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(54) AUTOMATED METHOD FOR DIAGNOSING AND MONITORING THE OUTCOMES OF ATRIAL FIBRILLATION

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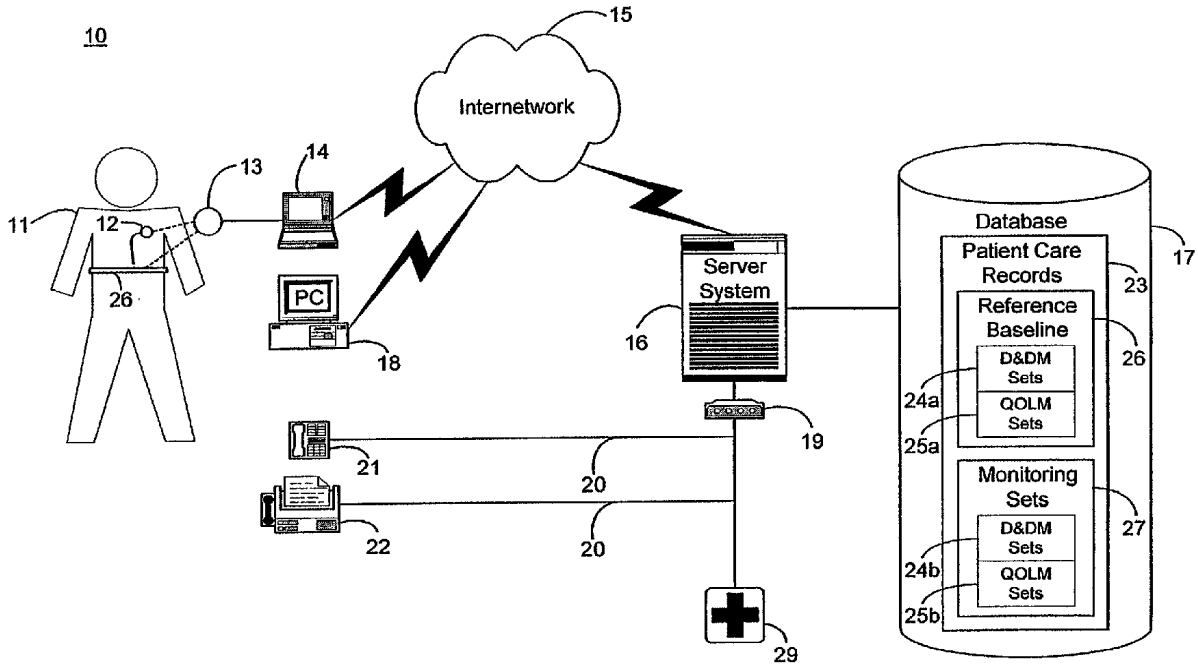
(57) ABSTRACT

An automated system and method for diagnosing and monitoring the outcomes of atrial fibrillation is described. A plurality of monitoring sets is retrieved from a database. Each of the monitoring sets include recorded measures relating to patient information recorded on a substantially continuous basis. A patient status change is determined in response to an atrial fibrillation diagnosis by comparing at least one recorded measure from each of the monitoring sets to at least one other recorded measure. Both recorded measures relate to the same type of patient information. Each patient status change is tested against an indicator threshold corresponding to the same type of patient information as the recorded measures which were compared. The indicator threshold corresponds to a quantifiable physiological measure of a pathophysiology resulting from atrial fibrillation.



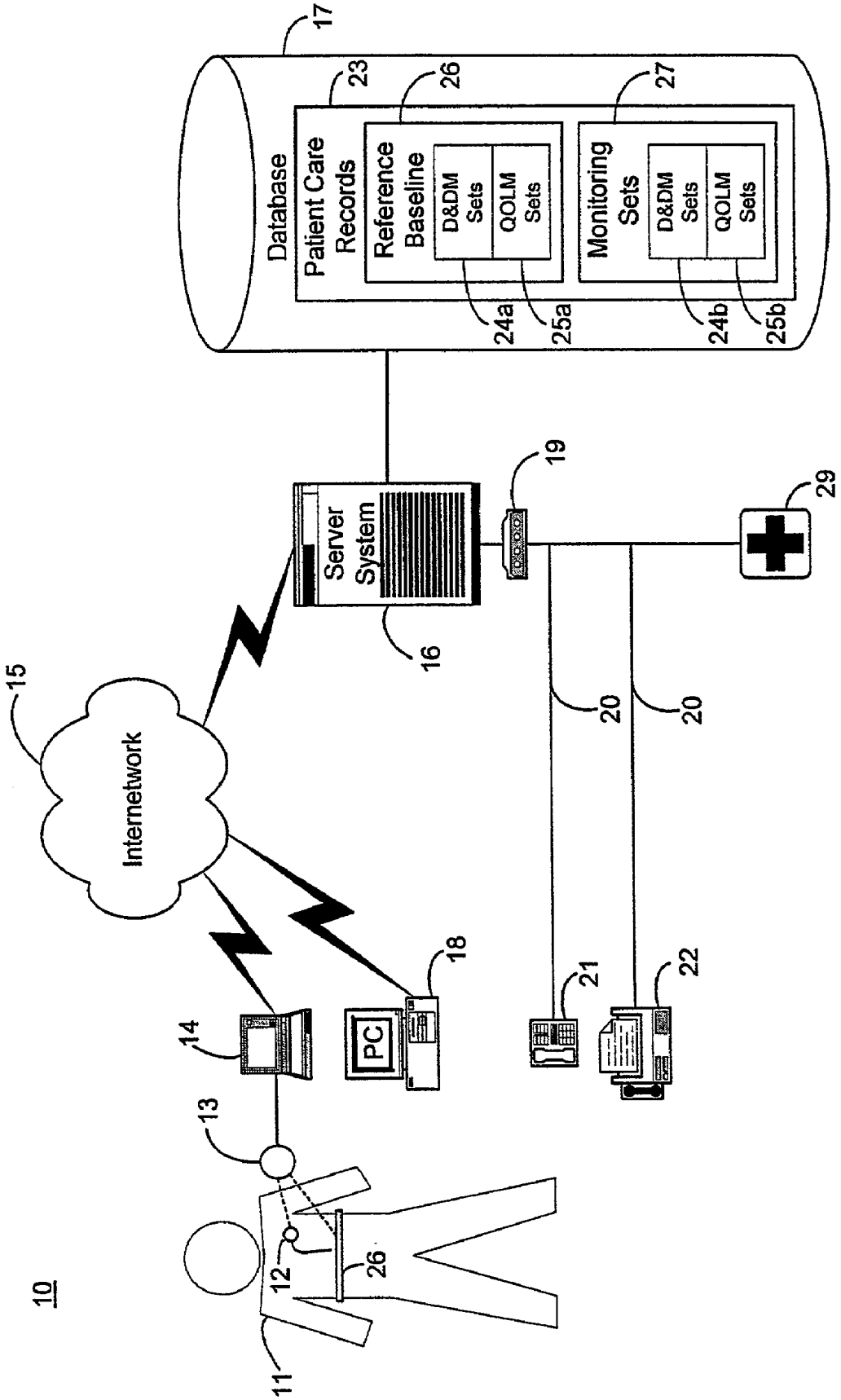

17
Database
23
Patient Care Records
26
Reference Baseline
D&DM Sets
QOLM Sets
27
Monitoring Sets
D&DM Sets
QOLM Sets
24a
25a
24b
25b
19
29
Server System
16
15
Internetwork
20
20
18
14
PC
21
22
13
12
26
11
10

FIGURE 1

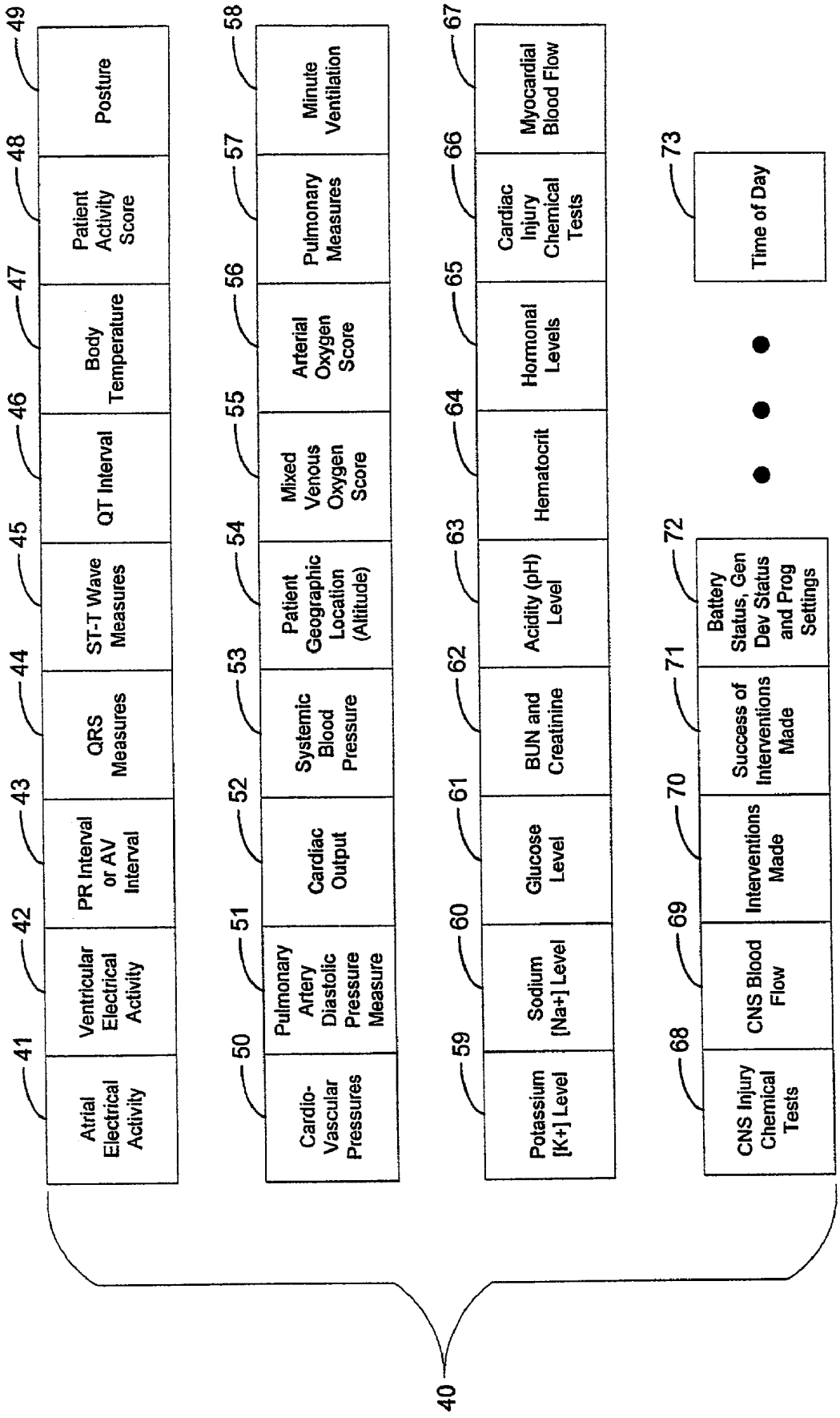

40
41
Atrial Electrical Activity
42
Ventricular Electrical Activity
43
PR Interval or AV Interval
44
QRS Measures
45
ST-T Wave Measures
46
QT Interval
47
Body Temperature
48
Patient Activity Score
49
Posture
50
Cardio-Vascular Pressures
51
Pulmonary Artery Diastolic Pressure Measure
52
Cardiac Output
53
Systemic Blood Pressure
54
Patient Geographic Location (Altitude)
55
Mixed Venous Oxygen Score
56
Arterial Oxygen Score
57
Pulmonary Measures
58
Minute Ventilation
59
Potassium [K+] Level
60
Sodium [Na+] Level
61
Glucose Level
62
BUN and Creatinine
63
Acidity (pH) Level
64
Hematocrit
65
Hormonal Levels
66
Cardiac Injury Chemical Tests
67
Myocardial Blood Flow
68
CNS Injury Chemical Tests
69
CNS Blood Flow
70
Interventions Made
71
Success of Interventions Made
72
Battery Status, Gen Dev Status and Prog Settings
73
Time of Day

FIGURE 2

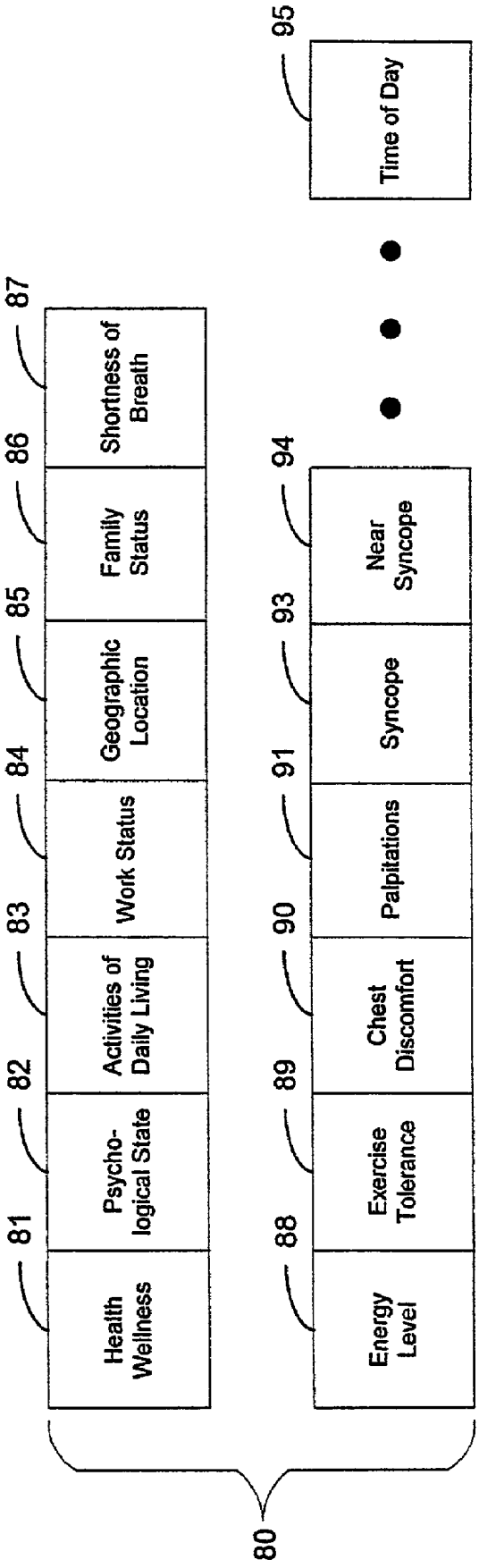

80
81
Health Wellness
82
Psycho-logical State
83
Activities of Daily Living
84
Work Status
85
Geographic Location
86
Family Status
87
Shortness of Breath
88
Energy Level
89
Exercise Tolerance
90
Chest Discomfort
91
Palpitations
93
Syncope
94
Near Syncope
95
Time of Day

FIGURE 3

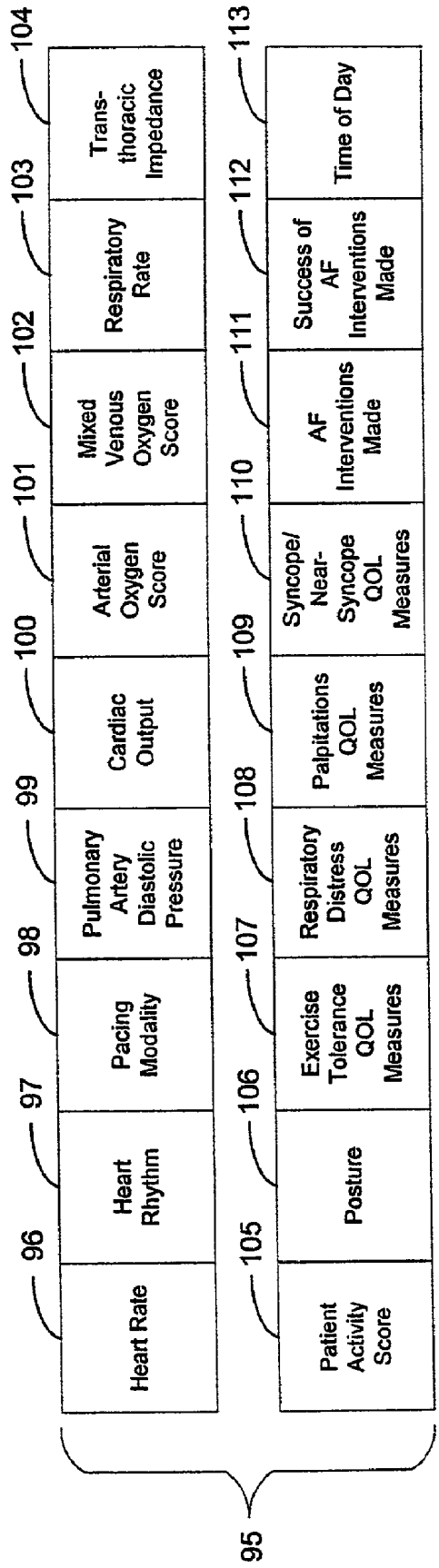

95
96
Heart Rate
97
Heart Rhythm
98
Pacing Modality
99
Pulmonary Artery Diastolic Pressure
100
Cardiac Output
101
Arterial Oxygen Score
102
Mixed Venous Oxygen Score
103
Respiratory Rate
104
Trans-thoracic Impedance
105
Patient Activity Score
106
Posture
107
Exercise Tolerance QOL Measures
108
Respiratory Distress QOL Measures
109
Palpitations QOL Measures
110
Syncope/ Near-Syncope QOL Measures
111
AF Interventions Made
112
Success of AF Interventions Made
113
Time of Day

FIGURE 4

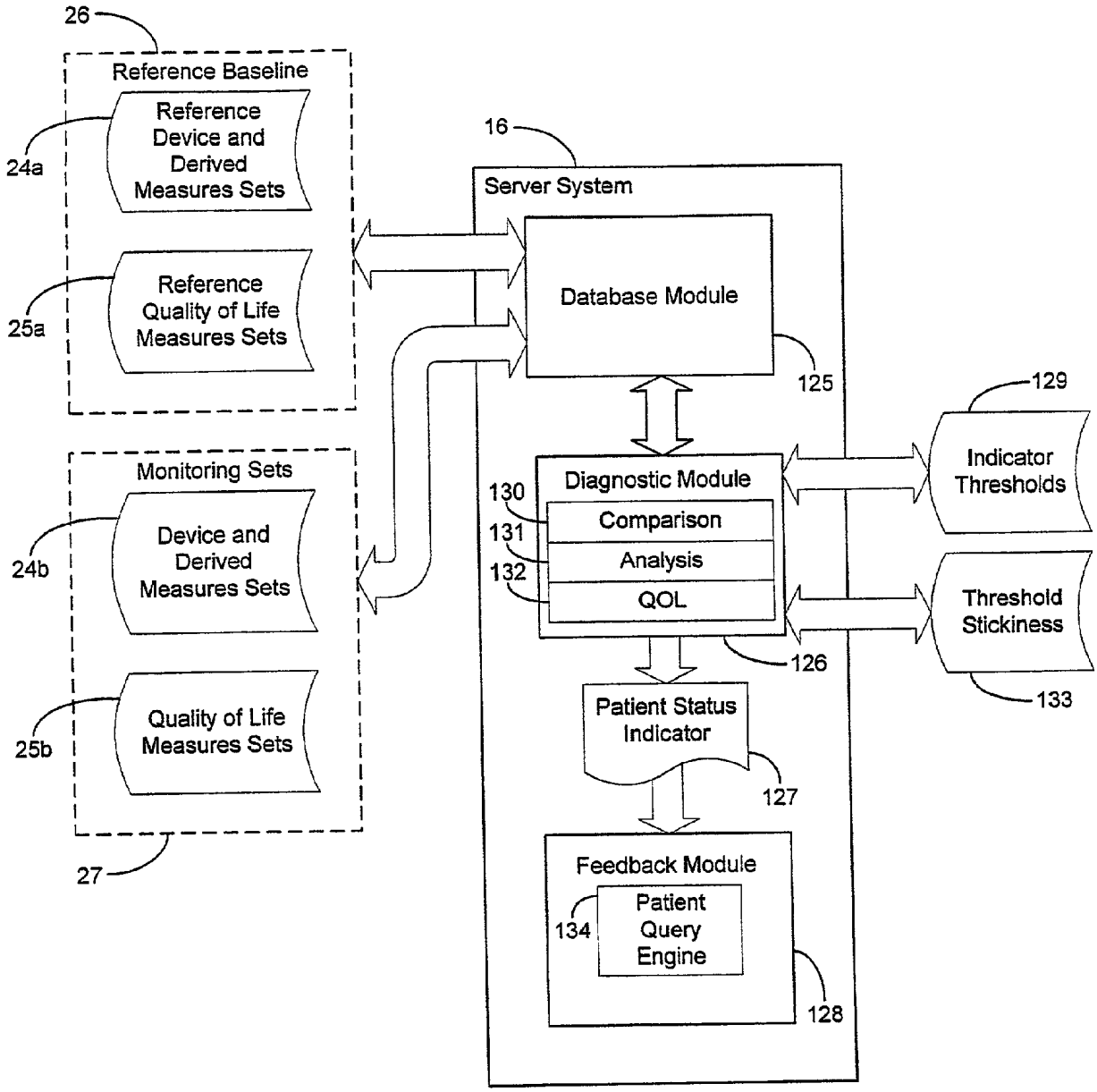

26
Reference Baseline
Reference Device and Derived Measures Sets
24a
Reference Quality of Life Measures Sets
25a
16
Server System
Database Module
125
129
Indicator Thresholds
Monitoring Sets
Device and Derived Measures Sets
24b
Quality of Life Measures Sets
25b
27
Diagnostic Module
130
Comparison
131
Analysis
132
QOL
126
Threshold Stickiness
133
Patient Status Indicator
127
Feedback Module
134
Patient Query Engine
128

FIGURE 5

Patient 1

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

time →

Patient 2

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

time →

Patient 3

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

time →

FIGURE 6

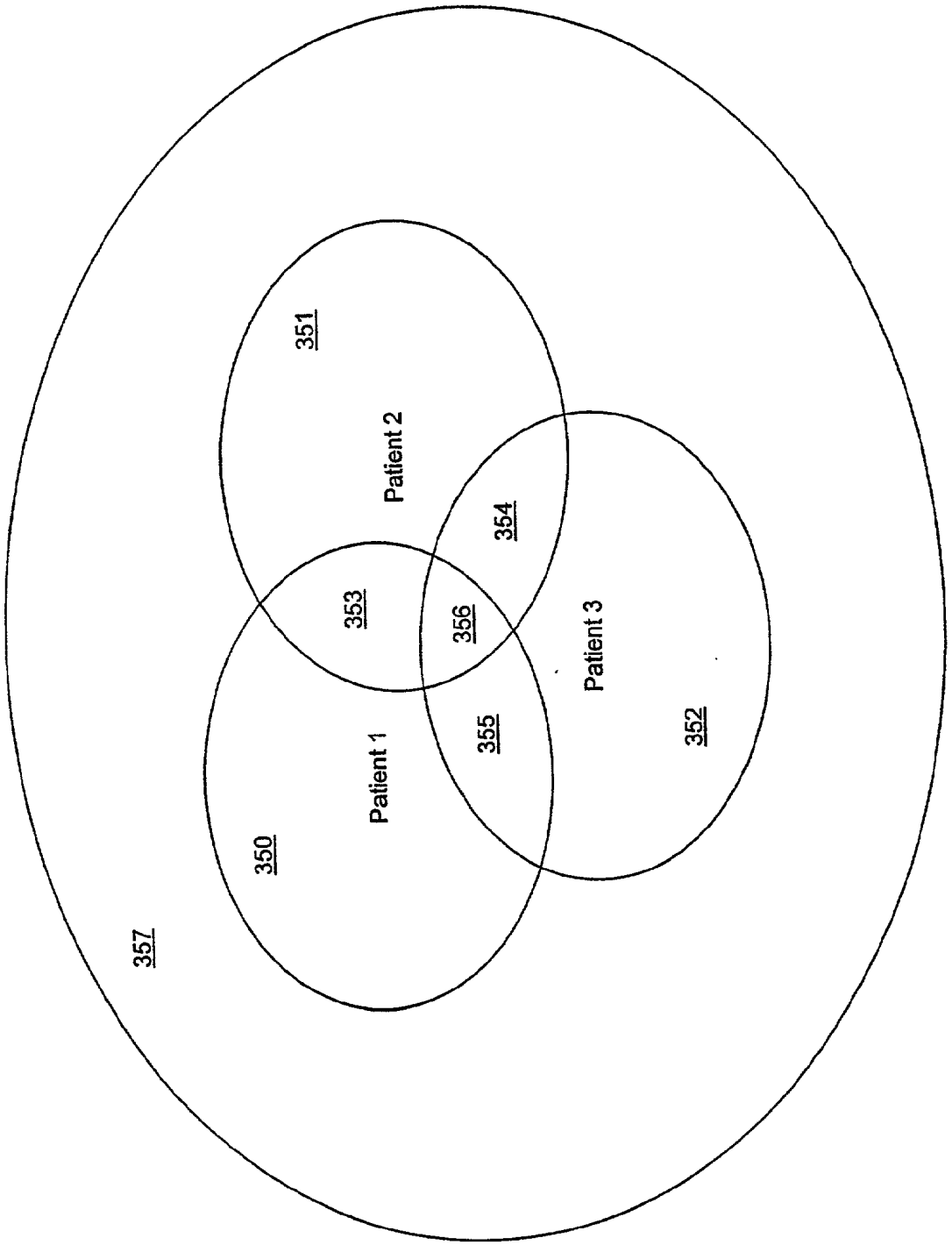


FIGURE 7

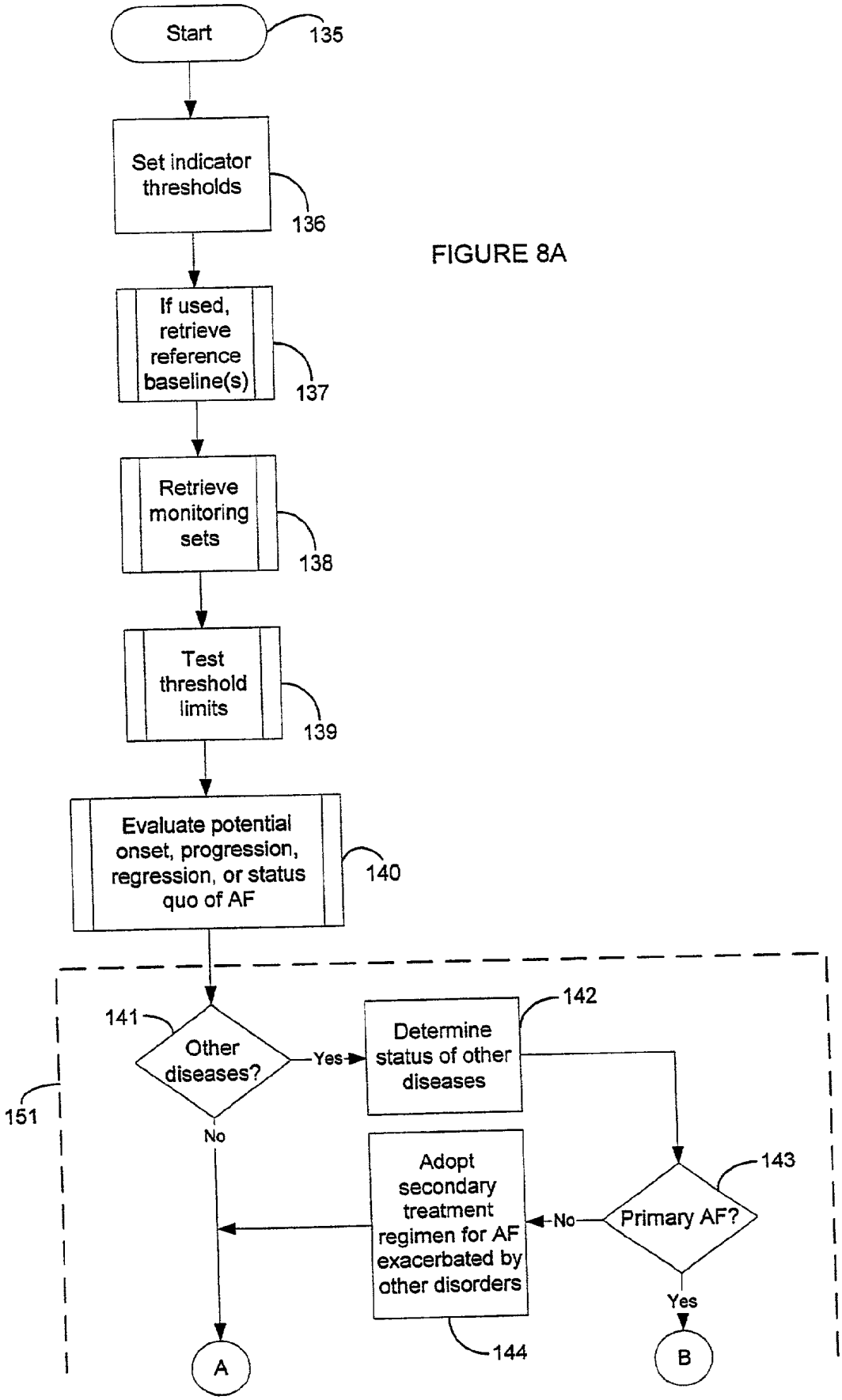

Start
135
Set indicator thresholds
136
If used, retrieve reference baseline(s)
137
Retrieve monitoring sets
138
Test threshold limits
139
Evaluate potential onset, progression, regression, or status quo of AF
140
141
Other diseases?
Yes
No
142
Determine status of other diseases
143
Primary AF?
No
Yes
Adopt secondary treatment regimen for AF exacerbated by other disorders
144
151
A
B

FIGURE 8A

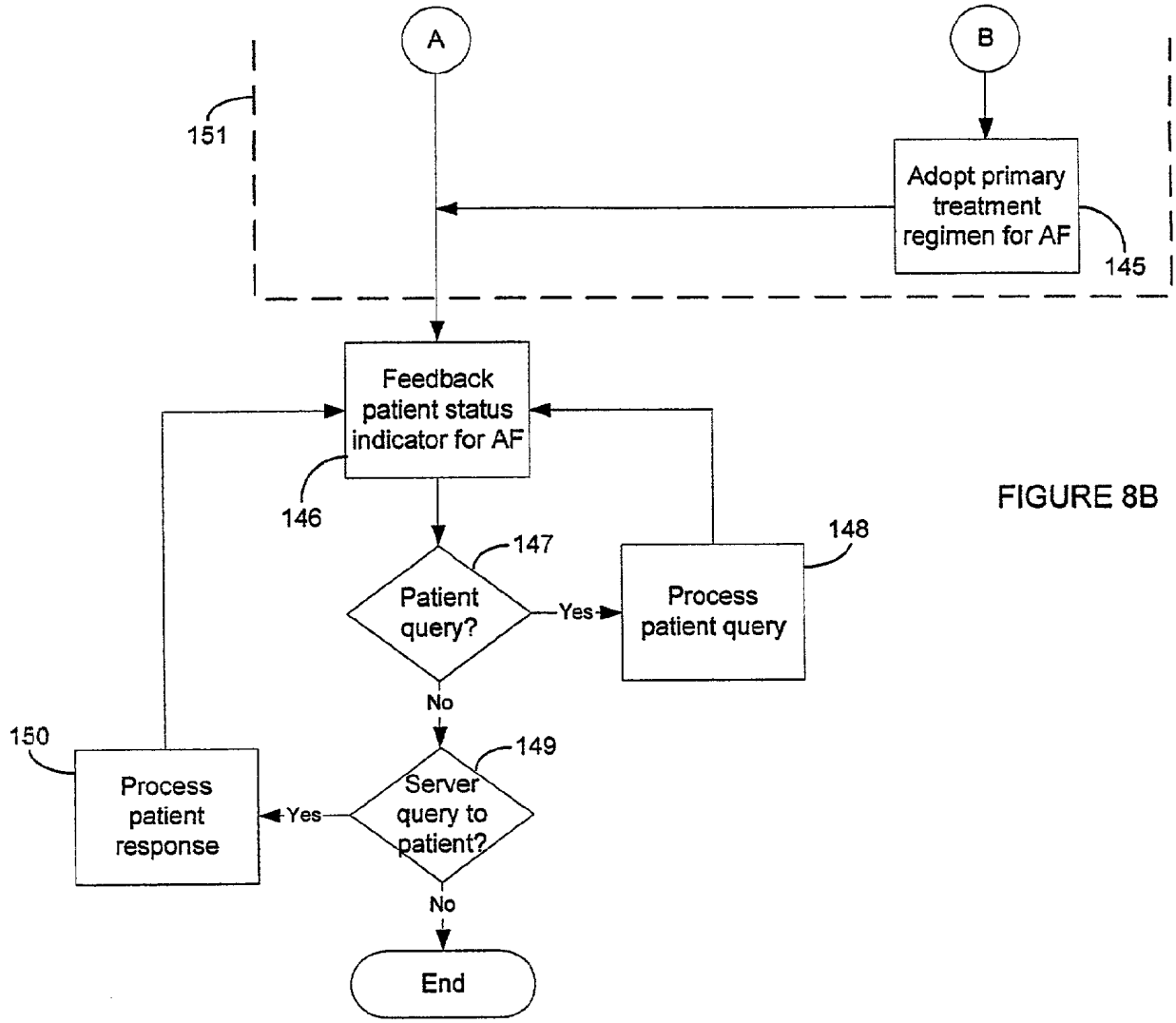

A
B
151
Adopt primary treatment regimen for AF
145
Feedback patient status indicator for AF
146
147
Patient query?
Yes
148
Process patient query
No
150
149
Process patient response
Server query to patient?
Yes
No
End

FIGURE 8B

FIGURE 9

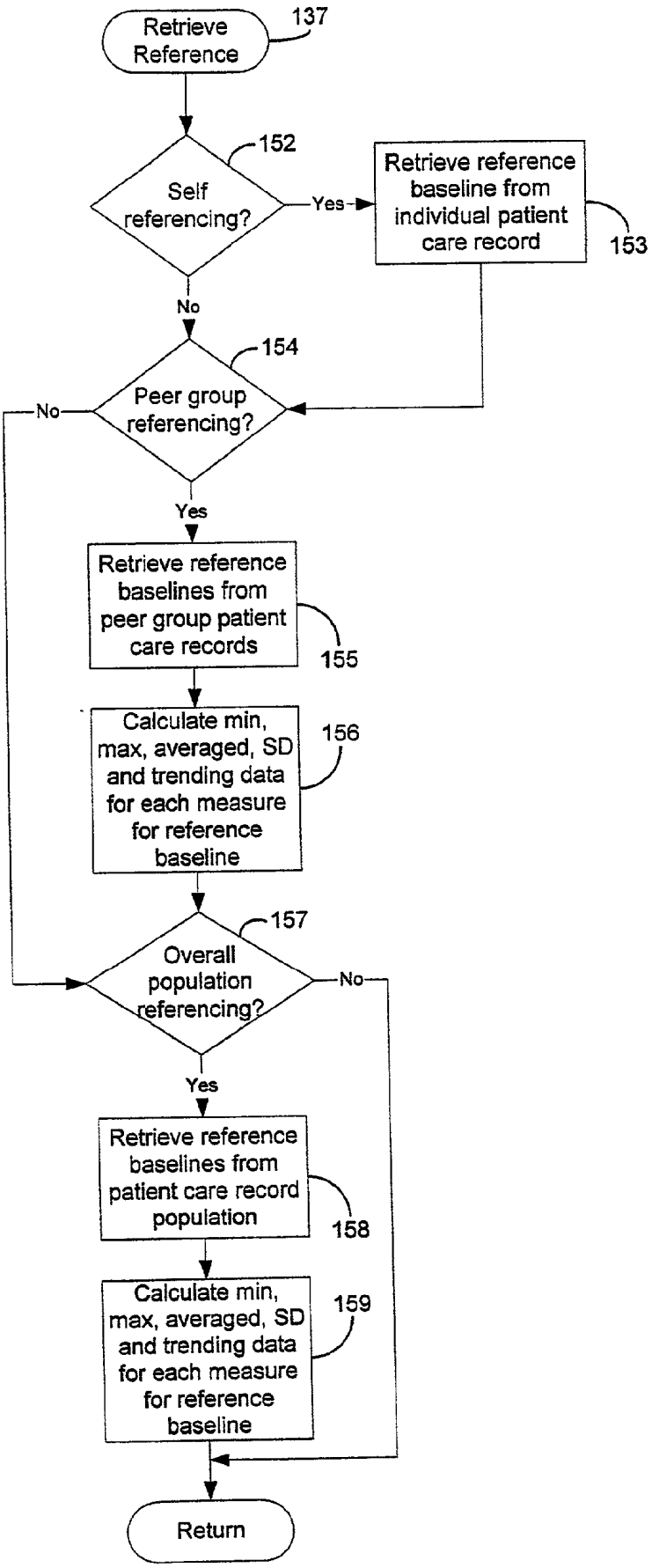

Retrieve Reference
137
Self referencing?
152
Yes
Retrieve reference baseline from individual patient care record
153
No
Peer group referencing?
154
No
Yes
Retrieve reference baselines from peer group patient care records
155
Calculate min, max, averaged, SD and trending data for each measure for reference baseline
156
Overall population referencing?
157
No
Yes
Retrieve reference baselines from patient care record population
158
Calculate min, max, averaged, SD and trending data for each measure for reference baseline
159
Return

FIGURE 10

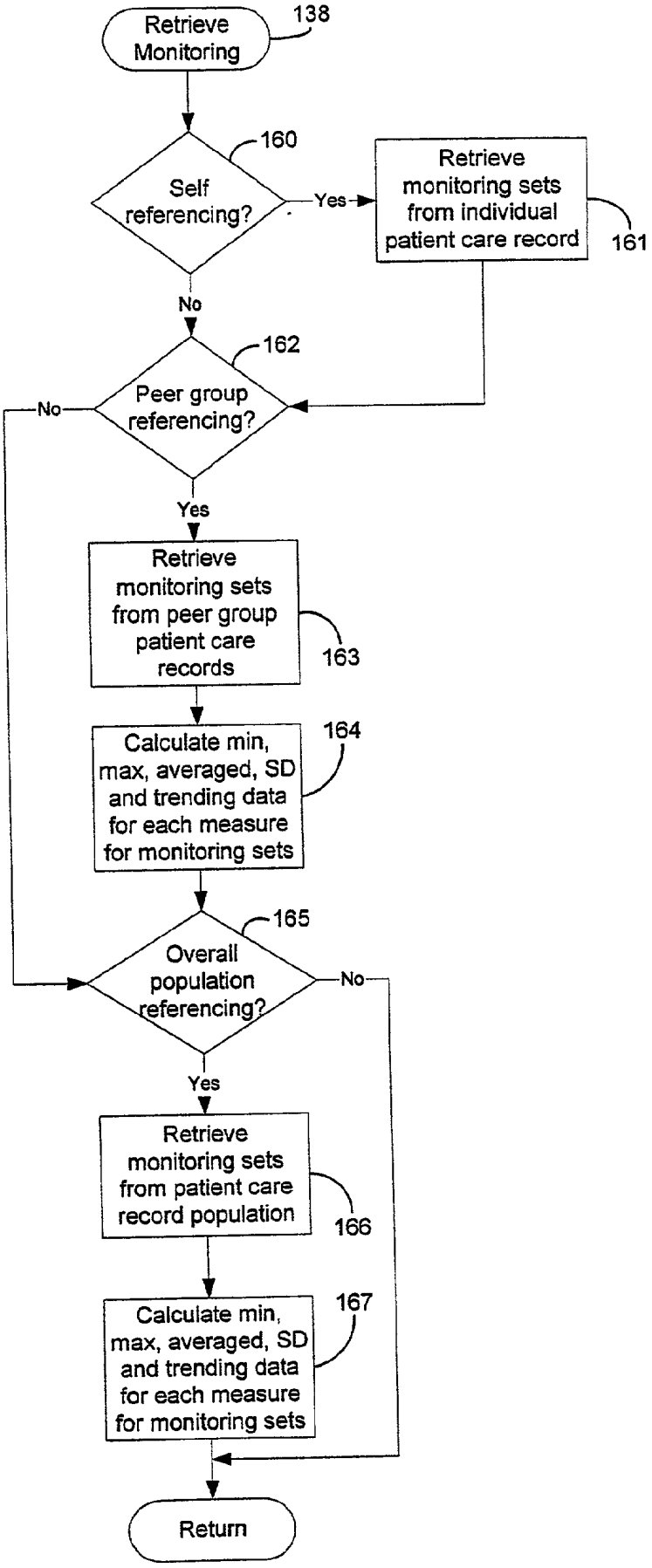

Retrieve Monitoring
138
160
Self referencing?
Yes
Retrieve monitoring sets from individual patient care record
161
No
162
Peer group referencing?
No
Yes
Retrieve monitoring sets from peer group patient care records
163
Calculate min, max, averaged, SD and trending data for each measure for monitoring sets
164
165
Overall population referencing?
No
Yes
Retrieve monitoring sets from patient care record population
166
Calculate min, max, averaged, SD and trending data for each measure for monitoring sets
167
Return

FIGURE 11A

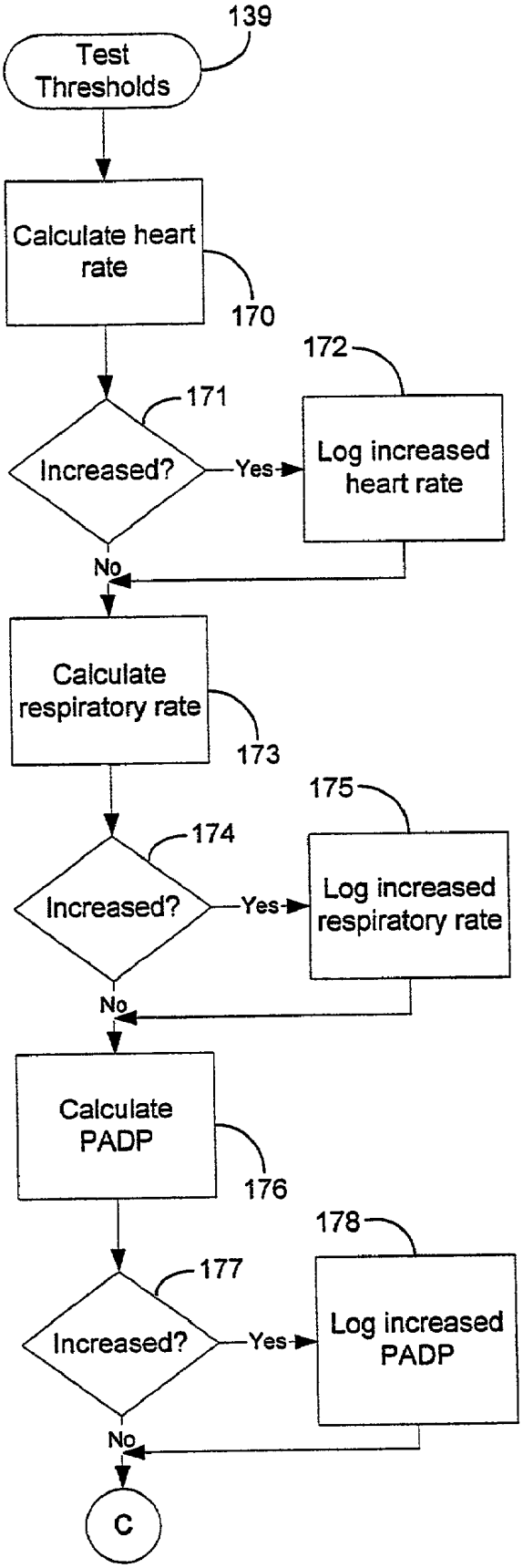

139
Test Thresholds
Calculate heart rate
170
172
171
Increased?
Yes
Log increased heart rate
No
Calculate respiratory rate
173
175
174
Increased?
Yes
Log increased respiratory rate
No
Calculate PADP
176
178
177
Increased?
Yes
Log increased PADP
No
C

FIGURE 11B

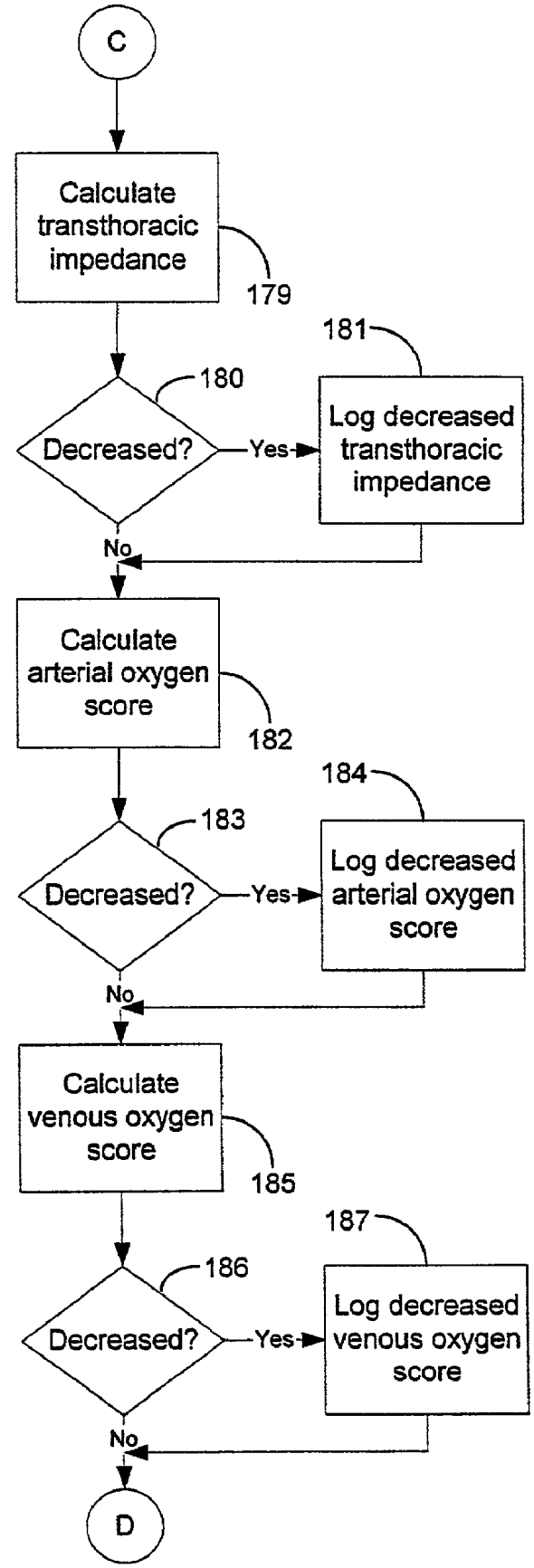

C
Calculate transthoracic impedance
179
181
180
Decreased?
Yes
Log decreased transthoracic impedance
No
Calculate arterial oxygen score
182
184
183
Decreased?
Yes
Log decreased arterial oxygen score
No
Calculate venous oxygen score
185
187
186
Decreased?
Yes
Log decreased venous oxygen score
No
D

FIGURE 11C

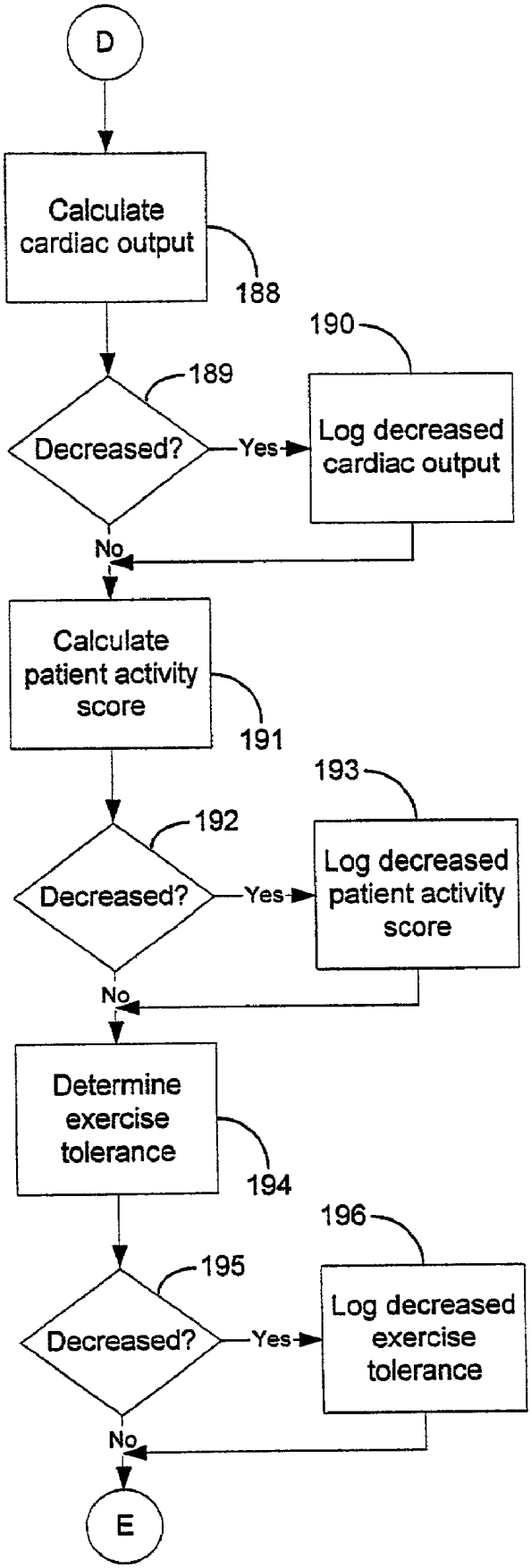

D
Calculate cardiac output
188
190
189
Decreased?
Yes
Log decreased cardiac output
No
Calculate patient activity score
191
193
192
Decreased?
Yes
Log decreased patient activity score
No
Determine exercise tolerance
194
196
195
Decreased?
Yes
Log decreased exercise tolerance
No
E

FIGURE 11D

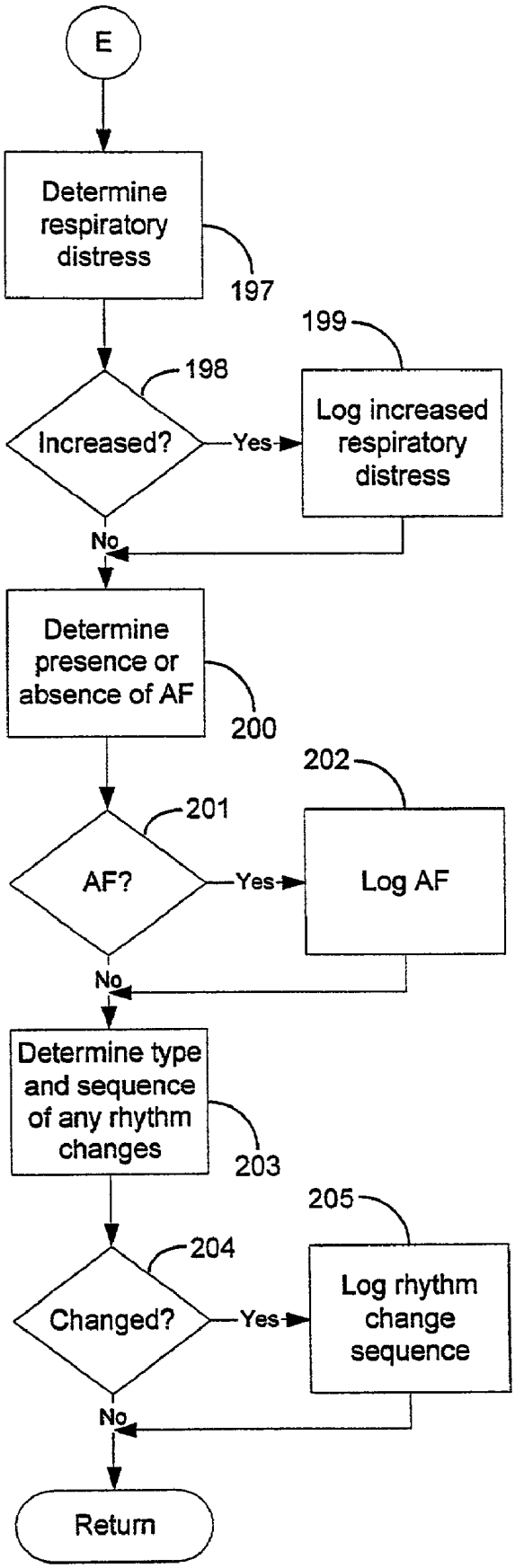

E
Determine respiratory distress
197
199
198
Increased?
Yes
Log increased respiratory distress
No
Determine presence or absence of AF
200
202
201
AF?
Yes
Log AF
No
Determine type and sequence of any rhythm changes
203
205
204
Changed?
Yes
Log rhythm change sequence
No
Return

FIGURE 12A

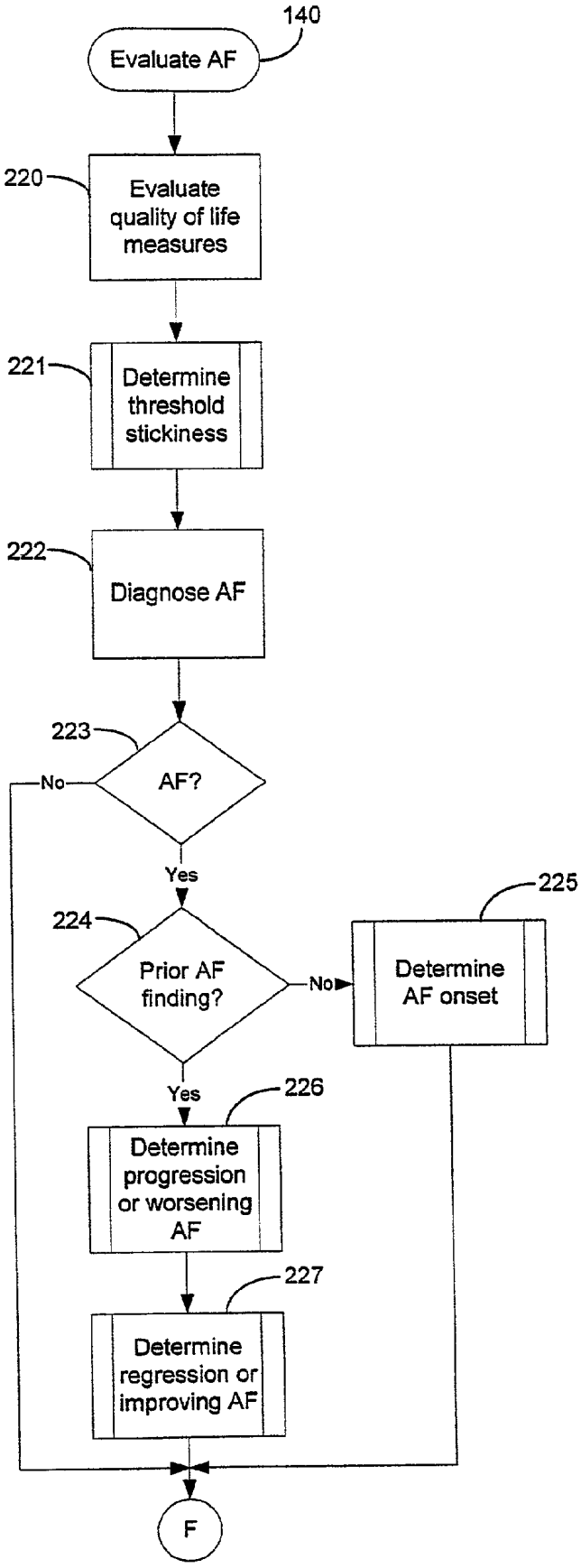

140
Evaluate AF
220
Evaluate quality of life measures
221
Determine threshold stickiness
222
Diagnose AF
223
AF?
No
Yes
224
Prior AF finding?
No
225
Determine AF onset
Yes
226
Determine progression or worsening AF
227
Determine regression or improving AF
F

FIGURE 12B

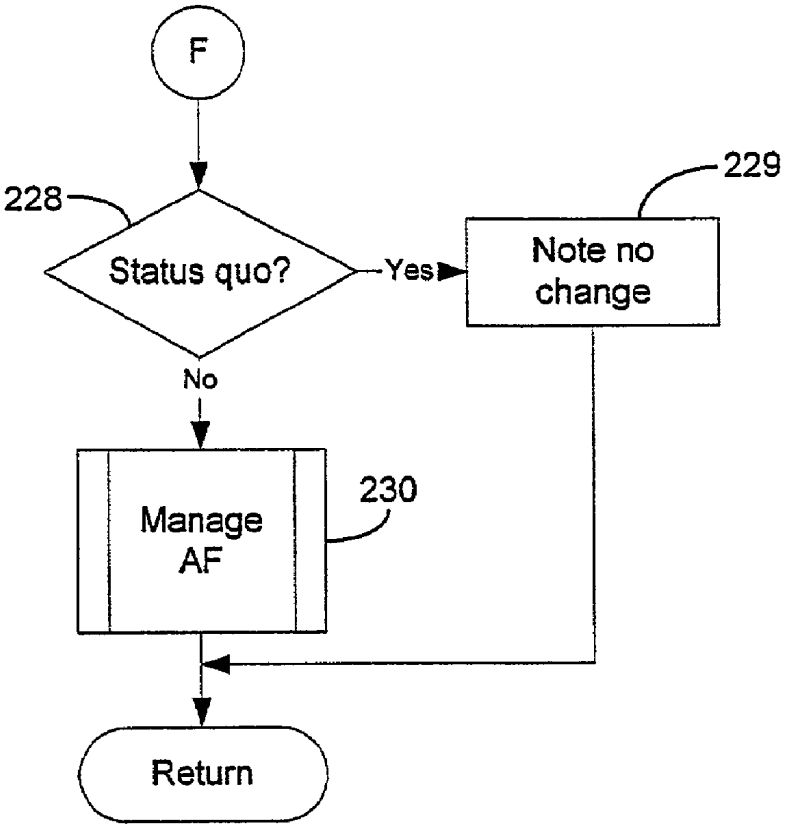

F
228
Status quo?
Yes
229
Note no change
No
Manage AF
230
Return

FIGURE 13A

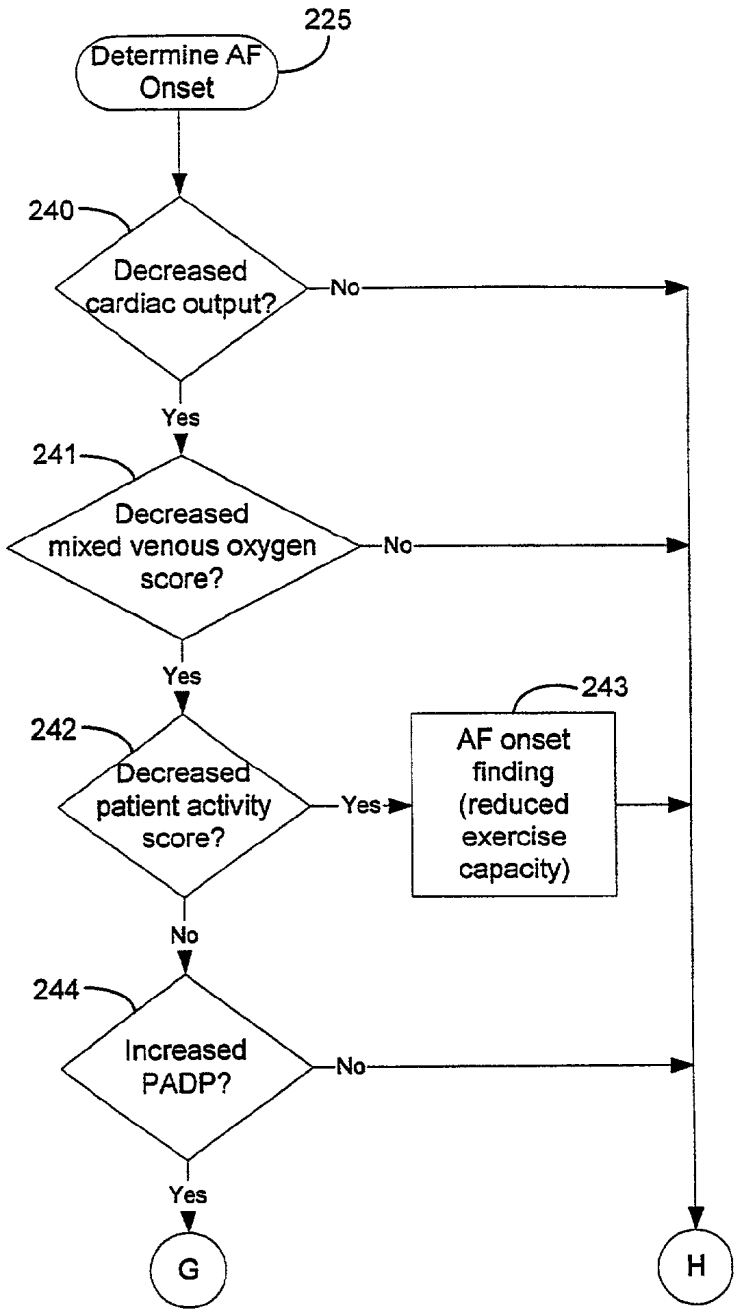

225
Determine AF Onset
240
Decreased cardiac output?
No
Yes
241
Decreased mixed venous oxygen score?
No
Yes
243
242
Decreased patient activity score?
Yes
AF onset finding (reduced exercise capacity)
No
244
Increased PADP?
No
Yes
G
H

FIGURE 13B

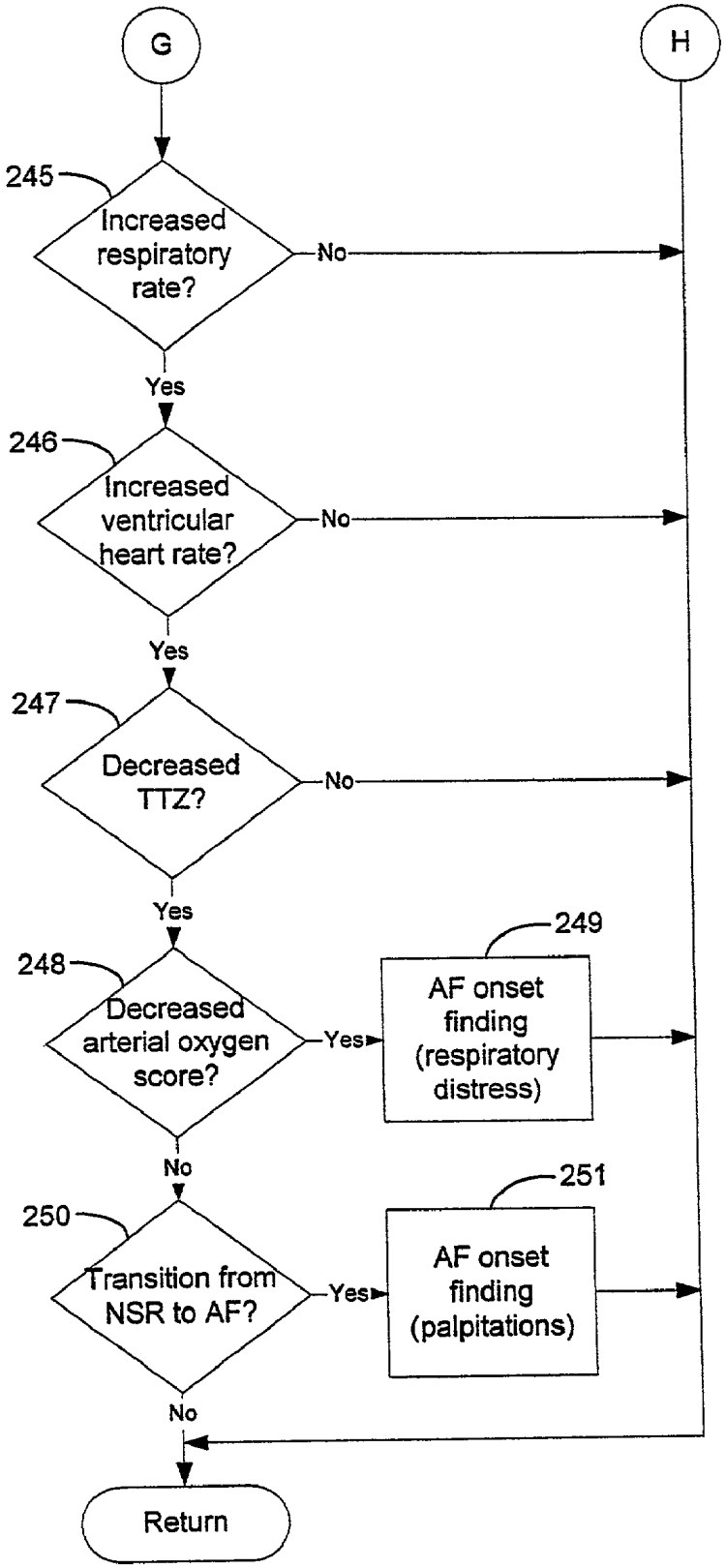

G
H
245
Increased respiratory rate?
No
Yes
246
Increased ventricular heart rate?
No
Yes
247
Decreased TTZ?
No
Yes
248
Decreased arterial oxygen score?
Yes
249
AF onset finding (respiratory distress)
No
250
Transition from NSR to AF?
Yes
251
AF onset finding (palpitations)
No
Return

FIGURE 14A

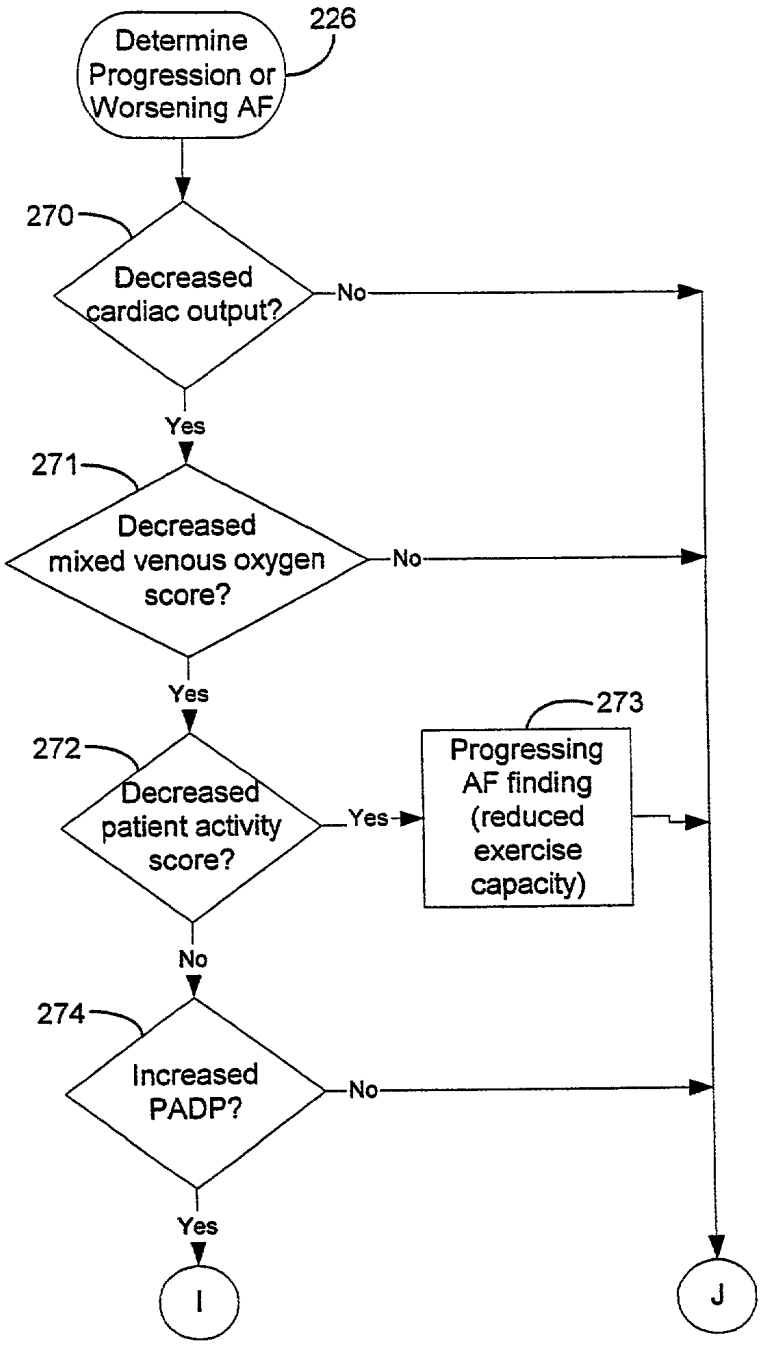

Determine Progression or Worsening AF
226
270
Decreased cardiac output?
No
Yes
271
Decreased mixed venous oxygen score?
No
Yes
272
Decreased patient activity score?
Yes
273
Progressing AF finding (reduced exercise capacity)
No
274
Increased PADP?
No
Yes
I
J

FIGURE 14B

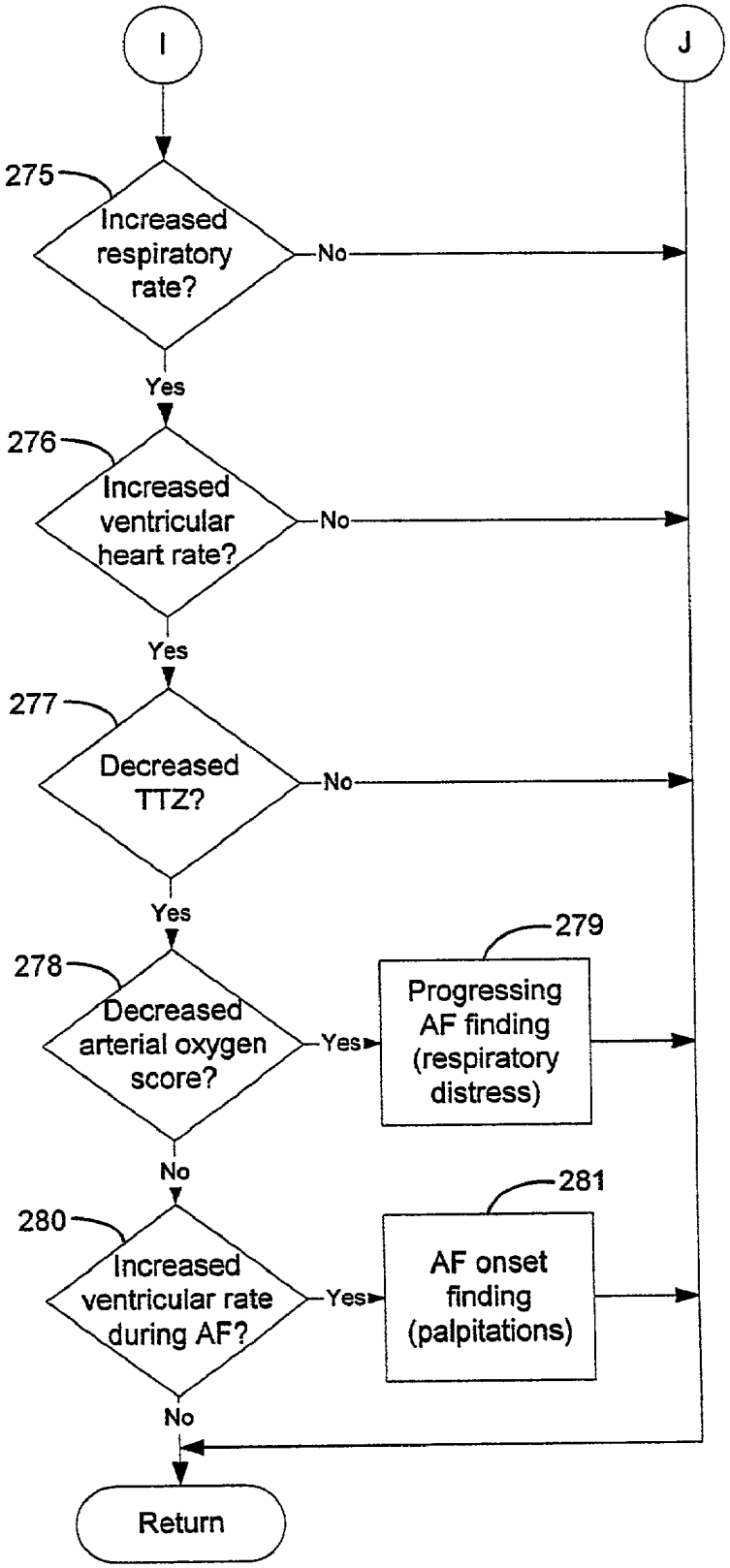

I
J
275
Increased respiratory rate?
No
Yes
276
Increased ventricular heart rate?
No
Yes
277
Decreased TTZ?
No
Yes
278
Decreased arterial oxygen score?
Yes
279
Progressing AF finding (respiratory distress)
No
280
Increased ventricular rate during AF?
Yes
281
AF onset finding (palpitations)
No
Return

FIGURE 15A

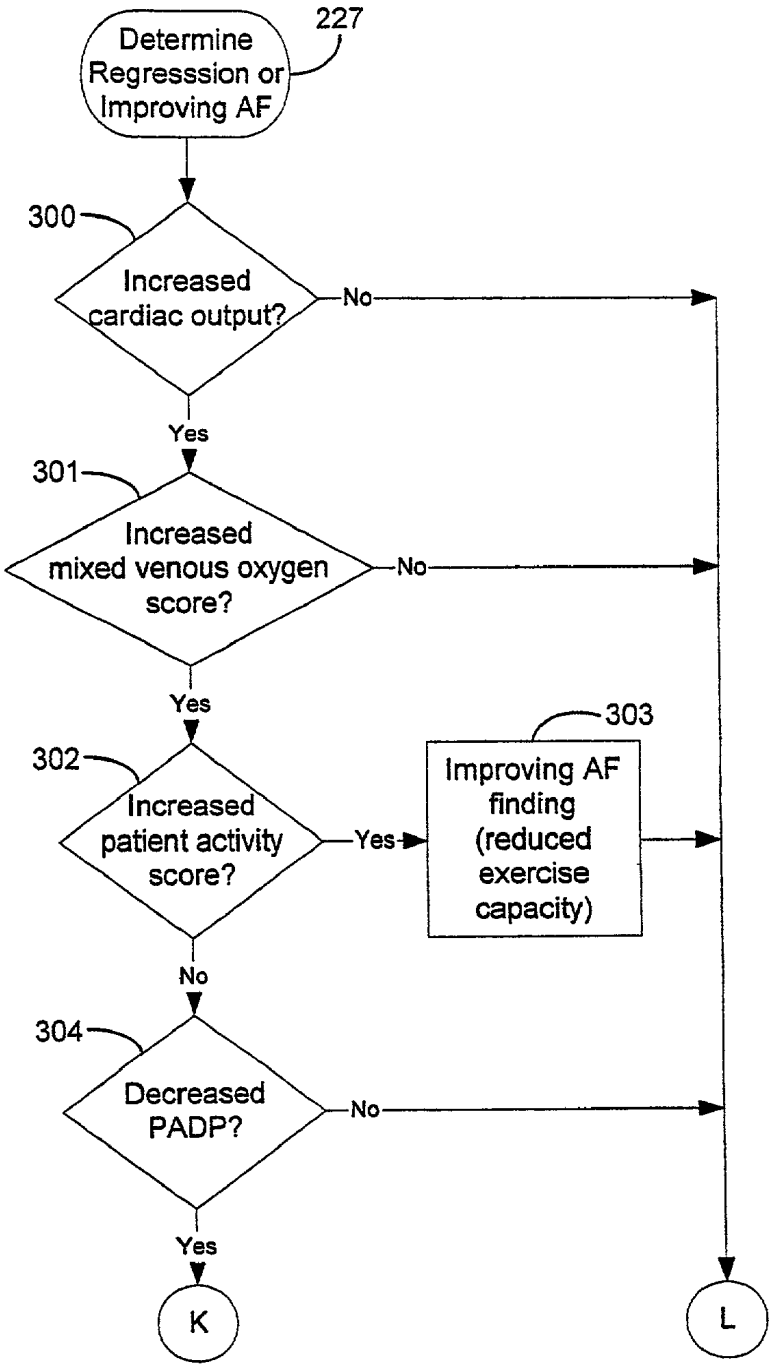

Determine Regresssion or Improving AF
227
300
Increased cardiac output?
No
Yes
301
Increased mixed venous oxygen score?
No
Yes
303
302
Increased patient activity score?
Yes
Improving AF finding (reduced exercise capacity)
No
304
Decreased PADP?
No
Yes
K
L

FIGURE 15B

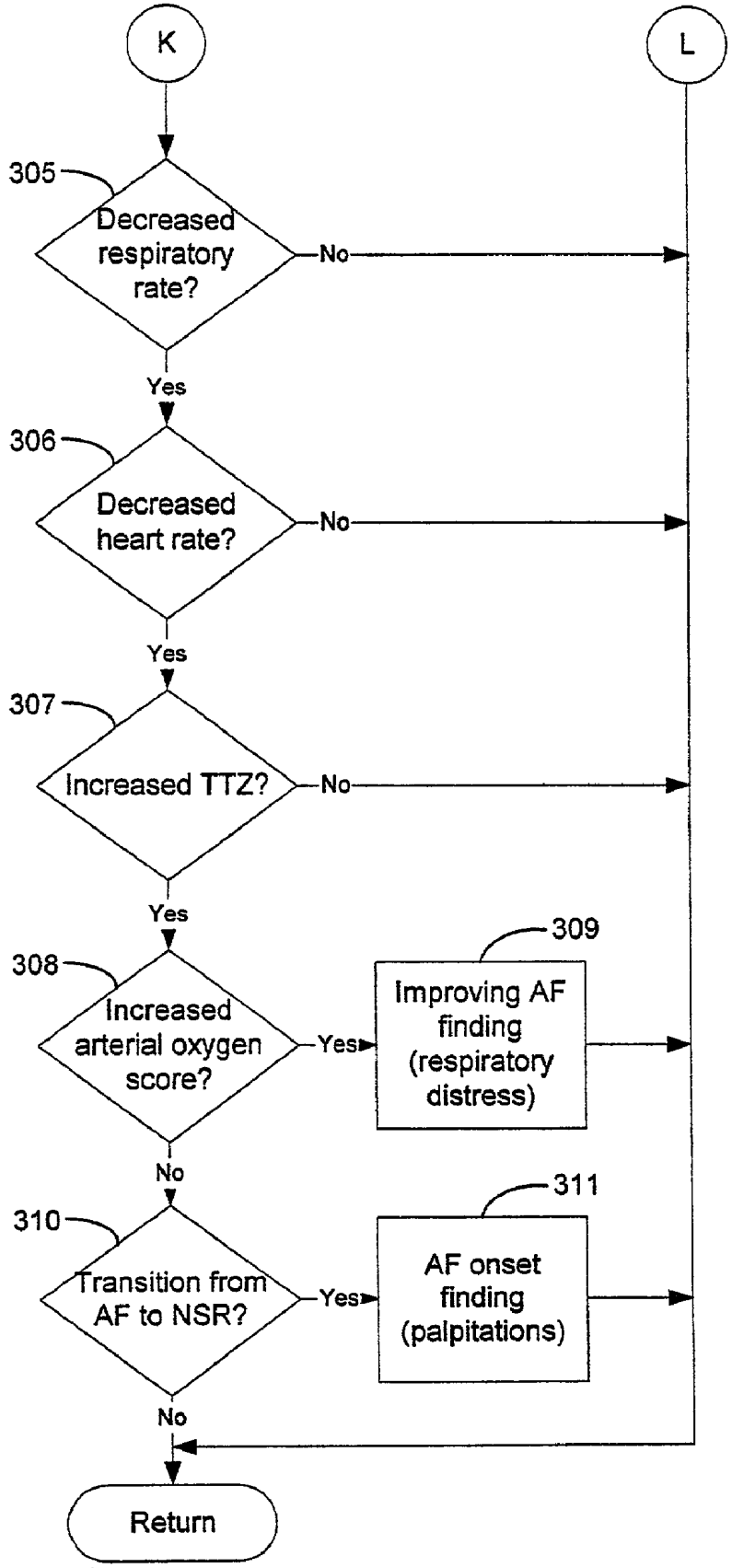

K
L
305
Decreased respiratory rate?
No
Yes
306
Decreased heart rate?
No
Yes
307
Increased TTZ?
No
Yes
308
Increased arterial oxygen score?
Yes
309
Improving AF finding (respiratory distress)
No
310
Transition from AF to NSR?
Yes
311
AF onset finding (palpitations)
No
Return

FIGURE 16

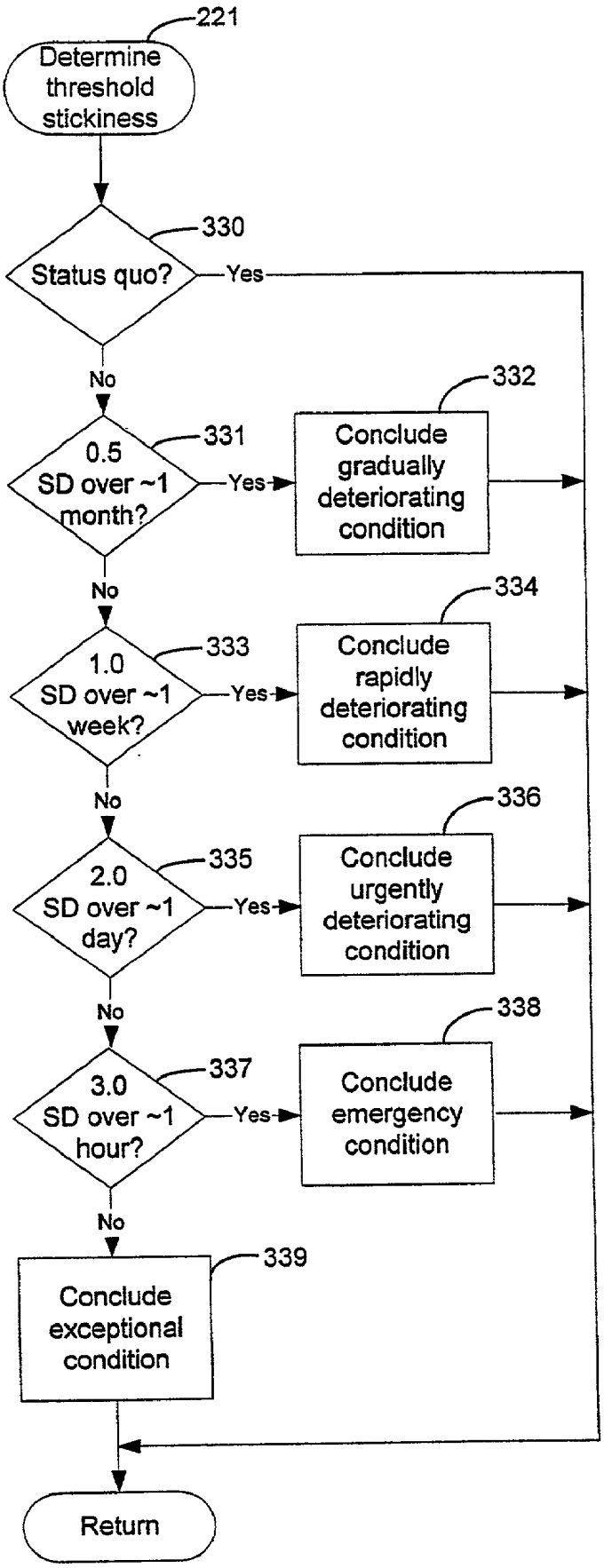
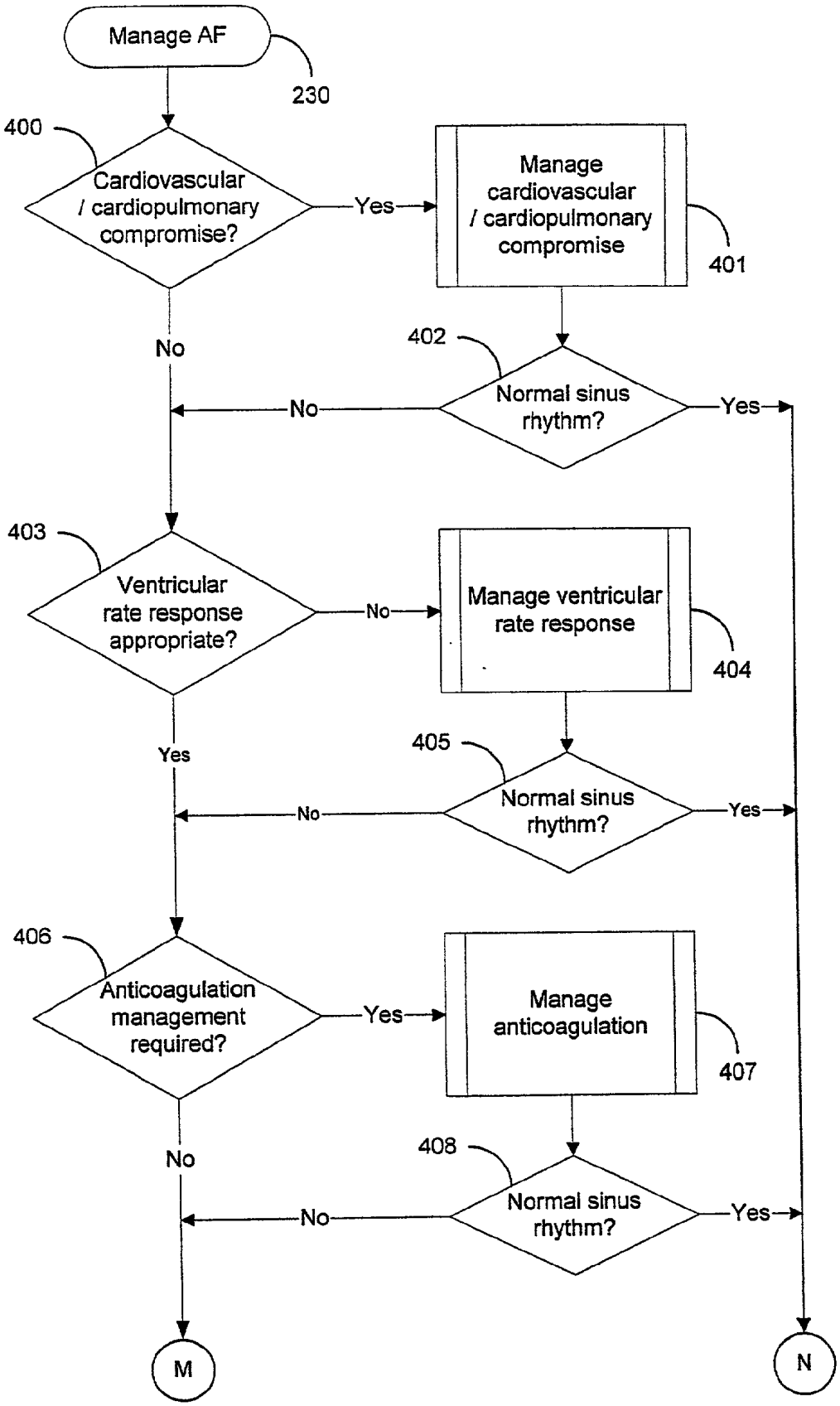

221
Determine threshold stickiness
330
Status quo?
Yes
No
331
0.5 SD over ~1 month?
Yes
332
Conclude gradually deteriorating condition
No
333
1.0 SD over ~1 week?
Yes
334
Conclude rapidly deteriorating condition
No
335
2.0 SD over ~1 day?
Yes
336
Conclude urgently deteriorating condition
No
337
3.0 SD over ~1 hour?
Yes
338
Conclude emergency condition
No
339
Conclude exceptional condition
Return

FIGURE 17A


Manage AF
230
400
Cardiovascular / cardiopulmonary compromise?
Yes
Manage cardiovascular / cardiopulmonary compromise
401
No
402
Normal sinus rhythm?
No
Yes
403
Ventricular rate response appropriate?
No
Manage ventricular rate response
404
Yes
405
Normal sinus rhythm?
No
Yes
406
Anticoagulation management required?
Yes
Manage anticoagulation
407
No
408
Normal sinus rhythm?
No
Yes
M
N

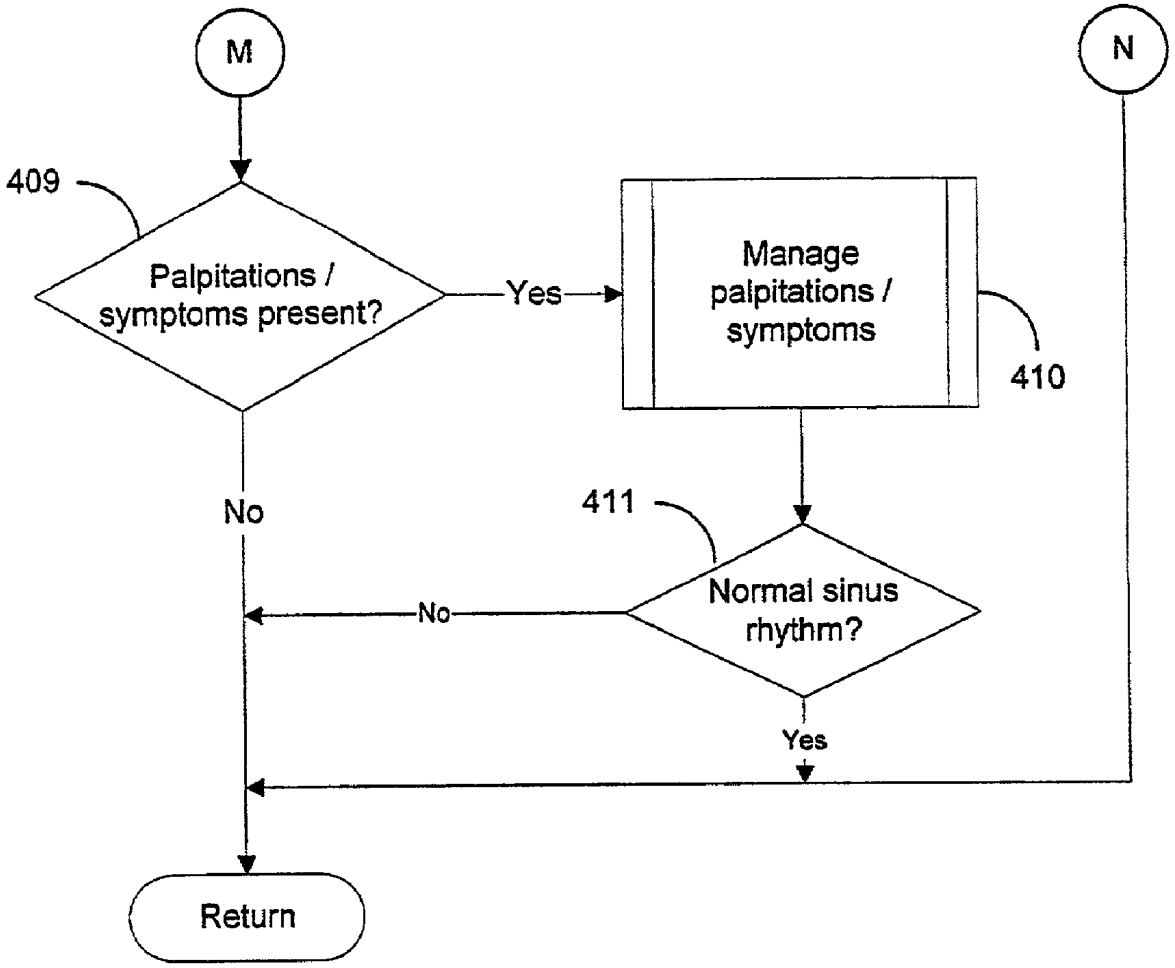
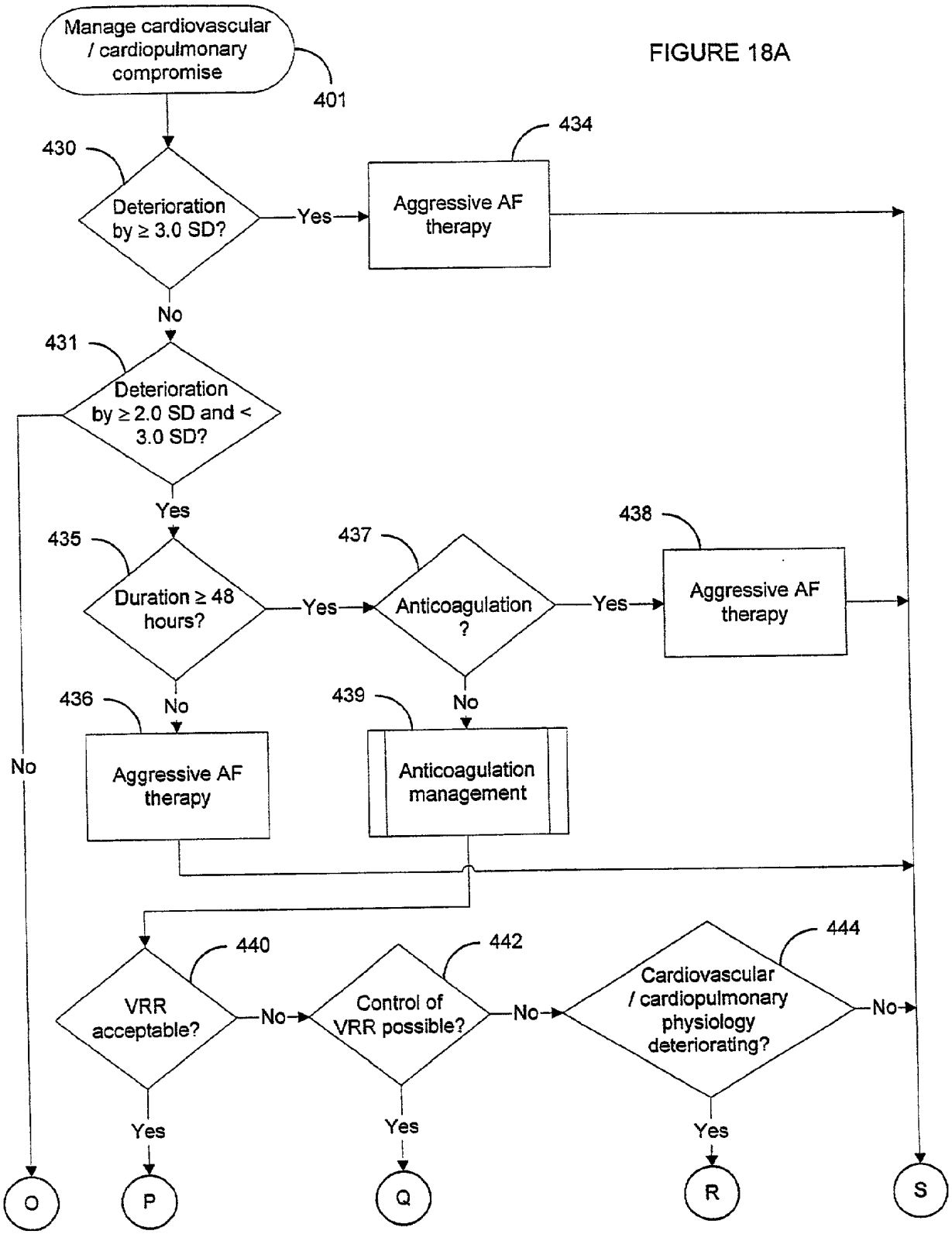

M
N
409
Palpitations / symptoms present?
Yes
Manage palpitations / symptoms
410
No
411
Normal sinus rhythm?
No
Yes
Return

FIGURE 17B

FIGURE 18A


Manage cardiovascular / cardiopulmonary compromise
401
430
Deterioration by ≥ 3.0 SD?
Yes
434
Aggressive AF therapy
No
431
Deterioration by ≥ 2.0 SD and < 3.0 SD?
Yes
435
Duration ≥ 48 hours?
Yes
437
Anticoagulation ?
Yes
438
Aggressive AF therapy
No
436
Aggressive AF therapy
No
439
Anticoagulation management
No
440
VRR acceptable?
No
442
Control of VRR possible?
No
444
Cardiovascular / cardiopulmonary physiology deteriorating?
No
Yes
Yes
Yes
O
P
Q
R
S

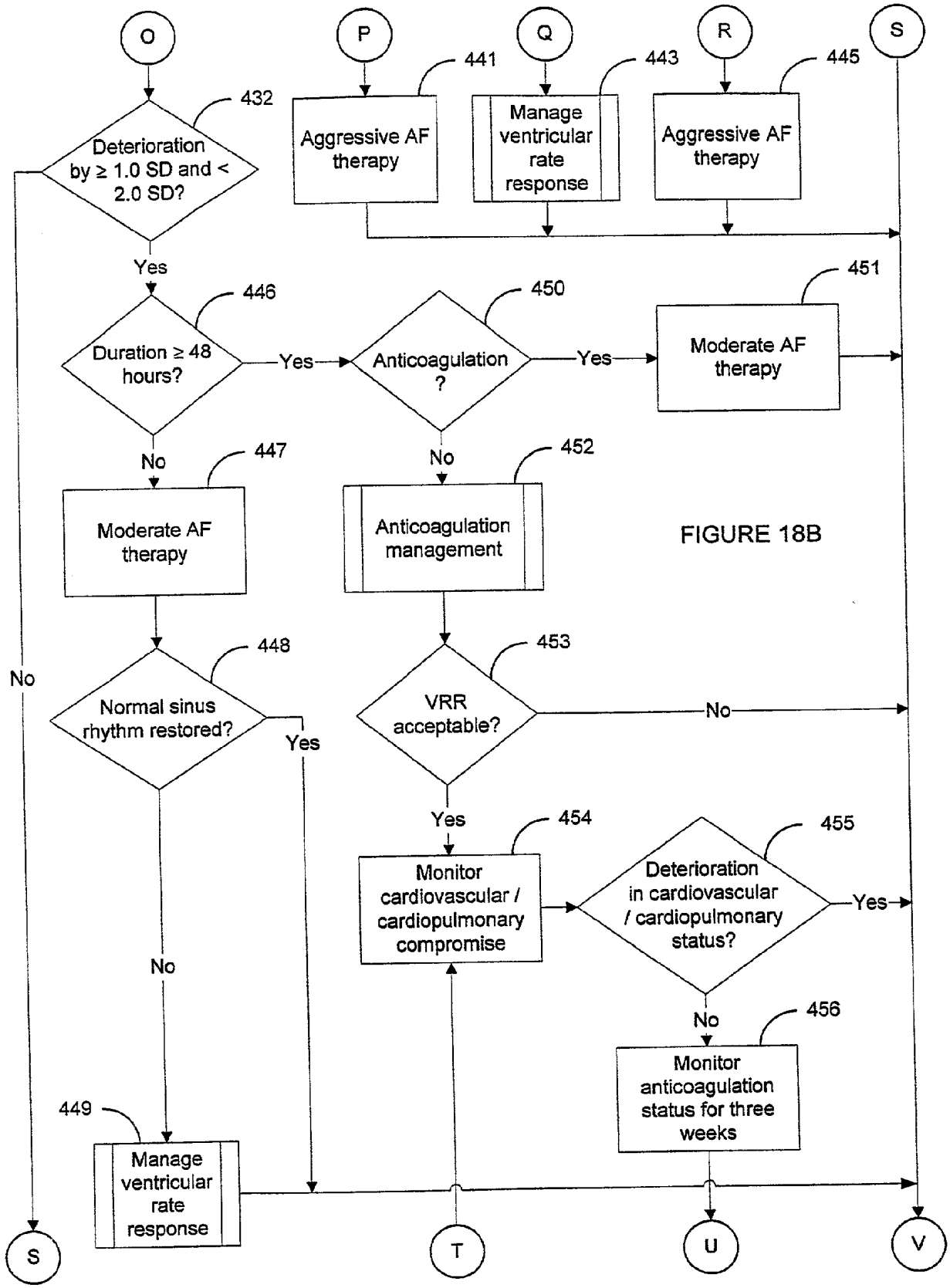
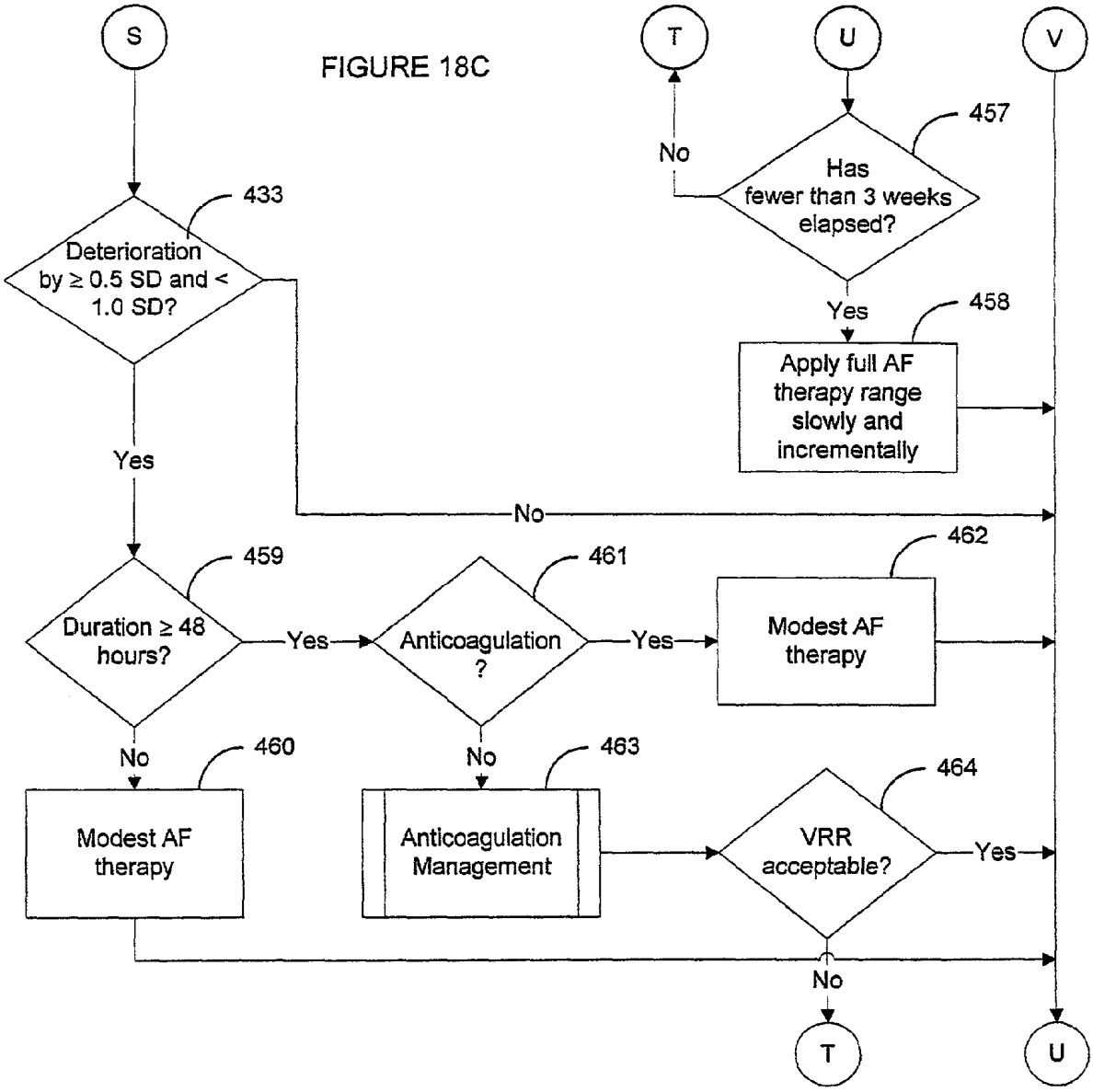

O
P
Q
R
S
441
443
445
432
Deterioration by ≥ 1.0 SD and < 2.0 SD?
Aggressive AF therapy
Manage ventricular rate response
Aggressive AF therapy
Yes
446
450
451
Duration ≥ 48 hours?
Yes
Anticoagulation ?
Yes
Moderate AF therapy
No
447
No
452
Moderate AF therapy
Anticoagulation management
448
453
No
Normal sinus rhythm restored?
Yes
VRR acceptable?
No
Yes
454
455
Monitor cardiovascular / cardiopulmonary compromise
Deterioration in cardiovascular / cardiopulmonary status?
Yes
No
456
Monitor anticoagulation status for three weeks
449
Manage ventricular rate response
S
T
U
V

FIGURE 18B

FIGURE 18C


S
T
U
V
433
Deterioration by ≥ 0.5 SD and < 1.0 SD?
No
457
Has fewer than 3 weeks elapsed?
Yes
458
Apply full AF therapy range slowly and incrementally
Yes
No
459
Duration ≥ 48 hours?
Yes
461
Anticoagulation ?
Yes
462
Modest AF therapy
No
460
Modest AF therapy
No
463
Anticoagulation Management
464
VRR acceptable?
Yes
No
T
U

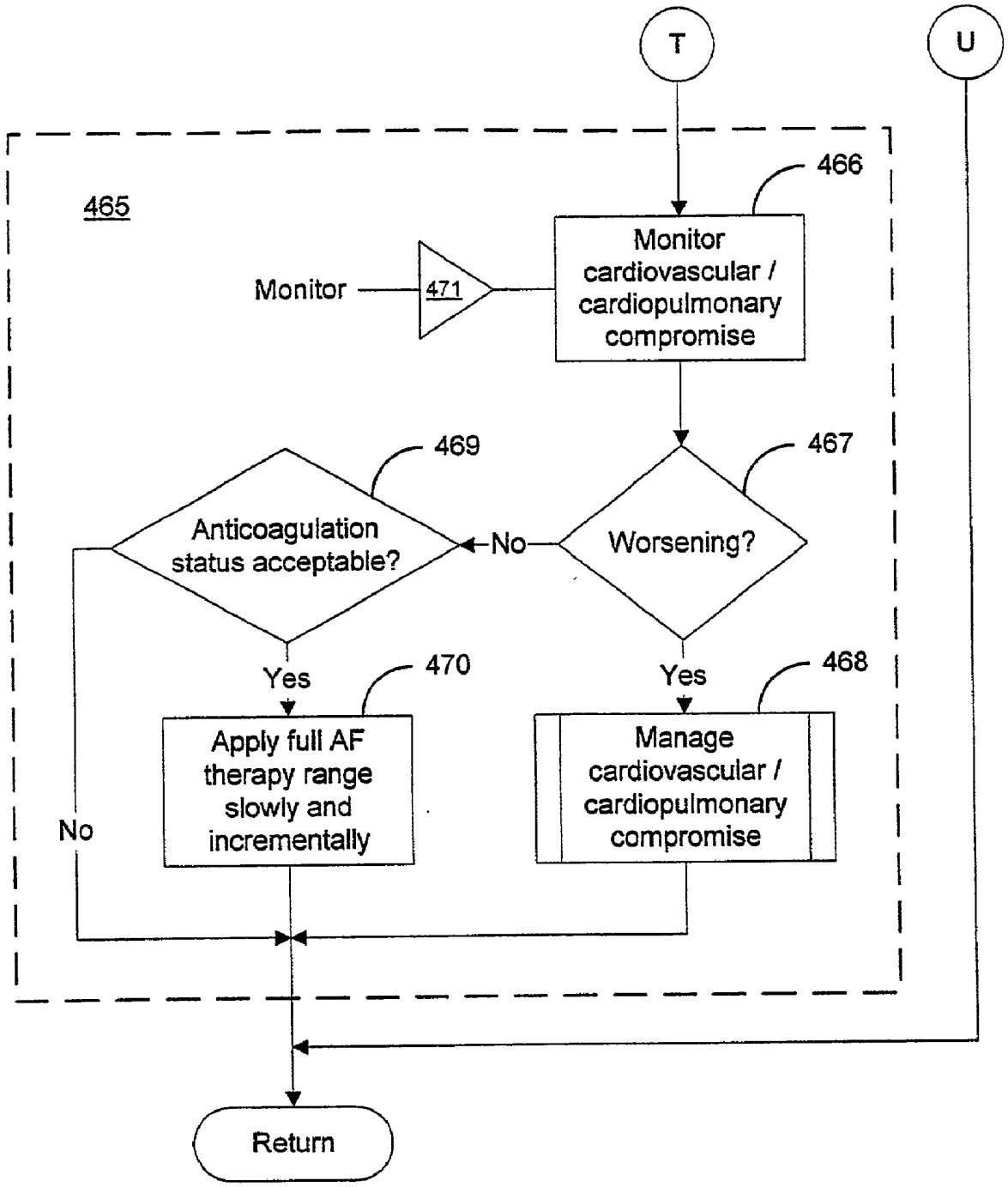

T
U
465
466
Monitor
471
Monitor cardiovascular / cardiopulmonary compromise
469
467
Anticoagulation status acceptable?
No
Worsening?
Yes
470
Yes
468
Apply full AF therapy range slowly and incrementally
Manage cardiovascular / cardiopulmonary compromise
No
Return

FIGURE 18D

FIGURE 19

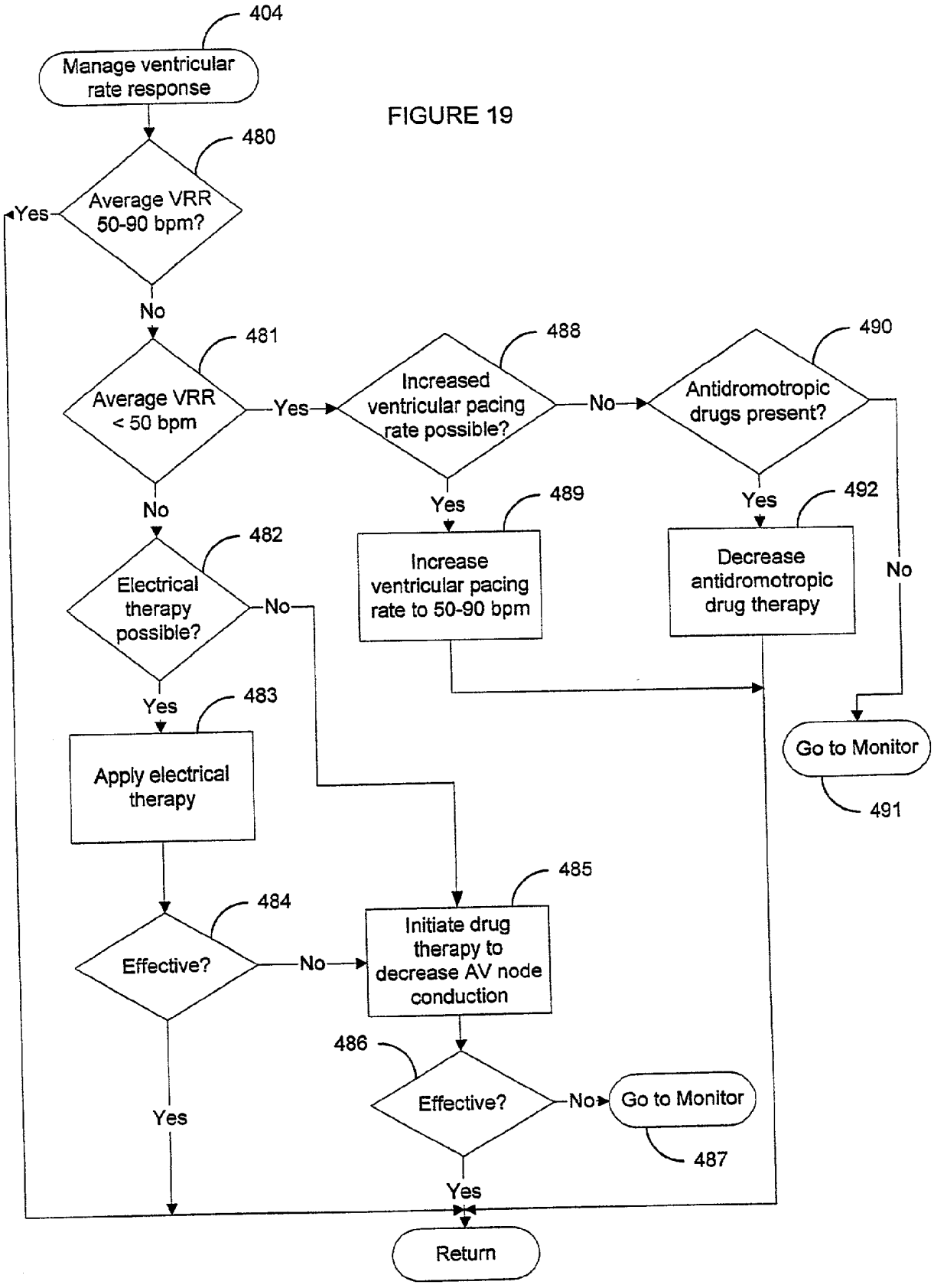
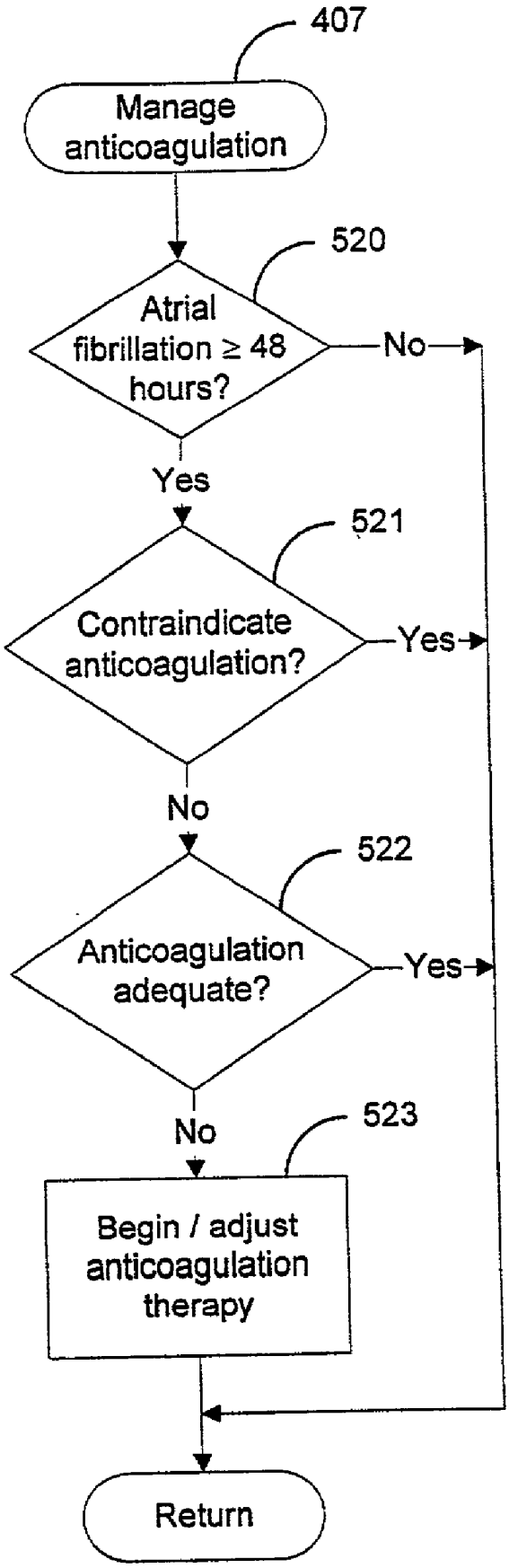

404
Manage ventricular rate response
480
Average VRR 50-90 bpm?
Yes
No
481
Average VRR < 50 bpm
Yes
488
Increased ventricular pacing rate possible?
No
490
Antidromotropic drugs present?
Yes
No
Yes
489
Increase ventricular pacing rate to 50-90 bpm
Yes
492
Decrease antidromotropic drug therapy
No
482
Electrical therapy possible?
No
Yes
483
Apply electrical therapy
Go to Monitor
491
485
Initiate drug therapy to decrease AV node conduction
484
Effective?
No
Yes
486
Effective?
No
Go to Monitor
487
Yes
Return

FIGURE 20


407
Manage anticoagulation
520
Atrial fibrillation ≥ 48 hours?
No
Yes
521
Contraindicate anticoagulation?
Yes
No
522
Anticoagulation adequate?
Yes
No
523
Begin / adjust anticoagulation therapy
Return

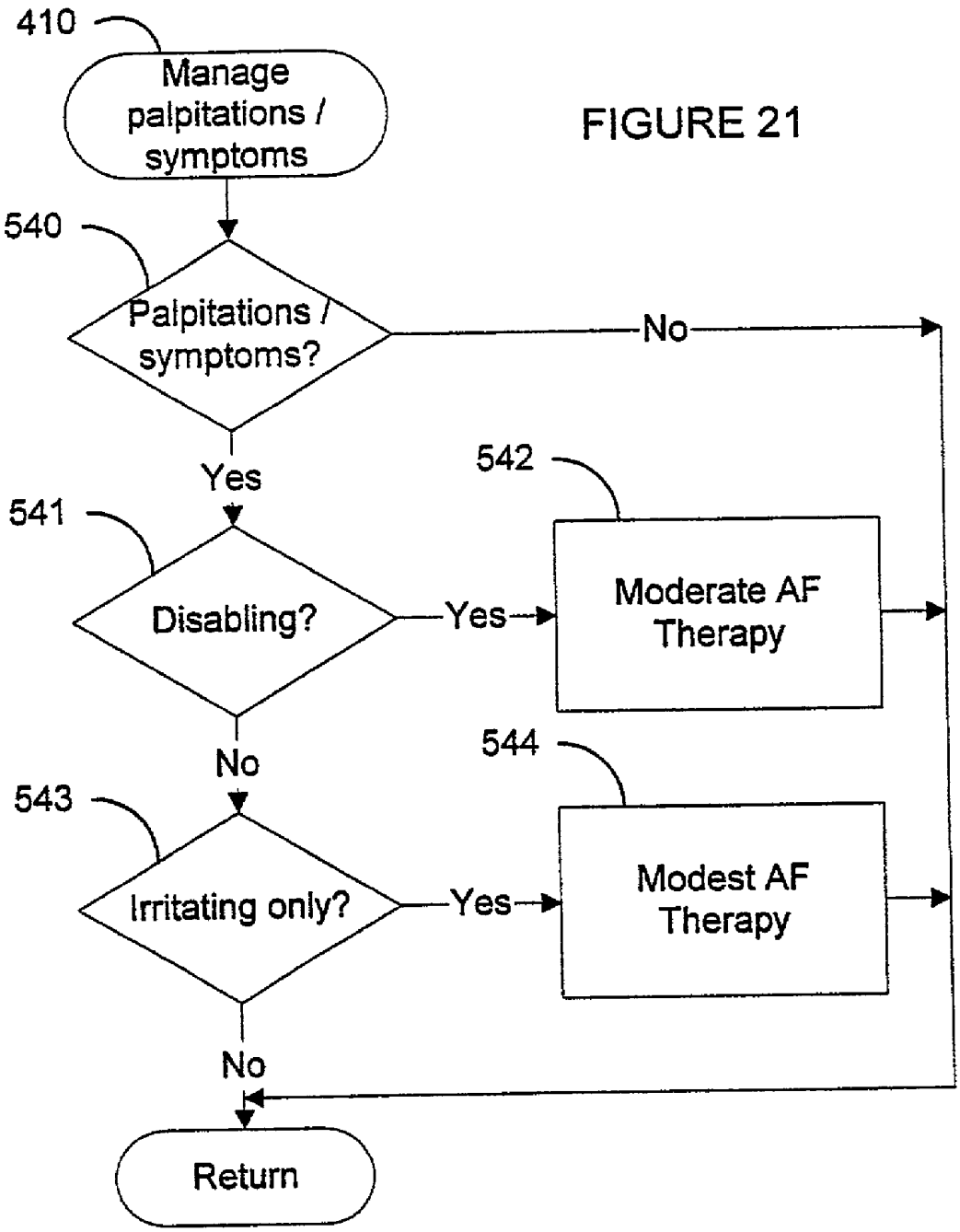

410
Manage palpitations / symptoms
540
Palpitations / symptoms?
No
Yes
542
541
Disabling?
Yes
Moderate AF Therapy
No
544
543
Irritating only?
Yes
Modest AF Therapy
No
Return

FIGURE 21

AUTOMATED METHOD FOR DIAGNOSING AND MONITORING THE OUTCOMES OF ATRIAL FIBRILLATION

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This patent application is related to a commonly owned U.S. patent application, Ser. No. _____, entitled "Automated Collection And Analysis Patient Care System And Method For Ordering And Prioritizing Multiple Health Disorders To Identify An Index Disorder," pending, filed Nov. 16, 1999, the disclosure of which is incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The present invention relates in general to atrial fibrillation (AF) diagnosis and analysis, and, in particular, to an automated collection and analysis patient care system and method for diagnosing and monitoring the outcomes, including cardiovascular consequences, of atrial fibrillation throughout disease onset, progression, regression and status quo.

BACKGROUND OF THE INVENTION

[0003] Atrial fibrillation is a heart rhythm abnormality that is one of the leading causes of cardiovascular disease-related morbidity in the world. Clinically, atrial fibrillation involves an abnormality of electrical impulse formation and conduction that originates in the atria, that is, the upper chambers of the heart. Atrial fibrillation can occur in patients with any type of underlying structural heart abnormality, such as coronary artery disease, valvular heart disease, congenital heart disease, and cardiomyopathies of various kinds, thereby complicating patient management and therapy. Further, atrial fibrillation can sometimes occur in patients with no known underlying structural abnormalities or in patients with lung disease or hormonal or metabolic disorders. As well, the occurrence of atrial fibrillation can exacerbate other disorders, for example, myocardial ischemia or congestive heart failure. Effective treatment must include weighing the presence of any comorbidities primary or secondary to atrial fibrillation and whether therapy should be directed against rate control or restoration of normal sinus rhythm.

[0004] Atrial fibrillation is characterized by multiple swirling wavelets of electrical current spreading across the atria in a disorganized manner. The irregularity of electrical conduction throughout the atria creates irregular impulse propagation through the atrioventricular node into the ventricle and can frequently cause a patient to notice a disturbingly erratic sensation of the heartbeat. These symptoms of an erratic heartbeat, or palpitation, can be trivial or seriously disturbing to the patient's daily functions. Occasionally, the impulse conduction is extremely rapid, leading to reduced diastolic filling of the heart chambers and reduced cardiac pumping action. Rapid heart rate, as well as poor coordination of atrial and ventricular pumping functions, not only lead to a decrease in cardiac output, but also, depending upon the nature of any underlying heart disease, can exacerbate heart failure, coronary blood flow, and pulmonary disorders. Atrial fibrillation may also occur and be totally inconsequential in its cardiovascular and cardiopulmonary consequences or its affect on the patient's quality of life. Yet, even if silent from a cardiovascular and symptom perspective, if persisting beyond a 48 hour period, atrial fibrillation can also result in blood clot formation in the atria, thereby creating the potential for thromboembolism which can lead to strokes or injuries to limbs and major organs. Thus, the outcomes or consequences of atrial fibrillation can be gross or subtle and be rapid or gradual in onset, consequently requiring a range of approaches, from observation to providing emergent interventions.

[0005] The early diagnosis, prevention and monitoring of the consequences of atrial fibrillation can be relatively difficult. First, atrial fibrillation onset runs an erratic, unpredictable course and is generally silent and undetectable to the patient. More often, atrial fibrillation either results in no symptoms at least for some period of time early in the course of onset, or in fatigue or difficulties in breathing usually in the case of those patients having comorbid conditions. Occasionally, a patient will have no complaints but will unconsciously compensate by limiting his or her daily activities. Sometimes, the consequences of atrial fibrillation are more overt. In any case, fatigue or difficulty breathing is often a consequence of atrial fibrillation complicating the pathophysiology of coexisting conditions of congestive heart failure, myocardial ischemia, and/or respiratory insufficiency, for example.

[0006] The susceptibility to suffer from atrial fibrillation depends upon the patient's age, gender, physical condition, presence or absence of heart failure, coronary artery disease, lung disease, and the incidence of other factors, such as diabetes, lung disease, high blood pressure, anemia and kidney function. No one factor is dispositive. Evaluations for atrial fibrillation and its consequences, with annual or even monthly checkups, provide, at best, a "snapshot" of patient wellness and the incremental and subtle clinicophysiological changes which portend the onset or progression of atrial fibrillation often go unnoticed, unless electrocardiographic documentation is obtained and simultaneously correlated with cardiovascular and cardiopulmonary physiological measures. Documentation of improvements following initiation of therapy can be equally elusive.

[0007] Nevertheless, taking advantage of frequently and regularly measured physiological measures, such as recorded manually by a patient, via an external monitoring or therapeutic device, or via implantable device technologies, can provide a degree of detection, treatment and prevention heretofore unknown. In addition, monitoring of the physiological consequences of the onset and offset of atrial fibrillation can provide invaluable guidance in directing when and what therapeutic intervention is most appropriate, particularly when atrial fibrillation is coupled with other comorbidities. For instance, patients already suffering from some form of treatable heart disease often receive an implantable pulse generator (IPG), cardiovascular or arrhythmia monitor, therapeutic device, or similar external wearable device, with which rhythm and structural problems of the heart can be monitored and treated. These types of devices are useful for detecting physiological changes in patient conditions through the retrieval and analysis of telemetered signals stored in an on-board, volatile memory. Typically, these devices can store more than thirty minutes of per heartbeat data recorded on a per heartbeat, binned average basis, or on a derived basis from, for example, extensive data regarding atrial or ventricular electrical activ-

ity, minute ventilation, patient activity score, cardiac output score, mixed venous oxygen score, cardiovascular pressure measures, and the like. However, the proper analysis of retrieved telemetered signals requires detailed medical subspecialty knowledge, particularly by cardiologists and cardiac electrophysiologists.

[0008] Alternatively, these telemetered signals can be remotely collected and analyzed using an automated patient care system. One such system is described in a related, commonly owned U.S. patent application, Ser. No. 09/324,894, filed Jun. 3, 1999, pending, the disclosure of which is incorporated herein by reference. A medical device adapted to be implanted in an individual patient records telemetered signals that are then retrieved on a regular, periodic basis using an interrogator or similar interfacing device. The telemetered signals are downloaded via an internetwork onto a network server on a regular, e.g., daily, basis and stored as sets of collected measures in a database along with other patient care records. The information is then analyzed in an automated fashion and feedback, which includes a patient status indicator, is provided to the patient.

[0009] While such an automated system can serve as a valuable tool in providing remote patient care, an approach to systematically correlating and analyzing the raw collected telemetered signals, as well as manually collected physiological measures, through applied cardiovascular medical knowledge to accurately diagnose the consequences of the onset of a particular medical condition, such as atrial fibrillation, is needed. One automated patient care system directed to a patient-specific monitoring function, albeit focused on ventricular rather than atrial arrhythmias, is described in U.S. Pat. No. 5,113,869 ('869) to Nappholz et al. The '869 patent discloses an implantable, programmable electrocardiography (ECG) patient monitoring device that senses and analyzes ECG signals to detect ECG and physiological signal characteristics predictive of malignant cardiac arrhythmias. The monitoring device can communicate a warning signal to an external device when arrhythmias are predicted. However, the Nappholz device is limited to detecting tachycardias. Unlike requirements for automated monitoring of the consequences of atrial fibrillation, the Nappholz device focuses on rudimentary ECG signals indicative of malignant cardiac tachycardias, an already well-established technique that can be readily used with on-board signal detection techniques. Also, the Nappholz device is patient specific only and is unable to automatically take into consideration a broader patient or peer group history for reference to detect and consider the progression or improvement of cardiovascular disease. Moreover, the Nappholz device has a limited capability to automatically self-reference multiple data points in time and cannot detect disease regression even in the individual patient. In addition, the Nappholz device must be implanted and cannot function as an external monitor. Also, the Nappholz device neither monitors nor treats the cardiovascular and cardiopulmonary consequences of atrial fibrillation.

[0010] More specifically, the diagnosis and treatment of atrial fibrillation using implantable anti-arrhythmia devices has been widely addressed in the prior art and is described, for example, in U.S. Pat. No. 5,931,857 ('857) to Prieve et al. and U.S. Pat. No. 5,855,593 ('593) to Olson et al. The '857 patent discloses an implantable device which continuously monitors for tachyarrhythmia conditions and an associated patient activator. Two sets of arrhythmia detection criteria are utilized for evaluating autonomous and patient-activated anti-arrhythmia therapy. The '593 patent discloses a device capable of arrhythmia detection and classification based on a set of prioritized rules. However, both the Prieve and Olson devices are directed to diagnosing and treating the arrhythmias in isolation without detailed consideration of coexisting conditions and the cardiovascular and cardiopulmonary consequences of those disorders.

[0011] As a result, there is a need for a systematic approach to detecting trends in regularly collected physiological data indicative of the onset, progression, regression, or status quo of atrial fibrillation diagnosed and monitored using an automated, remote patient care system, such need being particularly heightened in the presence of comorbidities, such as congestive heart failure, myocardial ischemia, respiratory insufficiency, and related disorders. The physiological data could be telemetered signals data recorded either by an external or an implantable medical device or, alternatively, individual measures collected through manual means. Preferably, such an approach would be capable of diagnosing the cardiovascular and cardiopulmonary consequences of both acute and chronic atrial fibrillation conditions, as well as the symptoms of other cardiovascular diseases. In addition, findings from individual, peer group, and general population patient care records could be integrated into continuous, on-going monitoring and analysis.

SUMMARY OF THE INVENTION

[0012] The present invention provides a system and method for diagnosing and monitoring the consequences of the onset, progression, regression, and status quo of atrial fibrillation and its related pathophysiological, especially cardiovascular and cardiopulmonary, consequences using an automated collection and analysis patient care system. Measures of patient cardiovascular information are either recorded by an external or implantable medical device, such as an IPG, cardiovascular or heart failure monitor, or therapeutic device, or manually through conventional patient-operable means. The measures are collected on a regular, periodic basis for storage in a database along with other patient care records. Derived measures are developed from the stored measures. Select stored and derived measures are analyzed and changes in patient condition are logged. The logged changes are compared to quantified indicator thresholds to detect findings of reduced exercise capacity, respiratory distress, or other symptoms, including palpitations, indicative of the principal cardiovascular pathophysiological manifestations of atrial fibrillation.

[0013] An embodiment of the present invention is an automated system and method for diagnosing and monitoring the outcomes, including cardiovascular and cardiopulmonary consequences, of atrial fibrillation. A plurality of monitoring sets is retrieved from a database. Each of the monitoring sets includes recorded measures relating to patient information recorded on a substantially continuous basis. A patient status change is determined in response to an atrial fibrillation diagnosis by comparing at least one recorded measure from each of the monitoring sets to at least one other recorded measure. Both recorded measures relate to the same type of patient information. Each patient status change is tested against an indicator threshold corresponding to the same type of patient information as the recorded

measures that were compared. The indicator threshold corresponds to a quantifiable physiological measure of a pathophysiology resulting from atrial fibrillation.

[0014] A further embodiment is an automated collection and analysis patient care system and method for diagnosing and monitoring the outcomes of atrial fibrillation. A plurality of monitoring sets is retrieved from a database. Each monitoring set includes recorded measures that each relates to patient information and include either medical device measures or derived measures calculable therefrom. The medical device measures are recorded on a substantially continuous basis. A set of indicator thresholds is defined. Each indicator threshold corresponds to a quantifiable physiological measure of a pathophysiology resulting from atrial fibrillation and relates to the same type of patient information as at least one of the recorded measures. A change in patient status is determined in response to an atrial fibrillation diagnosis by comparing at least one recorded measure to at least one other recorded measure with both recorded measures relating to the same type of patient information. Each patient status change is compared to the indicator threshold corresponding to the same type of patient information as the recorded measures that were compared.

[0015] A further embodiment is an automated patient care system for diagnosing and monitoring the outcomes of atrial fibrillation and method thereof. Recorded measures organized into a monitoring set for an individual patient are stored into a database. Each recorded measure is recorded on a substantially continuous basis and relates to at least one aspect of monitoring reduced exercise capacity, respiratory distress, and palpitations/symptoms. A plurality of the monitoring sets is periodically retrieved from the database. At least one measure related to the onset, progression, regression, and status quo of atrial fibrillation and its consequences is evaluated. A patient status change is determined in response to an atrial fibrillation diagnosis by comparing at least one recorded measure from each of the monitoring sets to at least one other recorded measure with both recorded measures relating to the same type of patient information. Each patient status change is tested against an indicator threshold corresponding to the same type of patient information as the recorded measures that were compared. The indicator threshold corresponds to a quantifiable physiological measure of a pathophysiology indicative of reduced exercise capacity, respiratory distress, palpitations, syncope, near-syncope or other cardiovascular consequences of atrial fibrillation.

[0016] A further embodiment is an automated system and method for managing a pathophysiological outcome of atrial fibrillation. A plurality of monitoring sets is retrieved from a database. Each monitoring set includes recorded measures relating to patient information recorded on a substantially continuous basis. Atrial fibrillation is diagnosed. A pathophysiological outcome of atrial fibrillation is determined in response to the atrial fibrillation diagnosis. At least one recorded measure from each of the monitoring sets is compared to at least one other recorded measure with both recorded measures relating to the same type of patient information. Each recorded measure comparison is tested against an indicator threshold corresponding to the same type of patient information as the recorded measures which were compared. The indicator threshold corresponds to a quantifiable physiological measure of a pathophysiology resulting from atrial fibrillation. The atrial fibrillation outcome is managed through interventive administration of therapy contributing to normal sinus rhythm restoration and ventricular rate response control.

[0017] The present invention provides a capability to detect and track subtle trends and incremental changes in recorded patient information for diagnosing and monitoring the outcomes of atrial fibrillation. When coupled with an enrollment in a remote patient monitoring service having the capability to remotely and continuously collect and analyze external or implantable medical device measures, atrial fibrillation detection, prevention and tracking regression from therapeutic maneuvers become feasible.

[0018] 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

[0019] **FIG. 1** is a block diagram showing an automated collection and analysis patient care system for diagnosing and monitoring the outcomes of atrial fibrillation in accordance with the present invention;

[0020] **FIG. 2** is a database schema showing, by way of example, the organization of a device and derived measures set record for care of patients with atrial fibrillation stored as part of a patient care record in the database of the system of **FIG. 1**;

[0021] **FIG. 3** 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 with atrial fibrillation stored as part of a patient care record in the database of the system of **FIG. 1**;

[0022] **FIG. 4** is a database schema showing, by way of example, the organization of a combined measures set record for care of patients with atrial fibrillation stored as part of a patient care record in the database of the system of **FIG. 1**;

[0023] **FIG. 5** is a block diagram showing the software modules of the server system of the system of **FIG. 1**;

[0024] **FIG. 6** is a record view showing, by way of example, a set of partial patient care records for care of patients with atrial fibrillation stored in the database of the system of **FIG. 1**;

[0025] **FIG. 7** is a Venn diagram showing, by way of example, peer group overlap between the partial patient care records of **FIG. 6**;

[0026] FIGS. **8A-8B** are flow diagrams showing a method for diagnosing and monitoring the outcomes of atrial fibrillation using an automated collection and analysis patient care system in accordance with the present invention;

[0027] **FIG. 9** is a flow diagram showing the routine for retrieving reference baseline sets for use in the method of FIGS. **8**A-**8**B;

[0028] **FIG. 10** is a flow diagram showing the routine for retrieving monitoring sets for use in the method of FIGS. **8**A-**8**B;

[0029] FIGS. **11**A-**11**D are flow diagrams showing the routine for testing threshold limits for use in the method of FIGS. **8**A-**8**B;

[0030] FIGS. **12**A-**12**B are flow diagrams showing the routine for evaluating the consequences of the onset, progression, regression, and status quo associated with atrial fibrillation for use in the method of FIGS. **8**A-**8**B;

[0031] FIGS. **13**A-**13**B are flow diagrams showing the routine for categorizing an onset of atrial fibrillation for use in the routine of FIGS. **12**A-**12**B;

[0032] FIGS. **14**A-**14**B are flow diagrams showing the routine for categorizing a progression or worsening of atrial fibrillation for use in the routine of FIGS. **12**A-**12**B;

[0033] FIGS. **15**A-**15**B are flow diagrams showing the routine for categorizing a regression or improving of atrial fibrillation **227** and its cardiovascular and cardiopulmonary consequences for use in the routine of FIGS. **12**A-**12**B;

[0034] **FIG. 16** is a flow diagram showing the routine for determining threshold stickiness ("hysteresis") for use in the method of FIGS. **12**A-**12**B;

[0035] FIGS. **17**A-**17**B is a flow diagram showing the routine for managing the consequences of atrial fibrillation for use in the routine of FIGS. **12**A-**12**B;

[0036] FIGS. **18**A-**18**D are flow diagrams showing the routine for managing a cardiovascular/cardiopulmonary compromise for use in the method of FIGS. **17**A-**17**B;

[0037] **FIG. 19** is a flow diagram showing the routine for managing ventricular rate response for use in the method of FIGS. **17**A-**17**B;

[0038] **FIG. 20** is a flow diagram showing the routine for managing anticoagulation for use in the method of FIGS. **17**A-**17**B; and

[0039] **FIG. 21** is a flow diagram showing the routine for managing palpitations for use in the method of FIGS. **17**A-**17**B.

DETAILED DESCRIPTION

[0040] **FIG. 1** is a block diagram showing an automated collection and analysis patient care system **10** for diagnosing and monitoring the outcomes of atrial fibrillation in accordance with the present invention. An exemplary automated collection and analysis patient care system suitable for use with the present invention is disclosed in the related, commonly-owned U.S. patent application Ser. No. 09/324,894, pending, filed Jun. 3, 1999, the disclosure of which is incorporated herein by reference. Preferably, an individual patient **11** is a recipient of an implantable medical device **12**, such as, by way of example, an IPG, cardiovascular or heart failure monitor, or therapeutic device, with a set of leads extending into his or her heart and electrodes implanted throughout the cardiopulmonary system. In the described embodiment, an implantable anti-arrhythmia device capable of diagnosing and treating arrhythmias can be used, such as disclosed in U.S. Pat. No. 5,931,857 to Prieve et al. and U.S. Pat. No. 5,855,593 to Olson et al. Alternatively, an external monitoring or therapeutic medical device **26**, a subcutaneous monitor or device inserted into other organs, a cutaneous monitor, or even a manual physiological measurement device, such as an electrocardiogram or heart rate monitor, could be used. The implantable medical device **12** and external medical device **26** include circuitry for recording into a short-term, volatile memory telemetered signals stored for later retrieval, which become part of a set of device and derived measures, such as described below, by way of example, with reference to **FIG. 2**. Exemplary implantable medical devices suitable for use in the present invention include the Discovery line of pacemakers, manufactured by Guidant Corporation, Indianapolis, Ind., and the Gem line of ICDs, manufactured by Medtronic Corporation, Minneapolis, Minn.

[0041] The telemetered signals stored in the implantable medical device **12** are preferably retrieved upon the completion of an initial observation period and subsequently thereafter on a continuous, periodic (daily) basis, such as described in the related, commonly-owned U.S. patent application, Ser. No. 09/361,332, pending, filed Jul. 26, 1999, the disclosure of which is incorporated herein by reference. A programmer **14**, personal computer **18**, or similar device for communicating with an implantable medical device **12** can be used to retrieve the telemetered signals. A magnetized reed switch (not shown) within the implantable medical device **12** closes in response to the placement of a wand **13** over the site of the implantable medical device **12**. The programmer **14** sends programming or interrogating instructions to and retrieves stored telemetered signals from the implantable medical device **12** via RF signals exchanged through the wand **13**. Similar communication means are used for accessing the external medical device **26**. Once downloaded, the telemetered signals are sent via an internetwork **15**, such as the Internet, to a server system **16** which periodically receives and stores the telemetered signals as device measures in patient care records **23** in a database **17**, as further described below, by way of example, with reference to **FIGS. 2 and 3**. An exemplary programmer **14** suitable for use in the present invention is the Model 2901 Programmer Recorder Monitor, manufactured by Guidant Corporation, Indianapolis, Ind.

[0042] The patient **11** is remotely monitored by the server system **16** via the internetwork **15** through the periodic receipt of the retrieved device measures from the implantable medical device **12** or external medical device **26**. The patient care records **23** in the database **17** are organized into two identified sets of device measures: an optional reference baseline **26** recorded during an initial observation period and monitoring sets **27** recorded subsequently thereafter. The device measures sets are periodically analyzed and compared by the server system **16** to indicator thresholds corresponding to quantifiable physiological measures of a pathophysiology resulting from atrial fibrillation and any related comorbidities, as further described below with reference to **FIG. 5**. As necessary, feedback is provided to the patient **11**. By way of example, the feedback includes an electronic mail message automatically sent by the server system **16** over the internetwork **15** to a personal computer **18** (PC) situated for local access by the patient **11**. Alternatively, the feedback can be sent through a telephone interface

device **19** as an automated voice mail message to a telephone **21** or as an automated facsimile message to a facsimile machine **22**, both also situated for local access by the patient **11**. Moreover, simultaneous notifications can also be delivered to the patient's physician, hospital, or emergency medical services provider **29** using similar feedback means to deliver the information.

[**0043**] The server system **10** can consist of either a single computer system or a cooperatively networked or clustered set of computer systems. Each computer system is a general purpose, programmed digital computing device consisting of a central processing unit (CPU), random access memory (RAM), non-volatile secondary storage, such as a hard drive or CD ROM drive, network interfaces, and peripheral devices, including user interfacing means, such as a keyboard and display. Program code, including software programs, and data are loaded into the RAM for execution and processing by the CPU and results are generated for display, output, transmittal, or storage, as is known in the art.

[**0044**] The database **17** stores patient care records **23** for each individual patient to whom remote patient care is being provided. Each patient care record **23** contains normal patient identification and treatment profile information, as well as medical history, medications taken, height and weight, and other pertinent data (not shown). The patient care records **23** consist primarily of two sets of data: device and derived measures (D&DM) sets **24***a,* **24***b* and quality of life (QOL) and symptom measures sets **25***a,* **25***b,* the organization of which are further described below with respect to **FIGS. 2 and 3**, respectively. The device and derived measures sets **24***a,* **24***b* and quality of life and symptom measures sets **25***a,* **25***b* can be further logically categorized into two potentially overlapping sets. The reference baseline **26** is a special set of device and derived reference measures sets **24***a* and quality of life and symptom measures sets **25***a* recorded and determined during an initial observation period. Monitoring sets **27** are device and derived measures sets **24***b* and quality of life and symptom measures sets **25***b* recorded and determined thereafter on a regular, continuous basis. Other forms of database organization are feasible.

[**0045**] The implantable medical device **12** and, in a more limited fashion, the external medical device **26**, record patient information for care of patients with atrial fibrillation on a regular basis. The recorded patient information is downloaded and stored in the database **17** as part of a patient care record **23**. Further patient information can be derived from recorded data, as is known in the art. **FIG. 2** is a database schema showing, by way of example, the organization of a device and derived measures set record **40** for patient care stored as part of a patient care record in the database **17** of the system of **FIG. 1**. Each record **40** stores patient information which includes a snapshot of telemetered signals data which were recorded by the implantable medical device **12** or the external medical device **26**, for instance, on per heartbeat, binned average or derived bases; measures derived from the recorded device measures; and manually collected information, such as obtained through a patient medical history interview or questionnaire. The following non-exclusive information can be recorded for a patient: atrial electrical activity **41**, ventricular electrical activity **42**, PR interval or AV interval **43**, QRS measures **44**, ST-T wave measures **45**, QT interval **46**, body temperature **47**, patient activity score **48**, posture **49**, cardiovascular pressures **50**, pulmonary artery diastolic pressure measure **51**, cardiac output **52**, systemic blood pressure **53**, patient geographic location and location (altitude) **54**, mixed venous oxygen score **55**, arterial oxygen score **56**, pulmonary measures **57**, minute ventilation **58**, potassium [K+] level **59**, sodium [Na+] level **60**, glucose level **61**, blood urea nitrogen (BUN) and creatinine **62**, acidity (pH) level **63**, hematocrit **64**, hormonal levels **65**, cardiac injury chemical tests **66**, myocardial blood flow **67**, central nervous system (CNS) injury chemical tests **68**, central nervous system blood flow **69**, interventions made by the implantable medical device or external medical device **70**, and the relative success of any interventions made **71**. In addition, the implantable medical device or external medical device communicates device-specific information, including battery status, general device status and program settings **72** and the time of day **73** for the various recorded measures. Other types of collected, recorded, combined, or derived measures are possible, as is known in the art.

[**0046**] The device and derived measures sets **24***a,* **24***b* (shown in **FIG. 1**), along with quality of life and symptom measures sets **25***a,* **25***b,* as further described below with reference to **FIG. 3**, are continuously and periodically received by the server system **16** as part of the on-going patient care monitoring and analysis function. These regularly collected data sets are collectively categorized as the monitoring sets **27** (shown in **FIG. 1**). In addition, select device and derived measures sets **24***a* and quality of life and symptom measures sets **25***a* can be designated as a reference baseline **26** at the outset of patient care to improve the accuracy and meaningfulness of the serial monitoring sets **27**. Select patient information is collected, recorded, and derived during an initial period of observation or patient care, such as described in the related, commonly-owned U.S. patent application, Ser. No. 09/361,332, pending, filed Jul. 26, 1999, the disclosure of which is incorporated herein by reference.

[**0047**] As an adjunct to remote patient care through the monitoring of measured physiological data via the implantable medical device **12** or external medical device **26**, quality of life and symptom measures sets **25***a* can also be stored in the database **17** as part of the reference baseline **26**, if used, and the monitoring sets **27**. A quality of life measure is a semi-quantitative self-assessment of an individual patient's physical and emotional well-being and a record of symptoms, such as provided by the Duke Activities Status Indicator. These scoring systems can be provided for use by the patient **11** on the personal computer **18** (shown in **FIG. 1**) to record his or her quality of life scores for both initial and periodic download to the server system **16**. **FIG. 3** is a database schema showing, by way of example, the organization of a quality of life record **80** for use in the database **17**. The following information is recorded for a patient: overall health wellness **81**, psychological state **82**, activities of daily living **83**, work status **84**, geographic location **85**, family status **86**, shortness of breath **87**, energy level **88**, exercise tolerance **89**, chest discomfort **90**, palpitations **91**, syncope **92**, near syncope **93**, time of day **94**, and other quality of life and symptom measures as would be known to one skilled in the art.

[**0048**] 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.

[0049] The patient may also add non-device quantitative measures, such as the six-minute walk distance, as complementary data to the device and derived measures sets **24***a*, **24***b* and the symptoms associated with the six minute walk to the quality of life and symptom measures sets **25***a*, **25***b*.

[0050] On a periodic basis, the patient information stored in the database **17** is analyzed and compared to pre-determined cutoff levels, which, when exceeded, can provide etiological indications of atrial fibrillation symptoms. **FIG. 4** is a database schema showing, by way of example, the organization of a combined measures set record **95** for use in the database **17**. Each record **95** stores patient information obtained or derived from the device and derived measures sets **24***a*, **24***b* and quality of life and symptom measures sets **25***a*, **25***b* as maintained in the reference baseline **26**, if used, and the monitoring sets **27**. The combined measures set **95** represents those measures most (but not exhaustively or exclusively) relevant to a pathophysiology resulting from atrial fibrillation and are determined as further described below with reference to FIGS. **8A-8B**. The following information is stored for a patient: heart rate **96**, heart rhythm (e.g., normal sinus vs. atrial fibrillation) **97**, pacing modality **98**, pulmonary artery diastolic pressure **99**, cardiac output **100**, arterial oxygen score **101**, mixed venous oxygen score **102**, respiratory rate **103**, transthoracic impedance **104**, patient activity score **105**, posture **106**, exercise tolerance quality of life and symptom measures **107**, respiratory distress quality of life and symptom measures **108**, palpitations quality of life measures **109**, syncope/near syncope quality of life measures **110**, any interventions made to treat atrial fibrillation **111**, including treatment by medical device, via drug infusion administered by the patient or by a medical device, surgery, and any other form of medical intervention as is known in the art, the relative success of any such interventions made **112**, and date and time of day **113**. Other types of comparison measures regarding atrial fibrillation are possible as is known in the art. In the described embodiment, each combined measures set **95** is sequentially retrieved from the database **17** and processed. Alternatively, each combined measures set **95** could be stored within a dynamic data structure maintained transitorily in the random access memory of the server system **16** during the analysis and comparison operations. **FIG. 5** is a block diagram showing the software modules of the server system **16** of the system **10** of **FIG. 1**. Each module is a computer program written as source code in a conventional programming language, such as the C or Java programming languages, and is presented for execution by the CPU of the server system **16** as object or byte code, as is known in the art. The various implementations of the source code and object and byte codes can be held on a computer-readable storage medium or embodied on a transmission medium in a carrier wave. The server system **16** includes three primary software modules, database module **125**, diagnostic module **126**, and feedback module **128**, which perform integrated functions as follows.

[0051] First, the database module **125** organizes the individual patient care records **23** stored in the database **17** (shown in **FIG. 1**) and efficiently stores and accesses the reference baseline **26**, monitoring sets **27**, and patient care data maintained in those records. Any type of database organization could be utilized, including a flat file system, hierarchical database, relational database, or distributed database, such as provided by database vendors, such as Oracle Corporation, Redwood Shores, Calif.

[0052] Next, the diagnostic module **126** makes findings of atrial fibrillation and attendant cardiovascular consequences through the implantable medical device **12** and, in a more limited fashion, the external medical device **26**, and categorizes the findings into reduced exercise capacity-, respiratory distress-, palpitations-, and syncope/near syncope-related atrial fibrillation based on the comparison and analysis of the data measures from the reference baseline **26** and monitoring sets **27**. The diagnostic module includes three modules: comparison module **130**, analysis module **131**, and quality of life module **132**. The comparison module **130** compares recorded and derived measures retrieved from the reference baseline **26**, if used, and monitoring sets **27** to indicator thresholds **129**. The database **17** stores individual patient care records **23** for patients suffering from various health disorders and diseases for which they are receiving remote patient care. For purposes of comparison and analysis by the comparison module **130**, these records can be categorized into peer groups containing the records for those patients suffering from similar disorders, as well as being viewed in reference to the overall patient population. The definition of the peer group can be progressively refined as the overall patient population grows. To illustrate, **FIG. 6** is a record view showing, by way of example, a set of partial patient care records for care of patients with atrial fibrillation stored in the database **17** for three patients, Patient 1, Patient 2, and Patient 3. For each patient, three sets of peer measures, X, Y, and Z, are shown. Each of the measures, X, Y, and Z, could be either collected or derived measures from the reference baseline **26**, if used, and monitoring sets **27**.

[0053] The same measures are organized into time-based sets with Set **0** representing sibling measures made at a reference time t=0. Similarly, Set n−2, Set n−1 and Set n each represent sibling measures made at later reference times t=n−2, t=n−1 and t=n, respectively. Thus, for a given patient, such as Patient 1, serial peer measures, such as peer measure X_0 through X_n, represent the same type of patient information monitored over time. The combined peer measures for all patients can be categorized into a health disorder- or disease-matched peer group. The definition of disease-matched peer group is a progressive definition, refined over time as the number of monitored patients grows. Measures representing different types of patient information, such as measures X_0, Y_0, and Z_0, are sibling measures. These are measures which are also measured over time, but which might have medically significant meaning when compared to each other within a set for an individual patient.

[0054] The comparison module **130** performs two basic forms of comparison. First, individual measures for a given patient can be compared to other individual measures for

that same patient (self-referencing). These comparisons might be peer-to-peer measures, that is, measures relating to a one specific type of patient information, projected over time, for instance, X_n, X_{n-1}, X_{n-2}, . . . X_0, or sibling-to-sibling measures, that is, measures relating to multiple types of patient information measured during the same time period, for a single snapshot, for instance, X_n, Y_n, and Z_n, or projected over time, for instance, X_n, Y_n, Z_n, X_{n-1}, Y_{n-1}, Z_{n-1}, X_{n-2}, Y_{n-2}, Z_{n-2}, . . . X_0, Y_0, Z_0. Second, individual measures for a given patient can be compared to other individual measures for a group of other patients sharing the same disorder- or disease-specific characteristics (peer group referencing) or to the patient population in general (population referencing). Again, these comparisons might be peer-to-peer measures projected over time, for instance, X_n, $X_{n'}$, $X_{n''}$, X_{n-1}, $X_{n-1'}$, $X_{n-1''}$, X_{n-2}, $X_{n-2'}$, $X_{n-2''}$, . . . X_0, $X_{0'}$, $X_{0''}$, or comparing the individual patient's measures to an average from the group. Similarly, these comparisons might be sibling-to-sibling measures for single snapshots, for instance, X_n, $X_{n'}$, $X_{n''}$, Y_n, $Y_{n'}$, $Y_{n''}$, and Z_n, $Z_{n'}$, $Z_{n''}$, or projected over time, for instance, X_n, $X_{n'}$, $X_{n''}$, Y_n, $Y_{n'}$, $Y_{n''}$, Z_n, $Z_{n'}$, $Z_{n''}$, X_{n-1}, $X_{n-1'}$, $X_{n-1''}$, Y_{n-1}, $Y_{n-1'}$, $Y_{n-1''}$, Z_{n-1}, $Z_{n-1'}$, $Z_{n-1''}$, X_{n-2}, $X_{n-2'}$, $X_{n-2''}$, Y_{n-2}, $Y_{n-2'}$, $Y_{n-2''}$, Z_{n-2}, $Z_{n-2'}$, $Z_{n-2''}$. . . X_0, $X_{0'}$, $X_{0''}$, Y_0, $Y_{0'}$, $Y_{0''}$, and Z_0, $Z_{0'}$, $Z_{0''}$, Other forms of comparisons are feasible, including multiple disease diagnoses for diseases exhibiting similar abnormalities in physiological measures that might result from a second disease but manifest in different combinations or onset in different temporal sequences.

[**0055**] **FIG. 7** is a Venn diagram showing, by way of example, peer group overlap between the partial patient care records **23** of **FIG. 1**. Each patient care record **23** includes characteristics data **350**, **351**, **352**, including personal traits, demographics, medical history, and related personal data, for patients 1, 2 and 3, respectively. For example, the characteristics data **350** for patient 1 might include personal traits which include gender and age, such as male and an age between 40-45; a demographic of resident of New York City; and a medical history consisting of anterior myocardial infraction, paroxysmal atrial fibrillation and diabetes. Similarly, the characteristics data **351** for patient 2 might include identical personal traits, thereby resulting in partial overlap **353** of characteristics data **350** and **351**. Similar characteristics overlap **354**, **355**, **356** can exist between each respective patient. The overall patient population **357** would include the universe of all characteristics data. As the monitoring population grows, the number of patients with personal traits matching those of the monitored patient will grow, increasing the value of peer group referencing. Large peer groups, well matched across all monitored measures, will result in a well known natural history of disease and will allow for more accurate prediction of the clinical course of the patient being monitored. If the population of patients is relatively small, only some traits **356** will be uniformly present in any particular peer group. Eventually, peer groups, for instance, composed of 100 or more patients each, would evolve under conditions in which there would be complete overlap of substantially all salient data, thereby forming a powerful core reference group for any new patient being monitored.

[**0056**] Referring back to **FIG. 5**, the analysis module **131** analyzes the results from the comparison module **130**, which are stored as a combined measures set **95** (not shown), to a set of indicator thresholds **129**, as further described below with reference to FIGS. **8A-8B**. Similarly, the quality of life module **132** compares quality of life and symptom measures set **25***a*, **25***b* from the reference baseline **26** and monitoring sets **27**, the results of which are incorporated into the comparisons performed by the analysis module **131**, in part, to either refute or support the findings based on physiological "hard" data. Finally, the feedback module **128** provides automated feedback to the individual patient based, in part, on the patient status indicator **127** generated by the diagnostic module **126**. As described above, the feedback could be by electronic mail or by automated voice mail or facsimile. The feedback can also include normalized voice feedback, such as described in the related, commonly-owned U.S. patent application, Ser. No. 09/361,777, pending, filed Jul. 26, 1999, the disclosure of which is incorporated herein by reference. In addition, the feedback module **128** determines whether any changes to interventive measures are appropriate based on threshold stickiness ("hysteresis") **133**, as further described below with reference to **FIG. 16**. The threshold stickiness **133** can prevent fickleness in diagnostic routines resulting from transient, non-trending and non-significant fluctuations in the various collected and derived measures in favor of more certainty in diagnosis. In a further embodiment of the present invention, the feedback module **128** includes a patient query engine **134** which enables the individual patient 11 to interactively query the server system **16** regarding the diagnosis, therapeutic maneuvers, and treatment regimen. Conversely, the patient query engines **134**, found in interactive expert systems for diagnosing medical conditions, can interactively query the patient. Using the personal computer **18** (shown in **FIG. 1**), the patient can have an interactive dialogue with the automated server system **16**, as well as human experts as necessary, to self assess his or her medical condition. Such expert systems are well known in the art, an example of which is the MYCIN expert system developed at Stanford University and described in Buchanan, B. & Shortlife, E., "RULE-BASED EXPERT SYSTEMS. The MYCIN Experiments of the Stanford Heuristic Programming Project," Addison-Wesley (1984). The various forms of feedback described above help to increase the accuracy and specificity of the reporting of the quality of life and symptomatic measures.

[**0057**] FIGS. **8A-8B** are flow diagrams showing a method for diagnosing and monitoring the outcomes of atrial fibrillation **135** using an automated collection and analysis patient care system **10** in accordance with the present invention. First, the indicator thresholds **129** (shown in **FIG. 5**) are set (block **136**) by defining a quantifiable physiological measure of a pathophysiology resulting from atrial fibrillation and relating to each type of patient information in the combined device and derived measures set **95** (shown in **FIG. 4**). The actual values of each indicator threshold can be finite cutoff values, weighted values, or statistical ranges, as discussed below with reference to FIGS. **11A-11D**. Next, the reference baseline **26** (block **137**) and monitoring sets **27** (block **138**) are retrieved from the database **17**, as further described below with reference to **FIGS. 9 and 10**, respectively. Each measure in the combined device and derived measures set **95** is tested against the threshold limits defined for each indicator threshold **129** (block **139**), as further described below with reference to FIGS. **11A-11D**. The potential onset, progression (where progression of atrial fibrillation is defined as a ventricular rate increase and/or a deterioration in physiological cardiovascular and cardiopulmonary mea-

sures regardless of rate change), regression (where regression of atrial fibrillation is defined as its offset, a decrease in ventricular rate, and/or an improvement in cardiovascular and cardiopulmonary physiological measures), or status quo of atrial fibrillation is then evaluated (block **140**) based upon the findings of the threshold limits tests (block **139**), as further described below with reference to FIGS. **13**A-**13**B, **14**A-**14**B, **15**A-**15**B.

[**0058**] In a further embodiment, multiple near-simultaneous disorders are considered in addition to primary atrial fibrillation. Primary atrial fibrillation is defined as the onset or progression of atrial fibrillation without obvious inciting identifiable cause. Secondary atrial fibrillation is defined as the onset or progression of atrial fibrillation (in a patient with or without a history of previously documented atrial fibrillation) from another disease process, such as congestive heart failure, myocardial ischemia, coronary insufficiency, respiratory insufficiency, specific identifiable electrophysiological abnormalities, and so forth. Other health disorders and diseases can potentially share the same forms of symptomatology as atrial fibrillation, such as myocardial ischemia, respiratory insufficiency, pneumonia, exacerbation of chronic bronchitis, renal failure, sleep-apnea, stroke, anemia, other cardiac arrhythmias, and so forth. If more than one abnormality is present, the relative sequence and magnitude of onset of abnormalities in the monitored measures becomes most important in sorting and prioritizing disease diagnosis and treatment.

[**0059**] Thus, if other disorders or diseases are being cross-referenced and diagnosed (block **141**), their status is determined (block **142**). In the described embodiment, the operations of ordering and prioritizing multiple near-simultaneous disorders (box **151**) by the testing of threshold limits and analysis in a manner similar to congestive heart failure as described above, preferably in parallel to the present determination, is described in the related, commonly-owned U.S. patent application, Ser. No. _____, entitled "Automated Collection And Analysis Patient Care System And Method For Ordering And Prioritizing Multiple Health Disorders To Identify An Index Disorder," pending, filed Nov. 16, 1999, the disclosure of which is incorporated herein by reference. If atrial fibrillation is due to an obvious inciting cause, i.e., secondary atrial fibrillation, (block **143**), an appropriate treatment regimen is adopted that includes treatment of secondary disorders, e.g., myocardial ischemia, respiratory insufficiency, and so forth (block **144**), as well as atrial fibrillation if needed, and a suitable patient status indicator **127** for atrial fibrillation is provided (block **146**) to the patient indicating diagnosis and management recommendations for both atrial fibrillation and inciting causes. Suitable devices and approaches to diagnosing and treating congestive heart failure, myocardial infarction, and respiratory insufficiency are described in related, commonly-owned U.S. patent applications, Ser. No. _____, entitled "Automated Collection And Analysis Patient Care System And Method For Diagnosing And Monitoring Congestive Heart Failure And Outcomes Thereof," pending, filed Nov. 16, 1999; Ser. No. _____,entitled "Automated Collection And Analysis Patient Care System And Method For Diagnosing And Monitoring Myocardial Ischemia And Outcomes Thereof," pending, filed Nov. 16, 1999; and Ser. No. _____, entitled "Automated Collection And Analysis Patient Care System And Method For Diagnosing And Monitoring Respiratory Insufficiency And Outcomes Thereof," pending, filed Nov. 16, 1999, the disclosures of which are incorporated herein by reference.

[**0060**] Otherwise, if primary atrial fibrillation is indicated (block **143**), a primary treatment regimen is followed (block **145**). A patient status indicator **127** for atrial fibrillation is provided (block **146**) to the patient regarding physical well-being, disease prognosis, including any determinations of disease onset, progression, regression, or status quo, and other pertinent medical and general information of potential interest to the patient.

[**0061**] Finally, in a further embodiment, if the patient submits a query to the server system **16** (block **147**), the patient query is interactively processed by the patient query engine (block **148**). Similarly, if the server elects to query the patient (block **149**), the server query is interactively processed by the server query engine (block **150**). The method then terminates if no further patient or server queries are submitted.

[**0062**] **FIG. 9** is a flow diagram showing the routine for retrieving reference baseline sets **137** for use in the method of FIGS. **8**A-**8**B. The purpose of this routine is to retrieve the appropriate reference baseline sets **26**, if used, from the database **17** based on the types of comparisons being performed. First, if the comparisons are self referencing with respect to the measures stored in the individual patient care record **23** (block **152**), the reference device and derived measures set **24***a* and reference quality of life and symptom measures set **25***a*, if used, are retrieved for the individual patient from the database **17** (block **153**). Next, if the comparisons are peer group referencing with respect to measures stored in the patient care records **23** for a health disorder- or disease-specific peer group (block **154**), the reference device and derived measures set **24***a* and reference quality of life and symptom measures set **25***a*, if used, are retrieved from each patient care record **23** for the peer group from the database **17** (block **155**). Data for each measure (e.g., minimum, maximum, averaged, standard deviation (SD), and trending data) from the reference baseline **26** for the peer group is then calculated (block **156**). Finally, if the comparisons are population referencing with respect to measures stored in the patient care records **23** for the overall patient population (block **157**), the reference device and derived measures set **24***a* and reference quality of life and symptom measures set **25***a*, if used, are retrieved from each patient care record **23** from the database **17** (block **158**). Minimum, maximum, averaged, standard deviation, and trending data and other numerical processes using the data, as is known in the art, for each measure from the reference baseline **26** for the peer group is then calculated (block **159**). The routine then returns.

[**0063**] **FIG. 10** is a flow diagram showing the routine for retrieving monitoring sets **138** for use in the method of FIGS. **8**A-**8**B. The purpose of this routine is to retrieve the appropriate monitoring sets **27** from the database **17** based on the types of comparisons being performed. First, if the comparisons are self referencing with respect to the measures stored in the individual patient care record **23** (block **160**), the device and derived measures set **24***b* and quality of life and symptom measures set **25***b*, if used, are retrieved for the individual patient from the database **17** (block **161**). Next, if the comparisons are peer group referencing with respect to measures stored in the patient care records **23** for

a health disorder- or disease-specific peer group (block **162**), the device and derived measures set **24***b* and quality of life and symptom measures set **25***b*, if used, are retrieved from each patient care record **23** for the peer group from the database **17** (block **163**). Data for each measure (e.g., minimum, maximum, averaged, standard deviation, and trending data) from the monitoring sets **27** for the peer group is then calculated (block **164**). Finally, if the comparisons are population referencing with respect to measures stored in the patient care records **23** for the overall patient population (block **165**), the device and derived measures set **24***b* and quality of life and symptom measures set **25***b*, if used, are retrieved from each patient care record **23** from the database **17** (block **166**). Minimum, maximum, averaged, standard deviation, and trending data and other numerical processes using the data, as is known in the art, for each measure from the monitoring sets **27** for the peer group is then calculated (block **167**). The routine then returns.

[**0064**] FIGS. **11A-11D** are flow diagrams showing the routine for testing threshold limits **139** for use in the method of **FIG. 8A and 8B**. The purpose of this routine is to analyze, compare, and log any differences between the observed, objective measures stored in the reference baseline **26**, if used, and the monitoring sets **27** to the indicator thresholds **129**. Briefly, the routine consists of tests pertaining to each of the indicators relevant to diagnosing and monitoring the outcomes of atrial fibrillation and cardiovascular consequences. The threshold tests focus primarily on: (1) changes to and rates of change for the indicators themselves, as stored in the combined device and derived measures set **95** (shown in **FIG. 4**) or similar data structure; and (2) violations of absolute threshold limits which trigger an alert. The timing and degree of change may vary with each measure and with the natural fluctuations noted in that measure during the reference baseline period. In addition, the timing and degree of change might also vary with the individual and the natural history of a measure for that patient.

[**0065**] One suitable approach to performing the threshold tests uses a standard statistical linear regression technique using a least squares error fit. The least squares error fit can be calculated as follows:

$$y=\beta_0+\beta_1 x \tag{1}$$

[**0066**]

$$\beta = \frac{SS_{xy}}{SS_{xx}} \tag{2}$$

$$SS_{xy} = \sum_{i=1}^{n} x_i y_i - \frac{\left(\sum_{i=1}^{n} x_i\right)\left(\sum_{i=1}^{n} y_i\right)}{n} \tag{3}$$

$$SS_{xx} = \sum_{i=1}^{n} x_i^2 - \frac{\left(\sum_{i=1}^{n} x_i\right)^2}{n} \tag{4}$$

[**0067**] where n is the total number of measures, x_i is the time of day for measure i, and y_i is the value of measure i, β_1 is the slope, and β_0 is the y-intercept of the least squares error line. A positive slope β_1 indicates an increasing trend, a negative slope β_1 indicates a decreasing trend, and no slope indicates no change in patient condition for that particular measure. A predicted measure value can be calculated and compared to the appropriate indicator threshold **129** for determining whether the particular measure has either exceeded an acceptable threshold rate of change or the absolute threshold limit.

[**0068**] For any given patient, three basic types of comparisons between individual measures stored in the monitoring sets **27** are possible: self referencing, peer group, and general population, as explained above with reference to **FIG. 6**. In addition, each of these comparisons can include comparisons to individual measures stored in the pertinent reference baselines **24**.

[**0069**] The indicator thresholds **129** for detecting a trend indicating an adverse consequence of atrial fibrillation or a state of imminent or likely cardiovascular or cardiopulmonary deterioration, for example, over a one week time period, can be as follows:

[**0070**] (1) Heart rate (block **170**): If the ventricular heart rate during atrial fibrillation has increased over 1.0 SD from the mean heart rate in the reference baseline **26**, if used (block **171**), the increased ventricular heart rate and time span over which it occurs are logged in the combined measures set **95** (block **172**).

[**0071**] (2) Respiratory rate (block **173**): If the respiratory rate has increased over 1.0 SD from the mean respiratory rate in the reference baseline **26**, if used (block **174**), the increased respiratory rate and time span over which it occurs are logged in the combined measures set **95** (block **175**).

[**0072**] (3) Pulmonary artery diastolic pressure (PADP) (block **176**) reflects left ventricular filling pressure and is a measure of left ventricular dysfunction. Ideally, the left ventricular end diastolic pressure (LVEDP) should be monitored, but in practice is difficult to measure. Consequently, without the LVEDP, the PADP, or derivatives thereof, is suitable for use as an alternative to LVEDP in the present invention. If the PADP has increased over 1.0 SD from the mean PADP in the reference baseline **26** (block **177**), the increased PADP and time span over which that increase occurs, are logged in the combined measures set **95** (block **178**). Other cardiac pressures or derivatives could also apply.

[**0073**] (4) Transthoracic impedance (block **179**): If the transthoracic impedance has decreased over 1.0 SD from the mean transthoracic impedance in the reference baseline **26** (block **180**), the decreased transthoracic impedance and time span are logged in the combined measures set **95** (block **181**).

[**0074**] (5) Arterial oxygen score (block **182**): If the arterial oxygen score has decreased over 1.0 SD from the arterial oxygen score in the reference baseline **26** (block **183**), the decreased arterial oxygen score and time span are logged in the combined measures set **95** (block **184**).

[**0075**] (6) Venous oxygen score (block **185**): If the venous oxygen score has decreased over 1.0 SD

from the mean venous oxygen score in the reference baseline **26** (block **186**), the decreased venous oxygen score and time span are logged in the combined measures set **95** (block **187**).

[**0076**] (7) Cardiac output (block **188**): If the cardiac output has decreased over 1.0 SD from the mean cardiac output in the reference baseline **26** (block **189**), the decreased cardiac output and time span are logged in the combined measures set **95** (block **190**).

[**0077**] (8) Patient activity score (block **191**): If the mean patient activity score has decreased over 1.0 SD from the mean patient activity score in the reference baseline **26** (block **192**), the decreased patient activity score and time span are logged in the combined measures set **95** (block **193**).

[**0078**] (9) Exercise tolerance quality of life (QOL) measures (block **194**): If the exercise tolerance QOL has decreased over 1.0 SD from the mean exercise tolerance in the reference baseline **26** (block **195**), the decrease in exercise tolerance and the time span over which it occurs are logged in the combined measures set **95** (block **196**).

[**0079**] (10) Respiratory distress quality of life (QOL) measures (block **197**): If the respiratory distress QOL measure has deteriorated by more than 1.0 SD from the mean respiratory distress QOL measure in the reference baseline **26** (block **198**), the increase in respiratory distress and the time span over which it occurs are logged in the combined measures set **95** (block **199**).

[**0080**] (11) Atrial fibrillation (block **200**): The presence or absence of atrial fibrillation (AF) is determined and, if present (block **201**), atrial fibrillation is logged (block **202**).

[**0081**] (12) Rhythm changes (block **203**): The type and sequence of rhythm changes is significant and is determined based on the timing of the relevant rhythm measure, such as sinus rhythm. For instance, a finding that a rhythm change to atrial fibrillation precipitated circulatory measures changes can indicate therapy directions against atrial fibrillation rather than primary progression of atrial fibrillation. Thus, if there are rhythm changes (block **204**), the sequence of the rhythm changes and time span are logged (block **205**).

[**0082**] Note also that an inversion of the indicator thresholds **129** defined above could similarly be used for detecting a trend in disease regression. One skilled in the art would recognize that these measures would vary based on whether or not they were recorded during rest or during activity and that the measured activity score can be used to indicate the degree of patient rest or activity. The patient activity score can be determined via an implantable motion detector, for example, as described in U.S. Pat. No. 4,428,378, issued Jan. 31, 1984, to Anderson et al., the disclosure of which is incorporated herein by reference.

[**0083**] FIGS. **12A-12B** are flow diagrams showing the routine for evaluating the onset, progression, regression and status quo of atrial fibrillation **140** for use in the method of **FIGS. 8A and 8B**. The purpose of this routine is to evaluate the presence of sufficient indicia to warrant a diagnosis of the onset, progression, regression, and status quo of atrial fibrillation and the consequential changes, if any, of comorbid disorders. Quality of life and symptom measures set **25** can be included in the evaluation (block **220**) by determining whether any of the individual quality of life and symptom measures set **25** have changed relative to the previously collected quality of life and symptom measures from the monitoring sets **27** and the reference baseline **26**, if used. For example, a deterioration in the shortness of breath measure **87** and exercise tolerance measure **89** would corroborate a finding of atrial fibrillation exacerbating cardiovascular or cardiopulmonary measures. Similarly, a transition from NYHA Class II to NYHA Class III would indicate a deterioration or, conversely, a transition from NYHA Class III to NYHA Class II status would indicate improvement or progress. Incorporating the quality of life and symptom measures set **25** into the evaluation can help, in part, to refute or support findings based on physiological data. Next, a determination as to whether any changes to interventive measures are appropriate based on threshold stickiness ("hysteresis") is made (block **221**), as further described below with reference to **FIG. 16**.

[**0084**] The routine returns upon either the determination of a finding or elimination of all factors as follows. A diagnosis of atrial fibrillation is made (block **222**) via one of many methods known in the art through the implantable medical device **12** and, in a more limited fashion, via the external medical device **26**, such as described in U.S. Pat. No. 5,931,857 ('857) to Prieve et al. and U.S. Pat. No. 5,855,593 ('593) to Olson et al, the disclosures of which are incorporated herein by reference. If atrial fibrillation has occurred (block **223**), the findings are categorized into reduced exercise capacity-, respiratory distress-palpitations-, and syncope-/near syncope-related atrial fibrillation as follows. First, if a finding of atrial fibrillation was not previously diagnosed (block **224**), a determination categorizing disease onset is made (block **225**), as further described below with reference to FIGS. **13A-13B**. Otherwise, if atrial fibrillation was previously diagnosed (block **224**), a further determination categorizing either disease progression (block **226**) or regression (block **227**) is made, as further described below with reference to FIGS. **14A-14B** and **15A-15B**, respectively. If, upon evaluation, neither disease onset (block **225**), progression (block **226**) or regression (block **227**) is indicated, a finding of status quo is appropriate (block **228**) and duly noted (block **229**). Finally, if status quo does not exist, that is, atrial fibrillation has occurred, either as an initial onset, progression or regression (block **230**), the occurrence is managed from the perspective of an effort to terminate atrial fibrillation and restore sinus rhythm, to decrease ventricular rate response, and/or to minimize the consequences of the presence of atrial fibrillation, e.g., provide anticoagulants to prevent a stroke and/or diuretics to reverse progression in congestive heart failure (block **230**), as further described below with reference to FIGS. **17A-17B**. The routine then returns.

[**0085**] FIGS. **13A-13B** are flow diagrams showing the routine for categorizing an onset of atrial fibrillation **225** for use in the routine of FIGS. **12A-12B**. An effort is made to categorize atrial fibrillation manifesting primarily as resulting in reduced exercise capacity (block **243**), increased respiratory distress (block **249**), and/or palpitations (block **251**). The clinical aspects of atrial fibrillation are described,

by way of example, in E. Braunwald, ed., "Heart Disease-A Textbook of Cardiovascular Medicine," Chs. 1 and 22, W. B. Saunders Co. (1997), the disclosure of which is incorporated herein by reference.

[0086] In the described embodiment, the reduced exercise capacity, respiratory distress, and palpitations findings (blocks **243**, **249**, **251**) can be established by consolidating the individual indications (blocks **240-242**, **244-248**, **250**) in several ways. First, in a preferred embodiment, each individual indication (blocks **240-242**, **244-248**, **250**) is assigned a scaled index value correlating with the relative severity of the indication. For example, decreased cardiac output (block **240**) could be measured on a scale from '1' to '5' wherein a score of '1' indicates no change in cardiac output from the reference point, a score of '2' indicates a change exceeding 0.5 SD, a score of '3' indicates a change exceeding 1.0 SD, a score of '4' indicates a change exceeding 2.0 SD, and a score of '5' indicates a change exceeding 3.0 SD. The index value for each of the individual indications (blocks **240-242**, **244-248**, **250**) can then either be aggregated or averaged with a result exceeding the aggregate or average maximum indicating an appropriate atrial fibrillation finding.

[0087] Preferably, all scores are weighted depending upon the assignments made from the measures in the reference baseline **26**. For instance, arterial partial pressure of oxygen **102** could be weighted more importantly than respiratory rate **104** if the respiratory rate in the reference baseline **26** is particularly high at the outset, making the detection of further disease progression from increases in respiratory rate, less sensitive. In the described embodiment, cardiac output receives the most weight in determining a reduced exercise capacity finding, pulmonary artery diastolic pressure receives the most weight in determining a respiratory distress or dyspnea finding, and a transition from normal sinus rhythm to atrial fibrillation receives the most weight in determining a palpitations finding.

[0088] Alternatively, a simple binary decision tree can be utilized wherein each of the individual indications (blocks **240-242**, **244-248**, **250**) is either present or is not present. Any of the individual indications (blocks **240-242**, **244-248**, **250**) should be present for the relevant effect of atrial fibrillation on cardiovascular and cardiopulmonary measures to be affirmed as long as the atrial fibrillation is temporally related to onset.

[0089] Other forms of consolidating the individual indications (blocks **240-242**, **244-248**, **250**) are feasible.

[0090] FIGS. **14A-14B** are flow diagrams showing the routine for categorizing a progression or worsening of atrial fibrillation **226** for use in the routine of FIGS. **12A-12B**. The primary difference between the determinations of disease onset, as described with reference to FIGS. **13A-13B**, and disease progression is a demonstration of an increased ventricular rate response in atrial fibrillation or deterioration in cardiovascular or cardiopulmonary measures regardless of ventricular rate during atrial fibrillation. Whereas, to define atrial fibrillation onset, the heart rhythm must transition from normal sinus rhythm (or any non-atrial fibrillation rhythm) to atrial fibrillation as detected by any of the methods known in the art for heart rhythm diagnosis. Thus, a revised atrial fibrillation finding is possible based on the same three general symptom categories: reduced exercise capacity (block **273**), respiratory distress (block **279**), and palpitations (block **281**). The same factors which need be indicated to warrant a diagnosis of atrial fibrillation onset and its consequences are also evaluated to determine disease progression.

[0091] Similarly, FIGS. **15A-15B** are flow diagrams showing the routine for categorizing a regression or improving of atrial fibrillation **227** and its cardiovascular and cardiopulmonary consequences for use in the routine of FIGS. **12A-12B**. The same factors as described above with reference to FIGS. **13A-13B** and **14A-14B**, trending in opposite directions from disease onset or progression, are evaluated to determine disease regression. As primary cardiac disease considerations, multiple individual indications (blocks **300-302**, **304-308**, **310**) should be present for the three principal findings of atrial fibrillation related reduced exercise capacity (block **303**), atrial fibrillation related respiratory distress (block **309**), and palpitations (block **311**), to indicate disease regression.

[0092] **FIG. 16** is a flow diagram showing the routine for determining threshold stickiness ("hysteresis") **221** for use in the method of FIGS. **12A-12B**. Stickiness, also known as hysteresis, is a medical practice doctrine whereby a diagnosis or therapy will not be changed based upon small or temporary changes in a patient reading, even though those changes might temporarily move into a new zone of concern. For example, if a patient measure can vary along a scale of '1' to '10' with '10' being worse, a transient reading of '6,' standing alone, on a patient who has consistently indicated a reading of '5' for weeks will not warrant a change in diagnosis without a definitive prolonged deterioration first being indicated. Stickiness dictates that small or temporary changes in cardiovascular or cardiopulmonary physiology associated with atrial fibrillation onset, progression or regression require more diagnostic certainty, as confirmed by the persistence of the changes, than large changes would require for any of the monitored (device) measures. Stickiness also makes reversal of important diagnostic decisions, particularly those regarding life-threatening disorders, more difficult than reversal of diagnoses of modest import. As an example, automatic external defibrillators (AEDs) manufactured by Heartstream, a subsidiary of Agilent Technologies, Seattle, Washington, monitor heart rhythms and provide interventive shock treatment for the diagnosis of ventricular fibrillation. Once diagnosis of ventricular fibrillation and a decision to shock the patient has been made, a pattern of no ventricular fibrillation must be indicated for a relatively prolonged period before the AED changes to a "no-shock" decision. As implemented in this AED example, stickiness mandates certainty before a decision to shock is disregarded.

[0093] In practice, stickiness also dictates that acute deteriorations in disease state are treated aggressively while chronic, more slowly progressing disease states are treated in a more tempered fashion. Thus, if the patient status indicates a status quo (block **330**), no changes in treatment or diagnosis are indicated and the routine returns. Otherwise, if the patient status indicates a change away from status quo (block **330**), the relative quantum of change and the length of time over which the change has occurred is determinative. If the change of approximately 0.5 SD has occurred over the course of about one month (block **331**), a gradually deteriorating condition exists (block **332**) and a very tempered diagnostic, and if appropriate, treatment program is under-

taken. If the change of approximately 1.0 SD has occurred over the course of about one week (block **333**), a more rapidly deteriorating condition exists (block **334**) and a slightly more aggressive diagnostic, and if appropriate, treatment program is undertaken. If the change of approximately 2.0 SD has occurred over the course of about one day (block **335**), an urgently deteriorating condition exists (block **336**) and a moderately aggressive diagnostic, and if appropriate, treatment program is undertaken. If the change of approximately 3.0 SD has occurred over the course of about one hour (block **337**), an emergency condition exists (block **338**) and an immediate diagnostic, and if appropriate, treatment program is undertaken as is practical. Finally, if the change and duration fall outside the aforementioned ranges (blocks **331-338**), an exceptional condition exists (block **339**) and the changes are reviewed manually, if necessary. The routine then returns. These threshold limits and time ranges may then be adapted depending upon patient history and peer-group guidelines.

[**0094**] The form of the revised treatment program depends on the extent to which the time span between changes in the device measures exceed the threshold stickiness **133** (shown in **FIG. 5**) relating to that particular type of device measure. For example, threshold stickiness **133** indicator for monitoring a change in heart rate in a chronic patient suffering from atrial fibrillation might be 10% over a week. Consequently, a change in average heart rate **96** (shown in **FIG. 4**) from 80 bpm to 95 bpm over a seven day period, where a 14 beat per minute average change would equate to a 1.0 SD change, would exceed the threshold stickiness **133** and would warrant a revised medical diagnosis perhaps of disease progression. One skilled in the art would recognize the indications of acute versus chronic disorders which will vary upon the type of disease, patient health status, disease indicators, length of illness, and timing of previously undertaken interventive measures, plus other factors.

[**0095**] FIGS. **17A-17B** is a flow diagram showing the routine for managing the consequences of atrial fibrillation **230** for use in the routine of FIGS. **12A-12B**. The management of atrial fibrillation focuses principally on restoring normal sinus rhythm and controlling ventricular rate response (VRR). However, effective atrial fibrillation management requires considering four individual areas of concern: cardiovascular/cardiopulmonary compromise, ventricular rate response, anticoagulation status, and associated symptoms, like the presence of palpitations. An overriding theme is that restoration of normal sinus rhythm should not be attempted for atrial fibrillation greater than or equal to 48 hours in duration in the absence of anticoagulation or serious cardiovascular/cardiopulmonary compromise to prevent stroke. Consequently, therapy should usually be directed to control of ventricular rate response under such circumstances.

[**0096**] Each of these areas of concern may potentially overlap and require coordinated therapeutic treatment. The management process that follows, although outlined in linear, sequential fashion, can be performed in a simultaneous manner, where clinically reasonable and necessary. One concern of persistent atrial fibrillation is a time-based threat of thromboembolic disease if atrial fibrillation persists for longer than 48 hours and the patient's blood is not anticoagulated. Atrial fibrillation should, if possible and clinically reasonable, be terminated if atrial fibrillation reaches a duration exceeding 48 hours. In addition, atrial fibrillation of any duration may be accompanied by cardiovascular decompensation, including a decrease in cardiac output, an increase in cardiac filling pressures, a decrease in blood pressure, a decrease in oxygenation, and an increase in myocardial ischemia, particularly if atrial fibrillation presents in conjunction with comorbid disorders. Again, if possible and clinically reasonable, atrial fibrillation should be terminated. Although atrial fibrillation may, in and of itself, affect cardiovascular physiology adversely, a component of the response may be due to a ventricular rate response which is either too rapid or too slow. Thus, control of ventricular rate response constitutes a third management concern. Palpitations are caused by an irregular heartbeat which, while possibly uncomfortable to a patient, usually need only be monitored and not treated. In the event of disabling palpitations, or other related symptoms such as dyspnea or fatigue, however, atrial fibrillation can be electrically or pharmacologically terminated.

[**0097**] The four areas of concern regarding atrial fibrillation management are addressed as follows. First, if a cardiovascular/cardiopulmonary compromise exists (block **400**), the compromise must be actively managed (block **401**), as further described below with reference to FIGS. **18A-18D**. After the completion of cardiovascular/cardiopulmonary compromise management (block **401**), if normal sinus rhythm has been restored (block **402**), the routine returns. If ventricular rate response is inappropriate, that is, either too rapid or too slow (block **403**), ventricular rate response must be actively managed (block **404**), as further described below with reference to **FIG. 19**. After the completion of ventricular rate response management (block **404**), if ventricular rate response has been controlled (block **405**), the routine returns. If anticoagulation management is required (block **406**), such management is undertaken (block **407**), as further described below with reference to **FIG. 20**. After the completion of anticoagulation management (block **407**), if normal sinus rhythm has been restored (block **408**), the routine returns. Otherwise, if palpitations/symptoms are present (block **409**), the palpitations/symptoms are actively managed (block **410**), as further described below with reference to **FIG. 21**. After the completion of palpitations/symptoms management (block **410**), if normal sinus rhythm has been restored (block **411**), the routine returns. Finally, if none of cardiovascular/cardiopulmonary compromise (block **400**), inappropriate ventricular rate response (block **403**), anticoagulation management (block **406**), or palpitations/symptoms (block **409**) are presented, no further action is taken and the routine returns.

[**0098**] FIGS. **18A-18D** are flow diagrams showing the routine for managing a cardiovascular/cardiopulmonary compromise **401** for use in the method of FIGS. **17A-17B**. The purpose of this routine is to determine an appropriate treatment regimen for a cardiovascular/cardiopulmonary compromise by classifying the relative magnitude of change in physiological measures obtained or derived from the device and derived measures sets **24***a*, **24***b* (shown in **FIG. 1**) into ranges of severity. The degree of medical intervention varies proportionate to the severity, magnitude of change and the time span over which the change occurred. Thus, deterioration greater than or equal to 3.0 SD (block **430**) requires immediate, aggressive therapy regardless of

anticoagulation status, whereas deterioration greater than or equal to than 0.5 SD but less than 1.0 SD (block **433**) may require only modest therapy.

[**0099**] Beginning with maximum change, if the deterioration in physiological measures is greater than or equal to 3.0 SD (block **430**), aggressive atrial fibrillation therapy, as defined below, is undertaken (block **434**). Otherwise, if the deterioration in physiological measures is greater than or equal to 2.0 SD but less than 3.0 SD (block **431**), the duration of atrial fibrillation and usage of anticoagulation drug therapy is considered. Thus, if atrial fibrillation has lasted fewer than 48 hours (block **435**) or if at least 48 hours or longer and with anticoagulation therapy (block **437**), aggressive atrial fibrillation therapy is undertaken (blocks **436**, **438**, respectively). Otherwise, if atrial fibrillation has lasted at least 48 hours or longer (block **435**) but without anticoagulation therapy (block **437**), anticoagulation management is undertaken (block **439**), as further described below with reference to **FIG. 20**.

[**0100**] Upon completion of anticoagulation management (block **435**), a ventricular rate response analysis (blocks **440-444**) is performed as follows. First, if ventricular rate response is acceptable (block **440**), aggressive atrial fibrillation therapy is undertaken (block **441**). Otherwise, if ventricular rate response in not acceptable (block **440**) and control of ventricular rate response is possible (block **442**), ventricular rate response management is undertaken (block **443**), as further described below with reference to **FIG. 19**. Conversely, if ventricular rate response is not acceptable (block **442**), control of ventricular rate response is not possible (block **442**), and cardiovascular/cardiopulmonary physiology is deteriorating (block **444**), aggressive atrial fibrillation therapy is undertaken (block **445**).

[**0101**] On the lower range of change in physiological measures, if the deterioration in physiological measures is greater than 1.0 SD but less than 2.0 SD (block **432**), the duration of atrial fibrillation and usage of anticoagulation drug therapy is considered. Thus, if atrial fibrillation has lasted fewer than 48 hours (block **446**), moderate atrial fibrillation therapy, as defined below, is undertaken (block **447**). If normal sinus rhythm has been restored (block **448**), no further action is required. Otherwise, ventricular rate response management is (block **449**), as further described below with reference to **FIG. 19**. If atrial fibrillation has lasted at least 48 hours or longer (block **446**), the administration of anticoagulation drug therapy is considered. If anticoagulation drug therapy has already been undertaken (block **450**), moderate atrial fibrillation therapy is undertaken (block **451**). Otherwise, anticoagulation management is undertaken (block **452**), as further described below with reference to **FIG. 20**.

[**0102**] Upon completion of anticoagulation management (block **452**), a ventricular rate response analysis (blocks **453-458**) is performed during atrial fibrillation as follows. First, if ventricular rate response is acceptable (block **453**), cardiovascular/cardiopulmonary compromise is monitored (block **454**). If the cardiovascular/cardiopulmonary status shows deterioration (block **455**), the anticoagulation status is monitored (block **456**) and, if fewer than three weeks have elapsed (block **457**), therapy is dictated by cardiovascular/cardiopulmonary status (block **454**). Otherwise, if appropriate anticoagulation drug therapy has continued for at least three weeks with no substantial change in cardiovascular/cardiopulmonary compromise status (block **455**), the full range of atrial fibrillation therapies are slowly and incrementally applied, that is, from modest to moderate to aggressive, as is reasonably necessary and matched to the patient's condition (block **458**).

[**0103**] Finally, if the deterioration in physiological measures at the onset of atrial fibrillation is greater than 0.5 SD but less than 1.0 SD (block **433**), the duration of atrial fibrillation and usage of anticoagulation drug therapy is again considered. Thus, if atrial fibrillation has lasted fewer than 48 hours (block **459**), modest atrial fibrillation therapy, as defined below, is undertaken (block **460**). However, if atrial fibrillation has lasted at least 48 hours or longer (block **459**), the administration of anticoagulation drug therapy is considered. If anticoagulation drug therapy has already been undertaken (block **461**), modest atrial fibrillation therapy is undertaken (block **462**). Otherwise, anticoagulation management is undertaken (block **463**), as further described below with reference to **FIG. 20**.

[**0104**] Upon completion of anticoagulation management (block **463**), a ventricular rate response analysis (blocks **464-470**) is performed as follows. First, if ventricular rate response is acceptable (block **464**), no further action is taken. Otherwise, cardiovascular/cardiopulmonary compromise is monitored (block **466**) using a standard cardiovascular/cardiopulmonary monitoring procedure (box **465**). If the cardiovascular/cardiopulmonary status shows a worsening of the atrial fibrillation condition (block **467**), the compromise is managed (block **468**) by recursively performing the present routine. Otherwise, if the condition is improving (or maintaining status quo) (block **467**) and the anticoagulation drug therapy status is acceptable (block **469**), the full range of atrial fibrillation therapies are slowly and incrementally applied, that is, from modest to moderate to aggressive, as is reasonably necessary and matched to the patient's condition (block **470**). The routine then returns.

[**0105**] Note if the deterioration in physiological measures is less than 0.5 SD (block **433**), no action is taken unless dictated by cardiovascular/cardiopulmonary measures.

[**0106**] **FIG. 19** is a flow diagram showing the routine for managing ventricular rate response **404** for use in the method of FIGS. **17A-17B**. The purpose of this routine is to bring ventricular rate response into a 50-90 beats per minute (bpm) average range. Thus, if the average ventricular rate response is within a "good" range of 50-90 bpm (block **480**), no further action need be taken and the routine returns. Otherwise, if the average ventricular rate response is not less than **50** bpm, that is, in excess of 90 bpm and thence too fast (block **481**), actions to decrease the ventricular pacing rate are considered. First, electrical therapy is undertaken (block **483**) if such therapy is possible (block **482**), such as described in U.S. Pat. No. 5,356,425 to Bardy et al., the disclosure of which is incorporated herein by reference. If the electrical therapy was not effective (block **484**) or if electrical therapy is not possible (block **482**), drug therapy to decrease atrioventricular (AV) node conduction is undertaken (block **485**). If the drug therapy was not effective (block **486**), cardiovascular/cardiopulmonary comprise is monitored (block **487**) by performing the standard monitoring procedure (starting at block **471** in box **465** in FIGS. **18A-18D**) where further management is dictated by the cardiovascular/cardiopulmonary measures.

[0107] If the average ventricular rate response is less than 50 bpm, that is, too slow (block **481**), actions to increase the ventricular pacing rate are considered. If an increased ventricular pacing rate is possible (block **488**), the ventricular pacing rate is increased, preferably to within a range of 50-90 bpm (block **489**), modified by the outcome in cardiovascular/cardiopulmonary measures. Otherwise, if increased ventricular pacing is not possible (block **488**) and antidromotropic drugs (drugs that slow atrioventricular node conduction) are present (block **492**), the antidromotropic drug therapy is decreased (block **492**). Otherwise, if antidromotropic drugs are present (block **490**), cardiovascular/cardiopulmonary compromise is monitored (block **491**) by performing the standard monitoring procedure (starting at block **471** in box **465** in FIGS. **18**A-**18**D). The routine then returns.

[0108] **FIG. 20** is a flow diagram showing the routine for managing anticoagulation **407** for use in the method of FIGS. **17**A-**17**B. The purpose of this routine is to initiate or adjust anticoagulation drug therapy based on the duration of atrial fibrillation and anticoagulation drug therapy status. Anticoagulation drug therapy is not required if atrial fibrillation has persisted for less than 48 hours (block **520**) or if the condition of the patient contraindicates such therapy (block **521**). Similarly, an adjustment to existing anticoagulation drug therapy is inappropriate if the anticoagulation is already adequate (block **522**). Thus, if atrial fibrillation has lasted at least 48 hours or longer (block **520**), anticoagulation is not contraindicated (block **521**) and any present anticoagulation drug therapy is insufficient (block **522**), anticoagulation drug therapy is started or adjusted, as appropriate (block **523**) to maintain an International Normalized Ratio (INR) of 2.0-3.0. The routine then returns.

[0109] **FIG. 21** is a flow diagram showing the routine for managing palpitations/symptoms **410** for use in the method of FIGS. **17**A-**17**B. The purpose of this routine is to determine the proper quantum of atrial fibrillation therapy for a palpitating heartbeat, fatigue, dyspnea, or related symptoms. If palpitations/symptoms are present (block **540**) and disabling to the patient (block **541**), moderate atrial fibrillation therapy is undertaken (block **542**). However, if the palpitations/symptoms are not disabling (block **541**) and are merely irritating to the patient (block **543**), modest atrial fibrillation is undertaken (block **544**). Finally, if the palpitations/symptoms are not disabling (block **541**) nor irritating (block **543**), no action is taken. The routine then returns.

[0110] A range of therapies with which to treat atrial fibrillation are available, including the following, non-exclusive exemplary list:

[0111] 1. Electrical shock to restore normal sinus rhythm.

[0112] 2. Antitachycardia pacing maneuvers to restore normal sinus rhythm.

[0113] 3. Implantable medical device (or non-device) infusion of drugs to restore normal sinus rhythm.

[0114] 4. Oral administration of drugs to restore normal sinus rhythm.

[0115] 5. Electrical pacing maneuvers to decrease ventricular rate response.

[0116] 6. Electrical pacing maneuvers to increase ventricular rate response.

[0117] 7. Implantable medical device (or non-device) infusion of drugs to decrease ventricular rate response.

[0118] 8. Implantable medical device (or non-device) infusion of drugs to increase ventricular rate response.

[0119] 9. Oral administration of drugs to decrease ventricular rate response.

[0120] 10. Oral administration of drugs to increase ventricular rate response.

[0121] 11. Discontinuation or withdrawal of drug therapy to restore normal sinus rhythm.

[0122] 12. Discontinuation or withdrawal of drug therapy to decrease ventricular rate response.

[0123] 13. Discontinuation or withdrawal of drug therapy to increase ventricular rate response.

[0124] Other therapies for restoration of normal sinus rhythm or to favorably alter ventricular rate response are also feasible, as is known in the art.

[0125] The foregoing therapies can be approximately categorized into three groupings of treatments to attempt to restore normal sinus rhythm or, as appropriate, to increase or decrease ventricular rate response, as follows:

[0126] 1. Aggressive Therapy (in order of preference):

[0127] a. Apply immediate electrical shock therapy to effect termination of atrial fibrillation.

[0128] b. If electrical shock therapy is ineffective, administer most effective drug intravenously, regardless of drug side effects.

[0129] c. If drug thereby in isolation is ineffective, apply further electrical shock therapy in the presence of drug therapy.

[0130] 2. Moderate Therapy (in order of preference):

[0131] a. Apply time restricted electrical pacing therapies, not more than one hour in duration.

[0132] b. If time restricted electrical pacing therapies are ineffective, administer most effective drug intravenously or by implantable medical device (or non-device), regardless of drug side effects.

[0133] c. If time restricted electrical pacing and drug therapies are ineffective, apply electrical shock therapy.

[0134] d. Administer oral drug therapy using agents of any potency and side effect profile.

[0135] e. Combine oral drug therapy with electrical therapy.

[0136] 3. Modest Therapy (in order of preference):

[0137] a. Liberally apply electrical pacing therapies, not more than one day in duration.

[0138] b. Administer oral drug therapy using agents with only modest side effects.

[0139] c. Only with patient approval, consider electrical shock or more aggressive drug therapies.

[0140] The present invention provides several benefits. One benefit is improved predictive accuracy from the outset of patient care when a reference baseline is incorporated into the automated diagnosis and when physiological measures immediately antecedent to the onset of atrial fibrillation can be examined to gauge the likelihood of precipitating factors, like heart failure, myocardial ischemia and pulmonary insufficiency as well as more subtle measures of cardiac electrophysiology. This post-hoc analysis following each episode of atrial fibrillation onset is likely to prove particular important in patients with primary atrial fibrillation, that is those with no known associated diseases or explanations for the onset of atrial fibrillation.

[0141] A further benefit is an expanded knowledge base created by expanding the methodologies applied to a single patient to include patient peer groups and the overall patient population. Collaterally, the information maintained in the database could also be utilized for the development of further predictive techniques and for medical research purposes. Yet a further benefit is the ability to hone and improve the predictive techniques employed through a continual reassessment of patient outcomes.

[0142] Other benefits include an automated, expert system approach to the cross-referral, consideration, and potential finding or elimination of other diseases and health disorders with similar or related etiological indicators and for those other disorders that may have an impact on atrial fibrillation. Although disease specific markers will prove very useful in discriminating the underlying cause of symptoms, many diseases, other than atrial fibrillation, will alter some of the same physiological measures resulting from atrial fibrillation. Consequently, an important aspect of considering the potential impact of other disorders will be, not only the monitoring of atrial fibrillation onset and offset and the ventricular rate during atrial fibrillation, but the sequencing of change and the temporal evolution of physiological measures, for example respiratory rate, arterial oxygenation, ST segment evolution and cardiac output, to reflect the pathophysiological consequences of atrial fibrillation onset, progression or regression in other disease processes.

[0143] Finally, the benefit of this invention tempers therapy of atrial fibrillation in a measured and clinically balanced fashion comparable to the management afforded by expert human cardiac care.

[0144] 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. An automated system for diagnosing and monitoring the outcomes of atrial fibrillation, comprising:

a database storing a plurality of monitoring sets which each comprise recorded measures relating to patient information recorded on a substantially continuous basis;

a comparison module determining a patient status change in response to an atrial fibrillation diagnosis by comparing at least one recorded measure from each of the monitoring sets to at least one other recorded measure with both recorded measures relating to the same type of patient information; and

an analysis module testing each patient status change against an indicator threshold corresponding to the same type of patient information as the recorded measures which were compared, the indicator threshold corresponding to a quantifiable physiological measure of a pathophysiology resulting from atrial fibrillation.

2. An automated system according to claim 1, further comprising:

the analysis module managing the atrial fibrillation diagnosis through administration of at least one of ventricular rate response control and normal sinus rhythm restoration.

3. An automated system according to claim 1, further comprising:

a database module periodically receiving a monitoring set for an individual patient, each recorded measure in the monitoring set having been recorded by at least one of a medical device adapted to be implanted in an individual patient and an external medical device proximal to the individual patient when the device measures are recorded and storing the received monitoring set in the database as part of a patient care record for the individual patient.

4. An automated system according to claim 3, further comprising:

a set of further indicator thresholds, each indicator threshold corresponding to a quantifiable physiological measure used to detect a pathophysiology indicative of diseases other than atrial fibrillation;

the comparison module comparing each patient status change to each such further indicator threshold corresponding to the same type of patient information as the at least one recorded measure and the at least one other recorded measure; and

testing each patient status change against each such further indicator threshold corresponding to the same type of patient information as the recorded measures which were compared.

5. An automated system according to claim 1, further comprising:

the comparison determining a change in patient status by comparing at least one recorded quality of life measure to at least one other corresponding recorded quality of life measure.

6. An automated system according to claim 1, further comprising:

a set of stickiness indicators for each type of patient information, each stickiness indicator corresponding to a temporal limit related to a program of patient diagnosis or treatment;

the comparison module comparing a time span occurring between each patient status change for each recorded measure to the stickiness indicator relating to the same type of patient information as the recorded measure being compared; and

the analysis module determining a revised program of patient diagnosis or treatment responsive to each patient status change occurring subsequent to a time span exceeding the stickiness indicator.

7. An automated system according to claim 1, further comprising:

a database module retrieving the plurality of monitoring sets from one of a patient care record for an individual patient, a peer group, and a overall patient population.

8. An automated system according to claim 1, further comprising:

the database further storing a reference baseline comprising recorded measures which each relate to patient information recorded during an initial time period and comprise either medical device measures or derived measures calculable therefrom; and

a database module obtaining at least one of the at least one recorded measure and the at least one other recorded measure from the retrieved reference baseline.

9. An automated system according to claim 1, wherein the indicator thresholds relate to at least one of a finding of reduced exercise capacity, respiratory distress and palpitations/symptoms.

10. An automated system according to claim 9, wherein the indicator thresholds relating to the finding of reduced exercise capacity are selected from the group comprising decreased cardiac output, decreased mixed venous oxygen score and decreased patient activity score.

11. An automated system according to claim 9, wherein the indicator thresholds relating to the finding of respiratory distress are selected from the group comprising increased pulmonary artery diastolic pressure, increased respiratory rate and decreased transthoracic impedance.

12. An automated method for diagnosing and monitoring the outcomes of atrial fibrillation, comprising:

retrieving a plurality of monitoring sets from a database which each comprise recorded measures relating to patient information recorded on a substantially continuous basis;

determining a patient status change in response to an atrial fibrillation diagnosis by comparing at least one recorded measure from each of the monitoring sets to at least one other recorded measure with both recorded measures relating to the same type of patient information; and

testing each patient status change against an indicator threshold corresponding to the same type of patient information as the recorded measures which were compared, the indicator threshold corresponding to a quantifiable physiological measure of a pathophysiology resulting from atrial fibrillation.

13. An automated method according to claim 12, further comprising:

managing the atrial fibrillation diagnosis through administration of at least one of ventricular rate response control and normal sinus rhythm restoration.

14. An automated method according to claim 12, further comprising:

periodically receiving a monitoring set for an individual patient, each recorded measure in the monitoring set having been recorded by at least one of a medical device adapted to be implanted in an individual patient and an external medical device proximal to the individual patient when the device measures are recorded; and

storing the received monitoring set in the database as part of a patient care record for the individual patient.

15. An automated method according to claim 14, further comprising:

defining a set of further indicator thresholds, each indicator threshold corresponding to a quantifiable physiological measure used to detect a pathophysiology indicative of diseases other than atrial fibrillation;

comparing each patient status change to each such further indicator threshold corresponding to the same type of patient information as the at least one recorded measure and the at least one other recorded measure; and

testing each patient status change against each such further indicator threshold corresponding to the same type of patient information as the recorded measures which were compared.

16. An automated method according to claim 12, further comprising:

determining a change in patient status by comparing at least one recorded quality of life measure to at least one other corresponding recorded quality of life measure.

17. An automated method according to claim 12, further comprising:

defining a set of stickiness indicators for each type of patient information, each stickiness indicator corresponding to a temporal limit related to a program of patient diagnosis or treatment;

comparing a time span occurring between each patient status change for each recorded measure to the stickiness indicator relating to the same type of patient information as the recorded measure being compared; and

determining a revised program of patient diagnosis or treatment responsive to each patient status change occurring subsequent to a time span exceeding the stickiness indicator.

18. An automated method according to claim 12, further comprising:

retrieving the plurality of monitoring sets from one of a patient care record for an individual patient, a peer group, and a overall patient population.

19. An automated method according to claim 12, further comprising:

retrieving a reference baseline comprising recorded measures which each relate to patient information recorded during an initial time period and comprise either medical device measures or derived measures calculable therefrom; and

obtaining at least one of the at least one recorded measure and the at least one other recorded measure from the retreived reference baseline.

20. An automated method according to claim 12, wherein the indicator thresholds relate to at least one of a finding of reduced exercise capacity, respiratory distress and palpitations/symptoms.

21. An automated method according to claim 20, wherein the indicator thresholds relating to the finding of reduced exercise capacity are selected from the group comprising decreased cardiac output, decreased mixed venous oxygen score and decreased patient activity score.

22. An automated method according to claim 20, wherein the indicator thresholds relating to the finding of respiratory distress are selected from the group comprising increased pulmonary artery diastolic pressure, increased respiratory rate and decreased transthoracic impedance.

23. A computer-readable storage medium containing code for an automated method for diagnosing and monitoring the outcomes of atrial fibrillation, comprising:

retrieving a plurality of monitoring sets from a database which each comprise recorded measures relating to patient information recorded on a substantially continuous basis;

determining a patient status change in response to an atrial fibrillation diagnosis by comparing at least one recorded measure from each of the monitoring sets to at least one other recorded measure with both recorded measures relating to the same type of patient information; and

testing each patient status change against an indicator threshold corresponding to the same type of patient information as the recorded measures which were compared, the indicator threshold corresponding to a quantifiable physiological measure of a pathophysiology resulting from atrial fibrillation.

24. A storage medium according to claim 23, further comprising:

managing the atrial fibrillation diagnosis through administration of at least one of ventricular rate response control and normal sinus rhythm restoration.

25. A storage medium according to claim 23, further comprising:

periodically receiving a monitoring set for an individual patient, each recorded measure in the monitoring set having been recorded by at least one of a medical device adapted to be implanted in an individual patient and an external medical device proximal to the individual patient when the device measures are recorded; and

storing the received monitoring set in the database as part of a patient care record for the individual patient.

26. A storage medium according to claim 25, further comprising:

defining a set of further indicator thresholds, each indicator threshold corresponding to a quantifiable physiological measure used to detect a pathophysiology indicative of diseases other than atrial fibrillation;

comparing each patient status change to each such further indicator threshold corresponding to the same type of patient information as the at least one recorded measure and the at least one other recorded measure; and

testing each patient status change against each such further indicator threshold corresponding to the same type of patient information as the recorded measures which were compared.

27. A storage medium according to claim 23, further comprising:

determining a change in patient status by comparing at least one recorded quality of life measure to at least one other corresponding recorded quality of life measure.

28. A storage medium according to claim 23, further comprising:

defining a set of stickiness indicators for each type of patient information, each stickiness indicator corresponding to a temporal limit related to a program of patient diagnosis or treatment;

comparing a time span occurring between each patient status change for each recorded measure to the stickiness indicator relating to the same type of patient information as the recorded measure being compared; and

determining a revised program of patient diagnosis or treatment responsive to each patient status change occurring subsequent to a time span exceeding the stickiness indicator.

29. A storage medium according to claim 23, further comprising:

retrieving the plurality of monitoring sets from one of a patient care record for an individual patient, a peer group, and a overall patient population.

30. A storage medium according to claim 23, further comprising:

retrieving a reference baseline comprising recorded measures which each relate to patient information recorded during an initial time period and comprise either medical device measures or derived measures calculable therefrom; and

obtaining at least one of the at least one recorded measure and the at least one other recorded measure from the retrieved reference baseline.

31. An automated collection and analysis patient care system for diagnosing and monitoring the outcomes of atrial fibrillation, comprising:

a database storing a plurality of monitoring sets, each monitoring set comprising recorded measures which each relate to patient information and comprise either medical device measures or derived measures calculable therefrom, the medical device measures having been recorded on a substantially continuous basis;

a set of stored indicator thresholds, each indicator threshold corresponding to a quantifiable physiological measure of a pathophysiology resulting from atrial fibrillation and relating to the same type of patient information as at least one of the recorded measures; and

a diagnostic module diagnosing an atrial fibrillation finding, comprising:

an analysis module determining a change in patient status in response to an atrial fibrillation diagnosis by comparing at least one recorded measure to at least

one other recorded measure with both recorded measures relating to the same type of patient information; and

a comparison module comparing each patient status change to the indicator threshold corresponding to the same type of patient information as the recorded measures which were compared.

32. A system according to claim 31, wherein the device measures are recorded by at least one of a medical device adapted to be implanted in an individual patient and an external medical device proximal to the individual patient when the device measures are recorded.

33. A system according to claim 31, wherein each of the monitoring sets comprises recorded measures relating to patient information solely for the individual patient, further comprising:

a database module retrieving each monitoring set from a patient care record for the individual patient and obtaining the at least one recorded measure and the at least one other recorded measure from the retrieved monitoring sets.

34. A system according to claim 31, wherein each of the monitoring sets comprises recorded measures relating to patient information for a peer group of patients to which the individual patient belongs, further comprising:

a database module retrieving at least one monitoring set from a patient care record for the individual patient, retrieving at least one other monitoring set from a patient care record in the same patient peer group, and obtaining the at least one recorded measure from the at least one monitoring set and the at least one other recorded measure from the at least one other monitoring set.

35. A system according to claim 31, wherein each of the monitoring sets comprises recorded measures relating to patient information for the general population of patients, further comprising:

a database module retrieving at least one monitoring set from a patient care record for the individual patient, retrieving at least one other monitoring set from a patient care record in the overall patient population, and obtaining the at least one recorded measure from the at least one monitoring set and the at least one other recorded measure from the at least one other monitoring set.

36. A system according to claim 31, further comprising:

the database further storing a reference baseline comprising recorded measures which each relate to patient information recorded by the medical device adapted to be implanted during an initial time period and comprise either device measures recorded by the medical device adapted to be implanted or derived measures calculable therefrom; and

a database module obtaining at least one of the at least one recorded measure and the at least one other recorded measure from the retrieved reference baseline.

37. A system according to claim 36, wherein the reference baseline comprises recorded measures relating to patient information for one of the individual patients solely, a peer group of patients to which the individual patient belongs, and a general population of patients.

38. A system according to claim 31, the comparison module further comprising:

a module grading the comparisons between each patient status change and corresponding indicator threshold on a fixed scale based on a degree of deviation from the indicator threshold; and

the comparison module determining an overall patient status change by performing a summation over the individual graded comparisons.

39. A system according to claim 31, the comparison module further comprising:

a module determining probabilistic weightings of the comparisons between each patient status change and corresponding indicator threshold based on a statistical deviation and trends via linear fits from the indicator threshold; and

the comparison module determining an overall patient status change by performing a summation over the individual graded comparisons.

40. A system according to claim 31, wherein each monitoring set further comprises quality of life and symptom measures recorded by the individual patient, the diagnostic module further comprising:

a quality of life module determining a change in patient status by comparing at least one recorded quality of life measure to at least one other corresponding recorded quality of life measure; and

the diagnostic module incorporating each patient status change in quality of life into the atrial fibrillation finding to either refute or support the diagnosis.

41. A system according to claim 31, further comprising:

a set of stored further indicator thresholds, each indicator threshold corresponding to a quantifiable physiological measure used to detect a pathophysiology indicative of diseases other than atrial fibrillation; and

the diagnostic module diagnosing a finding of a disease other than atrial fibrillation, the comparison module further comprising comparing each patient status change to each such further indicator threshold corresponding to the same type of patient information as the at least one recorded measure and the at least one other recorded measure.

42. A system according to claim 31, further comprising:

a set of stickiness indicators, each indicator threshold corresponding to a temporal limit related to a course of patient care; and

a feedback module comparing a time span between each patient status change for each recorded measure to the stickiness indicator corresponding to the same type of patient information as the recorded measure being compared.

43. A system according to claim 31, further comprising:

a feedback module providing automated feedback to the individual patient when an atrial fibrillation finding is indicated.

44. A system according to claim 43, further comprising:

the feedback module performing an interactive dialogue between the individual patient and the patient care system regarding a medical condition of the individual patient.

45. A method for diagnosing and monitoring the outcomes of atrial fibrillation using an automated collection and analysis patient care system, comprising:

retrieving a plurality of monitoring sets from a database, each monitoring set comprising recorded measures which each relate to patient information and comprise either medical device measures or derived measures calculable therefrom, the medical device measures having been recorded on a substantially continuous basis;

defining a set of indicator thresholds, each indicator threshold corresponding to a quantifiable physiological measure of a pathophysiology resulting from atrial fibrillation and relating to the same type of patient information as at least one of the recorded measures; and

diagnosing an atrial fibrillation finding, comprising:

determining a change in patient status in response to an atrial fibrillation diagnosis by comparing at least one recorded measure to at least one other recorded measure with both recorded measures relating to the same type of patient information; and

comparing each patient status change to the indicator threshold corresponding to the same type of patient information as the recorded measures which were compared.

46. A method according to claim 45, wherein the device measures are recorded by at least one of a medical device adapted to be implanted in an individual patient and an external medical device proximal to the individual patient when the device measures are recorded.

47. A method according to claim 46, wherein each of the monitoring sets comprises recorded measures relating to patient information solely for the individual patient, further comprising:

retrieving each monitoring set from a patient care record for the individual patient; and

obtaining the at least one recorded measure and the at least one other recorded measure from the retrieved monitoring sets.

48. A method according to claim 45, wherein each of the monitoring sets comprises recorded measures relating to patient information for a peer group of patients to which the individual patient belongs, further comprising:

retrieving at least one monitoring set from a patient care record for the individual patient;

retrieving at least one other monitoring set from a patient care record in the same patient peer group; and

obtaining the at least one recorded measure from the at least one monitoring set and the at least one other recorded measure from the at least one other monitoring set.

49. A method according to claim 45, wherein each of the monitoring sets comprises recorded measures relating to patient information for the general population of patients, further comprising:

retrieving at least one monitoring set from a patient care record for the individual patient;

retrieving at least one other monitoring set from a patient care record in the overall patient population; and

obtaining the at least one recorded measure from the at least one monitoring set and the at least one other recorded measure from the at least one other monitoring set.

50. A method according to claim 45, further comprising:

retrieving a reference baseline comprising recorded measures which each relate to patient information recorded by the medical device adapted to be implanted during an initial time period and comprise either device measures recorded by the medical device adapted to be implanted or derived measures calculable therefrom; and

obtaining at least one of the at least one recorded measure and the at least one other recorded measure from the retrieved reference baseline.

51. A method according to claim 50, wherein the reference baseline comprises recorded measures relating to patient information for one of the individual patients solely, a peer group of patients to which the individual patient belongs, and a general population of patients.

52. A method according to claim 45, the operation of comparing each patient status change further comprising:

grading the comparisons between each patient status change and corresponding indicator threshold on a fixed scale based on a degree of deviation from the indicator threshold; and

determining an overall patient status change by performing a summation over the individual graded comparisons.

53. A method according to claim 45, the operation of comparing each patient status change further comprising:

determining probabilistic weightings of the comparisons between each patient status change and corresponding indicator threshold based on a statistical deviation and trends via linear fits from the indicator threshold; and

determining an overall patient status change by performing a summation over the individual graded comparisons.

54. A method according to claim 45, wherein each monitoring set further comprises quality of life and symptom measures recorded by the individual patient, the operation of diagnosing an atrial fibrillation finding further comprising:

determining a change in patient status by comparing at least one recorded quality of life measure to at least one other corresponding recorded quality of life measure; and

incorporating each patient status change in quality of life into the atrial fibrillation finding to either refute or support the diagnosis.

55. A method according to claim 45, further comprising:

defining a set of further indicator thresholds, each indicator threshold corresponding to a quantifiable physiological measure used to detect a pathophysiology indicative of diseases other than atrial fibrillation; and

diagnosing a finding of the disease other than atrial fibrillation, comprising comparing each patient status change to each such further indicator threshold corresponding to the same type of patient information as the at least one recorded measure and the at least one other recorded measure.

56. A method according to claim 45, further comprising:

defining a set of stickiness indicators, each indicator threshold corresponding to a temporal limit related to a course of patient care; and

comparing a time span between each patient status change for each recorded measure to the stickiness indicator corresponding to the same type of patient information as the recorded measure being compared.

57. A method according to claim 45, further comprising:

providing automated feedback to the individual patient when an atrial fibrillation finding is indicated.

58. A method according to claim 57, further comprising:

performing an interactive dialogue between the individual patient and the patient care system regarding a medical condition of the individual patient.

59. A computer-readable storage medium holding code for diagnosing and monitoring the outcomes of atrial fibrillation using an automated collection and analysis patient care system, comprising:

retrieving a plurality of monitoring sets from a database, each monitoring set comprising recorded measures which each relate to patient information and comprise either medical device measures or derived measures calculable therefrom, the medical device measures having been recorded on a substantially continuous basis;

defining a set of indicator thresholds, each indicator threshold corresponding to a quantifiable physiological measure of a pathophysiology resulting from atrial fibrillation and relating to the same type of patient information as at least one of the recorded measures; and

diagnosing an atrial fibrillation finding, comprising:

determining a change in patient status in response to an atrial fibrillation diagnosis by comparing at least one recorded measure to at least one other recorded measure with both recorded measures relating to the same type of patient information; and

comparing each patient status change to the indicator threshold corresponding to the same type of patient information as the recorded measures which were compared.

60. A storage medium according to claim 59, wherein each of the monitoring sets comprises recorded measures relating to patient information solely for the individual patient, further comprising:

retrieving each monitoring set from a patient care record for the individual patient; and

obtaining the at least one recorded measure and the at least one other recorded measure from the retrieved monitoring sets.

61. A storage medium according to claim 59, wherein each of the monitoring sets comprises recorded measures relating to patient information for a peer group of patients to which the individual patient belongs, further comprising:

retrieving at least one monitoring set from a patient care record for the individual patient;

retrieving at least one other monitoring set from a patient care record in the same patient peer group; and

obtaining the at least one recorded measure from the at least one monitoring set and the at least one other recorded measure from the at least one other monitoring set.

62. A storage medium according to claim 59, wherein each of the monitoring sets comprises recorded measures relating to patient information for the general population of patients, further comprising:

retrieving at least one monitoring set from a patient care record for the individual patient;

retrieving at least one other monitoring set from a patient care record in the overall patient population; and

obtaining the at least one recorded measure from the at least one monitoring set and the at least one other recorded measure from the at least one other monitoring set.

63. A storage medium according to claim 59, further comprising:

retrieving a reference baseline comprising recorded measures which each relate to patient information recorded by the medical device adapted to be implanted during an initial time period and comprise either device measures recorded by the medical device adapted to be implanted or derived measures calculable therefrom; and

obtaining at least one of the at least one recorded measure and the at least one other recorded measure from the retrieved reference baseline.

64. A storage medium according to claim 59, the operation of comparing each patient status change further comprising:

grading the comparisons between each patient status change and corresponding indicator threshold on a fixed scale based on a degree of deviation from the indicator threshold; and

determining an overall patient status change by performing a summation over the individual graded comparisons.

65. A storage medium according to claim 59, the operation of comparing each patient status change further comprising:

determining probabilistic weightings of the comparisons between each patient status change and corresponding indicator threshold based on a statistical deviation and trends via linear fits from the indicator threshold; and

determining an overall patient status change by performing a summation over the individual graded comparisons.

66. A storage medium according to claim 59, wherein each monitoring set further comprises quality of life and

symptom measures recorded by the individual patient, the operation of diagnosing an atrial fibrillation finding further comprising:

determining a change in patient status by comparing at least one recorded quality of life measure to at least one other corresponding recorded quality of life measure; and

incorporating each patient status change in quality of life into the atrial fibrillation finding to either refute or support the diagnosis.

67. A storage medium according to claim 59, further comprising:

defining a set of further indicator thresholds, each indicator threshold corresponding to a quantifiable physiological measure used to detect a pathophysiology indicative of diseases other than atrial fibrillation; and

diagnosing a finding of the disease other than atrial fibrillation, comprising comparing each patient status change to each such further indicator threshold corresponding to the same type of patient information as the at least one recorded measure and the at least one other recorded measure.

68. A storage medium according to claim 59, further comprising:

defining a set of stickiness indicators, each indicator threshold corresponding to a temporal limit related to a course of patient care; and

comparing a time span between each patient status change for each recorded measure to the stickiness indicator corresponding to the same type of patient information as the recorded measure being compared.

69. A storage medium according to claim 59, further comprising:

providing automated feedback to the individual patient when an atrial fibrillation finding is indicated.

70. A storage medium according to claim 69, further comprising:

performing an interactive dialogue between the individual patient and the patient care system regarding a medical condition of the individual patient.

71. An automated patient care system for diagnosing and monitoring the outcomes of atrial fibrillation, comprising:

a database storing recorded measures organized into a monitoring set for an individual patient with each recorded measure having been recorded on a substantially continuous basis and relating to at least one of monitoring reduced exercise capacity and respiratory distress;

a database module periodically retrieving a plurality of the monitoring sets from the database; and

a diagnostic module evaluating at least one of atrial fibrillation onset, progression, regression, and status quo, comprising:

a comparison module determining a patient status change in response to an atrial fibrillation diagnosis by comparing at least one recorded measure from each of the monitoring sets to at least one other recorded measure with both recorded measures relating to the same type of patient information; and

an analysis module testing each patient status change against an indicator threshold corresponding to the same type of patient information as the recorded measures which were compared, the indicator threshold corresponding to a quantifiable physiological measure of a pathophysiology indicative of reduced exercise capacity and respiratory distress.

72. A method for diagnosing and monitoring the outcomes of atrial fibrillation in an automated patient care system, comprising:

storing recorded measures organized into a monitoring set for an individual patient into a database with each recorded measure having been recorded on a substantially continuous basis and relating to at least one of monitoring reduced exercise capacity and respiratory distress;

periodically retrieving a plurality of the monitoring sets from the database;

evaluating at least one of atrial fibrillation onset, progression, regression, and status quo, comprising:

determining a patient status change in response to an atrial fibrillation diagnosis by comparing at least one recorded measure from each of the monitoring sets to at least one other recorded measure with both recorded measures relating to the same type of patient information; and

testing each patient status change against an indicator threshold corresponding to the same type of patient information as the recorded measures which were compared, the indicator threshold corresponding to a quantifiable physiological measure of a pathophysiology indicative of reduced exercise capacity and respiratory distress.

73. A computer-readable storage medium holding code for diagnosing and monitoring the outcomes of atrial fibrillation in an automated patient care system, comprising:

storing recorded measures organized into a monitoring set for an individual patient into a database with each recorded measure having been recorded on a substantially continuous basis and relating to at least one of monitoring reduced exercise capacity and respiratory distress;

periodically retrieving a plurality of the monitoring sets from the database;

evaluating at least one of atrial fibrillation onset, progression, regression, and status quo, comprising:

determining a patient status change in response to an atrial fibrillation diagnosis by comparing at least one recorded measure from each of the monitoring sets to at least one other recorded measure with both recorded measures relating to the same type of patient information; and

testing each patient status change against an indicator threshold corresponding to the same type of patient information as the recorded measures which were compared, the indicator threshold corresponding to a

quantifiable physiological measure of a pathophysiology indicative of reduced exercise capacity and respiratory distress.

74. An automated system for managing a pathophysiological outcome of atrial fibrillation, comprising:

a database storing a plurality of monitoring sets from a database which each comprise recorded measures relating to patient information recorded on a substantially continuous basis;

a comparison module determining a pathophysiological outcome of atrial fibrillation in response to an atrial fibrillation diagnosis, comprising comparing at least one recorded measure from each of the monitoring sets to at least one other recorded measure with both recorded measures relating to the same type of patient information and testing each recorded measure comparison against an indicator threshold corresponding to the same type of patient information as the recorded measures which were compared, the indicator threshold corresponding to a quantifiable physiological measure of a pathophysiology resulting from atrial fibrillation; and

an analysis module managing the atrial fibrillation outcome through interventive administration of therapy contributing to normal sinus rhythm restoration and ventricular rate response control.

75. An automated system according to claim 74, wherein the pathophysiological outcome comprises a cardiovascular/cardiopulmonary compromise, further comprising:

the comparison module classifying a severity of the cardiovascular/cardiopulmonary compromise according to magnitude of change and time span occurrence for each recorded measure comparison; and

the analysis module generating a therapy regimen based on the severity, comprising, in decreasing order of severity:

for the cardiovascular/cardiopulmonary compromise with a highest severity, administering an aggressive atrial fibrillation therapy;

for the cardiovascular/cardiopulmonary compromise of second highest severity, administering initial anticoagulation management coupled with selective ventricular rate response control for atrial fibrillation of long term duration and administering an aggressive atrial fibrillation therapy in the presence of anticoagulation drug therapy;

for the cardiovascular/cardiopulmonary compromise of third highest severity, administering initial monitored anticoagulation management coupled with selective ventricular rate response control for atrial fibrillation of long term duration, administering a moderate atrial fibrillation therapy coupled with ventricular rate response control for atrial fibrillation of long term duration and administering a moderate atrial fibrillation therapy for atrial fibrillation in the absence of anticoagulation drug therapy; and

for the cardiovascular/cardiopulmonary compromise of least severity, administering initial anticoagulation management coupled with selective ventricular rate response control and on-going cardiovascular/cardiopulmonary monitoring for atrial fibrillation of long term duration, administering a modest atrial fibrillation therapy for atrial fibrillation of long term duration and administering a modest atrial fibrillation therapy for atrial fibrillation in the absence of anticoagulation drug therapy.

76. An automated system according to claim 74, wherein the pathophysiological outcome comprises an inappropriate ventricular rate response, further comprising:

the comparison module classifying ventricular rate response according to average ventricular rate; and

the analysis module generating a therapy regimen based on the severity, comprising:

for overly slow ventricular rate response, performing at least one therapy selected from the group comprising increasing ventricular pacing rate and decreasing antidromotropic drug therapy; and

for overly rapid ventricular rate response, performing at least one therapy selected from the group comprising applying electrical therapy and administering initial drug therapy to decrease atrioventricular node conduction.

77. An automated system according to claim 74, wherein the pathophysiological outcome comprises a pathophysiological condition requiring anticoagulation drug therapy, further comprising:

the comparison module determining a duration for atrial fibrillation and anticoagulation drug therapy status; and

the analysis module administering anticoagulation drug therapy for atrial fibrillation of long term duration in the absence of a contraindication of anticoagulation drug therapy or inadequacy thereof.

78. An automated system according to claim 74, wherein the pathophysiological outcome comprises palpitations/symptoms, further comprising:

the comparison module classifying palpitations/symptoms according to disabling effect to the patient; and

the analysis module generating a therapy regimen based on the classification, comprising:

for disabling palpitations/symptoms, administering a moderate atrial fibrillation therapy for atrial fibrillation;

for non-disabling palpitations/symptoms, administering a modest atrial fibrillation therapy for atrial fibrillation.

79. An automated method for managing a pathophysiological outcome of atrial fibrillation, comprising:

retrieving a plurality of monitoring sets from a database which each comprise recorded measures relating to patient information recorded on a substantially continuous basis;

determining a pathophysiological outcome of atrial fibrillation in response to an atrial fibrillation diagnosis, comprising:

comparing at least one recorded measure from each of the monitoring sets to at least one other recorded measure with both recorded measures relating to the same type of patient information; and

testing each recorded measure comparison against an indicator threshold corresponding to the same type of patient information as the recorded measures which were compared, the indicator threshold corresponding to a quantifiable physiological measure of a pathophysiology resulting from atrial fibrillation; and

managing the atrial fibrillation outcome through interventive administration of therapy contributing to normal sinus rhythm restoration and ventricular rate response control.

80. An automated method according to claim 79, wherein the pathophysiological outcome comprises a cardiovascular/cardiopulmonary compromise, further comprising:

classifying a severity of the cardiovascular/cardiopulmonary compromise according to magnitude of change and time span occurrence for each recorded measure comparison; and

generating a therapy regimen based on the severity, comprising, in decreasing order of severity:

for the cardiovascular/cardiopulmonary compromise with a highest severity, administering an aggressive atrial fibrillation therapy;

for the cardiovascular/cardiopulmonary compromise of second highest severity, administering initial anticoagulation management coupled with selective ventricular rate response control for atrial fibrillation of long term duration and administering an aggressive atrial fibrillation therapy in the presence of anticoagulation drug therapy;

for the cardiovascular/cardiopulmonary compromise of third highest severity, administering initial monitored anticoagulation management coupled with selective ventricular rate response control for atrial fibrillation of long term duration, administering a moderate atrial fibrillation therapy coupled with ventricular rate response control for atrial fibrillation of long term duration and administering a moderate atrial fibrillation therapy for atrial fibrillation in the absence of anticoagulation drug therapy; and

for the cardiovascular/cardiopulmonary compromise of least severity, administering initial anticoagulation management coupled with selective ventricular rate response control and on-going cardiovascular/cardiopulmonary monitoring for atrial fibrillation of long term duration, administering a modest atrial fibrillation therapy for atrial fibrillation of long term duration and administering a modest atrial fibrillation therapy for atrial fibrillation in the absence of anticoagulation drug therapy.

81. An automated method according to claim 79, wherein the pathophysiological outcome comprises an inappropriate ventricular rate response, further comprising:

classifying ventricular rate response according to average ventricular rate; and

generating a therapy regimen based on the severity, comprising:

for overly slow ventricular rate response, performing at least one therapy selected from the group comprising increasing ventricular pacing rate and decreasing antidromotropic drug therapy; and

for overly rapid ventricular rate response, performing at least one therapy selected from the group comprising applying electrical therapy and administering initial drug therapy to decrease atrioventricular node conduction.

82. An automated method according to claim 79, wherein the pathophysiological outcome comprises a pathophysiological condition requiring anticoagulation drug therapy, further comprising:

determining a duration for atrial fibrillation and anticoagulation drug therapy status; and

administering anticoagulation drug therapy for atrial fibrillation of long term duration in the absence of a contraindication of anticoagulation drug therapy or inadequacy thereof.

83. An automated method according to claim 79, wherein the pathophysiological outcome comprises palpitations/symptoms, further comprising:

classifying palpitations/symptoms according to disabling effect to the patient; and

generating a therapy regimen based on the classification, comprising:

for disabling palpitations/symptoms, administering a moderate atrial fibrillation therapy for atrial fibrillation;

for non-disabling palpitations/symptoms, administering a modest atrial fibrillation therapy for atrial fibrillation.

84. A computer-readable storage medium holding code for managing a pathophysiological outcome of atrial fibrillation, comprising:

retrieving a plurality of monitoring sets from a database which each comprise recorded measures relating to patient information recorded on a substantially continuous basis;

determining a pathophysiological outcome of atrial fibrillation in response to an atrial fibrillation diagnosis, comprising:

comparing at least one recorded measure from each of the monitoring sets to at least one other recorded measure with both recorded measures relating to the same type of patient information; and

testing each recorded measure comparison against an indicator threshold corresponding to the same type of patient information as the recorded measures which were compared, the indicator threshold corresponding to a quantifiable physiological measure of a pathophysiology resulting from atrial fibrillation; and

managing the atrial fibrillation outcome through interventive administration of therapy contributing to normal sinus rhythm restoration and ventricular rate response control.

85. A storage medium according to claim 84, wherein the pathophysiological outcome comprises a cardiovascular/cardiopulmonary compromise, further comprising:

classifying a severity of the cardiovascular/cardiopulmonary compromise according to magnitude of change and time span occurrence for each recorded measure comparison; and

generating a therapy regimen based on the severity, comprising, in decreasing order of severity:

for the cardiovascular/cardiopulmonary compromise with a highest severity, administering an aggressive atrial fibrillation therapy;

for the cardiovascular/cardiopulmonary compromise of second highest severity, administering initial anticoagulation management coupled with selective ventricular rate response control for atrial fibrillation of long term duration and administering an aggressive atrial fibrillation therapy in the presence of anticoagulation drug therapy;

for the cardiovascular/cardiopulmonary compromise of third highest severity, administering initial monitored anticoagulation management coupled with selective ventricular rate response control for atrial fibrillation of long term duration, administering a moderate atrial fibrillation therapy coupled with ventricular rate response control for atrial fibrillation of long term duration and administering a moderate atrial fibrillation therapy for atrial fibrillation in the absence of anticoagulation drug therapy; and

for the cardiovascular/cardiopulmonary compromise of least severity, administering initial anticoagulation management coupled with selective ventricular rate response control and on-going cardiovascular/cardiopulmonary monitoring for atrial fibrillation of long term duration, administering a modest atrial fibrillation therapy for atrial fibrillation of long term duration and administering a modest atrial fibrillation therapy for atrial fibrillation in the absence of anticoagulation drug therapy.

86. A storage medium according to claim 84, wherein the pathophysiological outcome comprises an inappropriate ventricular rate response, further comprising:

classifying ventricular rate response according to average ventricular rate; and

generating a therapy regimen based on the severity, comprising:

for overly slow ventricular rate response, performing at least one therapy selected from the group comprising increasing ventricular pacing rate and decreasing antidromotropic drug therapy; and

for overly rapid ventricular rate response, performing at least one therapy selected from the group comprising applying electrical therapy and administering initial drug therapy to decrease atrioventricular node conduction.

87. A storage medium according to claim 84, wherein the pathophysiological outcome comprises a pathophysiological condition requiring anticoagulation drug therapy, further comprising:

determining a duration for atrial fibrillation and anticoagulation drug therapy status; and

administering anticoagulation drug therapy for atrial fibrillation of long term duration in the absence of a contraindication of anticoagulation drug therapy or inadequacy thereof.

88. A storage medium according to claim 84, wherein the pathophysiological outcome comprises palpitations/symptoms, further comprising:

classifying palpitations/symptoms according to disabling effect to the patient; and

generating a therapy regimen based on the classification, comprising:

for disabling palpitations/symptoms, administering a moderate atrial fibrillation therapy for atrial fibrillation;

for non-disabling palpitations/symptoms, administering a modest atrial fibrillation therapy for atrial fibrillation.

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专利名称(译)	用于诊断和监测心房颤动结果的自动化方法		
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摘要(译)

描述了用于诊断和监测心房颤动结果的自动系统和方法。从数据库检索多个监视集。每个监测组包括与基本连续记录的患者信息有关的记录测量。通过将来自每个监测组的至少一个记录的测量值与至少一个其他记录的测量值进行比较来确定响应于心房颤动诊断的患者状态变化。两种记录的测量都与相同类型的患者信息有关。针对与所比较的记录测量的相同类型的患者信息对应的指标阈值来测试每个患者状态变化。指标阈值对应于由心房颤动引起的病理生理学的可量化的生理测量。