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(54) **SYSTEM AND METHOD FOR PRIORITIZING MEDICAL CONDITIONS**

(76) Inventor: **Gust H. Bardy**, Seattle, WA (US)

Correspondence Address:
CASCADIA INTELLCTUAL PROPERTY
500 UNION STREET
STE.1005
SEATTLE, WA 98101 (US)

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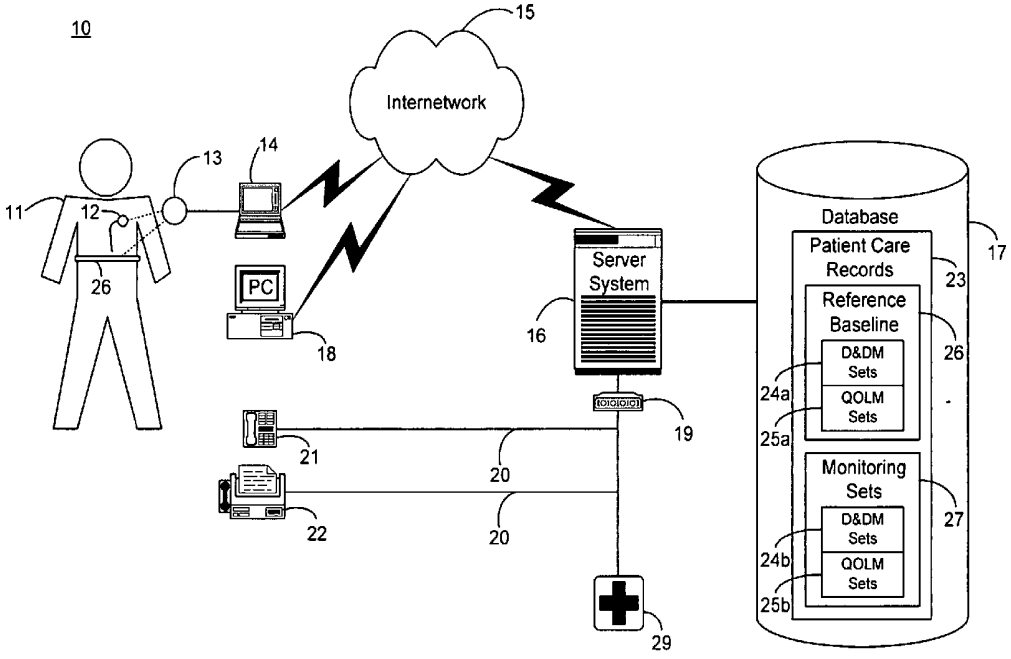
(57) **ABSTRACT**

A system for ordering and prioritizing multiple health disorders for automated remote patient care is presented. A database maintains information for an individual patient by organizing monitoring sets in a database, and measures relating to patient information previously recorded and derived on a substantially continuous basis into a monitoring set in the database. A server retrieving and processing the monitoring includes a comparison module comparing stored measures from each of the monitoring sets to other stored measures from another of the monitoring sets with both stored measures relating to the same type of patient information, and an analysis module ordering each patient status change in temporal sequence and categorizing health disorder candidates by quantifiable physiological measures, and identifying the health disorder candidate having the pathophysiology substantially corresponding to the patient status changes which occurred substantially least recently as the index disorder.



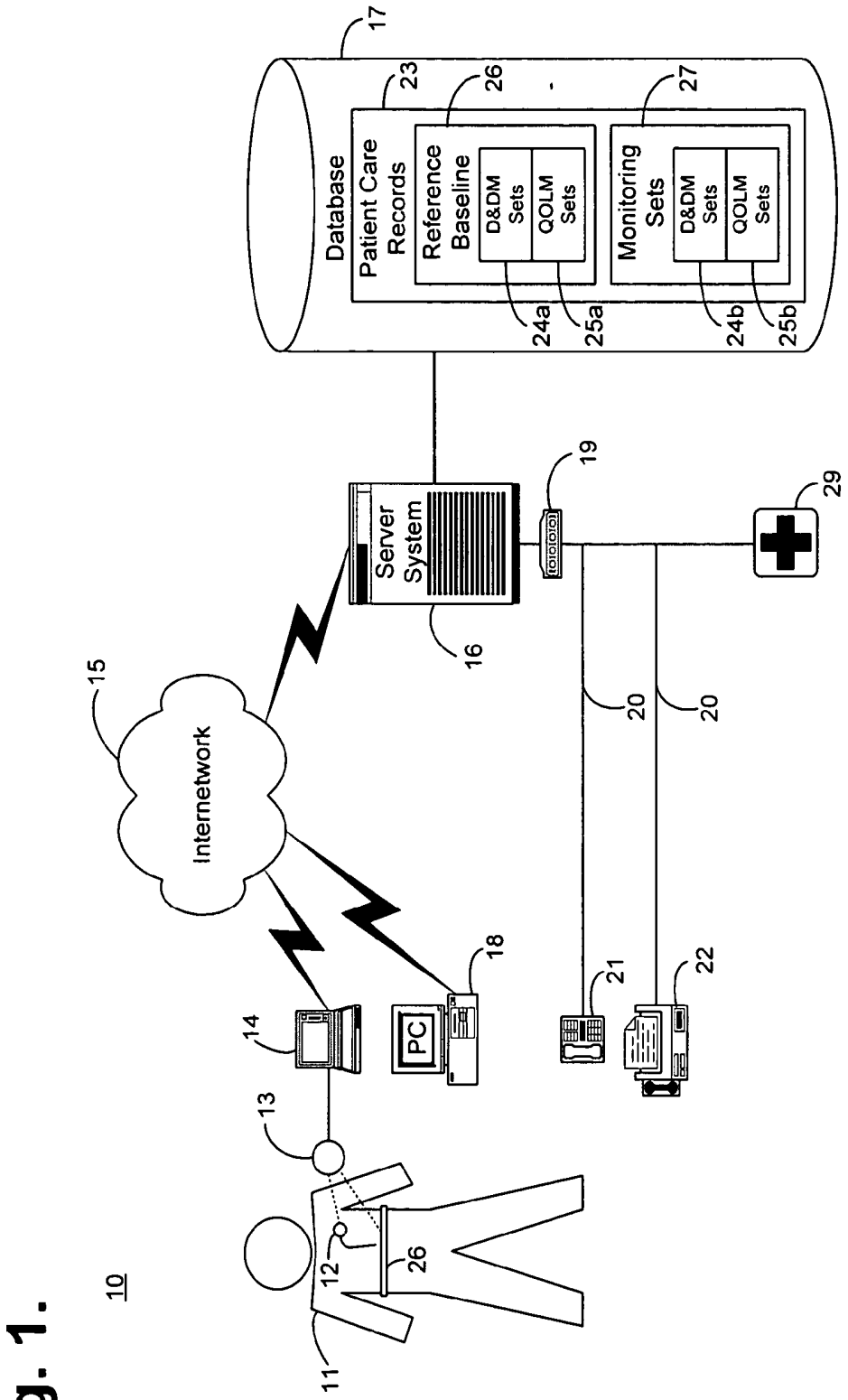

17
Database
23
Patient Care Records
26
Reference Baseline
D&DM Sets
QOLM Sets
27
Monitoring Sets
D&DM Sets
QOLM Sets
24a
25a
24b
25b
19
29
Server System
16
15
Internetwork
20
20
18
PC
14
21
22
13
12
26
11
10

Fig. 1.

Fig. 2.

40

Physiological Measure	Time of Day	Sequence
Acidity (pH) Level (41)	10/25/1999 14:00	1
Arterial Carbon Dioxide Score (42)	10/25/1999 14:00	2
Arterial Oxygen Score (43)	10/25/1999 14:00	3
Atrial Electrical Activity (44)	10/25/1999 14:00	4
Blood Pressure (45)	10/25/1999 14:00	5
Body Temperature (46)	10/25/1999 14:00	6
BUN and Creatinine (47)	10/25/1999 14:00	7
Cardiac Injury Chemical Tests (48)	10/25/1999 14:00	8
Cardiac Output (49)	10/25/1999 14:00	9
Cardiovascular Pressures (50)	10/25/1999 14:00	10
CNS Blood Flow (51)	10/25/1999 14:00	11
CNS Injury Chemical Tests (52)	10/25/1999 14:00	12
Coronary Sinus Lactate Production (53)	10/25/1999 14:00	13
Glucose Level (54)	10/25/1999 14:00	14
Hematocrit (55)	10/25/1999 14:00	15
Hormonal Levels (56)	10/25/1999 14:00	16
Interventions Made (57)	10/25/1999 14:00	17
Left Ventricular Wall Motion Changes (58)	10/25/1999 14:00	18
Lung Injury Chemical Tests (59)	10/25/1999 14:00	19
Minute Ventilation (60)	10/25/1999 14:00	20
Mixed Venous Oxygen Score (61)	10/25/1999 14:00	21
Myocardial Blood Flow (62)	10/25/1999 14:00	22
Patient Activity Score (63)	10/25/1999 14:00	23
Patient Geographic Location (Altitude) (64)	10/25/1999 14:00	24
Posture (65)	10/25/1999 14:00	25
Potassium [K+] Level (66)	10/25/1999 14:00	26
PR Interval or AV Interval (67)	10/25/1999 14:00	27
Pulmonary Artery Diastolic Pressure Measure (68)	10/25/1999 14:00	28
Pulmonary Artery Systolic Pressure Measure (69)	10/25/1999 14:00	29
Pulmonary Measures (70)	10/25/1999 14:00	30
QRS Measures (71)	10/25/1999 14:00	31
QT Interval (72)	10/25/1999 14:00	32
Respiratory Rate (73)	10/25/1999 14:00	33
Serum Myocardial Creatinine Kinase (74)	10/25/1999 14:00	34
Serum Troponin (75)	10/25/1999 14:00	35
Sodium [Na+] Level (76)	10/25/1999 14:00	36
ST Segment Measures (77)	10/25/1999 14:00	37
ST-T Wave Measures (78)	10/25/1999 14:00	38
Success of Interventions Made (79)	10/25/1999 14:00	39
T Wave Measures (80)	10/25/1999 14:00	40
Temperature (81)	10/25/1999 14:00	41
Transthoracic Impedance (82)	10/25/1999 14:00	42
Ventilatory Tidal Volume (83)	10/25/1999 14:00	43
Ventricular Electrical Activity (84)	10/25/1999 14:00	44
Time of Day (85)	10/25/1999 14:00	45

Fig. 3.

95

Quality of Life (QOL) Measure	Time of Day	Sequence
Overall Health Wellness (96)	10/25/1999 14:00	1
Psychological State (97)	10/25/1999 14:00	2
Chest Discomfort (98)	10/25/1999 14:00	3
Location of Chest Discomfort (99)	10/25/1999 14:00	4
Palpitations (100)	10/25/1999 14:00	5
Shortness of Breath (101)	10/25/1999 14:00	6
Exercise Tolerance (102)	10/25/1999 14:00	7
Cough (103)	10/25/1999 14:00	8
Sputum Production (104)	10/25/1999 14:00	9
Sputum Color (105)	10/25/1999 14:00	10
Energy Level (106)	10/25/1999 14:00	11
Syncope (107)	10/25/1999 14:00	12
Near Syncope (108)	10/25/1999 14:00	13
Nausea (109)	10/25/1999 14:00	14
Diaphoresis (110)	10/25/1999 14:00	15
Time of Day (111)	10/25/1999 14:00	16

Fig. 4.

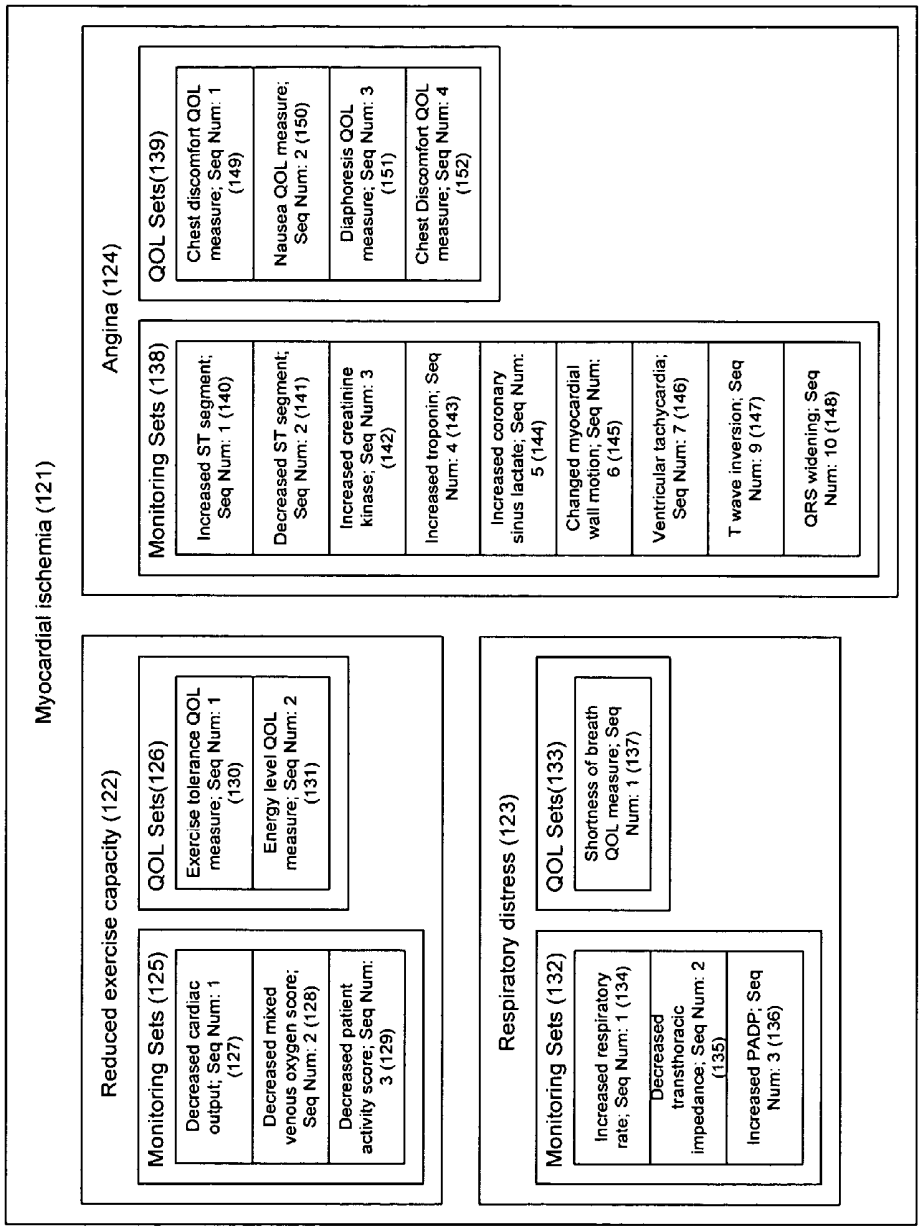

120
Myocardial ischemia (121)
Reduced exercise capacity (122)
Monitoring Sets (125)
Decreased cardiac output; Seq Num: 1 (127)
Decreased mixed venous oxygen score; Seq Num: 2 (128)
Decreased patient activity score; Seq Num: 3 (129)
QOL Sets(126)
Exercise tolerance QOL measure; Seq Num: 1 (130)
Energy level QOL measure; Seq Num: 2 (131)
Respiratory distress (123)
Monitoring Sets (132)
Increased respiratory rate; Seq Num: 1 (134)
Decreased transthoracic impedance; Seq Num: 2 (135)
Increased PADP; Seq Num: 3 (136)
QOL Sets(133)
Shortness of breath QOL measure; Seq Num: 1 (137)
Angina (124)
Monitoring Sets (138)
Increased ST segment; Seq Num: 1 (140)
Decreased ST segment; Seq Num: 2 (141)
Increased creatinine kinase; Seq Num: 3 (142)
Increased troponin; Seq Num: 4 (143)
Increased coronary sinus lactate; Seq Num: 5 (144)
Changed myocardial wall motion; Seq Num: 6 (145)
Ventricular tachycardia; Seq Num: 7 (146)
T wave inversion; Seq Num: 9 (147)
QRS widening; Seq Num: 10 (148)
QOL Sets(139)
Chest discomfort QOL measure; Seq Num: 1 (149)
Nausea QOL measure; Seq Num: 2 (150)
Diaphoresis QOL measure; Seq Num: 3 (151)
Chest Discomfort QOL measure; Seq Num: 4 (152)

Fig. 5.

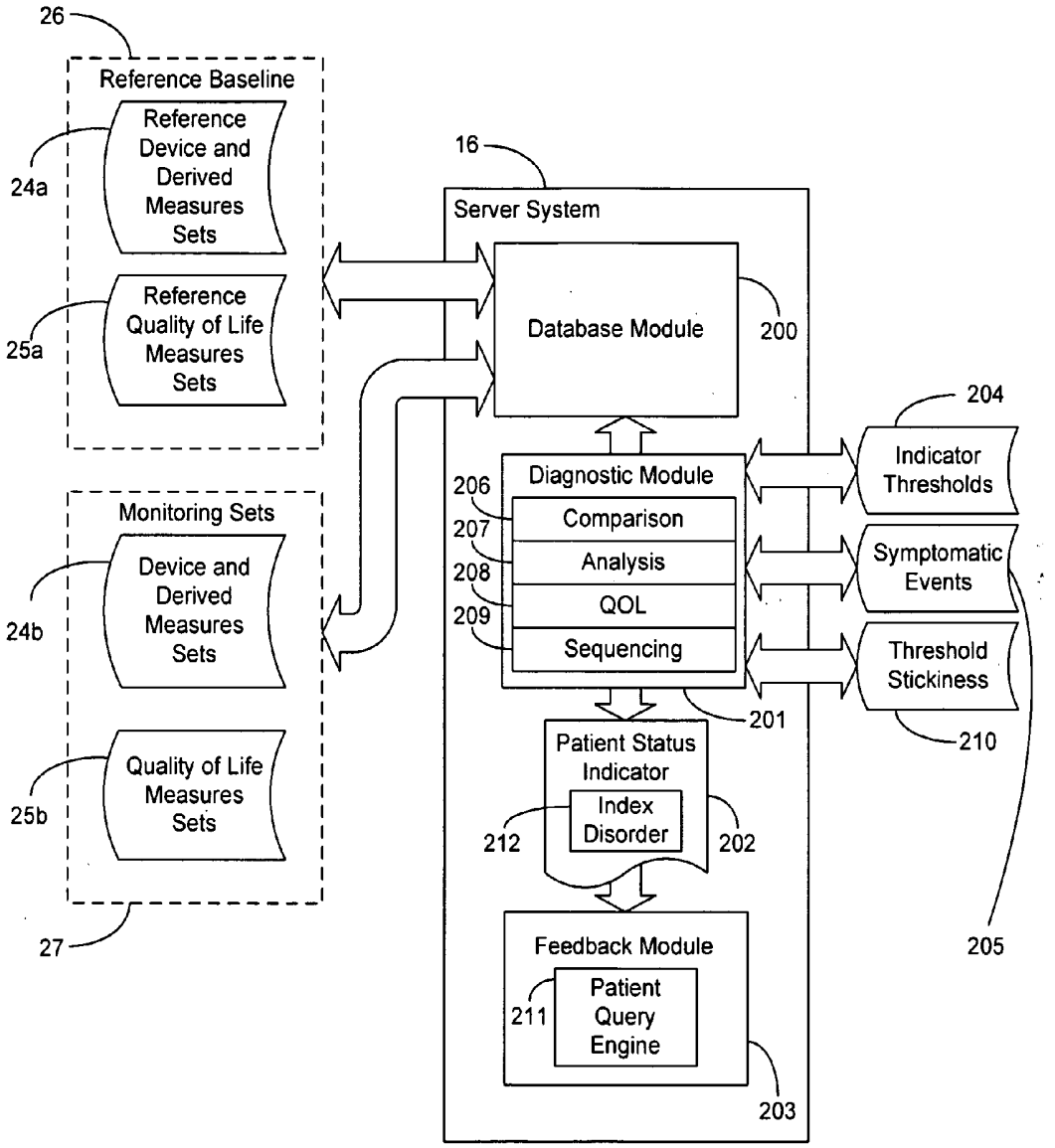

26
Reference Baseline
Reference Device and Derived Measures Sets
24a
Reference Quality of Life Measures Sets
25a
Monitoring Sets
Device and Derived Measures Sets
24b
Quality of Life Measures Sets
25b
27
16
Server System
Database Module
200
Diagnostic Module
206
Comparison
207
Analysis
208
QOL
209
Sequencing
201
Patient Status Indicator
Index Disorder
212
202
Feedback Module
211
Patient Query Engine
203
204
Indicator Thresholds
Symptomatic Events
Threshold Stickiness
210
205

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 →

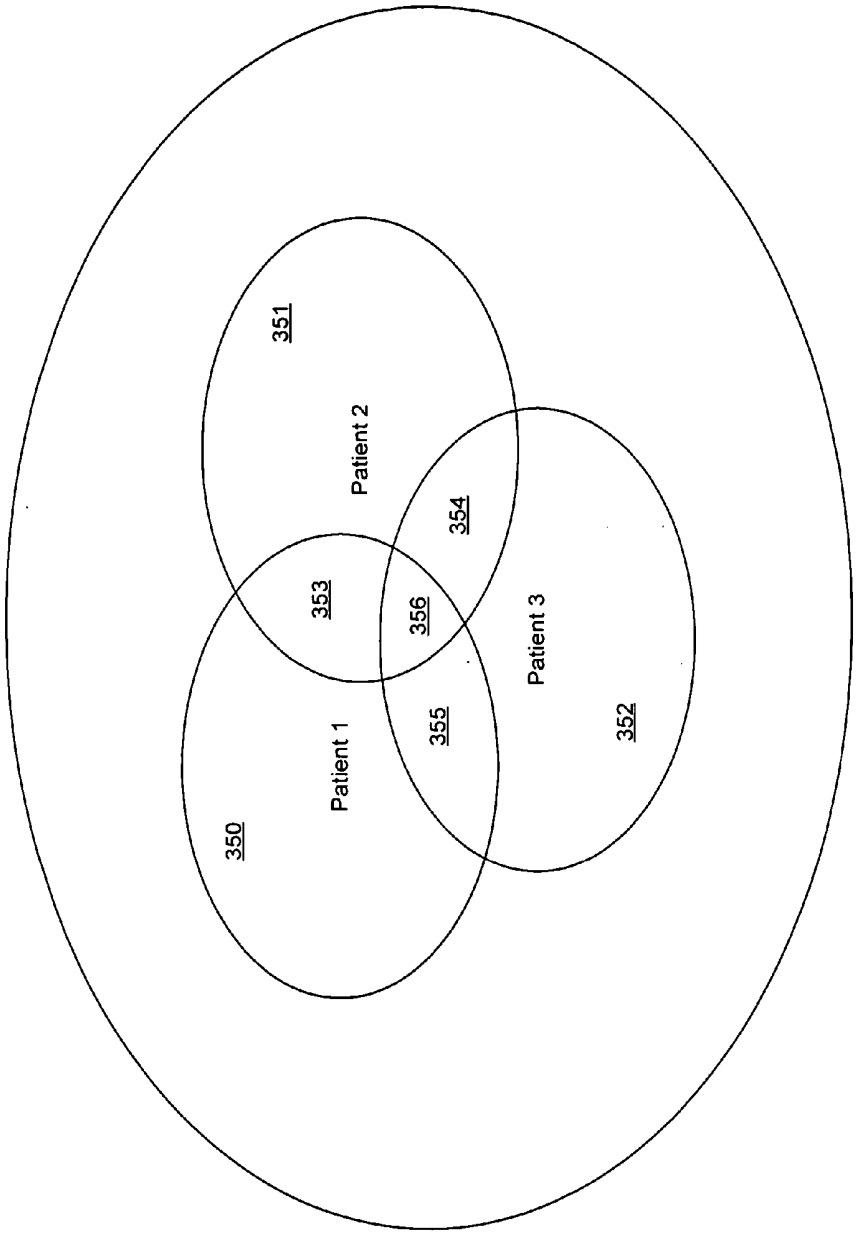


Fig. 7.

Fig. 8A.

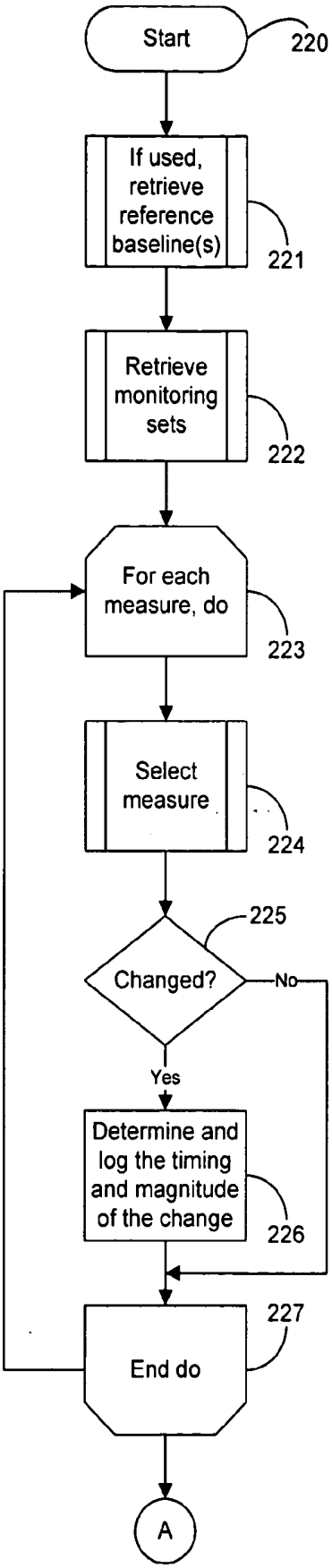

Start
220
If used, retrieve reference baseline(s)
221
Retrieve monitoring sets
222
For each measure, do
223
Select measure
224
225
Changed?
No
Yes
Determine and log the timing and magnitude of the change
226
227
End do
A

Fig. 8B.

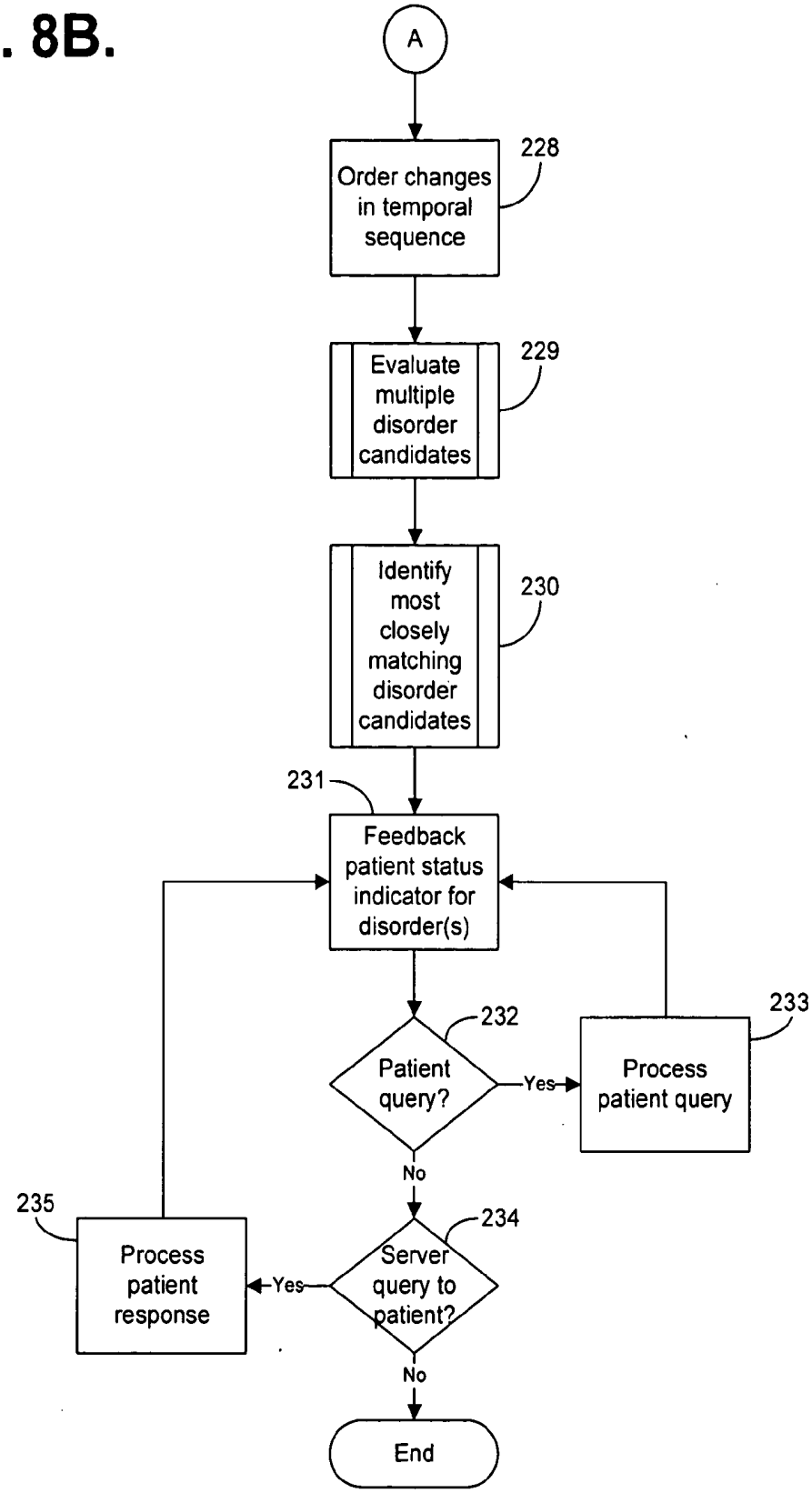

A
Order changes in temporal sequence
228
Evaluate multiple disorder candidates
229
Identify most closely matching disorder candidates
230
231
Feedback patient status indicator for disorder(s)
232
Patient query?
Yes
Process patient query
233
No
234
Server query to patient?
Yes
Process patient response
235
No
End

Fig. 9.

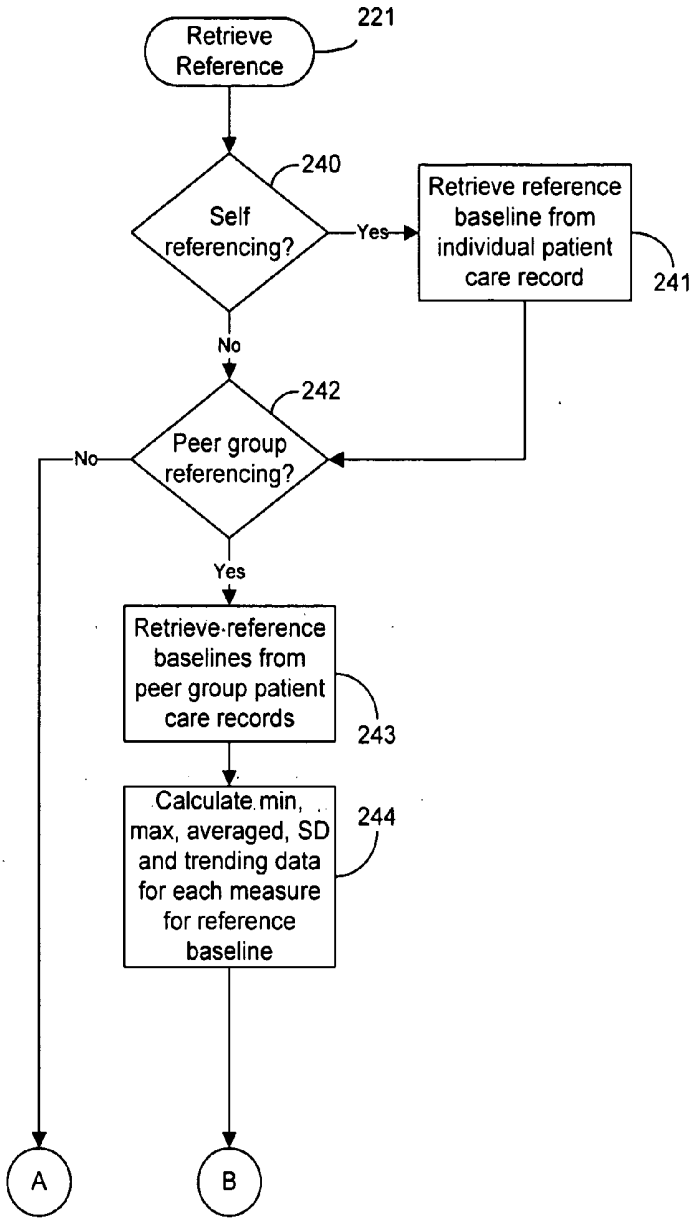

Retrieve Reference
221
240
Self referencing?
Yes
Retrieve reference baseline from individual patient care record
241
No
242
Peer group referencing?
No
Yes
Retrieve reference baselines from peer group patient care records
243
Calculate min, max, averaged, SD and trending data for each measure for reference baseline
244
A
B

Fig. 9 (Cont).

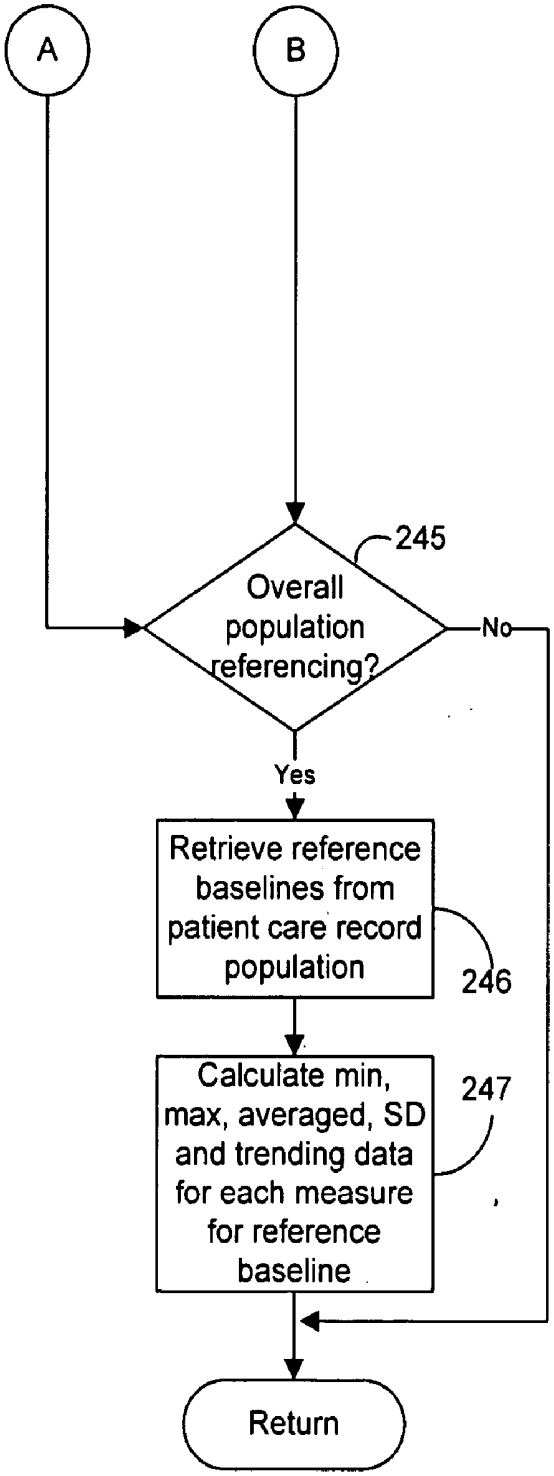

A
B
245
Overall population referencing?
No
Yes
Retrieve reference baselines from patient care record population
246
Calculate min, max, averaged, SD and trending data for each measure for reference baseline
247
Return

Fig. 10.

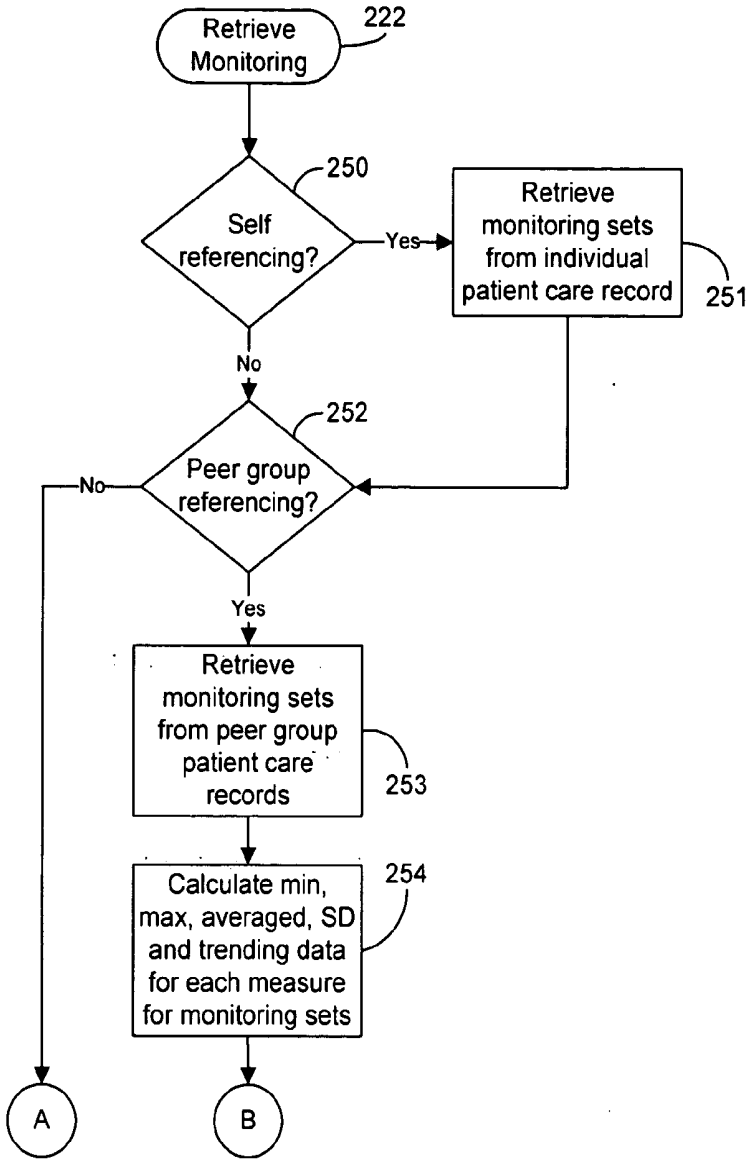

Retrieve Monitoring
222
Self referencing?
250
Yes
Retrieve monitoring sets from individual patient care record
251
No
Peer group referencing?
252
No
Yes
Retrieve monitoring sets from peer group patient care records
253
Calculate min, max, averaged, SD and trending data for each measure for monitoring sets
254
A
B

Fig. 10 (Cont).

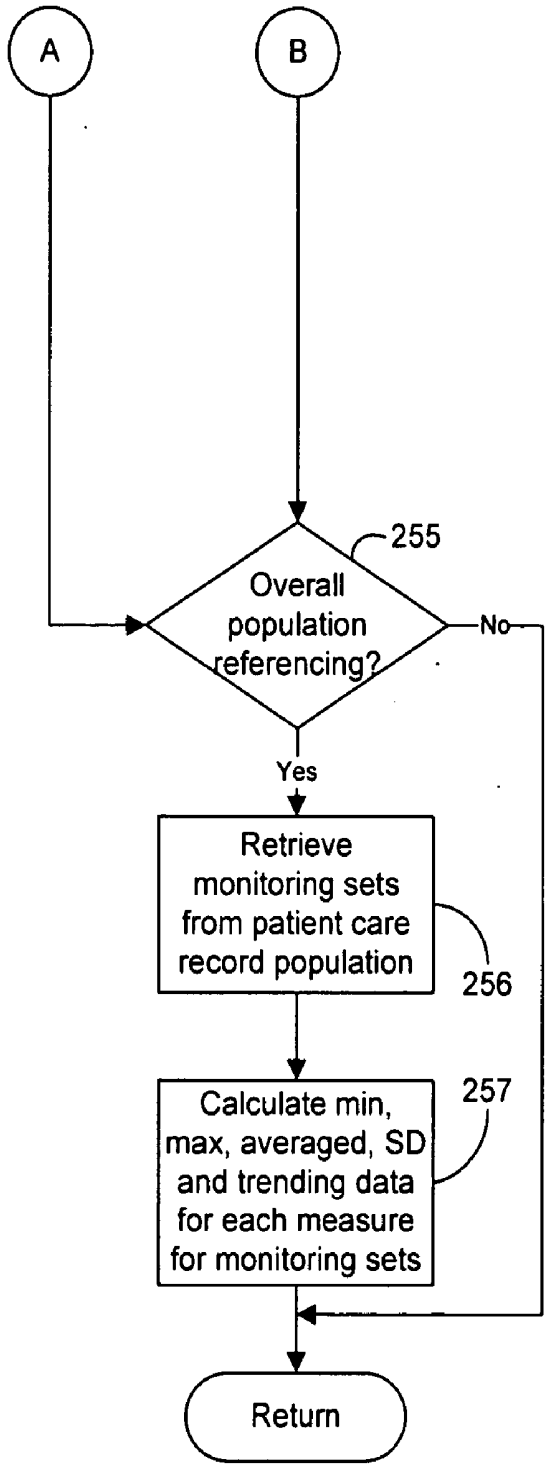

A
B
255
Overall population referencing?
No
Yes
Retrieve monitoring sets from patient care record population
256
Calculate min, max, averaged, SD and trending data for each measure for monitoring sets
257
Return

Fig. 11.

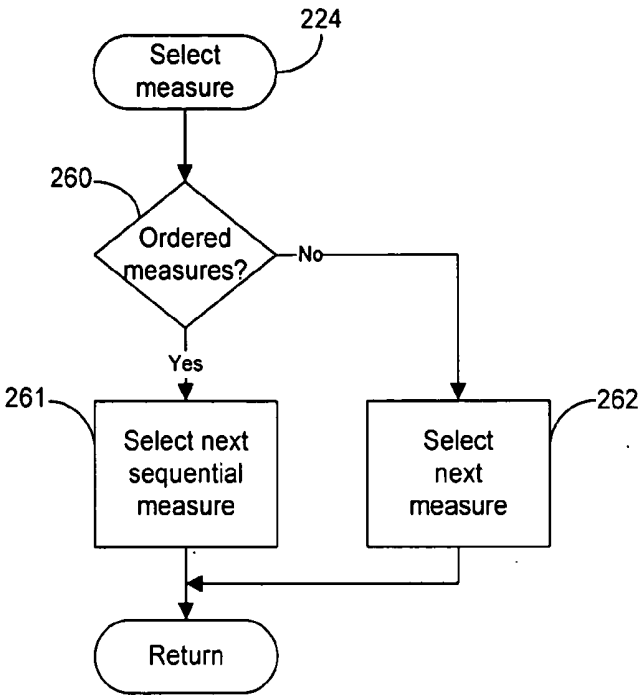

224
Select measure
260
Ordered measures?
No
Yes
261
Select next sequential measure
262
Select next measure
Return

Fig. 12A.

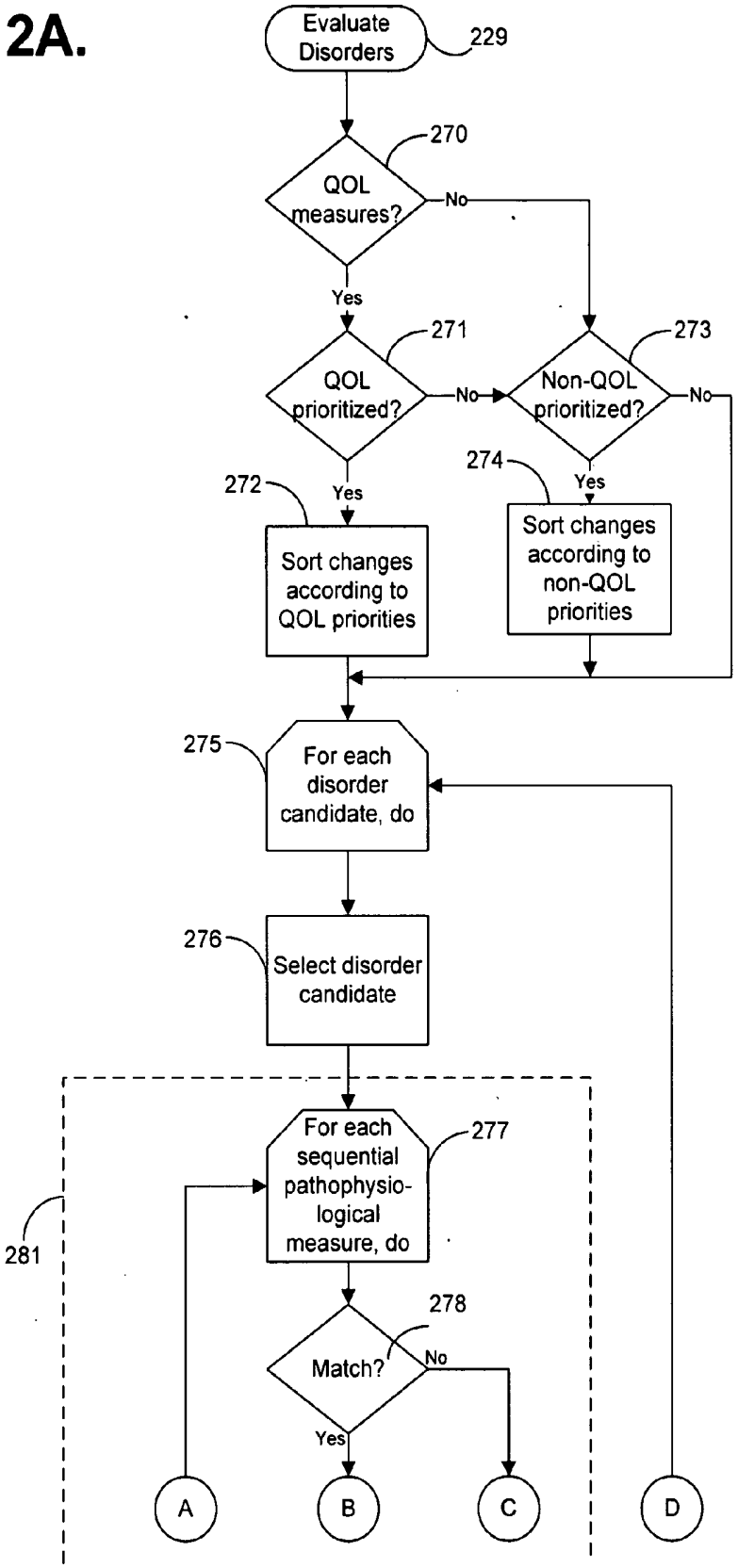

Evaluate Disorders
229
270
QOL measures?
No
Yes
271
QOL prioritized?
No
273
Non-QOL prioritized?
No
Yes
272
Sort changes according to QOL priorities
274
Yes
Sort changes according to non-QOL priorities
275
For each disorder candidate, do
276
Select disorder candidate
281
For each sequential pathophysio-logical measure, do
277
278
Match?
No
Yes
A
B
C
D

Fig. 12B.

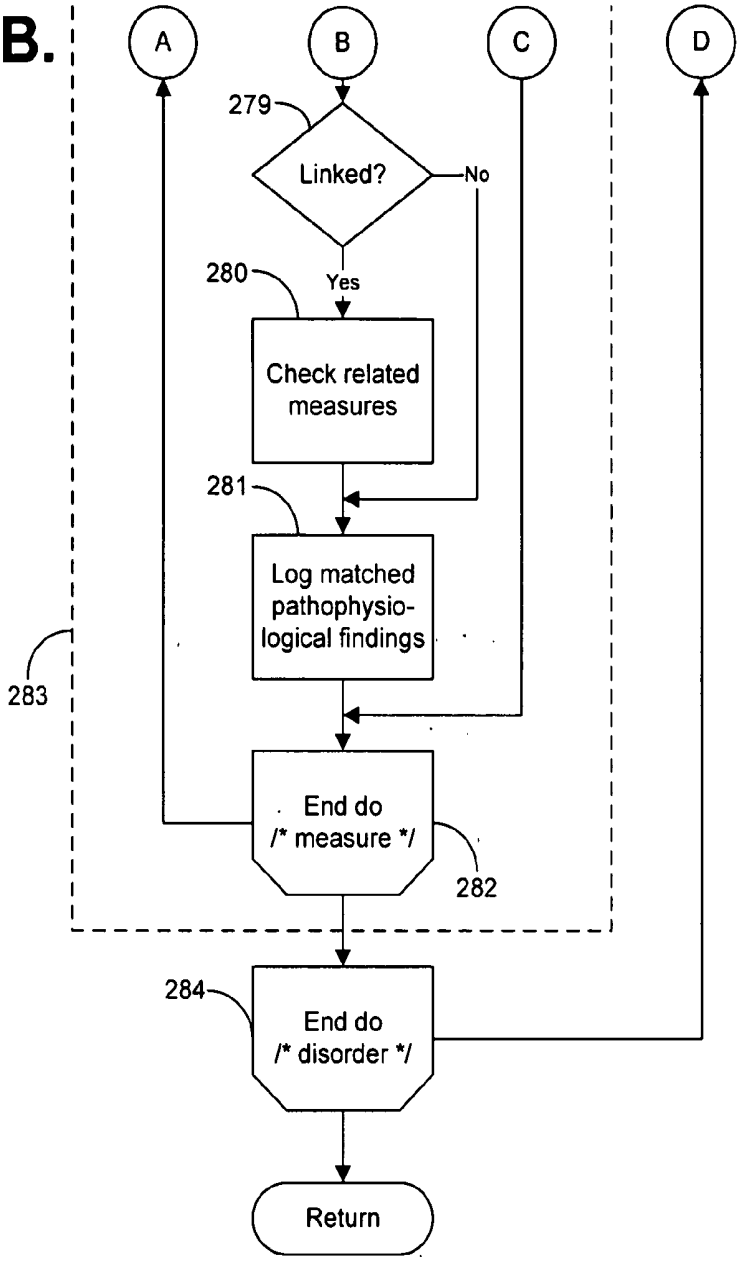

A
B
C
D
279
Linked?
No
Yes
280
Check related measures
281
Log matched pathophysio-logical findings
283
End do /* measure */
282
284
End do /* disorder */
Return

Fig. 13A.

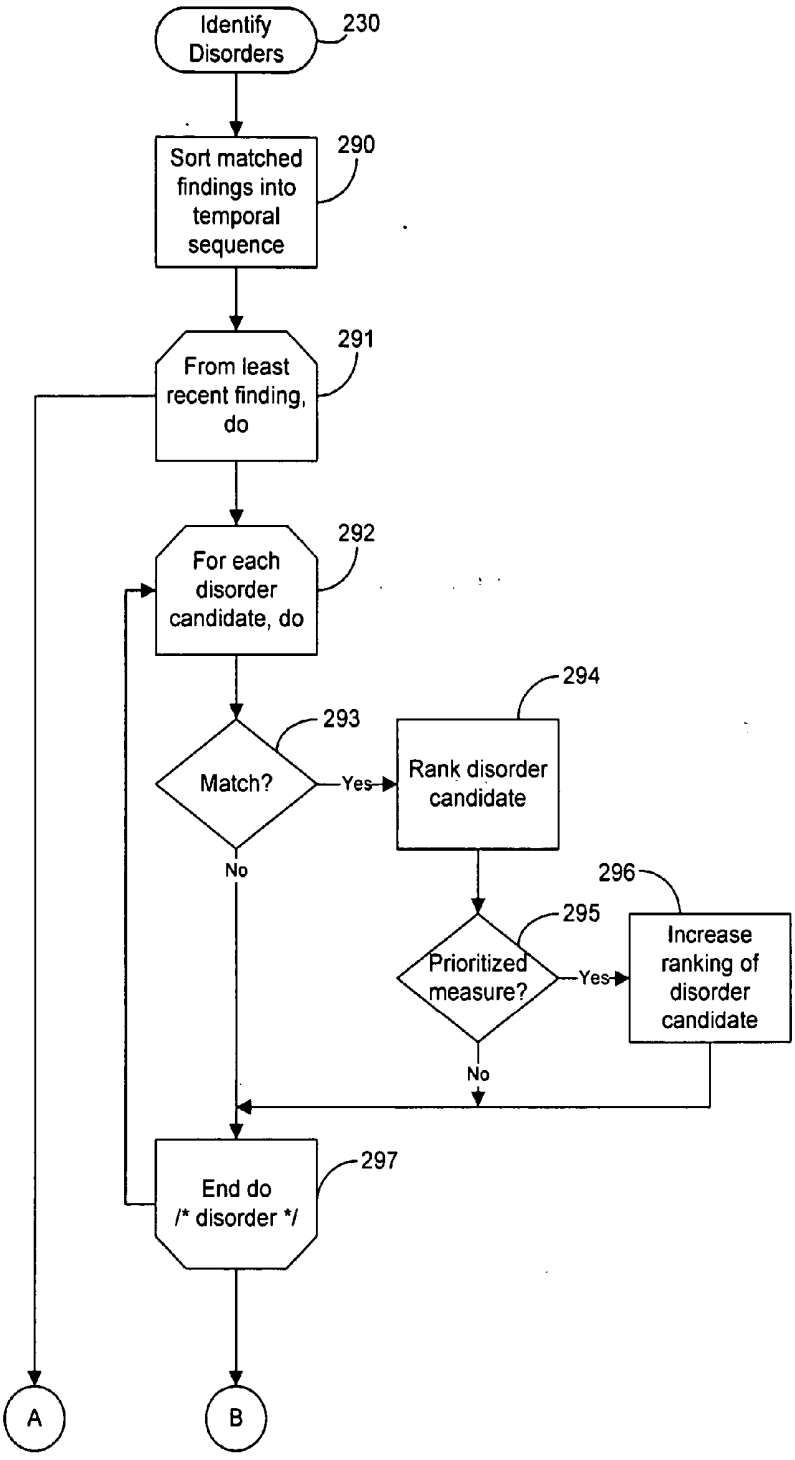
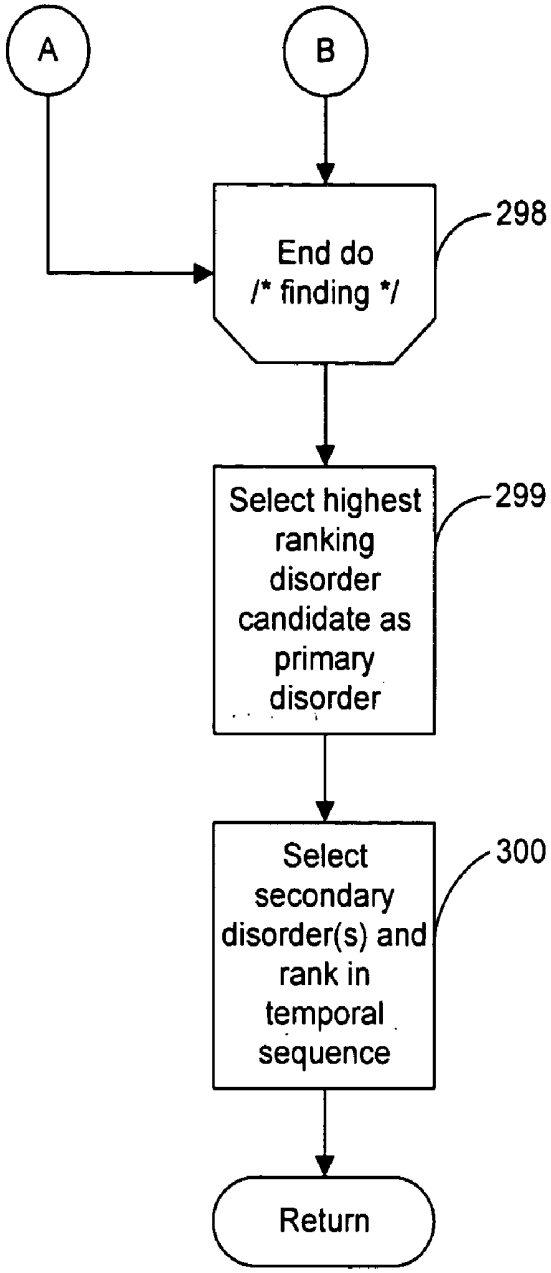

Identify Disorders
230
Sort matched findings into temporal sequence
290
From least recent finding, do
291
For each disorder candidate, do
292
Match?
293
Yes
Rank disorder candidate
294
No
Prioritized measure?
295
Yes
Increase ranking of disorder candidate
296
No
End do /* disorder */
297
A
B

Fig. 13B.


A
B
End do
/* finding */
298
Select highest ranking disorder candidate as primary disorder
299
Select secondary disorder(s) and rank in temporal sequence
300
Return

SYSTEM AND METHOD FOR PRIORITIZING MEDICAL CONDITIONS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This patent application is a divisional of U.S. patent application Ser. No. 10/976,665, filed Oct. 29, 2004, pending, which is a continuation of U.S. Pat. No. 6,951,539, issued Oct. 4, 2005, which is a continuation of U.S. Pat. No. 6,834,203, issued Dec. 21, 2004, which is a continuation of U.S. Pat. No. 6,440,066, issued Aug. 27, 2002, the disclosures of which are incorporated by reference, and the priority filing dates of which are claimed.

FIELD OF THE INVENTION

[0002] The present invention relates in general to automated multiple near-simultaneous health disorder diagnosis and analysis, and, in particular, to an automated collection and analysis patient care system and method for ordering and prioritizing multiple health disorders to identify an index disorder.

BACKGROUND OF THE INVENTION

[0003] The rising availability of networked digital communications means, particularly wide area networks (WANs), including public information internetworks such as the Internet, have made possible diverse opportunities for providing traditional storefront- or office-bound services through an automated and remote distributed system arrangement. For example, banking, stock trading, and even grocery shopping can now be performed on-line over the Internet. However, some forms of services, especially health care services which include disease diagnosis and treatment, require detailed and personal knowledge of the consumer/patient. The physiological data that would allow assessment of a disease has traditionally been obtained through the physical presence of the individual at the physician's office or in the hospital.

[0004] Presently, important physiological measures can be recorded and collected for patients equipped with an external monitoring or therapeutic device, or via implantable device technologies, or recorded manually by the patient. If obtained frequently and regularly, these recorded physiological measures can provide a degree of disease detection and prevention heretofore unknown. For instance, patients already suffering from some form of treatable heart disease often receive an implantable pulse generator (IPG), cardiovascular or heart failure monitor, therapeutic device, or similar external wearable device, with which rhythm and structural problems of the heart can be monitored and treated. These types of devices are useful for detecting physiological changes in patient conditions through the retrieval and analysis of telemetered signals stored in an on-board, volatile memory. Typically, these devices can store more than thirty minutes of per heartbeat data recorded on a per heartbeat, binned average basis, or on a derived basis from which can be measured or derived, for example, atrial or ventricular electrical activity, minute ventilation, patient activity score, cardiac output score, mixed venous oxygen score, cardiovascular pressure measures, and the like. However, the proper analysis of retrieved telemetered signals requires detailed medical subspecialty knowledge in the area of heart disease, such as by cardiologists and cardiac electrophysiologists.

[0005] Alternatively, these telemetered signals can be remotely collected and analyzed using an automated patient care system. One such system is described in a related, commonly assigned U.S. Pat. No. 6,312,378, issued Nov. 6, 2001, the disclosure of which is incorporated herein by reference. A medical device adapted to be implanted in an individual patient records telemetered signals that are then retrieved on a regular, periodic basis using an interrogator or similar interfacing device. The telemetered signals are downloaded via an internetwork onto a network server on a regular, e.g., daily, basis and stored as sets of collected measures in a database along with other patient care records. The information is then analyzed in an automated fashion and feedback, which includes a patient status indicator, is provided to the patient.

[0006] While such an automated system can serve as a valuable tool in providing remote patient care, an approach to systematically correlating and analyzing the raw collected telemetered signals, as well as manually collected physiological measures, through applied medical knowledge to accurately diagnose, order and prioritize multiple near-simultaneous health disorders, such as, by way of example, congestive heart failure, myocardial ischemia, respiratory insufficiency, and atrial fibrillation, is needed. As a case in point, a patient might develop pneumonia that in turn triggers the onset of myocardial ischemia that in turn leads to congestive heart failure that in turn causes the onset of atrial fibrillation that in turn exacerbates all three preceding conditions. The relative relationship of the onset and magnitude of each disease measure abnormality has direct bearing on the optimal course of therapy. Patients with one or more pre-existing diseases often present with a confusing array of problems that can be best sorted and addressed by analyzing the sequence of change in the various physiological measures monitored by the device.

[0007] One automated patient care system directed to a patient-specific monitoring function is described in U.S. Pat. No. 5,113,869 ('869) to Nappholz et al. The '869 patent discloses an implantable, programmable electrocardiography (ECG) patient monitoring device that senses and analyzes ECG signals to detect ECG and physiological signal characteristics predictive of malignant cardiac arrhythmias. The monitoring device can communicate a warning signal to an external device when arrhythmias are predicted. However, the Nappholz device is limited to detecting ventricular tachycardias. Moreover, the ECG morphology of malignant cardiac tachycardias is well established and can be readily predicted using on-board signal detection techniques. The Nappholz device is patient specific and is unable to automatically take into consideration a broader patient or peer group history for reference to detect and consider the progression or improvement of cardiovascular disease. Additionally, the Nappholz device is unable to automatically self-reference multiple data points in time and cannot detect disease regression. Also, the Nappholz device must be implanted and cannot function as an external monitor. Finally, the Nappholz device is incapable of tracking the cardiovascular and cardiopulmonary consequences of any rhythm disorder.

[0008] Consequently, there is a need for an approach for remotely ordering and prioritizing multiple, related medical diseases and disorders using an automated patient collection and analysis patient care system. Preferably, such an

approach would identify a primary or index disorder for diagnosis and treatment, while also aiding in the management of secondary disorders that arise as a consequence of the index event.

[0009] There is a further need for an automated, distributed system and method capable of providing medical health care services to remote patients via a distributed communications means, such as a WAN, including the Internet. Preferably, such a system and method should be capable of monitoring objective "hard" physiological measures and subjective "soft" quality of life and symptom measures and correlating the two forms of patient health care data to order, prioritize and identify disorders and disease.

SUMMARY OF THE INVENTION

[0010] The present invention provides a system and method for remotely ordering and prioritizing multiple, near-simultaneous health disorders using an automated collection and analysis patient care system. The various physiological measures of individual patients are continuously monitored using implantable, external, or manual medical devices and the recorded physiological measures are downloaded on a substantially regular basis to a centralized server system. Derived measures are extrapolated from the recorded measures. As an adjunct to the device-recorded measures, the patients may regularly submit subjective, quality of life and symptom measures to the server system to assist identifying a change in health condition and to correlate with objective health care findings. Changes in patient status are determined by observing differences between the various recorded, derived and quality of life and symptom measures over time. Any changes in patient status are correlated to multiple disorder candidates having similar abnormalities in physiological measures for identification of a primary index disorder candidate.

[0011] An embodiment of the present invention is an automated collection and analysis patient care system and method for ordering and prioritizing multiple health disorders to identify an index disorder. A plurality of monitoring sets is retrieved from a database. Each of the monitoring sets include stored measures relating to patient information recorded and derived on a substantially continuous basis. A patient status change is determined by comparing at least one stored measure from each of the monitoring sets to at least one other stored measure with both stored measures relating to the same type of patient information. Each patient status change is ordered in temporal sequence from least recent to most recent. A plurality of health disorder candidates categorized by quantifiable physiological measures of pathophysiologies indicative of each respective health disorder are evaluated and the health disorder candidate with the pathophysiology most closely matching those patient status changes which occurred least recently is identified as the index disorder, that is, the inciting disorder.

[0012] The present invention provides a capability to detect and track subtle trends and incremental changes in recorded patient medical information for automated multiple near-simultaneous health disorder diagnosis and analysis. When coupled with an enrollment in a remote patient monitoring service having the capability to remotely and continuously collect and analyze external or implantable medical device measures, automated multiple health disorder diagnosis and analysis ordering and prioritizing become feasible.

[0013] Another benefit is improved predictive accuracy from the outset of patient care when a reference baseline is incorporated into the automated diagnosis.

[0014] A further benefit is an expanded knowledge base created by expanding the methodologies applied to a single patient to include patient peer groups and the overall patient population. Collaterally, the information maintained in the database could also be utilized for the development of further predictive techniques and for medical research purposes.

[0015] Yet a further benefit is the ability to hone and improve the predictive techniques employed through a continual reassessment of patient therapy outcomes and morbidity rates.

[0016] Other benefits include an automated, expert system approach to the cross-referral, consideration, and potential finding or elimination of other diseases and health disorders with similar or related etiological indicators.

[0017] 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

[0018] **FIG. 1** is a block diagram showing an automated collection and analysis patient care system for ordering and prioritizing multiple health disorders in accordance with the present invention;

[0019] **FIG. 2** is a database table showing, by way of example, a partial record view of device and derived measures set records for remote patient care stored as part of a patient care record in the database of the system of **FIG. 1**;

[0020] **FIG. 3** is a database table showing, by way of example, a partial record view of quality of life and symptom measures set records for remote patient care stored as part of a patient care record in the database of the system of **FIG. 1**;

[0021] **FIG. 4** is a database schema showing, by way of example, the organization of a symptomatic event ordering set record for remote patient care stored as part of a symptomatic event ordering set for use in the system of **FIG. 1**;

[0022] **FIG. 5** is a block diagram showing the software modules of the server system of the system of **FIG. 1**;

[0023] **FIG. 6** is a record view showing, by way of example, a set of partial patient care records stored in the database of the system of **FIG. 1**;

[0024] **FIG. 7** is a Venn diagram showing, by way of example, peer group overlap between the partial patient care records of **FIG. 6**;

[0025] **FIGS. 8A-8B** are flow diagrams showing a method for ordering and prioritizing multiple health disorders using an automated collection and analysis patient care system in accordance with the present invention **FIG. 9** is a flow diagram showing the routine for retrieving reference baseline sets for use in the method of **FIGS. 8A-8B**;

[0026] **FIG. 10** is a flow diagram showing the routine for retrieving monitoring sets for use in the method of **FIGS. 8A-8B**;

[0027] **FIG. 11** is a flow diagram showing the routine for selecting a measure for use in the method of **FIGS. 8A-8B**;

[0028] **FIGS. 12A-12B** are flow diagrams showing the routine for evaluating multiple disorder candidates for use in the method of **FIGS. 8A-8B**; and

[0029] **FIGS. 13A-13B** are flow diagrams showing the routine for identifying disorder candidates for use in the method of **FIGS. 8A-8B**.

DETAILED DESCRIPTION

[0030] **FIG. 1** is a block diagram showing an automated collection and analysis patient care system **10** for ordering and prioritizing multiple health disorders in accordance with the present invention. An exemplary automated collection and analysis patient care system suitable for use with the present invention is disclosed in the related, commonly assigned U.S. Pat. No. 6,312,378, issued Nov. 6, 2001, the disclosure of which is incorporated herein by reference. Preferably, an individual patient **11** is a recipient of an implantable medical device **12**, such as, by way of example, an IPG, cardiovascular or heart failure monitor, or therapeutic device, with a set of leads extending into his or her heart and electrodes implanted throughout the cardiopulmonary system. Alternatively, an external monitoring or therapeutic medical device **26**, a subcutaneous monitor or device inserted into other organs, a cutaneous monitor, or even a manual physiological measurement device, such as an electrocardiogram or heart rate monitor, could be used. The implantable medical device **12** and external medical device **26** include circuitry for recording into a short-term, volatile memory telemetered signals stored for later retrieval, which become part of a set of device and derived measures, such as described below, by way of example, with reference to **FIG. 2**. Exemplary implantable medical devices suitable for use in the present invention include the Discovery line of pacemakers, manufactured by Guidant Corporation, Indianapolis, Ind., and the Gem line of ICDs, manufactured by Medtronic Corporation, Minneapolis, Minn.

[0031] The telemetered signals stored in the implantable medical device **12** are preferably retrieved upon the completion of an initial observation period and subsequently thereafter on a continuous, periodic (daily) basis, such as described in the related, commonly assigned U.S. Pat. No. 6,221,011, issued Apr. 24, 2001, the disclosure of which is incorporated herein by reference. A programmer **14**, personal computer **18**, or similar device for communicating with an implantable medical device **12** can be used to retrieve the telemetered signals. A magnetized reed switch (not shown) within the implantable medical device **12** closes in response to the placement of a wand **13** over the site of the implantable medical device **12**. The programmer **14** sends programming or interrogating instructions to and retrieves stored telemetered signals from the implantable medical device **12** via RF signals exchanged through the wand **13**. Similar communication means are used for accessing the external medical device **26**. 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 as device measures in patient care records **23** in a database **17**, as further described below, by way of example, with reference to **FIG. 2**. An exemplary programmer **14** suitable for use in the present invention is the Model 2901 Programmer Recorder Monitor, manufactured by Guidant Corporation, Indianapolis, Ind.

[0032] The patient **11** is remotely monitored by the server system **16** via the internetwork **15** through the periodic receipt of the retrieved device measures from the implantable medical device **12** or external medical device **26**. The patient care records **23** in the database **17** are organized into two identified sets of device measures: an optional reference baseline **26** recorded during an initial observation period and monitoring sets **27** recorded subsequently thereafter. The monitoring measures sets **27** are periodically analyzed and compared by the server system **16** to indicator thresholds **204** (shown in **FIG. 5** below) corresponding to quantifiable physiological measures of pathophysiologies indicative of multiple, near-simultaneous disorders, as further described below with reference to **FIG. 5**. As necessary, feedback is provided to the patient **11**. By way of example, the feedback includes an electronic mail message automatically sent by the server system **16** over the internetwork **15** to a 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**. Moreover, simultaneous notifications can also be delivered to the patient's physician, hospital, or emergency medical services provider **29** using similar feedback means to deliver the information.

[0033] The server system **10** can consist of either a single computer system or a cooperatively networked or clustered set of computer systems. Each computer system is a general purpose, programmed digital computing device 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, as is known in the art.

[0034] The database **17** stores patient care records **23** for each individual patient to whom remote patient care is being provided. Each patient care record **23** contains normal patient identification and treatment profile information, as well as medical history, medications taken, height and weight, and other pertinent data (not shown). The patient care records **23** consist primarily of two sets of data: device and derived measures (D&DM) sets **24***a*, **24***b* and quality of life (QOL) and symptom measures sets **25***a*, **25***b*, the organization and contents of which are further described below with respect to **FIGS. 2 and 3**, respectively. The device and derived measures sets **24***a*, **24***b* and quality of life and

symptom measures sets **25***a*, **25***b* can be further logically categorized into two potentially overlapping sets. The reference baseline **26** is a special set of device and derived reference measures sets **24***a* and quality of life and symptom measures sets **25***a* recorded and determined during an initial observation period. Monitoring sets **27** are device and derived measures sets **24***b* and quality of life and symptom measures sets **25***b* recorded and determined thereafter on a regular, continuous basis. Other forms of database organization and contents are feasible.

[**0035**] The implantable medical device **12** and, in a more limited fashion, the external medical device **26**, record patient medical information on a regular basis. The recorded patient information is downloaded and stored in the database **17** as part of a patient care record **23**. Further patient information can be derived from the recorded patient information, as is known in the art. **FIG. 2** is a database table showing, by way of example, a partial record view **40** of device and derived measures set records **41-85** for remote patient care stored as part of a patient care record in the database **17** of the system of **FIG. 1**. Each record **41-85** stores physiological measures, the time of day and a sequence number, non-exclusively. The physiological measures can include a snapshot of telemetered signals data which were recorded by the implantable medical device **12** or the external medical device **26**, for instance, on per heartbeat, binned average or derived basis; measures derived from the recorded device measures; and manually collected information, such as obtained through a patient medical history interview or questionnaire. The time of day records the time and date at which the physiological measure was recorded. Finally, the sequence number indicates the order in which the physiological measures are to be processed. Other types of collected, recorded, combined, or derived measures are possible, as is known in the art.

[**0036**] The device and derived measures sets **24***a*, **24***b* (shown in **FIG. 1**), along with quality of life and symptom measures sets **25***a*, **25***b*, as further described below with reference to **FIG. 3**, are continuously and periodically received by the server system **16** as part of the on-going patient care monitoring and analysis function. These regularly collected data sets are collectively categorized as the monitoring sets **27** (shown in **FIG. 1**). In addition, select device and derived measures sets **24***a* and quality of life and symptom measures sets **25***a* can be designated as a reference baseline **26** at the outset of patient care to improve the accuracy and meaningfulness of the serial monitoring sets **27**. Select patient information is collected, recorded, and derived during an initial period of observation or patient care, such as described in the related, commonly assigned U.S. Pat. No. 6,221,011, issued Apr. 24, 2001, the disclosure of which is incorporated herein by reference.

[**0037**] As an adjunct to remote patient care through the monitoring of measured physiological data via the implantable medical device **12** or external medical device **26**, quality of life and symptom measures sets **25***a* can also be stored in the database **17** as part of the reference baseline **26**, if used, and the monitoring sets **27**. A quality of life measure is a semi-quantitative self-assessment of an individual patient's physical and emotional well being and a record of symptoms, such as provided by the Duke Activities Status Indicator. These scoring systems can be provided for use by the patient **11** on the personal computer **18** (shown in **FIG. 1**) to record his or her quality of life scores for both initial and periodic download to the server system **16**. **FIG. 3** is a database table showing, by way of example, a partial record view **95** of quality of life and symptom measures set records **96-111** for remote patient care stored as part of a patient care record in the database **17** of the system of **FIG. 1**. Similar to the device and derived measures set records **41-85**, each record **96-111** stores the quality of life (QOL) measure, the time of day and a sequence number, non-exclusively.

[**0038**] Other types of quality of life and symptom measures are possible, such as those indicated by responses to the Minnesota Living with Heart Failure Questionnaire described in E. Braunwald, ed., "Heart Disease—A Textbook of Cardiovascular Medicine," pp. 452-454, W.B. Saunders Co. (1997), the disclosure of which is incorporated herein by reference. Similarly, functional classifications based on the relationship between symptoms and the amount of effort required to provoke them can serve as quality of life and symptom measures, such as the New York Heart Association (NYHA) classifications I, II, III and IV, also described in Ibid.

[**0039**] The patient may also add non-device quantitative measures, such as the six-minute walk distance, as complementary data to the device and derived measures sets **24***a*, **24***b* and the symptoms during the six-minute walk to quality of life and symptom measures sets **25***a*, **25***b*.

[**0040**] On a periodic basis, the patient information stored in the database **17** is evaluated and, if medically significant changes in patient wellness are detected and medical disorders are identified. The sequence of symptomatic events is crucial. **FIG. 4** is a database schema showing, by way of example, the organization of a symptomatic event ordering set record **120** for remote patient care stored as part of a symptomatic event ordering set **205** (shown in **FIG. 5** below) for use in the system of **FIG. 1**. By way of example, the record **120** stores and categorizes the general symptomatic event markers for myocardial ischemia **121** into event marker sets: reduced exercise capacity **122**, respiratory distress **123**, and angina **124**. In turn, each of the event marker sets **122-124** contain monitoring sets **125**, **132**, **138** and quality of life (QOL) sets **126**, **133**, **139**, respectively. Finally, each respective monitoring set and quality of life set contains a set of individual symptomatic events which together form a set of related and linked dependent measures. Here, the monitoring set **125** for reduced exercise capacity **122** contains decreased cardiac output **127**, decreased mixed venous oxygen score **128**, and decreased patient activity score **129** and the quality of life set **126** contains exercise tolerance quality of life measure **130** and energy level quality of life measure **131**. Each symptomatic event contains a sequence number (Seq Num) indicating the order in which the symptomatic event will be evaluated, preferably proceeding from highly indicative to least indicative. For example, reduced exercise capacity in congestive heart failure is characterized by decreased cardiac output, as opposed to, say, reduced exercise capacity in primary pulmonary insufficiency where cardiac output is likely to be normal. An absolute limit of cardiac output, indexed for weight, can therefore serve as an a priori marker of congestive heart failure in the absence of intravascular volume depletion, i.e., low pulmonary artery diastolic pressure. Consequently, the markers of reduced exercise capacity in congestive heart failure order cardiac output as the indicator

having the highest priority with a sequence number of "1." Quality of life symptomatic events are similarly ordered.

[0041] **FIG. 5** 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 of the server system **16** as object or byte code, as is known in the art. 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. The server system **16** includes three primary software modules, database module **200**, diagnostic module **201**, and feedback module **203**, which perform integrated functions as follows.

[0042] First, the database module **200** organizes the individual patient care records **23** stored in the database **17** (shown in **FIG. 1**) and efficiently stores and accesses the reference baseline **26**, monitoring sets **27**, and patient care data maintained in those records. 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.

[0043] Next, the diagnostic module **201** determines the ordering and prioritization of multiple near-simultaneous disorders to determine an index disorder **212**, that is, the inciting disorder, based on the comparison and analysis of the data measures from the reference baseline **26** and monitoring sets **27**. The diagnostic module includes four modules: comparison module **206**, analysis module **207**, quality of life module **208**, and sequencing module **209**. The comparison module **206** compares recorded and derived measures retrieved from the reference baseline **26**, if used, and monitoring sets **27** to indicator thresholds **204**. The comparison module **206** also determines changes between recorded and derived measures retrieved from the reference baseline **26**, if used, and monitoring sets **27** to determine the occurrence of a symptomatic event using the symptomatic event ordering set **205**. The database **17** stores individual patient care records **23** for patients suffering from various health disorders and diseases for which they are receiving remote patient care. For purposes of comparison and analysis by the comparison module **206**, these records can be categorized into peer groups containing the records for those patients suffering from similar disorders and diseases, as well as being viewed in reference to the overall patient population. The definition of the peer group can be progressively refined as the overall patient population grows. To illustrate, **FIG. 6** is a record view showing, by way of example, a set of partial patient care records stored in the database **17** for three patients, Patient **1**, Patient **2**, and Patient **3**. For each patient, three sets of peer measures, X, Y, and Z are shown. Each of the measures, X, Y, and Z could be either collected or derived measures from the reference baseline **26**, if used, and monitoring sets **27**.

[0044] The same measures are organized into time-based 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. Thus, for a given patient, such as Patient **1**, serial peer measures, such as peer measure X_0 through X_n, represent the same type of patient information monitored over time. The combined peer measures for all patients can be categorized into a health disorder- or disease-matched peer group. The definition of disease-matched peer group is a progressive definition, refined over time as the number of monitored patients grows and the features of the peer group become increasingly well-matched and uniform. Measures representing different types of patient information, such as measures X_0, Y_0, and Z_0, 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 set for an individual patient.

[0045] The comparison module **206** performs two basic forms of comparison. First, individual measures for a given patient can be compared to other individual measures for that same patient (self-referencing). 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}, Z_{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 disorder- or disease-specific characteristics (peer group referencing) or to the patient population in general (population referencing). 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, $X_{0'}$, $X_{0''}$, 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, Z_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, including multiple disease diagnoses for diseases exhibiting similar physiological measures or which might be a secondary disease candidate.

[0046] **FIG. 7** is a Venn diagram showing, by way of example, peer group overlap between the partial patient care records **23** of **FIG. 1**. Each patient care record **23** includes characteristics data **350**, **351**, **352**, including personal traits, demographics, medical history, and related personal data, for patients **1**, **2** and **3**, respectively. For example, the characteristics data **350** for patient **1** might include personal traits which include gender and age, such as male and an age between 40-45; a demographic of resident of New York City; and a medical history consisting of anterior myocardial infraction, congestive heart failure and diabetes. Similarly, the characteristics data **351** for patient **2** might include identical personal traits, thereby resulting in partial overlap **353** of characteristics data **350** and **351**. Similar characteristics overlap **354**, **355**, **356** can exist between each respective patient. The overall patient population **357** would include the universe of all characteristics data. As the monitoring population grows, the number of patients with personal traits matching those of the monitored patient will grow, increasing the value of peer group referencing. Large peer groups, well matched across all monitored measures, will result in a well known natural history of disease and will allow for more accurate prediction of the clinical course of the patient being monitored. If the population of patients is

relatively small, only some traits **356** will be uniformly present in any particular peer group. Eventually, peer groups, for instance, composed of 100 or more patients each, would evolve under conditions in which there would be complete overlap of substantially all salient data, thereby forming a powerful core reference group for any new patient being monitored with similar characters.

[**0047**] Referring back to **FIG. 5**, the analysis module **207** orders any patient status changes resulting from differences between physiological measures and identifies an index disorder **212**, as further described below with reference to **FIGS. 8A-8B**. Similarly, the quality of life module **208** compares quality of life and symptom measures set **25***a*, **25***b* from the reference baseline **26** and monitoring sets **27**, the results of which are incorporated into the comparisons performed by the analysis module **13**, in part, to either refute or support the findings based on physiological "hard" data. The sequencing module **209** prioritizes patient changes in accordance with pre-defined orderings, if used, or as modified by quality of life and symptom measures.

[**0048**] Finally, the feedback module **203** provides automated feedback to the individual patient based, in part, on the patient status indicator **202** generated by the diagnostic module **201**.

[**0049**] In addition, the feedback module **203** determines whether any changes to interventive measures are appropriate based on threshold stickiness ("hysteresis") **210**. The threshold stickiness **210** can limit the diagnostic measures to provide a buffer against transient, non-trending and non-significant fluctuations in the various collected and derived measures in favor of more certainty in diagnosis. As described above, the feedback could be by electronic mail or by automated voice mail or facsimile. The feedback can also include normalized voice feedback, such as described in the related, commonly assigned U.S. Pat. No. 6,203,495, issued Mar. 20, 2001, the disclosure of which is incorporated herein by reference.

[**0050**] In a further embodiment of the present invention, the feedback module **203** includes a patient query engine **211**, which enables the individual patient **11** to interactively query the server system **16** regarding the diagnosis, therapeutic maneuvers, and treatment regimen. Similar patient query engines **211** can be found in interactive expert systems for diagnosing medical conditions. Using the personal computer **18** (shown in **FIG. 1**), the patient can have an interactive dialogue with the automated server system **16**, as well as human experts as necessary, to self assess his or her medical condition. Such expert systems are well known in the art, an example of which is the MYCIN expert system developed at Stanford University and described in Buchanan, B. & Shortlife, E., "RULE-BASED EXPERT SYSTEMS. The MYCIN Experiments of the Stanford Heuristic Programming Project," Addison-Wesley (1984). The various forms of feedback described above help to increase the accuracy and specificity of the reporting of the quality of life and symptomatic measures.

[**0051**] **FIGS. 8A-8B** are flow diagrams showing a method for ordering and prioritizing multiple health disorders **220** to identify an index disorder **212** (shown in **FIG. 5**) using an automated collection and analysis patient care system **10** in accordance with the present invention. A primary purpose of this method is to determine what happened first to sort through multiple near-simultaneously-occurring disorders. For example, congestive heart failure can lead to myocardial insufficiency and vice versa. Moreover, congestive heart failure can complicate preexisting borderline pulmonary insufficiency. Similarly, when individuals have borderline or sub-clinical congestive heart failure or myocardial ischemia, primary pulmonary insufficiency, for example, an exacerbation of chronic bronchitis, can lead to fulminant congestive heart failure, myocardial ischemia, or both. Atrial fibrillation can complicate all of the above-noted disorders, either as a result of or as a precipitant of one of the foregoing disorders.

[**0052**] The sequence of the events resulting from changes in physiological measures, as may be corroborated by quality of life and symptom measures, is crucial. In patients with more than one disease, certain physiological measures are the key to identifying the index disorder; however, these same physiological measures might not be uniquely abnormal to any particular disorder. Consequently, a diagnosis depending upon these particular non-diagnostic physiological measures will be more dependent upon the ordering of changes or measure creep than the physiological measure value itself. For example, cardiac output **49** (shown in **FIG. 2**) or its derivatives can decrease in congestive heart failure, myocardial ischemia, respiratory insufficiency, or atrial fibrillation. However, decreased cardiac output in myocardial ischemia would be preceded by an abnormality of ST elevation (ST segment measures **77**), T-wave inversion (T wave measures **79**), troponin increase (serum troponin **74**), wall motion abnormality onset (left ventricular wall motion changes **58**), increased coronary sinus lactate production **53**, and possibly QRS widening (as a marker of myocardial ischemia) (QRS measures **70**).

[**0053**] Similarly, decreased cardiac output in respiratory insufficiency would be preceded by other physiological measures, which, although not as diagnostic as myocardial ischemia, can include, for example, elevation in respiratory rate **72**, elevation in minute ventilation **60**, elevation in tidal volume (derived from minute ventilation **60** and respiratory rate **72**), increase in transthoracic impedance **81** consistent with increased aeration of the lungs, decrease in QT interval **71** (or other surrogate for increase in temperature), spikes in the activity sensor **63** or pulmonary artery pressures **66**, **68** as markers of cough **103**, decrease in arterial partial pressure of oxygen **43**, and decreases in arterial partial pressure of carbon dioxide **42** in probable association with low or normal pulmonary artery diastolic pressure **67**. Once pulmonary insufficiency onsets, the subsequent fall in arterial oxygen pressure may be enough to trigger myocardial ischemia, in the case of a patient with borderline coronary artery disease, or to trigger congestive heart failure, in the case of a patient with borderline left ventricular dysfunction. However, these disorders would be identified as secondary disorders with the aid of the present invention.

[**0054**] Note that the foregoing interrelationships between the respective physiological measures for diagnosing and treating congestive heart failure, myocardial ischemia, respiratory insufficiency and atrial fibrillation are merely illustrative and not exhaustive. Moreover, other heretofore unidentified disorders can also share such interrelationships, as is known in the art, to cover, non-specified disorder diagnostics, such as for diabetes, hypertension, sleep-apnea, stroke, anemia, and so forth.

[0055] Thus, the method begins by retrieving the reference baseline **26** (block **221**) and monitoring sets **27** (block **222**) from the database **17**, as further described below with reference to **FIGS. 9 and 10**, respectively. Each measure in the device and derived measures sets **24***a*, **24***b* (shown in **FIG. 1**) and quality of life and symptom measures sets **25***a*, **25***b*, if used, is iteratively processed (blocks **223-227**). These measures are obtained from the monitoring sets **27** and, again if used, the reference baseline **26**. During each iteration loop, a measure is selected (block **224**), as further described below with reference to **FIG. 11**. If the measure has changed (block **225**), the timing and magnitude of the change is determined and logged (block **226**). Iterative processing (blocks **223-227**) continues until all measures have been selected at which time any changes are ordered in temporal sequence (block **228**) from least recent to most recent. Next, multiple disorder candidates are evaluated (block **229**) and the most closely matching disorder candidates, including a primary or index disorder and any secondary disorders, are identified (block **230**), as further described below respectively in **FIGS. 12A-12B** and **13A-13B**. A patient status indicator **202** for any identified disorders, including the primary or index disorder **212** (shown in **FIG. 5**), is provided (block **231**) to the patient regarding physical well-being, disease prognosis, including any determinations of disease onset, progression, regression, or status quo, and other pertinent medical and general information of potential interest to the patient.

[0056] Finally, in a further embodiment, if the patient submits a query to the server system **16** (block **232**), the patient query is interactively processed by the patient query engine (block **233**). Similarly, if the server elects to query the patient (block **234**), the server query is interactively processed by the server query engine (block **235**). The method then terminates if no further patient or server queries are submitted.

[0057] In the described embodiment, both the time at which a change occurred and the relative magnitude of the change are utilized for indexing the diagnosis. In addition, related measures are linked into dependent sets of measures, preferably by disorder and principal symptom findings (e.g., as shown in **FIG. 4**), such that any change in one measure will automatically result in the examination of the timing and magnitude in any changes in the related measures. For example, ST segment changes (measure **76** shown in **FIG. 2**) can fluctuate slightly with or without severe consequences in patient condition. A 0.5 SD change in ST segment, for instance, is generally considered modest when not tied to other physiological measure changes. However, a 0.5 SD ST segment change followed by a massive left ventricular wall motion change **58** can indicate, for example, left anterior descending coronary artery occlusion. The magnitude of change therefore can help determine the primacy of the pertinent disorder and the timing and sequence of related changes can help categorize the clinical severity of the inciting event.

[0058] Also, an adjustable time window can be used to detect measure creep by widening the time period over which a change in physiological measure can be observed. For example, mean cardiac output **49** may appear unchanging over a short term period of observation, for instance, one week, but might actually be decreasing subtly from month-to-month marking an insidious, yet serious disease process. The adjustable time window allows such subtle, trending changes to be detected.

[0059] Similarly, a clinically reasonable time limit can be placed on the adjustable time window as an upper bound. The length of the upper bound is disease specific. For example, atrial fibrillation preceded by congestive heart failure by 24 hours is correlative; however, atrial fibrillation preceded by congestive heart failure one year earlier will likely not be considered an inciting factor without more closely temporally linked changes. Similarly, congestive heart failure secondary to atrial fibrillation can occur more gradually than congestive heart failure secondary to myocardial ischemia. The upper bound therefore serves to limit the scope of the time period over which changes to physiological measures are observed and adjusted for disease-specific diagnostic purposes.

[0060] **FIG. 9** is a flow diagram showing the routine for retrieving reference baseline sets **221** for use in the method of **FIGS. 8A-8B**. The purpose of this routine is to retrieve the appropriate reference baseline sets **26**, if used, from the database **17** based on the types of comparisons being performed. First, if the comparisons are self referencing with respect to the measures stored in the individual patient care record **23** (block **240**), the reference device and derived measures set **24***a* and reference quality of life and symptom measures set **25***a*, if used, are retrieved for the individual patient from the database **17** (block **241**). Next, if the comparisons are peer group referencing with respect to measures stored in the patient care records **23** for a health disorder- or disease-specific peer group (block **242**), the reference device and derived measures set **24***a* and reference quality of life and symptom measures set **25***a*, if used, are retrieved from each patient care record **23** for the peer group from the database **17** (block **243**). Minimum, maximum, averaged, standard deviation (SD), and trending data for each measure from the reference baseline **26** for the peer group is then calculated (block **244**). Finally, if the comparisons are population referencing with respect to measures stored in the patient care records **23** for the overall patient population (block **245**), the reference device and derived measures set **24***a* and reference quality of life and symptom measures set **25***a*, if used, are retrieved from each patient care record **23** from the database **17** (block **246**). Minimum, maximum, averaged, standard deviation, and trending data for each measure from the reference baseline **26** for the peer group is then calculated (block **247**). The routine then returns.

[0061] **FIG. 10** is a flow diagram showing the routine for retrieving monitoring sets **222** for use in the method of **FIGS. 8A-8B**. The purpose of this routine is to retrieve the appropriate monitoring sets **27** from the database **17** based on the types of comparisons being performed. First, if the comparisons are self referencing with respect to the measures stored in the individual patient care record **23** (block **250**), the device and derived measures set **24***b* and quality of life and symptom measures set **25***b*, if used, are retrieved for the individual patient from the database **17** (block **251**). Next, if the comparisons are peer group referencing with respect to measures stored in the patient care records **23** for a health disorder- or disease-specific peer group (block **252**), the device and derived measures set **24***b* and quality of life and symptom measures set **25***b*, if used, are retrieved from

each patient care record **23** for the peer group from the database **17** (block **253**). Minimum, maximum, averaged, standard deviation, and trending data for each measure from the monitoring sets **27** for the peer group is then calculated (block **254**). Finally, if the comparisons are population referencing with respect to measures stored in the patient care records **23** for the overall patient population (block **255**), the device and derived measures set **24***b* and quality of life and symptom measures set **25***b*, if used, are retrieved from each patient care record **23** from the database **17** (block **256**). Minimum, maximum, averaged, standard deviation, and trending data for each measure from the monitoring sets **27** for the peer group is then calculated (block **257**). The routine then returns.

[**0062**] **FIG. 11** is a flow diagram showing the routine for selecting a measure **224** for use in the method of **FIGS. 8A-8B**. The purpose of this routine is to select a measure from the device and derived measures sets **24***a*, **24***b* or quality of life and symptom measures sets **25***a*, **25***b* in an appropriate order. Thus, if the measures are ordered in a pre-defined sequence (block **260**), the next sequential measure is selected for comparison in the method of **FIGS. 8A-8B** (block **261**). Otherwise, the next measure appearing in the respective measures set is selected (block **262**). The routine then returns.

[**0063**] **FIGS. 12A-12B** are flow diagrams showing the routine for evaluating multiple disorder candidates **229** for use in the method of **FIGS. 8A-8B**. The purpose of this routine is to generate a log of findings based on comparisons of patient status changes to the various pathophysiological markers characteristic of each of the multiple, near-simultaneous disorders. Quality of life and symptom measures can be used in two ways. First, changes in a quality of life and symptom measures can serve as a starting point in diagnosing a disorder. For instance, shortness of breath **93** (shown in **FIG. 3**) can serve as a marker of respiratory distress congestive heart failure. Second, quality of life and symptom measures can corroborate disorder findings. In the described embodiment, the use of quality of life and symptom measures as a diagnostic starting point is incorporated into the analysis by prioritizing the importance of related physiological measure changes based on the least recent quality of life measure change. For example, if shortness of breath **93** followed the corresponding physiological changes for respiratory distress congestive heart failure, that is, decreased cardiac output **127** (shown in **FIG. 4**), decreased mixed venous oxygen score **128**, and decreased patient activity score **129**, would be assigned a higher priority than the other physiological measures. Similarly, in the described embodiment, certain physiological measures can also be assigned a higher priority independent of any changes to the quality of life and symptom measures.

[**0064**] Thus, if quality of life and symptom measures are included in the diagnostic process (block **270**) and the related physiological measures are prioritized based on quality of life changes (block **271**), the changes in physiological measures are sorted according to the quality of life-assigned priorities (block **272**). Alternatively, if quality of life and symptom measures are not being used (block **270**) or the changes in physiological measures are not assigned quality of life priorities (block **271**), the physiological changes could still be independently prioritized (block **273**). If so, the physiological measures are sorted according to the non-quality of life assigned-priorities (block **274**).

[**0065**] Next, each of the multiple disorder candidates and each measure in their respective sets of physiological measures, including any linked measures, and, if used, quality of life and symptom measures, are iteratively processed in a pair of nested processing loops (blocks **275-284** and **277-282**, respectively). Other forms of flow control are feasible, including recursive processing. Each disorder candidate is iteratively processed in the outer processing loop (blocks **275-284**). During each outer processing loop, a disorder candidate is selected (block **276**) and each of the physiological measures, and quality of life and symptom measures, if used, are iteratively processed in the inner processing loop (blocks **277-282**). Each measure is assigned a sequence number, such as shown, by way of example, in each symptomatic event ordering set records **121-152** (shown in **FIG. 4**) for a principal symptom finding of the disorder candidate. The measures are evaluated in sequential order for timing and magnitude changes (block **278**). If the measure is linked to other related measures (block **279**), the related measures are also checked for timing and magnitude changes (block **280**). Any matched pathophysiological findings are logged (block **281**). The operations of evaluating and matching pathophysiological measures (box **283**) for diagnosing congestive heart failure, myocardial infarction, respiratory distress, and atrial fibrillation are described in related, commonly assigned U.S. Pat. No. 6,336,903, entitled "Automated Collection And Analysis Patient Care System And Method For Diagnosing And Monitoring Congestive Heart Failure And Outcomes Thereof," issued Jan. 8, 2002; U.S. Pat. No. 6,368,284, entitled "Automated Collection And Analysis Patient Care System And Method For Diagnosing And Monitoring Myocardial Ischemia And Outcomes Thereof," issued Apr. 9, 2002; U.S. Pat. No. 6,398,728, entitled "Automated Collection And Analysis Patient Care System And Method For Diagnosing And Monitoring Respiratory Insufficiency And Outcomes Thereof," issued Jun. 4, 2002; and U.S. Pat. No. 6,411,840, entitled "Automated Collection And Analysis Patient Care System And Method For Diagnosing And Monitoring The Outcomes Of Atrial Fibrillation," issued Jun. 25, 2002, the disclosures of which are incorporated herein by reference. Note the evaluation and matching of pathophysiological measures **283** can also encompass disease worsening and improvement.

[**0066**] Iterative processing of measures (blocks **277-282**) continues until all pathophysiological measures of the disorder have been evaluated, whereupon the next disorder candidate is selected. Iterative processing of disorders (blocks **275-284**) continues until all disorders have been selected, after which the routine returns.

[**0067**] **FIGS. 13A-13B** are flow diagrams showing the routine for identifying disorder candidates **230** for use in the method of **FIGS. 8A-8B**. The purpose of this routine is to identify a primary or index disorder **212** and any secondary disorder(s). At this stage, all changes in physiological measures and quality of life and symptom measures have been identified and any matches between the changes and the pathophysiological indicators of each near-simultaneous disorder have been logged. The findings must now be ordered and ranked. First, the matched findings are sorted into temporal sequence (block **290**), preferably from least recent to most recent. Next, each of the findings and each of

the disorder candidates are iteratively processed in a pair of nested processing loops (blocks **291-298** and **292-297**, respectively). Other forms of flow control are feasible, including recursive processing. Each finding is iteratively processed in the outer processing loop (blocks **291-298**) beginning with the least recent finding. For each finding, each disorder candidate is iteratively processed during each inner processing loop (blocks **292-297**) to determine the relative strength of any match. If the disorder candidate has a pathophysiological indicator which matches the current finding (block **293**), the disorder candidate is ranked above any other disorder candidate not matching the current finding (block **294**). This form of ranking ensures the disorder candidate with a pathophysiological indicator matching a least recent change in measure is considered ahead of other disorder candidates which may be secondary disorders. In addition, if the measure is prioritized (block **295**), that is, the measure is a member of a group of related linked measures which have also changed or is an a priori measure, the ranking of the disorder candidate is increased (block **296**). Iterative processing of disorders (blocks **292-297**) continues until all disorder candidates have been considered. Similarly, iterative processing of findings (blocks **291-298**) continues until all findings have been evaluated, whereupon the highest ranking disorder candidate is identified as the primary or index disorder **212** (shown in **FIG. 5**) (block **299**). If other disorders rank close to the primary or index disorder and similarly reflect a strong match to the set of findings, any secondary disorder(s) are likewise identified and temporally ranked (block **300**). The routine then returns.

[**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. Stored multiple health disorders data for use in automated patient care, comprising:

patient information identifying a patient under automated patient care and comprising at least one of treatment profile information and medical history; and

a monitoring set comprising measures relating to patient information previously recorded and derived on a substantially continuous basis and formed by processing the measures through derived measure determination and statistical value calculation into an index health disorder.

2. Stored multiple health disorders data according to claim 1, further comprising:

health disorder candidates categorized by pathophysiology, wherein the health disorder candidate has a pathophysiology substantially comparable to a change in pathophysiology that occurred either substantially least or most recently.

3. Stored multiple health disorders data according to claim 1, further comprising:

a stored reference baseline comprising at least one of treatment profile information and medical history recorded during an initial time period or derived therefrom.

4. Stored multiple health disorders data according to claim 1, further comprising:

stored quality of life measures comprising qualitative patient information.

5. Stored multiple health disorders data according to claim 1, wherein the measures comprise physiological measures for at least one of an individual patient, a peer group, and a overall patient population.

6. Stored multiple health disorders data according to claim 1, wherein the measures comprise physiological measures recorded by at least one of an implantable medical device and an external medical device.

7. A medical device providing an index health disorder for use in automated patient care, comprising:

one or more signal monitors sensing physiological data of a patient under automated patient care as telemetered signals;

a memory store storing the telemetered signals sensed by the signal sensors for a short term; and

an interface providing external access to the staged telemetered signals, wherein the staged telemetered signals are periodically retrieved and processed through derived measure determination and statistical value calculation into an index health disorder.

8. A medical device according to claim 7, further comprising:

a processor to record the telemetered signals during an initial time period, and to derive values therefrom.

9. A medical device according to claim 7, further comprising:

a processor to record the telemetered signals on a substantially continuous basis, and to derive values therefrom.

10. A medical device according to claim 7, further comprising:

a stored indicator threshold corresponding to a pathophysiology indicative of at least one of congestive heart failure, myocardial ischemia, respiratory insufficiency, and atrial fibrillation health disorders; and

a processor to detect changes against the indicator thresholds to determine pathophysiologies indicating one of an absence, onset, progression, regression, and status quo of the health disorder.

11. A medical device according to claim 7, further comprising:

programming specifying therapy for health disorders selected from the group comprising congestive heart failure, myocardial ischemia, respiratory insufficiency, and atrial fibrillation.

12. A medical device according to claim 7, wherein the medical device comprises at least one of a pacemaker, cardioverter defibrillator and event monitor.

13. An analysis system for providing an index health disorder for use in automated patient care, comprising:

a database storing a set of device measures and providing quantitative health care data indicators regularly recorded by a medical device for a patient under automated patient care; and

a processor retrieving the collected device measures and forming an index health disorder through derived measure determination and statistical value calculation.

14. An analysis system according to claim 13, further comprising:

an ordering component to compare a plurality of the processed raw and physiological measures to quantify one or more changes in pathophysiology, and to order the pathophysiology changes in temporal sequence.

15. An analysis system according to claim 13, further comprising:

a categorizing component to categorize health disorder candidates by pathophysiology, and to identify the health disorder candidate having a pathophysiology substantially comparable to a change in pathophysiology that occurred either substantially least or most recently.

16. An analysis system according to claim 13, further comprising:

a comparison component to compare at least one of the processed raw and physiological measures to at least one other of the processed raw and physiological measures that were previously recorded within an adjustable time window.

17. An analysis system according to claim 13, further comprising:

an evaluation component to sort a plurality of previously-related pathophysiologies for at least one health disorder candidate into a symptomatic event ordering set, and to evaluate each pathophysiology in the symptomatic event ordering set in response to an observed change in the pathophysiology being evaluated.

18. An analysis system according to claim 13, further comprising:

a comparison component to prioritize pathophysiology changes using a predefined ordering, and to compare the pathophysiology changes having higher priorities that occurred least recently before the pathophysiology changes having lower priorities.

19. An analysis system according to claim 13, further comprising:

a hysteresis component to track temporal changes in pathophysiology, and apply hysteresis in patient diagnosis and treatment to the temporal changes.

20. An analysis system according to claim 13, further comprising:

a stored indicator threshold corresponding to a pathophysiology indicative of at least one of congestive heart failure, myocardial ischemia, respiratory insufficiency, and atrial fibrillation health disorders; and

a testing component to test observed pathophysiology changes against the indicator thresholds to determine pathophysiologies indicating one of an absence, onset, progression, regression, and status quo of the health disorder.

21. A structured record storing an index health disorder for use in automated patient care, comprising:

structured data for a patient under automated patient care, comprising at least one of:

physiological measures directly recorded by a medical device; and

physiological measures derived from the directly recorded physiological measures,

wherein the structured data is collected and processed through derived measure determination and statistical value calculation into an index health disorder.

22. A structured record according to claim 21, further comprising:

recording the at least one recorded physiological measure and the at least one other recorded physiological measure with at least one of an implantable medical device and an external medical device.

23. A structured record according to claim 21, further comprising:

physiological measures for at least one of an individual patient, a peer group, and a overall patient population.

24. A structured record according to claim 21, further comprising:

health disorders selected from the group comprising congestive heart failure, myocardial ischemia, respiratory insufficiency, and atrial fibrillation.

25. A process for forming an index health disorder for use in automated patient care, comprising:

collecting device measures for a patient under automated patient care;

assembling the collected device measures into at least one of raw and derived physiological measures;

processing the raw and physiological measures through derived measure determination and statistical value calculation; and

forming an index health disorder.

26. A process according to claim 25, further comprising:

comparing a plurality of the processed raw and physiological measures to quantify one or more changes in pathophysiology; and

ordering the pathophysiology changes in temporal sequence.

27. A process according to claim 25, further comprising:

categorizing health disorder candidates by pathophysiology; and

identifying the health disorder candidate having a pathophysiology substantially comparable to a change in pathophysiology that occurred either substantially least or most recently.

28. A process according to claim 25, further comprising:

comparing at least one of the processed raw and physiological measures to at least one other of the processed

raw and physiological measures that were previously recorded within an adjustable time window.

29. A process according to claim 25, further comprising:

sorting a plurality of previously-related pathophysiologies for at least one health disorder candidate into a symptomatic event ordering set; and

evaluating each pathophysiology in the symptomatic event ordering set in response to an observed change in the pathophysiology being evaluated.

30. A process according to claim 25, further comprising:

prioritizing pathophysiology changes using a predefined ordering; and

comparing the pathophysiology changes having higher priorities that occurred least recently before the pathophysiology changes having lower priorities.

31. A process according to claim 25, further comprising:

tracking temporal changes in pathophysiology; and

applying hysteresis in patient diagnosis and treatment to the temporal changes.

32. A process according to claim 25, further comprising:

defining an indicator threshold corresponding to a pathophysiology indicative of at least one of congestive heart failure, myocardial ischemia, respiratory insufficiency, and atrial fibrillation health disorders; and

testing observed pathophysiology changes against the indicator thresholds to determine pathophysiologies indicating one of an absence, onset, progression, regression, and status quo of the health disorder.

33. A computer-readable storage medium holding code for performing the process according to claim 25.

* * * * *

专利名称(译)	用于优先考虑医疗状况的系统和方法		
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摘要(译)

提出了一种用于对用于自动远程患者护理的多种健康障碍进行排序和优先排序的系统。数据库通过组织数据库中的监测集来维护个体患者的信息，并且将与先前记录并且基本上连续地导出的患者信息相关的测量值保存到数据库中的监测集中。检索和处理监视的服务器包括比较模块，其将来自每个监视集的存储的度量与来自另一个监视集的其他存储的度量进行比较，其中存储的度量与相同类型的患者信息有关，并且分析模块对每个患者进行排序时间序列中的状态变化和通过可量化的生理测量对健康障碍候选者进行分类，并且识别具有基本上对应于患者状态变化的病理生理学的健康障碍候选者，所述病理状态变化基本上最近最近发生为指数病症。