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(54) **SYSTEM AND METHOD FOR EVALUATING A PATIENT STATUS FOR USE IN HEART FAILURE ASSESSMENT**

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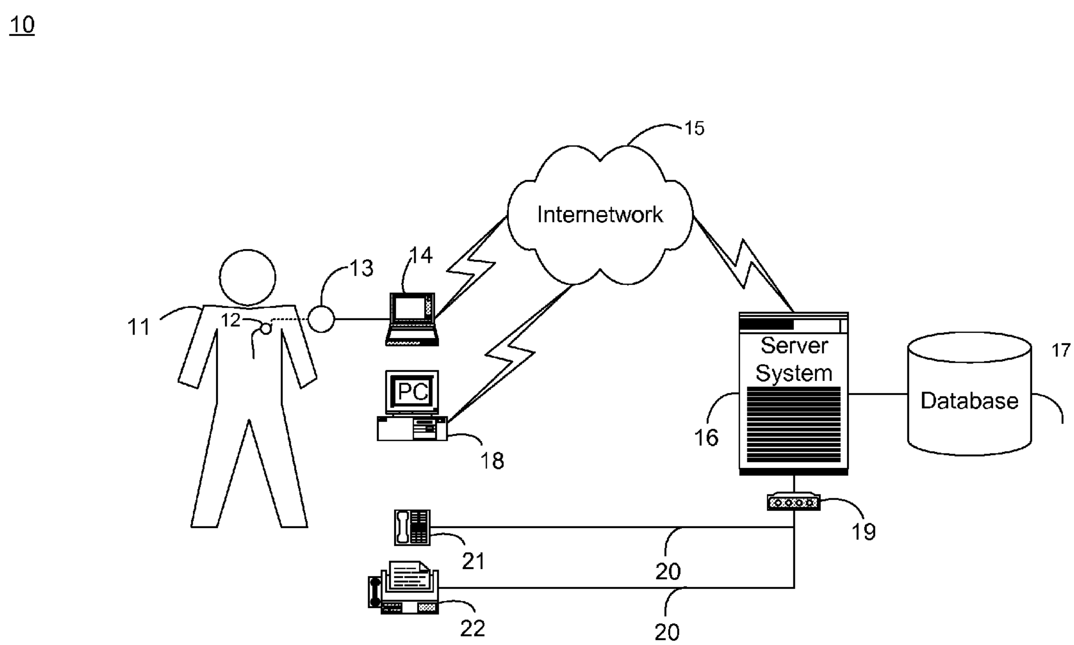
(57) **ABSTRACT**

A system and method for evaluating a patient status from sampled physiometry for use in heart failure assessment is presented. Physiological measures are stored, including at least one of direct measures regularly recorded on a substantially continuous basis by an implantable medical device for a patient and measures derived from the direct measures. At least one of those of the physiological measures, which each relate to a same type of physiometry, and those of the physiological measures, which each relate to a different type of physiometry are sampled. A status for the patient is determined through analysis of the sampled physiological measures assembled from a plurality of recordation points. The sampled physiological measures are evaluated. Trends that are indicated by the patient status, which might affect cardiac performance of the patient, are identified. Each trend is compared to worsening heart failure indications to generate a notification of parameter violations.



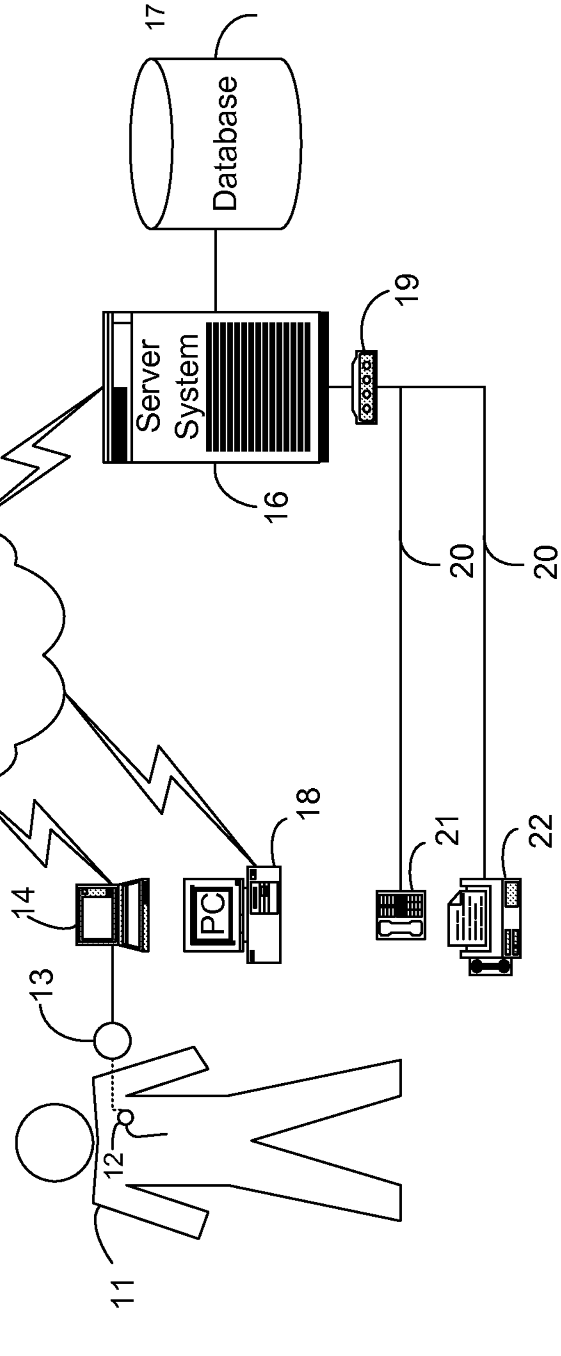

17
Database
19
Server
System
16
15
Internetwork
20
20
18
14
PC
21
22
13
12
11

Fig. 1.

10

Fig. 2.

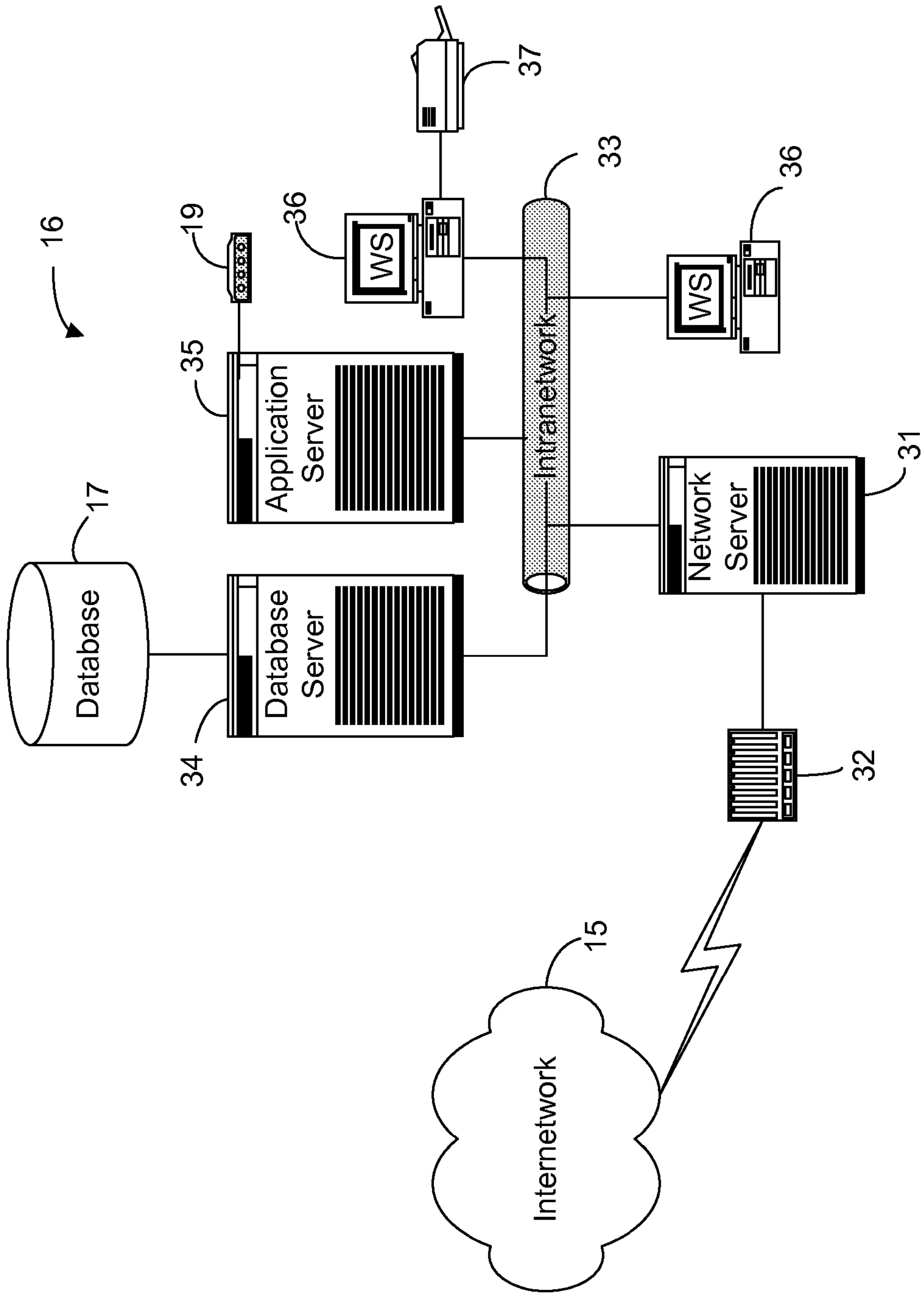

16
17
Database
19
35
Application Server
36
WS
37
33
36
WS
Intranetwork
34
Database Server
Network Server
31
32
15
Internetwork

Fig. 3.

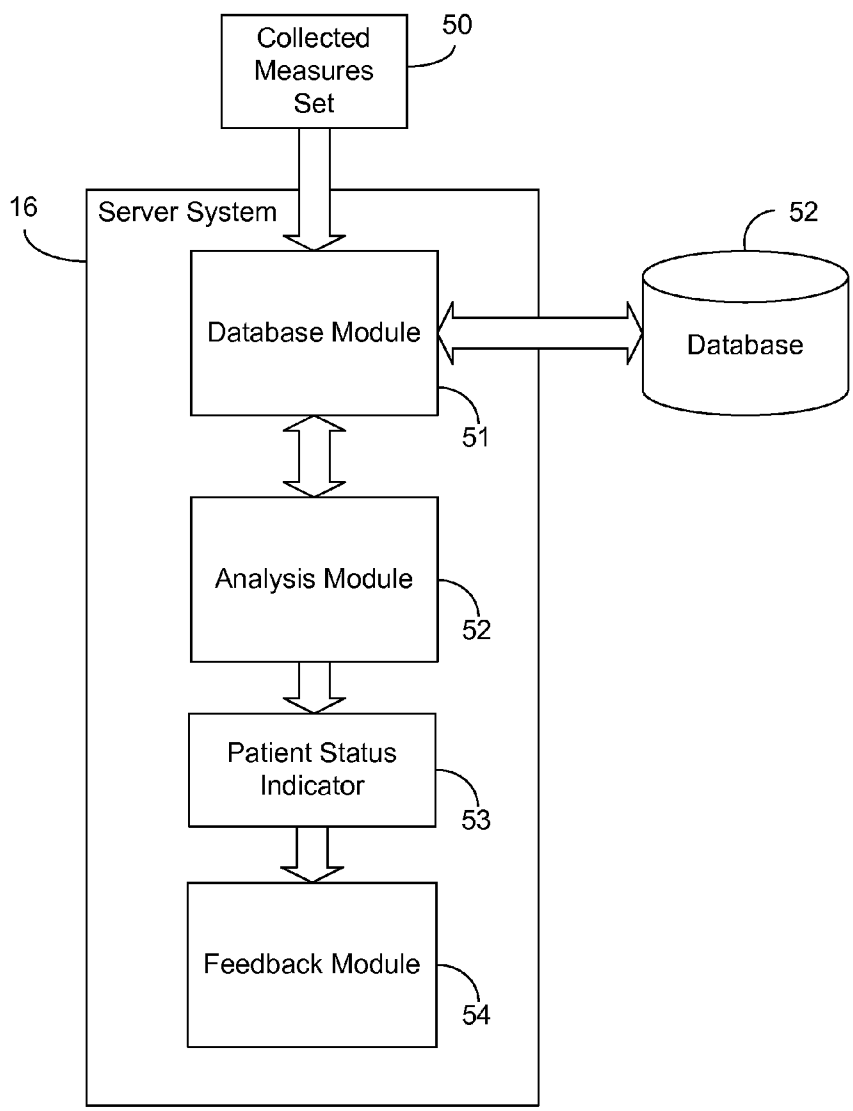
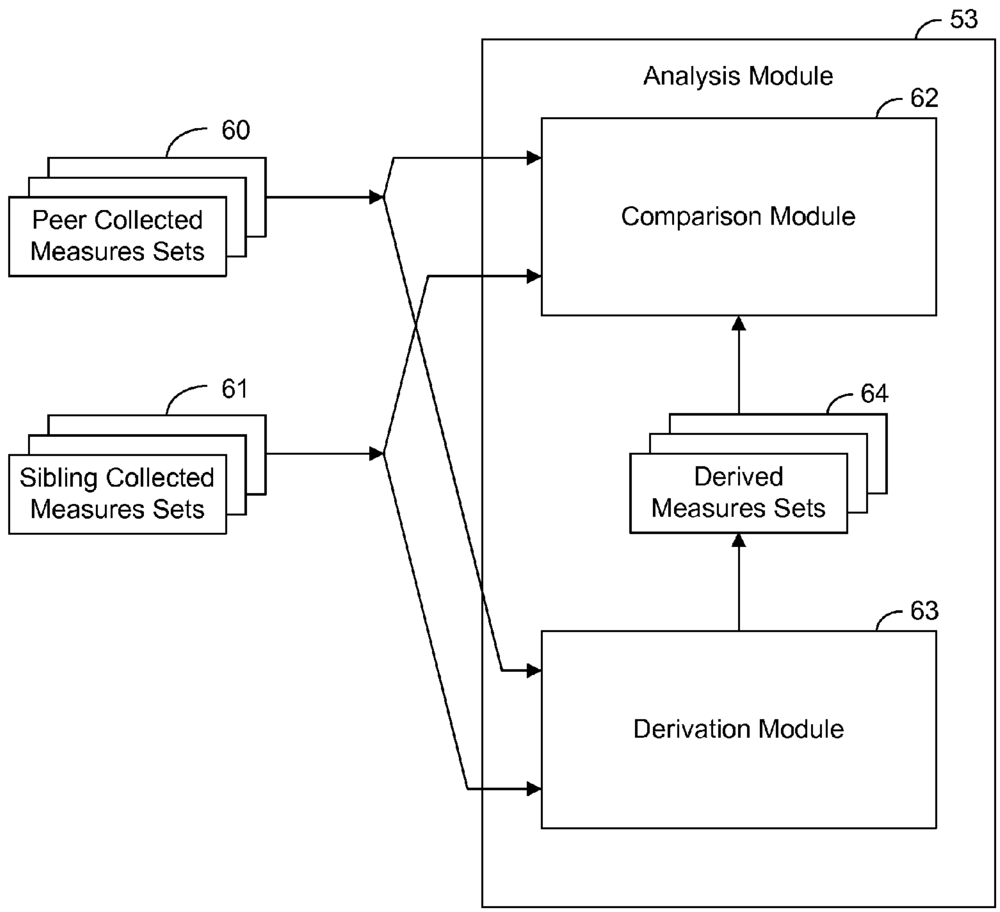

Collected
Measures
Set
50
16
Server System
52
Database Module
Database
51
Analysis Module
52
Patient Status
Indicator
53
Feedback Module
54

Fig. 4.



53
Analysis Module
62
60
Peer Collected Measures Sets
Comparison Module
61
64
Sibling Collected Measures Sets
Derived Measures Sets
63
Derivation Module

Fig. 5.

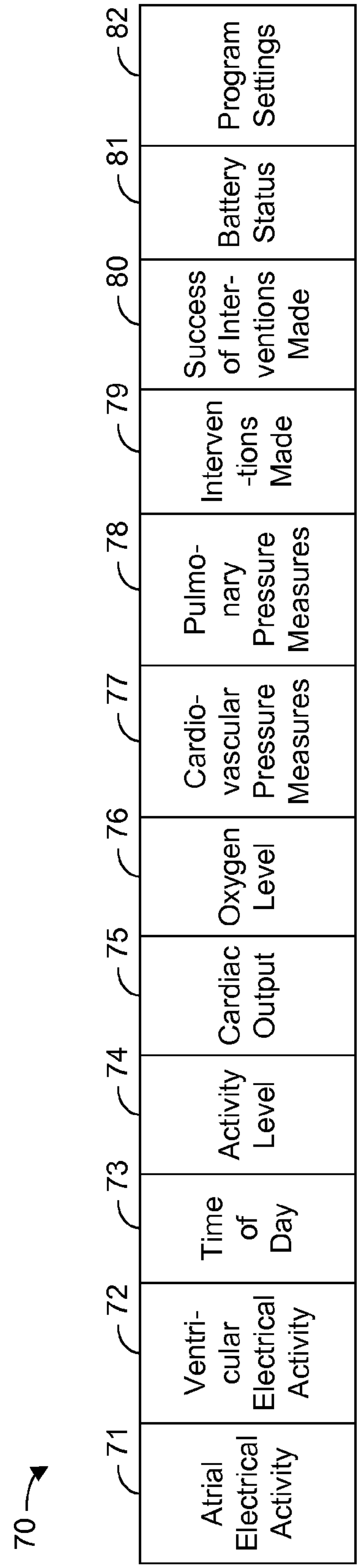

70
71
Atrial Electrical Activity
72
Ventri-cular Electrical Activity
73
Time of Day
74
Activity Level
75
Cardiac Output
76
Oxygen Level
77
Cardio-vascular Pressure Measures
78
Pulmo-nary Pressure Measures
79
Interven-tions Made
80
Success of Inter-ventions Made
81
Battery Status
82
Program Settings

Fig. 6.

Patient 1

Set 0				Set n-2	Set n-1	Set n
X_0	•	•	•	X_{n-2}	X_{n-1}	X_n
Y_0	•	•	•	Y_{n-2}	Y_{n-1}	Y_n
Z_0	•	•	•	Z_{n-2}	Z_{n-1}	Z_n

time →

Patient 2

Set 0				Set n-2	Set n-1	Set n
$X_{0'}$	•	•	•	$X_{n-2'}$	$X_{n-1'}$	$X_{n'}$
$Y_{0'}$	•	•	•	$Y_{n-2'}$	$Y_{n-1'}$	$Y_{n'}$
$Z_{0'}$	•	•	•	$Z_{n-2'}$	$Z_{n-1'}$	$Z_{n'}$

time →

Patient 3

Set 0				Set n-2	Set n-1	Set n
$X_{0''}$	•	•	•	$X_{n-2''}$	$X_{n-1''}$	$X_{n''}$
$Y_{0''}$	•	•	•	$Y_{n-2''}$	$Y_{n-1''}$	$Y_{n''}$
$Z_{0''}$	•	•	•	$Z_{n-2''}$	$Z_{n-1''}$	$Z_{n''}$

time →

Fig. 7.

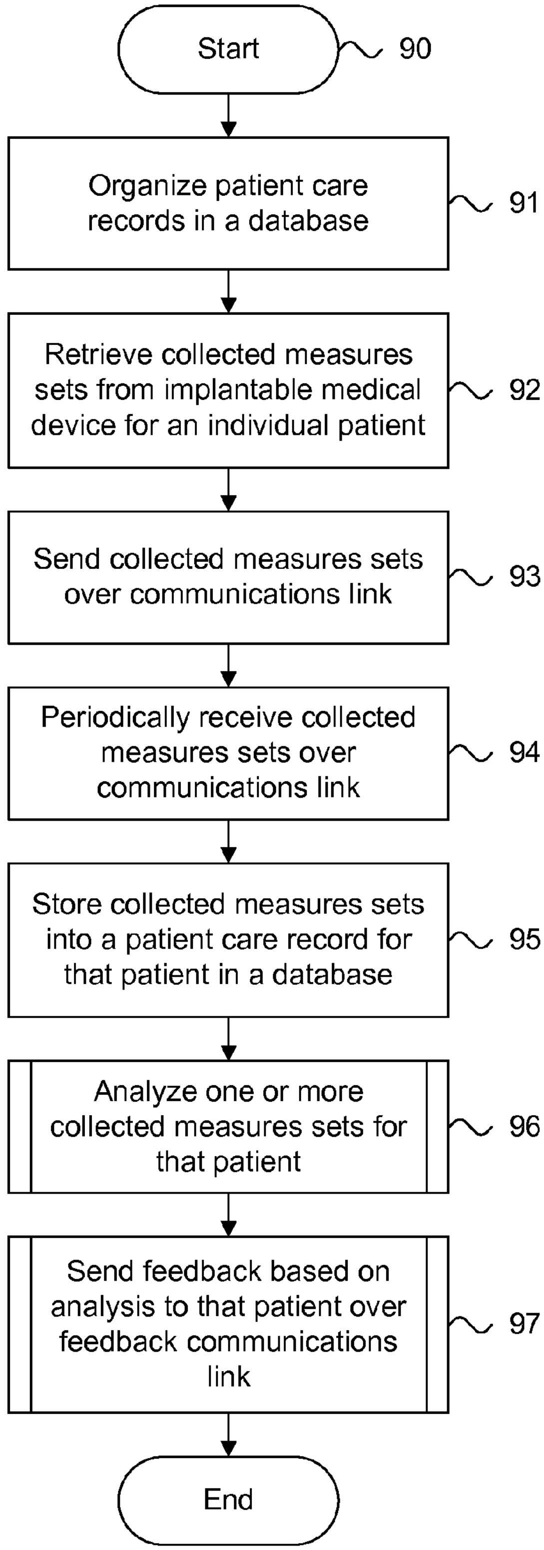

Start
90
Organize patient care records in a database
91
Retrieve collected measures sets from implantable medical device for an individual patient
92
Send collected measures sets over communications link
93
Periodically receive collected measures sets over communications link
94
Store collected measures sets into a patient care record for that patient in a database
95
Analyze one or more collected measures sets for that patient
96
Send feedback based on analysis to that patient over feedback communications link
97
End

Fig. 8.

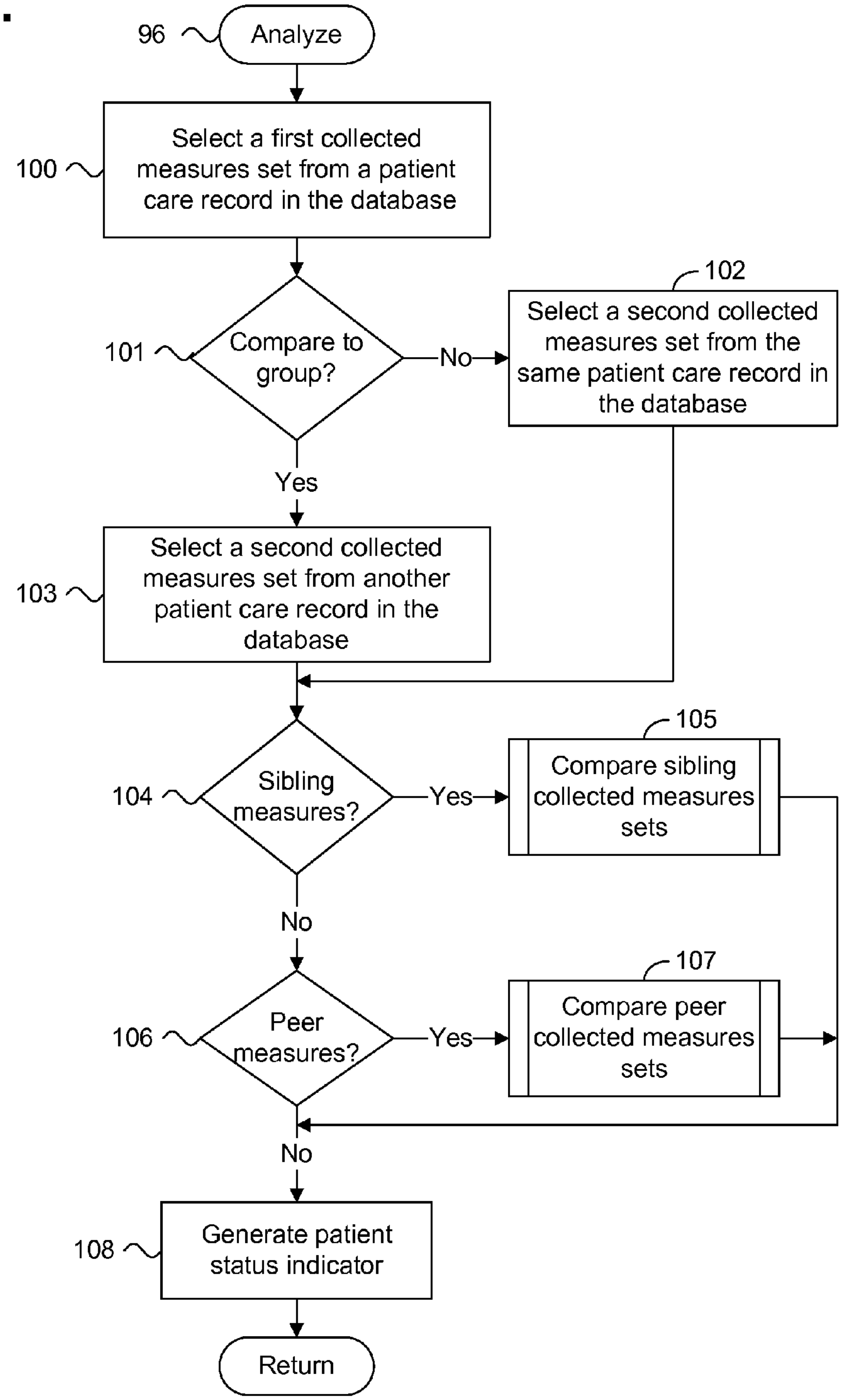

96
Analyze
100
Select a first collected measures set from a patient care record in the database
101
Compare to group?
No
102
Select a second collected measures set from the same patient care record in the database
Yes
103
Select a second collected measures set from another patient care record in the database
104
Sibling measures?
Yes
105
Compare sibling collected measures sets
No
106
Peer measures?
Yes
107
Compare peer collected measures sets
No
108
Generate patient status indicator
Return

Fig. 9.

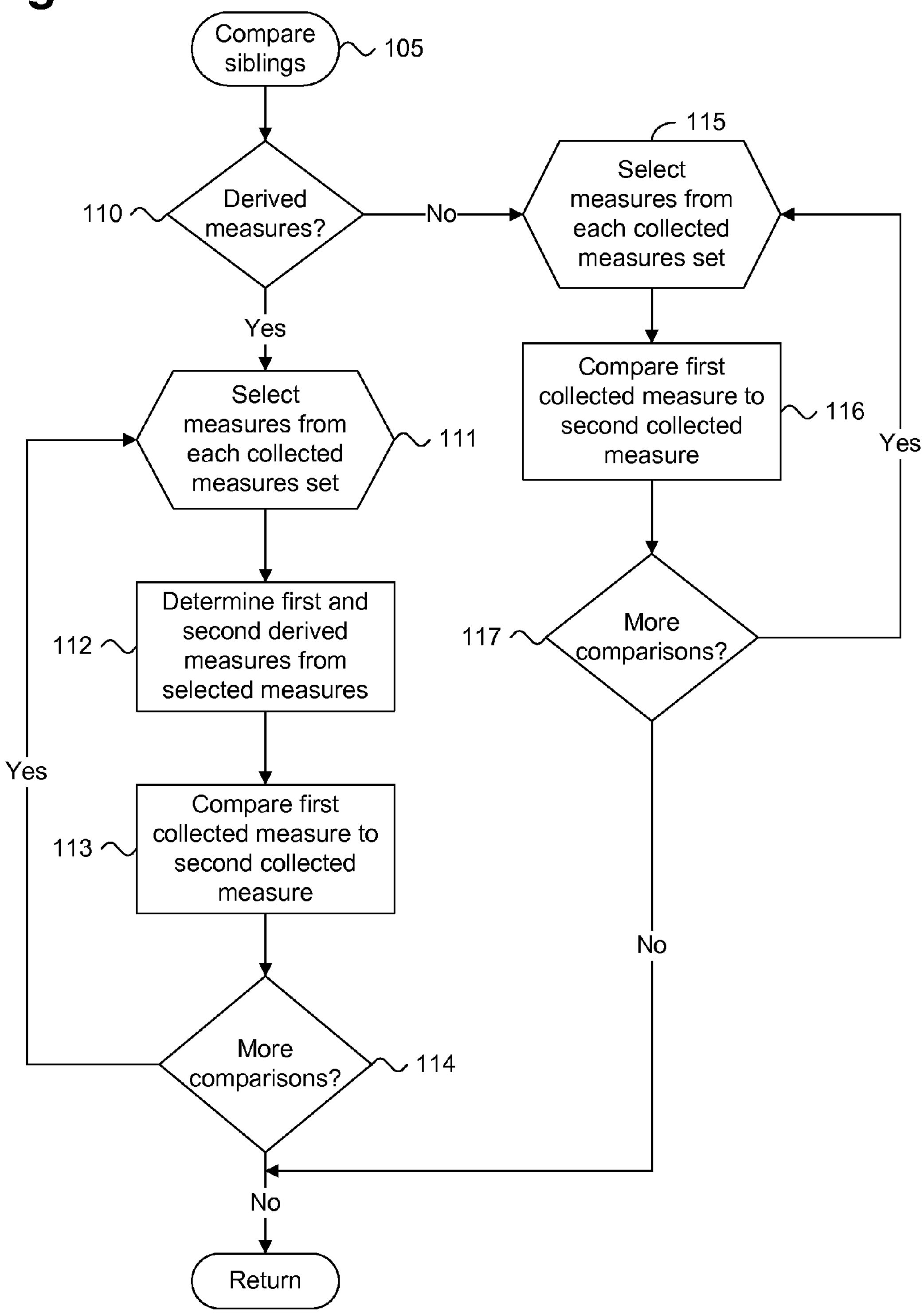

Compare siblings
105
Derived measures?
110
No
Yes
Select measures from each collected measures set
111
115
Select measures from each collected measures set
Compare first collected measure to second collected measure
116
Yes
Determine first and second derived measures from selected measures
112
More comparisons?
117
Compare first collected measure to second collected measure
113
Yes
No
More comparisons?
114
No
Return

Fig. 10A.

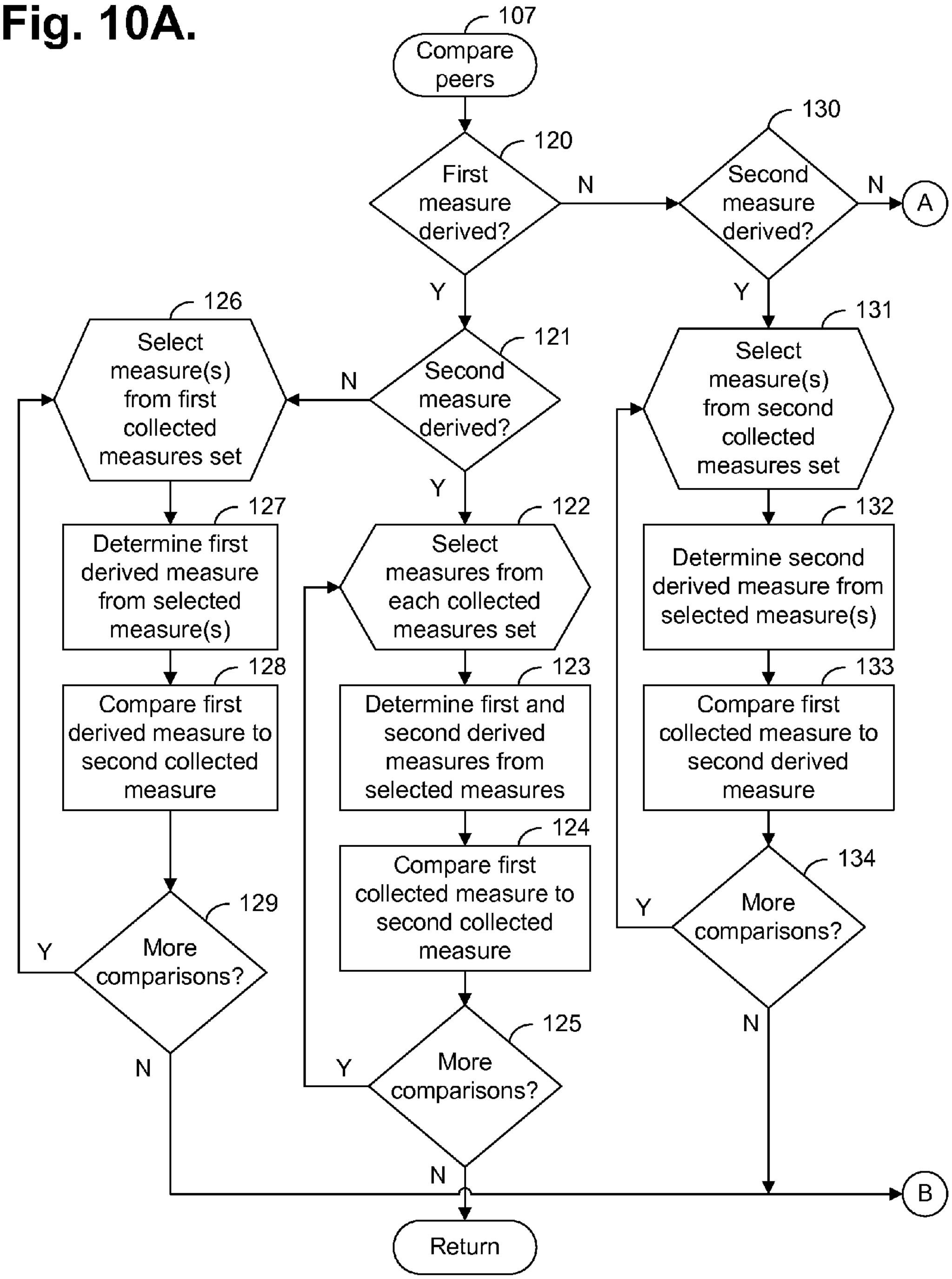

107
Compare peers
120
First measure derived?
N
130
Second measure derived?
N
A
Y
Y
126
Select measure(s) from first collected measures set
N
121
Second measure derived?
131
Select measure(s) from second collected measures set
Y
127
Determine first derived measure from selected measure(s)
122
Select measures from each collected measures set
132
Determine second derived measure from selected measure(s)
128
Compare first derived measure to second collected measure
123
Determine first and second derived measures from selected measures
133
Compare first collected measure to second derived measure
124
Compare first collected measure to second collected measure
134
More comparisons?
Y
129
More comparisons?
Y
N
125
More comparisons?
Y
N
N
B
Return

Fig. 10B.

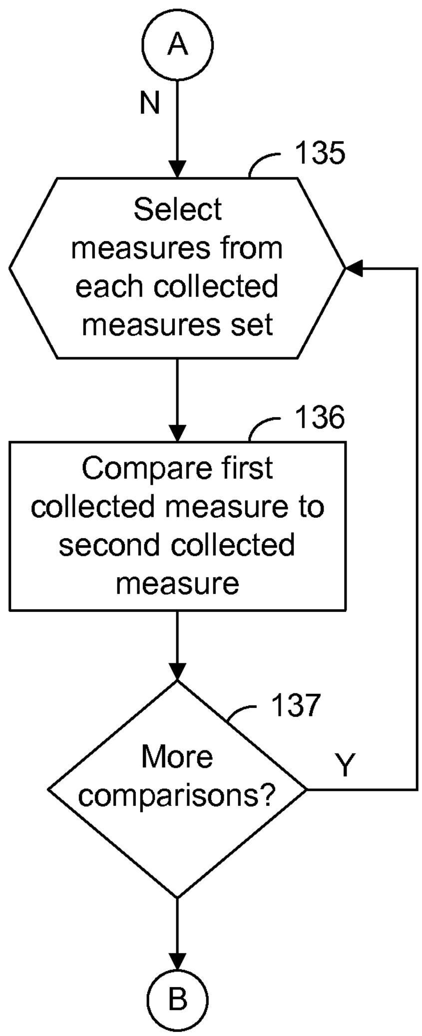
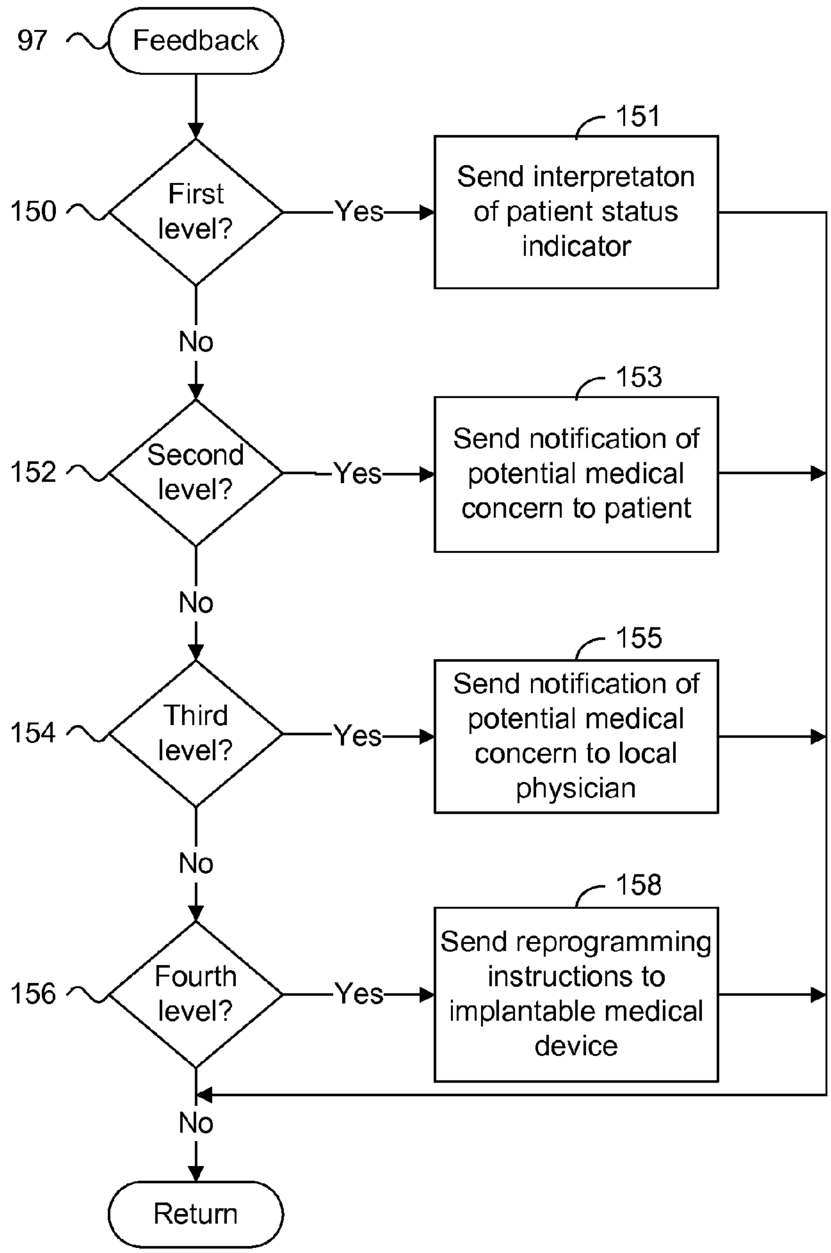

A
N
135
Select measures from each collected measures set
136
Compare first collected measure to second collected measure
137
More comparisons?
Y
B

Fig. 11.


97
Feedback
150
First level?
Yes
151
Send interpretaton of patient status indicator
No
152
Second level?
Yes
153
Send notification of potential medical concern to patient
No
154
Third level?
Yes
155
Send notification of potential medical concern to local physician
No
156
Fourth level?
Yes
158
Send reprogramming instructions to implantable medical device
No
Return

SYSTEM AND METHOD FOR EVALUATING A PATIENT STATUS FOR USE IN HEART FAILURE ASSESSMENT

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This patent application is a continuation of U.S. patent application Ser. No. 11/540,251, filed Sep. 29, 2006, pending, which is a divisional of U.S. Pat. No. 7,144,369, issued Dec. 5, 2006, which is a continuation of U.S. Pat. No. 6,312,378, issued Nov. 6, 2001, the priority filing dates of which are claimed and the disclosures of which are incorporated by reference.

FIELD

[0002] The present invention relates in general to heart failure assessment, and, in particular, to a system and method for evaluating a patient status for use in heart failure assessment.

BACKGROUND

[0003] Implantable pulse generators (IPGs) are medical devices commonly used to treat irregular heartbeats, known as arrhythmias. There are two basic types. Cardiac pacemakers are used to manage bradycardia, an abnormally slow or irregular heartbeat. Left untreated, bradycardia can cause symptoms such as fatigue, dizziness, and fainting. Implantable cardioverter defibrillators (ICDs) are used to treat tachycardia, heart rhythms that are abnormally fast and life threatening. Tachycardia can result in sudden cardiac death (SCD).

[0004] Pacemakers and ICDs are increasingly being equipped with an on-board, volatile memory in which telemetered signals can be stored for later retrieval and analysis. Typically, the telemetered signals provide patient device information regarding atrial electrical activity, ventricular electrical activity, time of day, activity level, cardiac output, oxygen level, cardiovascular pressure measures, pulmonary measures, and any interventions made on a per heartbeat or binned average basis. In addition, a growing class of cardiac medical devices, including implantable heart failure monitors, implantable event monitors, cardiovascular monitors, and therapy devices, are being used to provide similar stored device information. These devices are able to store approximately thirty minutes of per heartbeat data. Telemetered signals are also stored in a broader class of monitors and therapeutic devices for other areas of medicine, including metabolism, endocrinology, hematology, neurology, muscular, gastrointestinal, genital-urology, ocular, auditory, and the like.

[0005] Presently, stored device information is retrieved using a proprietary interrogator or programmer, often during a clinic visit or following a device event. The volume of data retrieved from a single device interrogation "snapshot" can be large and proper interpretation and analysis can require significant physician time and detailed subspecialty knowledge, particularly by cardiologists and cardiac electrophysiologists. The sequential logging and analysis of regularly scheduled interrogations can create an opportunity for recognizing subtle and incremental changes in patient condition otherwise undetectable by inspection of a single "snapshot." However, present approaches to data interpretation and understanding and practical limitations on time and physician availability make such analysis impracticable.

[0006] A prior art system for collecting and analyzing pacemaker and ICD telemetered signals in a clinical or office setting is the Model 9790 Programmer, manufactured by Medtronic, Inc., Minneapolis, Minn. This programmer can be used to retrieve data, such as patient electrocardiogram and any measured physiological conditions, collected by the IPG for recordation, display and printing. The retrieved data is displayed in chronological order and analyzed by a physician. Comparable prior art systems are available from other IPG manufacturers, such as the Model 2901 Programmer Recorder Monitor, manufactured by Guidant Corporation, Indianapolis, Ind., which includes a removable floppy diskette mechanism for patient data storage. These prior art systems lack remote communications facilities and must be operated with the patient present. These systems present a limited analysis of the collected data based on a single device interrogation and lack the capability to recognize trends in the data spanning multiple episodes over time or relative to a disease specific peer group.

[0007] A prior art system for locating and communicating with a remote medical device implanted in an ambulatory patient is disclosed in U.S. Pat. No. 5,752,976 ('976). The implanted device includes a telemetry transceiver for communicating data and operating instructions between the implanted device and an external patient communications device. The communications device includes a communication link to a remote medical support network, a global positioning satellite receiver, and a patient activated link for permitting patient initiated communication with the medical support network.

[0008] Related prior art systems for remotely communicating with and receiving telemetered signals from a medical device are disclosed in U.S. Pat. Nos. 5,113,869 ('869) and 5,336,245 ('245). In the '869 patent, an implanted AECG monitor can be automatically interrogated at preset times of day to telemeter out accumulated data to a telephonic communicator or a full disclosure recorder. The communicator can be automatically triggered to establish a telephonic communication link and transmit the accumulated data to an office or clinic through a modem. In the '245 patent, telemetered data is downloaded to a larger capacity, external data recorder and is forwarded to a clinic using an auto-dialer and fax modem operating in a personal computer-based programmer/interrogator. However, the '976 telemetry transceiver, '869 communicator, and '245 programmer/interrogator are limited to facilitating communication and transferal of downloaded patient data and do not include an ability to automatically track, recognize, and analyze trends in the data itself.

[0009] Thus, there is a need for a system and method for providing continuous retrieval, transferal, and automated analysis of retrieved implantable medical device information, such as telemetered signals, retrieved in general from a broad class of implantable medical devices and, in particular, from IPGs and cardiovascular monitors. Preferably, the automated analysis would include recognizing a trend and determining whether medical intervention is necessary.

[0010] There is a further need for a system and method that would allow consideration of sets of collected measures, both actual and derived, from multiple device interrogations. These collected measures sets could then be compared and analyzed against short and long term periods of observation.

[0011] There is a further need for a system and method that would enable the measures sets for an individual patient to be self-referenced and cross-referenced to similar or dissimilar patients and to the general patient population. Preferably, the historical collected measures sets of an individual patient could be compared and analyzed against those of other patients in general or of a disease specific peer group in particular.

SUMMARY

[0012] The present invention provides a system and method for providing collection and analysis of patient information for use in automated patient care. The patient device information relates to individual measures recorded by and retrieved from implantable medical devices, such as IPGs and monitors. The patient device information is received on a regular, e.g., daily, basis as sets of collected measures which are stored along with other patient records in a database. The information can be analyzed in an automated fashion and feedback provided to the patient at any time and in any location.

[0013] An embodiment provides a system and method for evaluating a patient status for use in heart failure assessment. Physiological measures are assembled, which were directly recorded as data on a substantially continuous basis by an implantable medical device for a patient or indirectly derived from the data. A status for the patient is determined through sampling and analysis of the physiological measures over a plurality of data assembly points. Trends that are indicated by the patient status are identified and each trend is compared to worsening heart failure indications.

[0014] A further embodiment provides a system and method for evaluating a patient status from sampled physiometry for use in heart failure assessment. Physiological measures are stored, including at least one of direct measures regularly recorded on a substantially continuous basis by an implantable medical device for a patient and measures derived from the direct measures. At least one of those of the physiological measures, which each relate to a same type of physiometry, and those of the physiological measures, which each relate to a different type of physiometry are sampled. A status for the patient is determined through analysis of the sampled physiological measures assembled from a plurality of recordation points. The sampled physiological measures are evaluated. Any trends that are indicated by the patient status, which might affect cardiac performance of the patient, are identified. Each trend is compared to worsening heart failure indications to generate a notification of parameter violations.

[0015] The present invention facilitates the gathering, storage, and analysis of critical patient information obtained on a routine basis and analyzed in an automated manner. Thus, the burden on physicians and trained personnel to evaluate the volumes of information is significantly minimized while the benefits to patients are greatly enhanced.

[0016] Still other embodiments of the present invention will become readily apparent to those skilled in the art from the following detailed description, wherein is described embodiments of the invention by way of illustrating the best mode contemplated for carrying out the invention. As will be realized, the invention is capable of other and different embodiments and its several details are capable of modifications in various obvious respects, all without departing from the spirit and the scope of the present invention. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not as restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] FIG. **1** is a block diagram showing a system for providing collection and analysis of patient information for use in automated patient care in accordance with the present invention;

[0018] FIG. **2** is a block diagram showing the hardware components of the server system of the system of FIG. **1**;

[0019] FIG. **3** is a block diagram showing the software modules of the server system of the system of FIG. **1**;

[0020] FIG. **4** is a block diagram showing the analysis module of the server system of FIG. **3**;

[0021] FIG. **5** is a database schema showing, by way of example, the organization of a cardiac patient care record stored in the database of the system of FIG. **1**;

[0022] FIG. **6** is a record view showing, by way of example, a set of partial cardiac patient care records stored in the database of the system of FIG. **1**;

[0023] FIG. **7** is a flow diagram showing a method for providing collection and analysis of patient information for use in automated patient care in accordance with the present invention;

[0024] FIG. **8** is a flow diagram showing a routine for analyzing collected measures sets for use in the method of FIG. **7**;

[0025] FIG. **9** is a flow diagram showing a routine for comparing sibling collected measures sets for use in the routine of FIG. **8**;

[0026] FIGS. **10**A and **10**B are flow diagrams showing a routine for comparing peer collected measures sets for use in the routine of FIG. **8**; and

[0027] FIG. **11** is a flow diagram showing a routine for providing feedback for use in the method of FIG. **7**.

DETAILED DESCRIPTION

[0028] FIG. **1** is a block diagram showing a system **10** for providing collection and analysis of patient information for use in automated patient care in accordance with the present invention. A patient **11** is a recipient of an implantable medical device **12**, such as, by way of example, an IPG or a heart failure or event monitor, with a set of leads extending into his or her heart. The implantable medical device **12** includes circuitry for recording into a short-term, volatile memory telemetered signals, which are stored as a set of collected measures for later retrieval.

[0029] For an exemplary cardiac implantable medical device, the telemetered signals non-exclusively present patient information relating to: atrial electrical activity, ventricular electrical activity, time of day, activity level, cardiac output, oxygen level, cardiovascular pressure measures, the number and types of interventions made, and the relative success of any interventions made on a per heartbeat or binned average basis, plus the status of the batteries and programmed settings. Examples of pacemakers suitable for use in the present invention include the Discovery line of pacemakers, manufactured by Guidant Corporation, Indianapolis, Ind. Examples of ICDs suitable for use in the present invention include the Ventak line of ICDs, also manufactured by Guidant Corporation, Indianapolis, Ind.

[0030] In the described embodiment, the patient **11** has a cardiac implantable medical device. However, a wide range of related implantable medical devices are used in other areas of medicine and a growing number of these devices are also capable of measuring and recording patient information for later retrieval. These implantable medical devices include monitoring and therapeutic devices for use in metabolism, endocrinology, hematology, neurology, muscularology, gastro-intestinalogy, genital-urology, ocular, auditory, and similar medical subspecialties. One skilled in the art would readily recognize the applicability of the present invention to these related implantable medical devices.

[0031] On a regular basis, the telemetered signals stored in the implantable medical device **12** are retrieved. By way of example, a programmer **14** can be used to retrieve the telemetered signals. However, any form of programmer, interrogator, recorder, monitor, or telemetered signals transceiver suitable for communicating with an implantable medical device **12** could be used, as is known in the art. In addition, a personal computer or digital data processor could be interfaced to the implantable medical device **12**, either directly or via a telemetered signals transceiver configured to communicate with the implantable medical device **12**.

[0032] Using the programmer **14**, a magnetized reed switch (not shown) within the implantable medical device **12** closes in response to the placement of a wand **13** over the location of the implantable medical device **12**. The programmer **14** communicates with the implantable medical device **12** via RF signals exchanged through the wand **14**. Programming or interrogating instructions are sent to the implantable medical device **12** and the stored telemetered signals are downloaded into the programmer **14**. Once downloaded, the telemetered signals are sent via an internetwork **15**, such as the Internet, to a server system **16** which periodically receives and stores the telemetered signals in a database **17**, as further described below with reference to FIG. **2**.

[0033] An example of a programmer **14** suitable for use in the present invention is the Model 2901 Programmer Recorder Monitor, manufactured by Guidant Corporation, Indianapolis, Ind., which includes the capability to store retrieved telemetered signals on a proprietary removable floppy diskette. The telemetered signals could later be electronically transferred using a personal computer or similar processing device to the internetwork **15**, as is known in the art.

[0034] Other alternate telemetered signals transfer means could also be employed. For instance, the stored telemetered signals could be retrieved from the implantable medical device **12** and electronically transferred to the internetwork **15** using the combination of a remote external programmer and analyzer and a remote telephonic communicator, such as described in U.S. Pat. No. 5,113,869, the disclosure of which is incorporated herein by reference. Similarly, the stored telemetered signals could be retrieved and remotely downloaded to the server system **16** using a world-wide patient location and data telemetry system, such as described in U.S. Pat. No. 5,752,976, the disclosure of which is incorporated herein by reference.

[0035] The received telemetered signals are analyzed by the server system **16**, which generates a patient status indicator. The feedback is then provided back to the patient **11** through a variety of means. By way of example, the feedback can be sent as an electronic mail message generated automatically by the server system **16** for transmission over the internetwork **15**. The electronic mail message is received by personal computer **18** (PC) situated for local access by the patient **11**. Alternatively, the feedback can be sent through a telephone interface device **19** as an automated voice mail message to a telephone **21** or as an automated facsimile message to a facsimile machine **22**, both also situated for local access by the patient **11**. In addition to a personal computer **18**, telephone **21**, and facsimile machine **22**, feedback could be sent to other related devices, including a network computer, wireless computer, personal data assistant, television, or digital data processor. Preferably, the feedback is provided in a tiered fashion, as further described below with reference to FIG. **3**.

[0036] FIG. **2** is a block diagram showing the hardware components of the server system **16** of the system **10** of FIG. **1**. The server system **16** consists of three individual servers: network server **31**, database server **34**, and application server **35**. These servers are interconnected via an intranetwork **33**. In the described embodiment, the functionality of the server system **16** is distributed among these three servers for efficiency and processing speed, although the functionality could also be performed by a single server or cluster of servers. The network server **31** is the primary interface of the server system **16** onto the internetwork **15**. The network server **31** periodically receives the collected telemetered signals sent by remote implantable medical devices over the internetwork **15**. The network server **31** is interfaced to the internetwork **15** through a router **32**. To ensure reliable data exchange, the network server **31** implements a TCP/IP protocol stack, although other forms of network protocol stacks are suitable.

[0037] The database server **34** organizes the patient care records in the database **17** and provides storage of and access to information held in those records. A high volume of data in the form of collected measures sets from individual patients is received. The database server **34** frees the network server **31** from having to categorize and store the individual collected measures sets in the appropriate patient care record.

[0038] The application server **35** operates management applications and performs data analysis of the patient care records, as further described below with reference to FIG. **3**. The application server **35** communicates feedback to the individual patients either through electronic mail sent back over the internetwork **15** via the network server **31** or as automated voice mail or facsimile messages through the telephone interface device **19**.

[0039] The server system **16** also includes a plurality of individual workstations **36** (WS) interconnected to the intranetwork **33**, some of which can include peripheral devices, such as a printer **37**. The workstations **36** are for use by the data management and programming staff, nursing staff, office staff, and other consultants and authorized personnel.

[0040] The database **17** consists of a high-capacity storage medium configured to store individual patient care records and related health care information. Preferably, the database **17** is configured as a set of high-speed, high capacity hard drives, such as organized into a Redundant Array of Inexpensive Disks (RAID) volume. However, any form of volatile storage, non-volatile storage, removable storage, fixed storage, random access storage, sequential access storage, permanent storage, erasable storage, and the like would be equally suitable. The organization of the database **17** is further described below with reference to FIG. **3**.

[0041] The individual servers and workstations are general purpose, programmed digital computing devices consisting of a central processing unit (CPU), random access memory (RAM), non-volatile secondary storage, such as a hard drive or CD ROM drive, network interfaces, and peripheral devices, including user interfacing means, such as a keyboard and display. Program code, including software programs, and data are loaded into the RAM for execution and processing by the CPU and results are generated for display, output, transmittal, or storage. In the described embodiment, the individual servers are Intel Pentium-based server systems, such as available from Dell Computers, Austin, Tex., or Compaq Computers, Houston, Tex. Each system is preferably equipped with 128 MB RAM, 100 GB hard drive capacity, data backup facilities, and related hardware for interconnection to the intranetwork **33** and internetwork **15**. In addition, the workstations **36** are also Intel Pentium-based personal computer or workstation systems, also available from Dell Computers, Austin, Tex., or Compaq Computers, Houston, Tex. Each workstation is preferably equipped with 64 MB RAM, 10 GB hard drive capacity, and related hardware for interconnection to the intranetwork **33**. Other types of server and workstation systems, including personal computers, minicomputers, mainframe computers, supercomputers, parallel computers, workstations, digital data processors and the like would be equally suitable, as is known in the art.

[0042] The telemetered signals are communicated over an internetwork **15**, such as the Internet. However, any type of electronic communications link could be used, including an intranetwork link, serial link, data telephone link, satellite link, radio-frequency link, infrared link, fiber optic link, coaxial cable link, television link, and the like, as is known in the art. Also, the network server **31** is interfaced to the internetwork **15** using a T-1 network router **32**, such as manufactured by Cisco Systems, Inc., San Jose, Calif. However, any type of interfacing device suitable for interconnecting a server to a network could be used, including a data modem, cable modem, network interface, serial connection, data port, hub, frame relay, digital PBX, and the like, as is known in the art.

[0043] FIG. **3** is a block diagram showing the software modules of the server system **16** of the system **10** of FIG. **1**. Each module is a computer program written as source code in a conventional programming language, such as the C or Java programming languages, and is presented for execution by the CPU as object or byte code, as is known in the arts. The various implementations of the source code and object and byte codes can be held on a computer-readable storage medium or embodied on a transmission medium in a carrier wave. There are three basic software modules, which functionally define the primary operations performed by the server system **16**: database module **51**, analysis module **53**, and feedback module **55**. In the described embodiment, these modules are executed in a distributed computing environment, although a single server or a cluster of servers could also perform the functionality of the modules. The module functions are further described below in more detail beginning with reference to FIG. **7**.

[0044] For each patient being provided remote patient care, the server system **16** periodically receives a collected measures set **50** which is forwarded to the database module **51** for processing. The database module **51** organizes the individual patent care records stored in the database **52** and provides the facilities for efficiently storing and accessing the collected measures sets **50** and patient data maintained in those records. An exemplary database schema for use in storing collected measures sets **50** in a patient care record is described below, by way of example, with reference to FIG. **5**. The database server **34** (shown in FIG. **2**) performs the functionality of the database module **51**. Any type of database organization could be utilized, including a flat file system, hierarchical database, relational database, or distributed database, such as provided by database vendors, such as Oracle Corporation, Redwood Shores, Calif.

[0045] The analysis module **53** analyzes the collected measures sets **50** stored in the patient care records in the database **52**. The analysis module **53** makes an automated determination of patient wellness in the form of a patient status indicator **54**. Collected measures sets **50** are periodically received from implantable medical devices and maintained by the database module **51** in the database **52**. Through the use of this collected information, the analysis module **53** can continuously follow the medical well being of a patient and can recognize any trends in the collected information that might warrant medical intervention. The analysis module **53** compares individual measures and derived measures obtained from both the care records for the individual patient and the care records for a disease specific group of patients or the patient population in general. The analytic operations performed by the analysis module **53** are further described below with reference to FIG. **4**. The application server **35** (shown in FIG. **2**) performs the functionality of the analysis module **53**.

[0046] The feedback module **55** provides automated feedback to the individual patient based, in part, on the patient status indicator **54**. As described above, the feedback could be by electronic mail or by automated voice mail or facsimile. Preferably, the feedback is provided in a tiered manner. In the described embodiment, four levels of automated feedback are provided. At a first level, an interpretation of the patient status indicator **54** is provided. At a second level, a notification of potential medical concern based on the patient status indicator **54** is provided. This feedback level could also be coupled with human contact by specially trained technicians or medical personnel. At a third level, the notification of potential medical concern is forwarded to medical practitioners located in the patient's geographic area. Finally, at a fourth level, a set of reprogramming instructions based on the patient status indicator **54** could be transmitted directly to the implantable medical device to modify the programming instructions contained therein. As is customary in the medical arts, the basic tiered feedback scheme would be modified in the event of bona fide medical emergency. The application server **35** (shown in FIG. **2**) performs the functionality of the feedback module **55**.

[0047] FIG. **4** is a block diagram showing the analysis module **53** of the server system **16** of FIG. **3**. The analysis module **53** contains two functional submodules: comparison module **62** and derivation module **63**. The purpose of the comparison module **62** is to compare two or more individual measures, either collected or derived. The purpose of the derivation module **63** is to determine a derived measure based on one or more collected measures which is then used by the comparison module **62**. For instance, a new and improved indicator of impending heart failure could be derived based on the exemplary cardiac collected measures set described with reference to FIG. **5**. The analysis module **53** can operate either in a batch mode of operation wherein patient status indicators are generated for a set of individual patients or in a dynamic mode wherein a patient status indicator is generated on the fly for an individual patient.

[0048] The comparison module **62** receives as inputs from the database **17** two input sets functionally defined as peer collected measures sets **60** and sibling collected measures sets **61**, although in practice, the collected measures sets are stored on a per sampling basis. Peer collected measures sets **60** contain individual collected measures sets that all relate to the same type of patient information, for instance, atrial electrical activity, but which have been periodically collected over time. Sibling collected measures sets **61** contain individual collected measures sets that relate to different types of patient information, but which may have been collected at the same time or different times. In practice, the collected measures sets are not separately stored as "peer" and "sibling" measures. Rather, each individual patient care record stores multiple sets of sibling collected measures. The distinction between peer collected measures sets **60** and sibling collected measures sets **61** is further described below with reference to FIG. **6**.

[0049] The derivation module **63** determines derived measures sets **64** on an as-needed basis in response to requests from the comparison module **62**. The derived measures **64** are determined by performing linear and non-linear mathematical operations on selected peer measures **60** and sibling measures **61**, as is known in the art.

[0050] FIG. **5** is a database schema showing, by way of example, the organization of a cardiac patient care record stored 70 in the database **17** of the system **10** of FIG. **1**. Only the information pertaining to collected measures sets are shown. Each patient care record would also contain normal identifying and treatment profile information, as well as medical history and other pertinent data (not shown). Each patient care record stores a multitude of collected measures sets for an individual patient. Each individual set represents a recorded snapshot of telemetered signals data which was recorded, for instance, per heartbeat or binned average basis by the implantable medical device **12**. For example, for a cardiac patient, the following information would be recorded as a collected measures set: atrial electrical activity **71**, ventricular electrical activity **72**, time of day **73**, activity level **74**, cardiac output **75**, oxygen level **76**, cardiovascular pressure measures **77**, pulmonary measures **78**, interventions made by the implantable medical device **78**, and the relative success of any interventions made **80**. In addition, the implantable medical device **12** would also communicate device specific information, including battery status **81** and program settings **82**. Other types of collected measures are possible. In addition, a well-documented set of derived measures can be determined based on the collected measures, as is known in the art.

[0051] FIG. **6** is a record view showing, by way of example, a set of partial cardiac patient care records stored in the database **17** of the system **10** of FIG. **1**. Three patient care records are shown for Patient 1, Patient 2, and Patient 3. For each patent, three sets of measures are shown, X, Y, and Z. The measures are organized into sets with Set 0 representing sibling measures made at a reference time t=0. Similarly, Set n−2, Set n−1 and Set n each represent sibling measures made at later reference times t=n−2, t=n−1 and t=n, respectively.

[0052] For a given patient, for instance, Patient 1, all measures representing the same type of patient information, such as measure X, are peer measures. These are measures, which are monitored over time in a disease-matched peer group. All measures representing different types of patient information, such as measures X, Y, and Z, are sibling measures. These are measures which are also measured over time, but which might have medically significant meaning when compared to each other within a single set. Each of the measures, X, Y, and Z, could be either collected or derived measures.

[0053] The analysis module **53** (shown in FIG. **4**) performs two basic forms of comparison. First, individual measures for a given patient can be compared to other individual measures for that same patient. These comparisons might be peer-to-peer measures projected over time, for instance, X_n, X_{n-1}, X_{n-2}, . . . X_0, or sibling-to-sibling measures for a single snapshot, for instance, X_n, Y_n, and Z_n, or projected over time, for instance, X_n, Y_n, Z_n, X_{n-1}, Y_{n-1}, X_{n-2}, Y_{n-2}, Z_{n-2}, . . . X_0, Y_0, Z_0. Second, individual measures for a given patient can be compared to other individual measures for a group of other patients sharing the same disease-specific characteristics or to the patient population in general. Again, these comparisons might be peer-to-peer measures projected over time, for instance, X_n, $X_{n'}$, $X_{n''}$, X_{n-1}, $X_{n-1'}$, $X_{n-1''}$, X_{n-2}, $X_{n-2'}$, $X_{n-2''}$ . . . X_0, $X_{0'}$, $X_{O''}$, or comparing the individual patient's measures to an average from the group. Similarly, these comparisons might be sibling-to-sibling measures for single snapshots, for instance, X_n, $X_{n'}$, $X_{n''}$, Y_n, $Y_{n'}$, $Y_{n''}$, and Z_n, $Z_{n'}$, $Z_{n''}$, or projected over time, for instance, X_n, $X_{n'}$, $X_{n''}$, Y_n, $Y_{n'}$, $Y_{n''}$, Z_n, $Z_{n'}$, $Z_{n''}$, X_{n-1}, $X_{n-1'}$, $X_{n-1''}$, Y_{n-1}, $Y_{n-1'}$, $Y_{n-1''}$, Z_{n-1}, $Z_{n-1'}$, $Z_{n-1''}$, X_{n-2}, $X_{n-2'}$, $X_{n-2''}$, Y_{n-2}, $Y_{n-2'}$, $Y_{n-2''}$, Z_{n-2}, $Z_{n-2'}$, $Z_{n-2''}$ . . . X_0, $X_{0'}$, $X_{0''}$, Y_0, $Y_{0'}$, $Y_{0''}$, and Z_0, $Z_{0'}$, $Z_{0''}$. Other forms of comparisons are feasible.

[0054] FIG. **7** is a flow diagram showing a method **90** for automated collection and analysis of patient information retrieved from an implantable medical device **12** for remote patient care in accordance with the present invention. The method **90** is implemented as a conventional computer program for execution by the server system **16** (shown in FIG. **1**). As a preparatory step, the patient care records are organized in the database **17** with a unique patient care record assigned to each individual patient (block **91**). Next, the collected measures sets for an individual patient are retrieved from the implantable medical device **12** (block **92**) using a programmer, interrogator, telemetered signals transceiver, and the like. The retrieved collected measures sets are sent, on a substantially regular basis, over the internetwork **15** or similar communications link (block **93**) and periodically received by the server system **16** (block **94**). The collected measures sets are stored into the patient care record in the database **17** for that individual patient (block **95**). One or more of the collected measures sets for that patient are analyzed (block **96**), as further described below with reference to FIG. **8**. Finally, feedback based on the analysis is sent to that patient over the internetwork **15** as an email message, via telephone line as an automated voice mail or facsimile message, or by similar feedback communications link (block **97**), as further described below with reference to FIG. **11**.

[0055] FIG. **8** is a flow diagram showing the routine for analyzing collected measures sets **96** for use in the method of FIG. **7**. The purpose of this routine is to make a determination of general patient wellness based on comparisons and heuristic trends analyses of the measures, both collected and derived, in the patient care records in the database **17**. A first collected measures set is selected from a patient care record in the database **17** (block **100**). If the measures comparison is to be made to other measures originating from the patient care record for the same individual patient (block **101**), a second collected measures set is selected from that patient care record (block **102**). Otherwise, a group measures comparison is being made (block **101**) and a second collected measures set is selected from another patient care record in the database **17** (block **103**). Note the second collected measures set could also contain averaged measures for a group of disease specific patients or for the patient population in general.

[0056] Next, if a sibling measures comparison is to be made (block **104**), a routine for comparing sibling collected measures sets is performed (block **105**), as further described below with reference to FIG. **9**. Similarly, if a peer measures comparison is to be made (block **106**), a routine for comparing sibling collected measures sets is performed (block **107**), as further described below with reference to FIGS. **10**A and **10**B.

[0057] Finally, a patient status indicator is generated (block **108**). By way of example, cardiac output could ordinarily be approximately 5.0 liters per minute with a standard deviation of ±1.0. An actionable medical phenomenon could occur when the cardiac output of a patient is ±3.0-4.0 standard deviations out of the norm. A comparison of the cardiac output measures **75** (shown in FIG. **5**) for an individual patient against previous cardiac output measures **75** would establish the presence of any type of downward health trend as to the particular patient. A comparison of the cardiac output measures **75** of the particular patient to the cardiac output measures **75** of a group of patients would establish whether the patient is trending out of the norm. From this type of analysis, the analysis module **53** generates a patient status indicator **54** and other metrics of patient wellness, as is known in the art.

[0058] FIG. **9** is a flow diagram showing the routine for comparing sibling collected measures sets **105** for use in the routine of FIG. **8**. Sibling measures originate from the patient care records for an individual patient. The purpose of this routine is either to compare sibling derived measures to sibling derived measures (blocks **111-113**) or sibling collected measures to sibling collected measures (blocks **115-117**). Thus, if derived measures are being compared (block **110**), measures are selected from each collected measures set (block **111**). First and second derived measures are derived from the selected measures (block **112**) using the derivation module **63** (shown in FIG. **4**). The first and second derived measures are then compared (block **113**) using the comparison module **62** (also shown in FIG. **4**). The steps of selecting, determining, and comparing (blocks **111-113**) are repeated until no further comparisons are required (block **114**), whereupon the routine returns.

[0059] If collected measures are being compared (block **110**), measures are selected from each collected measures set (block **115**). The first and second collected measures are then compared (block **116**) using the comparison module **62** (also shown in FIG. **4**). The steps of selecting and comparing (blocks **115-116**) are repeated until no further comparisons are required (block **117**), whereupon the routine returns.

[0060] FIGS. **10**A and **10**B are a flow diagram showing the routine for comparing peer collected measures sets **107** for use in the routine of FIG. **8**. Peer measures originate from patient care records for different patients, including groups of disease specific patients or the patient population in general. The purpose of this routine is to compare peer derived measures to peer derived measures (blocks **122-125**), peer derived measures to peer collected measures (blocks **126-129**), peer collected measures to peer derived measures (block **131-134**), or peer collected measures to peer collected measures (blocks **135-137**). Thus, if the first measure being compared is a derived measure (block **120**) and the second measure being compared is also a derived measure (block **121**), measures are selected from each collected measures set (block **122**). First and second derived measures are derived from the selected measures (block **123**) using the derivation module **63** (shown in FIG. **4**). The first and second derived measures are then compared (block **124**) using the comparison module **62** (also shown in FIG. **4**). The steps of selecting, determining, and comparing (blocks **122-124**) are repeated until no further comparisons are required (block **115**), whereupon the routine returns.

[0061] If the first measure being compared is a derived measure (block **120**) but the second measure being compared is a collected measure (block **121**), a first measure is selected from the first collected measures set (block **126**). A first derived measure is derived from the first selected measure (block **127**) using the derivation module **63** (shown in FIG. **4**). The first derived and second collected measures are then compared (block **128**) using the comparison module **62** (also shown in FIG. **4**). The steps of selecting, determining, and comparing (blocks **126-128**) are repeated until no further comparisons are required (block **129**), whereupon the routine returns.

[0062] If the first measure being compared is a collected measure (block **120**) but the second measure being compared is a derived measure (block **130**), a second measure is selected from the second collected measures set (block **131**). A second derived measure is derived from the second selected measure (block **132**) using the derivation module **63** (shown in FIG. **4**). The first collected and second derived measures are then compared (block **133**) using the comparison module **62** (also shown in FIG. **4**). The steps of selecting, determining, and comparing (blocks **131-133**) are repeated until no further comparisons are required (block **134**), whereupon the routine returns.

[0063] If the first measure being compared is a collected measure (block **120**) and the second measure being compared is also a collected measure (block **130**), measures are selected from each collected measures set (block **135**). The first and second collected measures are then compared (block **136**) using the comparison module **62** (also shown in FIG. **4**). The steps of selecting and comparing (blocks **135-136**) are repeated until no further comparisons are required (block **137**), whereupon the routine returns.

[0064] FIG. **11** is a flow diagram showing the routine for providing feedback **97** for use in the method of FIG. **7**. The purpose of this routine is to provide tiered feedback based on the patient status indicator. Four levels of feedback are provided with increasing levels of patient involvement and medical care intervention. At a first level (block **150**), an interpretation of the patient status indicator **54**, preferably phrased in lay terminology, and related health care information is sent to the individual patient (block **151**) using the feedback module **55** (shown in FIG. **3**). At a second level (block **152**), a notification of potential medical concern, based on the analysis and heuristic trends analysis, is sent to the individual patient (block **153**) using the feedback module **55**. At a third level (block **154**), the notification of potential medical concern is forwarded to the physician responsible for the individual patient or similar health care professionals (block **155**) using the feedback module **55**. Finally, at a fourth level (block **156**), reprogramming instructions are sent to the implantable medical device **12** (block **157**) using the feedback module **55**.

[0065] Therefore, through the use of the collected measures sets, the present invention makes possible immediate access to expert medical care at any time and in any place. For example, after establishing and registering for each patient an appropriate baseline set of measures, the database server could contain a virtually up-to-date patient history, which is available to medical providers for the remote diagnosis and prevention of serious illness regardless of the relative location of the patient or time of day.

[0066] Moreover, the gathering and storage of multiple sets of critical patient information obtained on a routine basis makes possible treatment methodologies based on an algorithmic analysis of the collected data sets. Each successive introduction of a new collected measures set into the database server would help to continually improve the accuracy and effectiveness of the algorithms used. In addition, the present invention potentially enables the detection, prevention, and cure of previously unknown forms of disorders based on a trends analysis and by a cross-referencing approach to create continuously improving peer-group reference databases.

[0067] Finally, the present invention makes possible the provision of tiered patient feedback based on the automated analysis of the collected measures sets. This type of feedback system is suitable for use in, for example, a subscription based health care service. At a basic level, informational feedback can be provided by way of a simple interpretation of the collected data. The feedback could be built up to provide a gradated response to the patient, for example, to notify the patient that he or she is trending into a potential trouble zone. Human interaction could be introduced, both by remotely situated and local medical practitioners. Finally, the feedback could include direct interventive measures, such as remotely reprogramming a patient's IPG.

[0068] While the invention has been particularly shown and described as referenced to the embodiments thereof, those skilled in the art will understand that the foregoing and other changes in form and detail may be made therein without departing from the spirit and scope of the invention.

What is claimed is:

1. A system for evaluating a patient status for use in heart failure assessment, comprising:

a data module to assemble physiological measures, which were directly recorded as data on a substantially continuous basis by an implantable medical device for a patient or indirectly derived from the data;

a status module to determine a status for the patient through sampling and analysis of the physiological measures over a plurality of data assembly points; and

an evaluation module to evaluate the physiological measures, comprising:

an analysis module to identify any trends that are indicated by the patient status; and

a comparison module to compare each such trend to worsening heart failure indications.

2. A system according to claim **1**, further comprising:

a sampling module to form sampling sets, comprising at least one of:

a peer module to group a plurality of the physiological measures, which each relate to a same type of physiometry, into one or more peer measures sets; and

a sibling module to group a plurality of the physiological measures, which each relate to a different type of physiometry, into one or more sibling measures sets,

wherein one or more of the sampling sets is selected as the physiological measures.

3. A system according to claim **1**, wherein physiological measures from one or more of the physiological measures for the patient, physiological measures for a peer group, and physiological measures for an overall patient population.

4. A system according to claim **1**, further comprising:

a feedback module to provide tiered feedback from the patient status, comprising at least one of:

a first level module to communicate, at a first level, an interpretation of the patient status;

a second level module to communicate, at a second level, a notification of potential medical concern based on the patient status;

a third level module to communicate, at a third level, a notification of potential medical concern based on the patient status to medical personnel; and

a fourth level module to communicate, at a fourth level, a set of reprogramming instructions based on the patient status to an implantable medical device.

5. A system according to claim **1**, wherein the worsening heart failure indications are selected from the group comprising pulmonary artery pressure, left atrial pressure, dyspnea, orthopnea, pulmonary edema, peripheral edema, and fatigue.

6. A system according to claim **1**, further comprising:

a measurement module to measure one or more of pulmonary artery pressure, heart rate, heart sounds, intrathoracic impedance, respiration, posture, lung fluid, activity, weight, and physiological response to activity.

7. A system according to claim **1**, further comprising:

a reprogramming module to reprogram an implantable medical device based on evaluation of the physiological measures.

8. A system according to claim **7**, wherein the worsening heart failure indications are factored into the reprogramming.

9. A system according to claim **1**, wherein respiration rate is tracked through the implantable medical device, further comprising:

a notification module to generate a notification triggered by a parameter assigned to the respiration rate.

10. A system according to claim **9**, wherein the parameter comprises one or more of an upper limit parameter applied over a short term and a counter parameter applied over a long term.

11. A method for evaluating a patient status for use in heart failure assessment, comprising:

assembling physiological measures, which were directly recorded as data on a substantially continuous basis by an implantable medical device for a patient or indirectly derived from the data;

determining a status for the patient through sampling and analysis of the physiological measures over a plurality of data assembly points; and

identifying any trends that are indicated by the patient status and comparing each such trend to worsening heart failure indications.

12. A method according to claim **11**, further comprising:

forming sampling sets, comprising at least one of:

grouping a plurality of the physiological measures, which each relate to a same type of physiometry, into one or more peer measures sets; and

grouping a plurality of the physiological measures, which each relate to a different type of physiometry, into one or more sibling measures sets; and

selecting one or more of the sampling sets as the physiological measures.

13. A method according to claim **11**, further comprising: including physiological measures from one or more of the physiological measures for the patient, physiological measures for a peer group, and physiological measures for an overall patient population.

14. A method according to claim **11**, further comprising: providing tiered feedback from the patient status, comprising at least one of:

at a first level, communicating an interpretation of the patient status;

at a second level, communicating a notification of potential medical concern based on the patient status;

at a third level, communicating a notification of potential medical concern based on the patient status to medical personnel; and

at a fourth level, communicating a set of reprogramming instructions based on the patient status to an implantable medical device.

15. A method according to claim **11**, wherein the worsening heart failure indications are selected from the group comprising pulmonary artery pressure, left atrial pressure, dyspnea, orthopnea, pulmonary edema, peripheral edema, and fatigue.

16. A method according to claim **11**, further comprising: measuring one or more of pulmonary artery pressure, heart rate, heart sounds, intrathoracic impedance, respiration, posture, lung fluid, activity, weight, and physiological response to activity.

17. A method according to claim **11**, further comprising: reprogramming an implantable medical device based on evaluation of the physiological measures.

18. A method according to claim **17**, further comprising: factoring the worsening heart failure indications into the reprogramming.

19. A method according to claim **11**, further comprising: tracking respiration rate through the implantable medical device; and

generating a notification triggered by a parameter assigned to the respiration rate.

20. A method according to claim **19**, wherein the parameter comprises one or more of an upper limit parameter applied over a short term and a counter parameter applied over a long term.

21. A system for evaluating a patient status from sampled physiometry for use in heart failure assessment, comprising:

a storage module to store physiological measures comprising at least one of direct measures regularly recorded on a substantially continuous basis by an implantable medical device for a patient and measures derived from the direct measures;

a sampling module to sample at least one of those of the physiological measures, which each relate to a same type of physiometry, and those of the physiological measures, which each relate to a different type of physiometry;

a status module to determine a status for the patient through analysis of those sampled physiological measures assembled from a plurality of recordation points; and

an evaluation module to evaluate the sampled physiological measures, comprising:

an analysis module to identify any trends that are indicated by the patient status, which might affect cardiac performance of the patient; and

a comparison module to compare each such trend to worsening heart failure indications to generate a notification of parameter violations.

22. A system according to claim **21**, further comprising: a reprogramming module to reprogram an implantable medical device based on extended evaluation of the direct measures and the derived measures.

23. A system according to claim **21**, further comprising: a tracking module to track respiration rate of the patient on a regular basis through the implantable medical device; and

a notification module to generate a notification triggered by one or more of an upper limit parameter applied over a short term and a counter parameter applied over a long term.

24. A method for evaluating a patient status from sampled physiometry for use in heart failure assessment, comprising:

storing physiological measures comprising at least one of direct measures regularly recorded on a substantially continuous basis by an implantable medical device for a patient and measures derived from the direct measures;

sampling at least one of those of the physiological measures, which each relate to a same type of physiometry, and those of the physiological measures, which each relate to a different type of physiometry;

determining a status for the patient through analysis of those sampled physiological measures assembled from a plurality of recordation points; and

evaluating the sampled physiological measures, comprising:

identifying any trends that are indicated by the patient status, which might affect cardiac performance of the patient; and

comparing each such trend to worsening heart failure indications to generate a notification of parameter violations.

25. A method according to claim **24**, further comprising: reprogramming an implantable medical device based on extended evaluation of the direct measures and the derived measures.

26. A method according to claim **24**, further comprising: tracking respiration rate of the patient on a regular basis through the implantable medical device; and

generating a notification triggered by one or more of an upper limit parameter applied over a short term and a counter parameter applied over a long term.

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