US008954139B2

(12) **United States Patent**
**Hopenfeld et al.**

(10) **Patent No.: US 8,954,139 B2**
(45) **Date of Patent: Feb. 10, 2015**

(54) **ACUTE ISCHEMIA DETECTION BASED ON PARAMETER VALUE RANGE ANALYSIS**

(71) Applicant: **Angel Medical Systems, Inc.**, Fair Haven, NJ (US)

(72) Inventors: **Bruce Hopenfeld**, Salt Lake City, UT (US); **Steven R. Johnson**, Fair Haven, NJ (US)

(73) Assignee: **Angel Medical Systems, Inc.**, Fair Haven, NJ (US)

( * ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **14/170,894**

(22) Filed: **Feb. 3, 2014**

(65) **Prior Publication Data**

US 2014/0148716 A1 May 29, 2014

**Related U.S. Application Data**

(63) Continuation of application No. 12/868,308, filed on Aug. 25, 2010, now Pat. No. 8,428,703, and a continuation-in-part of application No. 13/788,143, filed on Mar. 7, 2013, now Pat. No. 8,682,422.

(51) **Int. Cl.**

| | |
|---|---|
| ***A61B 5/0456*** | (2006.01) |
| ***A61B 5/02*** | (2006.01) |
| ***A61B 5/00*** | (2006.01) |
| ***A61B 5/0452*** | (2006.01) |
| ***A61B 5/024*** | (2006.01) |
| ***A61B 5/04*** | (2006.01) |

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

CPC ..... ***A61B 5/02028*** (2013.01); ***A61B 5/0006*** (2013.01); ***A61B 5/0452*** (2013.01); ***A61B 5/686*** (2013.01); ***A61B 5/02405*** (2013.01); ***A61B 5/7282*** (2013.01); ***A61B 5/04012*** (2013.01)

USPC ..... **600/516**; 600/509; 607/25

(58) **Field of Classification Search**

CPC ..... A61B 5/0452; A61B 5/0402; A61B 5/02405; A61B 5/0205; A61B 5/024; A61B 5/04012; A61B 5/046; A61B 5/0006; A61B 1/36053; A61B 1/36114; A61B 1/36592; A61B 1/3956

USPC ..... 600/508–509, 515–519; 607/25–26

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

| | | | | |
|---|---|---|---|---|
| 5,792,047 | A | 8/1998 | Coggins | |
| 6,324,421 | B1 | 11/2001 | Stadler et al. | |
| 6,972,938 | B2 | 12/2005 | Hiraga | |
| 7,512,438 | B2 | 3/2009 | Fischell et al. | |
| 7,930,017 | B1 * | 4/2011 | Fain et al. | 600/509 |
| 2004/0215092 | A1 | 10/2004 | Fischell et al. | |
| 2005/0137483 | A1 | 6/2005 | Fischell et al. | |
| 2009/0082682 | A1 | 3/2009 | Fischell et al. | |
| 2009/0216141 | A1 | 8/2009 | Fischell et al. | |
| 2011/0040199 | A1 | 2/2011 | Hopenfeld | |
| 2011/0245699 | A1 | 10/2011 | Snell et al. | |

* cited by examiner

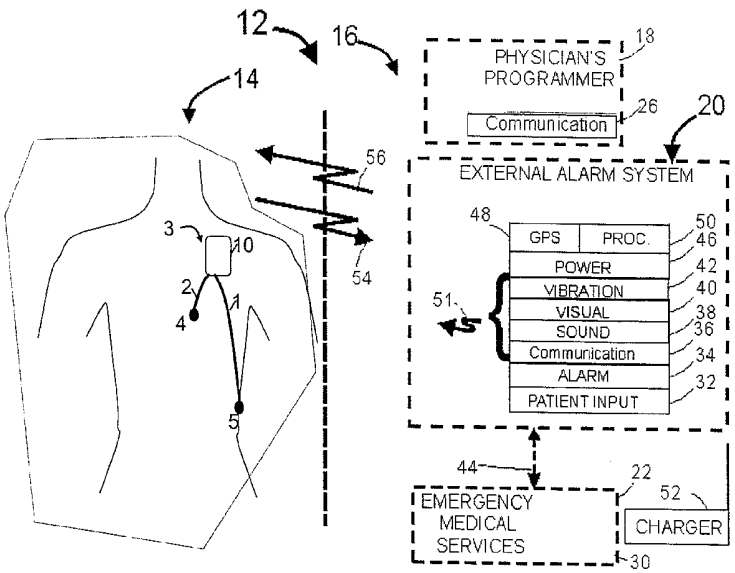
*Primary Examiner* — Rex R Holmes

(74) *Attorney, Agent, or Firm* — Rosenberg, Klein & Lee

(57) **ABSTRACT**

A heart monitor is disclosed. The monitor computes ST segment deviations and stores the results in heart rate based histograms. Periodically, the monitor analyzes the histogram data to determine a normal range of ST deviation for a particular heart rate range. The monitor computes heart rate dependent ischemia detection thresholds based on the upper and lower boundaries of the normal range.

**3 Claims, 23 Drawing Sheets**



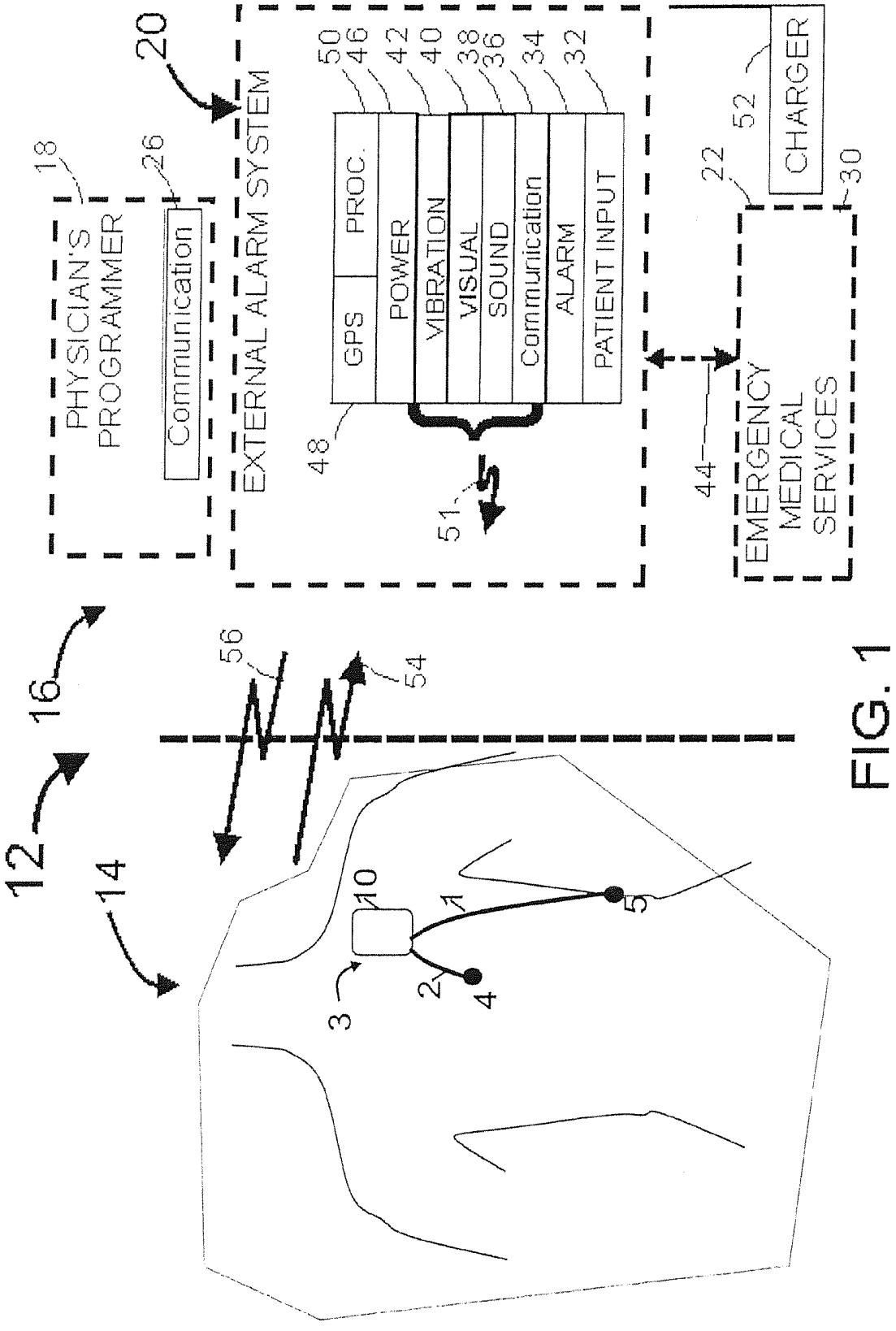

20
18
PHYSICIAN'S PROGRAMMER
26
Communication
EXTERNAL ALARM SYSTEM
50
46
42
40
38
36
34
32
GPS
PROC.
POWER
VIBRATION
VISUAL
SOUND
Communication
ALARM
PATIENT INPUT
48
51
52
CHARGER
22
30
44
EMERGENCY MEDICAL SERVICES
16
56
54
12
14
10
1
5
2
4
3

FIG. 1

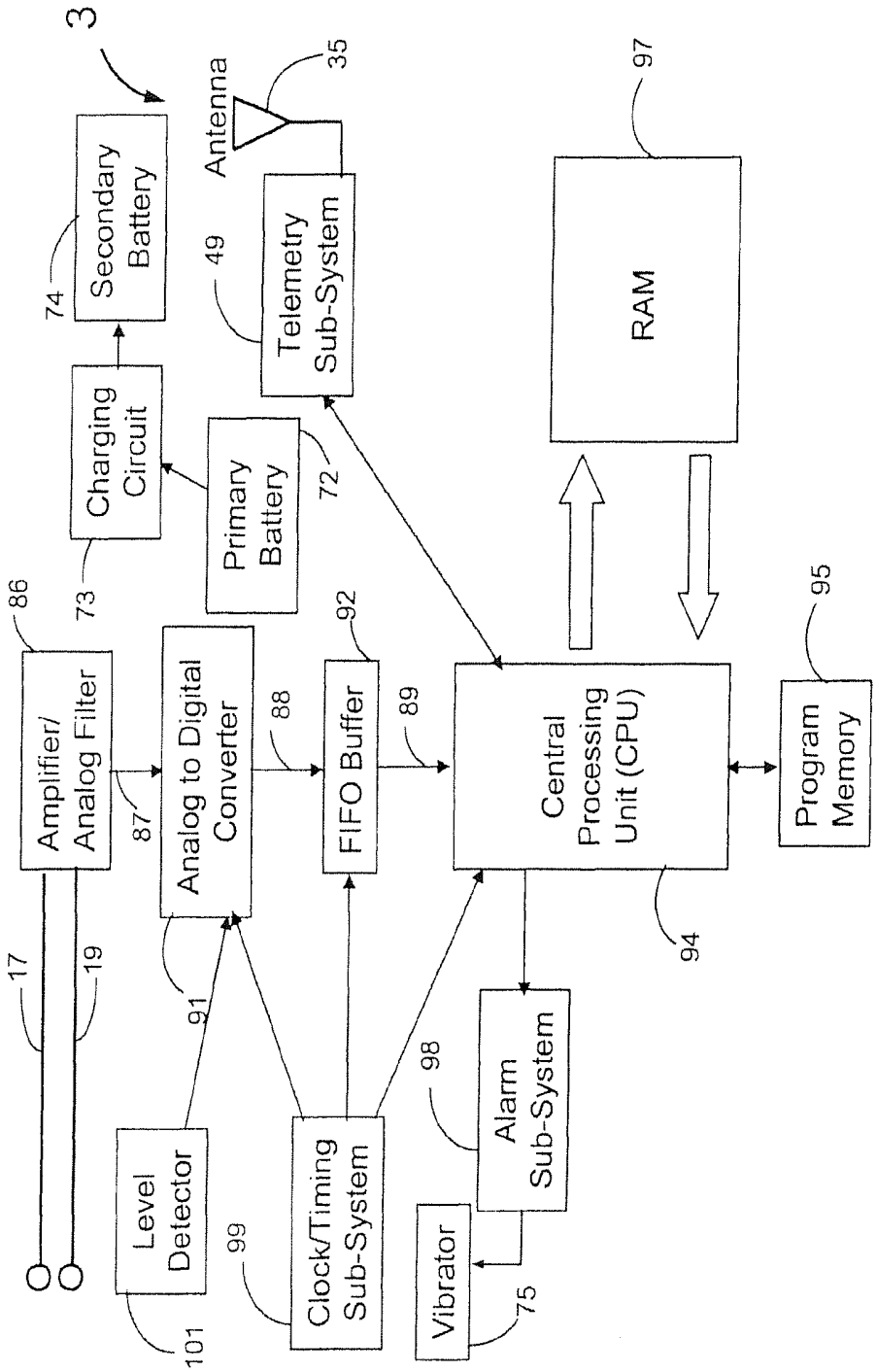
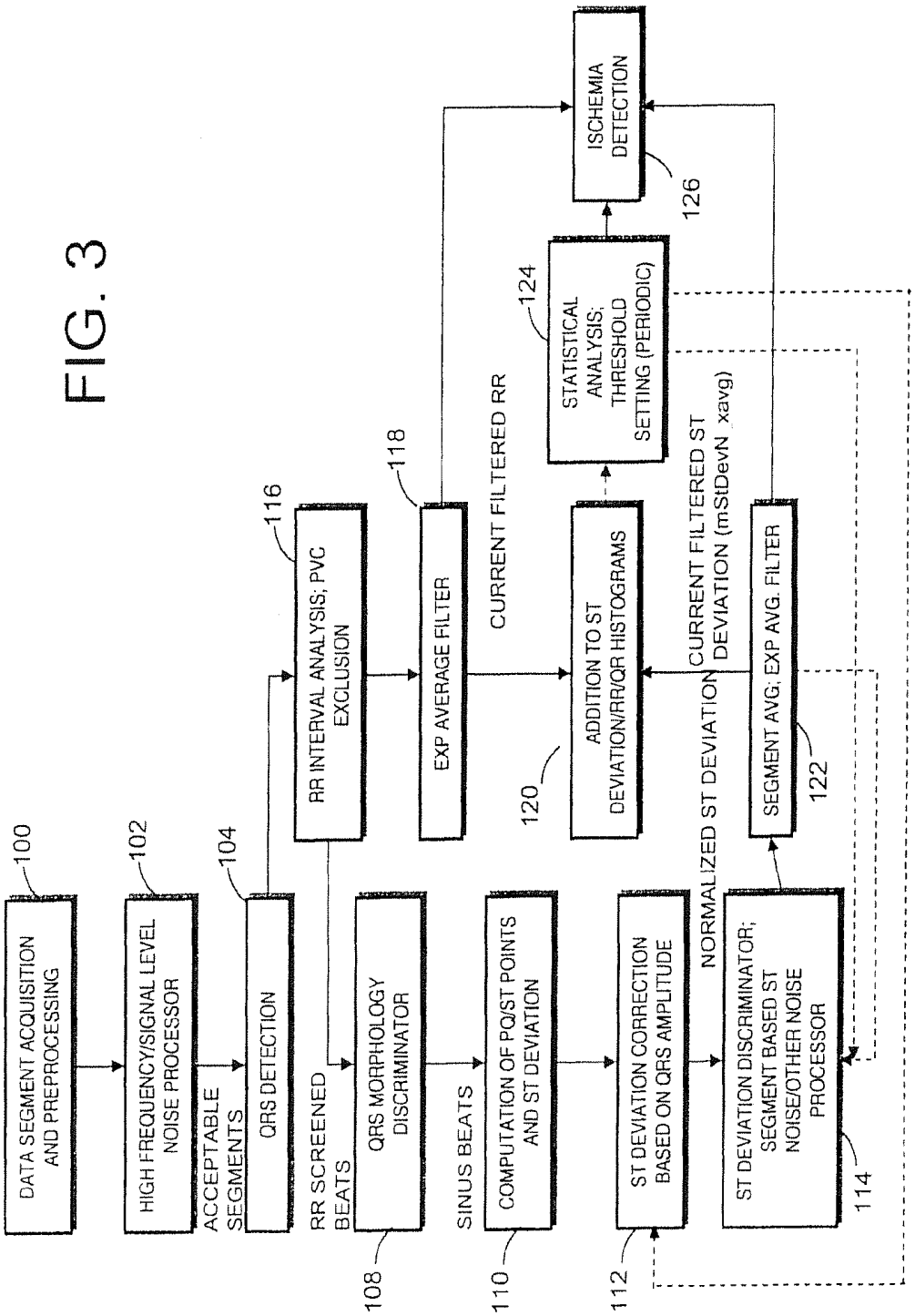

3
Secondary Battery
74
Antenna
35
Telemetry Sub-System
49
RAM
97
Charging Circuit
73
Primary Battery
72
Amplifier/ Analog Filter
86
Analog to Digital Converter
87
88
FIFO Buffer
92
89
Central Processing Unit (CPU)
94
Program Memory
95
17
19
91
Level Detector
101
99
Clock/Timing Sub-System
98
Alarm Sub-System
Vibrator
75

FIG. 2

FIG. 3


DATA SEGMENT ACQUISITION AND PREPROCESSING
100
HIGH FREQUENCY/SIGNAL LEVEL NOISE PROCESSOR
102
ACCEPTABLE SEGMENTS
QRS DETECTION
104
RR SCREENED BEATS
QRS MORPHOLOGY DISCRIMINATOR
108
SINUS BEATS
COMPUTATION OF PQ/ST POINTS AND ST DEVIATION
110
ST DEVIATION CORRECTION BASED ON QRS AMPLITUDE
112
NORMALIZED ST DEVIATION
ST DEVIATION DISCRIMINATOR; SEGMENT BASED ST NOISE/OTHER NOISE PROCESSOR
114
RR INTERVAL ANALYSIS; PVC EXCLUSION
116
EXP AVERAGE FILTER
118
CURRENT FILTERED RR
ADDITION TO ST DEVIATION/RR/QR HISTOGRAMS
120
CURRENT FILTERED ST DEVIATION (mStDevN_xavg)
SEGMENT AVG; EXP AVG. FILTER
122
STATISTICAL ANALYSIS; THRESHOLD SETTING (PERIODIC)
124
ISCHEMIA DETECTION
126

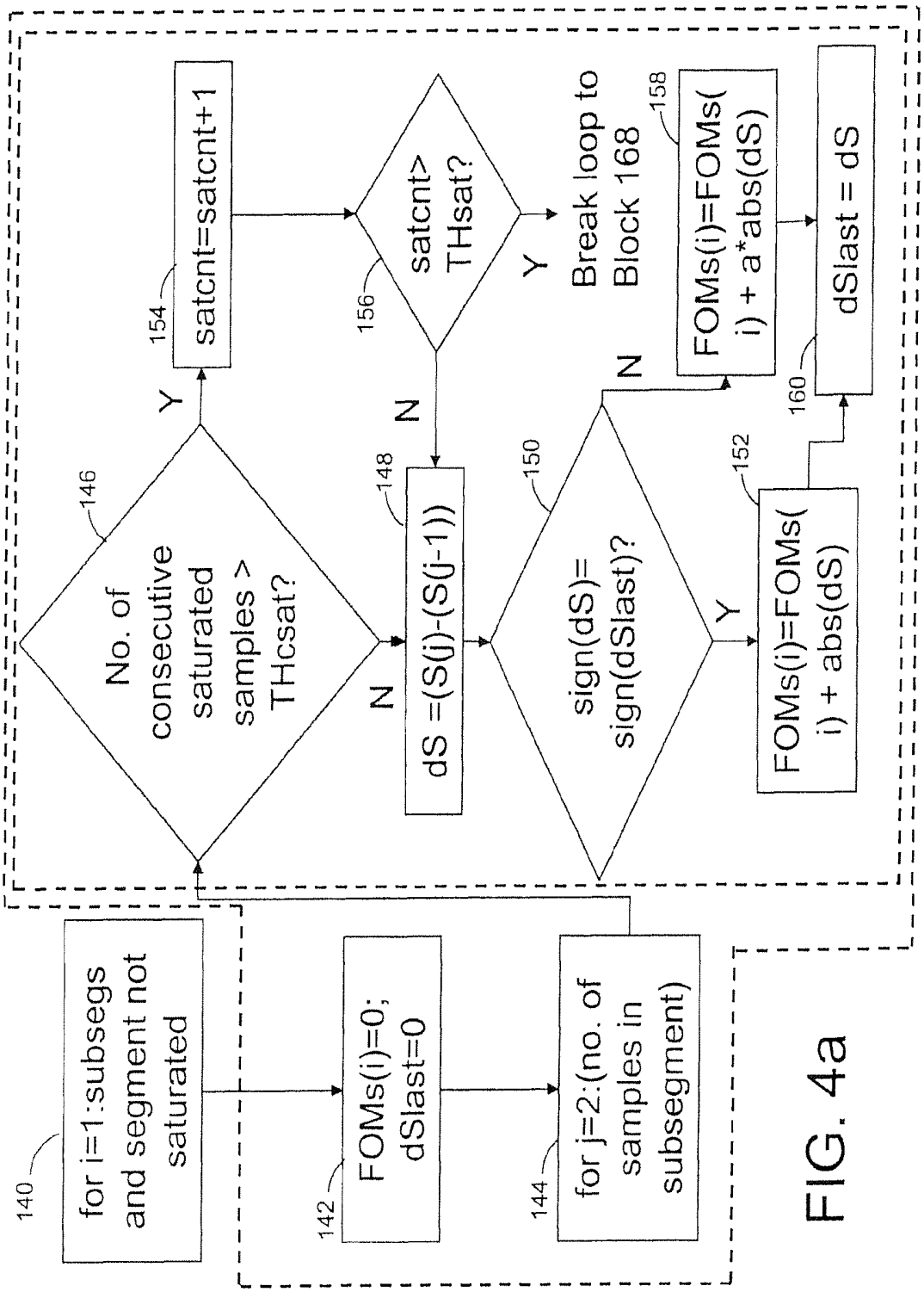

for i=1:subsegs and segment not saturated
140
FOMs(i)=0; dSlast=0
142
for j=2:(no. of samples in subsegment)
144
No. of consecutive saturated samples > THcsat?
146
Y
satcnt=satcnt+1
154
N
dS =(S(j)-(S(j-1))
148
sign(dS)= sign(dSlast)?
150
Y
FOMs(i)=FOMs( i) + abs(dS)
152
N
satcnt> THsat?
156
Y
Break loop to Block 168
FOMs(i)=FOMs( i) + a*abs(dS)
158
dSlast = dS
160

FIG. 4a

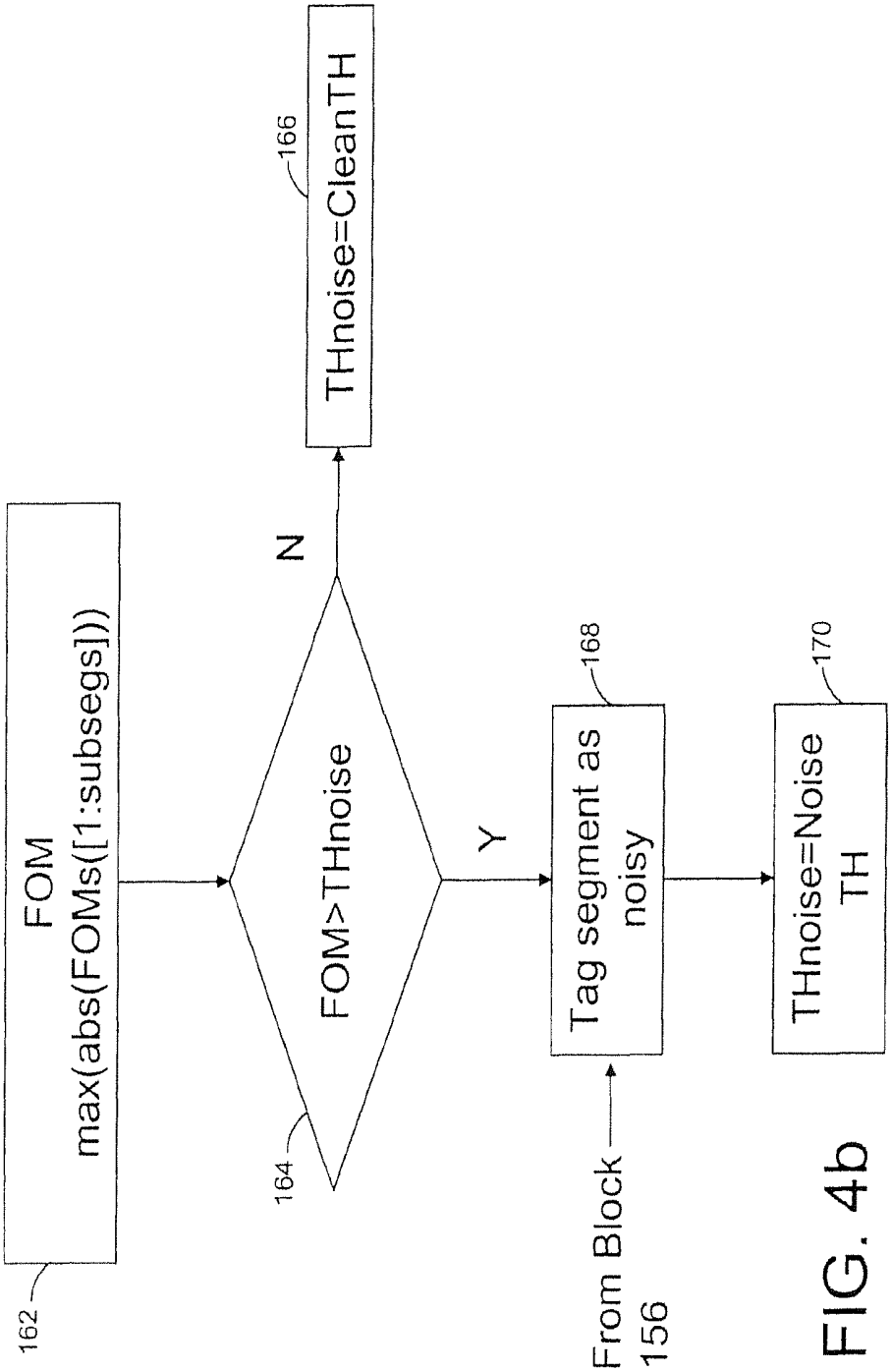

FOM
max(abs(FOMs([1:subsegs]))
162
FOM>THnoise
164
N
THnoise=CleanTH
166
Y
Tag segment as noisy
168
From Block 156
THnoise=Noise TH
170

FIG. 4b

FIG. 5

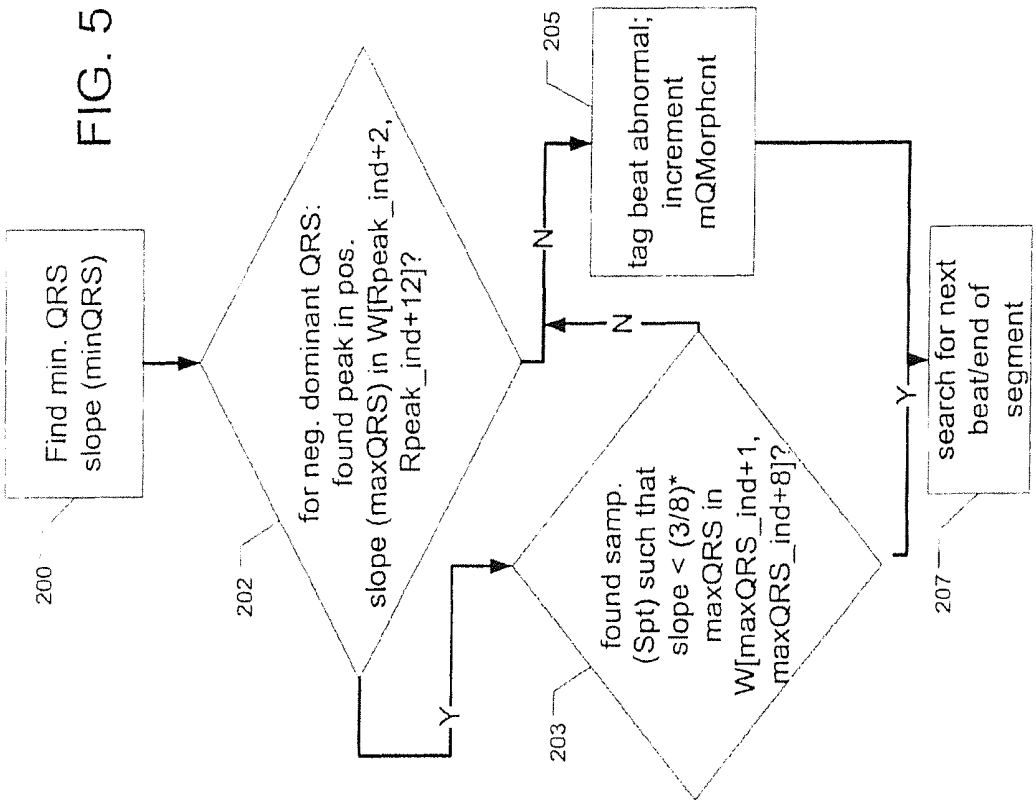

Find min. QRS slope (minQRS)
200
for neg. dominant QRS: found peak in pos. slope (maxQRS) in W[Rpeak_ind+2, Rpeak_ind+12]?
202
N
Y
found samp. (Spt) such that slope < (3/8)* maxQRS in W[maxQRS_ind+1, maxQRS_ind+8]?
203
N
Y
tag beat abnormal; increment mQMorphcnt
205
search for next beat/end of segment
207

FIG. 6a

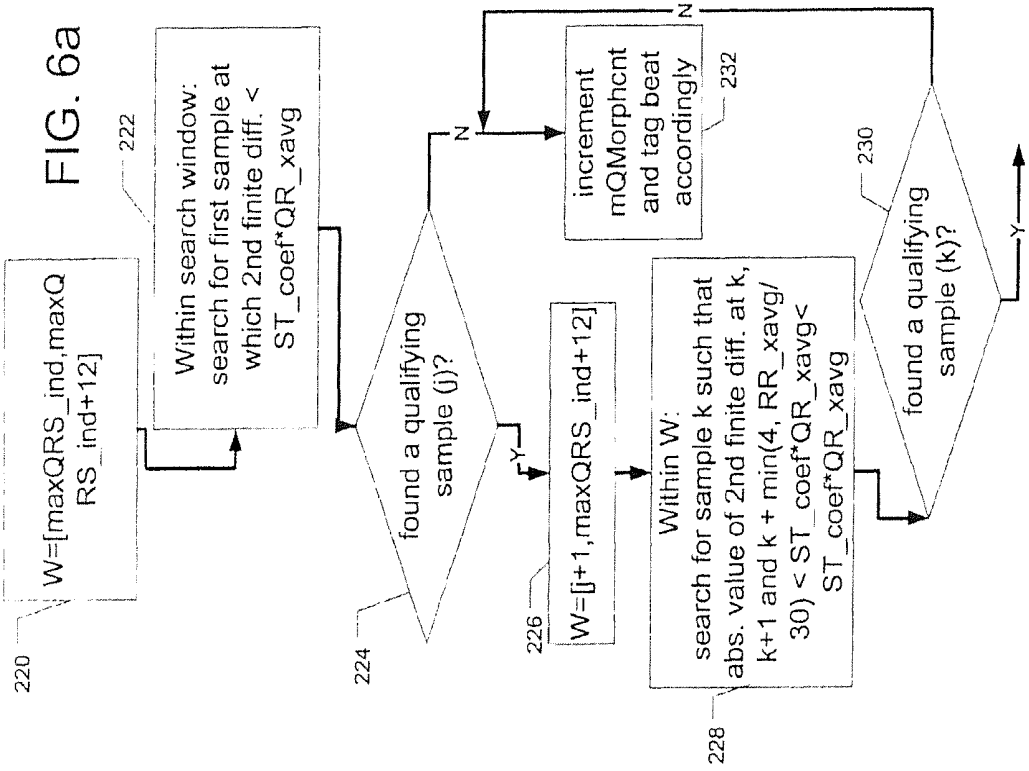
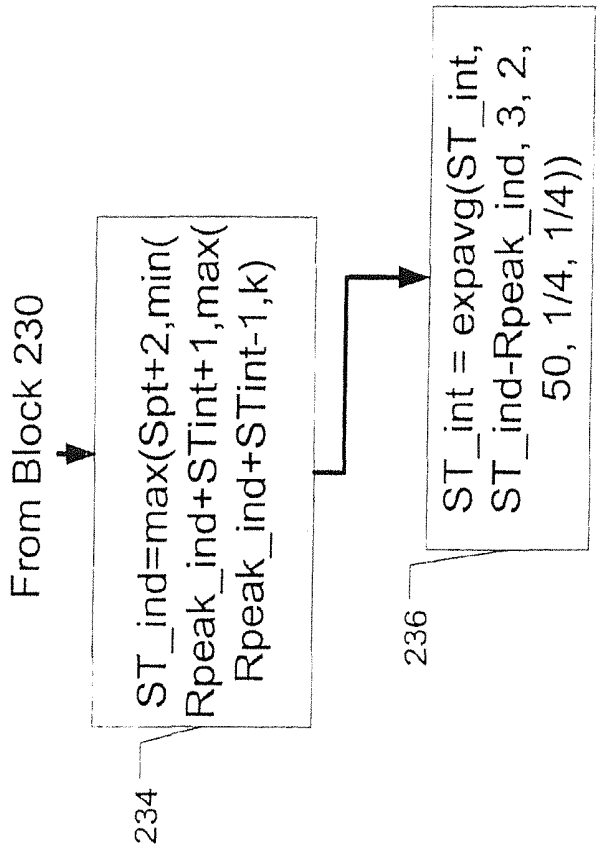

W=[maxQRS_ind,maxQRS_ind+12]
220
Within search window: search for first sample at which 2nd finite diff. < ST_coef*QR_xavg
222
found a qualifying sample (j)?
224
N
Y
increment mQMorphcnt and tag beat accordingly
232
W=[j+1,maxQRS_ind+12]
226
Within W: search for sample k such that abs. value of 2nd finite diff. at k, k+1 and k + min(4, RR_xavg/30) < ST_coef*QR_xavg< ST_coef*QR_xavg
228
found a qualifying sample (k)?
230
N
Y

FIG. 6b


From Block 230
ST_ind=max(Spt+2,min(
Rpeak_ind+STint+1,max(
Rpeak_ind+STint-1,k)
234
ST_int = expavg(ST_int,
ST_ind-Rpeak_ind, 3, 2,
50, 1/4, 1/4))
236

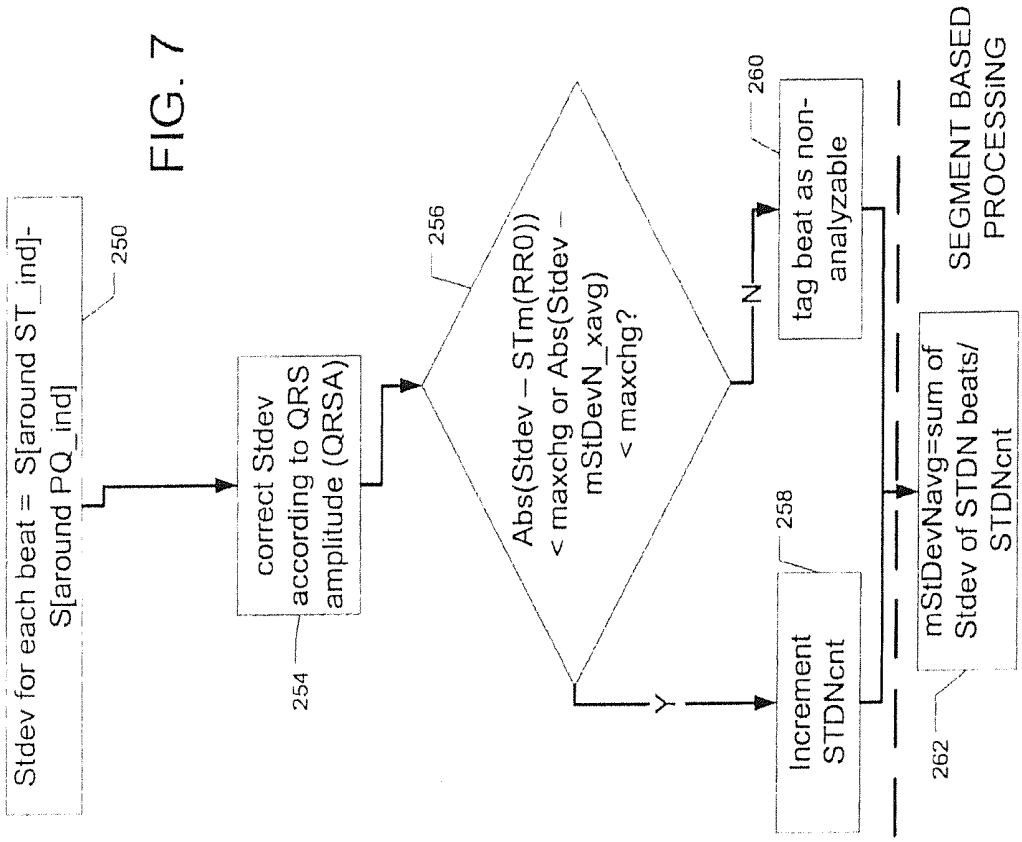

Stdev for each beat = S[around ST_ind]-S[around PQ_ind]
250
correct Stdev according to QRS amplitude (QRSA)
254
Abs(Stdev – STm(RR0)) < maxchg or Abs(Stdev – mStDevN_xavg) < maxchg?
256
Y
N
Increment STDNcnt
258
tag beat as non-analyzable
260
mStDevNavg=sum of Stdev of STDN beats/ STDNcnt
262
SEGMENT BASED PROCESSING

FIG. 7

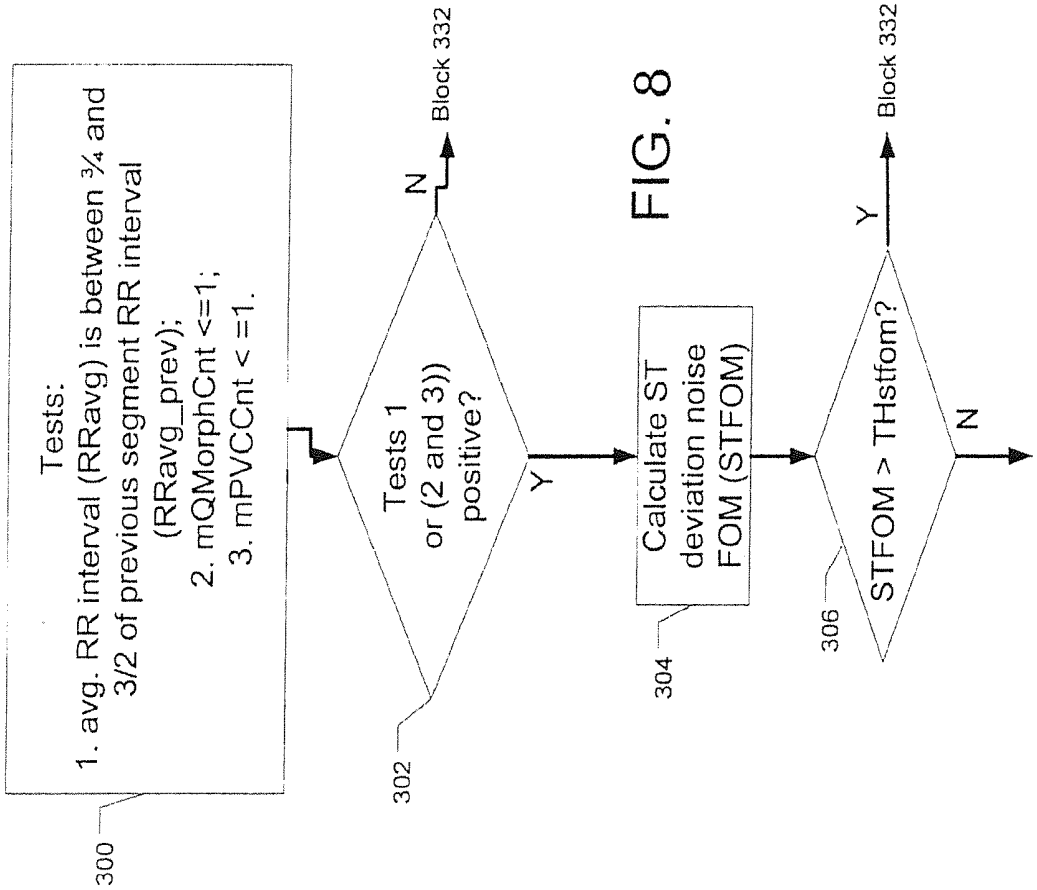

Tests:
1. avg. RR interval (RRavg) is between ¾ and 3/2 of previous segment RR interval (RRavg_prev);
2. mQMorphCnt <=1;
3. mPVCCnt < =1.
300
Tests 1 or (2 and 3)) positive?
302
N
Block 332
Y
Calculate ST deviation noise FOM (STFOM)
304
STFOM > THstfom?
306
Y
Block 332
N

FIG. 8

FIG. 9

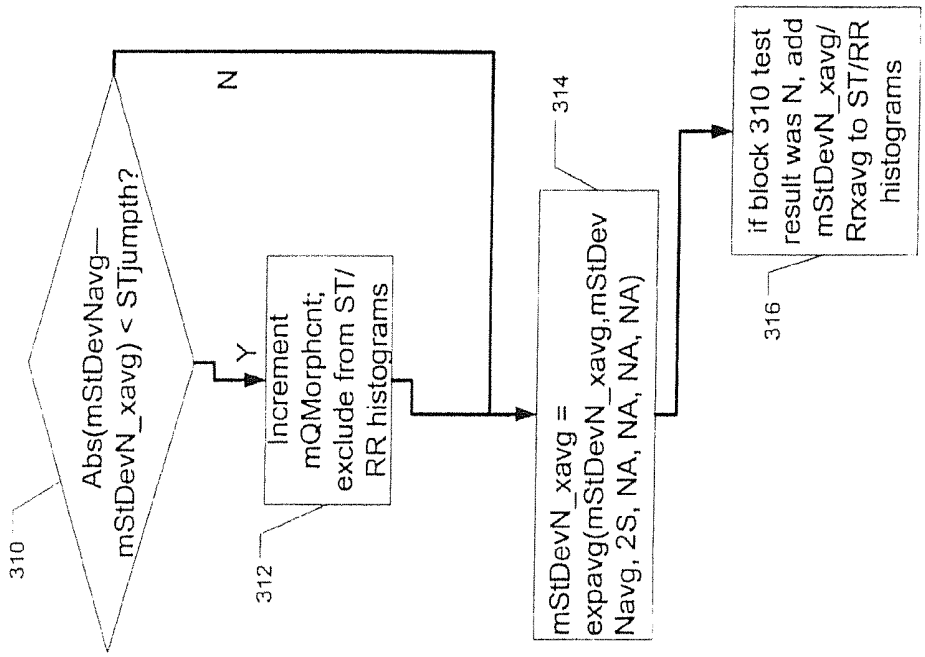
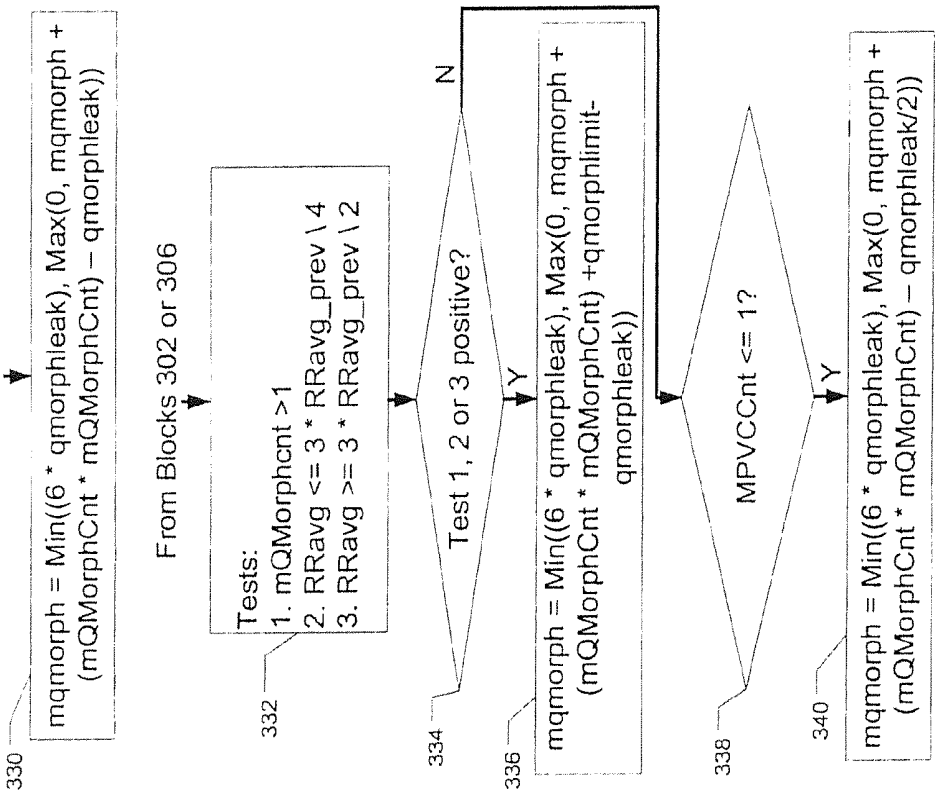

Abs(mStDevNavg—
mStDevN_xavg) < STjumpth?
310
N
Y
Increment
mQMorphcnt;
exclude from ST/
RR histograms
312
mStDevN_xavg =
expavg(mStDevN_xavg,mStDev
Navg, 2S, NA, NA, NA, NA)
314
if block 310 test
result was N, add
mStDevN_xavg/
Rrxavg to ST/RR
histograms
316

FIG. 10


From Block 316
330
mqmorph = Min((6 * qmorphleak), Max(0, mqmorph + (mQMorphCnt * mQMorphCnt) – qmorphleak))
From Blocks 302 or 306
332
Tests:
1. mQMorphcnt >1
2. RRavg <= 3 * RRavg_prev \ 4
3. RRavg >= 3 * RRavg_prev \ 2
334
Test 1, 2 or 3 positive?
N
Y
336
mqmorph = Min((6 * qmorphleak), Max(0, mqmorph + (mQMorphCnt * mQMorphCnt) +qmorphlimit-qmorphleak))
338
MPVCCnt <= 1?
Y
340
mqmorph = Min((6 * qmorphleak), Max(0, mqmorph + (mQMorphCnt * mQMorphCnt) – qmorphleak/2))

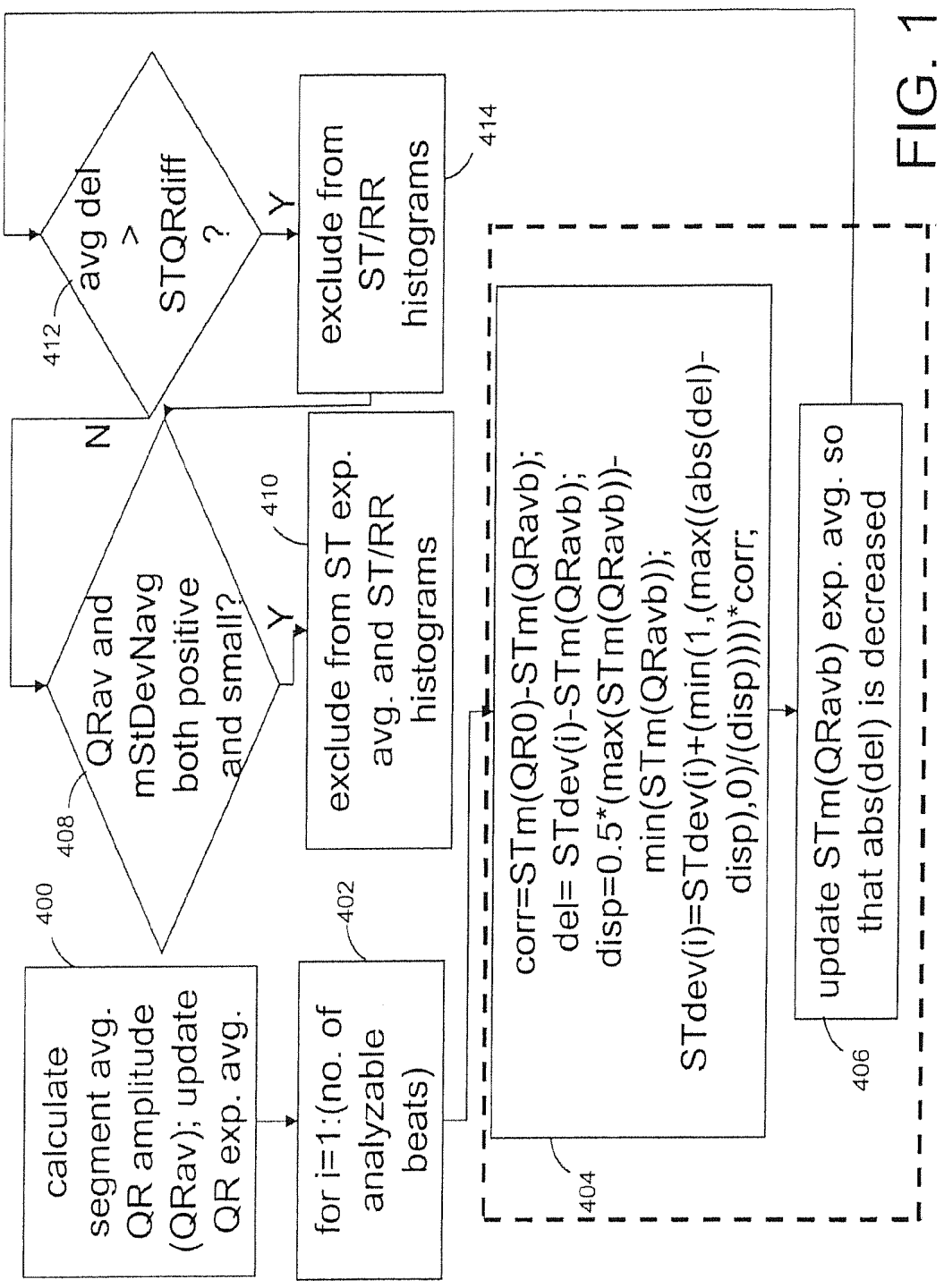

calculate segment avg. QR amplitude (QRav); update QR exp. avg.
400
for i=1:(no. of analyzable beats)
402
QRav and mStDevNavg both positive and small?
408
N
Y
exclude from ST exp. avg. and ST/RR histograms
410
avg del > STQRdiff ?
412
Y
exclude from ST/RR histograms
414
corr=STm(QR0)-STm(QRavb);
del= STdev(i)-STm(QRavb);
disp=0.5*(max(STm(QRavb))-min(STm(QRavb));
STdev(i)=STdev(i)+(min(1,(max((abs(del)-disp),0)/(disp))))*corr;
404
update STm(QRavb) exp. avg. so that abs(del) is decreased
406

FIG. 11

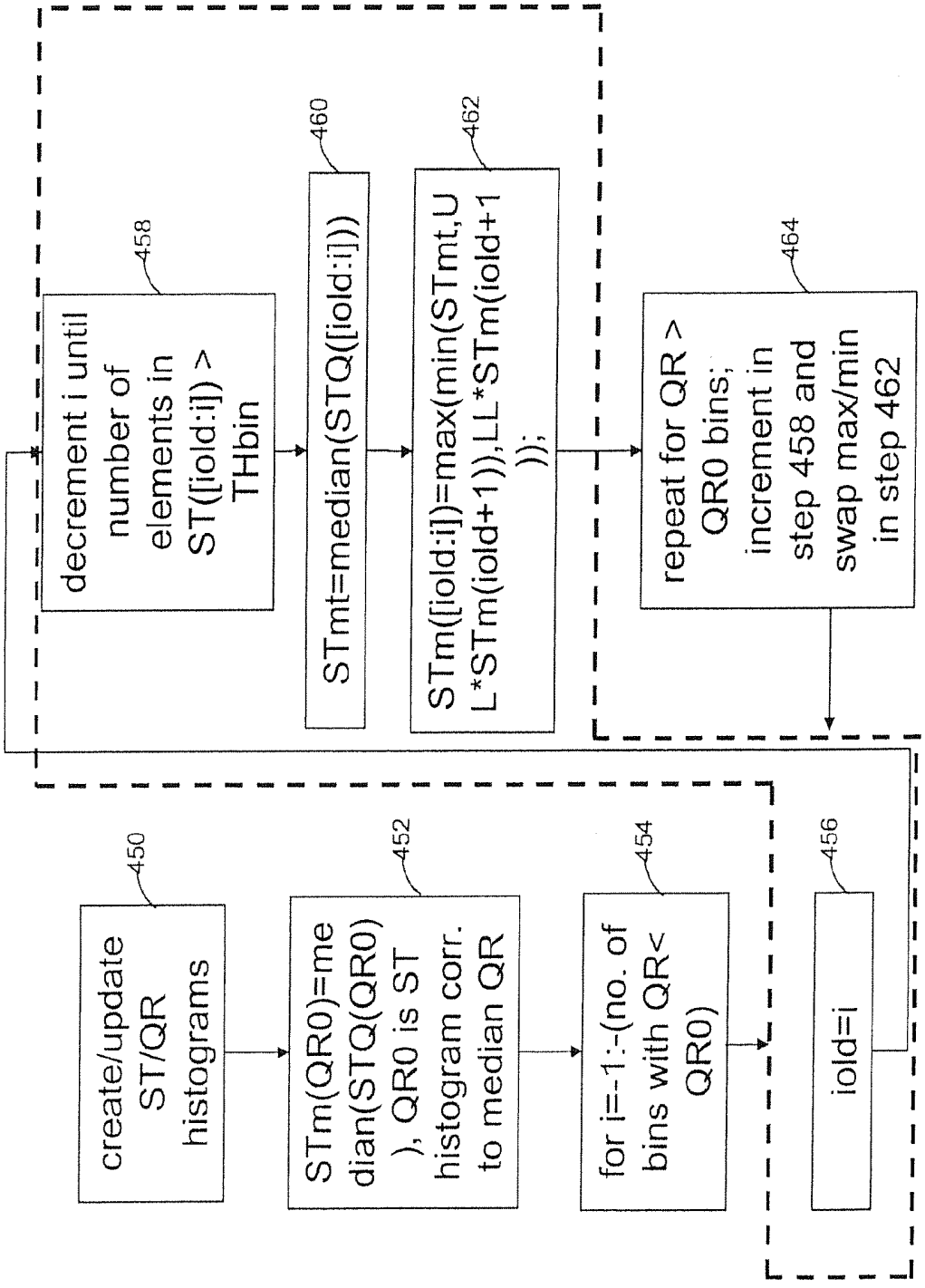
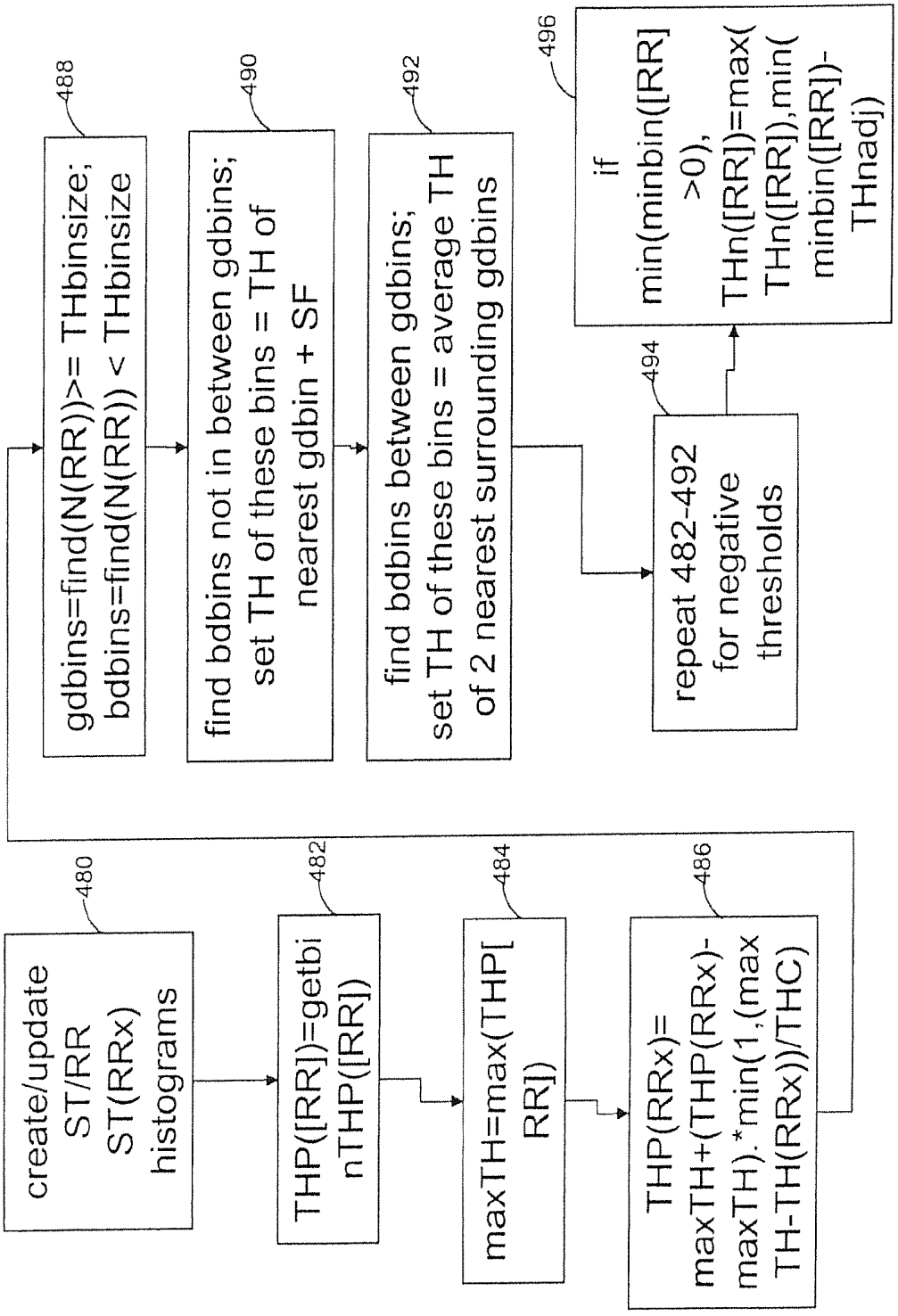

create/update ST/QR histograms
450
STm(QR0)=median(STQ(QR0)), QR0 is ST histogram corr. to median QR
452
for i=-1:-(no. of bins with QR< QR0)
454
iold=i
456
decrement i until number of elements in ST([iold:i]) > THbin
458
STmt=median(STQ([iold:i]))
460
STm([iold:i])=max(min(STmt,UL*STm(iold+1)),LL*STm(iold+1));
462
repeat for QR > QR0 bins; increment in step 458 and swap max/min in step 462
464

FIG. 12

FIGs. 13a


create/update ST/RR ST(RRx) histograms
480
THP([RR])=getbi nTHP([RR])
482
maxTH=max(THP[ RR])
484
THP(RRx)= maxTH+(THP(RRx)- maxTH).*min(1,(max TH-TH(RRx))/THC)
486
gdbins=find(N(RR))>= THbinsize; bdbins=find(N(RR)) < THbinsize
488
find bdbins not in between gdbins; set TH of these bins = TH of nearest gdbin + SF
490
find bdbins between gdbins; set TH of these bins = average TH of 2 nearest surrounding gdbins
492
repeat 482-492 for negative thresholds
494
if min(minbin([RR] >0), THn([RR])=max( THn([RR]),min( minbin([RR])- THnadj)
496

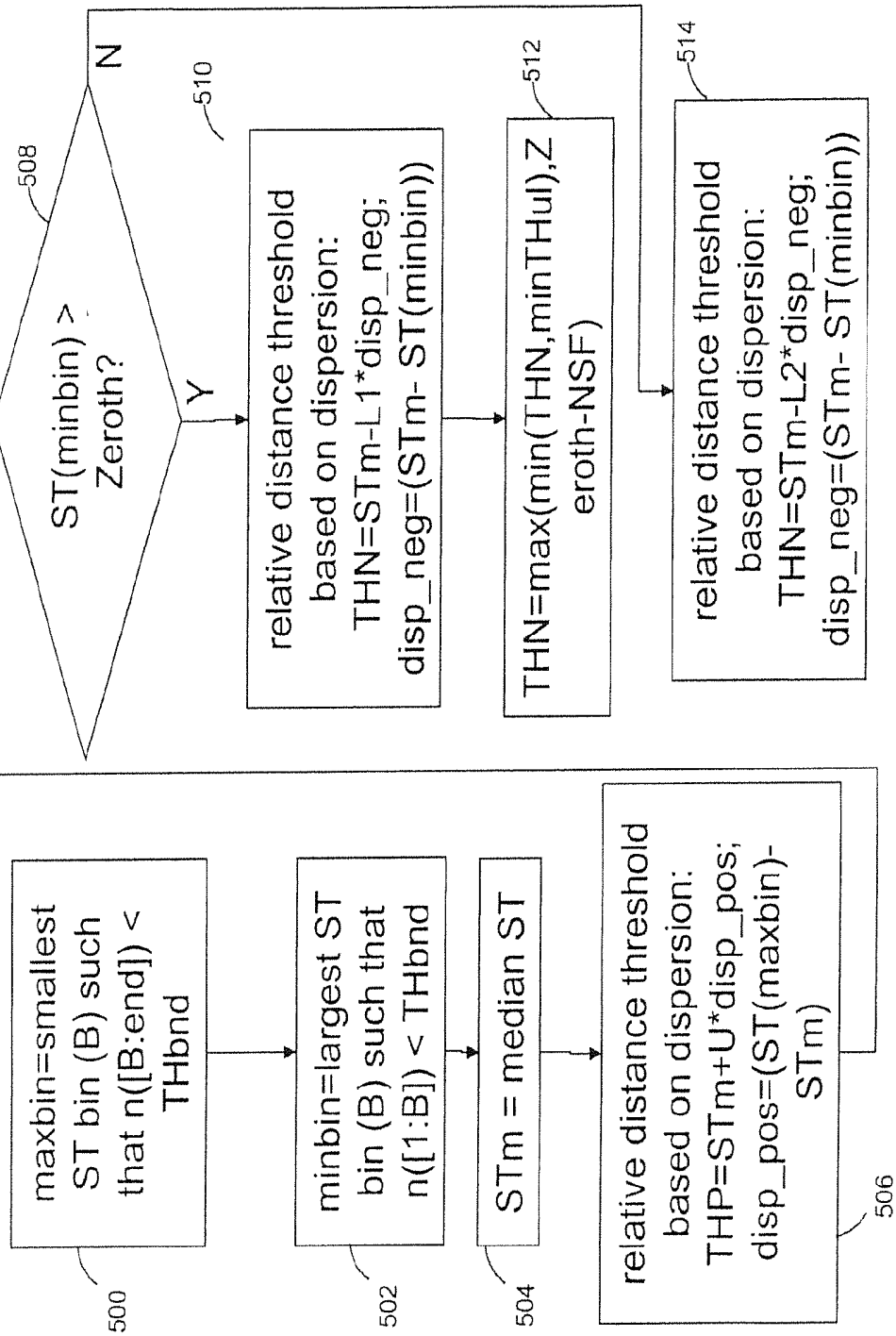

maxbin=smallest ST bin (B) such that n([B:end]) < THbnd
500
minbin=largest ST bin (B) such that n([1:B]) < THbnd
502
STm = median ST
504
relative distance threshold based on dispersion: THP=STm+U*disp_pos; disp_pos=(ST(maxbin)-STm)
506
ST(minbin) > Zeroth?
508
Y
N
relative distance threshold based on dispersion: THN=STm-L1*disp_neg; disp_neg=(STm- ST(minbin))
510
THN=max(min(THN,minTHul),Zeroth-NSF)
512
relative distance threshold based on dispersion: THN=STm-L2*disp_neg; disp_neg=(STm- ST(minbin))
514

FIG. 13b

Figure 14a

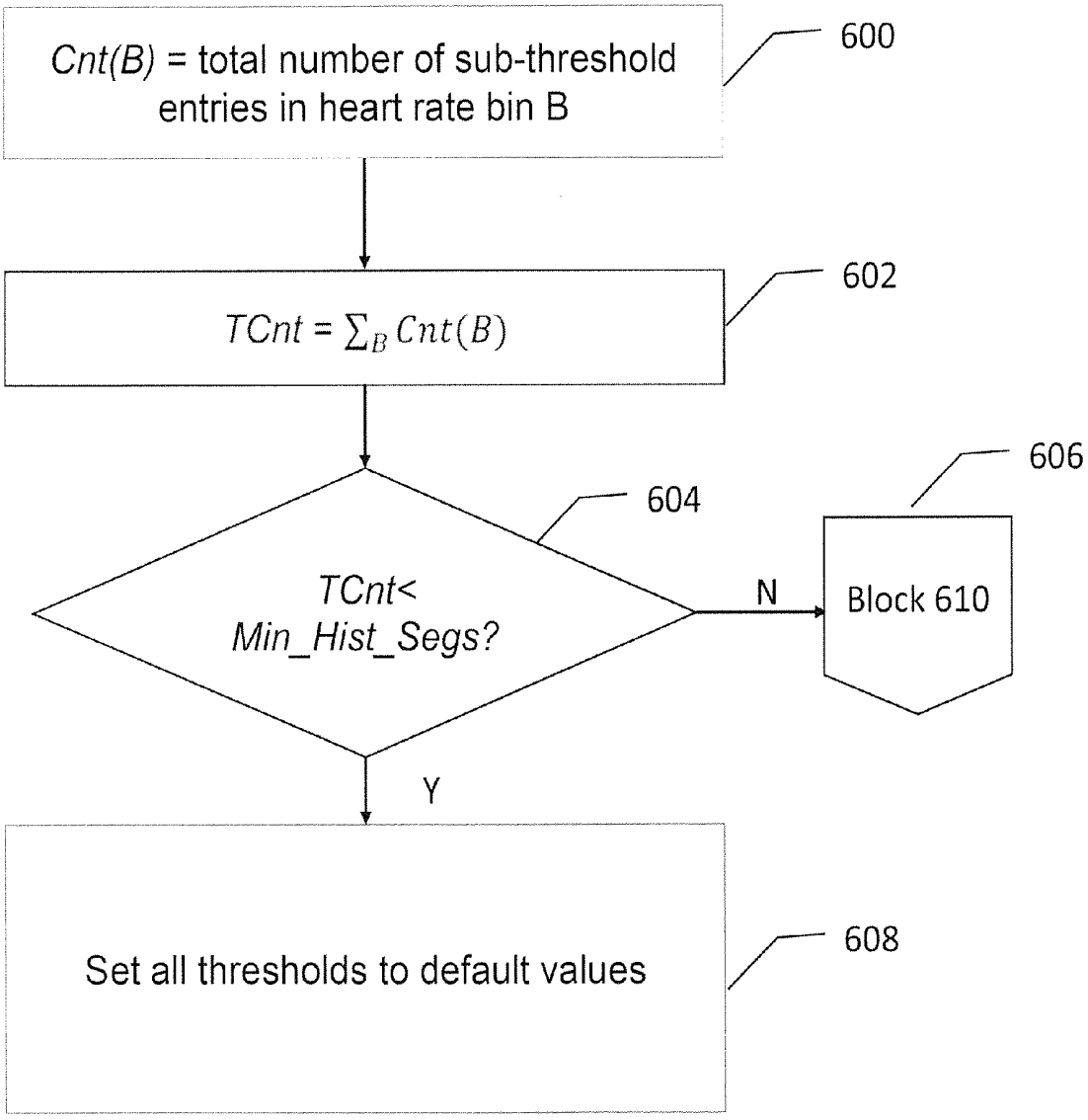

Cnt(B) = total number of sub-threshold entries in heart rate bin B
600
TCnt = $\sum_B Cnt(B)$
602
604
TCnt< Min_Hist_Segs?
N
606
Block 610
Y
Set all thresholds to default values
608

Figure 14b

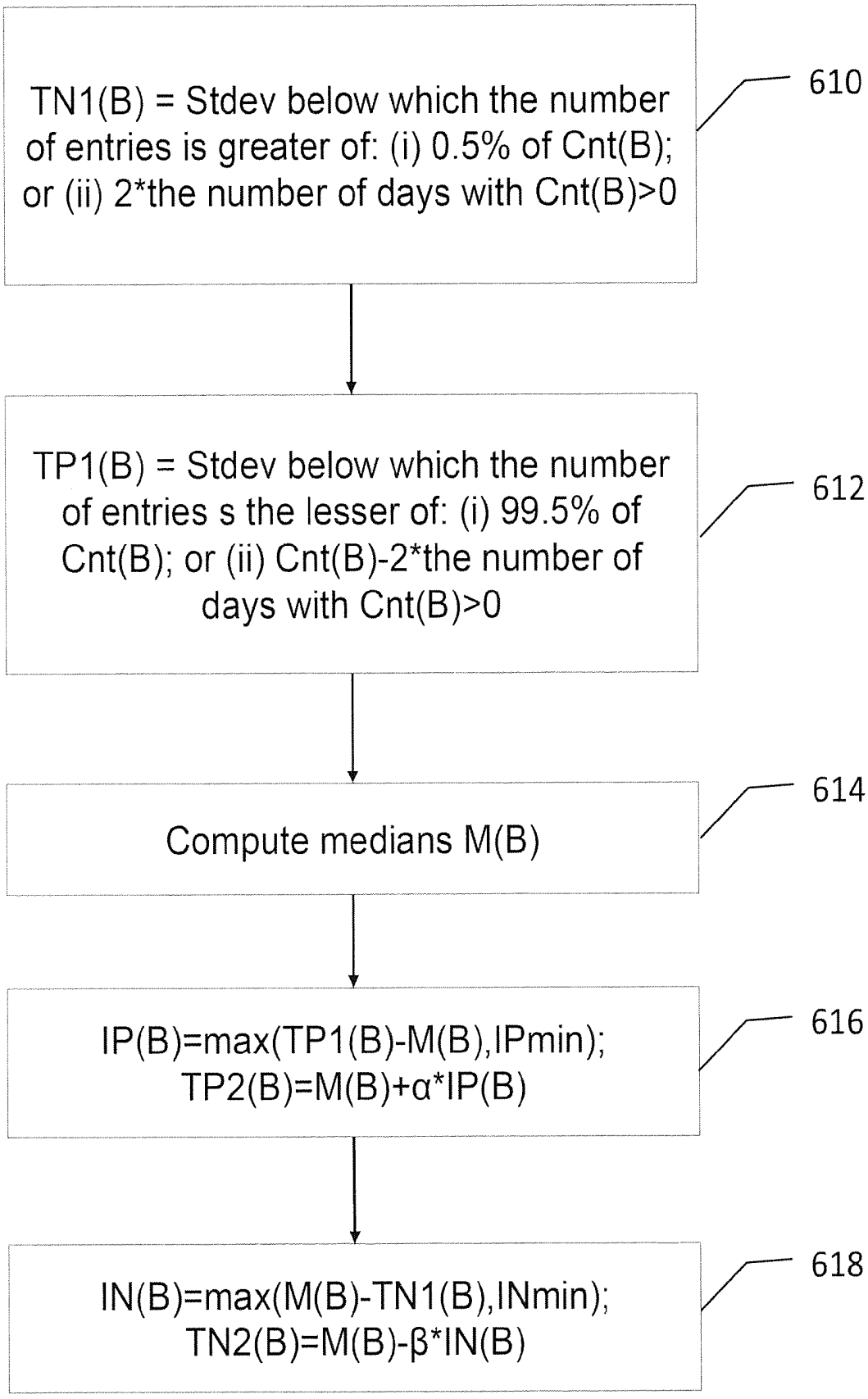

TN1(B) = Stdev below which the number of entries is greater of: (i) 0.5% of Cnt(B); or (ii) 2*the number of days with Cnt(B)>0
610
TP1(B) = Stdev below which the number of entries s the lesser of: (i) 99.5% of Cnt(B); or (ii) Cnt(B)-2*the number of days with Cnt(B)>0
612
Compute medians M(B)
614
IP(B)=max(TP1(B)-M(B),IPmin); TP2(B)=M(B)+α*IP(B)
616
IN(B)=max(M(B)-TN1(B),INmin); TN2(B)=M(B)-β*IN(B)
618

Figure 14c

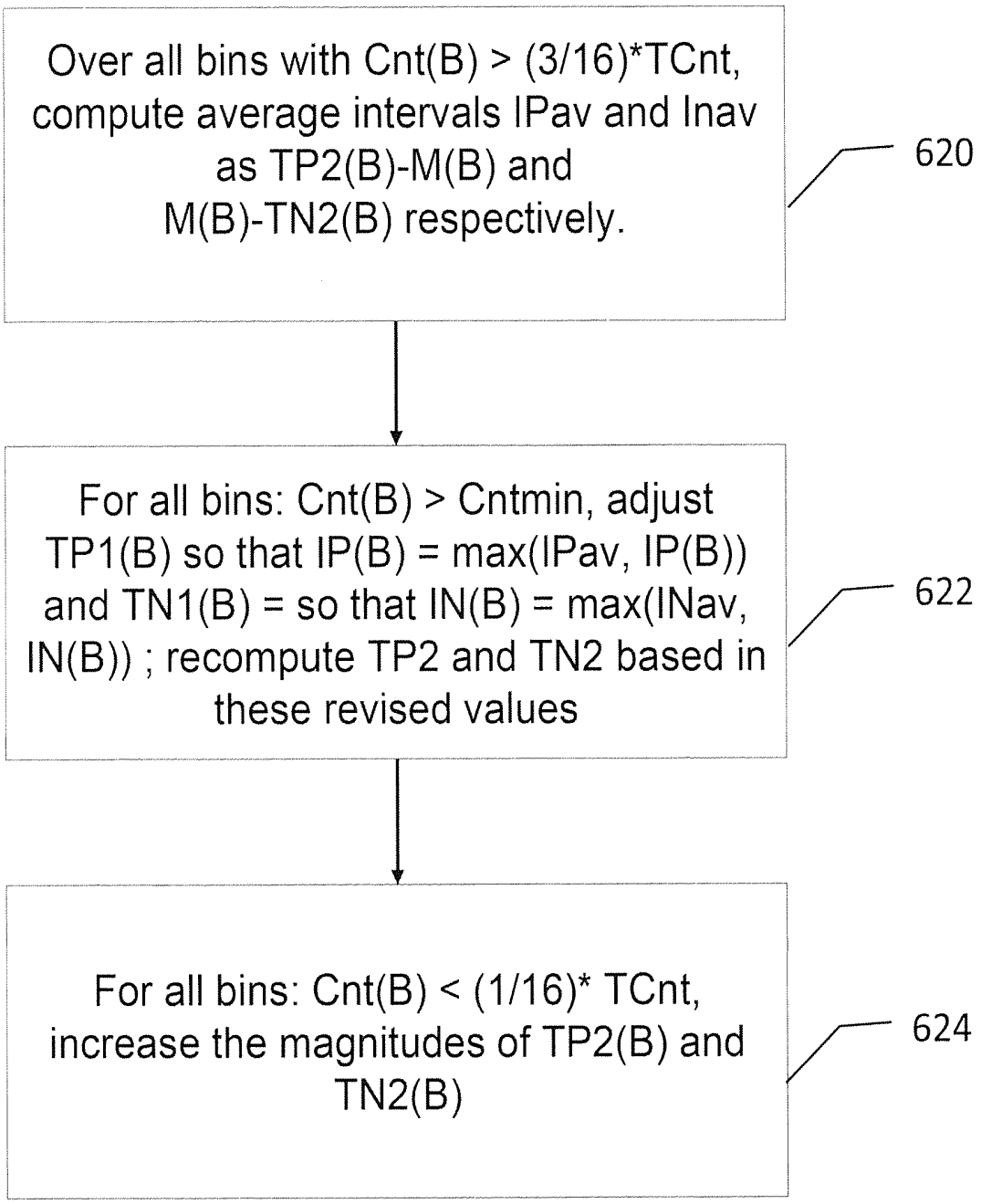

Over all bins with Cnt(B) > (3/16)*TCnt, compute average intervals IPav and Inav as TP2(B)-M(B) and M(B)-TN2(B) respectively.
620
For all bins: Cnt(B) > Cntmin, adjust TP1(B) so that IP(B) = max(IPav, IP(B)) and TN1(B) = so that IN(B) = max(INav, IN(B)) ; recompute TP2 and TN2 based in these revised values
622
For all bins: Cnt(B) < (1/16)* TCnt, increase the magnitudes of TP2(B) and TN2(B)
624

Figure 14d

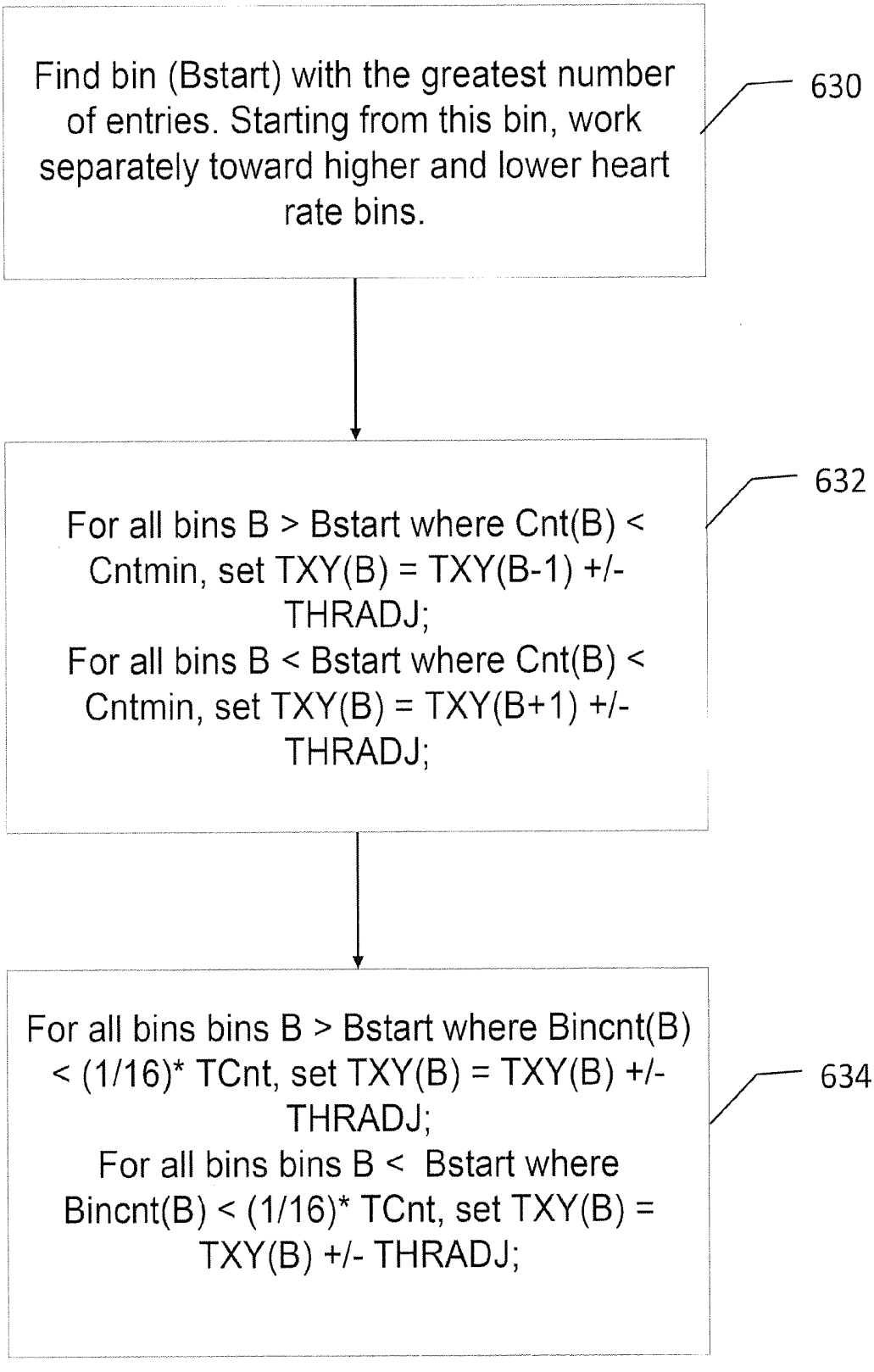

Find bin (Bstart) with the greatest number of entries. Starting from this bin, work separately toward higher and lower heart rate bins.
630
For all bins B > Bstart where Cnt(B) < Cntmin, set TXY(B) = TXY(B-1) +/- THRADJ;
For all bins B < Bstart where Cnt(B) < Cntmin, set TXY(B) = TXY(B+1) +/- THRADJ;
632
For all bins bins B > Bstart where Bincnt(B) < (1/16)* TCnt, set TXY(B) = TXY(B) +/- THRADJ;
For all bins bins B < Bstart where Bincnt(B) < (1/16)* TCnt, set TXY(B) = TXY(B) +/- THRADJ;
634

Figure 14e

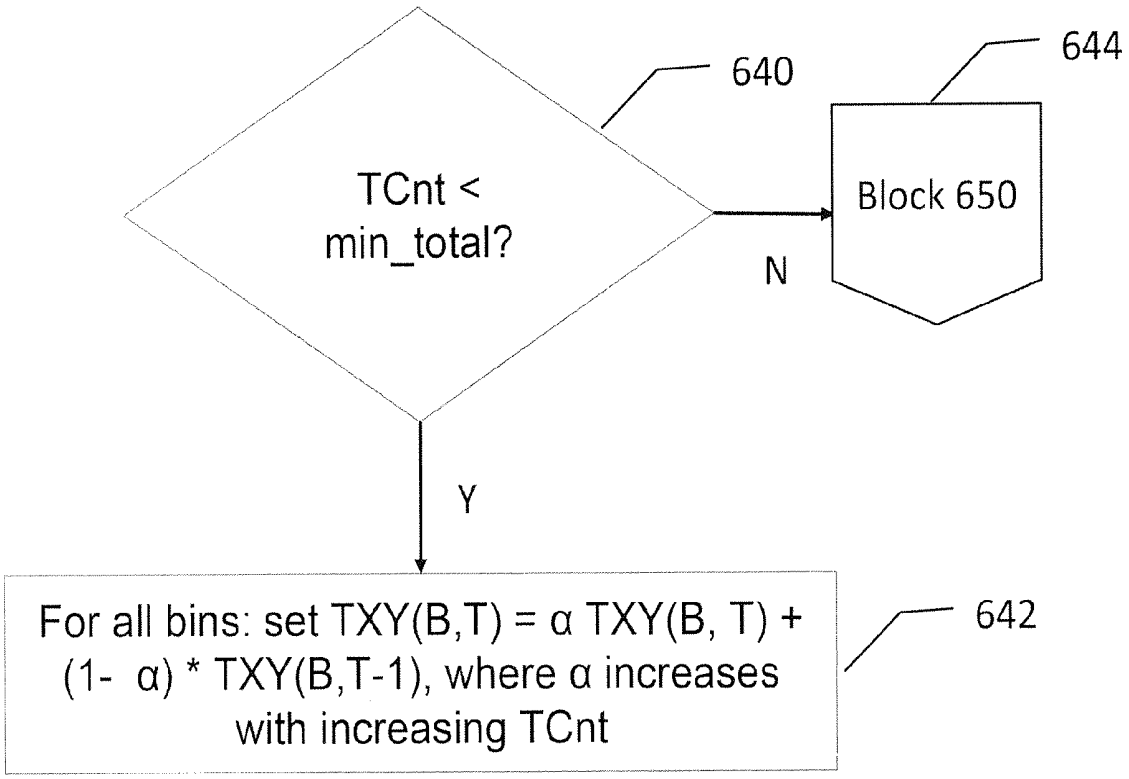

TCnt < min_total?
640
644
Block 650
N
Y
For all bins: set TXY(B,T) = α TXY(B, T) + (1- α) * TXY(B,T-1), where α increases with increasing TCnt
642

Figure 14f

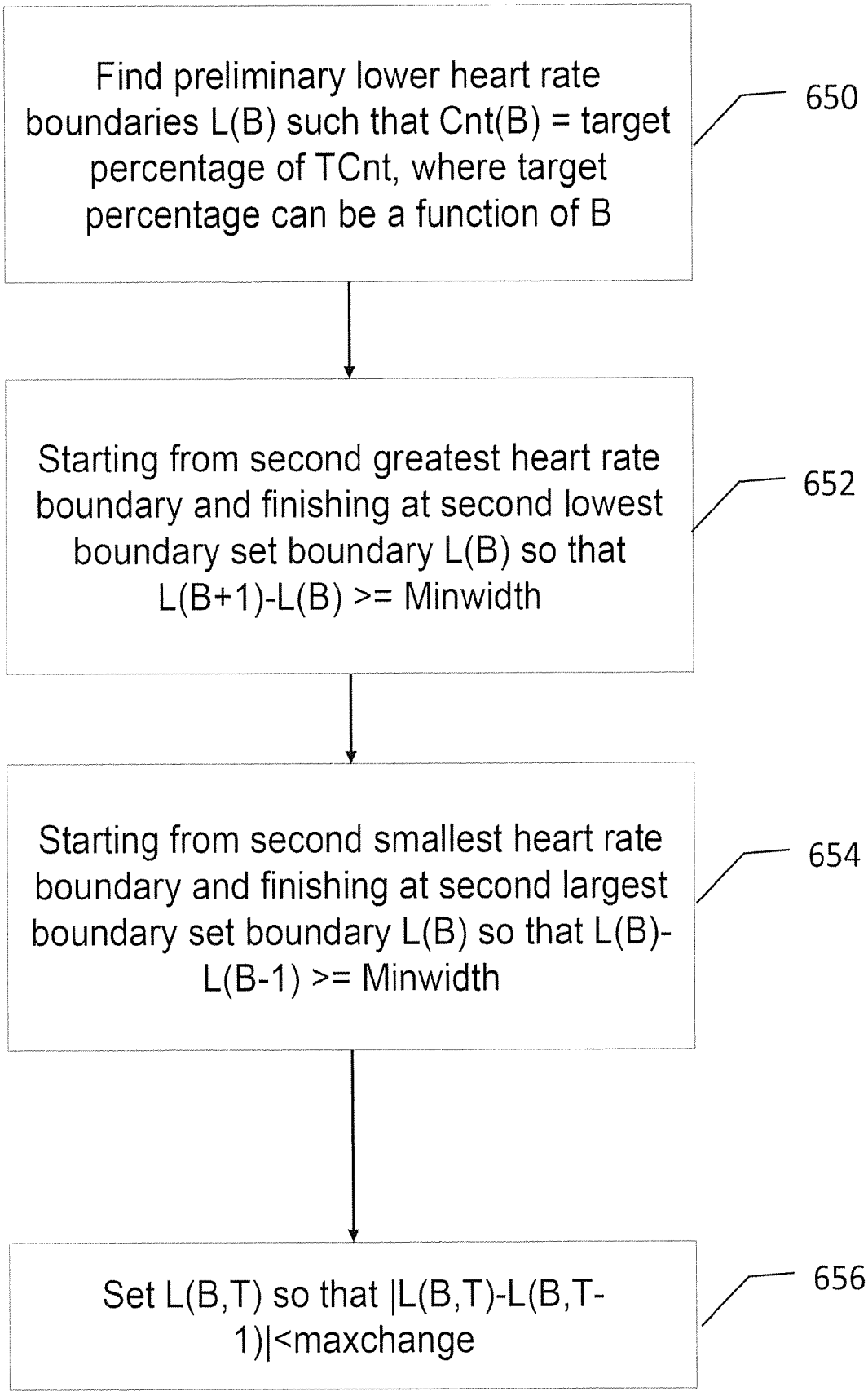

Find preliminary lower heart rate boundaries L(B) such that Cnt(B) = target percentage of TCnt, where target percentage can be a function of B
650
Starting from second greatest heart rate boundary and finishing at second lowest boundary set boundary L(B) so that L(B+1)-L(B) >= Minwidth
652
Starting from second smallest heart rate boundary and finishing at second largest boundary set boundary L(B) so that L(B)-L(B-1) >= Minwidth
654
Set L(B,T) so that |L(B,T)-L(B,T-1)|<maxchange
656

FIG. 15

700

| 702 ST states of the left and leftup leads | 704 Classifier | 706 Threshold |
|---|---|---|
| Left lead > median; Leftup lead > median | $(ST_{left}\text{-}STMX_{\_left})/(THP_{left}\text{-}STMX_{\_left})+(ST_{leftup}\text{-}STMX_{\_leftup})/(THP_{leftup}\text{-}STMX_{\_leftup})$ | 1.3 |
| Left lead > median; Leftup lead < median | $(ST_{left}\text{-}STMX_{\_left})/(THP_{left}\text{-}STMX_{\_left})+(ST_{leftup}\text{-}STMN_{\_leftup})/(THN_{leftup}\text{-}STMN_{leftup})$ | 1.3 |
| Left lead < median; Leftup lead > median | $(ST_{left}\text{-}STMN_{\_left})/(THN_{left}\text{-}STMN_{\_left})+(ST_{leftup}\text{-}STMX_{\_leftup})/(THP_{leftup}\text{-}STMX_{leftup})$ | 1.3 |
| Left lead < median; Leftup lead < median | $(ST_{left}\text{-}STMN_{\_left})/(THN_{left}\text{-}STMN_{\_left})+(ST_{leftup}\text{-}STMN_{\_leftup})/(THN_{leftup}\text{-}STMN_{leftup})$ | 1.3 |

708

# ACUTE ISCHEMIA DETECTION BASED ON PARAMETER VALUE RANGE ANALYSIS

## REFERENCE TO RELATED APPLICATIONS

This application is being filed as a Continuation-in-Part application of Ser. No. 13/788,143, filed 7 Mar. 2013, currently pending, which was a Continuation of application Ser. No. 12/868,308, filed 25 Aug. 2010, issued as U.S. Pat. No. 8,428,703 on 23 Apr. 2013.

## GOVERNMENT FUNDING

This invention was made with support under grant 1R43HL096158-01 awarded by the National Heart, Lung and Blood Institute of the National Institutes of Health. The United States government has certain rights in the invention.

## FIELD OF USE

This invention is in the field of medical device systems that monitor a patient's cardiovascular condition.

## BACKGROUND OF THE INVENTION

Heart disease is the leading cause of death in the United States. A heart attack, also known as an acute myocardial infarction (AMI), typically results from a blood clot or "thrombus" that obstructs blood flow in one or more coronary arteries. AMI is a common and life-threatening complication of coronary artery disease. Coronary ischemia is caused by an insufficiency of oxygen to the heart muscle. Ischemia is typically provoked by physical activity or other causes of increased heart rate when one or more of the coronary arteries is narrowed by atherosclerosis. AMI, which is typically the result of a completely blocked coronary artery, is the most extreme form of ischemia. Patients will often (but not always) become aware of chest discomfort, known as "angina", when the heart muscle is experiencing ischemia. Those with coronary atherosclerosis are at higher risk for AMI if the plaque becomes further obstructed by thrombus.

Detection of AMI often involves analyzing changes in a person's ST segment voltage. A common scheme for computing changes in the ST segment involves determining a quantity known as ST deviation for each beat. ST deviation is the value of the electrocardiogram at a point or points during the ST segment relative to the value of the electrocardiogram at some point or points during the PQ segment. Whether or not a particular ST deviation is indicative of AMI depends on a comparison of that ST deviation with a threshold.

The threshold may be absolute (e.g. 0.2 mV) or relative to a person's own ST deviation statistics, as disclosed in U.S. patent application Ser. No. 10/642,345, invented by Fischell et. al., owned by the assignee hereof, filed August 2003, and U.S. patent application Ser. No. 12/461,442, invented by Hopenfeld, filed August 2009, owned by the assignee hereof Despite this work, there is still a need for an effective system for setting patient specific thresholds for the detection of cardiac events.

## SUMMARY OF THE INVENTION

An embodiment of the present invention comprises a heart monitor that may be chronically implanted or external. The device, which includes an analog to digital convertor and a processor that performs beat detection, monitors the time course of a heart signal parameter, namely ST segment deviation, computed from an electrocardiogram. An ST deviation time series is generated by a recursive filter that is preferably an exponential average filter whose output is a weighted sum of the then existing ST time series value and current ST deviation values of analyzable beats. A heart rate value is analogously computed for each ST deviation value in the time series.

Information pertaining to the ST deviations is stored in histogram format according to heart rate so as to preserve characteristics of the statistical distribution of ST deviation as a function of heart rate. Periodically, the monitor analyzes the histogram data to determine a normal range of ST deviation for a particular heart rate range. The monitor computes heart rate dependent ischemia detection thresholds based on the upper and lower boundaries of the normal range. In some instances, the thresholds are set at specified distances from the boundaries, where the distances are functions of the dispersion of the ST deviation data for a particular heart rate range.



## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** illustrates a system for the detection of a cardiac event and for warning the patient that a medically relevant cardiac event is occurring.

FIG. **2** is a block diagram of an implanted cardiac diagnostic system according to the present invention.

FIG. **3** is a high level flow chart of a method for detecting ischemia.

FIGS. **4***a* and **4***b* are a flow chart of a method for classification of a data segment according to its high frequency noise content and signal level.

FIG. **5** is a flow chart of a routine that processes electrocardiogram/electrocardiogram segments to perform morphology checking on QRS complexes.

FIGS. **6***a* and **6***b* are a flow chart of the preferred embodiment for determining the location of PQ and ST points.

FIG. **7** is a flowchart that shows steps for determining a measure of segment based ST deviation.

FIG. **8** is a flow chart of a routine that analyzes a segment's ST deviation values and other segment characteristics to determine whether the segment's average ST deviation should contribute to long term Filtered measures of ST deviation, ischemia diction, and long term ST/RR histograms.

FIG. **9** is a routine that computes long term Filtered measure of ST deviation according to an exponential average filter.

FIG. **10** is a routine that maintains a counter that tracks the relative frequency of abnormal beats based on characteristics other than ST deviation.

FIG. **11** is a flowchart that shows steps for correcting ST deviation according to QRS amplitude.

FIG. **12** is a flowchart of a routine that calculates parameters for QRS amplitude correction.

FIGS. **13***a* and **13***b* are a flowchart of a method for determining ST deviation ischemia detection intervals according to RR interval.

FIG. **14***a*-**14***f* are flowcharts of an alternative method for determining ST deviation ischemia detection intervals according to RR interval.

FIG. **15** is a table describing ischemia detection thresholds based on the combination of ST segment information from two leads.

## DETAILED DESCRIPTION OF THE INVENTION

Architecture

FIG. **1** illustrates an example of a medical system **12** including implanted components **14** and external equipment **16**. An implantable medical device (IMD) **3** includes sensors to monitor a cardiac condition associated with a patient. In one embodiment, sensors include electrodes **4** and **5** incorporated into insulated electrical wire leads **2** and **1**, respectively,

that are preferably placed subcutaneously. The leads **2** and **1** are electrically connected to the IMD **3**, which comprises a case **10** that serves as a reference potential. Thus, the IMD **3** can obtain three bipolar voltage signals: between the electrode **4** and the case **10**, between the electrode **5** and the case **10**, and between electrodes **4** and **5**.

FIG. **1** also shows external equipment **16**, designed to communicate with the IMD **3**, that includes: 1. a physician's programmer **18**; 2. an external alarm system (EXD) **20** which may be implemented as one or more of: a pager-type device, a cell phone or PDA type device or a desktop unit; and, 3. a remote monitoring center **22**. The physician's programmer **18** has 2-way wireless communication **26** for communication between the programmer **18**, the IMD **3** and the EXD **20**. The EXD **20** includes a communication module **36** having one or more antenna for wireless communication with the IMD **3**, physician's programmer **18** and remote monitoring center **22**. The physician's programmer **18** provides users with the capability of interacting with the IMD **3**. The EXD **20** also provides external alarm signals for alerting a patient and allows two way wired or wireless communications with the remote monitoring center **22**. The remote monitoring center **22** can be one or more third parties including a monitoring service, the patient's doctor, or other intended target.

The programmer **18** shown in FIG. **1** can be used to communicate with the IMD **3** in order to adjust operational parameters and to retrieve data from the IMD **3**. Communication can include wireless signals **56** sent from the programmer **18** communications module **26** to the IMD **3** and incoming wireless signals **54** sent from the IMD **3** to the communications module **26** of the programmer **18**.

In FIG. **1**, the EXD **20** has a patient input module **32** which contains a series of physical controls such a buttons. A "patient initiate" button can allow for the initiation of communication between the EXD **20** and the IMD **3**. An "alarm disable" button can be used to cause an alarm of the IMD **3** and/or EXD **20** to halt rather than repetitively and needlessly re-alerting a patient. A "panic" button can allow a patient to send an alarm with or without attached data from the IMD **3** to a remote monitoring center **22**, even in the absence of IMD **3** or EXD **20** alarm notification. An "event" button can allow patients to tag events and thereby cause data to be tagged and/or sent remotely. An alarm module **34** can operate the communication module **36**, sound module **38**, visual module **40**, and vibration module **42**, to create an alarm signal **51** that comprises at least one of: communicating with a $3^{rd}$ party, a sonic alarm, a visual alarm, and a vibration alarm, respectively.

The communication module **36**, with the one or more antennae, provides near-field and far-field wireless communication. The near-field communication may use inductively coupled wake-up type communication methods such as are well known, while medium and far-field communication may rely upon other means. The communication module **36** can employ standardized wireless methods such as Bluetooth, WiFi, the FCC medical band, and/or cellular communications system such as GSM, CDMA, TDMA. The communication module **36** allows for data and/or voice transmission to and from the medical monitoring center **22** via a communication link **44**, and also allows communication with the IMD **3** and programmer **18**. The sound module **38** has both sound input and output such as a microphone, and speaker, respectively and associated electronics for providing two-way voice communication with the remote monitoring center **22**. Examples of external auditory alarm signals **51** include a periodic buzzing, a sequence of tones and/or speech which may be a prerecorded message that instructs the patient as to what is happening and what actions should be taken or which may be real speech communicated by the remote monitoring center **22**. The visual module **40** can include one or more colored diodes which are activated continuously, periodically, or according to a pattern that is associated with a particular alarm type. The visual module **40** may also include a display screen for displaying waveforms, pictures, and text related to system parameters, alarm information, or other information. The vibration module **42** can contain a vibration motor to produce the vibration alarm signal component of the alarm signal **51**, and can also contain an accelerometer which can be used to test the vibration alarm and also to measure a patient's physical activity level when the EXD **20** is worn by the patient.

A processing module **50** of the EXD **20** contains a real time clock or timer and other components included within portable smart-devices and pagers. Further, in a preferred embodiment, the EXD **20** is realized using a smart-phone (e.g., an iPhone, Blackberry or Palm), which may, if necessary, be implemented using specialized software and/or smartcards including means for wireless communication with the IMD **3**. The alarm module **34**, as well as the other modules of the EXD **20**, may be implemented in hardware or software, and contains all of the necessary components to implement alarming of the patient and/or remote station. The alarm module **34** collaborates with the processor module **50** to provide alerting by providing instructions to the processor or by receiving commands from the processor which cause it to implement alerting as defined in the alarm protocols, or both.

If an alarm notification is sent from the IMD **3** to the EXD **20**, then the alarm module **34** can alert the patient, alert a $3^{rd}$ party, or no alarm may be provided and the EXD **20** is simply operated to send data to a 3rd party for evaluation or storage. When the detection of a life threatening event (e.g., AMI or arrhythmia) is the cause of the alarm, the EXD **20** could automatically notify remote monitoring center **22** that a serious event has occurred.

If communication with remote monitoring center **22** occurs, then the message sent over the link **44** may include at least one of the following types of information as previously stored in the memory provided within the EXD's processor module **50** or as directly uploaded from the IMD **3**: (1) What type of medical event has occurred, (2) the patient's name, address and a brief medical history, (3) data provided by a GPS module **48**, the data including GPS coordinates and/or directions to the patient's location; (4) patient data, historical monitoring data, and the data that caused the alarm and (5) continuous real time data as it is collected after the alarm. The EXD **20** may be charged with a charger **52** to charge a rechargeable power supply **46** in the EXD **20**.

FIG. **2** is a block diagram of the IMD **3** with primary battery **72** and a secondary battery **74**. The secondary battery **74** is typically a rechargeable battery of smaller capacity but higher current or voltage output than the primary battery **72** and is used for short term high output components of the IMD **3** like the RF chipset in a telemetry sub-system **49** or a vibrator **75** attached to an alarm sub-system **98**. According to a dual battery configuration, the primary battery **72** will charge the secondary battery **74** through a charging circuit **73**. The primary battery **72** is typically a larger capacity battery than the secondary battery **74**. The primary battery **72** also typically has a lower self discharge rate as a percentage of its capacity than the secondary battery **74**. It is also envisioned that the secondary battery could be charged from an external induction coil by the patient or by the doctor during a periodic check-up.

A bipolar signal (e.g. reflecting the potential difference between electrodes **4** and **5** shown in FIG. **1**) is fed over wires

17 and 19 to an amplifier/analog filter 86. The amplifier/analog filter 86 amplifies the bipolar signal and filters the signal with a bandpass between 0.25 Hz and 50 Hz, resulting in a conditioned analog signal 87. The conditioned signal 87 is then converted to a digital signal 88 by an analog-to-digital converter 91, which preferably samples at a rate of 200 Hz. The digital signal 88 is buffered in a First-In-First-Out (FIFO) memory 92 and is digitally filtered with a filter whose transfer function is the inverse of the high pass transfer function of the amplifier/analog filter 86. Further details regarding this type of inverse digital filtering are found in EEG Handbook (revised series, Vol. 3), 1988, Chapter 2, Section 2.3.5.7.

For ease of description, only one bipolar signal is shown in FIG. 2. In the preferred embodiment, two bipolar signals are processed, and a third bipolar signal is derived by subtracting the digitized versions of the two bipolar signals. Furthermore, the two bipolar signals are preferably acquired simultaneously, so that fiducial points (e.g. an ST point, as will be described with reference to FIGS. 6*a* and 6*b* determined for one signal, preferably the signal corresponding to the voltage between electrodes 4 and 5, may be applied to the other bipolar signals (i.e., the electrode 4 referenced to the case 10 and the electrode 5 referenced to the case 10.)

A central processing unit (CPU) 94 is coupled to the FIFO memory 92. The CPU 94 is further coupled to a Random Access Memory (RAM) 97 and a program memory 95 that stores instructions that implement the methods described with reference to FIGS. 3-13. The CPU 94 performs the digital filtering described above.

A level detector/accelerometer 101 is coupled to the analog to digital converter 91. The level detector 101 detects whether a patient's torso is upright or supine and also, if the torso is supine, the extent of its rotation with respect to the earth (e.g. patient is lying flat on his/her back, lying on his/her right side or left side.) Many MEMS based level detectors can also operationally serve as inclinometers, accelerometers, and general detectors for motion/force exist.

Additional sensors may communicate with the IMD 3 wirelessly through the telemetry sub-system 49. The data from these leads may correspond to digitized electrocardiogram signals (that have been processed by a remote subcutaneous device).

The operation of most of the components in FIG. 2 is further described in U.S. patent application publication number 2004/0215092.

In a preferred embodiment of the present invention, the RAM 97 includes specific memory locations for 4 sets of electrocardiogram segment storage, including recent electrocardiogram storage, working memory for performing programming operations, memory for storing programming parameters that may be updated, and patient specific information (e.g. patient name, date of birth).

The telemetry sub-system 49 with an antenna 35 provides the IMD 3 the means for two-way wireless communication to and from the external equipment 16 of FIG. 1. Existing radiofrequency transceiver chip sets such as the Ash transceiver hybrids produced by RF Microdevices, Inc. can readily provide such two-way wireless communication over a range of up to 10 meters from the patient. It is also envisioned that short range telemetry such as that typically used in pacemakers and defibrillators could also be applied to the IMD 3. It is also envisioned that standard wireless protocols such as Bluetooth and 802.11a or 802.11b might be used to allow communication with a wider group of peripheral devices.

Flowcharts

FIG. 3 is a high level flow chart of a method for detecting cardiac ischemia. The method involves processing 10 second long data segments collected by the IMD 3 once every ninety seconds in normal conditions. The segment acquisition rate is preferably increased to once every thirty seconds under various circumstances when there is an abrupt change in RR interval between successive segments (see block 332 of FIG. 10, when there is a large jump in the segment average ST deviation (block 310 of FIG. 9), or when the ST deviation exponential average becomes close to a threshold (THP or THN in FIG. 13*b* or the thresholds n the table shown in FIG. 14).

In summary, the method comprises the steps of extracting ST segment information from beats within segments and generating a filtered ST time series therefrom. This filtered time series is labeled as "Current Filtered ST Deviation" in FIG. 3 and will also be referred to as "mStDevN_xavg" below. Current Filtered ST Deviation is then compared to a statistically generated, heart rate dependent ischemia detection threshold. If the Current Filtered ST Deviation persistently exceeds the threshold, then ischemia is detected.

Step 100 involves acquisition of a 10 second data segment, filtering, amplification, and analog-to-digital conversion by the IMD 3. The result is a digitized data segment comprising 2000 samples. In step 102, the high frequency noise content of the segment is assessed. In addition, if a segment has too many samples that saturate the voltage bandwidth, step 102 classifies the segment as noisy. Beat detection in block 104 is performed only on segments that step 102 has not rejected as too noisy. The RR interval between successive beats in the segment is determined in block 116, and beats associated with an abnormally short RR interval (e.g. premature ventricular contractions) are excluded from ST deviation calculations.

The next step 108 involves examining the QRS morphology of remaining beats by applying tests to various QRS parameters, for example the time between the maximum positive and maximum negative slopes. In block 110, the ST deviation for each normal beat is then computed according to the voltage difference between automatically determined ST and PQ points.

In block 112, the raw ST deviation for each beat is corrected for QRS amplitude based on a non-linear function of the average QRS amplitude of sinus beats in the segment. The correction is based, in part, on the statistical distribution of ST deviation as a function of QRS amplitude over a preceding time period. This feedback of ST deviation statistics is indicated by the dashed line from block 124 (discussed below) to block 112.

In block 114, the raw ST deviations are analyzed to determine whether the segment was contaminated by noise (such as motion artifact) within a frequency band high enough to disperse ST deviation measurements within a single segment (but low enough to avoid detection by the high frequency noise detection performed in block 102). Block 114 also involves additional noise analysis, as will be described below.

Step 122 involves the computation of the average QRS amplitude corrected ST deviation of acceptable beats within the current segment. Unless the segment meets certain exclusion criteria, this segment average updates an exponential average of ST deviation to generate Current Filtered ST Deviation. In step 120, the Current Filtered ST Deviation is added, again subject to certain exclusion criteria, to one of a set of ST deviation histograms where each member of the set corresponds to a range of RR intervals. ST(RR0) corresponds to the ST/RR histogram associated with the RR interval range RR0. More generally, ST(RRx) corresponds to the ST/RR histogram associated with the RR interval range RRx. The particular ST/RR histogram (ST(RRx)) that is updated depends on the RR interval which encompasses the exponen-

tial average of RR interval determined in block **118**. QRS amplitude histograms will analogously be referenced as ST(QRx), where QRx is a range of QRS amplitudes.

In block **126**, the Current Filtered ST Deviation is compared to an RR dependent ischemia detection threshold periodically determined by block **124**. If the Current Filtered ST Deviation is persistently above or below upper or lower ST deviation thresholds, respectively, acute ischemia is detected.

Block **124** also periodically performs an analysis of the relationship between QRS amplitude (QR) and ST deviation. This analysis is based on data in a set of ST deviation histograms, where each member in the set corresponds to a range of QRS amplitudes, updated in block **120**. The result of this analysis is QR dependent correction factors that parameterize QR correction performed in block **112**.

FIGS. **4***a* and **4***b* are a flow chart of step **102** (FIG. **3**) for classification of a data segment according to its high frequency noise content and signal level. Block **140** is the initiation of a loop. In this Figure and in other Figures in this Specification, loops are shown as an initial block with the steps in the loop shown in a dashed line. In FIG. **4***a*, the steps within the loop are steps **142** to **160**. In step **140**, the loop is set to repeat so that a number of non-overlapping subsegments are separately assessed for noise. In the preferred embodiment, where a 10 second long segment consists of 2000 samples, the segment is divided into 3 subsegments. According to block **140**, the loop is repeated for each of the subsegments or until a signal level saturation threshold is reached (block **156**), whichever occurs first.

In block **142**, a noise figure of merit (FOMs) variable for subsegment i is initialized to 0. A variable dSlast, which tracks the sign of signal changes, is initialized to 0. In block **144**, a loop through each sample in subsegment i is initialized. In block **146**, the number of consecutive saturated samples, which may be counted by a simple counter, is compared to a threshold THcsat, which is set to 6. If the number of consecutive saturated samples exceeds THcsat, control is transferred to block **154**, in which a saturation counter (satcnt) is incremented. Block **154** then transfers control to block **156**, which checks whether satcnt is greater than a threshold THsat, set to 100. If so, the segment is classified as noisy in block **168** (FIG. **4***b*). Otherwise, control transfers from block **156** to **148**, where processing also continues if the condition in block **146** is not satisfied.

In block **148**, the first difference of the signal S at the current sample (j) is computed. In block **150**, the sign of dS (positive or negative) is compared to dSlast. If the signs are the same, control transfers to block **152**, which increases FOMs(i) by the absolute value of dS. If the signs of dS and dSlast are different, control transfers to block **158**, which increments FOMs(i) by a multiple (a) of dS. In this manner, changes in signal polarity increase the assessed noise level of the signal more than deflections of the signal in the same direction. Weighting FOMs(i) according to signal amplitude (dS) allows a segment to be considered not noisy if it contains high frequency, low amplitude signal fluctuations. In an alternative embodiment, FOMs(i) is weighted by dS normalized to a measure of the maximum voltage difference within the segment (i.e., max(S(k))−min(S(k)) over all k within the segment).

From either block **152** or block **158**, control transfers to block **160**, which sets dSlast to dS.

Once all subsegments have been processed (if the loops have not been broken based on the outcome of block **156**), control transfers to block **162** in FIG. **4***b*. Block **162** sets the FOM for the segment as the maximum of the FOMs of the subsegments. In this and other Figures in this Specification, Matlab vector notation will be used to represent arrays such as FOMs=[FOMs(1) FOMs(2) FOMs(3)]=FOMs([1:3]).

Next, block **164** checks whether the segment FOM exceeds a threshold, THnoise. If not, in block **166**, THnoise is set equal to a constant CleanTH. If the FOM of the segment exceeds THnoise, the segment is tagged as noisy in block **168**, and THnoise is set equal to a threshold, NoiseTH, that is lower than CleanTH. In this manner, the noise threshold is characterized by hysteresis, whereby a segment is more likely to be classified as noisy if it follows a noisy segment.

FIG. **5** is a flow chart of a routine that performs morphology checking on QRS complexes. QRS complexes are classified as normal or abnormal. ST deviation is not computed for abnormal beats. Blocks **200** through **207** are performed iteratively for each beat in a segment of electrocardiogram data. The steps shown in FIG. **5** are performed after QRS complexes have been detected in block **104** (FIG. **3**), preferably by a routine based on the slope based scheme described in U.S. patent application Ser. No. 12/232,281, entitled "Methods and Apparatus for Detecting Cardiac Events Based on Heart Rate Sensitive Parameters", filed September 2008, owned by the assignee of the present invention. For each beat, the absolute minimum of the QRS (Rpeak) is located and the location of the preceding positive peak (initpk), if any, is determined. The average RR interval for the segment is computed. Based on the average RR interval, PVC beats are located, tagged, and not included in the segment's ST deviation. ST deviation is not determined for PVC beats.

For each non-PVC beat in the segment, the minimum QRS slope (minQRS) is located. For those beats that have a dominant negative QRS complex, block **202** searches for a positive peak in the slope (maxQRS) within a search window located after Rpeak. In particular, the search window begins at 2 samples after Rpeak and ends 12 samples after Rpeak. In the figures, a search window is denoted by W[a,b], where a is the window starting point (sample index integer) and b is the window ending point. The sample index (location) associated with a particular reference point is denoted by appending "_ind" to the particular reference point. For example, the index associated with Rpeak is Rpeak_ind.

If a local peak in the positive slope is found at either end of the purposely too wide search window designated in block **202**, block **205** tags the beat as abnormal and increments the "bad beat counter" labeled as mQMorphcnt and in block **207** the routine searches for the next beat or the end of the segment. Otherwise, if block **202** has found a local positive slope peak, control transfers to block **203**, which checks whether there is an appropriate decrease in the positive slope after maxQRS. In particular, within W[maxQRS_ind+1, maxQRS_ind+8], the routine searches for the first point where the slope is less than ⅜ of maxQRS. If no such sample can be found, the beat is tagged as irregular, and mQRMorphcnt is incremented in block **205**, and processing continues in block **207**. Otherwise, control passes from block **203** directly to block **207**, which repeats the above process for each QRS detected in the segment.

FIGS. **6***a* and **6***b* are collectively a flowchart that shows the preferred method for computing ST points. An analogous method may also be implemented to locate PQ points. In block **220** of FIG. **6***a*, the ST search window is set between maxQRS_ind+2 samples and maxQRS_ind+12 samples. In block **222**, the slope of the slope ("second finite difference") of the signal is computed by twice applying the slope operator: X(i+3)+2*X(i+2)+X(i+1)−X(i−1)−2*X(i−2)−X(i−3), where X(i) is the value of the waveform S at sample i for the first slope operation and then is the value of the slope at sample i for the second operation. The search stops at the first

sample at which the second finite difference is less than a specified multiple (ST_coef) of QR_xavg, an exponential average of peak to peak QRS amplitude (QR). In the preferred embodiment, ST_coef is 1.

If such a qualifying sample is found (at sample j), block **224** transfers control to block **226**, which sets a new search window starting at the sample after j (sample j+1) and again ending at maxQRS_ind+12. In block **228**, this window is searched for two consecutive samples at which the absolute value of the second finite difference is less than ST_coef*QR_xavg.

If two such consecutive samples are found, with the latter of the two labeled as "k", control is transferred from block **230** to block **234** (FIG. **6***b*), which sets the ST point (ST_ind) based on the value of k, subject to constraints on the location of the ST point. In particular, the ST point must be at least 2 samples after the Spt (defined in block **203** of FIG. **5**), and within a 3 sample window centered on Rpeak_ind+ST_int, where ST_int is an adaptive parameter that governs the location of the ST point.

Specifically, if k is within this three sample window, then the ST point (ST_ind) is chosen as the sample k. Otherwise, if k is before this window (i.e. closer to Spt than the beginning of this window), then ST_ind is set at the earliest sample in this window, Rpeak_ind+STint−1, subject to the previously mentioned constraint regarding the location of ST_ind relative to the Spt. If k is after the window, then ST_ind is set at the latest sample in this window, Rpeak_ind+STint+1.

Block **234** then transfers control to block **236**, which updates the adaptive parameter ST_int according to the number of samples between ST_ind and Rpeak. ST_int is preferably updated according to an exponential average filter. The exponential average of a variable (V) is expavg(V, Δ, α, min, max, mindelt, maxdelt), which means that the variable V is updated by the current value Δ, with an update weighting $\frac{1}{2^{\alpha}}$, subject to constraints on the maximum and minimum allowable value for the variable and changes in that variable. Ignoring the constraints, expavg(V, Δ, α, ( ), ( ), ( ), ( )) is $V(j+1)=((2^{\alpha}-1)*V(j)+\Delta)/2^{\alpha}$.

Returning to block **224**, if no second finite difference within the ST point search window was less than the threshold, then control transfers to block **232**, which increments mQMorphcnt. Similarly, if no qualifying sample is found in block **230**, control is transferred to block **232**.

The routine shown in FIGS. **6***a* and **6***b* may be modified to locate PQ points. In this case, the preferred search window (block **220**) is (MinQRSInd-4, MinQRSInd-20). ST_coef in block **1004** is −1 while the absolute value of ST_coef, 1, is used in block **222**. The sign of ST_coef will depend on expected QRS morphology; in the case of a QRS with a V2 like morphology (small R, large S), the curvature of the PQ and ST segments have opposing signs. In block **234**, the PQ point is not allowed to come within four samples of the R wave peak (i.e., maximum value of the initial upstroke of the QRS before the large downstroke.)

FIG. **7** is a flowchart that shows steps for determining a measure of segment based ST deviation (mStDevN_xavg), which is an averaged, effectively filtered version of a number of beat based ST deviation measurements. Steps **250** through **260** are performed for each (provisionally) analyzable beat that has associated ST and PQ points. In block **250**, ST deviation (Stdev) is determined by the difference between the signal values of the samples surrounding the ST and PQ points, respectively. In the preferred embodiment, the PQ signal value is equal to the average of the signal over four consecutive samples starting at the sample that is two samples earlier than the PQ point. In the preferred embodiment, the ST signal value is equal to the average of the signal over four consecutive samples starting at the sample that is one sample earlier than the ST point.

Stdev is corrected for QRS amplitude in block **254** according to the method described in FIG. **11**. Control passes to block **256**, which checks whether the difference between both (i) Stdev and the median ST deviation at the resting heart rate (STm(RR0)); and (ii) Stdev and the current long term ST deviation exponential average (mStDevN)_xavg), exceed a threshold maxchg. If so, the beat is tagged as non-analyzable in block **260** and does not figure into the segments average ST deviation. Otherwise, an analyzable ST deviation beat counter is incremented in block **258**. The segment average ST deviation (mStDevNavg) is calculated in block **262**.

Processing continues at block **300**, shown in FIG. **8**, which is a flow chart of a routine that analyzes a segment's ST deviation values and other segment characteristics to determine whether the segment's average ST deviation (mStDevNavg) should contribute to long term current filtered ST deviation (see block **122** of FIG. **3**), ischemia diction, and ST/RR histograms. Block **300** performs a number of tests to determine whether the current segment's ST deviation (mStDevNavg) should be considered valid for two purposes: (1) ischemia detection; and (2) contributing to the ST/RR histograms. If a segment is too abnormal, or appears to correspond to a rapid change in physiological state (e.g. a change in heart rate), as defined by the tests in block **300** (and block **306** described below), its ST deviation can not be relied on for ischemia detection or for contributing to ST/RR statistics. The three tests are: (1) whether the average RR interval of the current segment is within ¾ and 1.5 times the average RR interval of the previous segment; (2) whether mQMorphCnt (see blocks **205** of FIG. **5** and block **232** of FIG. **6***a*) is low; and (3) whether the number of PVC's is low (less than 2). If either test 1 or tests 2 and 3 are positive, then the segment's ST deviation may qualify for ischemia detection/statistics, so block **302** transfers control to block **304**. Otherwise, if both test 1 and tests 2 or 3 are negative, block **302** transfers control to block **332** of FIG. **10**, which results in the exclusion of the segment's ST deviation from ischemia detection/statistics (by skipping past block **316** of FIG. **9**).

Returning to the "yes" branch of block **302**, block **304** calculates a measure of the noisiness (STFOM) of the ST deviations of the beats in the current segment. If the segment was contaminated by noise such as motion artifact, the variance of the ST deviations will tend to be relatively large, which in turn implies that the average ST deviation should not be trusted. To assess ST deviation noise/variance, the routine described with reference to FIG. **4***a* is applied with the ST deviation of each individual (analyzable) beat constituting signal S, and with the signal saturation steps (**146**, **154** and **156**) excluded. After the ST deviations of all the analyzable beats have been processed, the resulting FOM (block **152** of FIG. **4***a*) is normalized by the number of analyzable beats in the current segment, and the result is the STFOM.

In block **306**, STFOM is compared to a threshold. If the threshold is exceeded, control passes to block **332** of FIG. **10**, which results in the exclusion of the segment's ST deviation from ischemia detection/statistics. Otherwise, processing continues in block **310** of FIG. **9**. (In an alternative embodiment, STFOM controls the weighting of the ST deviation exponential average updating, with an inverse relationship between the magnitude of STFOM and the amount the current segment's ST deviation contributes to the long term exponential average in block **314** of FIG. **9**.)

Block **310** (FIG. **9**) checks whether the difference between mStDevNavg and the current long term, filtered ST time

series (mStDevN_xavg) exceeds a threshold. If so, mQMorphcnt is incremented in block **312** and the segment is not added to the ST/RR histograms. Subject to block **410** of FIG. **11**, which describes an additional criterion for excluding mStDevNavg from contributing to mStDevN_xavg, control then passes to block **314**, which is also invoked from the "no" branch of block **310**. In block **314**, the Filtered exponential average (mStDevNavg) is updated according to mStDevNavg. In block **316**, if the result of the block **310** test was negative, mStDevN_xavg is added to the ST/RR histograms. Details regarding ST/RR histograms are described in U.S. Pat. No. 7,512,438, entitled "Implantable System for Monitoring the Condition of the Heart", owned by the assignee hereof. The exponential average of the RR interval time series determines which of the ST(RRx) histograms is incremented.

In an alternative embodiment, block **310** applies additional tests to help prevent noisy data from being added to ST/RR histograms. One additional test is to compare the current mStDevNavg with the most recent prior mStDevNavg. If the difference between the two exceeds a threshold, the histograms are not updated. In yet another alternative embodiment, a measure of the dispersion of the past few mStDevNavg results is computed and compared to a threshold. If the dispersion is too large, histograms are not updated. Measures of dispersion include, without limitation, standard deviation and a sum of first order differences (absolute values) from the mean.

FIG. **10** is a flow chart of a routine that tracks the relative frequency of variant beats. Variant beats are broadly defined as beats that deviate from an established pattern of normal sinus rhythm beats. Variant beats include beats that resulted in an increment of mQMorphcnt during the QRS processing described with respect to FIG. **5**. In addition, mQMorphcnt is also updated in block **232** (FIG. **6***a*) and block **312** (FIG. **9**). The relative frequency of variant beats is stored in a variable mqmorph. If mqmorph is above a threshold for a certain period of time, the system is preferably configured to respond in a user-programmable manner such as generating an alarm.

The mqmorph variable is updated after each segment is processed. The manner in which mqmoprh is updated depends on the outcome of the tests applied in blocks **302** and **306** (FIG. **8**). If the outcome of this test suggests that the current segment is relatively "normal", mqmorph is computed in block **330**. In particular, in block **330**, mqmorph is increased by $mQMorphCnt^2$−qmorphleak, subject to the constraints that mqmorph can not be negative or greater than 6*qmorphleak, where qmrophleak is a parameter. According to the above equation that updates mqmroph, qmorphleak acts like a "drain" that tends to "empty" mqmorph. Thus, mqmorph tends to remain at a low value unless there are a number of segments within a relatively short period of time with relatively high mQMorphCnts.

If the segment is considered relatively "abnormal" according to the tests applied in blocks **302** or **306**, control passes to block **332**. If mQMorphcnt is greater than 1 or the segment's average RR interval is very different from the previous segment's RR interval, then mqmorph is increased in block **336** by $mQMorphCnt^2$+qmorphlimit−qmorphleak, subject to the same constraints on the maximum and minimum mqmorph values described with respect to block **330**.

Returning to block **332**, if none of tests 1, 2 or 3 is positive, then control passes to block **338**, which determines whether the number of PVC's is low (less than 2). If so, block **340** increases mqmorph in the same manner as block **330** except that qmorphleak is divided by 2.

FIG. **11** is a flowchart that shows steps for correcting ST deviation according to QRS amplitude (QR). In block **400**, the segment average QR amplitude (QRav) is computed based on the values of all analyzable beats in the segment, i.e. those beats whose ST deviations are eligible to contribute to segment average ST deviation (mStDevNavg). Also, an exponential average of QR amplitude is updated based on QRav as follows: QR exp. avg=expavg(QR exp. avg., QRav, 2, NA, NA, NA, NA).

Block **402** is the beginning of a loop over all of the analyzable beats. In block **404**, the ST deviation (STdev(i)) of the analyzable beat i is corrected by adding a term min(1,(max((abs(del)−disp),0)/(disp))))*corr, where corr=STm(QR0)−STm(QRavb), del=STdev(i)−STm(QRavb), disp=0.5*(max(STm(QRavb))−min(STm(QRavb)). STm(QR0) is the median ST deviation associated with the median QR amplitude. STm(QR0) is computed from ST/QR histograms, as will be further described with reference to FIG. **12**. Similarly, STm(QRavb) is a quasi-median ST deviation for the QR bin associated with the QR amplitude of the current segment (QRav). (More specifically, QRavb in the expression is the QR bin corresponding to the QR range in which QRav falls.) STm(QRavb) is computed from ST/QR histograms, as will be further described with reference to FIG. **12**, and is further modified in block **406**, as will be discussed below.

The correction (corr) is not added directly to STdev(i). Instead, the amount of the correction (corr) that is added to STdev(i) depends on how close STdev(i) is to its expected value, which is STm(QRavb). If STdev(i) varies substantially from this expected value, then there is less confidence that the correction corr is appropriate. The quantity disp controls the amount of corr that is added as a function of the difference (del) between STdev(i) and STm(QRavb).

In step **406**, STm(QRavb) is updated to decrease del. For example, if the uncorrected STdev(i) was larger than STm (QRavb), then STm(QRavb) is slightly increased.

Returning to segment based processing, in block **412**, the average del over the segment is compared to a threshold. If the average del exceeds the threshold, the segment ST deviation (mStDevNavg) is excluded from the ST/RR histograms in block **414**. Block **408** tests whether both QRav and mStDevNavg are positive but sufficiently small that the applicable ST/QR histogram has few if any entries. If so, then block **410** excludes mStDevNavg from both the ST/RR histograms and the update of the ST exponential average (block **314** of FIG. **9**). Exclusion is appropriate because small positive values of both QRav and mStDevNavg could result from a device related factor such as high lead impedance. To enable the system to adapt to new, low values of QRav and mStDevNavg, mStDevNavg (not mStDevN_xavg) is added to the appropriate ST/QR histogram.

FIG. **12** is a flowchart of a routine that calculates parameters for QRS amplitude correction required by the routine described with reference to FIG. **11**. In block **450**, an array of ST deviation histograms are created and/or updated, which each histogram corresponding to a range of QRS amplitudes (QR), measured as the difference between the maximum and minimum waveform values of the QRS complex. Techniques for creating arrays of ST deviation histograms are described in U.S. Pat. No. 7,512,438, entitled "Implantable System for Monitoring the Condition of the Heart", owned by the assignee hereof. The ST/QR histograms are updated with the QR exponential average (block **400**, FIG. **11**) after every segment for which the QR exponential average was updated.

In block **452**, the median ST deviation (STm(QR0)) for the median QR histogram is computed. STm refers to median ST deviation, while the x in STm(QRx) refers to the QR histogram x. QR0 refers to the median QR histogram. For example, if there are ten ST deviation histograms as a func-

tion of QR amplitude, one histogram each for the QR ranges 1-10, 11-20 . . . , 91-100, and the median QR amplitude is 77, then QR0 refers to the ST deviation histogram associated with the QR range 71-80. In this example, the histogram associated with the range 61-70 would be QR-1, the histogram associated with the range 81-90 would be QR1, the histogram associated with the QR range 51-60 would be QR-2 etc.

Block **454** is the beginning of a loop that first processes each ST(QRx) histogram associated with QR<QRm and then processes each ST(QRx) histogram associated with QR>QR0. The current histogram being processed is tracked by index i. In block **456**, the current index i is stored. In block **458**, i is decremented until the number of elements in consecutive histograms exceeds a threshold, THbin. For example, if i=−1, THbin is 200, and the number of elements in STQ(QR-1) is 240, then i is not decremented at all. As used above, "number of elements" refers to the sum over all bins within a particular histogram. Returning to the above example, if the number of elements in STQ(QR-1) is 150 and the number of elements in STQ(QR-2) is 70, then i decremented once. The number operator n will refer to the number of elements in a histogram or array of histograms. Continuing with the above example, N(STQ([−1:−2]))=220.

In block **460**, the median ST deviation over the current set of ST(QRx) histograms ST([iold:i] is calculated. In block **462**, the quasi-median ST (STQm([iold:i])) for the current set of ST(QRx) histograms is set as max(min(STQm,UL*STm (iold+1)),LL*STm(iold+1)), where UL and LL are parameters that control the amount by which the current quasi-median is allowed to vary from the median ST of the adjacent QR histogram (STm(iold+1). Preferred values of UL and LL are 1.2 and 0.5, respectively, so that the quasi-median is not allowed to exceed 1.2 times the adjacent quasi-median or be less than 0.5 times the adjacent quasi-median. (When proceeding in the direction of larger QR values (block **464**), the max and min statements in block **462** are reversed.)

In block **464**, the above described process beginning with block **456** is repeated for ST histograms associated with QR>QR0.

FIGS. **13***a* and **13***b* are a flowchart of a process for setting ST deviation thresholds for detecting acute ischemic events. In block **480**, an array of ST deviation histograms are created and/or updated, which each histogram corresponding to a range of RR intervals. Techniques for creating arrays of ST deviation histograms are described in U.S. Pat. No. 7,512,438, entitled "Implantable System for Monitoring the Condition of the Heart", owned by the assignee hereof. An exponential average of the average segment RR interval preferably determines which ST(RRx) histogram is accessed. This histogram is updated with mStDevN_xavg, as previously described.

The threshold setting process will first be described for positive ST deviation thresholds, i.e. thresholds for detection of ST deviations that are greater than normal. An analogous procedure sets negative ST deviation thresholds, i.e. thresholds for detection of ST deviations that are less than normal.

In block **482**, the positive ST deviation threshold for each RR interval is determined according to the process to be described with reference to FIG. **13***b*. For example, if there are 5 RR ranges, from 301 ms-500 ms, 501 ms-700 ms, 701 ms-800 ms, 701 ms-900 ms, and 900 ms-2000 ms, then there are 5 ST(RRx) histograms. The notation [RR] means that the separate RR ranges are to be taken as a vector. Continuing with the above example, ST([RR])=ST([1:5]). The threshold function (implemented by the routine in FIG. **13***b*), is indicated by TH( ). Thus, in the above example, TH([RR]) is an array with 5 thresholds, one corresponding to each RR array, i.e. [TH(1) TH(2) TH(3) TH(4) TH(5)].

In block **484**, the maximum threshold over the threshold array is determined. In block **486**, the thresholds are set equal to maxTH+(TH(RRx)−maxTH).*min(1,(maxTH−TH (RRx))/THC), where THC is a constant that depends on the dynamic range of the ST measurements. If a typical ST range is between 0 and 1000, then a preferred value for THC is 2000. For example, TH(1) is equal to maxTH+(TH(1)−maxTH).*min(1,(maxTH−TH(1))/THC).

In block **488**, the RR arrays with a sufficiently large number of entries, i.e. at least THbinsize elements, are located and identified as "gdbins." Again, the number operator N refers to the number of elements in a particular histogram. Similarly, the RR arrays with less than THbinsize are located and identified as bdbins. In block **490**, for any bdbin that is not between gdbins, the threshold is set as the threshold of the nearest gdbin+SF, where SF is a safety factor. In block **492**, for bdbins inbetween gdbins, the threshold is set as the average of the two nearest surrounding gdbins.

In block **494**, steps **482-492** are repeated for negative thresholds. For this processing, the max operator in block **484** is replaced with the min operator, and (maxTH−TH(RRx))/THC in block **486** is replaced with −(minTH−TH(RRx))/THC.

In an alternate embodiment, instead of correcting ST deviation for QR (FIG. **12**) and setting RR dependent thresholds (FIGS. **13***a*-**13***b*), thresholds are set directly based on both QR and RR, which comprise a two dimensional parameter array. For example, if there are 8 QR ranges and 5 RR ranges, separate ST deviation statistics are kept for each of 40 bins. Thresholds are set as in FIG. **13***a*, with two dimensional interpolation/extrapolation in blocks **490** and **492** instead of one dimensional interpolation/extrapolation.

Finally, step **496** increases negative thresholds in the cases where the minimum negative ST deviation boundary (minbin) (described further below with respect to FIG. **13***b*) over all RR intervals is greater than 0. In this case, for reasons similar to those set forth below with regard to step **512** of FIG. **13***b*, the lower threshold (THn(RRx)) for each RRx interval is changed to a value based on the minimum lower threshold (min(THn(RRx)) plus an adjustment factor THnadj. For example, assuming that there are only two RRx ranges, and that the minimum ST deviation occurs in the second range (RR2), the minbin for RR2 is 50, and that the threshold for RR2 is −200, the negative threshold for RR2 is raised to −150 if THnadj is set to 100. Conversely, if the negative threshold for RR2 (before block **496** is invoked) is −125, then the threshold for RR2 remains at −125, since −125>−150. THn (RR1) is also increased to −150 if it was lower than that value. It will be appreciated that the choice of lead polarity is arbitrary, so that the above adjustments may apply to the positive thresholds depending on lead orientation and polarity.

FIG. **13***b* is a flowchart that shows the steps for computing the positive and negative detection thresholds for a particular ST(RRx) histogram. This routine is invoked by block **482** of FIG. **13***a*. In block **500**, the upper ST deviation boundary bin (maxbin) is found by locating the bin for which the sum of all elements in the bin and in bins with larger ST deviations is less than a threshold THbnd. For example, if there are 10 ST bins that cover ST deviations in the ranges of 0-9, 10-19 . . . 80-89 and >90, respectively, and there are 15 elements in bin 70-79, 5 elements in bin 80-89 and 3 elements in bin >90, and THbnd is 10, then maxbin is bin 80-89 since there are less than 10 elements collectively in bin 80-89 and above but more than ten elements collectively in bin 70-79 and above.

THbnd depends on the number of entries in a histogram. THbdn is preferably set at THbndbase*NH, where THbndbase is the desired ST deviation cutoff per unit time, and NH is amount of time during which data has been inserted into the histogram. For example, if THbndbase is 10 entries/day, and a histogram has 5 days of entries, then THbnd is 50.

In block **502**, the lower ST deviation boundary bin (minbin) is found analogously to the procedure described with reference to block **500**.

In block **504**, the median ST (STm) is found for the histogram ST(RRx). In block **506**, the positive threshold (THP) is set equal to STm+U*disp_pos, where disp_pos=(ST(maxbin)−STm) and U is a programmable parameter. (The RRx parenthetical is implied for quantities such as THP, STm and is not shown in blocks **506-514**.) Continuing with the above example, where maxbin corresponds to ST deviations between 80-89, ST(maxbin) is set equal to 85, the midpoint (in terms of ST deviation) of maxbin. If the median ST over all bins is 50 and U is 2, then THP is 50+2*(85−50)−120. The threshold THP is thus a function of the dispersion rate of the ST(RRx) distribution.

In an alternative embodiment, the threshold is a function of the rate of fall off in the tail of a distribution. The rate of fall off may be measured by locating the ST deviation boundaries, as described above. If the histogram bins are labeled as [B1, B2 . . . BN], with B1 the lower boundary bin and BN the higher boundary bin, the difference in the number of elements between bins B1 and B2 is n(B2)−n(B1)=d(2,1), where d(a,b) is defined as the difference operator between bins a and b. Two measures of the rate of fall off of the lower tail of the distribution are: (1) max(d(i+1,i)) with i taken over the first p histogram bins; and (2) n(1:p)/n(total histogram), so that if the cumulative number of entries in the first p histograms is relatively large compared to the total number of entries in the histogram, the rate of fall toward the boundary is relatively sharper. An analogous rate of fall off is computed for the upper boundary.

In another alternative embodiment, if particular lead registers a normal QRS morphology, the positive threshold is never allowed to fall beneath a minimum value that is selected according to population based statistics. In yet another alternative embodiment, THP=STm+U*disp_pos*f(disp_pos), where f is a function that maps relatively low values of disp_pos to values greater than one, and maps relatively high values of disp_pos to values less than or equal to one, in such a manner that the detection thresholds for small and large dispersions are brought somewhat closer together. An inverted sigmoidal type shape for f is preferred. In this manner, the thresholds associated with small dispersions are relatively increased, which may help to avoid false positive detections that would otherwise result from very small dispersions.

Next, block **508** determines whether the ST deviation associated with the minimum bin is greater than a parameter Zeroth, which is a programmable parameter that governs the ST deviation level at which an ST deviation polarity change is deemed to occur, i.e. Zeroth is the boundary between positive and negative ST deviations. Zeroth will generally be 0, except that for some subjects, it may be desirable to set Zeroth as slightly negative since some random fluctuations in ST deviation can cause some negative (but small) ST deviations to accumulate in the ST histograms. Also, device related issues such as filtering could result in an offset to "true" ST deviations and thus result in a non-zero value for Zeroth.

If the ST level associated with minBin is greater than Zeroth, then block **510** provisionally sets the negative threshold analogously to the positive threshold setting described with reference to block **506**. Programmable parameter L1 (block **510**) may be set to a different value than programmable parameter U (block **506**). In block **512**, THN is not allowed to be greater than minTHul, a programmable parameter. THN is not allowed to be less than Zeroth less a margin of safety (NSF). For example, if Zeroth is 0, and NSF is 10, THN will be set no lower than −10. This floor on THN allows for greater sensitivity to detect changes in polarity. That is, if a negative ST deviation is not normal for a particular RR interval and lead, then the floor on THN allows a negative ST deviation to be detected with greater sensitivity if the provisional threshold set in block **510** is less than Zeroth-NSF.

On the other hand, if the provisional threshold set in block **510** is positive and "too large", then specificity may be compromised since small but positive ST deviations may be normal, even if not previously occurring in a particular subject. If the small ST deviations are associated with small QR amplitudes, then blocks **408** and **410** of FIG. **11** will prevent false positive detections. However, if the QR amplitude is not "small" but the ST deviation is small and positive, detection may still not be appropriate. The parameter minTHul dictates the level at which an ST deviation can not be considered as a true positive, regardless of ST/RR distributions. If a typical ST deviation distribution ranges between 400 and 1000, then minTHul is preferably set at 50 (relatively close to zero).

Returning to block **508**, if ST(minbin) is less than or equal to Zeroth, then the negative threshold is set in block **514** analogously to block **506**, with L2 being an individually set programmable parameter.

In the preferred embodiment, the parameters U, L1 and L2 (blocks **506**, **510** and **514**) change from relatively large values to lower values over time after the device **3** (FIG. **1**) is first implanted.

In an alternative embodiment, U (block **506**), L1 (block **510**) and L2 (block **514**) are heart rate dependent, so that the values of U, L1 and L2 increase with increasing heart rate.

Referring now to FIGS. **14***a*-**14***f* there is shown an alternative embodiment of a processor for setting ST deviation thresholds for detecting acute ischemic events. In block **600**, the number of sub-threshold entries Cnt(B) in each heart rate bin B is determined. An entry within a bin B is subthreshold if it did not exceed the major positive threshold (TP2(B)) and did not fall below the major negative threshold (TN2(B)). In block **602**, the total count (TCnt) of entries over all bins is computed. As will be described below, Cnt(B) and TCnt are used an a variety of computations.

In block **604**, TCnt is compared to a preset value that determines the minimum number of entries that are required to set detection thresholds based on gathered ST deviation statistics. If TCnt is below this minimum number of entries, which may occur e.g. if the device has been recently implanted, then control passes to block **608** and all detection thresholds are set to default values. Otherwise, if TCnt is not below this minimum number of entries, then control passes to block **610** (FIG. **14***b*), which is the first step in the patient specific threshold setting process.

In block **610**, minor negative thresholds for each heart rate bin (TN1(B), where N denotes negative/lower threshold and 1 denotes minor threshold) are set. As will be further described below, minor thresholds partly define ST deviation dispersion measures and also serve as detection thresholds when combined with a ST deviation change variable. TN1(B) is the ST deviation (Stdev) value below which the number of entries is the greater of: (i) 0.5% of Cnt(B); or (ii) 2*the number of days with Cnt(B)>0.

In block **612**, the minor positive threshold (TP1(B)) is set analogously to the minor negative threshold in block **610**: it is

the Stdev below which the number of entries is the lesser of: (i) 99.5% of Cnt(B); or (ii) Cnt(B)−2*the number of days with Cnt(B)>0.

In block **614**, the medians (M(B)) for each heart rate bin are computed. In block **616**, major positive thresholds (TP2(B)) for each bin are set based on a measure of the STdev dispersion of the bin. The dispersion measure is the interval IP(B)=TP1(B)−M(B), subject to a minimum value of IPmin. The threshold for each bin B is then set at the median plus some multiple α (greater than 1) of the interval IP(B): TP2(B)=M(B)+α*IP(B). Similarly, in block **618**, the major negative threshold TN2(B) is set to M(B)+β*IN(B).

After the minor and major thresholds are provisionally set in the manner described above, a number of smoothing adjustments are made. In block **620** shown in FIG. **14***c*, for all bins with Cnt(B)>(3/16)*TCnt, compute the average of positive and negative intervals IPav and INav as TP2(B)−M(B) and M(B)−TN2(B) respectively. In block **622**, for all bins whose count (Cnt(B)) is greater than a preset value (Cntmin), the minor positive and negative thresholds are adjusted so that the corresponding intervals (IP(B) and IP(N)) are at least as large as these average values: IP(B)=max(INav, IP(B)) and IN(B)=max(INav, IN(B)), respectively. For all of the adjusted minor thresholds, the corresponding major thresholds are recomputed according to the equations in blocks **616** and **618** respectively.

In block **624**, the magnitudes of the major thresholds are increased for all bins that have relatively few entries. (In this instance, increasing the magnitude of a threshold means increasing the distance between that threshold and the pertinent median value.) More particularly, the major thresholds are increased for bins whose count (Cnt(B)) is less than 1/16 of the total count across all bins (TCnt).

The above described smoothing adjustments help to harmonize the thresholds by utilizing global variables (IPav and INav). Another round of adjustments, which begins in block **630** of FIG. **14***d*, smoothes the jumps between thresholds in adjacent bins in the case where at least one of the bins has a relatively small number of entries. In block **630**, the bin with the greatest number of entries is located. Starting from this bin (Bstart), higher heart rate bins (Bstart+1 to Bmax) are processed in order and then lower heart rate bins are processed in order (Bstart−1 to Bmin). (The choice of processing the higher heart rate bin set before the lower heart rate bin set is arbitrary.)

In block **632**, for each bin, the number of entries is compared to a threshold Cntmin. For each bin with less than Cntmin entries, all thresholds (major and minor, positive and negative thresholds (TXY(B), where X is either N or P and Y is either 1 or 2) are set equal to the corresponding threshold TXY(B−1) or TXY(B+1) of the adjacent processed bin+/− (for positive and negative thresholds respectively) an adjustment THRADJ.

In block **634**, an additional adjustment is made for bins that have a relatively small number of entries. In particular, for all bins with less than (1/16)*TCnt entries, the magnitudes of the (previously adjusted) thresholds are again increased by the amount THRADJ.

The final threshold value adjustment is meant to cover the case where there aren't many total beats, typically because the histogram data was cleared because of a recent gain change. In that case, previously calculated thresholds (e.g. yesterday's thresholds), prior to the gain change, are more likely better estimates than those calculate on the data from only a fraction of one day. Thus, in block **640** of FIG. **14***e*, TCnt is compared to a threshold min total. If TCnt is less than this threshold, then control transfer to block **642**, where the thresholds for each bin are set equal to an average of the current thresholds and the previous thresholds, where the weighting accorded to the current thresholds increases with TCnt.

FIG. **14***f* is a flow chart for a routine that adjusts histogram bin boundaries to even out the number of entries across bins. In an embodiment where there are 8 bins (B0, B2 . . . B7), where B0 represents the lowest heart rate range and B7 represents the highest heart rate range, a possible target distribution for entries across the bins is: B0-B1: 10%; B2: 15%; B3: 25%; B4: 25%; B5: 15%; B6-B7: 10%. In step **650**, bin boundaries (L(2) . . . L(N−2)), where N is the total number of bins, are located such that the bin counts match the target distribution as closely as possible. (According to this embodiment, boundaries L(1) and L(N−1) are set by other means and not adjustable.)

Next, to ensure that the heart rate bins aren't too close to one another, the steps in blocks **652** and **654** are performed. In block **652**, starting from second greatest heart rate boundary L(N−2) and finishing at the second lowest boundary L(2), set each boundary L(B) so that L(B+1)−L(B)>=Minwidth. In block **654**, starting from second lowest heart rate boundary L(2) and finishing at the second highest boundary L(N−2), set each boundary L(B) so that L(B)−L(B−1)>=Minwidth.

Finally, to ensure that the boundaries don't change too drastically from one time period to the next, in block **656**, each current boundary value L(B) is set so that |L(B,T)−L(B,T−1)|<maxchange.

FIG. **15** is a table **700** that shows ischemia detection thresholds based on the combination of ST segment information from two leads, designated as the left and leftup leads respectively (leads **2** and **1** of FIG. **1**). ST deviations of the leads are combined by effectively normalizing the individual leads' ST deviations to their corresponding thresholds. (Thresholds are assumed to be RR dependent but this need not be the case.) Column **702** of the table indicates the relative polarities of the ST shifts associated with the two leads. Column **704** shows the classifier that is generated to compare to a threshold shown in column **706**.

The second row **708** in the table applies when the ST deviations of both the leads are above the pertinent (preferably RR dependent) median levels. The ST deviations are effectively normalized by subtracting the positive boundary ST deviation (STMX, which is label for the quantity ST(maxbin) described with reference to blocks **500** and **506** of FIG. **13***b*) and dividing the resulting quantity by the difference between the positive threshold and the positive boundary. For example, for the left lead, if the positive boundary STMX_left is 10, the positive threshold THP left is 20, and the ST deviation (ST_left) is 14, the effective normalized ST deviation is (14−10)/(20−10)=0.4.

Because the thresholds in column **706** are less than 2, ischemia may be detected when detection would not occur from either lead alone. Continuing with the above example for the left lead but adding in the leftup lead, if the positive boundary STMX leftup is 14, the positive threshold THP leftup is 30, and the ST deviation (ST_leftup) is 29, the effective normalized ST deviation for the leftup lead is (29−14)/(30−14)=0.9 (with integer based arithmetic). When the 0.9 for the leftup is added to the 0.4 of the left, the result is 1.3, the threshold for detection.

Combinations of ST deviations above and below the medians are shown in the remaining rows in the table **700**.

In the preferred embodiment, it is desirable to base ischemia detection both on the relative "distance" classifiers described above but also on absolute "distance" from the boundary thresholds, as described in U.S. patent application

Ser. No. 12/461,442, invented by Hopenfeld, filed August 2009. (The "absolute" distance may be either based in units of absolute voltage or be based on a fraction of QRS amplitude.) Ischemia is detected when any of the absolute or relative classifiers is above its corresponding threshold for a certain number of consecutive segments.

As is well known, integer based arithmetic, which is the preferred system for carrying out the operations described above, can produce undesirable results if the pertinent operands do not have sufficient granularity. For example, if 10 is divided by 6, the result is 1, compared to the desired result of 5/3. To reduce these types of problems, the data may be appropriate scaled. Continuing with the above example, if 10 is scaled up to 100 and then divided by 6, the result is 5, which (when divided by 10), is closer to the desired number 5/3. Appropriate scaling is performed to compare quantities that have been maintained at different scales. Continuing with the above example, if a threshold (to be applied to the value 10/6) is 2, it is scaled to 20, which may then be compared with the scaled value of 5.

For ease of understanding, the scaling factors (which are device and data dependent) have been omitted from the above description. The preferred scaling factors for various quantities are as follows. With regard to blocks **262** and **314** of FIGS. **7** and **9** respectively, mStDevNavg and MStDevN_x-avg are both scaled by a factor of 5. With regard to FIG. **6***b*, ST_int and ST_ind-Rpeak_ind are scaled by a factor of 16 for purposes of computing the exponential average in block **236**. Because integer based arithmetic results in rounding down of fractions, the quantity of ½ is added to compensate for bias that would otherwise result from such truncation. All QR related quantities are scaled by a factor of 128.

The invention claimed is:

**1**. A cardiac monitor for detecting a cardiac event, the monitor comprising:

(a) a sensor for sensing an analog signal from a human heart;

(b) a device coupled to the sensor, the device having an analog-to-digital circuit system contained therein for digitizing the analog signal to produce a digitized waveform; and

(c) a processor electrically coupled to the analog-to-digital circuit system, said processor configured to:

(i) compute a plurality of values of a heart signal parameter from the digitized waveform;

(ii) compute a plurality of heart rate values associated with the plurality of values of the heart signal parameter;

(iii) store data pertaining to the plurality of values of the heart signal parameter and the plurality of heart rate values;

(iv) select a plurality of heart rate boundaries defining a plurality of heart rate bins, thereby grouping the data pertaining to the plurality of values of the heart signal parameter according to heart rate, wherein the heart rate boundaries are based on a target number of entries in the plurality of heart rate bins;

(v) set a plurality of detection thresholds corresponding to the plurality of heart rate bins;

(vi) determine a first major positive threshold and a first major negative threshold for said heart values in each of said bins;

(vii) determine a number of data entries of said heart values which exist between said first positive and said first negative major thresholds for each bin defining sub-threshold entries;

(viii) sum the number of heart value entries within said first major positive and first major negative thresholds for all of said bins defining a total number of sub-threshold entries;

(ix) set the first major positive and first major negative thresholds to a predetermined set of values if said total number of sub-threshold entries is less than predetermined number of entries needed for ischemia detection, or calculate a minor negative threshold and a minor positive threshold for a selected bin as a function of the sub-threshold entries; and

(x) apply a test to detect a cardiac event, wherein the test is based on at least one of the detection thresholds.

**2**. The cardiac monitor as recited in claim **1** where processor is further configured to:

(i) compute a median of said heart rate values in a selected bin; data entry deviations as a function of the sub-threshold entries for each bin; and

(ii) calculate a second major positive and negative threshold for a selected bin as a function of the median of said heart rate values and a positive and negative dispersion of heart rate values in said selected bin.

**3**. The cardiac monitor as recited in claim **2** where the processor is further configured to:

(i) calculate an average positive and negative interval as a function of the second major positive and negative thresholds and said median for a selected bin where the sub-threshold entries are greater than a function of the total number of sub-threshold entries over all bins; and

(ii) calculate a further minor negative and positive threshold within each bin as a function of the positive and negative measure of dispersion and average positive and negative intervals.

* * * * *

| | | | |
|---|---|---|---|
| 专利名称(译) | 基于参数值范围分析的急性缺血检测 | | |
| 公开(公告)号 | US8954139 | 公开(公告)日 | 2015-02-10 |
| 申请号 | US14/170894 | 申请日 | 2014-02-03 |
| 申请(专利权)人(译) | ANGEL医疗系统，INC. | | |
| 当前申请(专利权)人(译) | ANGEL医疗系统，INC. | | |
| [标]发明人 | HOPENFELD BRUCE<br>JOHNSON STEVEN R | | |
| 发明人 | HOPENFELD, BRUCE<br>JOHNSON, STEVEN R. | | |
| IPC分类号 | A61B5/0456 A61B5/00 A61B5/02 A61B5/024 A61B5/04 A61B5/0452 | | |
| CPC分类号 | A61B5/02028 A61B5/0006 A61B5/0452 A61B5/686 A61B5/02405 A61B5/7282 A61B5/04012 A61B5/0022 A61B5/742 A61B5/746 A61B5/7465 | | |
| 代理机构(译) | ROSENBERG，KLEIN＆LEE | | |
| 其他公开文献 | US20140148716A1 | | |
| 外部链接 | Espacenet USPTO | | |


摘要(译)

公开了一种心脏监测器。监视器计算ST段偏差并将结果存储在基于心率的直方图中。监视器周期性地分析直方图数据以确定特定心率范围的ST偏差的正常范围。监测器基于正常范围的上边界和下边界计算心率依赖性缺血检测阈值。