US008888698B2

(12) United States Patent
Bardy

(10) Patent No.: US 8,888,698 B2
(45) Date of Patent: Nov. 18, 2014

(54) SYSTEM AND METHOD FOR DETERMINING A REFERENCE BASELINE FOR USE IN HEART FAILURE ASSESSMENT

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1200 days.

(21) Appl. No.: **11/894,514**

(22) Filed: **Aug. 20, 2007**

(65) **Prior Publication Data**

US 2007/0293741 A1 Dec. 20, 2007

Related U.S. Application Data

(63) Continuation of application No. 11/102,522, filed on Apr. 8, 2005, now abandoned, which is a continuation of application No. 09/860,987, filed on May 18, 2001, now Pat. No. 6,945,934, which is a continuation of application No. 09/476,601, filed on Dec. 31, 1999, now Pat. No. 6,280,380, which is a continuation-in-part of application No. 09/361,332, filed on Jul. 26, 1999, now Pat. No. 6,221,011.

(51) **Int. Cl.**

A61B 5/00	(2006.01)
A61B 5/02	(2006.01)
G06F 19/00	(2011.01)

(52) **U.S. Cl.**

CPC ***A61B 5/0002*** (2013.01); ***G06F 19/324*** (2013.01); ***G06F 19/3418*** (2013.01); ***A61B 5/4884*** (2013.01); ***G06F 19/322*** (2013.01)

USPC **600/300**; 600/333; 600/481

(58) **Field of Classification Search**

CPC A61B 5/02; A61B 5/021; A61B 5/0205; A61B 5/02055; A61B 5/0002; A61B 5/4884; G06F 19/32; G06F 19/34; G06F 19/36

See application file for complete search history.

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(57) **ABSTRACT**

A system and method for determining a stressor-based reference baseline for use in heart failure assessment is presented. A patient is monitored during an observation time period while the patient performs prescribed physical stressors and by applying pacing stimulus stressors to a medical device. Physiological measures are stored from the observation period, including at least one of direct measures regularly recorded on a substantially continuous basis by the medical device and measures derived therefrom. The measures that originate from the observation time period as a reference baseline for the patient are identified. The reference baseline and those measures originating subsequent to the observation period are evaluated. The measures are analyzed to detect any trends, including one of a status quo and a change in cardiac performance of the patient. Each trend is compared to parameters corresponding to worsening heart failure indications to generate a notification of parameter violations.

8 Claims, 23 Drawing Sheets

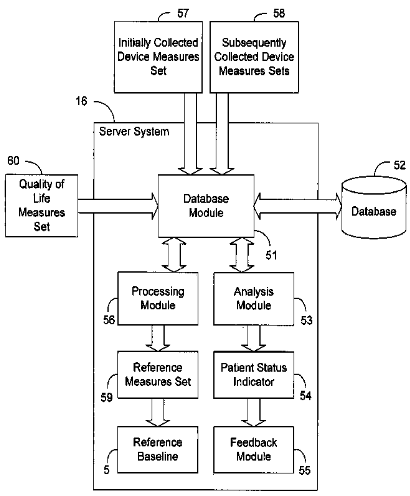

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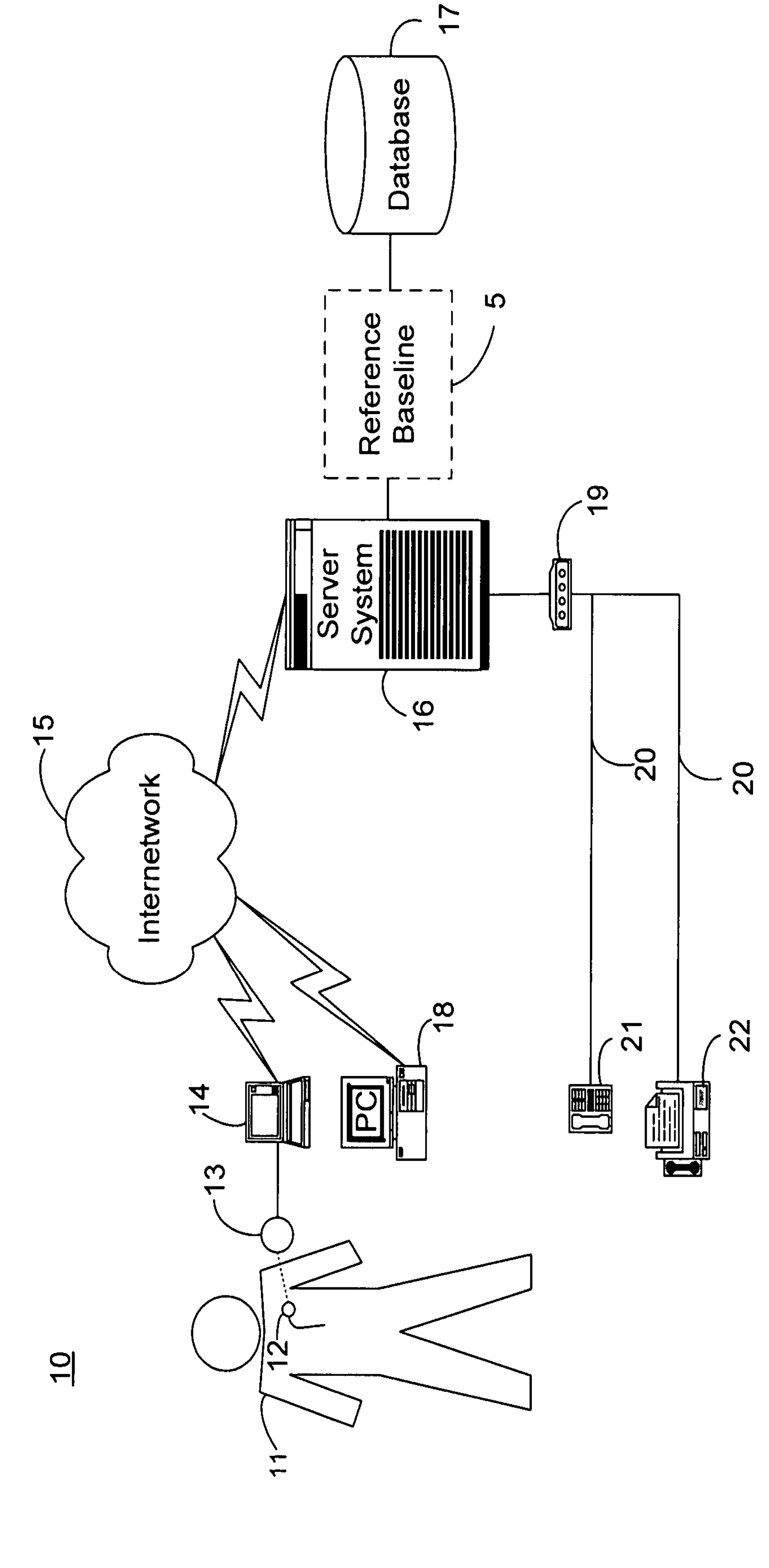
Fig. 1A.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Reference Baseline
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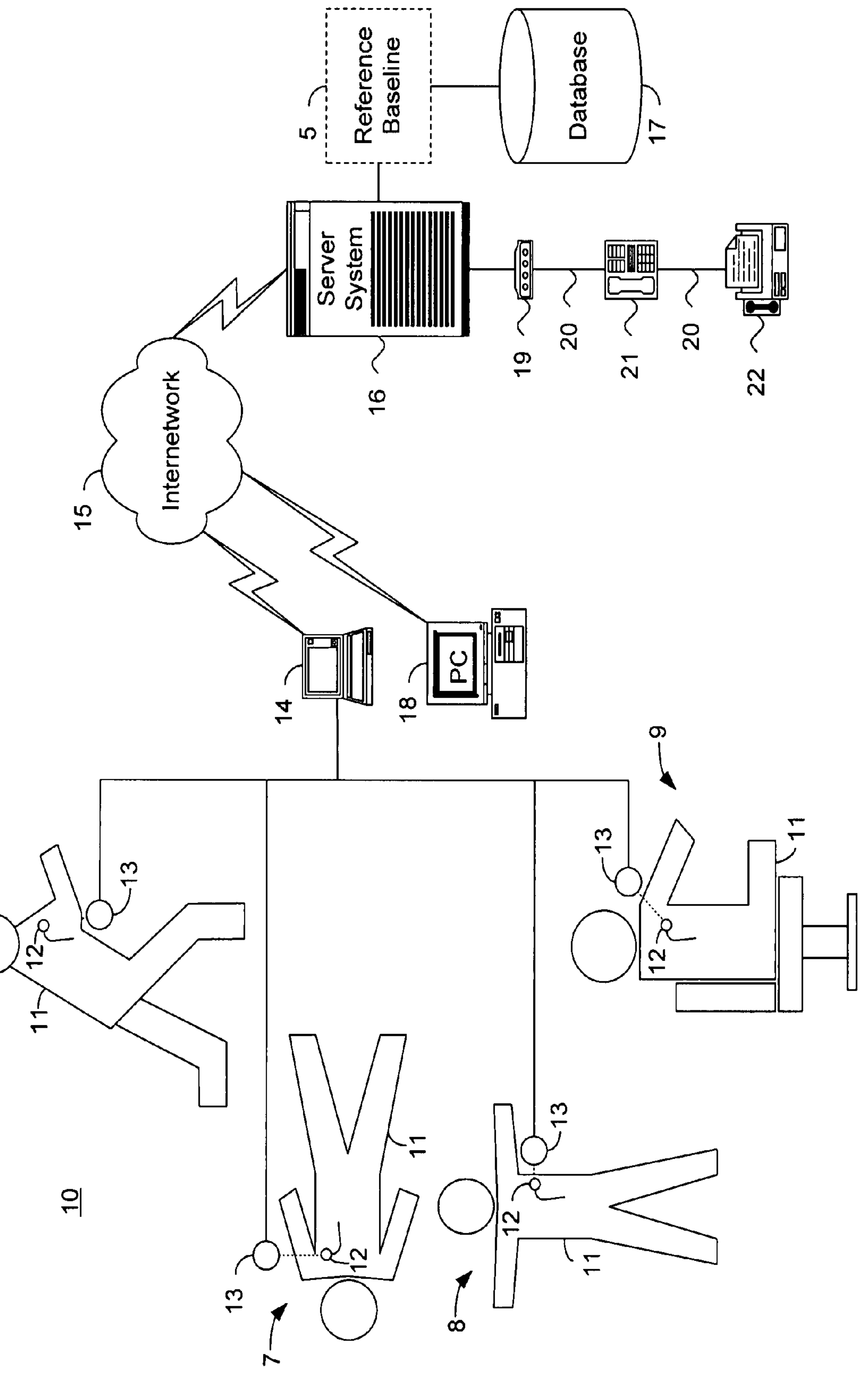
Database

Fig. 1B.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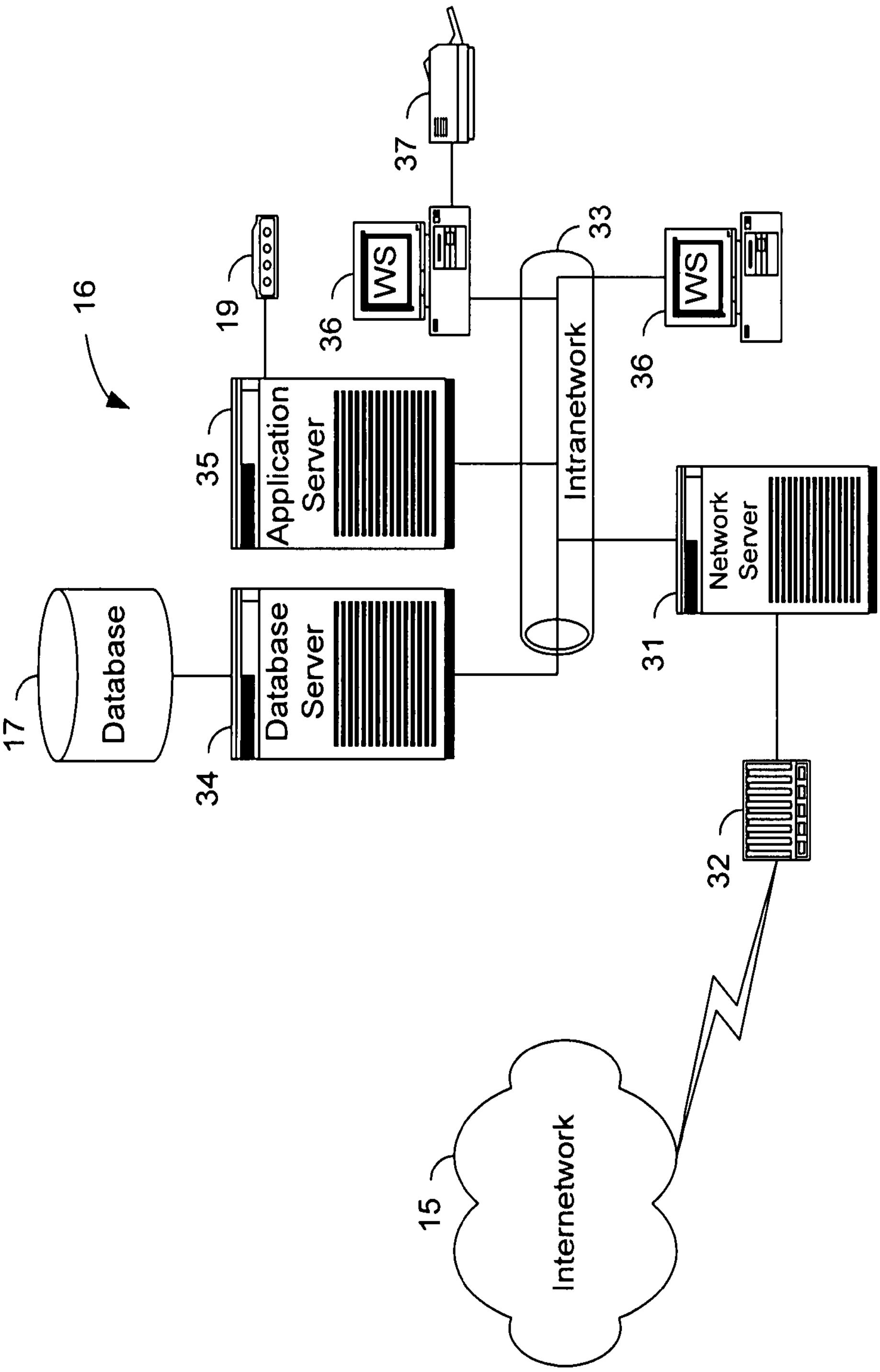

16
17
Database
34
Database Server
35
Application Server
19
36
WS
37
33
Intranetwork
36
WS
31
Network Server
32
15
Internetwork

Fig. 2.

Fig. 3.

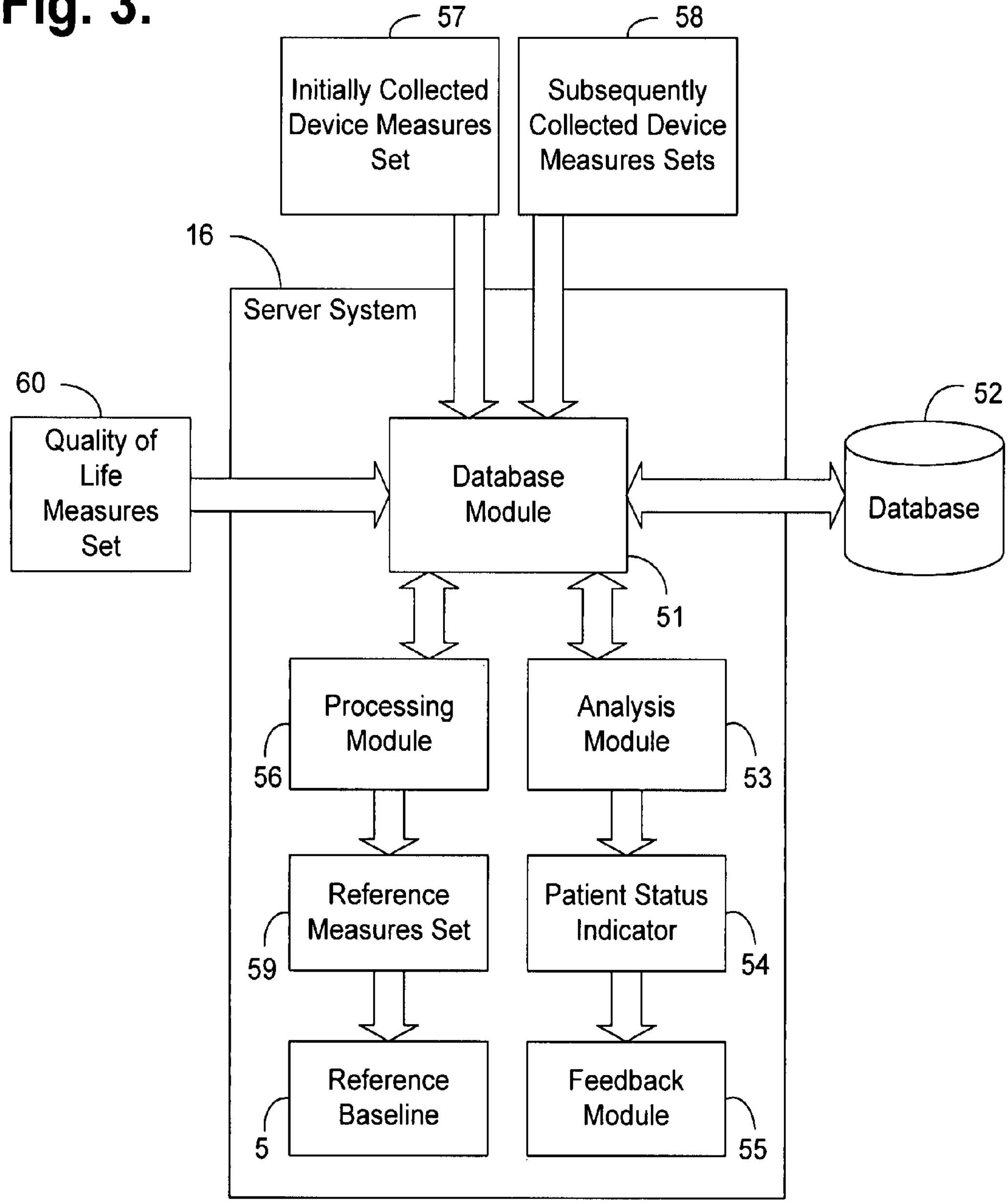

57
58
Initially Collected Device Measures Set
Subsequently Collected Device Measures Sets
16
Server System
60
Quality of Life Measures Set
Database Module
52
Database
51
Processing Module
56
Analysis Module
53
Reference Measures Set
59
Patient Status Indicator
54
Reference Baseline
5
Feedback Module
55

Fig. 4.

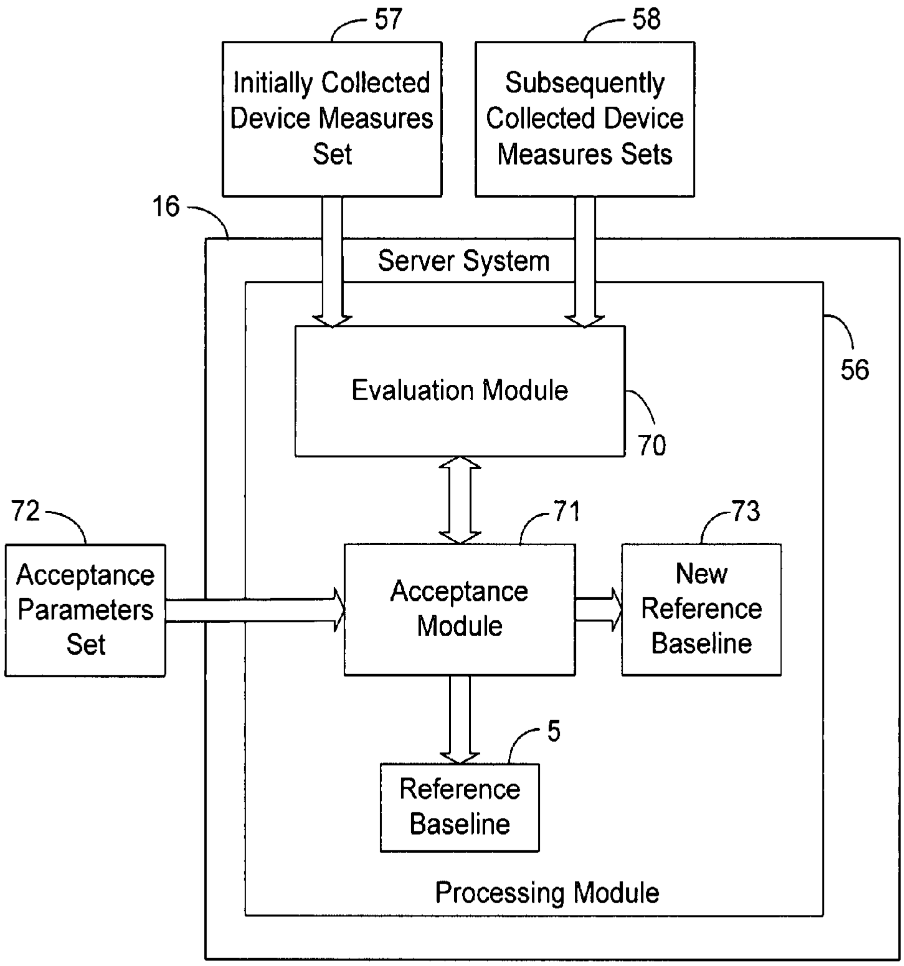

57
Initially Collected Device Measures Set
58
Subsequently Collected Device Measures Sets
16
Server System
56
Evaluation Module
70
72
Acceptance Parameters Set
71
Acceptance Module
73
New Reference Baseline
5
Reference Baseline
Processing Module

Fig. 5.

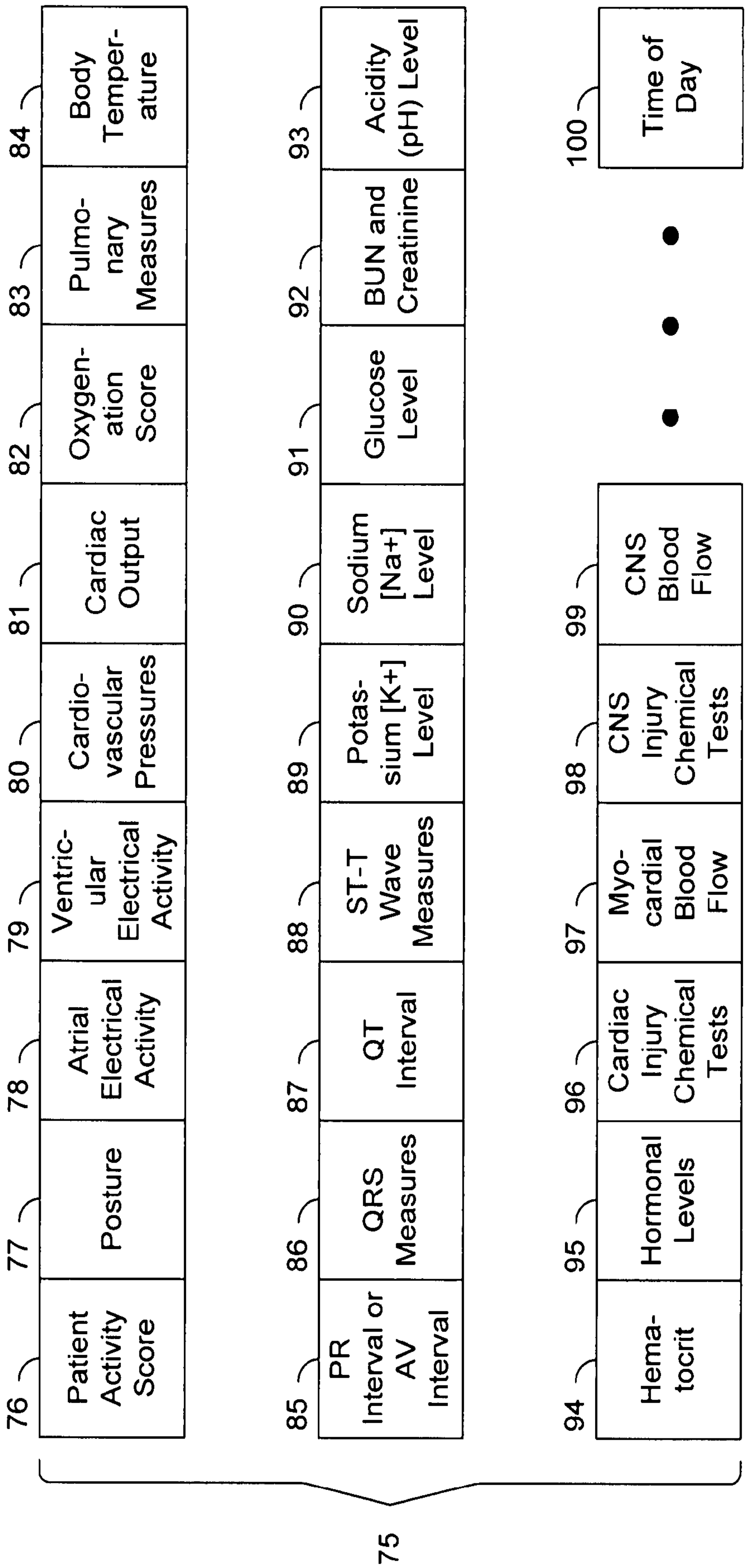

75
76
Patient Activity Score
77
Posture
78
Atrial Electrical Activity
79
Ventricular Electrical Activity
80
Cardiovascular Pressures
81
Cardiac Output
82
Oxygenation Score
83
Pulmonary Measures
84
Body Temperature
85
PR Interval or AV Interval
86
QRS Measures
87
QT Interval
88
ST-T Wave Measures
89
Potassium [K+] Level
90
Sodium [Na+] Level
91
Glucose Level
92
BUN and Creatinine
93
Acidity (pH) Level
94
Hematocrit
95
Hormonal Levels
96
Cardiac Injury Chemical Tests
97
Myocardial Blood Flow
98
CNS Injury Chemical Tests
99
CNS Blood Flow
100
Time of Day

Fig. 6.

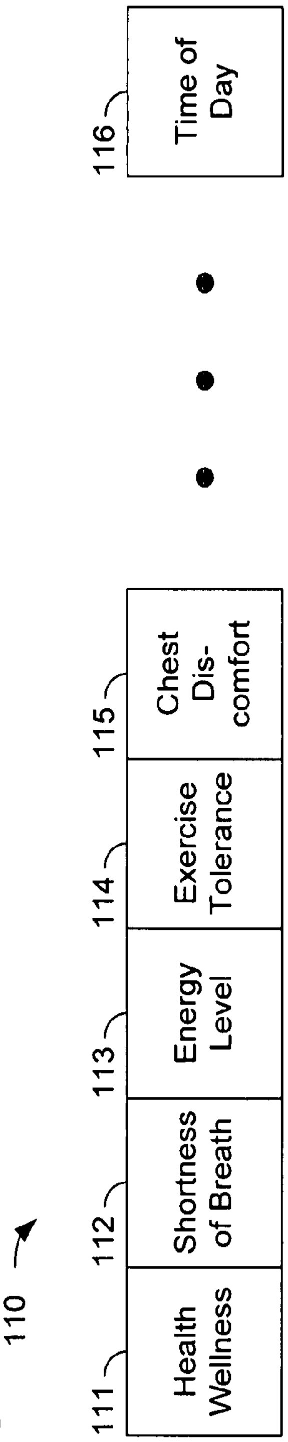

110
111
Health Wellness
112
Shortness of Breath
113
Energy Level
114
Exercise Tolerance
115
Chest Dis-comfort
116
Time of Day

Fig. 7.

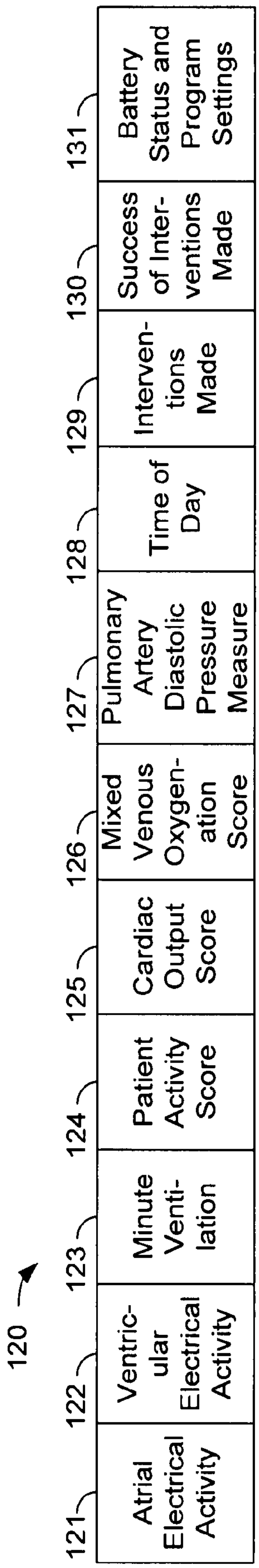

120
121
Atrial Electrical Activity
122
Ventric-ular Electrical Activity
123
Minute Venti-lation
124
Patient Activity Score
125
Cardiac Output Score
126
Mixed Venous Oxygen-ation Score
127
Pulmonary Artery Diastolic Pressure Measure
128
Time of Day
129
Interven-tions Made
130
Success of Inter-ventions Made
131
Battery Status and Program Settings

Fig. 8A.

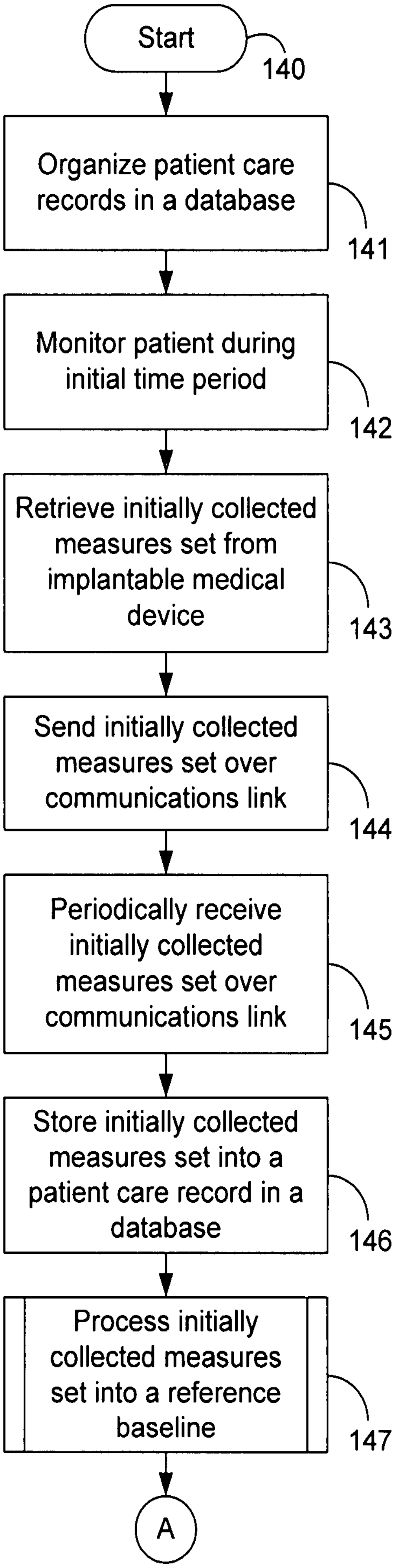

Start
140
Organize patient care records in a database
141
Monitor patient during initial time period
142
Retrieve initially collected measures set from implantable medical device
143
Send initially collected measures set over communications link
144
Periodically receive initially collected measures set over communications link
145
Store initially collected measures set into a patient care record in a database
146
Process initially collected measures set into a reference baseline
147
A

Fig. 8B.

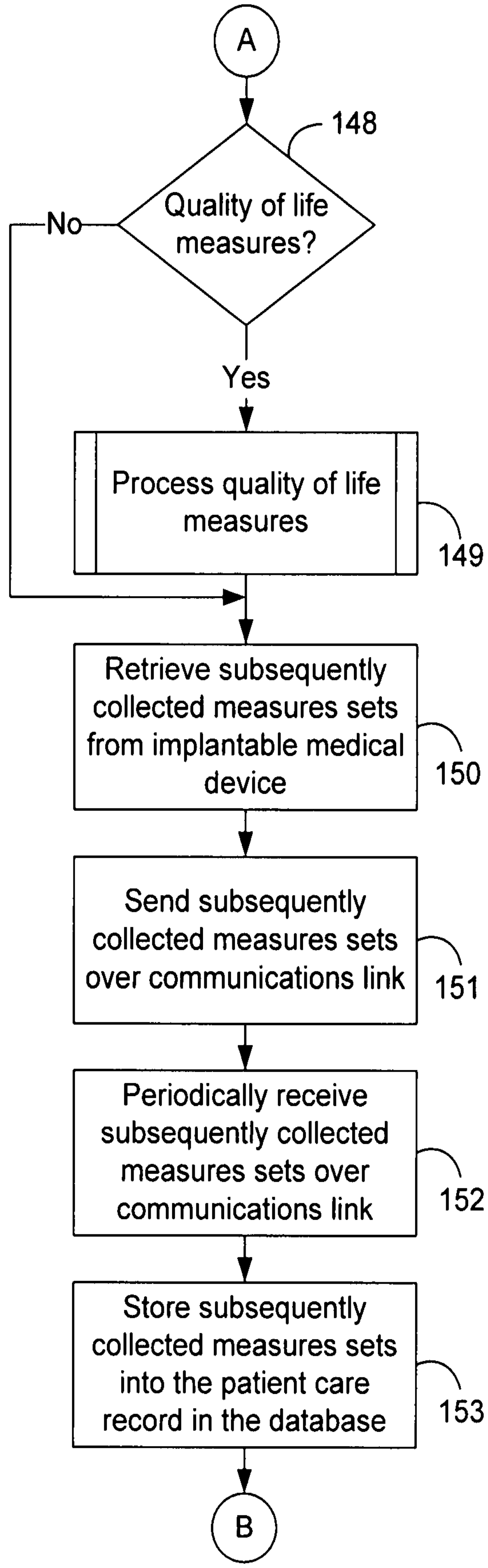

A
148
Quality of life measures?
No
Yes
Process quality of life measures
149
Retrieve subsequently collected measures sets from implantable medical device
150
Send subsequently collected measures sets over communications link
151
Periodically receive subsequently collected measures sets over communications link
152
Store subsequently collected measures sets into the patient care record in the database
153
B

Fig. 8C.

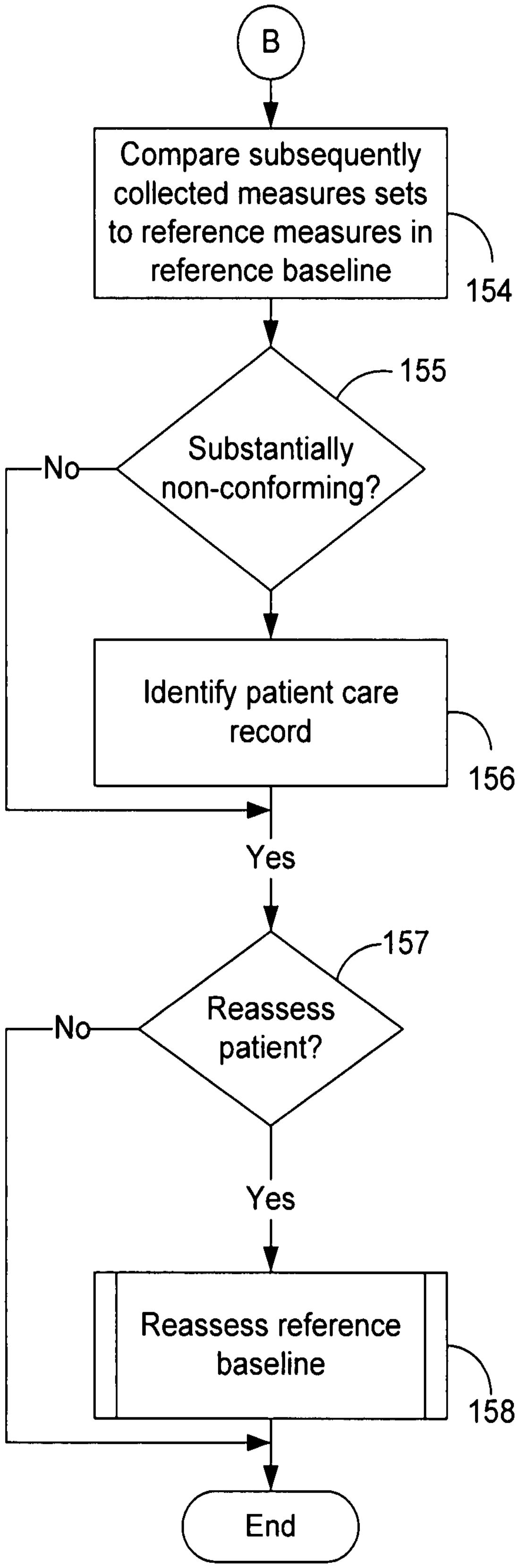
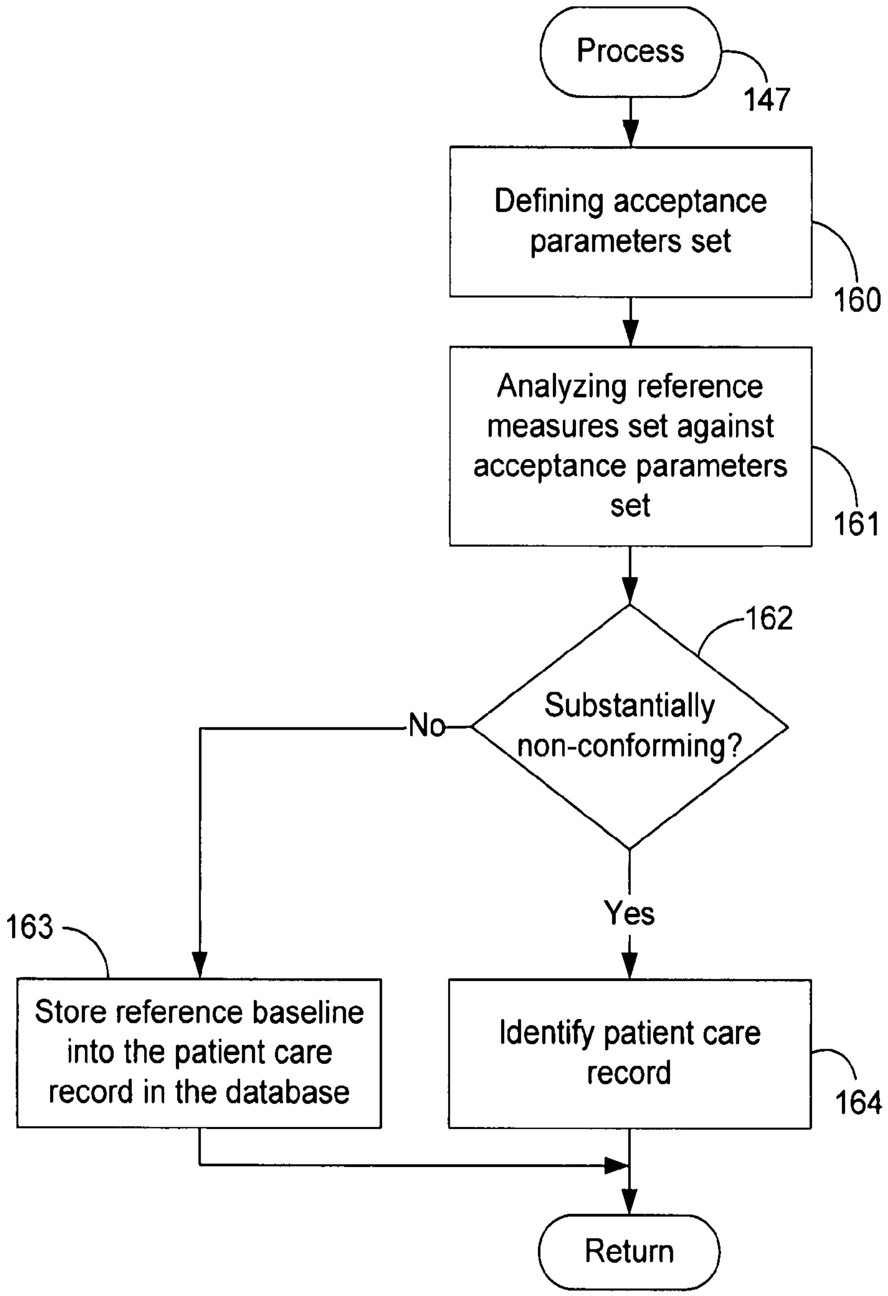
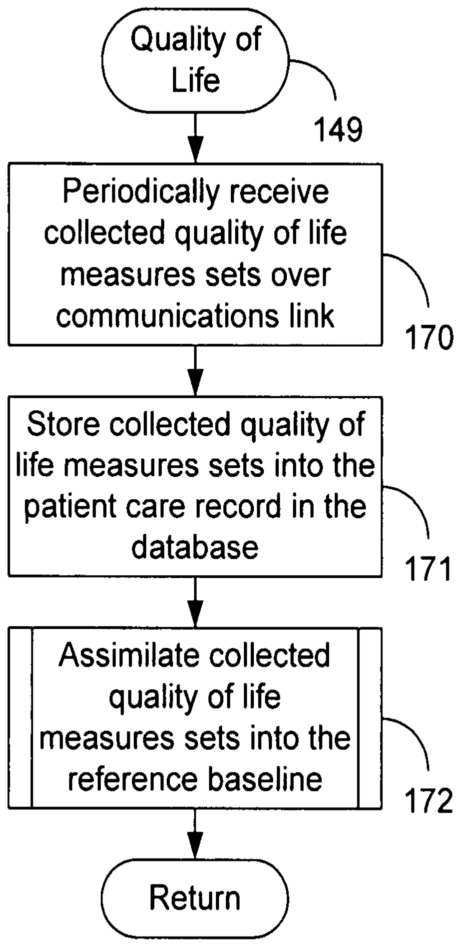

B
Compare subsequently collected measures sets to reference measures in reference baseline
154
155
Substantially non-conforming?
No
Identify patient care record
156
Yes
157
Reassess patient?
No
Yes
Reassess reference baseline
158
End

Fig. 9.



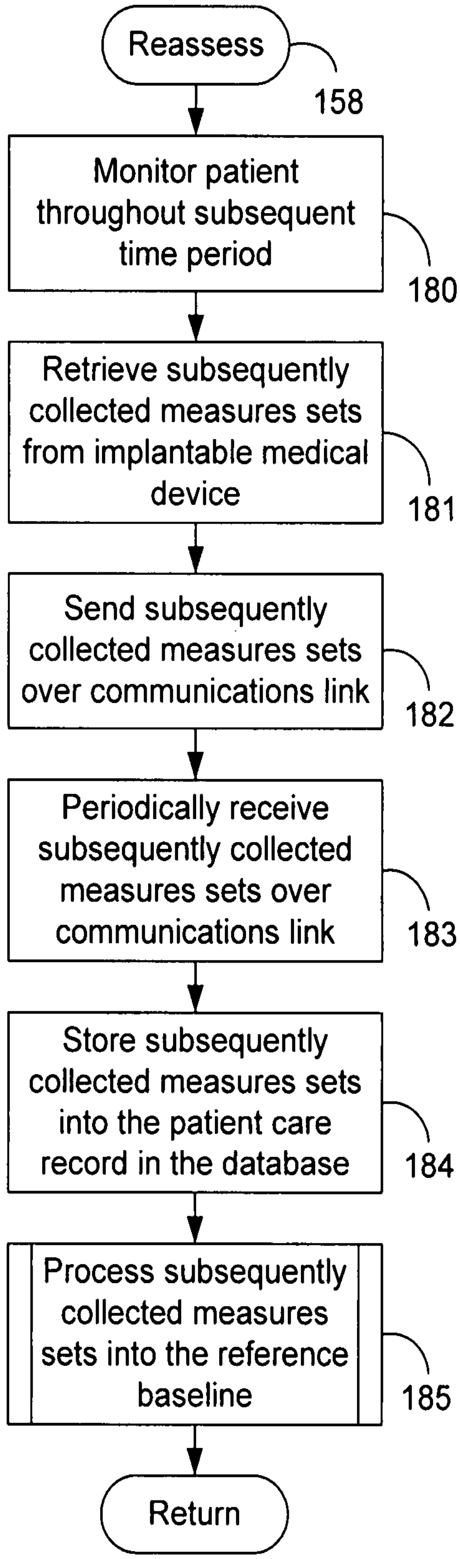
Process
147
Defining acceptance parameters set
160
Analyzing reference measures set against acceptance parameters set
161
162
Substantially non-conforming?
No
Yes
163
Store reference baseline into the patient care record in the database
Identify patient care record
164
Return

Fig. 10.



Quality of Life
149
Periodically receive collected quality of life measures sets over communications link
170
Store collected quality of life measures sets into the patient care record in the database
171
Assimilate collected quality of life measures sets into the reference baseline
172
Return

Fig. 11.


Reassess
158
Monitor patient throughout subsequent time period
180
Retrieve subsequently collected measures sets from implantable medical device
181
Send subsequently collected measures sets over communications link
182
Periodically receive subsequently collected measures sets over communications link
183
Store subsequently collected measures sets into the patient care record in the database
184
Process subsequently collected measures sets into the reference baseline
185
Return

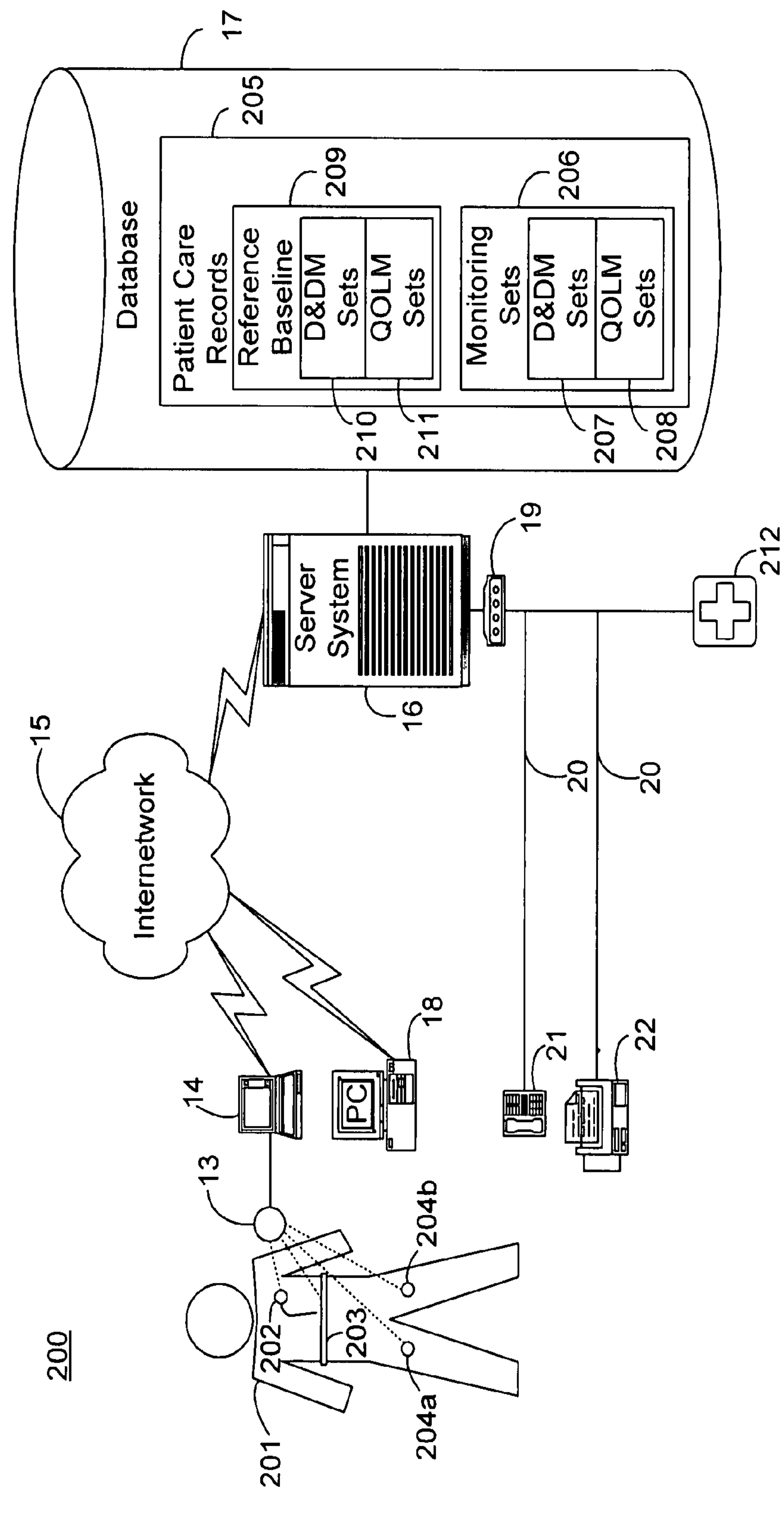
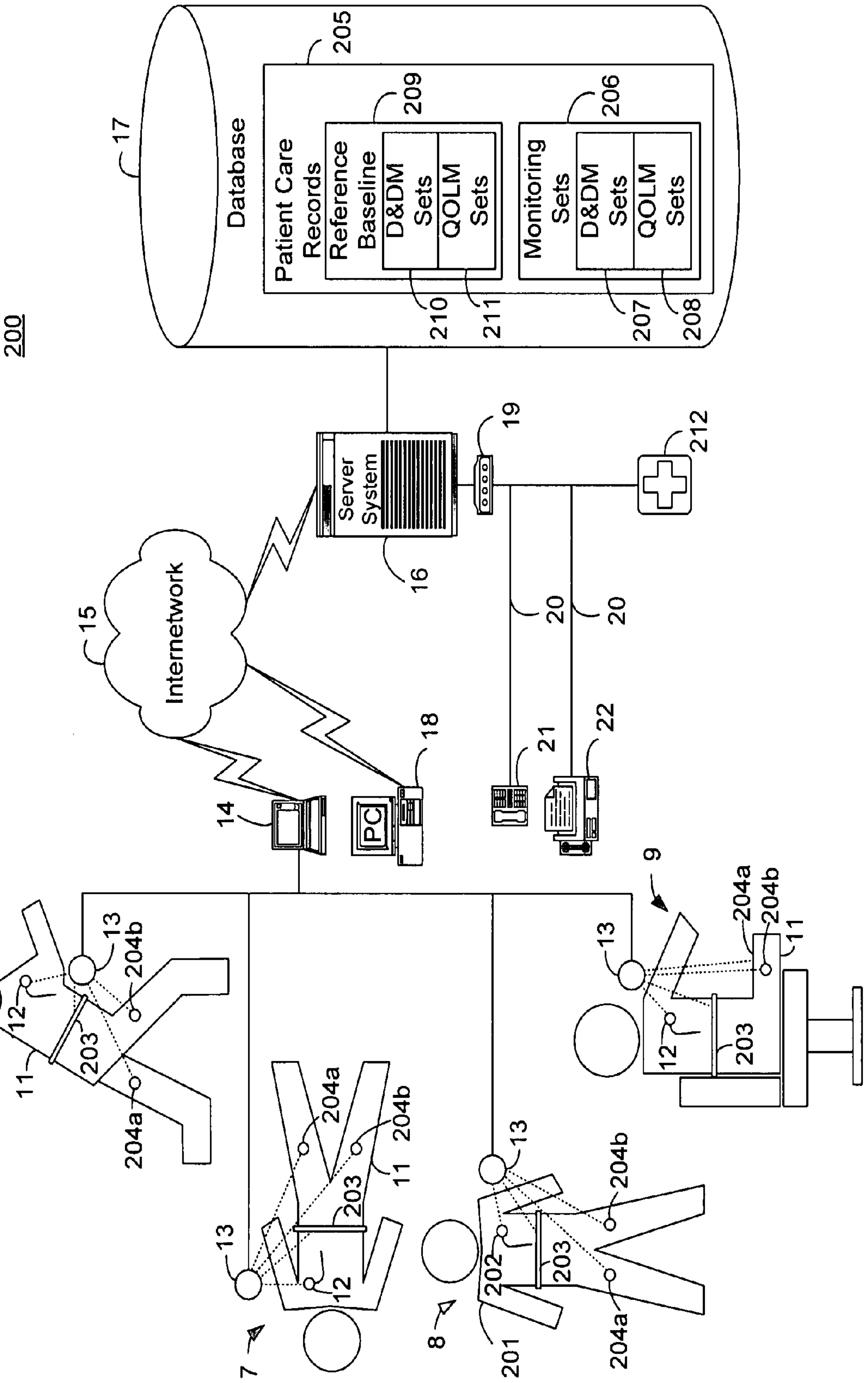
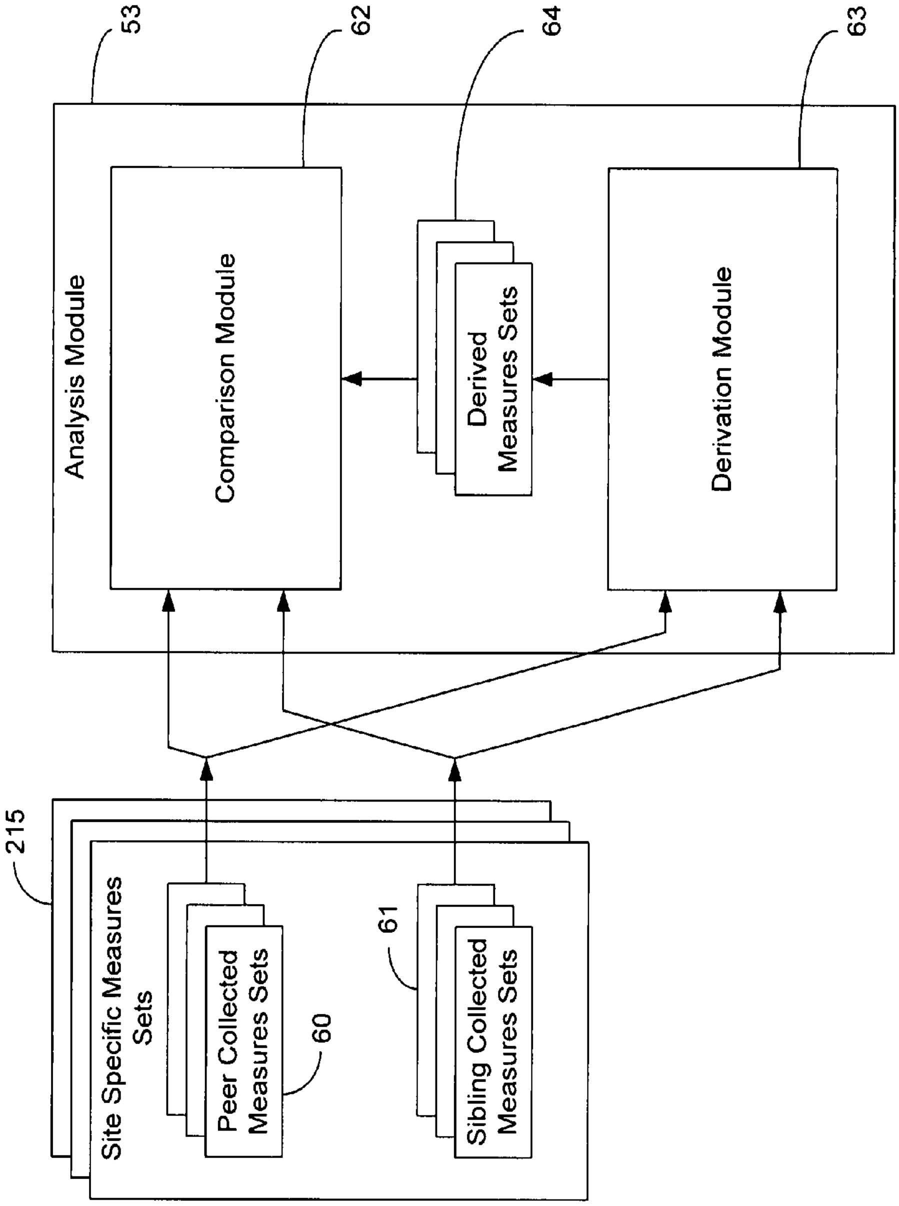

17
Database
205
Patient Care Records
209
Reference Baseline
D&DM Sets
QOLM Sets
210
211
206
Monitoring Sets
D&DM Sets
QOLM Sets
207
208
Server System
16
19
212
15
Internetwork
20
20
14
PC
18
21
22
13
204b
202
203
204a
201
200

Fig. 12A.

Fig. 12B.


200
Database
Patient Care Records
Reference Baseline
D&DM Sets
QOLM Sets
Monitoring Sets
D&DM Sets
QOLM Sets
205
209
206
210
211
207
208
17
Internetwork
15
Server System
16
19
212
20
20
21
22
14
PC
18
6
7
8
9
11
12
13
201
202
203
204a
204b



53
62
64
63
Analysis Module
Comparison Module
Derived Measures Sets
Derivation Module
215
Site Specific Measures Sets
Peer Collected Measures Sets
60
61
Sibling Collected Measures Sets

Fig. 13.

Fig. 14.

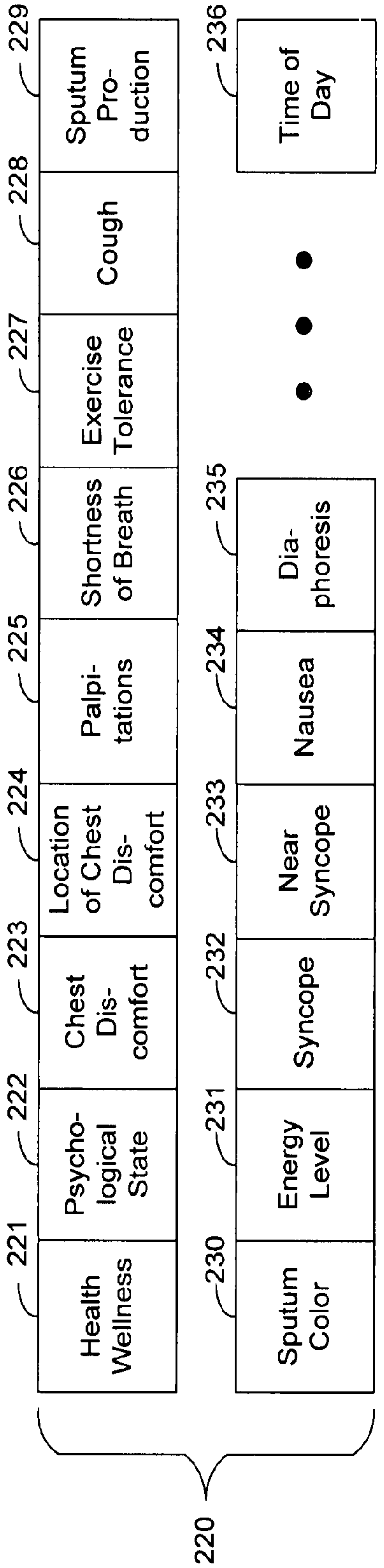

220
221
Health Wellness
222
Psycho-logical State
223
Chest Dis-comfort
224
Location of Chest Dis-comfort
225
Palpi-tations
226
Shortness of Breath
227
Exercise Tolerance
228
Cough
229
Sputum Pro-duction
230
Sputum Color
231
Energy Level
232
Syncope
233
Near Syncope
234
Nausea
235
Dia-phoresis
236
Time of Day

Fig. 15.

Patient 1

Set 0				Set *n*-2	Set *n*-1	Set *n*
Site *A*						
X_{0_A}	•	•	•	X_{n-2_A}	X_{n-1_A}	X_{n_A}
Y_{0_A}	•	•	•	Y_{n-2_A}	Y_{n-1_A}	Y_{n_A}
Z_{0_A}	•	•	•	Z_{n-2_A}	Z_{n-1_A}	Z_{n_A}
Site *B*						
X_{0_B}	•	•	•	X_{n-2_B}	X_{n-1_B}	X_{n_B}
Y_{0_B}	•	•	•	Y_{n-2_B}	Y_{n-1_B}	Y_{n_B}
Z_{0_B}	•	•	•	Z_{n-2_B}	Z_{n-1_B}	Z_{n_B}
Site *C*						
X_{0_C}	•	•	•	X_{n-2_C}	X_{n-1_C}	X_{n_C}
Y_{0_C}	•	•	•	Y_{n-2_C}	Y_{n-1_C}	Y_{n_C}
Z_{0_C}	•	•	•	Z_{n-2_C}	Z_{n-1_C}	Z_{n_C}

time →

Patient 2

Set 0				Set *n*-2	Set *n*-1	Set *n*
Site *A*						
$X_{0'_A}$	•	•	•	$X_{n-2'_A}$	$X_{n-1'_A}$	$X_{n'_A}$
$Y_{0'_A}$	•	•	•	$Y_{n-2'_A}$	$Y_{n-1'_A}$	$Y_{n'_A}$
$Z_{0'_A}$	•	•	•	$Z_{n-2'_A}$	$Z_{n-1'_A}$	$Z_{n'_A}$
Site *B*						
$X_{0'_B}$	•	•	•	$X_{n-2'_B}$	$X_{n-1'_B}$	$X_{n'_B}$
$Y_{0'_B}$	•	•	•	$Y_{n-2'_B}$	$Y_{n-1'_B}$	$Y_{n'_B}$
$Z_{0'_B}$	•	•	•	$Z_{n-2'_B}$	$Z_{n-1'_B}$	$Z_{n'_B}$

time →

Patient 3

Set 0				Set *n*-2	Set *n*-1	Set *n*
Site *A*						
$X_{0''_A}$	•	•	•	$X_{n-2''_A}$	$X_{n-1''_A}$	$X_{n''_A}$
$Y_{0''_A}$	•	•	•	$Y_{n-2''_A}$	$Y_{n-1''_A}$	$Y_{n''_A}$
$Z_{0''_A}$	•	•	•	$Z_{n-2''_A}$	$Z_{n-1''_A}$	$Z_{n''_A}$
Site *D*						
$X_{0''_D}$	•	•	•	$X_{n-2''_B}$	$X_{n-1''_D}$	$X_{n''_D}$
$Y_{0''_D}$	•	•	•	$Y_{n-2''_D}$	$Y_{n-1''_D}$	$Y_{n''_D}$
$Z_{0''_D}$	•	•	•	$Z_{n-2''_D}$	$Z_{n-1''_D}$	$Z_{n''_D}$

time →

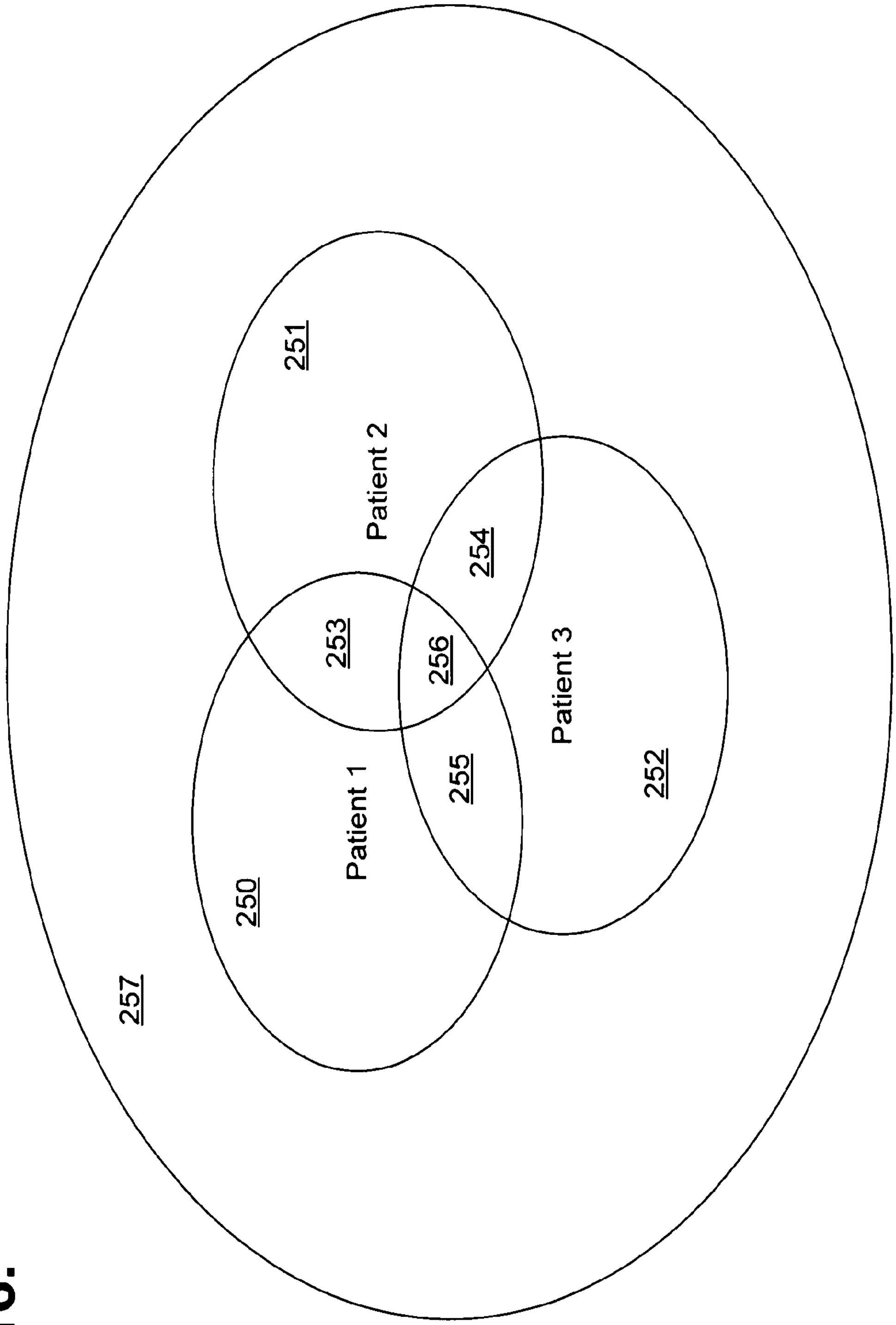
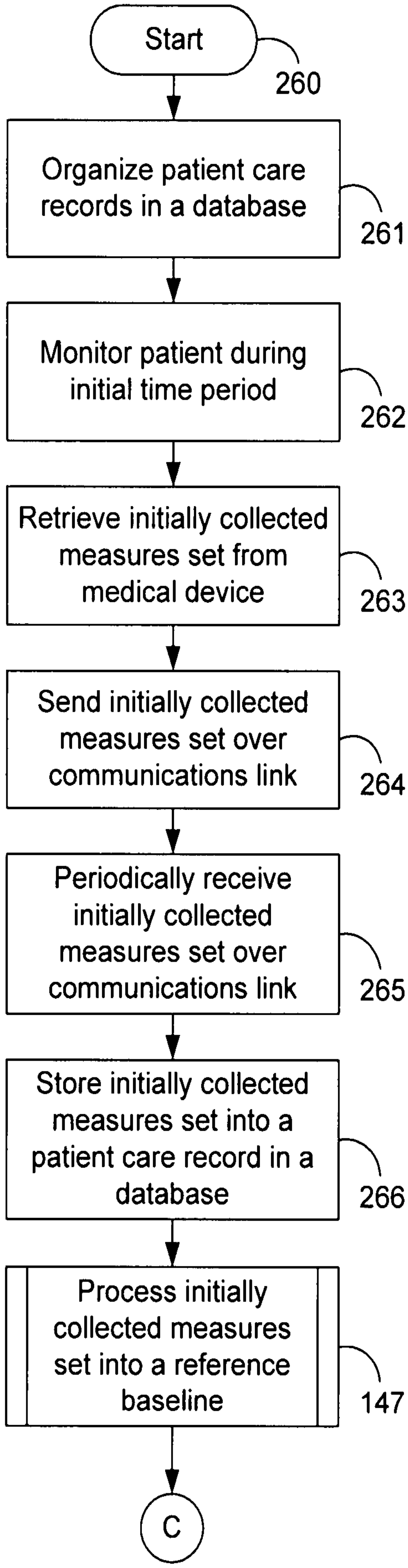


Fig. 16.

Fig. 17A.



Start
260
Organize patient care records in a database
261
Monitor patient during initial time period
262
Retrieve initially collected measures set from medical device
263
Send initially collected measures set over communications link
264
Periodically receive initially collected measures set over communications link
265
Store initially collected measures set into a patient care record in a database
266
Process initially collected measures set into a reference baseline
147
C

Fig. 17B.

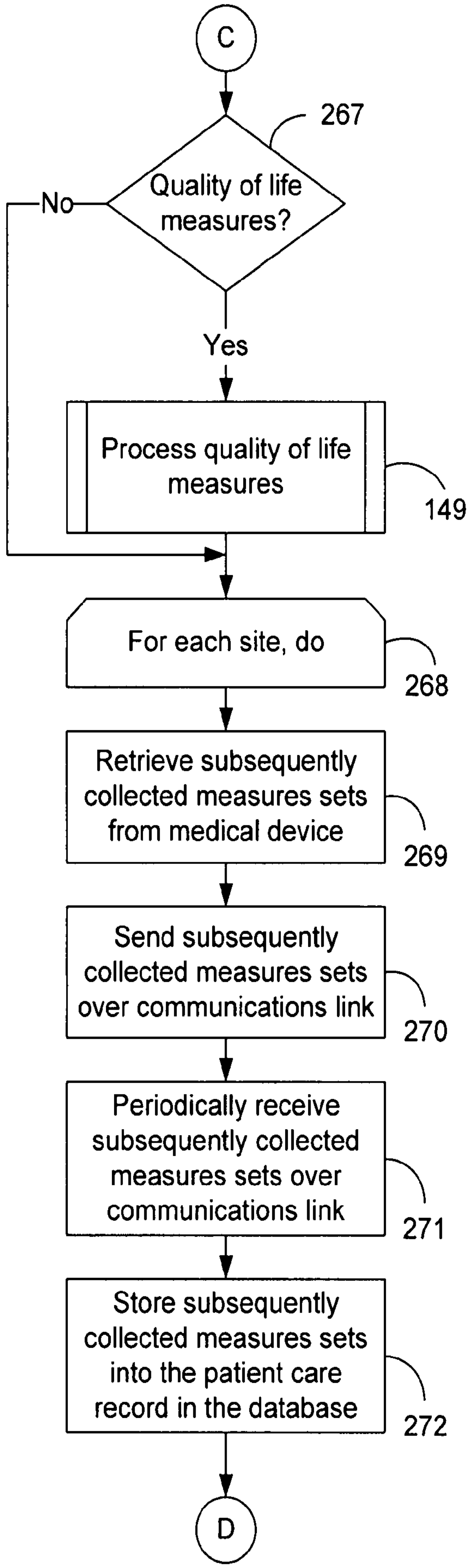

C
267
Quality of life measures?
No
Yes
Process quality of life measures
149
For each site, do
268
Retrieve subsequently collected measures sets from medical device
269
Send subsequently collected measures sets over communications link
270
Periodically receive subsequently collected measures sets over communications link
271
Store subsequently collected measures sets into the patient care record in the database
272
D

Fig. 17C.

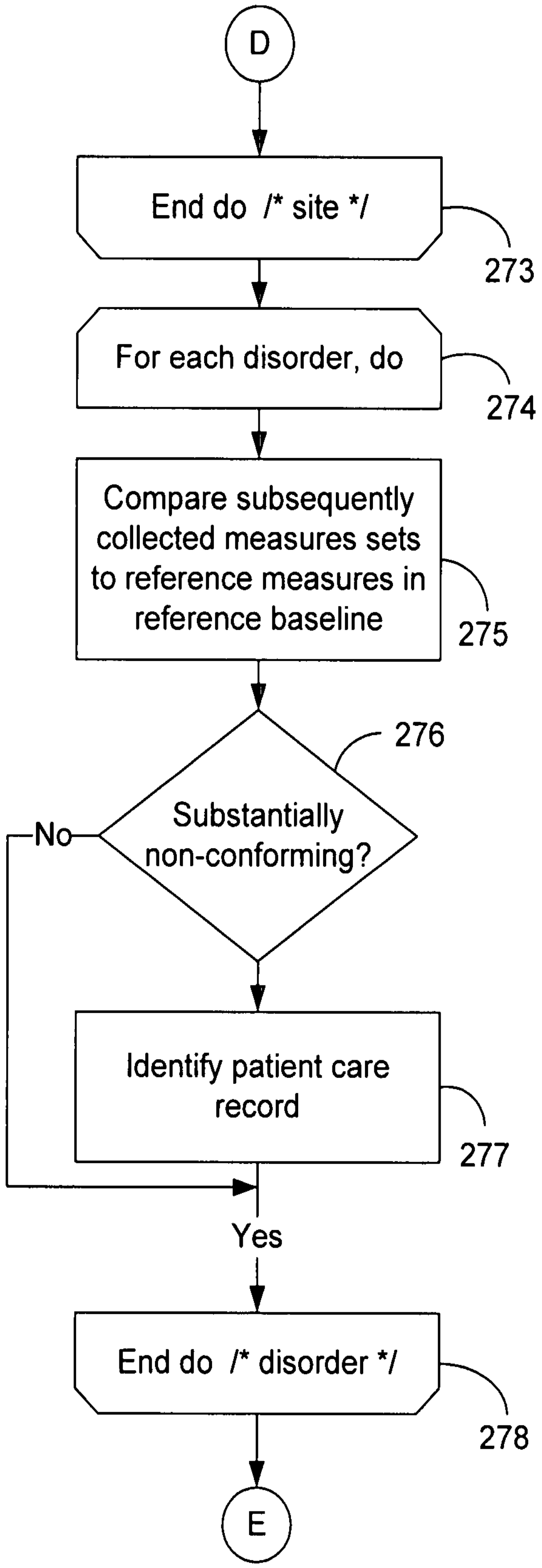
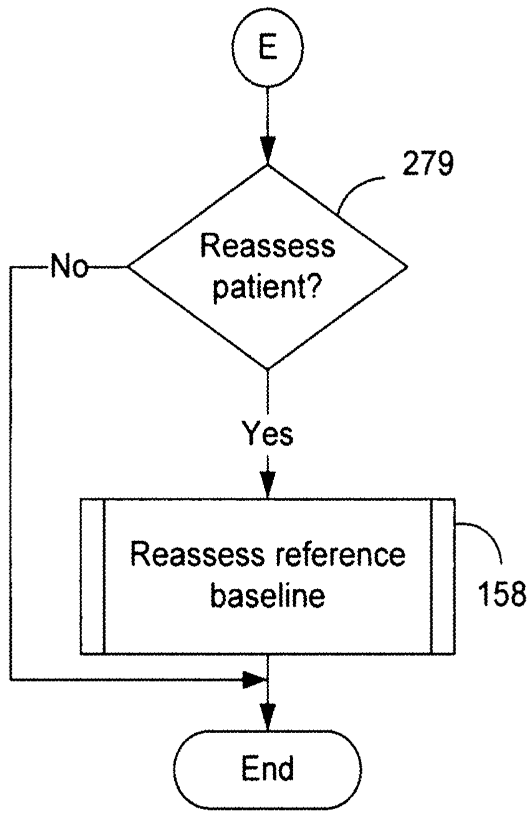

D
End do /* site */
273
For each disorder, do
274
Compare subsequently collected measures sets to reference measures in reference baseline
275
276
Substantially non-conforming?
No
Identify patient care record
277
Yes
End do /* disorder */
278
E

Fig. 17D.


E
279
Reassess patient?
No
Yes
Reassess reference baseline
158
End

SYSTEM AND METHOD FOR DETERMINING A REFERENCE BASELINE FOR USE IN HEART FAILURE ASSESSMENT

CROSS-REFERENCE TO RELATED APPLICATION

This Patent application is a continuation of U.S. patent application Ser. No. 11/102,522, filed on Apr. 8, 2005, abandoned, which is a continuation of U.S. patent application Ser. No. 09/860,987, U.S. Pat. No. 6,945,934, issued Sep. 20, 2005, which is a continuation of U.S. patent application Ser. No. 09/476,601, U.S. Pat. No. 6,280,380, issued Aug. 28, 2001, which is a continuation-in-part of U.S. patent application Ser. No. 09/361,332, U.S. Pat. No. 6,221,011, issued Apr. 24, 2001, the priority of filing dates of which are claimed, and the disclosures of which are incorporated by reference

FIELD

The present invention relates in general to heart failure assessment, and, in particular, to a system and method for determining a reference baseline for use in heart failure assessment.

BACKGROUND

A broad class of medical subspecialties, including cardiology, endocrinology, hematology, neurology, gastroenterology, urology, opthalmology, and otolaryngology, to name a few, rely on accurate and timely patient information for use in aiding health care providers in diagnosing and treating diseases and disorders. Often, proper medical diagnosis requires information on physiological events of short duration and sudden onset, yet these types of events are often occur infrequently and with little or no warning. Fortunately, such patient information can be obtained via external, implantable, cutaneous, subcutaneous, and manual medical devices, and combinations thereof. For example, in the area of cardiology, implantable pulse generators (IPGs) are medical devices commonly used to treat irregular heartbeats, known as arrhythmias. There are three basic types of IPGs. Cardiac pacemakers are used to manage bradycardia, an abnormally slow or irregular heartbeat. 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). Finally, implantable cardiovascular monitors and therapeutic devices are used to monitor and treat structural problems of the heart, such as congestive heart failure, as well as rhythm problems.

Pacemakers and ICDs, as well as other types of implantable and external medical devices, are equipped with an on-board, volatile memory in which telemetered signals can be stored for later retrieval and analysis. 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 more than thirty minutes of per heartbeat data. Typically, the telemetered signals can provide patient device information recorded on a per heartbeat, binned average basis, or derived basis from, for example, atrial electrical activity, ventricular electrical activity, minute ventilation, patient activity score, cardiac output score, mixed venous oxygen score, cardiovascular pressure measures, time of day, and any interventions and the relative success of such interventions. In addition, many such devices can have multiple sensors, or several devices can work together, for monitoring different sites within a patient's body.

These telemetered signals can be remotely collected and analyzed using an automated patient care system. One such system is described in U.S. Pat. No. 6,312,378. The telemetered signals are recorded by an implantable medical device, such as an IPG or monitor, and periodically retrieved using an interrogator, programmer, telemetered signals transceiver, or similar device, for subsequent download. The downloaded telemetered signals are received by a network server 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 is analyzed in an automated fashion and feedback, which includes a patient status indicator, is provided to the patient.

While such a system can serve as a valuable tool in automated, remote patient care, the accuracy of the patient care, particularly during the first few weeks of care, and the quality of the feedback provided to the patient would benefit from being normalized to a reference baseline of patient wellness. In particular, a starting point needs to be established for each individual patient for use in any such system in which medical device information, such as telemetered signals from implantable and external medical devices, is continuously monitored, collected, and analyzed. The starting point could serve as a reference baseline indicating overall patient status and wellness from the outset of remote patient care.

In addition, automated remote patient care poses a further challenge vis-à-vis evaluating quality of life issues. Unlike in a traditional clinical setting, physicians participating in providing remote patient care are not able to interact with their patients in person. Consequently, quality of life measures, such as how the patient subjectively looks and feels, whether the patient has shortness of breath, can work, can sleep, is depressed, is sexually active, can perform activities of daily life, and so on, cannot be implicitly gathered and evaluated.

Reference baseline health assessments are widely used in conventional patient health care monitoring services. Typically, a patient's vital signs, consisting of heart rate, blood pressure, weight, and blood sugar level, are measured both at the outset of care and periodically throughout the period of service. However, these measures are limited in their usefulness and do not provide the scope of detailed medical information made available through implantable and external medical devices. Moreover, such measures are generally obtained through manual means and do not ordinarily directly tie into quality of life assessments. Further, a significant amount of time generally passes between the collection of sets of these measures.

In addition, the uses of multiple sensors situated within a patient's body at multiple sites are disclosed in U.S. Pat. No. 5,040,536 ('536) and U.S. Pat. No. 5,987,352 ('352). In the '536 patent, an intravascular pressure posture detector includes at least two pressure sensors implanted in different places in the cardiovascular system, such that differences in pressure with changes in posture are differentially measurable. However, the physiological measurements are used locally within the device, or in conjunction with any implantable device, to effect a therapeutic treatment. In the '352 patent, an event monitor can include additional sensors for monitoring and recording physiological signals during arrhythmia and syncopal events. The recorded signals can be used for diagnosis, research or therapeutic study, although no systematic approach to analyzing these signals, particularly with respect to peer and general population groups, is presented.

Thus, there is a need for an approach to determining a meaningful reference baseline of individual patient status for use in a system and method for providing automated, remote patient care through the continuous monitoring and analysis of patient information retrieved from an implantable medical device. Preferably, such an approach would establish the reference baseline through initially received measures or after a reasonable period of observation. The reference baseline could be tied to the completion of a set of prescribed physical stressors. Periodic reassessments should be obtainable as necessary. Moreover, the reference baseline should preferably be capable of correlation to quality of life assessments.

There is a further need for an approach to monitoring patient wellness based on a reference baseline for use in an automated patient care system. Preferably, such an approach would dynamically determine whether the patient is trending into an area of potential medical concern, including indicating disease onset, progression, regression, and status quo.

There is a further need for an approach to determining a situation in which remote patient care is inappropriate based on a reference baseline of patient wellness. Preferably, such an approach would include a range of acceptance parameters as part of the reference baseline, thereby enabling those potential patients whose reference baseline falls outside those acceptance parameters to be identified.

SUMMARY

The present invention provides a system and method for determining a reference baseline for use in an automated collection and analysis patient care system. The present invention further provides a system and method for monitoring a patient status using a reference baseline in an automated collection and analysis patient care system.

An embodiment provides a system and method for determining a reference baseline 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. The physiological measures that originate from an observation time period as a reference baseline for the patient are identified. The physiological measures are evaluated by determining patient wellness, including one of a status quo and a change in cardiac performance relative to the reference baseline and comparing the patient wellness to worsening heart failure indications.

A further embodiment provides a system and method for determining a stressor-based reference baseline for use in heart failure assessment. A patient is monitored during an observation time period while the patient performs prescribed physical stressors and by applying pacing stimulus stressors to a medical device of the patient. Physiological measures from the observation period are stored, including at least one of direct measures regularly recorded on a substantially continuous basis by the medical device and measures derived therefrom. Those physiological measures that originate from the observation time period as a reference baseline for the patient are identified. The reference baseline and those physiological measures originating subsequent to the observation period are evaluated. The direct measures and the derived measures are analyzed to detect any trends, including one of a status quo and a change in cardiac performance of the patient. Each trend is compared to parameters corresponding to worsening heart failure indications to generate a notification of parameter violations.

The present invention provides a meaningful, quantitative measure of patient wellness for use as a reference baseline in an automated system and method for continuous, remote patient care. The reference baseline increases the accuracy of remote patient care, particularly during the first few weeks of care, by providing a grounded starting assessment of the patient's health and well-being.

A collateral benefit of the reference baseline is the removal of physician "bias" which can occur when the apparent normal outward appearance of a patient belies an underlying condition that potentially requires medical attention. The reference baseline serves to objectify a patient's self-assessment of wellness.

The present invention also provides an objective approach to humanizing the raw measures recorded by medical devices, including implantable medical devices. Using known quality of life assessment instruments, a patient can be evaluated and scored for relative quality of life at a given point in time. The reference baseline of the present invention provides a means for correlating the quality of life assessment to machine-recorded measures, thereby assisting a physician in furthering patient care.

Finally, the present invention improves the chronicling of legal responsibility in patient care. A prescribed course of treatment can be traced back to a grounded point in time memorialized by the reference baseline. Thus, a medical audit trail can be generated with a higher degree of accuracy and certainty based on having an established originating point of reference.

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

FIGS. **1**A and **1**B are block diagrams showing a system for determining a reference baseline of individual patient status for use in an automated collection and analysis patient care system in accordance with the present invention;

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

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

FIG. **4** is a block diagram showing the processing module of the server system of FIG. **1**A;

FIG. **5** is a database schema showing, by way of example, the organization of a reference baseline record for cardiac patient care stored as part of a patient care record in the database of the system of FIG. **1**A;

FIG. **6** is a database schema showing, by way of example, the organization of a reference baseline quality of life record for cardiac patient care stored as part of a patient care record in the database of the system of FIG. **1**A;

FIG. **7** is a database schema showing, by way of example, the organization of a monitoring record for cardiac patient care stored as part of a patient care record in the database of the system of FIG. **1**A;

FIGS. **8**A-**8**C are flow diagrams showing a method for determining a reference baseline for use in monitoring a patient status in an automated collection and analysis patient care system in accordance with the present invention; and

FIG. **9** is a flow diagram showing the routine for processing a reference baseline for use in the method of FIGS. **8**A-**8**C;

FIG. **10** is a flow diagram showing the routine for processing quality of life measures for use in the method of FIGS. **8**A-**8**C; and

FIG. **11** is a flow diagram showing the routine for reassessing a new reference baseline for use in the method of FIGS. **8**A-**8**C;

FIGS. **12**A and **12**B are block diagrams showing system for determining a reference baseline of individual patient status for use in an automated collection and analysis patient care system in accordance with a further embodiment of the present invention;

FIG. **13** is a block diagram showing the analysis module of the server system of FIGS. **12**A and **12**B;

FIG. **14** is a database schema showing, by way of example, the organization of a quality of life and symptom measures set record for care of patients stored as part of a patient care record in the database of the system of FIGS. **12**A and **12**B;

FIG. **15** 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 FIGS. **12**A and **12**B;

FIG. **16** is a Venn diagram showing, by way of example, peer group overlap between the partial patient care records of FIG. **15**; and

FIGS. **17**A-**17**D are flow diagrams showing a method for determining a reference baseline of individual patient status for use in an automated collection and analysis patient care system in accordance with a further embodiment of the present invention.

DETAILED DESCRIPTION

FIG. **1**A is a block diagram showing a system **10** for determining a reference baseline **5** of patient status for an individual patient **11** for use in an automated collection and analysis patient care system in accordance with the present invention. An automated collection and analysis patient care system suitable for use with the present invention is disclosed in U.S. Pat. No. 6,312,378, the disclosure of which is incorporated herein by reference. 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. Alternatively, subcutaneous monitors or devices inserted into other organs (not shown) without leads could also be used. 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.

For an exemplary cardiac implantable medical device, the telemetered signals non-exclusively present patient information recorded on a per heartbeat, binned average or derived basis and relating to: atrial electrical activity, ventricular electrical activity, minute ventilation, patient activity score, cardiac output score, mixed venous oxygenation score, cardiovascular pressure measures, time of day, the number and types of interventions made, and the relative success of any interventions, 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 Gem line of ICDs, manufactured by Medtronic Corporation, Minneapolis, Minn.

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, muscular disorders, gastroenterology, urology, opthalmology, otolaryngology, orthopedics, and similar medical subspecialties. One skilled in the art would readily recognize the applicability of the present invention to these related implantable medical devices.

The telemetered signals stored in the implantable medical device **12** are retrieved upon completion of an initial observation period and subsequently retrieved on a continuous, periodic basis. 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**.

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 **14** 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**.

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.

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.

The initial set of telemetered signals recorded during the initial observation period is processed by the server system **16** into a set of reference measures and stored as a reference baseline **5** in the database **17**, as further described below with reference to FIG. **3**. The purpose of the observation period is to establish a reference baseline **5** containing a set of reference measures that can include both measured and derived patient information. The reference baseline **5** can link "hard" machine-recorded data with "soft" patient-provided self-assessment data from which can be generated a wellness status indicator. In addition, the reference baseline **5** can be used to identify patients for whom remote patient care may be inappropriate and for patient wellness comparison and analysis during subsequent, on-going remote patient care. The reference baseline **5** is maintained in the database **17** and can be reassessed as needed or on a periodic basis.

Subsequent to the initial observation period, the patient is remotely monitored by the server system **16** through the periodic receipt of telemetered signals from the implantable medical device **12** via the internetwork **15**. 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.

FIG. **1**B is a block diagram showing a further embodiment of the present invention in which the patient **11** is monitored by the implantable medical device **12** while engaged in performing a prescribed set of timed physical stressors during an initial observation period or during a subsequent observation period if the patient **11** is being reassessed. The stressors are a set of normal, patient activities and cardiovascular and respiratory maneuvers that allow consistent, reproducible physiological functions to be measured by the implantable medical device **12**. These maneuvers include activities such as a change in posture, simple physical exercises, breathing state, including holding breath and hyperventilating, and oxygen challenges. By way of example, the stressors include timed physical activities such as running in place **6**, recumbency **7**, standing **8**, sitting motionless **9**, and reprogramming at least one of pacing interventions and pacing modes of the implantable medical device **12**, as further described below with reference to FIG. **5**.

In a still further embodiment of the present invention, at least one of pacing interventions and pacing modes of the implantable medical device **12** is reprogrammed by the programmer **14** during the initial observation period or during a subsequent observation period if the patient **11** is being reassessed. The patient **11** is then monitored by the reprogrammed implantable medical device **12**.

FIG. **2** is a block diagram showing the hardware components of the server system **16** of the system **10** of FIG. **1**A. 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.

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 device 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 device measures sets in the appropriate patient care record.

The application server **35** operates management applications, assimilates the reference measures into the reference baseline **5** (shown in FIG. **1**A), 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**.

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.

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 FIGS. **5-7**.

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.

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.

FIG. **3** is a block diagram showing the software modules of the server system **16** of the system **10** of FIG. **1**A. 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 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.

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 processing module **56**. 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 these modules. The module functions are further described below beginning with reference to FIGS. **8**A-**8**C.

A reference baseline **5** is established at the outset of providing a patient with remote patient care. The server system **16** periodically receives an initially collected device measures set **57**. This set represents patient information which was collected from the implantable medical device **12** (shown in FIG. **1**A) during the initial observation period, as further discussed below with reference to FIG. **5**. In addition, the server system **16** can also periodically receive quality of life measures sets **60** recorded by the patient **11**, as further described below with reference to FIG. **6**. Both the initially collected device measures set **57** and quality of life measures set **60** are forwarded to the database module **51** for storage in the patient's patient care record in the database **52**. During subsequent, on-going monitoring for remote patient care, the server system **16** periodically receives subsequently collected device measures sets **58**, which are also forwarded to the database module **51** for storage.

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 device measures sets **57**, **58** and patient data maintained in those records. Exemplary database schemes for use in storing the initially collected device measures set **57**, quality of life measures set **60**, and subsequently collected device measures sets **58** in a patient care record are described below, by way of example, with reference to FIGS. **5**-**7**. 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.

The processing module **56** processes the initially collected device measures set **57** and, if available, the quality of life measures set **60**, stored in the patient care records in the database **52** into the reference baseline **5**. The reference baseline **5** includes a set of reference measures **59** which can be either directly measured or indirectly derived patient information. The reference baseline **5** can be used to identify patients for whom remote patient care might be inappropriate and to monitor patient wellness in a continuous, on-going basis.

On a periodic basis or as needed, the processing module **56** reassesses the reference baseline **5**. Subsequently collected device measures sets **58** are received from the implantable medical device **12** (shown in FIG. **1**A) subsequent to the initial observation period. The processing module **56** reassimilates these additional collected device measures sets into a new reference baseline. The operations performed by the processing module **56** are further described below with reference to FIG. **4**. The application server **35** (shown in FIG. **2**) performs the functionality of the processing module **56**.

The analysis module **53** analyzes the subsequently collected device measures sets **58** stored in the patient care records in the database **52**. The analysis module **53** monitors patient wellness and makes an automated determination in the form of a patient status indicator **54**. Subsequently collected device measures sets **58** 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**.

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**.

FIG. **4** is a block diagram showing the processing module **56** of the server system **16** of FIG. **1**A. The processing module **53** contains two functional submodules: evaluation module **70** and acceptance module **71**. The purpose of the evaluation module **70** is to process the initially collected device measures set **57** by determining any derived measures and calculating appropriate statistical values, including means and standard deviations, for the reference measures set **59** in the reference baseline **5**. The purpose of the acceptance module **71** is to analyze the reference measures set **59** against the acceptance parameters set **72**. A patient care record storing a reference measures set **59** substantially out of conformity with the acceptance parameters set **72** could be indicative of a patient for whom remote patient care is inappropriate. Consequently, the acceptance module **71** identifies each patient care record storing at least one reference measure which is substantially non-conforming to a corresponding parameter in the acceptance parameters set **72**.

For instance, an acceptance parameter for heart rate might be specified as a mean heart rate within a range of 40-90 beats per minute (bpm) over a 24-hour period. However, a patient care record storing a reference measure falling either substantially above or below this acceptance parameter, for example, in excess of 90 bpm, would be considered substantially non-conforming. The acceptance parameters set **72** are further described below with reference to FIG. **5**.

The evaluation module **70** also determines new reference baselines **73** when necessary. For instance, the new reference baseline **73** might be reassessed on an annual or quarterly basis, as the needs of the patient **11** dictate. Similarly, the new reference baseline **73** might be reassessed for a patient whose patient care record stores a subsequently collected device measures set **58** substantially out of conformity with the reference measures set **59** in the original reference baseline **5**. The new reference baseline **73** would be assessed by the processing module **56** using subsequently collected device measures sets **58** during a subsequent observation period.

FIG. **5** is a database schema showing, by way of example, the organization of a reference baseline record **75** for cardiac patient care stored as part of a patient care record in the database **17** of the system **10** of FIG. **1**A. The reference baseline record **75** corresponds to the reference baseline **5**, although only the information pertaining to the set of reference measures in the reference baseline **5** 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). For instance, during the initial observation period, the patient **11** maintains a diary of activities, including the onset of bedtime and waking time, plus the time and dosing of any medications, including non-prescription drugs. The observation period can be expanded to include additional information about the normal range of patient activities as necessary, including a range of potential anticipated activities as well as expected travel times and periods away from home. In addition, information from any set of medical records could be included in the patient care record. The diary, medication, activity, and medical record information and medical test information (e.g., electrocardiogram, echocardiogram, and/or coronary angiogram) is incorporated into the patient care record and is updated with continuing patient information, such as changes in medication, as is customary in the art.

The reference measures set **59** stored in the reference baseline record **75** are processed from the initial collected device measures set **57** (shown in FIG. **3**), as further described below with reference to FIG. **9**. The implantable medical device **12** (shown in FIG. **1**A) records the initial collected device measures set **57** during the initial observation period. For example, for a cardiac patient, the reference baseline record **75** stores the following information as part of the reference measures set **59**: patient activity score **76**, posture **77** (e.g., from barometric pressure), atrial electrical activity **78** (e.g., atrial rate), ventricular electrical activity **79** (e.g., ventricular rate), cardiovascular pressures **80**, cardiac output **81**, oxygenation score **82** (e.g., mixed venous oxygenation), pulmonary measures **83** (e.g., transthoracic impedance, measures of lung wetness, and/or minute ventilation), body temperature **84**, PR interval **85** (or AV interval), QRS measures **86** (e.g., width, amplitude, frequency content, and/or morphology), QT interval **87**, ST-T wave measures **88** (e.g., T wave alternans or ST segment depression or elevation), potassium [K+] level **89**, sodium [Na+] level **90**, glucose level **91**, blood urea nitrogen and creatinine **92**, acidity (pH) level **93**, hematocrit **94**, hormonal levels **95** (e.g., insulin, epinephrine), cardiac injury chemical tests **96** (e.g., troponin, myocardial band creatinine kinase), myocardial blood flow **97**, central nervous system injury chemical tests **98** (e.g., cerebral band creatinine kinase), central nervous system (CNS) blood flow **99**, and time of day **100**. Other types of reference measures are possible. In addition, a well-documented set of derived measures can be determined based on the reference measures, as is known in the art.

In the described embodiment, the initial and any subsequent observation periods last for about one 7-day period during which time the patient **11** might be asked to perform, if possible, repeated physical stressors representative of both relatively normal activity and/or activities designed to test the response of the body to modest activity and physiologic perturbations for use as the baseline “reference” measures that might be recorded daily for a period of one week prior to initiating fee-for-service monitoring. Reference measures taken and derived from the observation period are recorded, processed, and stored by the system **10**. The reference measures include both measured and derived measures, including patient activity score **76**, posture **77**, atrial electrical activity **78**, ventricular electrical activity **79**, cardiovascular pressures **80**, cardiac output **81**, oxygenation score **82**, pulmonary measures **83**, body temperature **84**, PR interval **85** (or AV interval), QRS measures **86**, QT interval **87**, ST-T wave measures **88**, potassium [K+] level **89**, sodium [Na+] level **90**, glucose level **91**, blood urea nitrogen and creatinine **92**, acidity (pH) level **93**, hematocrit **94**, hormonal levels **95**, cardiac injury chemical tests **96**, myocardial blood flow **97**, central nervous system injury chemical tests **98**, central nervous system (CNS) blood flow **99**, and time of day **100**. Other combination and derivative measures can also be determined, as known in the art.

An illustrative prescribed set of timed physical stressors for a non-ambulatory patient **11** is as follows:

(1) Running in place **6**: if possible, the patient **11** must run in place for about five minutes;

(2) Walking (not shown): if possible, the patient **11** must walk for about six minutes and the total distance walked is measured;

(3) Ascending stairs (not shown): if possible, the patient **11** must ascend two flights of stairs;

(4) Recumbency **7**: if possible, the patient **11** must recline following about two minutes of motionless immobile upright posture. Upon recumbency, the patient **11** must remain as immobile as possible for about ten minutes;

(5) Standing **8**: if possible, the patient **11** must briskly assume an upright standing posture after the ten-minute recumbency **7** and must remain standing without activity for about five minutes;

(6) Coughing (not shown): if possible, the patient **11** must cough forcefully about three times when in an upright position to record the cardiovascular pressures **80**;

(7) Hyperventilation (not shown): if possible, the patient **11** must hyperventilate over thirty seconds with full deep and rapid breaths to record ventilatory status;

(8) Sitting motionless **9**: when a physician is complicit, the patient **11** must, if possible, use an approximately 2.0 liter per minute nasal cannula while transmitting data for about twenty minutes while sitting to evaluate cardiopulmonary response;

(9) Program AAI and VVI temporary pacing interventions for five minutes, at low and high rates, if applicable (e.g., 40 bpm and 120 bpm) to evaluate cardiopulmonary response; and

(10) Test dual site or biventricular pacing modes, if applicable, for approximately 20 minutes to evaluate cardiopulmonary response.

These physical and pacing stimulus stressors must be annotated with date and time of day **100** and correlated with symptoms and the quality of life measures **110**. Heart rate, temperature, and time of day are directly measured while the patient activity score and cardiac output score are derived. These physical stressors are merely illustrative in nature and the set of physical and pacing stimulus stressors actually performed by any given patient would necessarily depend upon their age and physical condition as well as device implanted. Also, during the observation period, the temperature is monitored with QT interval shortening and, if the patient is in atrial fibrillation, the patient **11** must undergo an incremental ventricular pacing protocol to assess his or her response to rate stabilization. Finally, a T-wave alternans measurement (not shown) can be integrated into the reference baseline **5** during rest and sinus rhythm activities.

In a further embodiment of the present invention, the reference measures set **59** in the reference baseline **5** are reassessed on an annual or, if necessary, quarterly, basis. In addition, if the reference measures set **59** was recorded during a period when the patient **11** was unstable or recovering from a recent illness, the reference baseline **5** is reassessed when the patient **11** is again stable, as further described below with reference to FIG. **11**.

As further described below with reference to FIG. **9**, the reference measures are analyzed against the acceptance parameters set **72**. The acceptance parameters are those indicator values consistent with the presence of some form of chronic yet stable disease which does not require immediate emergency care. In the described embodiment, the acceptance parameters set **72** for the reference measures **59** in the reference baseline record **75** are, by way of example, as follows: cardiac output **81** falling below 2.5 liters/minute/m2; heart rate below 40 bpm or above 120 bpm; body temperature **84** over 101° F. and below 97° F.; patient activity **76** score of 1.0 or below; oxygenation score **82** of less than 60% mixed venous saturation at rest; pulmonary artery diastolic pressure greater than 20 mm Hg at rest; and minute ventilation less than 10.0 liters/minute at rest.

FIG. **6** is a database schema showing, by way of example, the organization of a reference baseline quality of life record **110** for cardiac patient care stored as part of a patient care record in the database **17** of the system **10** of FIG. **1**A. A quality of life score is a semi-quantitative self-assessment of an individual patient's physical and emotional well being. Non-commercial, non-proprietary standardized automated quality of life scoring systems are readily available, 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**A) and the patient **11** can then record his or her quality of life scores for periodic download to the server system **16**.

For example, for a cardiac patient, the reference baseline quality of life record **110** stores the following information as part of the reference measures set **59**: health wellness **111**, shortness of breath **112**, energy level **113**, exercise tolerance **114**, chest discomfort **115**, time of day **116**, and other quality of life measures as would be known to one skilled in the art. Using the quality of life scores **111-116** in the reference baseline quality of life record **110**, the patient **11** can be notified automatically when variable physiological changes matches his or her symptomatology.

A quality of life indicator is a vehicle through which a patient can remotely communicate to the patient care system how he or she is subjectively feeling. When tied to machine-recorded physiological measures, a quality of life indicator can provide valuable additional information to medical practitioners and the automated collection and analysis patient care system **10** not otherwise discernible without having the patient physically present. For instance, a scoring system using a scale of 1.0 to 10.0 could be used with 10.0 indicating normal wellness and 1.0 indicating severe health problems. Upon the completion of the initial observation period, a patient might indicate a health wellness score **111** of 5.0 and a cardiac output score of 5.0. After one month of remote patient care, the patient might then indicate a health wellness score **111** of 4.0 and a cardiac output score of 4.0 and a week later indicate a health wellness score **111** of 3.5 and a cardiac output score of 3.5. Based on a comparison of the health wellness scores **111** and the cardiac output scores, the system **10** would identify a trend indicating the necessity of potential medical intervention while a comparison of the cardiac output scores alone might not lead to the same prognosis.

FIG. **7** is a database schema showing, by way of example, the organization of a monitoring record **120** for cardiac patient care stored as part of a patient care record in the database **17** of the system **10** of FIG. **1**A. Each patient care record stores a multitude of subsequently collected device measures sets **58** (shown in FIG. **3**) for each individual patient **11**. Each set represents a recorded snapshot of telemetered signals data which were recorded, for instance, on a 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 subsequently collected device measures set **58**: atrial electrical activity **121**, ventricular electrical activity **122**, minute ventilation **123**, patient activity score **124**, cardiac output score **125**, mixed venous oxygen score **126**, pulmonary artery diastolic pressure measure **127**, time of day **128**, interventions made by the implantable medical device **129**, and the relative success of any interventions made **130**. In addition, the implantable medical device **12** would also communicate device specific information, including battery status and program settings **131**. Other types of collected or combined measures are possible as previously described. In addition, a well-documented set of derived measures can be determined based on the collected measures, as is known in the art.

FIGS. **8**A-**8**C are flow diagrams showing a method **140** for determining a reference baseline **5** for use in monitoring a patient status in an automated collection and analysis patient care system **10** in accordance with the present invention. The method **140** operates in two phases: collection and processing of an initial reference baseline **5** (blocks **141-149**) and monitoring using the reference baseline **5** (blocks **150-158**). The method **140** is implemented as a conventional computer program for execution by the server system **16** (shown in FIG. **1**A). 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 **141**).

The collection and processing of the initial reference baseline **5** begins with the patient **11** being monitored by the implantable medical device **12** (shown in FIG. **1**A). The implantable medical device **12** records the initially collected device measures set **57** during the initial observation period (block **142**), as described above with reference to FIG. **5**. Alternatively, the patient **11** could be engaged in performing the prescribed set of timed physical stressors during the initial observation period, as described above with reference to FIG. 1B. As well, the implantable medical device **12** could be reprogrammed by the programmer **14** during the initial observation period, also as described above with reference to FIG. 1B. The initially collected device measures set **57** is retrieved from the implantable medical device **12** (block **143**) using a programmer, interrogator, telemetered signals transceiver, and the like. The retrieved initially collected device measures sets are sent over the internetwork **15** or similar communications link (block **144**) and periodically received by the server system **16** (block **145**). The initially collected device measures set **57** is stored into a patient care record in the database **17** for the individual patient **11** (block **146**). The initially collected device measures set **57** is processed into the reference baseline **5** (block **147**) which stores a reference measures set **59**, as further described below with reference to FIG. **9**.

If quality of life measures are included as part of the reference baseline **5** (block **148**), the set of quality of life measures are processed (block **149**), as further described below with reference to FIG. **10**. Otherwise, the processing of quality of life measures is skipped (block **148**).

Monitoring using the reference baseline **5** begins with the retrieval of the subsequently collected device measures sets **58** from the implantable medical device **12** (block **150**) using a programmer, interrogator, telemetered signals transceiver, and the like. The subsequently collected device measures sets **58** are sent, on a substantially regular basis, over the internetwork **15** or similar communications link (block **151**) and periodically received by the server system **16** (block **152**). The subsequently collected device measures sets **58** are stored into the patient care record in the database **17** for that individual patient (block **153**).

The subsequently collected device measures sets **58** are compared to the reference measures in the reference baseline **5** (block **154**). If the subsequently collected device measures sets **58** are substantially non-conforming (block **155**), the patient care record is identified (block **156**). Otherwise, monitoring continues as before.

In the described embodiment, substantial non-conformity refers to a significant departure from a set of parameters defining ranges of relative normal activity and normal exercise responses for that patient. Relative normal activity is defined as follows. Note the "test exercise period" refers to running in place, walking, and ascending stairs physical stressors described above:

(1) Heart rate stays within a range of 40-90 bpm without upward or downward change in mean heart rate (1.0 standard deviation (SD) over a 24 hour period;

(2) Wake patient activity score during awake hours stays within a range of (1.0 SD without change in the mean activity score over a 24 hour period with no score equal to the minimum activity score noted during sleep;

(3) Sleep period activity score stays within a range of (1.0 SD of typical sleep scores for that patient for the six to ten hour period of sleep with no score less than the minimum score observed during normal awake behavior during the initial observation period or during normal sleep;

(4) Minute ventilation **123** during normal awake hours stays within a range of (1.0 SD without change in the mean score over a 24 hour period with no score equal to the minimum or maximum minute ventilation **123** noted during the test exercise period or the minimum or maximum minute ventilation **123** noted during the initial observation period;

(5) Cardiac output score **125** during normal awake hours stays within a range of (1.0 SD without change in the mean cardiac output score over a 24 hour period with no score equal to the minimum cardiac output score noted during the test exercise period or the minimum cardiac output score noted during the initial observation period;

(6) Mixed venous oxygenation score **126** during normal awake hours stays within a range of (1.0 SD without change in the mean mixed venous oxygenation score over a 24 hour period with no score equal to the minimum mixed venous oxygenation score noted during the test exercise period or the minimum mixed venous oxygenation score noted during the initial observation period;

(7) Pulmonary artery diastolic pressure measure **127** during normal awake hours stays within a range of (1.0 SD without change in the mean pulmonary artery diastolic pressure measure **127** over a 24 hour period with no score equal to the minimum or maximum pulmonary artery diastolic pressure measure **127** noted during the test exercise period or during the initial observation period;

(8) Potassium levels [K+] score during normal awake hours stays within a range of (1.0 SD without change in the mean K+ levels over a 24 hour period with no score less than 3.5 meq/liter or greater than 5.0 meq/liter noted during the test exercise period or during the initial observation period;

(9) Sodium levels [Na+] score during normal awake hours stays within a range of (1.0 SD without change in the mean Na+ levels over a 24 hour period with no score less than 135 meq/liter or greater than 145 meq/liter during the test exercise period or during the initial observation period;

(10) Acidity (pH) score during normal awake hours stays within a range of (1.0 SD without change in the mean pH score over a 24 hour period with no score equal to the minimum or maximum pH score noted during the test exercise period or the minimum or maximum pH scores noted during the initial observation period;

(11) Glucose levels during normal awake hours stays within a range of (1.0 SD without change in the mean glucose levels over a 24 hour period with no score less than 60 mg/dl or greater than 200 mg/dl during the test exercise period or during the initial observation period;

(12) Blood urea nitrogen (BUN) or creatinine (Cr) levels during normal awake hours stays within a range of (1.0 SD without change in the mean BUN or Cr levels score over a 24 hour period with no score equal to the maximum BUN or creatinine levels noted during the test exercise period or the maximum BUN or Cr levels noted during the initial observation period;

(13) Hematocrit levels during normal awake hours stays within a range of (1.0 SD without change in the mean hematocrit levels score over a 24 hour period with no score less than a hematocrit of 30 during the test exercise period or during the initial observation period;

(14) Troponin, creatinine kinase myocardial band, or other cardiac marker of myocardial infarction or ischemia, level during normal awake hours stays within a range of (1.0 SD without change in the mean troponin level score over a 24 hour period with no score equal to the maximum troponin level score noted during the test exercise period or the maximum troponin level scores noted during the initial observation period;

(15) Central nervous system (CNS) creatinine kinase (CK) or equivalent markers of CNS ischemia or infarction levels during normal awake hours stays within a range of (1.0 SD without change in the mean CNS CK levels over

a 24 hour period with no score equal to the maximum CNS CK levels score noted during the test exercise period or the maximum CNS CK levels scores noted during the initial observation period;

(16) Barometric pressure during normal awake hours stays within a range of (1.0 SD without change in the mean barometric pressure score over a 24 hour period with no score equal to the minimum or maximum barometric pressure noted during the test exercise period or the minimum or maximum barometric pressure noted during the initial observation period;

(17) PR interval (or intrinsic AV interval) of sinus rhythm during normal awake hours stays within a range of (1.0 SD without change in the mean PR interval over a 24 hour period with no score equal to the minimum or maximum PR interval noted during the test exercise period or the minimum or maximum PR interval noted during the initial observation period;

(18) QT interval during normal awake hours stays within a range of (1.0 SD without change in the mean QT interval over a 24 hour period with no score equal to the minimum or maximum QT interval noted during the test exercise period or the minimum or maximum QT interval noted during the initial observation period;

(19) QRS duration during normal awake hours stays within a range of (1.0 SD without change in the mean QRS duration over a 24 hour period with no score equal to the maximum QRS duration noted during the test exercise period or the maximum QRS duration noted during the initial observation period;

(20) ST segment depression or elevation during normal awake hours stays within a range of (1.0 SD without change in the mean ST segment depression or elevation over a 24 hour period with no score equal to the maximum ST segment depression or elevation noted during the test exercise period or the maximum ST segment depression or elevation noted during the initial observation period; and

(21) Temperature during normal awake hours stays within a range of (1.0 SD without change in the mean temperature over a 24 hour period with no score equal to the minimum or maximum temperature score noted during the test exercise period or the minimum or maximum temperature noted during the initial observation period.

For an exemplary, non-ambulatory patient with no major impairments of the major limbs, reference exercise can be defined as follows:

(1) Heart rate increases by 10 bpm for each one point increase in activity score. Note that to be considered "normal exercise," heart rate generally should not increase when the activity score does not increase at least 1.0 SD above that noted during the twenty-four hour reference period or greater than that observed during any reference exercise periods. Heart rate should decrease to the baseline value over fifteen minutes once activity stops or returns to the baseline activity level;

(2) Patient activity score **124** rises at least 1.0 SD over that observed in the mean activity score over a 24 hour period or greater than that observed during any reference exercise periods;

(3) Cardiac output score **125** rises at least 1.0 SD over that observed in the mean cardiac output score over a 24 hour period or within 0.5 SD of the two minute test exercise period. Cardiac output score should increase 0.5 liters per minute with each 10 bpm increase in heart rate period or greater than that observed during any reference exercise periods;

(4) In conjunction with an increase in activity score and heart rate, mixed venous oxygenation score **126** falls at least 1.0 SD below observed in the mean oxygenation score over a 24 hour period or be less than any oxygenation score observed during the reference exercise periods. Oxygenation score should decrease 5.0 mm Hg with each 10 bpm increase in heart rate or 1.0 SD increase in cardiac output score during exercise;

(5) In conjunction with an increase in activity score and heart rate, pulmonary artery diastolic pressure measure **127** rises at least 1.0 SD over that observed in the mean cardiovascular pressure score over a 24 hour period or is greater than that observed during the reference exercise periods;

(6) In conjunction with an increase in activity score and heart rate, minute ventilation **123** rises at least 1.0 SD over that observed over a 24 hour reference period or greater than that observed during any reference exercise period. Minute ventilation should rise 1.0 liter per minute with each 10 bpm increase in heart rate; and

(7) In conjunction with an increase in activity score and heart rate, temperature should rise at least 1.0 SD over that observed in the mean temperature over a 24 hour period or greater than that observed during the reference exercise periods. Temperature should rise 0.1° F. with each 10 bpm increase in heart rate.

Finally, if the time for a periodic reassessment has arrived or the subsequently collected device measures sets **58** are substantially non-conforming (block **157**), the reference baseline **5** is reassessed (block **158**) and a new reference baseline **73** determined, as further described below with reference to FIG. **11**. Otherwise, the routine returns.

In the described embodiment, the reference baseline **5** is preferably reassessed on an annual or, if necessary, quarterly basis. In addition, the reference baseline **5** might be reassessed if physiological findings dictate that new interventions might be indicated or if the patient **11** indicates a change in medications and general health status. Other bases for reassessing the reference baseline **5** are feasible.

FIG. **9** is a flow diagram showing the routine **147** for processing a reference baseline **5** for use in the method **140** of FIGS. **8**A-**8**C. The purpose of this routine is to analyze the initially collected device measures set **57** and create a reference baseline **5**, if possible. First, the acceptance parameters set **72** (shown in FIG. **3**) is defined (block **160**) and the reference measures set **59** in the reference baseline **5**, including any quality of life measures, are analyzed against the acceptance parameters set (block **161**), as described above with reference to FIG. **5**. If the reference measures in the reference baseline **5** are substantially non-conforming to the acceptance parameters set (block **162**), the patient care record is identified (block **164**). Otherwise, if conforming (block **162**), the baseline reference **72** is stored into the patient care record in the database **17** (block **163**). The routine then returns.

FIG. **10** is a flow diagram showing the routine **149** for processing quality of life measures for use in the method **140** of FIGS. **8**A-**8**C. The purpose of this routine is to process and store a collected quality of life measures set **60** into the reference baseline **5**. Collected quality of life measures sets **60** are periodically received by the server system **16** over the internetwork **15** or similar communications link (block **170**). The quality of life measures were previously recorded by the patient **11** using, for example, the personal computer **18** (shown in FIG. **1**A) and downloaded onto the internetwork **15** or similar communications link. The collected quality of life measures set **60** is stored into a patient care record in the database **17** for the individual patient **11** (block **171**). The collected quality of life measures set **60** is then assimilated into the reference baseline **5** (block **172**), as further described above with reference to FIG. **9**. The routine then returns.

FIG. **11** is a flow diagram showing the routine **158** for reassessing a new reference baseline **73** for use in the method **140** of FIGS. **8**A-**8**C. The purpose of this routine is to reassess a new reference baseline **5** periodically or when necessary. Similar to the collection and assimilation of the initial reference baseline **5**, the routine begins with the patient **11** being monitored by the implantable medical device **12** (shown in FIG. **1**A). The implantable medical device **12** records subsequently collected device measures sets **58** throughout a subsequent observation period (block **180**), as described above with reference to FIG. **5**. Alternatively, the patient **11** could be engaged in performing the prescribed set of timed physical stressors, as described above with reference to FIG. **1**B. As well, the implantable medical device **12** could be reprogrammed by the programmer **14** during the subsequent observation period, also as described above with reference to FIG. **1**B. The subsequently collected device measures sets **58** are retrieved from the implantable medical device **12** (block **181**) using a programmer, interrogator, telemetered signals transceiver, and the like. The retrieved subsequently collected device measures sets are sent over the internetwork **15** or similar communications link (block **182**) and periodically received by the server system **16** (block **183**). The subsequently collected device measures sets **58** are stored into the patient care record in the database **17** for the individual patient **11** (block **184**). Finally, the subsequently collected device measures sets **58** are assimilated into the new reference baseline **73** (block **185**), as further described above with reference to FIG. **9**. The routine then returns.

FIGS. **12**A and **12**B are block diagrams showing system for determining a reference baseline of individual patient status for use in an automated collection and analysis patient care system **200** in accordance with a further embodiment of the present invention. The system **200** provides remote patient care in a manner similar to the system **10** of FIGS. **1**A and **1**B, but with additional functionality for diagnosing and monitoring multiple sites within a patient's body using a variety of patient sensors for diagnosing one or more disorder. The patient **201** can be the recipient of an implantable medical device **202**, as described above, or have an external medical device **203** attached, such as a Holter monitor-like device for monitoring electrocardiograms. In addition, one or more sites in or around the patient's body can be monitored using multiple sensors **204***a*, **204***b*, such as described in U.S. Pat. Nos. 4,987,897; 5,040,536; 5,113,859; and 5,987,352, the disclosures of which are incorporated herein by reference. One automated system and method for collecting and analyzing retrieved patient information suitable for use with the present invention is described in U.S. Pat. No. 6,270,457, the disclosure of which is incorporated herein by reference. Other types of devices with physiological measure sensors, both heterogeneous and homogenous, could be used, either within the same device or working in conjunction with each other, as is known in the art.

As part of the system **200**, the database **17** stores patient care records **205** for each individual patient to whom remote patient care is being provided. Each patient care record **205** 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 **205** consist primarily of monitoring sets **206** storing device and derived measures (D&DM) sets **207** and quality of life and symptom measures (QOLM) sets **208** recorded and determined thereafter on a regular, continuous basis. The organization of the device and derived measures sets **205** for an exemplary cardiac patient care record is described above with reference to FIG. **5**. The organization of the quality of life and symptom measures sets **208** is further described below with reference to FIG. **14**.

The patient care records **205** also include a reference baseline **209**, similar to the reference baseline **5** described above, which stores an augmented set of device and derived reference measures sets **210** and quality of life and symptom measures sets **211** recorded and determined during the initial observation period. Other forms of database organization are feasible.

Finally, simultaneous notifications can also be delivered to the patient's physician, hospital, or emergency medical services provider **209** using feedback means similar to that used to notify the patient. 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 U.S. Pat. No. 6,261,230, the disclosure of which is incorporated herein by reference.

FIG. **13** is a block diagram showing the analysis module **53** of the server system **16** of FIGS. **12**A and **12**B. The peer collected measures sets **60** and sibling collected measures sets **61** can be organized into site specific groupings based on the sensor from which they originate, that is, implantable medical device **202**, external medical device **203**, or multiple sensors **204***a*, **204***b*. The functionality of the analysis module **53** is augmented to iterate through a plurality of site specific measures sets **215** and one or more disorders.

As described above, as an adjunct to remote patient care through the monitoring of measured physiological data via implantable medical device **202**, external medical device **203** and multiple sensors **204***a*, **204***b*, quality of life and symptom measures sets **208** can also be stored in the database **17** as part of the monitoring sets **206**. 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. **14** is a database schema which augments the database schema described above with reference to FIG. **6** and showing, by way of example, the organization of a quality of life and symptom measures set record **220** for care of patients stored as part of a patient care record **205** in the database **17** of the system **200** of FIGS. **12**A and **12**B. The following exemplary information is recorded for a patient: overall health wellness **221**, psychological state **222**, chest discomfort **223**, location of chest discomfort **224**, palpitations **225**, shortness of breath **226**, exercise tolerance **227**, cough **228**, sputum production **229**, sputum color **230**, energy level **231**, syncope **232**, near syncope **233**, nausea **234**, diaphoresis **235**, time of day **91**, and other quality of life and symptom measures as would be known to one skilled in the art.

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.

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 **207** and the symptoms during the six-minute walk to quality of life and symptom measures sets **208**.

FIG. **15** 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 **200** of FIGS. **12**A and **12**B. Three patient care records are again shown for Patient 1, Patient 2, and Patient 3 with each of these records containing site specific measures sets **215**, grouped as follows. First, the patient care record for Patient 1 includes three site specific measures sets A, B and C, corresponding to three sites on Patient 1's body. Similarly, the patient care record for Patient 2 includes two site specific measures sets A and B, corresponding to two sites, both of which are in the same relative positions on Patient 2's body as the sites for Patient 1. Finally, the patient care record for Patient 3 includes two site specific measures sets A and D, also corresponding to two medical device sensors, only one of which, Site A, is in the same relative position as Site A for Patient 1 and Patient 2.

The analysis module **53** (shown in FIG. **13**) performs two further forms of comparison in addition to comparing the individual measures for a given patient to other individual measures for that same patient or to other individual measures for a group of other patients sharing the same disease-specific characteristics or to the patient population in general. First, the individual measures corresponding to each body site for an individual patient can be compared to other individual measures for that same patient, a peer group or a general patient population. Again, these comparisons might be peer-to-peer measures projected over time, for instance, comparing measures for each site, A, B and C, for Patient 1, X_{n_A}, $X_{n'_A}$, $X_{n''_A}$, X_{n-1_A}, $X_{n-1'_A}$, $X_{n-1''_A}$, X_{n-2_A}, $X_{n-2'_A}$, $X_{n-2''_A}$, . . . X_{0_A}, $X_{0'_A}$, $X_{n''_A}$, X_{n_B}, $X_{n'_B}$, $X_{n''_B}$, X_{n-1_B}, $X_{n-1'_B}$, $X_{n-1''_B}$, X_{n-2_B}, $X_{n-2'_B}$, $X_{n-2''_B}$, . . . X_{0_B}, $X_{0'_B}$, $X_{0''_B}$, X_{n_C}, $X_{n'_C}$, $X_{n''_C}$, X_{n-1_C}, $X_{n-1'_C}$, $X_{n-1''_C}$, X_{n-2_C}, $X_{n-2'_C}$, $X_{n-2''_C}$, . . . X_{0_C}, $X_{0'_C}$, $X_{0''_C}$; comparing comparable measures for Site A for the three patients, X_{n_A}, $X_{n'_A}$, $X_{n''_A}$, X_{n-1_A}, $X_{n-1'_A}$, $X_{n-1''_A}$, X_{n-2_A}, $X_{n-2'_A}$, $X_{n-2''_A}$, . . . X_{0_A}, $X_{0'_A}$, $X_{0''_A}$; 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, comparing comparable measures for Site A for the three patients, X_{n_A}, $X_{n'A}$, $X_{n''_A}$, Y_{n_A}, $Y_{n'A}$, $Y_{n''_A}$, and Z_{n_A}, $Z_{n'_A}$, $Z_{n''_A}$, or comparing those same comparable measures for Site A projected over time, for instance, X_{n_A}, $X_{n'_A}$, $X_{n''_A}$, Y_{n_A}, $Y_{n'_A}$, $Y_{n''_A}$, Z_{n_A}, $Z_{n'_A}$, $Z_{n''_A}$, X_{n-1_A}, $X_{n-1'_A}$, $X_{n-1''_A}$, Y_{n-1_A}, $Y_{n-1'_A}$, $Y_{n-1''_A}$, Z_{n-1_A}, $Z_{n-1'_A}$, $Z_{n-1''_A}$, X_{n-2_A}, $X_{n-2'_A}$, $X_{n-2''_A}$, Y_{n-2_A}, $Y_{n-2'_A}$, $Y_{n-2''_A}$, Z_{n-2_A}, $Z_{n-2'_A}$, $Z_{n-2''_A}$, . . . X_{0_A}, $X_{0'_A}$, $X_{0''_A}$, Y_{0_A}, $Y_{0'_A}$, $Y_{0''_A}$, and Z_{0_A}, $Z_{0'_A}$, $Z_{0''_A}$. Other forms of site-specific comparisons, including comparisons between individual measures from non-comparable sites between patients, are feasible.

Second, the individual measures can be compared on a disorder specific basis. The individual measures stored in each cardiac patient record can be logically grouped into measures relating to specific disorders and diseases, for instance, congestive heart failure, myocardial infarction, respiratory distress, and atrial fibrillation. The foregoing comparison operations performed by the analysis module **53** are further described below with reference to FIGS. **17**A-**17**D.

FIG. **16** is a Venn diagram showing, by way of example, peer group overlap between the partial patient care records **205** of FIG. **15**. Each patient care record **205** includes characteristics data **250**, **251**, **252**, including personal traits, demographics, medical history, and related personal data, for patients 1, 2 and 3, respectively. For example, the characteristics data **250** 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 **251** for patient 2 might include identical personal traits, thereby resulting in partial overlap **253** of characteristics data **250** and **251**. Similar characteristics overlap **254**, **255**, **256** can exist between each respective patient. The overall patient population **257** 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 **256** 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.

FIGS. **17**A-**17**D are flow diagrams showing a method for determining a reference baseline of individual patient status for use in an automated collection and analysis patient care system **260** in accordance with a further embodiment of the present invention. As with the method **140** of FIGS. **8**A-**8**C, this method is also implemented as a conventional computer program and performs the same set of steps as described with reference to FIGS. **8**A-**8**C with the following additional functionality. As before, the method **260** operates in two phases: collection and processing of an initial reference baseline **209** (blocks **261**-**149**) and monitoring using the reference baseline **209** (blocks **268**-**158**). Thus, the patient care records are organized in the database **17** with a unique patient care record assigned to each individual patient (block **261**).

Next, the reference baseline **209** is determined, as follows. First, the implantable medical device **202**, external medical device **203**, or the multiple sensors **204***a*, **204***b* record the initially collected device measures set **57** during the initial observation period (block **262**), as described above with reference to FIG. **5**. The initially collected device measures set **57** is retrieved from the medical device (block **263**) and sent over the internetwork **15** or similar communications link (block **264**) and periodically received by the server system **16** (block **265**). The initially collected device measures set **57** is stored into a patient care record in the database **17** for the individual patient **11** (block **266**) and processed into the reference baseline **209** (block **147**) which stores a reference measures set **59**, as described above with reference to FIG. **9**. If the quality of life and symptom measures sets **211** are included as part of the reference baseline **209** (block **267**), the quality of life and symptom measures sets **211** are processed (block **149**), as described above with reference to FIG. **10**. Otherwise, the processing of quality of life and symptom measures is skipped (block **267**).

Monitoring using the reference baseline **209** involves two iterative processing loops. The individual measures for each site are iteratively obtained in the first processing loop (blocks **268**-**273**) and each disorder is iteratively analyzed in the second processing loop (blocks **274**-**278**). Other forms of flow control are feasible, including recursive processing.

During each iteration of the first processing loop (blocks **268**-**273**), the subsequently collected measures sets for an individual patient are retrieved from the medical device or sensor located at the current site (block **269**) 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 **270**) and periodically received by the server system **16** (block **271**). The collected measures sets are stored into the patient care record **205** in the database **17** for that individual patient (block **272**).

During each iteration of the second processing loop (blocks **274-278**), each of the subsequently collected device measures sets **58** are compared to the reference measures in the reference baseline **209** (block **275**). If the subsequently collected device measures sets **58** are substantially non-conforming (block **276**), the patient care record is identified (block **277**). Otherwise, monitoring continues as before for each disorder. In addition, the measures sets can be further evaluated and matched to diagnose specific medical disorders, such as congestive heart failure, myocardial infarction, respiratory distress, and atrial fibrillation, as described in U.S. Pat. No. 6,336,903; U.S. Pat. No. 6,368,284; U.S. Pat. No. 6,398,728; and U.S. Pat. No. 6,411,840, the disclosures of which are incorporated herein by reference. In addition, multiple near-simultaneous disorders can be ordered and prioritized as part of the patient status indicator as described in U.S. Pat. No. 6,440,066, the disclosure of which is incorporated herein by reference.

Finally, if the time for a periodic reassessment has arrived or the subsequently collected device measures sets **58** are substantially non-conforming (block **279**), the reference baseline **209** is reassessed (block **158**) and a new reference baseline **209** determined, as described above with reference to FIG. **11**.

The determination of a reference baseline consisting of reference measures makes possible improved and more accurate treatment methodologies based on an algorithmic analysis of the subsequently collected data sets. Each successive introduction of a new collected device measures set into the database server would help to continually improve the accuracy and effectiveness of the algorithms used.

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 determining a stressor-based reference baseline for use in heart failure assessment, comprising:

a programmer to receive monitoring of a patient that was performed during an observation time period while the patient performed prescribed physical stressors and while pacing stimulus stressors were applied to a medical device of the patient; and

a server, comprising,

a storage module to store physiological measures from the observation period into a patient care record comprising at least one of direct measures regularly recorded on a continuous basis by the medical device and measures derived therefrom;

a reference baseline module to identify those of the physiological measures that originate from the observation time period as a reference baseline for the patient; and

an evaluation module to evaluate the reference baseline and those physiological measures originating subsequent to the observation period, comprising:

an analyzer module to compare the direct measures and derived measures to the physiological measures from the observation period to detect a patient status comprising one of a status quo and a change in cardiac performance of the patient; and

a comparison module to compare the patient status to parameters corresponding to worsening heart failure indications to generate a notification of parameter violations.

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

a reprogramming module to reprogram a medical device based on extended evaluation of the direct measures and the derived measures.

3. A system according to claim **1**, the server further comprising:

a tracking module to track respiration rate of the patient on a regular basis through the medical device; and

a notification module to generate a notification triggered by an upper limit parameter applied over a short term.

4. The system according to claim **1**, wherein the pacing stimulus stressors are applied via a reprogramming of at least one of pacing interventions and pacing modes of the patient's implantable medical device.

5. A method for determining a stressor-based reference baseline for use in heart failure assessment, comprising:

monitoring a patient during an observation time period while the patient performs prescribed physical stressors and by applying pacing stimulus stressors to a medical device of the patient;

storing from the observation period physiological measures into a patient care record on a server, wherein the patient care record comprises at least one of direct measures regularly recorded on a continuous basis by the medical device and measures derived therefrom;

using the server to identify those of the physiological measures that originate from the observation time period as a reference baseline for the patient;

receiving, by the server, physiological measures originating subsequent to the observation period from a remote programmer; and

using the server to evaluate the reference baseline and the physiological measures originating subsequent to the observation period, comprising:

comparing the direct measures and derived measures to the physiological measures from the observation period to detect patient status comprising one of a status quo and a change in cardiac performance of the patient; and

comparing the patient status to parameters corresponding to worsening heart failure indications to generate a notification of parameter violations.

6. A method according to claim **5**, further comprising:

using the server to reprogram a medical device based on extended evaluation of the direct measures and the derived measures.

7. A method according to claim **5**, further comprising:

using the server to track respiration rate of the patient on a regular basis through the medical device; and

using the server to generate a notification triggered by an upper limit parameter applied over a short term.

8. The method according to claim **5**, wherein the pacing stimulus stressors are applied via a reprogramming of at least one of pacing interventions and pacing modes of the patient's implantable medical device.

* * * * *

patsnap

专利名称(译)	用于确定用于心力衰竭评估的参考基线的系统和方法		
公开(公告)号	US8888698	公开(公告)日	2014-11-18
申请号	US11/894514	申请日	2007-08-20
[标]申请(专利权)人(译)	BARDY GUST ^ h		
申请(专利权)人(译)	BARDY GUST ^ h		
当前申请(专利权)人(译)	心脏起搏器，INC.		
[标]发明人	BARDY GUST H		
发明人	BARDY, GUST, H.		
IPC分类号	A61N1/372 A61B5/02 G06F19/00 A61B5/00		
CPC分类号	A61B5/7282 G06F19/3431 G06F19/3418 G06F19/324 G06F19/322 A61B5/7278 A61B5/4884 A61B5/0002 G16H10/60 G16H40/67 G16H50/30 G16H70/00		
审查员(译)	THOMSON，WILLIAM		
其他公开文献	US20070293741A1		
外部链接	Espacenet USPTO		

摘要(译)

提出了一种用于确定用于心力衰竭评估的基于应激源的参考基线的系统和方法。在观察时间段期间监视患者，同时患者执行规定的身体压力源并且通过向医疗设备施加起搏刺激应激物。从观察期存储生理测量，包括由医疗装置基本连续地定期记录的直接测量和由此导出的测量中的至少一种。确定源自观察时间段的测量值作为患者的参考基线。评估参考基线和在观察期后发起的那些测量。分析这些措施以检测任何趋势，包括患者的现状和心脏性能的变化之一。将每个趋势与对应于恶化的心力衰竭指示的参数进行比较，以生成参数违规的通知。