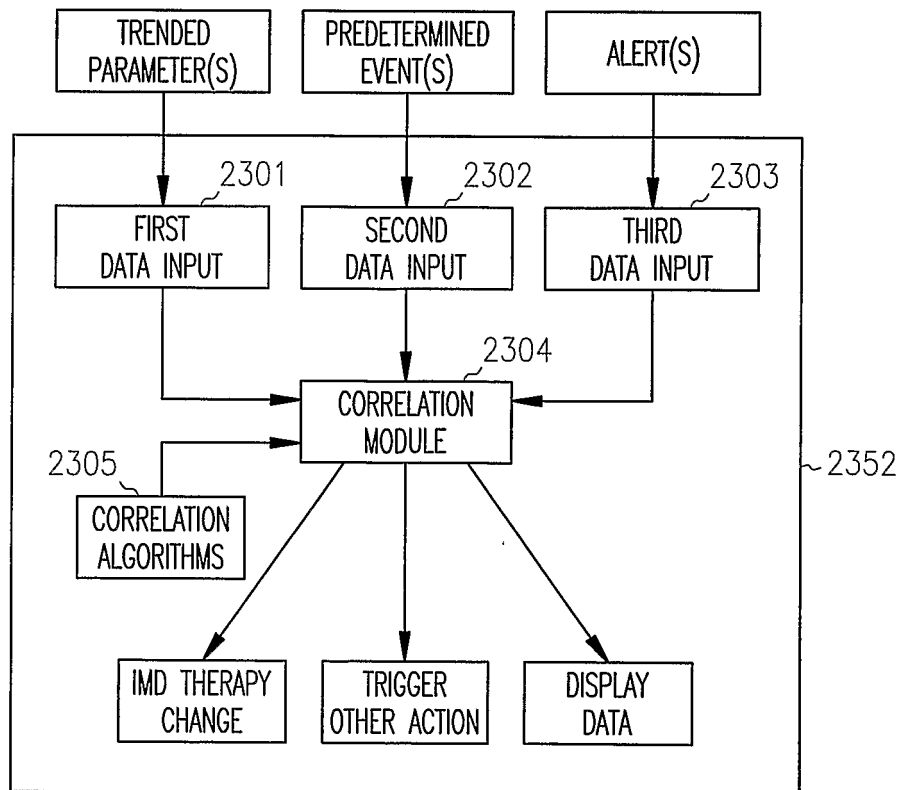


FIG. 23

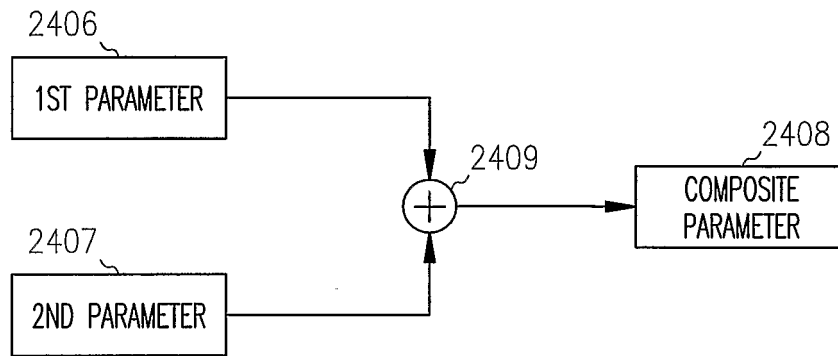


FIG. 24

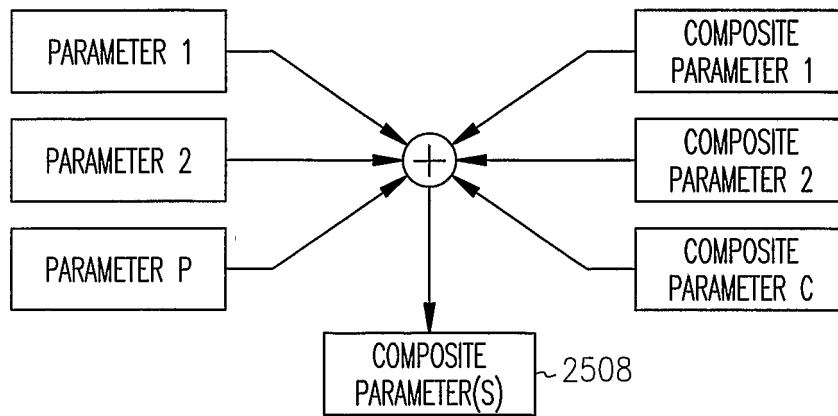


FIG. 25

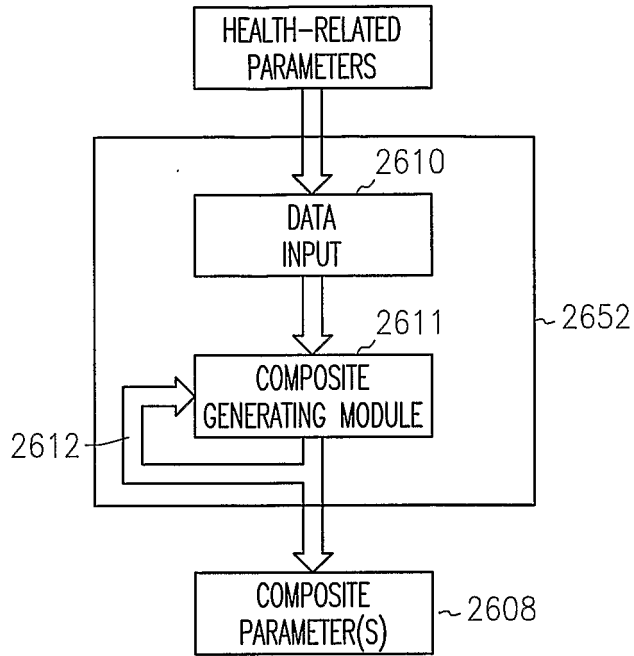


FIG. 26

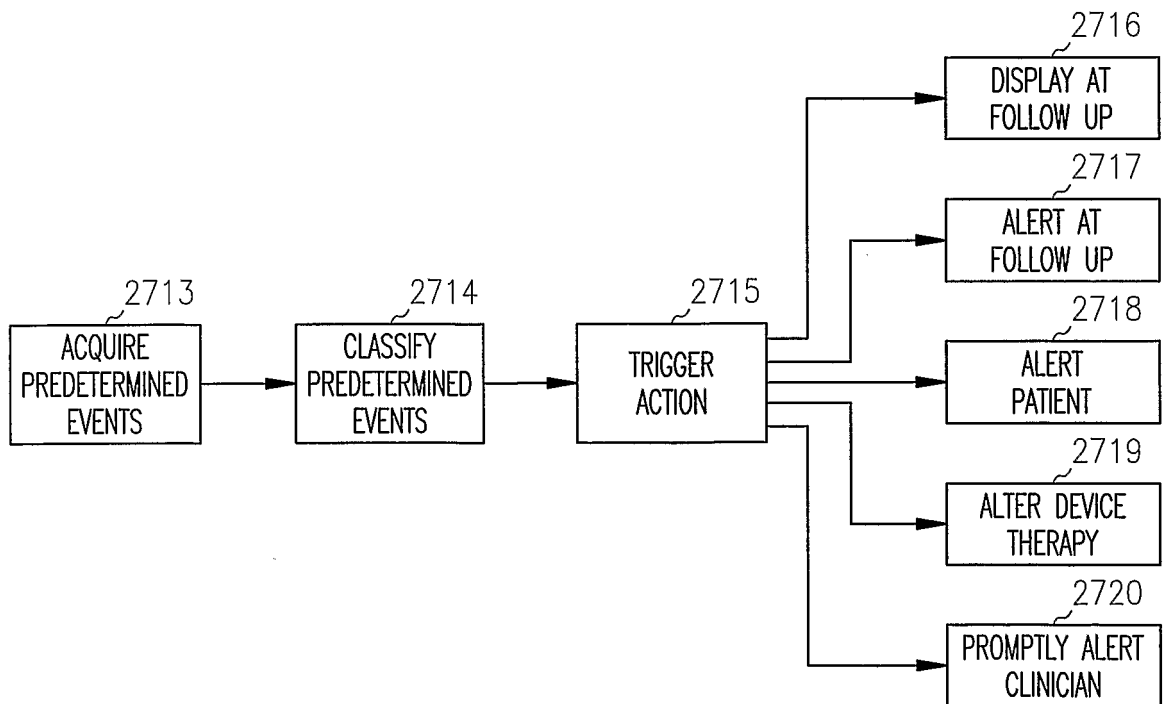


FIG. 27

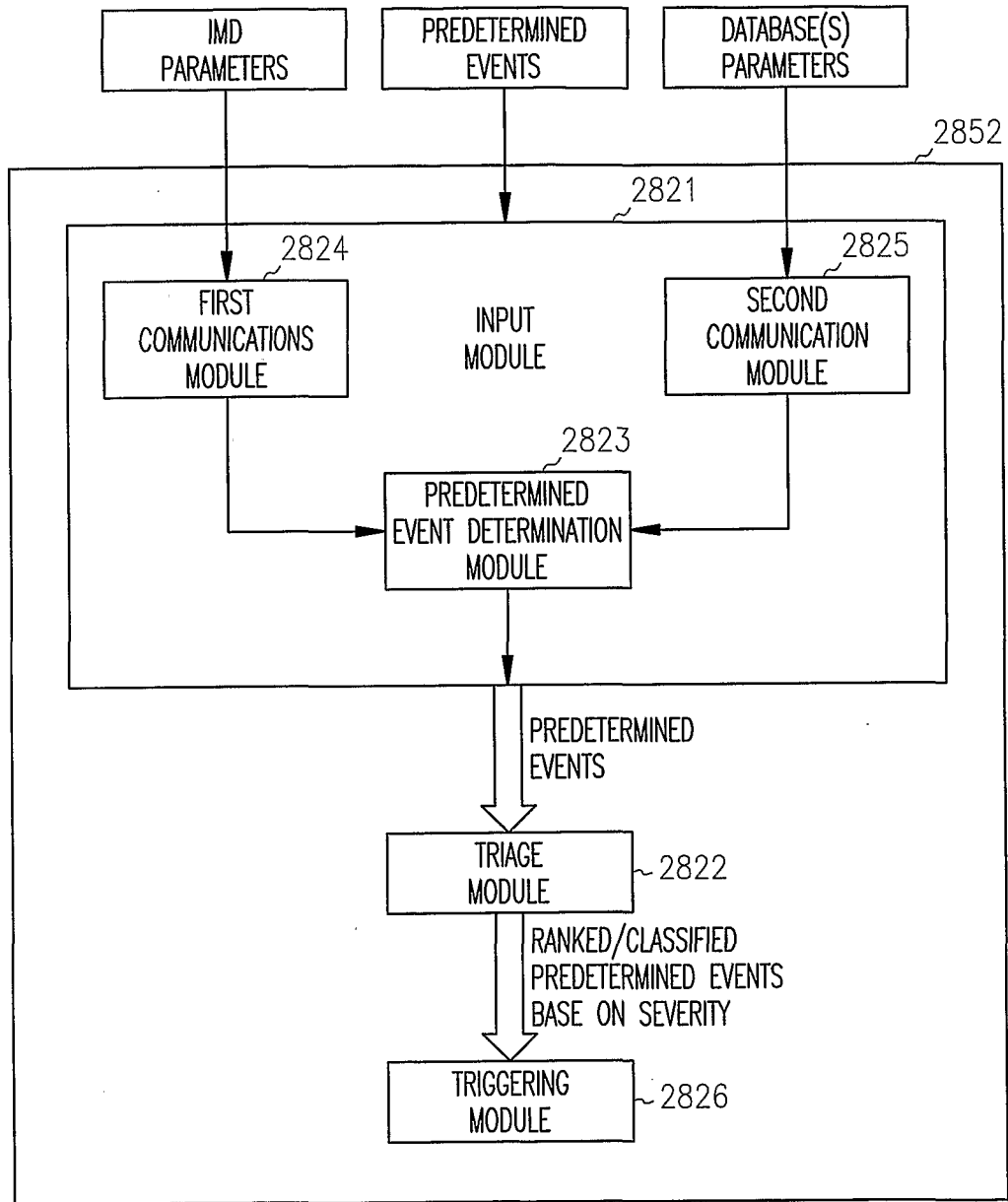


FIG. 28

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 03/40662

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61B5/00 A61B5/0205 G06F17/00		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61B G06F		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal, WPI Data		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/019586 A1 (PACIONE CHRISTOPHER D ET AL) 14 February 2002 (2002-02-14) paragraphs '0043!-'0047!, '0056!, '0057!, '0073!; figures; tables 1,2	1,3-17, 19-22, 26-33, 35,36,41
X	EP 0 709 058 A (TECHNOGYM SRL) 1 May 1996 (1996-05-01) column 2, line 18-39,45-49,55,56 column 3, line 18 -column 4, line 15; figure 1	1,3-7, 9-14,16, 17,21, 22,26, 28, 30-32, 36,41
<div style="display: flex; justify-content: space-between;"> <input checked="" type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex. </div>		
° Special categories of cited documents :		
A document defining the general state of the art which is not considered to be of particular relevance *E* earlier document but published on or after the international filing date *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) *O* document referring to an oral disclosure, use, exhibition or other means *P* document published prior to the international filing date but later than the priority date claimed	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. *&* document member of the same patent family	
Date of the actual completion of the international search <p style="text-align: center; font-weight: bold;">14 May 2004</p>	Date of mailing of the international search report <p style="text-align: center; font-weight: bold;">28/05/2004</p>	
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer <p style="text-align: center; font-weight: bold;">Küster, G</p>	

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 03/40662

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/24876 A (CARDIAC PACEMAKERS) 12 April 2001 (2001-04-12) page 10, line 1,2,16-19 page 19, line 10-16 page 23, line 22 -page 24, line 5 page 28, line 28 -page 29, line 14 ----	1,2,4, 8-10,17, 18,20, 22-25, 27,28, 32-36
X	WO 01/67948 A (GOOR DANIEL ;COTTER GAD (IL); MOSHKOVITZ YARON (IL)) 20 September 2001 (2001-09-20) page 3, line 1-4 page 4, line 21-28 ----	37
X	EP 0 297 675 A (HEUVELMANS JOHANNES H A ;GOSLINGA HIELTJE (NL)) 4 January 1989 (1989-01-04) column 7, line 8-10 ----	38
X	US 4 777 960 A (CHEN MING H ET AL) 18 October 1988 (1988-10-18) column 3, line 54 -column 4, line 31 column 7, line 28-39 ----	39
X	US 6 015 388 A (INMAN D MICHAEL ET AL) 18 January 2000 (2000-01-18) column 9, line 64 -column 10, line 25 -----	40

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 03/40662

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2002019586 A1	14-02-2002	US 6605038 B1	12-08-2003
		CA 2454655 A1	20-02-2003
		EP 1414340 A2	06-05-2004
		WO 03015005 A2	20-02-2003
		AU 7009201 A	08-01-2002
		BR 0111918 A	13-05-2003
		CA 2413148 A1	03-01-2002
		EP 1292218 A1	19-03-2003
		JP 2004500949 T	15-01-2004
		WO 0200111 A1	03-01-2002
		US 2004034289 A1	19-02-2004
		AU 6708301 A	24-12-2001
		CA 2413220 A1	20-12-2001
		EP 1292217 A2	19-03-2003
WO 0196986 A2	20-12-2001		
EP 0709058 A	01-05-1996	IT 80940472 A1	29-04-1996
		DE 69529717 D1	03-04-2003
		DE 69529717 T2	18-12-2003
		EP 0709058 A1	01-05-1996
WO 0124876 A	12-04-2001	US 6272377 B1	07-08-2001
		AU 7728700 A	10-05-2001
		EP 1218060 A1	03-07-2002
		WO 0124876 A1	12-04-2001
		US 2002120306 A1	29-08-2002
		US 2003055461 A1	20-03-2003
		US 2001020136 A1	06-09-2001
		US 2002016550 A1	07-02-2002
WO 0167948 A	20-09-2001	AU 4101201 A	24-09-2001
		CA 2402532 A1	20-09-2001
		CN 1422137 T	04-06-2003
		EP 1263317 A2	11-12-2002
		WO 0167948 A2	20-09-2001
		JP 2003526436 T	09-09-2003
		US 2003158493 A1	21-08-2003
EP 0297675 A	04-01-1989	NL 8701536 A	16-01-1989
		AT 120630 T	15-04-1995
		AU 627425 B2	27-08-1992
		AU 1956888 A	30-01-1989
		BR 8807593 A	29-05-1990
		CA 1333291 C	29-11-1994
		DE 3853495 D1	11-05-1995
		DE 3853495 T2	05-10-1995
		EP 0297675 A1	04-01-1989
		ES 2072860 T3	01-08-1995
		JP 1086935 A	31-03-1989
		JP 2109979 C	21-11-1996
		JP 8015483 B	21-02-1996
		WO 8900025 A1	12-01-1989
		US 5035246 A	30-07-1991
US 4777960 A	18-10-1988	CA 1298656 C	07-04-1992
		DE 3751813 D1	27-06-1996
		DE 3751813 T2	02-01-1997
		EP 0256887 A2	24-02-1988

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/40662

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4777960 A		JP 1634297 C JP 2057933 B JP 63068145 A	20-01-1992 06-12-1990 28-03-1988
US 6015388 A	18-01-2000	EP 0969763 A1 JP 2001516253 T WO 9841146 A1	12-01-2000 25-09-2001 24-09-1998

专利名称(译)	具有复合参数索引的高级患者管理		
公开(公告)号	EP1581104A1	公开(公告)日	2005-10-05
申请号	EP2003813800	申请日	2003-12-16
[标]申请(专利权)人(译)	心脏起搏器股份公司		
申请(专利权)人(译)	心脏起搏器, INC.		
当前申请(专利权)人(译)	心脏起搏器, INC.		
[标]发明人	HATLESTAD JOHN STAHMANN JEFFREY E ZHU QINGSHENG		
发明人	HATLESTAD, JOHN STAHMANN, JEFFREY, E. ZHU, QINGSHENG		
IPC分类号	A61B5/00 A61B5/024 A61B5/08 A61B5/091 G06F19/00 A61B5/0205 G06F17/00		
CPC分类号	A61B5/7475 A61B5/0031 A61B5/024 A61B5/02405 A61B5/0816 A61B5/091 A61B5/743 A61B2560/0271 G06F19/3475 G06F19/3481 G16H40/63 G16H50/30		
代理机构(译)	UEXKÜLL & STOLBERG		
优先权	10/323860 2002-12-18 US		
外部链接	Espacenet		

摘要(译)

公开了用于从健康相关参数定义, 识别和利用复合参数索引的装置和方法, 其中获取第一组至少两个健康相关参数, 并且使用第一组至少两个健康生成第一复合参数相关参数。一个方面是一种可编程设备, 其具有用于执行帮助管理患者健康的方法的机器可执行指令。本文提供了其他方面和实施方案。