US 20080027757A1

(19) United States

(12) Patent Application Publication

(10) Pub. No.: US 2008/0027757 A1

(43) Pub. Date: Jan. 31, 2008

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(54) SYSTEM AND METHOD FOR CORRELATING BIOMETRIC TRENDS WITH A RELATED TEMPORAL EVENT

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(21) Appl. No.: **11/869,611**

(22) Filed: **Oct. 9, 2007**

Related U.S. Application Data

(63) Continuation of application No. 10/335,396, filed on Jan. 3, 2003.

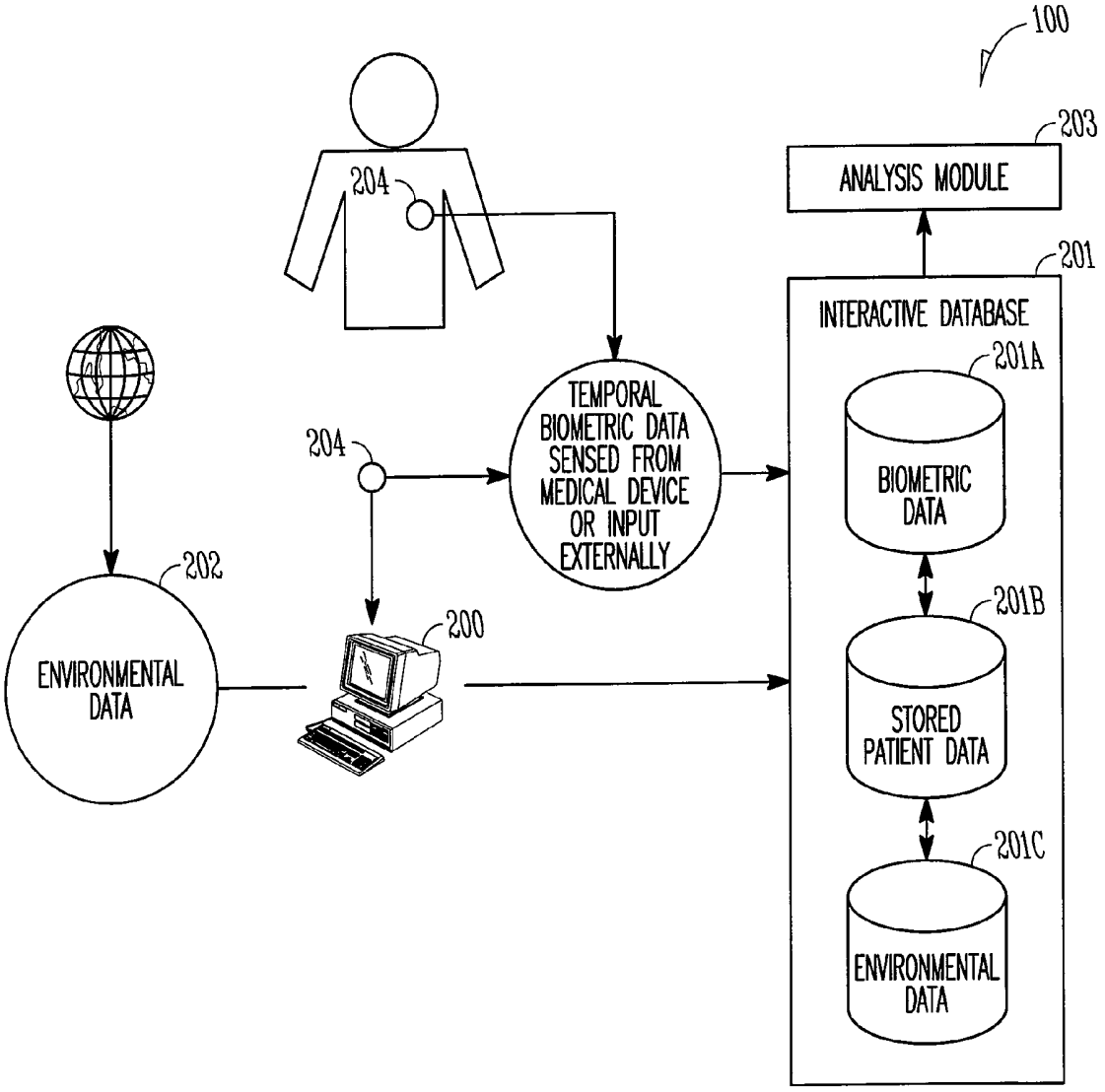
Publication Classification

(51) **Int. Cl.**
G06Q 50/00 (2006.01)

(52) **U.S. Cl.** **705/2**

(57) **ABSTRACT**

Systems and methods for correlating biometric trends with a related temporal event are disclosed. A preferred embodiment utilizes an implantable medical device comprising at least one sensor in electronic communication with a patient management system adapted to temporally analyze and correlate biometric data. Some embodiments of a system disclosed herein also can be configured as an Advanced Patient Management system that helps better monitor, predict and manage chronic diseases.



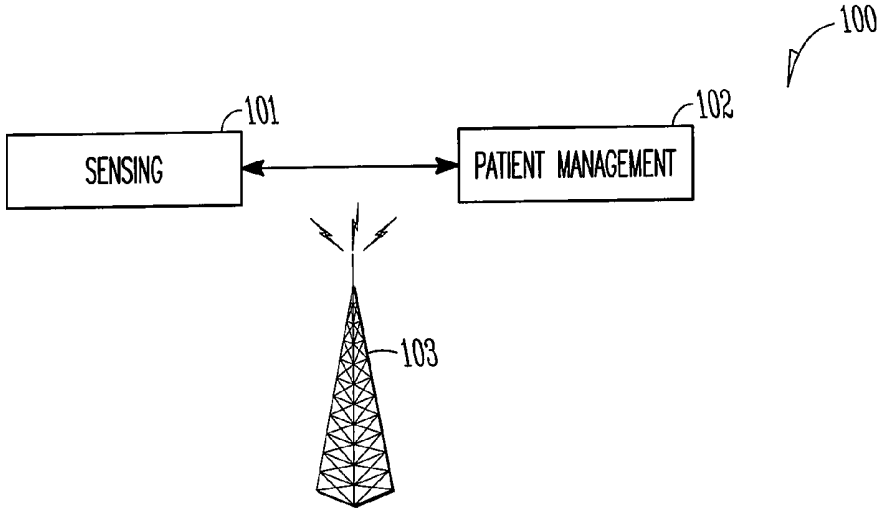

100
101
SENSING
102
PATIENT MANAGEMENT
103

FIG. 1

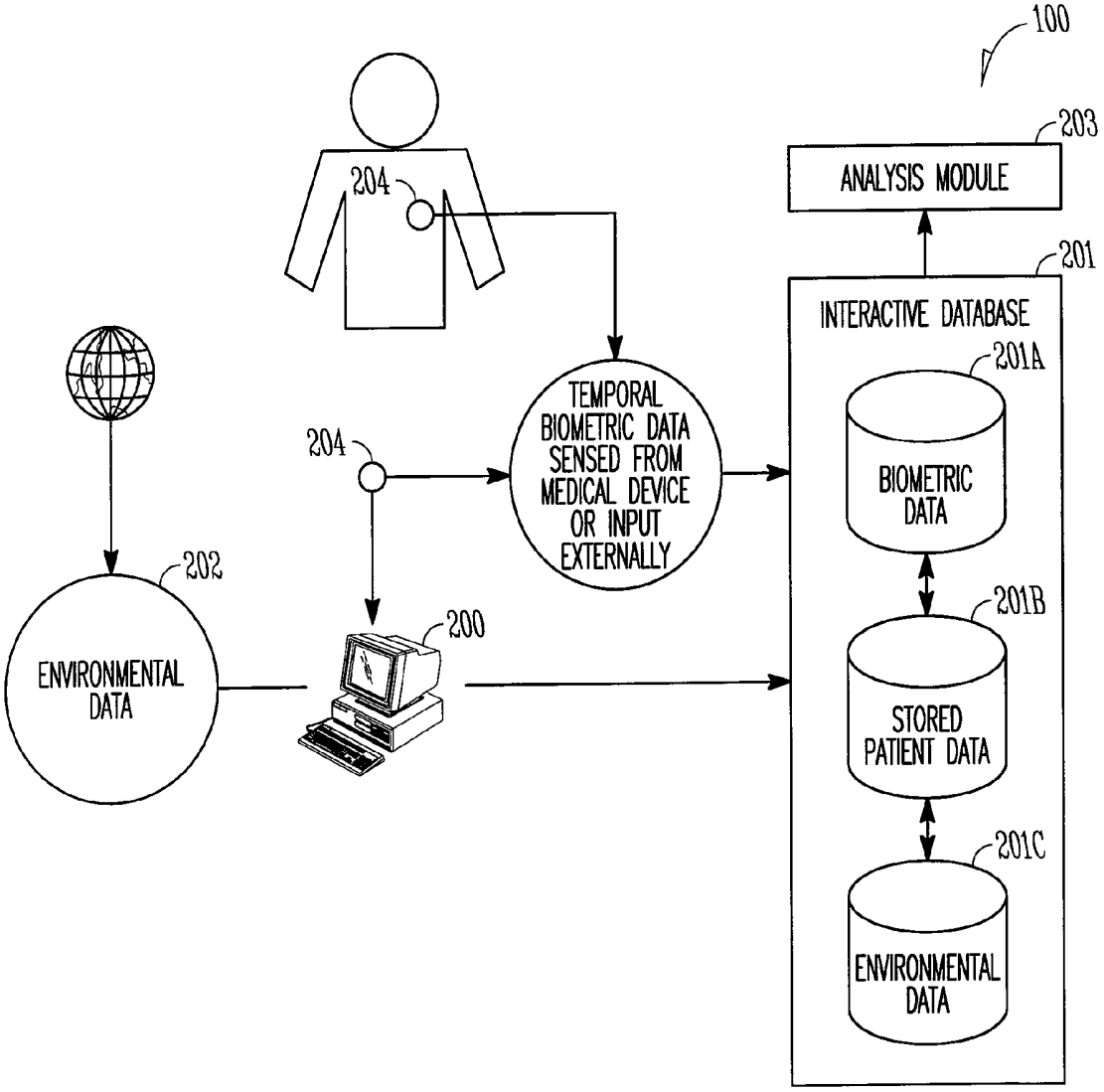

100
203
ANALYSIS MODULE
204
201
INTERACTIVE DATABASE
201A
TEMPORAL BIOMETRIC DATA SENSED FROM MEDICAL DEVICE OR INPUT EXTERNALLY
BIOMETRIC DATA
204
202
201B
200
ENVIRONMENTAL DATA
STORED PATIENT DATA
201C
ENVIRONMENTAL DATA

FIG. 2

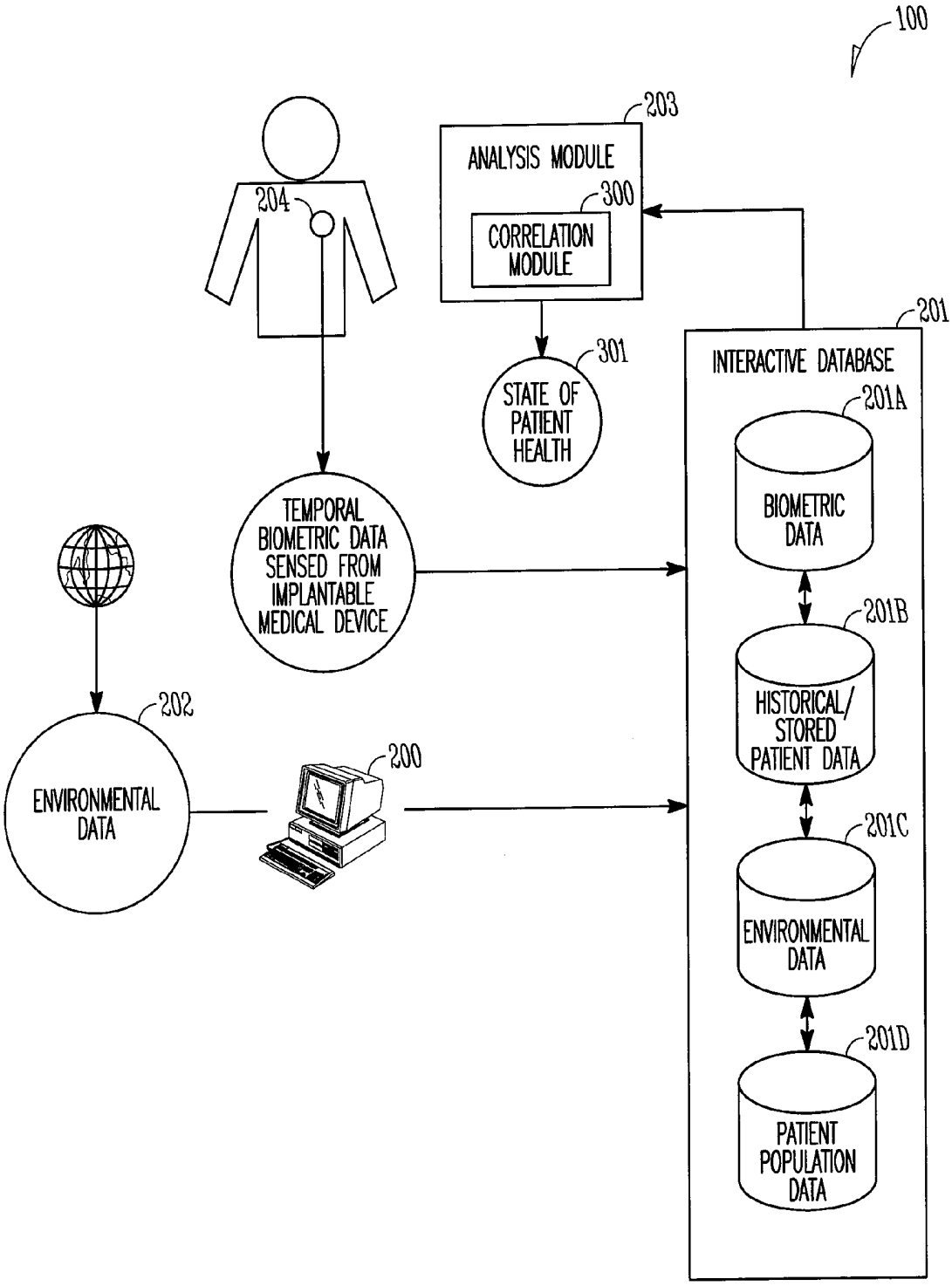

100
203
ANALYSIS MODULE
300
CORRELATION MODULE
204
301
STATE OF PATIENT HEALTH
201
INTERACTIVE DATABASE
201A
BIOMETRIC DATA
TEMPORAL BIOMETRIC DATA SENSED FROM IMPLANTABLE MEDICAL DEVICE
201B
HISTORICAL/ STORED PATIENT DATA
202
ENVIRONMENTAL DATA
200
201C
ENVIRONMENTAL DATA
201D
PATIENT POPULATION DATA

FIG. 3

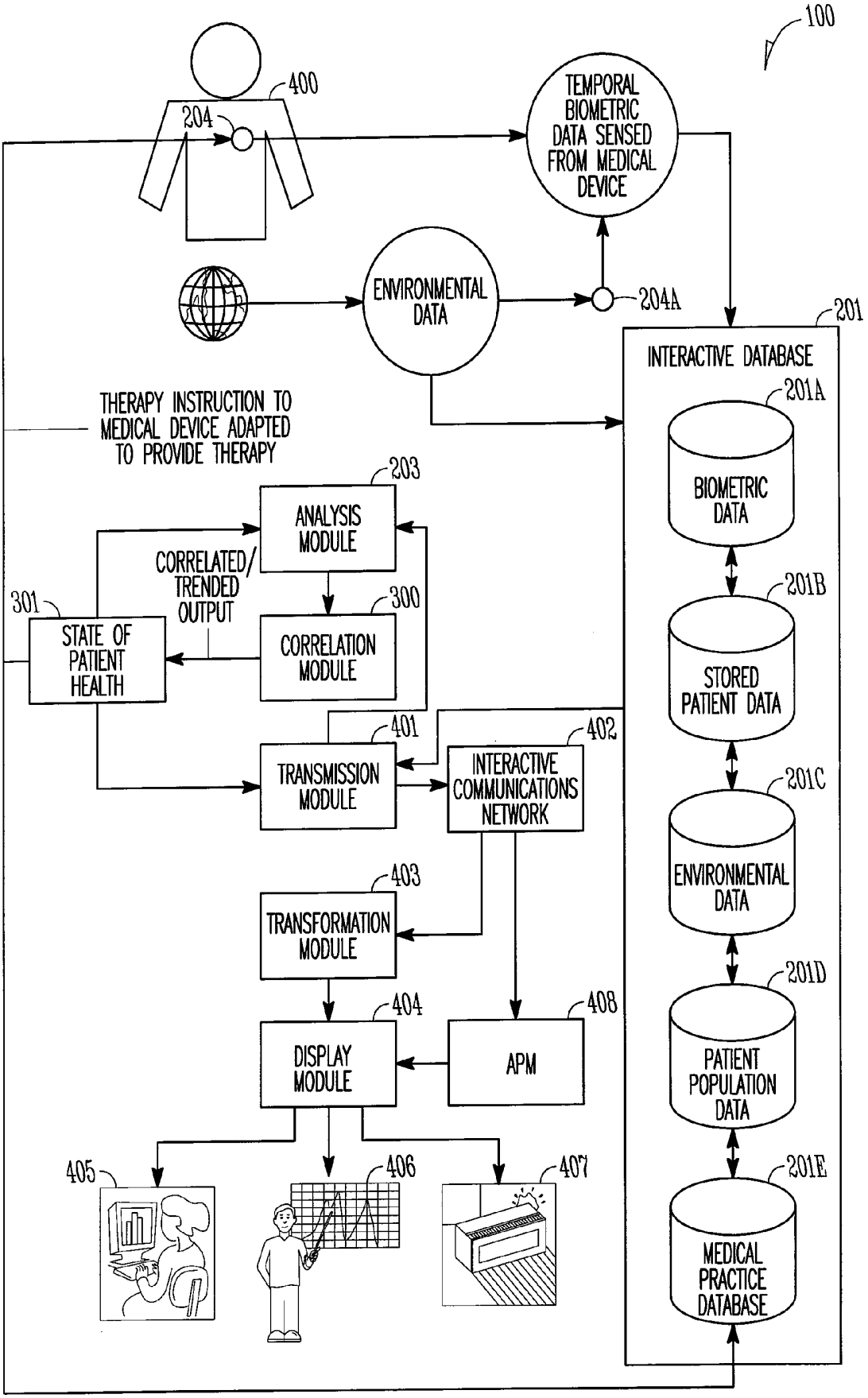

100
400
204
TEMPORAL BIOMETRIC DATA SENSED FROM MEDICAL DEVICE
ENVIRONMENTAL DATA
204A
201
INTERACTIVE DATABASE
201A
BIOMETRIC DATA
201B
STORED PATIENT DATA
201C
ENVIRONMENTAL DATA
201D
PATIENT POPULATION DATA
201E
MEDICAL PRACTICE DATABASE
THERAPY INSTRUCTION TO MEDICAL DEVICE ADAPTED TO PROVIDE THERAPY
203
ANALYSIS MODULE
CORRELATED/ TRENDED OUTPUT
301
STATE OF PATIENT HEALTH
300
CORRELATION MODULE
401
TRANSMISSION MODULE
402
INTERACTIVE COMMUNICATIONS NETWORK
403
TRANSFORMATION MODULE
404
DISPLAY MODULE
408
APM
405
406
407

FIG. 4

SYSTEM AND METHOD FOR CORRELATING BIOMETRIC TRENDS WITH A RELATED TEMPORAL EVENT

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. patent application Ser. No. 10/335,396, filed on Jan. 3, 2003, the specification of which is incorporated herein by reference.

TECHNICAL FIELD

[0002] The present device relates generally to a Patient Management System and particularly, but not by way of limitation, to such a system that is adapted to correlate biometric information or trends to a specific temporal event to provide a snapshot of patient health.

BACKGROUND

[0003] Management of patients with chronic disease consumes a significant proportion of the total health care expenditure in the United States. Many of these diseases are widely prevalent and have significant annual incidences as well. Heart failure prevalence alone is estimated at over 5.5 million patients in 2000 with incidence rates of over half a million additional patients annually, resulting in a total health care burden in excess of $20 billion. Heart failure, like many other chronic diseases such as asthma, chronic obstructive pulmonary disease ("COPD"), chronic pain, and epilepsy is event driven, where acute episodes of disease result in hospitalization. In addition to causing considerable physical and emotional trauma to the patient and family, event driven hospitalizations consume a majority of the total health care expenditure allocated to the treatment of heart failure.

[0004] An interesting fact about the treatment of acute episodes of disease is that hospitalization and treatment occurs after the acute event has happened. However, most Heart Failure patients exhibit prior non-traumatic symptoms, such as steady weight gain, in the weeks or days prior to the acute episode. If the physician is made aware of these symptoms, it is possible to intervene before the event, at substantially less cost to the patient and the health care system.

[0005] Intervention before the event is usually in the form of a re-titration the patient's drug cocktail, reinforcement of the patient's compliance with the prescribed drug regimen, or acute changes to the patient's diet and exercise. Such intervention is usually effective in preventing the acute episode and thus avoiding hospitalization. NYHA Class III and late Class II HF patients often have acute episodes three or four times annually, each episode resulting in hospital stays of three or four days.

[0006] However, many acute episodes of disease can be predicted by analyzing biometric trends. Predictive accuracy may be improved by analyzing such biometric trends in view of clinically derived algorithms. In practice, the algorithmic analysis of contemporaneous biometric information or data in reference to a temporal event can report and assist in the identification of a state of patient health or disease progression. Yet, data collection and rapid analysis is a limiting factor in effectively using clinical algorithms to report such states of patient health.

[0007] Thus, for these and other reasons, there is a need for a system and method for efficiently and effectively reporting a state of patient health or disease progression by correlating biometric information or trends with a related temporal event and alerting the patient or physician of the state of patient health or disease progression.

SUMMARY

[0008] According to one aspect of the invention, there is provided a system and method for correlating sensed biometric information or trends using clinically derived algorithms to report a state of patient health. The report of patient health enables a patient or clinician to examine and further analyze a state of health or disease progression in view of a temporal event that may confer additional clinical meaning to or understanding of the reported state of health. The system also may deliver therapy when configured as an implantable medical device.

[0009] In one embodiment, the system comprises at least one sensor to sense biometric data, an interactive database, an analysis module to analyze the biometric data, a correlation module to correlate the biometric data with a temporal event, an electronic transmission module to transmit the output to an interactive communications network, a transformation module to transform transmitted output to a recognizable clinical result, and a display module to display the transformed output. By way of non-limiting example only, a temporal event may comprise a change in patient medication, a heart attack, physical injury, dates of personal interest, or other events.

[0010] In another embodiment, the interactive communications network comprises a sensor implanted within a patient, a host in communication with the sensor comprising means to input biometric and/or environmental data to an interactive database, an analysis module to analyze biometric data, and a delivery module that communicates the analyzed data in the form of an identified state of patient health via the communications network.

[0011] In yet another embodiment, the system comprises a plurality of interactive databases adapted to store historical and patient population data. In this embodiment, the system is adapted to provide therapy to a patient through a specially adapted implantable medical device based on the identified state of patient health. The implantable medical device may also comprise a sensor. The sensor can be internal or external. External sensors may be adapted to record environmental data. The system also may comprise a diagnostic module for diagnosing the performance of the sensor and the interactive communications network.

[0012] In a preferred embodiment of the system and method for correlating biometric trends with a related temporal event, the identified state of patient health is made by analyzing biometric data in view of clinically derived algorithms and monitoring the success of previous identifications of a state of patient health. If warranted by the identified state of patient health, the display module displays a configurable alert for action in the form of a clinically relevant graphic or an audible signal.

[0013] The various embodiments described above are provided by way of illustration only and should not be construed to limit the invention. Those skilled in the art will

readily recognize various modifications and changes that may be made to the present invention without following the example embodiments and applications illustrated and described herein, and without departing from the true spirit and scope of the present invention, which is set forth in the following claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] In the drawings, which are not necessarily drawn to scale, like numerals describe substantially similar components throughout the several views. Like numerals having different letter suffixes represent different instances of substantially similar components. The drawings illustrate generally, by way of example, but not by way of limitation, various embodiments discussed in the present document.

[0015] FIG. **1** is a schematic/block diagram illustrating generally, among other things, one embodiment of the system and method for correlating biometric trends with a related temporal event.

[0016] FIG. **2** is a schematic/block diagram illustrating generally, among other things, another embodiment of the system and method for correlating biometric trends with a related temporal event comprising an interactive database and analysis module.

[0017] FIG. **3** is a schematic/block diagram illustrating generally, among other things, another embodiment of the system and method for correlating biometric trends with a related temporal event of the present invention comprising a correlation module as a component of an analysis module in electronic communication with an interactive database to report a state of patient health.

[0018] FIG. **4** is a schematic/block diagram illustrating generally, among other things, another embodiment of the system and method for correlating biometric trends with a related temporal event comprising an Advanced Patient Management system in electronic communication with the components of the system.

DETAILED DESCRIPTION

[0019] In the following detailed description, reference is made to the accompanying drawings that form a part hereof, and in which is shown by way of illustration specific embodiments or examples. These embodiments may be combined, other embodiments may be utilized, and structural, logical, and electrical changes may be made without departing from the spirit and scope of the present invention. The following detailed description is, therefore, not to be taken in a limiting sense, and the scope of the present invention is defined by the appended claims and their equivalents.

[0020] The present system and method are described with respect to a system and method that is adapted to report a state of patient health by correlating biometric data or trends with a related temporal event. In this way, the system can provide appropriate therapy to a patient in its embodiment as an implantable medical device or provide a clinician with retrospective environmental and/or perceptual data in time coincidence with objective implanted sensor data. The term "biometric" generally refers to the measurement of a living, human characteristic. The term "Advanced Patient Management" refers to the process of creating and collecting patient specific information, storing and collating the information, and generating actionable recommendations to enable the predictive management of patients with chronic disease. The term "temporal event" refers to events in a patient's environment that may or may not cause a health state change. The term "correlation" refers to time coincident events that have been analyzed for causation and health consequence outcome.

[0021] FIG. **1** is a schematic/block diagram illustrating generally one embodiment of a system and method for correlating biometric trends with a related temporal event to report a state of patient health. The system **100** further comprises at least one sensor **101** in electronic communication **103** with a patient management system **102** to allow automatic transmission of sensed biometric data to the patient management system **102**. Such electronic communication may include wired and/or wireless communication technologies.

[0022] FIG. **2** is a schematic/block diagram illustrating generally another embodiment of the system and method for correlating biometric trends with a related temporal event comprising external means **200** to enter biometric **201***a* and/or environmental data **202**, **201***c* into at least one interactive database **201** for analysis by an analysis module **203**. Environmental data may include temperature, atmospheric pressure, humidity, stress, drug change, diet change, emotional state and/or other objective or subjective data. The database **201** stores data from internal and/or external sensors **204**, medical records **201***b* of a patient, and environmental data **202**, **201***c*. The analysis module **203** identifies a state of patient health based on the information stored in the database **201**.

[0023] FIG. **3** is a schematic/block diagram illustrating generally an embodiment of a correlation module **300** of the system and method for correlating biometric trends with a related temporal event. In addition to at least one internal sensor **204** to sense biometric data and at least one interactive database **201**, the system further comprises a correlation module **300** to correlate the biometric data **201***a* against reference data to create a biometric data set. The reference data may include historical/stored patient data **201***b*, environmental data **201***c* and patient population data **201***d*. Historical patient data may comprise the patient's medical history as manually or electronically entered into the historical/stored patient database **201***b*. Correlation module **300** may comprise a component of analysis module **203**. Biometric **201***a* and reference data sets **201***b*, **201***c* and **201***d* are transmitted to correlation module **300**. Correlation module **300** then correlates the biometric data set with a temporal event to create an output that identifies a state of patient health **301**.

[0024] FIG. **4** is a schematic/block diagram illustrating generally an embodiment of sensors **204** implanted within a patient **400** of the system and method for correlating biometric trends with a related temporal event. The system further comprises an electronic transmission module **401** and an interactive communications network **402**. In this embodiment, the correlated output **301** is transmitted via the electronic transmission module **401** to an interactive communications network **402**. The output **301** may be transformed by a transformation module **403** and displayed to a clinician or patient **405** via a display module **404** in a human-recognizable format.

[0025] In another embodiment as illustrated in FIG. **4**, the interactive communications network **402** is in electronic communication with an Advanced Patient Management System ("APM) **408**. APM is a system that helps patients, their physicians and their families to better monitor, predict and manage chronic diseases. In the embodiment shown in FIG. **4**, the APM system **408** consists of three primary components: 1) an implantable medical device **204** with sensors adapted to monitor temporal biometric data, 2) a Data Management System ("DMS"), which in this embodiment is shown as interactive database **201** and 3) an analytical component **203** adapted to analyze and correlate data from the DMS. APM is designed to support physicians and other clinicians in using a variety of different devices, patient-specific and non-specific data, along with medication therapy, to provide the best possible care to patients. Currently, implanted devices often provide only limited sensing, analysis and therapy to patients. APM moves the device from a reactive mode into a predictive one that allows a clinician to use APM to predict patient health.

[0026] In a further embodiment as illustrated in FIG. **4**, the interactive database **201** comprises a plurality of interactive databases **201***a*, **201***b*, **201***c*, **201***d* and **201***e*. The plurality of interactive databases are adapted to process and store biometric data **201***a* collected from the sensors, store patient data **201***b*, environmental data **201***c*, patient population data **201***d* and medical practice data **201***e*. In this embodiment, therapy is provided to a patient via a specially adapted implantable medical device **204** in response to the identified state of patient health **301**. A sensor **204***a* also may be external to a patient **400** to record biometric and environmental data in the database **201**.

[0027] In a yet another embodiment as illustrated in FIG. **4**, the identified state of patient health **301** is based on rules of practicing medicine **201***e* and revised based on monitoring the success of previous identifications. In this embodiment, the medical practice database **201***e* comprises clinically derived algorithms of biometric data for automatically reporting a state of patient health **301**. The algorithms can be the result of the extraction, codification and use of collected expert knowledge for the analysis or diagnosis of medical conditions. For example, the algorithms can comprise institutional analytical or diagnostic techniques used in specific clinical settings. By reducing the analytical or diagnostic methodologies of institutions like the Cleveland Clinic, the Mayo Clinic or the Kaiser Permanente system to algorithmic expression, a patient will enjoy the benefit of the medical expertise of a leading medical institution without having to visit the institution. The display module **403** is adapted to display a configurable alert for action in the form of a graphical representation **406** of the correlated biometric data and temporal event or an audible signal **407**.

[0028] It is to be understood that the above description is intended to be illustrative, and not restrictive. For example, the above-described embodiments may be used in combination with each other. Many other embodiments will be apparent to those of skill in the art upon reviewing the above description. The scope of the invention should, therefore, be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled. In the appended claims, the terms "including,""includes" and "in which" are used as the plain-English equivalents of the respective terms "comprising,""comprises" and "wherein."

What is claimed is:

1. A method comprising:

sensing biometric data using an implanted medical device;

transmitting the biometric data to a database;

determining a correlation between the biometric data and an environmental event,

wherein the environmental event is one that is capable of causing a health state change in a patient; and

displaying the biometric data and the correlated environmental event in a formatted output.

2. The method of claim 1, wherein the environmental event is selected from a group of events consisting of: a change in temperature, a change in atmospheric pressure, a change in humidity, a change in stress, a change in patient medication, a change in patient diet, and a change in patient emotional state.

3. A method for correlating biometric trends with a related temporal event, comprising the steps of:

sensing biometric data, wherein the biometric data is obtained from an implanted medical device and stored in at least one interactive database;

analyzing the biometric data against a reference data set to create a biometric data set;

correlating the biometric data set with a temporal event to create an output, wherein the temporal event is an environmental event that is capable of causing a health state change in a patient;

transforming the output to a human-recognizable format; and

displaying the transformed output, wherein the transformed output comprises the biometric data set displayed with the corresponding temporal event.

4. The method of claim 3, further comprising wirelessly transmitting the output to at least one communications device in communication with an interactive communications network.

5. The method of claim 3, wherein the displaying of the transformed output further comprises displaying a configurable alert.

6. The method of claim 5, wherein the configurable alert comprises a graphical representation.

7. The method of claim 6, wherein the configurable alert comprises an audible signal.

8. The method of claim 3, wherein the environmental event comprises a change in atmospheric pressure.

9. The method of claim 3, wherein the environmental event comprises a change in patient medication.

10. A system for correlating biometric trends with a related temporal event, comprising:

a sensor coupled to an implantable medical device to sense biometric data;

an analysis module to analyze the biometric data against a reference data set to create a biometric data set;

a correlation module to correlate the biometric data set with a temporal event to create a correlated output, wherein the temporal event is an environmental event that is capable of causing a health state change in a patient;

an electronic transmission module to transmit the output to at least one communications device in communication with a communications network;

a transformation module to transform the output to a human-recognizable format; and

a display module to display the transformed output, wherein the transformed output comprises the biometric data set displayed with the corresponding temporal event.

11. The system of claim 10, further comprising:

a host, in communication with the sensor via the communications network, the host comprising a database and a report module, wherein the database stores data from the sensor and medical information related to the patient, and wherein the report module reports an identification of a state of patient health based on information stored in the database; and

a delivery module that communicates the state of patient health via the communications network for examination.

12. The system of claim 11, wherein the database stores historical data corresponding to a population of patients.

13. The system of claim 11, wherein the state of patient health is revised based on monitoring the success of previous predictive diagnoses.

14. The system of claim 10, further comprising a diagnostic module for diagnosing the performance of the sensor and the communications network.

15. The system of claim 10, wherein the display module displays a configurable alert for action.

16. The system of claim 15, wherein the configurable alert for action comprises a graphical representation of the correlated biometric data and temporal event.

17. The system of claim 10, wherein the environmental event comprises a change in temperature.

18. The system of claim 10, wherein the environmental event comprises a change in stress.

19. The system of claim 10, wherein the environmental event comprises a change in patient medication.

20. The system of claim 10, wherein the environmental event comprises a change in atmospheric pressure.

21. The system of claim 10, wherein the environmental event comprises a change in humidity.

22. The system of claim 10, wherein the environmental event comprises a change in patient diet.

23. The system of claim 10, wherein the environmental event comprises a change in patient emotional state.

24. A system comprising:

a first means for sensing biometric data;

a second means for analyzing the biometric data against a reference data set to create a biometric data set;

a third means for correlating the biometric data set with a temporal event to create a correlated output, wherein the temporal event is an environmental event that is capable of causing a health state change in a patient;

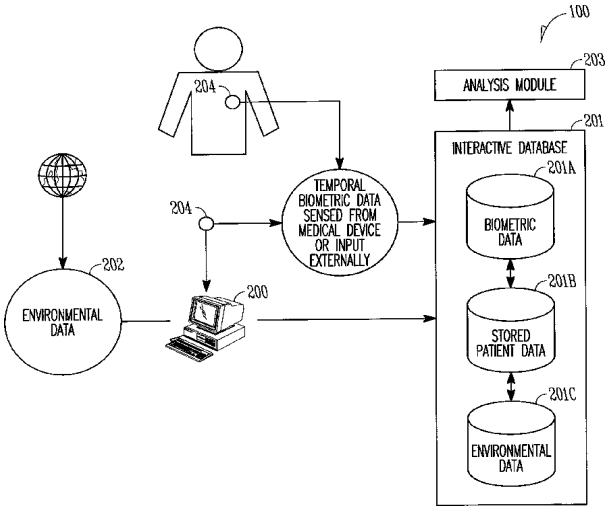
a fourth means for transmitting the output to a communications device;

a fifth means for transforming the output to a human-recognizable format; and

a sixth means for displaying the transformed output, wherein the transformed output comprises the biometric data set displayed with the corresponding temporal event.

* * * * *

专利名称(译)	用于将生物统计趋势与相关时间事件相关联的系统和方法		
公开(公告)号	US20080027757A1	公开(公告)日	2008-01-31
申请号	US11/869611	申请日	2007-10-09
[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	MAZAR SCOTT THOMAS KENKNIGHT BRUCE H		
发明人	MAZAR, SCOTT THOMAS KENKNIGHT, BRUCE H.		
IPC分类号	G06Q50/00 A61B5/00 A61N1/372 G06Q50/22		
CPC分类号	G06Q50/22 A61B5/0002 G16H50/20		
其他公开文献	US7554438		
外部链接	Espacenet USPTO		

摘要(译)

公开了用于将生物统计趋势与相关时间事件相关联的系统和方法。优选实施例利用可植入医疗设备，该医疗设备包括至少一个与患者管理系统电子通信的传感器，该患者管理系统适于在时间上分析和关联生物统计数据。本文公开的系统的一些实施例还可以配置为高级患者管理系统，其有助于更好地监测，预测和管理慢性疾病。