US009993205B2

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

(10) **Patent No.: US 9,993,205 B2**
(45) **Date of Patent: Jun. 12, 2018**

(54) **CARDIAC RESPONSE CLASSIFICATION USING RETRIGGERABLE CLASSIFICATION WINDOWS**

(75) Inventors: **Scott A. Meyer**, Lakeville, MN (US); **Yanting Dong**, Shoreview, MN (US); **Jeremy Maniak**, Columbia Heights, MN (US); **Doug Birholz**, Shoreview, MN (US); **John Voegele**, East Bethel, MN (US)

(73) Assignee: **Cardiac Pacemakers, Inc.**, St. Paul, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1215 days.

(21) Appl. No.: **12/818,066**

(22) Filed: **Jun. 17, 2010**

(65) **Prior Publication Data**

US 2010/0256703 A1 Oct. 7, 2010

Related U.S. Application Data

(63) Continuation of application No. 10/734,599, filed on Dec. 12, 2003, now Pat. No. 7,774,064.

(51) **Int. Cl.**
A61N 1/08 (2006.01)
A61B 5/00 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 5/7264*** (2013.01); ***A61N 1/371*** (2013.01); *A61B 5/04525* (2013.01); *A61B 5/7217* (2013.01)

(58) **Field of Classification Search**
CPC A61B 5/7264
(Continued)

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,782,367 A * 1/1974 Hochberg et al. 600/510
3,920,005 A 11/1975 Gombrich et al.
(Continued)

FOREIGN PATENT DOCUMENTS

EP 0468720 1/1992
EP 0560569 9/1993
(Continued)

OTHER PUBLICATIONS

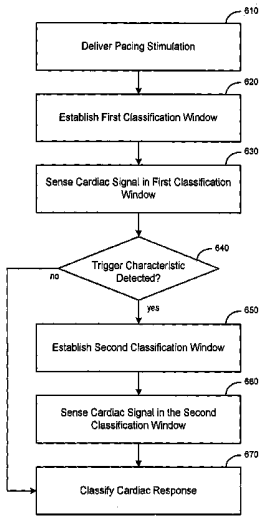
Acar et al., "SVD-based on-line exercise ECG signal orthogonalization", IEEE Transactions on Biomedical Engineering, vol. 46, No. 3, Mar. 1999. Abstract only.
(Continued)

Primary Examiner — Alyssa M Alter
(74) *Attorney, Agent, or Firm* — Schwegman Lundberg & Woessner, P.A.

(57) **ABSTRACT**

Methods and devices for classifying a cardiac response to pacing involve establishing a retriggerable cardiac response classification window. A first cardiac response classification window is established subsequent to delivery of a pacing pulse. A cardiac signal following the pacing stimulation is sensed in the first classification window. A second cardiac response classification may be triggered if a trigger characteristic is detected in the first classification window. The cardiac signal is sensed in the second classification window if the second classification window is established. The cardiac response to the pacing stimulation is determined based on characteristics of the cardiac signal. The cardiac response may be determined to be one of a captured response, a non-captured response, a non-captured response added to an intrinsic beat, and a fusion/pseudofusion beat, for example.

23 Claims, 23 Drawing Sheets



(51) **Int. Cl.**
A61N 1/37 (2006.01)
A61B 5/0452 (2006.01)

(58) **Field of Classification Search**
USPC 607/28
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,023,564 A 5/1977 Valiquette et al.
4,340,063 A 7/1982 Maurer
4,365,636 A 12/1982 Barker
4,458,692 A 7/1984 Simson
4,550,221 A 10/1985 Mabusth
4,552,154 A 11/1985 Hartlaub
4,562,841 A 1/1986 Brockway et al.
4,573,481 A 3/1986 Bullara
4,648,407 A 3/1987 Sackner
4,680,708 A 7/1987 Ambos et al.
4,686,332 A 8/1987 Greanias et al.
4,827,935 A 5/1989 Geddes et al.
4,860,766 A 8/1989 Sackner
4,878,497 A 11/1989 Callaghan et al.
4,928,688 A 5/1990 Mower
4,953,551 A 9/1990 Mehra et al.
4,979,507 A 12/1990 Heinz
5,000,189 A 3/1991 Throne et al.
5,033,467 A 7/1991 Bocchi et al.
5,036,849 A 8/1991 Hauck et al.
5,101,831 A 4/1992 Koyama et al.
5,105,354 A 4/1992 Nishimura
5,133,353 A 7/1992 Hauser
5,146,918 A 9/1992 Kallok et al.
5,170,784 A 12/1992 Ramon et al.
5,178,156 A 1/1993 Takishima et al.
5,179,945 A 1/1993 Van Hofwegen et al.
5,184,615 A 2/1993 Nappholz et al.
5,187,657 A 2/1993 Forbes
5,203,348 A 4/1993 Dahl et al.
5,209,229 A 5/1993 Gilli
5,217,021 A 6/1993 Steinhaus et al.
5,222,493 A 6/1993 Sholder
5,230,337 A 7/1993 Dahl et al.
5,233,983 A 8/1993 Markowitz
5,261,400 A 11/1993 Bardy
5,271,411 A 12/1993 Ripley et al.
5,273,035 A 12/1993 Markowitz et al.
5,284,136 A 2/1994 Hauck et al.
5,292,338 A 3/1994 Bardy
5,300,106 A 4/1994 Dahl et al.
5,301,677 A 4/1994 Hsung
5,313,953 A 5/1994 Yomtov et al.
5,314,430 A 5/1994 Bardy
5,314,459 A 5/1994 Swanson et al.
5,318,597 A 6/1994 Hauck et al.
5,324,310 A 6/1994 Greeninger et al.
5,331,966 A 7/1994 Bennett et al.
5,331,996 A 7/1994 Ziehm
5,333,095 A 7/1994 Stevenson et al.
5,334,222 A 8/1994 Salo et al.
5,335,657 A 8/1994 Terry, Jr. et al.
5,350,410 A 9/1994 Kleks et al.
5,353,788 A 10/1994 Miles
5,360,442 A 11/1994 Dahl et al.
5,366,496 A 11/1994 Dahl et al.
5,372,606 A 12/1994 Lang et al.
5,374,280 A 12/1994 den Dulk
5,376,106 A 12/1994 Stahmann et al.
5,376,476 A 12/1994 Eylon
5,388,578 A 2/1995 Yomtov et al.
5,391,200 A 2/1995 KenKnight et al.
5,397,342 A 3/1995 Heil, Jr. et al.
5,411,031 A 5/1995 Yomtov
5,411,525 A 5/1995 Swanson et al.
5,411,529 A 5/1995 Hudrlik
5,411,533 A 5/1995 Dubreuil
5,411,539 A 5/1995 Neisz
5,431,693 A 7/1995 Schroeppel
5,439,482 A 8/1995 Adams et al.
5,441,518 A 8/1995 Adams et al.
5,443,485 A 8/1995 Housworth et al.
5,447,519 A 9/1995 Peterson
5,468,254 A 11/1995 Hahn et al.
5,485,851 A 1/1996 Erickson
5,517,983 A 5/1996 Deighan et al.
5,520,191 A 5/1996 Karlsson et al.
5,522,860 A 6/1996 Molin et al.
5,531,779 A 7/1996 Dahl et al.
5,534,017 A 7/1996 Van Krieken et al.
5,540,727 A 7/1996 Tockman et al.
5,540,732 A 7/1996 Testerman
5,545,186 A 8/1996 Olson et al.
5,545,202 A 8/1996 Dahl et al.
5,549,655 A 8/1996 Erickson
5,591,216 A 1/1997 Testerman et al.
5,603,732 A 2/1997 Dahl et al.
5,620,466 A 4/1997 Haefner et al.
5,626,620 A 5/1997 Kieval et al.
5,634,938 A 6/1997 Swanson et al.
5,641,326 A 6/1997 Adams
5,650,759 A 7/1997 Hittman et al.
5,658,318 A 8/1997 Stroetmann et al.
5,662,688 A 9/1997 Haefner et al.
5,674,254 A 10/1997 van Krieken
5,683,431 A 11/1997 Wang
5,683,434 A 11/1997 Archer
5,697,953 A 12/1997 Kroll et al.
5,697,956 A 12/1997 Bornzin
5,704,365 A 1/1998 Albrecht et al.
5,713,933 A 2/1998 Condie et al.
5,715,812 A 2/1998 Deighan et al.
5,718,720 A 2/1998 Prutchi et al.
5,724,984 A 3/1998 Arnold et al.
5,735,883 A 4/1998 Paul et al.
5,738,102 A 4/1998 Lemelson
5,779,645 A 7/1998 Olson et al.
5,814,087 A 9/1998 Renirie
5,817,027 A 10/1998 Arand et al.
5,827,326 A 10/1998 Kroll et al.
5,836,987 A 11/1998 Baumann et al.
5,844,506 A 12/1998 Binstead
5,855,593 A 1/1999 Olson et al.
5,857,977 A 1/1999 Caswell et al.
5,860,918 A 1/1999 Schradi et al.
5,861,011 A 1/1999 Stoop
5,861,013 A 1/1999 Peck et al.
5,871,512 A 2/1999 Hemming et al.
5,873,898 A 2/1999 Hemming et al.
5,876,353 A 3/1999 Riff
5,895,414 A 4/1999 Sanchez-Zambrano
5,916,243 A 6/1999 KenKnight et al.
5,944,680 A 8/1999 Christopherson et al.
5,957,956 A 9/1999 Kroll et al.
5,964,778 A 10/1999 Fugoso et al.
5,974,340 A 10/1999 Kadhiresan
5,987,352 A 11/1999 Klein et al.
6,026,320 A 2/2000 Carlson et al.
6,038,474 A * 3/2000 Zhu et al. 607/9
6,044,298 A 3/2000 Salo et al.
6,045,513 A 4/2000 Stone et al.
6,049,730 A 4/2000 Kristbjarnarson
6,052,620 A 4/2000 Gillberg et al.
6,055,454 A 4/2000 Heemels
6,064,910 A 5/2000 Andersson et al.
6,076,014 A 6/2000 Alt
6,076,015 A 6/2000 Hartley et al.
6,084,253 A 7/2000 Turner, Jr.
6,091,973 A 7/2000 Colla et al.
6,101,416 A 8/2000 Sloman
6,115,628 A 9/2000 Stadler et al.
6,120,441 A 9/2000 Griebel
6,126,611 A 10/2000 Bourgeois et al.
6,128,534 A 10/2000 Park et al.
6,128,535 A 10/2000 Maarse
6,132,384 A 10/2000 Christopherson et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,134,473 A 10/2000 Hemming et al.
6,141,581 A 10/2000 Olson et al.
6,147,680 A 11/2000 Tareev
6,148,230 A 11/2000 KenKnight
6,148,234 A 11/2000 Struble
6,163,724 A 12/2000 Hemming et al.
6,169,921 B1 1/2001 KenKnight et al.
6,175,766 B1 1/2001 Bornzin et al.
6,190,326 B1 2/2001 McKinnon et al.
6,192,275 B1 2/2001 Zhu et al.
6,221,011 B1 4/2001 Bardy
6,226,551 B1 5/2001 Zhu et al.
6,227,072 B1 5/2001 Ritchey et al.
6,238,419 B1 5/2001 Lindgren
6,251,126 B1 6/2001 Ottenhoff et al.
6,253,102 B1 6/2001 Hsu et al.
6,258,039 B1 7/2001 Okamoto et al.
6,259,947 B1 7/2001 Olson et al.
6,266,554 B1 7/2001 Hsu et al.
6,270,457 B1 8/2001 Bardy
6,272,377 B1 8/2001 Sweeney et al.
6,275,731 B1 8/2001 Zhu et al.
6,277,072 B1 8/2001 Bardy
6,280,380 B1 8/2001 Bardy
6,280,462 B1 8/2001 Hauser et al.
6,282,440 B1 8/2001 Brodnick et al.
6,285,907 B1 9/2001 Kramer et al.
6,295,330 B1 9/2001 Skog
6,299,581 B1 10/2001 Rapoport et al.
6,312,378 B1 11/2001 Bardy
6,312,388 B1 11/2001 Marcovecchio et al.
6,324,421 B1 11/2001 Stadler et al.
6,324,427 B1 * 11/2001 Florio 607/28
6,336,903 B1 1/2002 Bardy
6,345,201 B1 2/2002 Sloman et al.
6,351,669 B1 2/2002 Hartley et al.
6,351,673 B1 2/2002 Ding et al.
6,353,759 B1 3/2002 Hartley et al.
6,358,203 B2 3/2002 Bardy
6,360,127 B1 3/2002 Ding et al.
6,363,270 B1 3/2002 Colla et al.
6,363,281 B1 3/2002 Zhu et al.
6,368,284 B1 4/2002 Bardy
6,368,287 B1 4/2002 Hadas
6,371,922 B1 4/2002 Baumann et al.
6,375,621 B1 4/2002 Sullivan
6,393,316 B1 5/2002 Gillberg et al.
6,398,728 B1 6/2002 Bardy
6,409,675 B1 6/2002 Turcott
6,411,848 B2 6/2002 Kramer et al.
6,415,174 B1 7/2002 Bebehani et al.
6,415,183 B1 7/2002 Scheiner et al.
6,418,340 B1 7/2002 Conley et al.
6,418,343 B1 7/2002 Zhang et al.
6,424,234 B1 7/2002 Stevenson
6,424,865 B1 7/2002 Ding
6,434,417 B1 8/2002 Lovett
6,434,428 B1 8/2002 Sloman et al.
6,438,409 B1 8/2002 Malik et al.
6,438,410 B2 8/2002 Hsu et al.
6,440,066 B1 8/2002 Bardy
6,449,503 B1 9/2002 Hsu
6,456,481 B1 9/2002 Stevenson
6,456,880 B1 9/2002 Park et al.
6,456,881 B1 9/2002 Bornzin et al.
6,459,929 B1 10/2002 Hopper et al.
6,466,820 B1 10/2002 Juran et al.
6,477,422 B1 11/2002 Splett
6,480,733 B1 11/2002 Turcott
6,480,734 B1 11/2002 Zhang et al.
6,487,443 B2 11/2002 Olson et al.
6,491,639 B1 12/2002 Turcott
6,493,586 B1 12/2002 Stahmann et al.
6,496,715 B1 12/2002 Lee et al.
6,505,067 B1 1/2003 Lee et al.
6,505,071 B1 1/2003 Zhu et al.
6,512,940 B1 1/2003 Brabec et al.
6,512,953 B2 1/2003 Florio et al.
6,522,915 B1 2/2003 Ceballos et al.
6,542,775 B2 4/2003 Ding et al.
6,553,259 B2 4/2003 Mouchawar et al.
6,564,106 B2 5/2003 Guck et al.
6,567,701 B2 5/2003 Vonk
6,574,507 B1 6/2003 Bonnet
6,589,188 B1 7/2003 Street et al.
6,595,927 B2 7/2003 Pitts-Crick
6,597,951 B2 7/2003 Kramer et al.
6,600,949 B1 7/2003 Turcott
6,607,509 B2 8/2003 Bobroff et al.
6,611,712 B2 8/2003 Spinelli et al.
6,615,082 B1 9/2003 Mandell
6,615,083 B2 9/2003 Küpper
6,615,089 B1 9/2003 Russie et al.
6,618,619 B1 9/2003 Florio et al.
6,622,046 B2 9/2003 Fraley et al.
6,631,290 B1 10/2003 Guck et al.
6,640,136 B1 10/2003 Helland et al.
6,641,542 B2 11/2003 Cho et al.
6,654,637 B2 11/2003 Rouw et al.
6,658,293 B2 12/2003 Vonk
6,684,100 B1 1/2004 Sweeney et al.
6,690,967 B2 2/2004 Meij
6,701,170 B2 3/2004 Stetson
6,708,058 B2 3/2004 Kim et al.
6,725,085 B2 4/2004 Schwartzman et al.
6,731,973 B2 5/2004 Voith
6,731,983 B2 5/2004 Ericksen et al.
6,731,984 B2 5/2004 Cho et al.
6,731,985 B2 5/2004 Bradley et al.
6,738,668 B1 5/2004 Mouchawar et al.
6,738,669 B1 5/2004 Sloman et al.
6,754,523 B2 6/2004 Toole
6,754,528 B2 6/2004 Bardy et al.
6,760,615 B2 7/2004 Ferek-Petric
6,766,190 B2 7/2004 Ferek-Petric
6,768,923 B2 7/2004 Ding et al.
6,768,924 B2 7/2004 Ding et al.
6,772,008 B2 8/2004 Zhu et al.
6,773,404 B2 8/2004 Poezevera et al.
6,778,860 B2 8/2004 Ostroff et al.
6,788,974 B2 9/2004 Bardy et al.
6,830,548 B2 12/2004 Bonnet et al.
6,834,204 B2 12/2004 Ostroff et al.
6,856,835 B2 2/2005 Bardy et al.
6,865,417 B2 3/2005 Rissmann et al.
6,866,044 B2 3/2005 Bardy et al.
6,881,192 B1 4/2005 Park
6,884,218 B2 4/2005 Olson et al.
6,885,893 B1 4/2005 Lu
6,888,538 B2 5/2005 Ely et al.
6,889,079 B2 5/2005 Bocek et al.
6,890,306 B2 5/2005 Poezevera
6,895,274 B2 5/2005 Mower
6,904,315 B2 6/2005 Panken et al.
6,904,320 B2 6/2005 Park et al.
6,915,160 B2 7/2005 Auricchio et al.
6,915,164 B2 7/2005 Bradley et al.
6,917,832 B2 7/2005 Hutten et al.
6,925,324 B2 8/2005 Shusterman
6,925,330 B2 8/2005 Kleine
6,927,721 B2 8/2005 Ostroff
6,928,324 B2 8/2005 Park et al.
6,937,907 B2 8/2005 Bardy et al.
6,944,495 B2 9/2005 MacAdam et al.
6,944,579 B2 9/2005 Shimizu
6,950,702 B2 9/2005 Sweeney
6,950,705 B2 9/2005 Bardy et al.
6,952,608 B2 10/2005 Ostroff
6,952,610 B2 10/2005 Ostroff
6,954,670 B2 10/2005 Ostroff
6,959,214 B2 10/2005 Pape et al.
6,961,613 B2 11/2005 Bjorling et al.
6,961,619 B2 11/2005 Casey
6,973,350 B1 12/2005 Levine et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,975,904 B1 12/2005 Sloman
6,978,178 B2 12/2005 Sommer et al.
6,983,264 B2 1/2006 Shimizu
6,988,003 B2 1/2006 Bardy et al.
6,993,379 B1 1/2006 Kroll
6,993,389 B2 1/2006 Ding
6,999,817 B2 2/2006 Park et al.
7,006,869 B2 2/2006 Bradley
7,025,730 B2 4/2006 Cho et al.
7,027,861 B2 4/2006 Thompson
7,027,868 B2 4/2006 Rueter et al.
7,027,871 B2 4/2006 Burnes et al.
7,031,773 B1 4/2006 Levine et al.
7,039,459 B2 5/2006 Bardy
7,039,465 B2 5/2006 Bardy
7,043,299 B2 5/2006 Erlinger
7,050,851 B2 5/2006 Plombon et al.
7,062,327 B2 6/2006 Bradley et al.
7,065,400 B2 6/2006 Schechter
7,065,407 B2 6/2006 Bardy
7,065,410 B2 6/2006 Bardy et al.
7,069,080 B2 6/2006 Bardy
7,076,296 B2 7/2006 Rissmann et al.
7,079,988 B2 7/2006 Albera
7,081,095 B2 7/2006 Lynn et al.
7,085,599 B2 8/2006 Kim et al.
7,090,682 B2 8/2006 Sanders et al.
7,092,754 B2 8/2006 Bardy et al.
7,094,207 B1 8/2006 Koh
7,096,064 B2 8/2006 Deno et al.
7,103,404 B2 9/2006 Stadler et al.
7,107,093 B2 9/2006 Burnes
7,113,823 B2 9/2006 Yonce et al.
7,115,097 B2 10/2006 Johnson
7,117,036 B2 10/2006 Florio
7,120,495 B2 10/2006 Bardy et al.
7,123,960 B2 10/2006 Ding
7,127,290 B2 10/2006 Girouard
7,129,935 B2 10/2006 Mackey
7,139,610 B2 11/2006 Ferek-Petric
7,144,586 B2 12/2006 Levy et al.
7,146,212 B2 12/2006 Bardy et al.
7,149,575 B2 12/2006 Ostroff et al.
7,155,278 B2 12/2006 King et al.
7,160,252 B2 1/2007 Cho
7,177,689 B2 2/2007 Ternes et al.
7,179,229 B1 2/2007 Koh
7,181,285 B2 2/2007 Lindh et al.
7,184,825 B2 2/2007 Leinsing et al.
7,184,835 B2 2/2007 Kramer
7,191,003 B2 3/2007 Greenhut et al.
7,191,004 B2 3/2007 Kim et al.
7,194,302 B2 3/2007 Bardy et al.
7,194,309 B2 3/2007 Ostroff et al.
7,194,313 B2 3/2007 Libbus
7,203,540 B2 4/2007 Ding et al.
7,203,542 B2 4/2007 Obel
7,203,543 B2 4/2007 Meyer et al.
7,212,862 B2 5/2007 Park et al
7,225,021 B1 5/2007 Park et al.
7,228,173 B2 6/2007 Cazares
7,233,821 B2 6/2007 Hettrick et al.
7,236,819 B2 6/2007 Brockway et al.
7,242,978 B2 7/2007 Cao
7,245,962 B2 7/2007 Ciaccio et al.
7,248,921 B2 7/2007 Palreddy et al.
7,248,925 B2 7/2007 Bruhns et al.
7,263,399 B2 8/2007 Carlson
7,277,754 B2 10/2007 McCabe et al.
7,286,876 B2 10/2007 Yonce et al.
7,299,086 B2 11/2007 McCabe et al.
7,299,093 B2 11/2007 Zhu et al.
7,308,311 B2 12/2007 Sorensen
7,319,900 B2 1/2008 Kim et al.
7,330,761 B2 2/2008 Zhang
7,337,000 B2 2/2008 Meyer et al.
7,359,749 B2 4/2008 Quenet et al.
7,369,889 B2 5/2008 Astrom et al.
7,392,086 B2 6/2008 Sathaye
7,426,412 B1 9/2008 Schecter
7,438,686 B2 10/2008 Cho
7,457,664 B2 11/2008 Zhang et al.
7,468,040 B2 12/2008 Hartley
7,477,932 B2 1/2009 Lee
7,499,751 B2 3/2009 Meyer et al.
7,509,170 B2 3/2009 Zhang et al.
7,587,240 B2 9/2009 Zhang et al.
7,617,002 B2 11/2009 Goetz
7,647,108 B2 1/2010 Freeberg
7,680,536 B2 3/2010 Sathaye et al.
7,684,861 B2 3/2010 Sanders
7,734,347 B2 6/2010 Sathaye et al.
7,738,959 B2 6/2010 Manrodt et al.
7,774,064 B2 8/2010 Meyer et al.
2001/0049542 A1 12/2001 Florio et al.
2002/0002327 A1 1/2002 Grant et al.
2002/0035377 A1 3/2002 Bardy et al.
2002/0035378 A1 3/2002 Bardy et al.
2002/0035379 A1 3/2002 Bardy et al.
2002/0035381 A1 3/2002 Bardy et al.
2002/0052631 A1 5/2002 Sullivan et al.
2002/0082658 A1 6/2002 Heinrich et al.
2002/0095184 A1 7/2002 Bardy et al.
2002/0107544 A1 8/2002 Ostroff et al.
2002/0107545 A1 8/2002 Rissmann et al.
2002/0138111 A1 9/2002 Greenhut et al.
2003/0023175 A1 1/2003 Arzbaecher et al.
2003/0050671 A1 3/2003 Bradley
2003/0083710 A1 5/2003 Ternes et al.
2003/0083711 A1 5/2003 Yonce et al.
2003/0135248 A1 7/2003 Stypulkowski
2003/0195571 A1 10/2003 Burnes et al.
2003/0199945 A1 10/2003 Ciulla
2003/0204213 A1 10/2003 Jensen et al.
2003/0212436 A1 11/2003 Brown
2004/0116978 A1 6/2004 Bradley
2004/0127950 A1 7/2004 Kim et al.
2004/0172065 A1 9/2004 Sih et al.
2004/0215253 A1 10/2004 Weinberg
2004/0215277 A1 10/2004 Oosterhoff et al.
2004/0230229 A1 11/2004 Lovett et al.
2004/0243014 A1 12/2004 Lee et al.
2004/0260351 A1 12/2004 Holmstrom et al.
2005/0004612 A1 1/2005 Scholten et al.
2005/0010120 A1 1/2005 Jung
2005/0038478 A1 2/2005 Klepfer et al.
2005/0043652 A1 2/2005 Lovett et al.
2005/0065587 A1 3/2005 Gryzwa
2005/0085865 A1 4/2005 Tehrani
2005/0107839 A1 5/2005 Sanders
2005/0113710 A1 5/2005 Stahmann et al.
2005/0131477 A1 6/2005 Meyer et al.
2005/0131478 A1 6/2005 Kim et al.
2005/0288600 A1 12/2005 Zhang et al.
2006/0069322 A1 3/2006 Zhang et al.
2006/0074331 A1 4/2006 Kim et al.
2006/0111747 A1 5/2006 Cazares et al.
2006/0116593 A1 6/2006 Zhang et al.
2006/0129193 A1 6/2006 Zhang
2006/0129194 A1 6/2006 Zhang
2006/0129196 A1 6/2006 Dong et al.
2006/0129199 A1 6/2006 Zhang et al.
2006/0241706 A1 10/2006 Yonce et al.
2006/0247693 A1 11/2006 Dong et al.
2006/0247695 A1 11/2006 Stalsberg et al.
2006/0253043 A1 11/2006 Zhang et al.
2006/0253044 A1 11/2006 Zhang et al.
2007/0049974 A1 3/2007 Li et al.
2007/0055124 A1 3/2007 Viswanathan et al.
2007/0142737 A1 6/2007 Cazares et al.
2007/0142741 A1 6/2007 Berthon-Jones et al.
2007/0239057 A1 10/2007 Pu et al.
2007/0255321 A1 11/2007 Gerber et al.
2008/0004665 A1 1/2008 McCabe et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2008/0009909	A1	1/2008	Sathaye et al.
2008/0045851	A1	2/2008	Cazares et al.
2008/0071318	A1	3/2008	Brooke et al.
2008/0275522	A1	11/2008	Dong
2008/0294215	A1	11/2008	Sathaye
2008/0300644	A1	12/2008	Sathaye
2009/0030470	A1	1/2009	Holmstrom
2009/0043351	A1	2/2009	Sathaye
2009/0043352	A1	2/2009	Brooke

FOREIGN PATENT DOCUMENTS

EP	0940155	9/1999
EP	1038498	9/2000
EP	1151718	11/2001
EP	1291038	3/2003
EP	1629863	3/2006
WO	WO9217240	10/1992
WO	WO9220402	11/1992
WO	WO9904841	4/1999
WO	WO0001438	1/2000
WO	WO0017615	3/2000
WO	WO0240097	5/2002
WO	WO0247761	6/2002
WO	WO02087696	11/2002
WO	WO03003905	1/2003
WO	WO03028550	4/2003
WO	WO2004026398	4/2004
WO	WO2004091720	10/2004
WO	WO2005058412	6/2005
WO	WO2005089865	9/2005
WO	WO2006065707	6/2006
WO	WO2007087025	8/2007
WO	WO2008005270	1/2008
WO	WO2009020639	2/2009

OTHER PUBLICATIONS

Ajilore et al., Nightcap: Laboratory and home-based evaluation of a portable sleep monitor, 32 Psychophysiology, 32-98 (1995). Abstract only.

Belouchrani et al., "Blind Source Separation Based on Time-Frequency Signal Representations", IEEE Transactions on Signal Processing, vol. 46, No. 11, pp. 2888-2897, Nov. 1998.

Cohen et al. Capture Management Efficacy in children and young adults with endocardial and unipolar epicardial systems. Europace, vol. 6, pp. 248-255 (2004).

Comon,"Independent component analysis, A new concept?", Signal Processing, vol. 36, No. 3, pp. 287-314, Apr. 1994.

Gallois et al., "Multi-Channel Analysis of the EEG Signals and Statistic Particularities for Epileptic Seizure Forecast", Second Joint EMBS/BMES Conference, pp. 208-215 (Oct. 23-26, 2002).

Gradaus et al., "Nonthoracotomy Implantable Cardioverter Defibrillator Placement in Children: Use of a Subcutaneous Array Leads and Abdominally Placed Implantable Cardioverter Defibrillators in Children", Journal of Cardiovascular Electrophysiology, vol. 12, No. 3, pp. 356-360, Mar. 2001.

Hartz et al., "New Approach to Defibrillator Insertion", Journal of Thoracic Cardiovascular Surgery, vol. 97, pp. 920-922, 1989.

Hyvärinen et al., "Independent Component Analysis: A Tutorial", Helsinski University of Technology, Apr. 1999.

Kolettis et al., "Submammary Implantation of a Cardioverter-Defibrillator with a Nonthoractomy Lead System", American Heart Journal, vol. 126, pp. 1222-1223, Nov. 1993.

Krahn et al. "Recurrent syncope. Experience with an implantable loop record", Cardiol. Clin., vol. 15(2), pp. 316-326, May 1997.

Leng et al., "Lead Configuration for Defibrillator Implantation in a Patient with Congenital Heart Disease and a Mechanical Prosthetic Tricuspid Valve", PACE, vol. 24, No. 8, pp. 1291-1292, Aug. 2001.

Park et al., "Use of an Implantable Cardioverter Defibrillator in an Eight-Month-Old Infant with Ventricular Fibrillation Arising from a Myocardial Fibroma", PACE, vol. 22, No. 1, pp. 138-139, Jan. 1999.

Rieta, et al., "Atrial Activity Extraction Based on Blind Source Separation as an Alternative to QRST Cancellation for Atrial Fibrillation Analysis", Computers in Cardiology, vol. 27, pp. 69-72, 2000.

Schuder et al., "Experimental Ventricular Defibrillation with an Automatic and Completely Implanted System", Trans. American Society Artif. Int. Organs, vol. 16, pp. 207-212, 1970.

Schuder et al., "Transthoracic Ventricular Defibrillation in the Dog with Truncated and Untruncated Exponential Stimuli", IEEE Transitions on Bio-Medical Engineering, vol. BME-18, No. 6, pp. 410-415, Nov. 1971.

Schuder et al., "Ventricular Defibrillation in the Dog Using Implanted and Partially Implanted Electrode Systems", American Journal of Cardiology, vol. 33, pp. 243-247, Feb. 1974.

Smits et al., Defibrillation Threshold (DFT) Model of a Fully Subcutaneous ICD System, Europace Supplements, vol. 2, Jun. 2001 at col. 778, p. B83.

Splett et al., Detemrination of Pacing Capture in Implantable Defibrillators Benefit of Evoked Response Detection Using RV Coil to Can Vector, PACE, vol. 23, pp. 1645-1650.

Stirbis et al., "Optimizing of the Shape of Implanted Artificial Pacemakers", Kaunas Medical Institute, Translated from Meditsinskaya Tekhnika, No. 6, pp. 25-27, 1986.

Verrier et al., Sleep, dreams, and sudden death: the case for sleep as an autonomic stress test for the heart, 31 Cardiovascular Research 181-211 (1996).

Verrier et al., Sleep Related Cardiovascular Risk: New Home-Based Monitoring Technology for Improved Diagnosis and Therapy, 2 A.N.E. 158-175 (1997).

Waldemark et al., Detection of Apnea using Short Window FFT Technique and Artificial Neural Network, 3390 SPIE International Society for Optical Engineering 122-133 (1998). (partial article).

Zarzoso et al., "Blind Separation of Independent Sources for Virtually Any Source Probability Density Function", IEEE Transactions on Signal Processing, vol. 47, No. 9, pp. 2419-2432, Sep. 1999.

Zarzoso et al., "Noninvasive Fetal Electrocardiogram Extraction: Blind Separation Versus Adaptive Noise Cancellation", IEEE Transactions on Biomedical Engineering, vol. 48, No. 1, pp. 12-18, Jan. 2001.

Notice of Allowance dated Mar. 19, 2010 from U.S. Appl. No. 10/734,599, 4 pages.

Office Action Response dated Dec. 21, 2009 from U.S. Appl. No. 10/734,599, 14 pages.

Office Action dated Sep. 21, 2009 from U.S. Appl. No. 10/734,599, 8 pages.

Interview Summary dated Sep. 18, 2009 from U.S. Appl. No. 10/734,599, 2 pages.

Office Action Response dated Jun. 9, 2009 from U.S. Appl. No. 10/734,599, 14 pages.

Office Action dated Mar. 18, 2009 from U.S. Appl. No. 10/734,599, 10 pages.

Office Action Response dated Sep. 22, 2008 from U.S. Appl. No. 10/734,599, 16 pages.

Office Action Response dated Feb. 6, 2008 from U.S. Appl. No. 10/734,599, 16 pages.

Office Action dated Dec. 6, 2007 from U.S. Appl. No. 10/734,599, 9 pages.

Office Action Response dated Jan. 22, 2007 from U.S. Appl. No. 10/734,599, 16 pages.

Office Action dated Sep. 21, 2006 from U.S. Appl. No. 10/734,599, 7 pages.

Office Action Response dated Jun. 5, 2006 from U.S. Appl. No. 10/734,599, 20 pages.

Office Action dated Feb. 7, 2006 from U.S. Appl. No. 10/734,599, 16 pages.

Examiner Interview dated Dec. 8, 2009 from U.S. Appl. No. 10/734,599, 3 pages.

Examiner Interview dated May 28, 2008 from U.S. Appl. No. 11/116,558, 3 pages.

Office Action Response dated May 6, 2008 from U.S. Appl. No. 11/116,558, 11 pages.

(56) **References Cited**

OTHER PUBLICATIONS

Examiner Interview dated Mar. 6, 2008 from U.S. Appl. No. 11/116,558, 3 pages.
Office Action Response dated Oct. 29, 2007 from U.S. Appl. No. 11/116,558, 7 pages.
Office Action Response dated Sep. 28, 2007 from U.S. Appl. No. 11/116,558, 15 pages.
Office Action dated Mar. 28, 2007 from U.S. Appl. No. 11/116,558, 14 pages.
File History for U.S. Appl. No. 12/217,652.
"U.S. Appl. No. 10/734,599, 312 Amendment filed Jun. 9, 2010", 4 pgs.
"U.S. Appl. No. 10/734,599, Preliminary Amendment filed Apr. 6, 2004", 12 pgs.
"U.S. Appl. No. 10/734,599, PTO Response to Rule 312 Communication dated Jul. 15, 2010", 2 pgs.

* cited by examiner

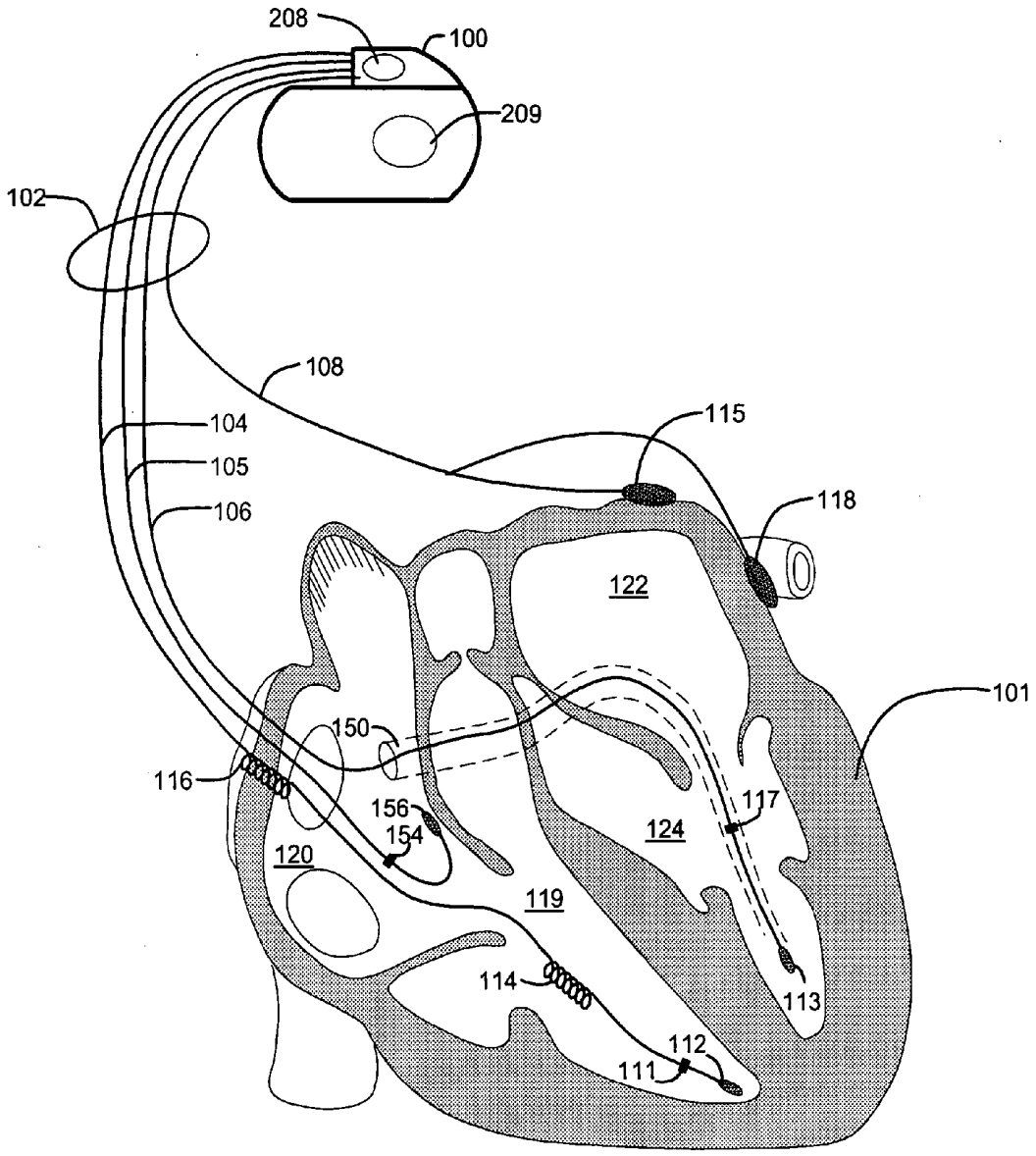

208
100
209
102
108
104
105
106
115
118
122
101
150
116
156
154
120
124
117
119
114
113
112
111

Figure 1

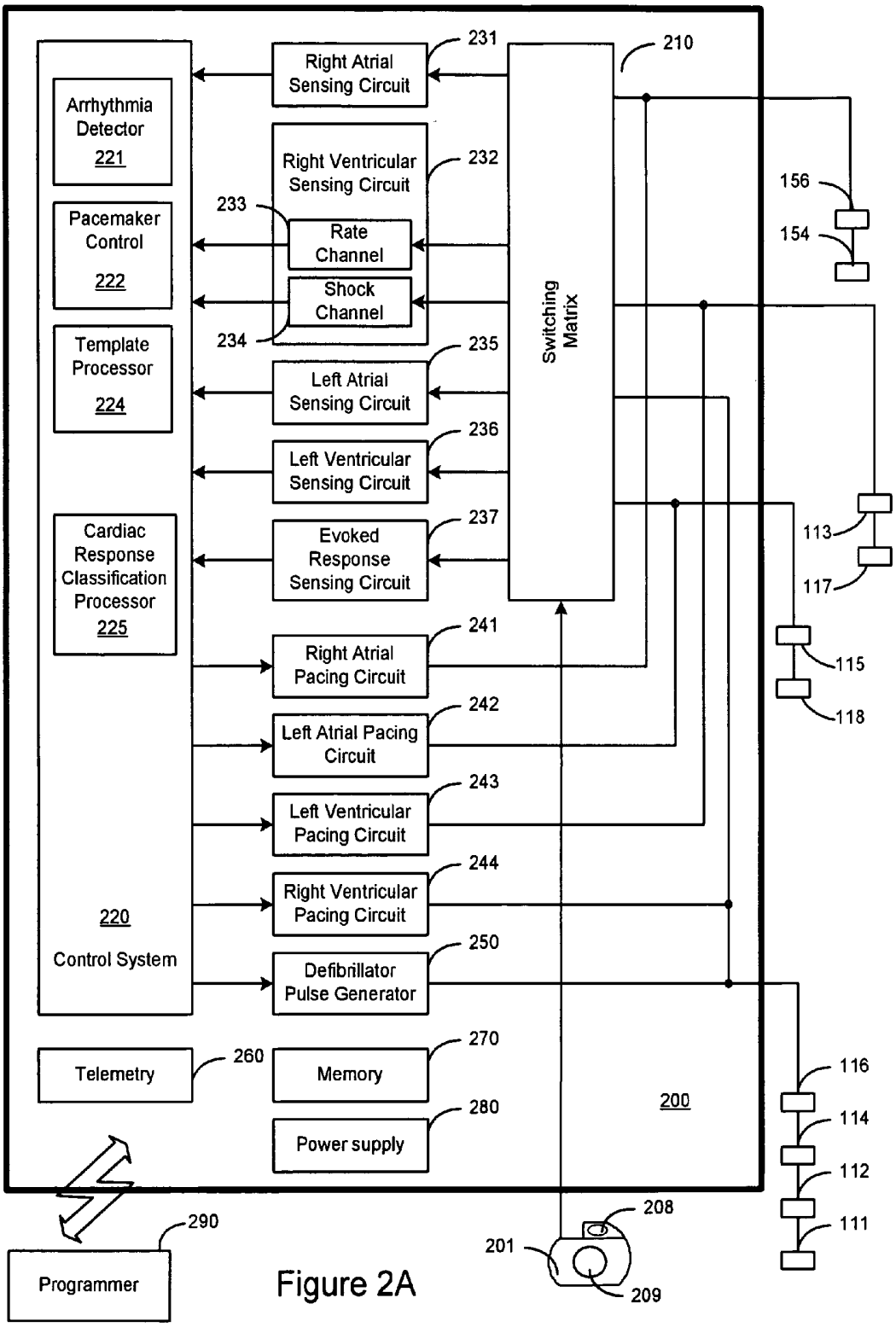

Arrhythmia Detector 221
Pacemaker Control 222
Template Processor 224
Cardiac Response Classification Processor 225
220 Control System
Right Atrial Sensing Circuit
231
Right Ventricular Sensing Circuit
232
233
Rate Channel
Shock Channel
234
Left Atrial Sensing Circuit
235
Left Ventricular Sensing Circuit
236
Evoked Response Sensing Circuit
237
Right Atrial Pacing Circuit
241
Left Atrial Pacing Circuit
242
Left Ventricular Pacing Circuit
243
Right Ventricular Pacing Circuit
244
Defibrillator Pulse Generator
250
Telemetry
260
Memory
270
Power supply
280
Switching Matrix
210
200
156
154
113
117
115
118
116
114
112
111
208
201
209
290
Programmer

Figure 2A

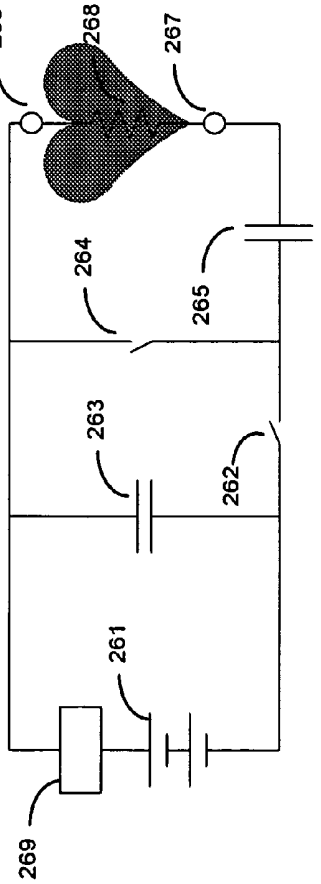


Figure 2B

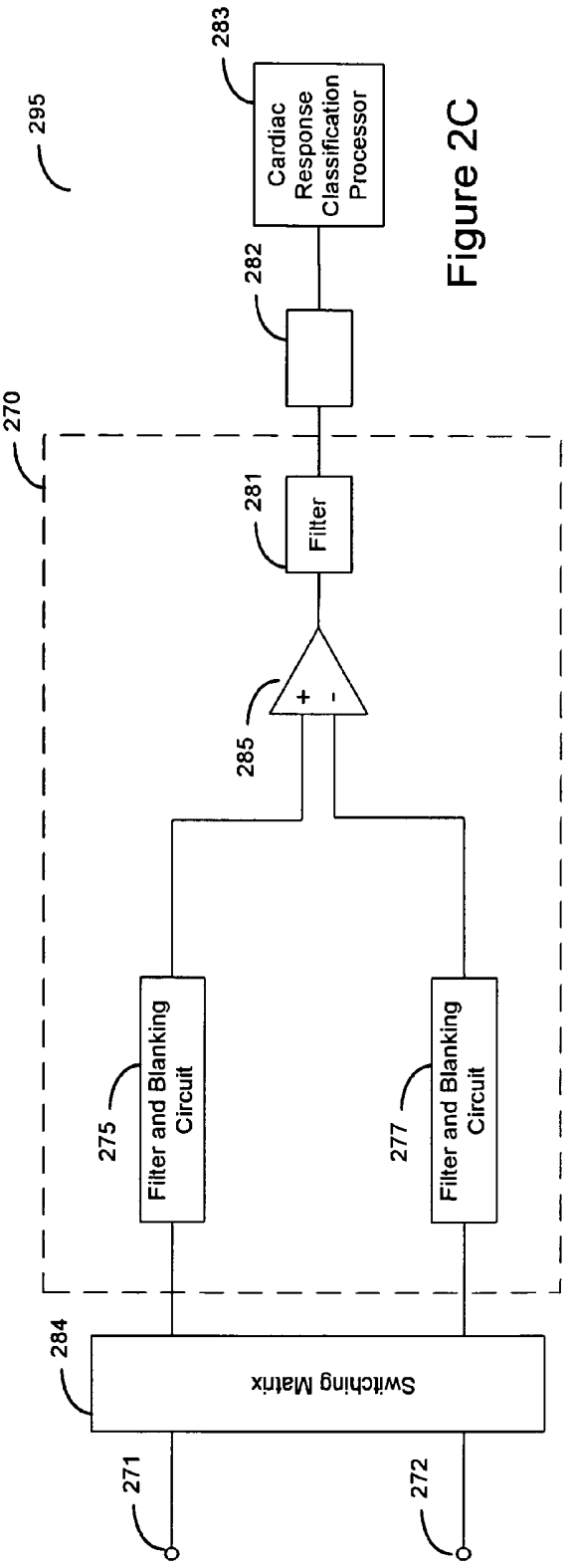


Figure 2C

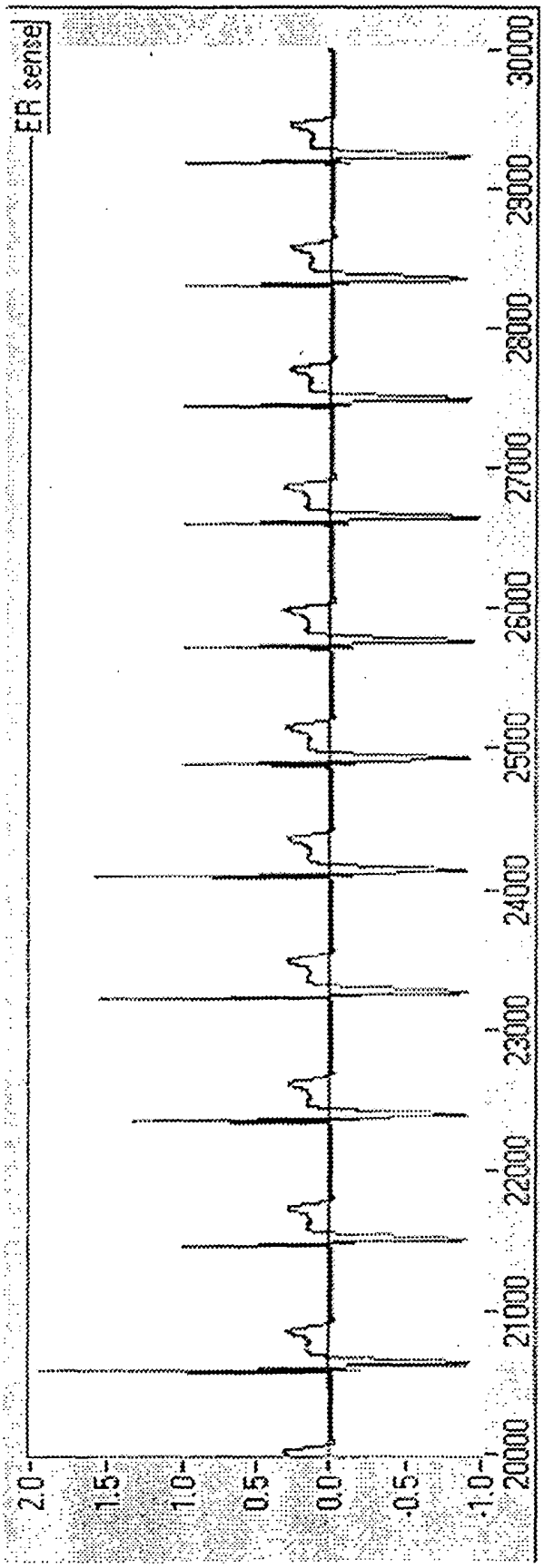

ER sense
2.0
1.5
1.0
0.5
0.0
-0.5
-1.0
20000
21000
22000
23000
24000
25000
26000
27000
28000
29000
30000

Figure 3

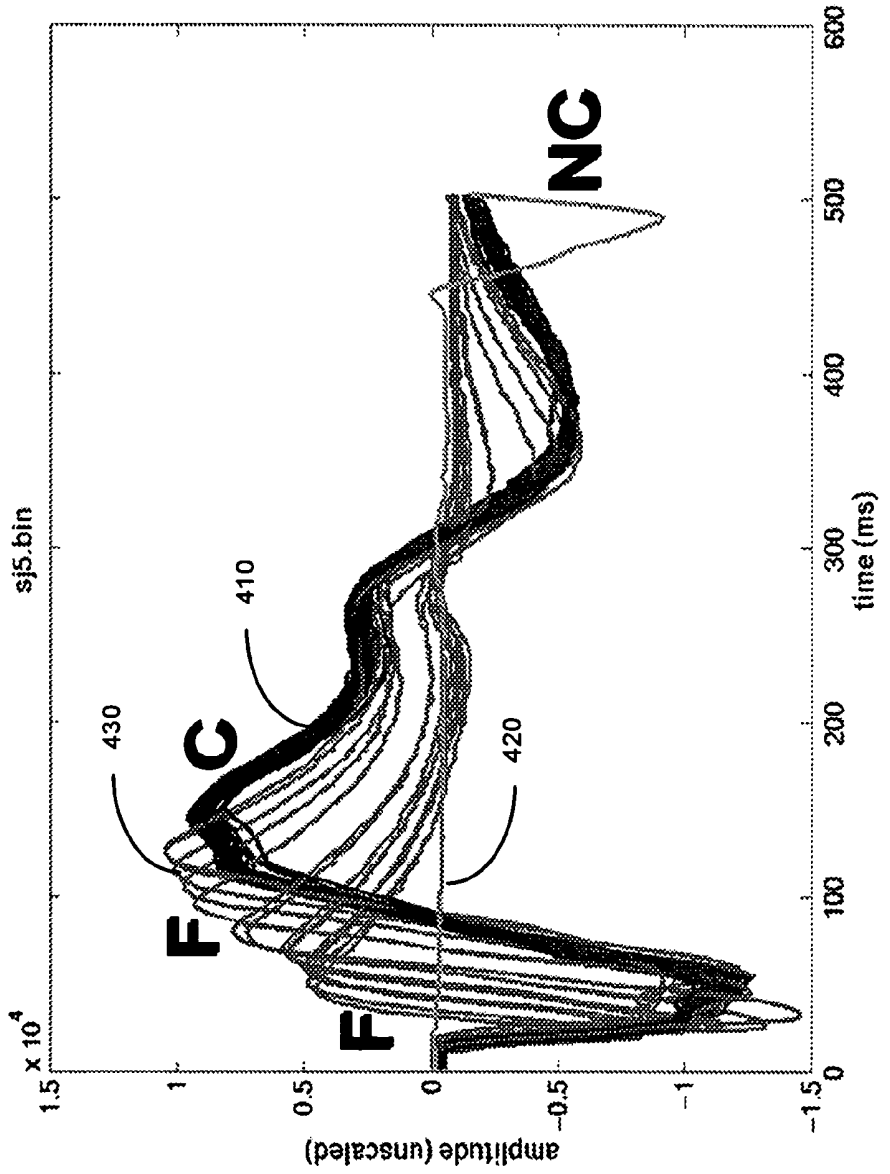

sj5.bin
x 10^4
1.5
1
0.5
0
−0.5
−1
−1.5
amplitude (unscaled)
0
100
200
300
400
500
600
time (ms)
F
C
NC
410
420
430

Figure 4A

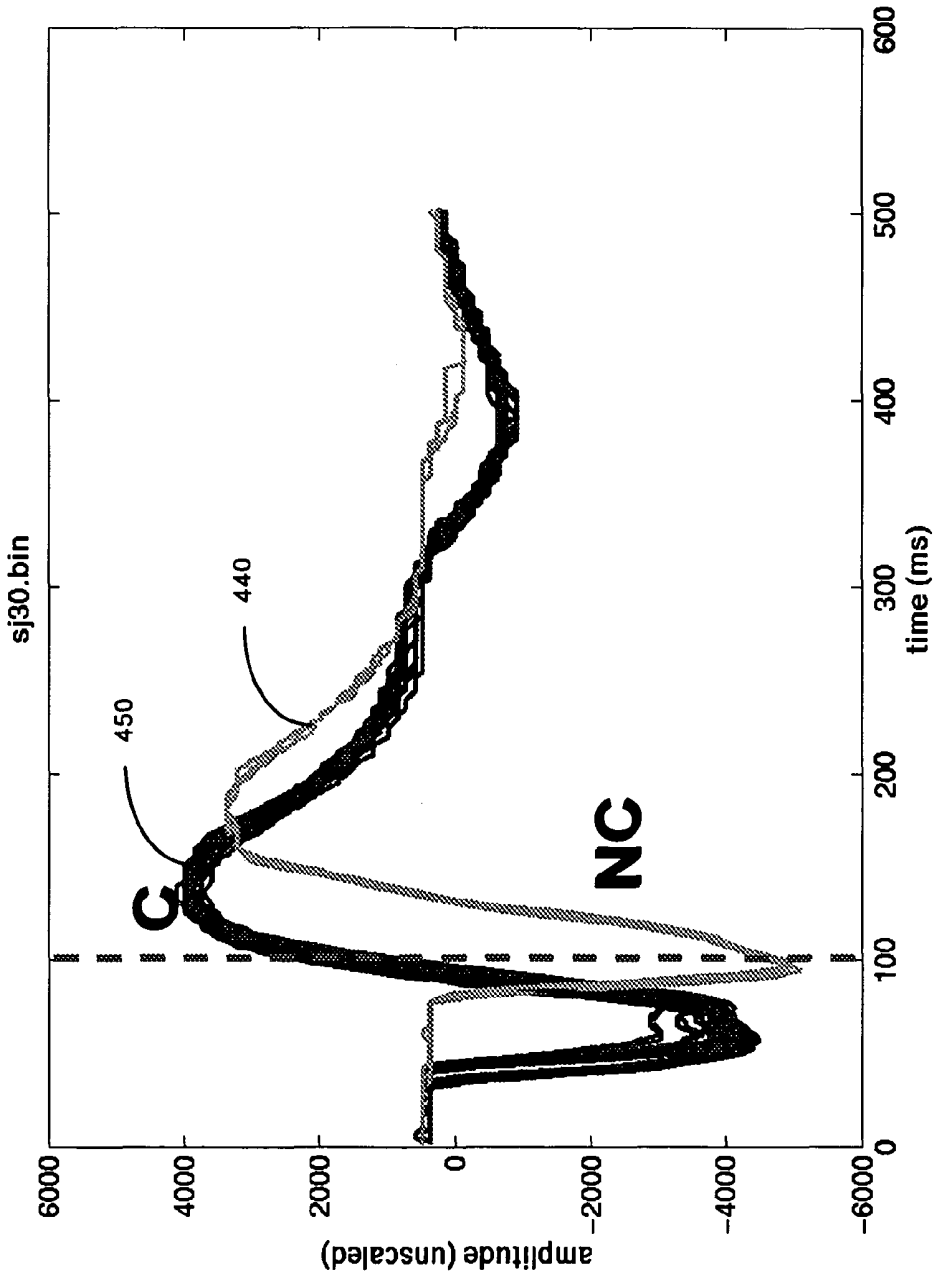

sj30.bin
450
440
C
NC
amplitude (unscaled)
time (ms)
6000
4000
2000
0
−2000
−4000
−6000
0
100
200
300
400
500
600

Figure 4B

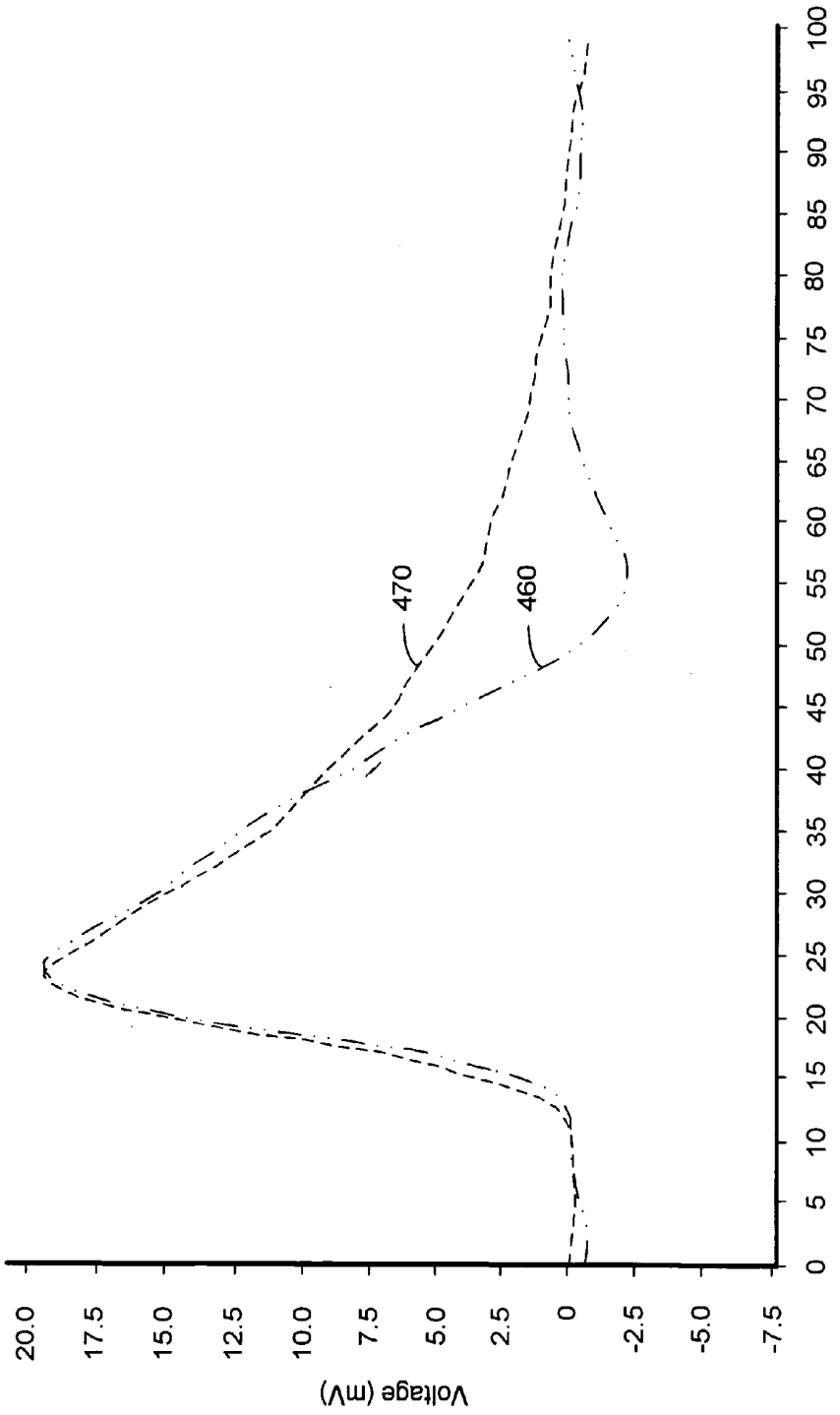

Voltage (mV)
20.0
17.5
15.0
12.5
10.0
7.5
5.0
2.5
0
-2.5
-5.0
-7.5
Time (msec)
0
5
10
15
20
25
30
35
40
45
50
55
60
65
70
75
80
85
90
95
100
470
460
End of Blanking

Figure 4C

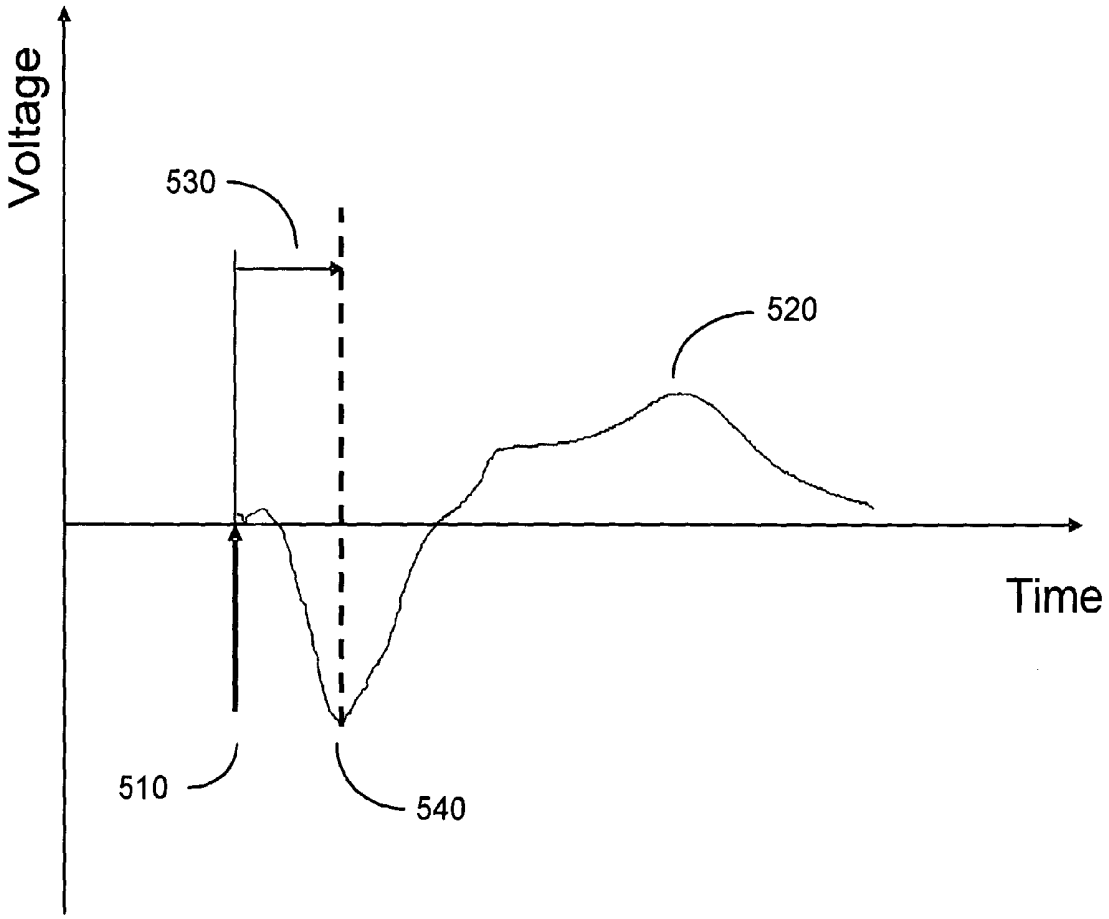


Figure 5

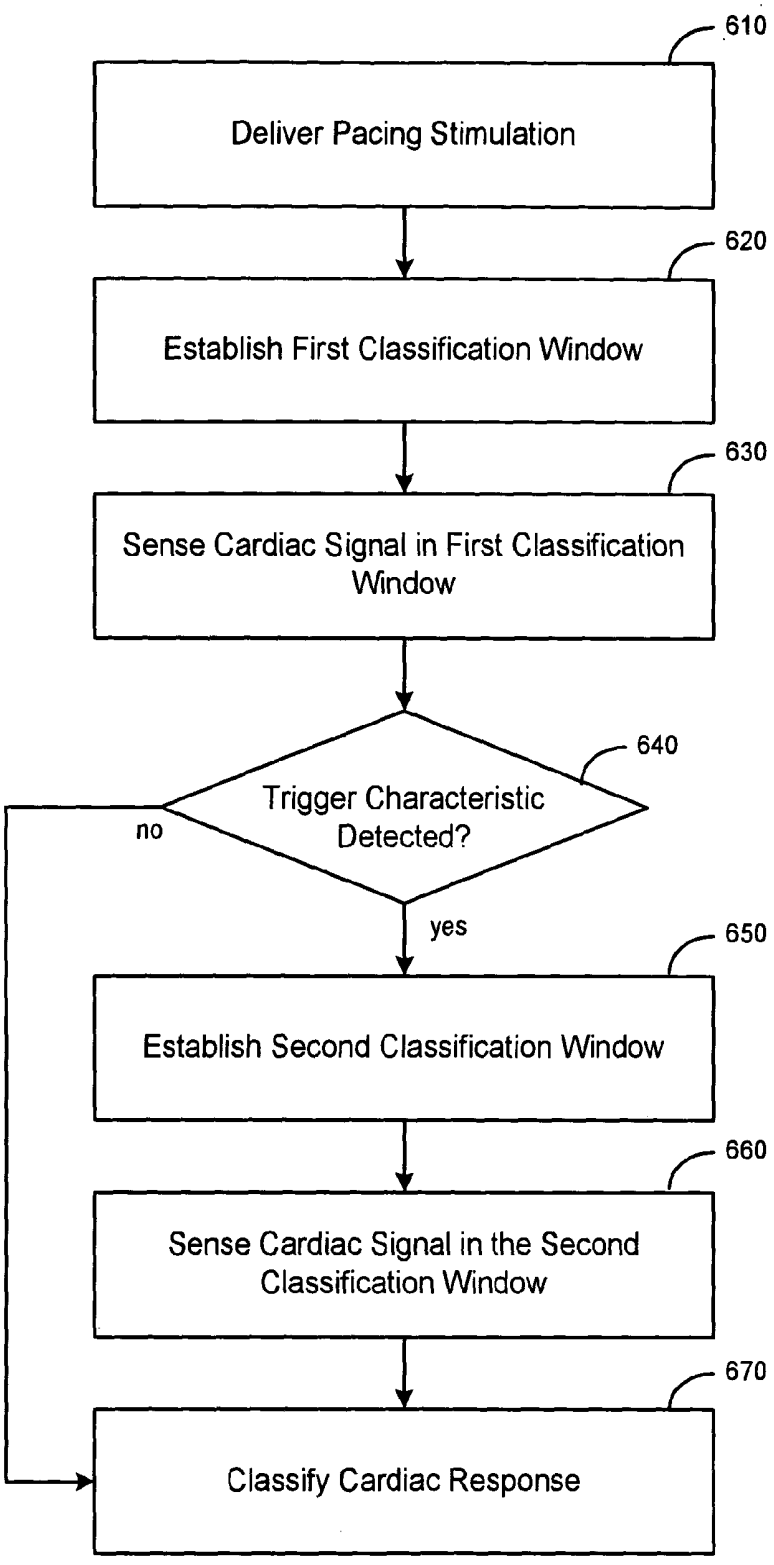

610
Deliver Pacing Stimulation
620
Establish First Classification Window
630
Sense Cardiac Signal in First Classification Window
640
Trigger Characteristic Detected?
no
yes
650
Establish Second Classification Window
660
Sense Cardiac Signal in the Second Classification Window
670
Classify Cardiac Response

Figure 6

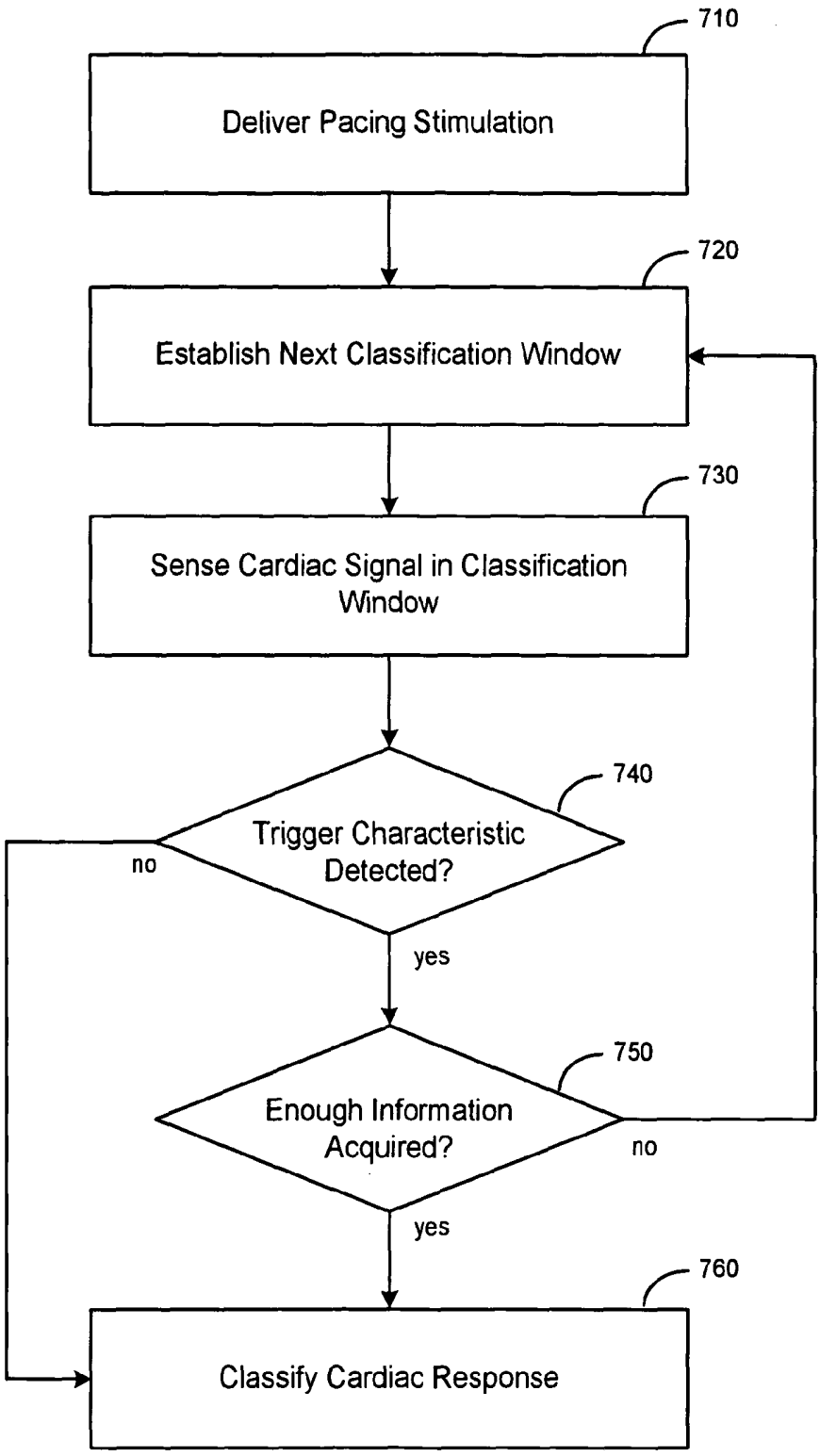

710
Deliver Pacing Stimulation
720
Establish Next Classification Window
730
Sense Cardiac Signal in Classification Window
740
Trigger Characteristic Detected?
no
yes
750
Enough Information Acquired?
no
yes
760
Classify Cardiac Response

Figure 7

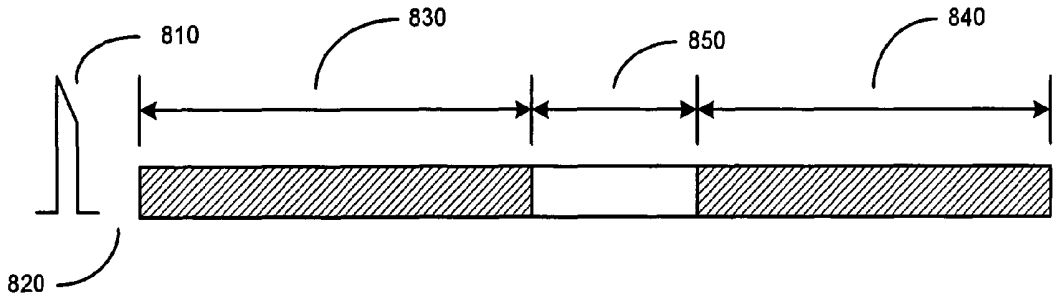


Figure 8

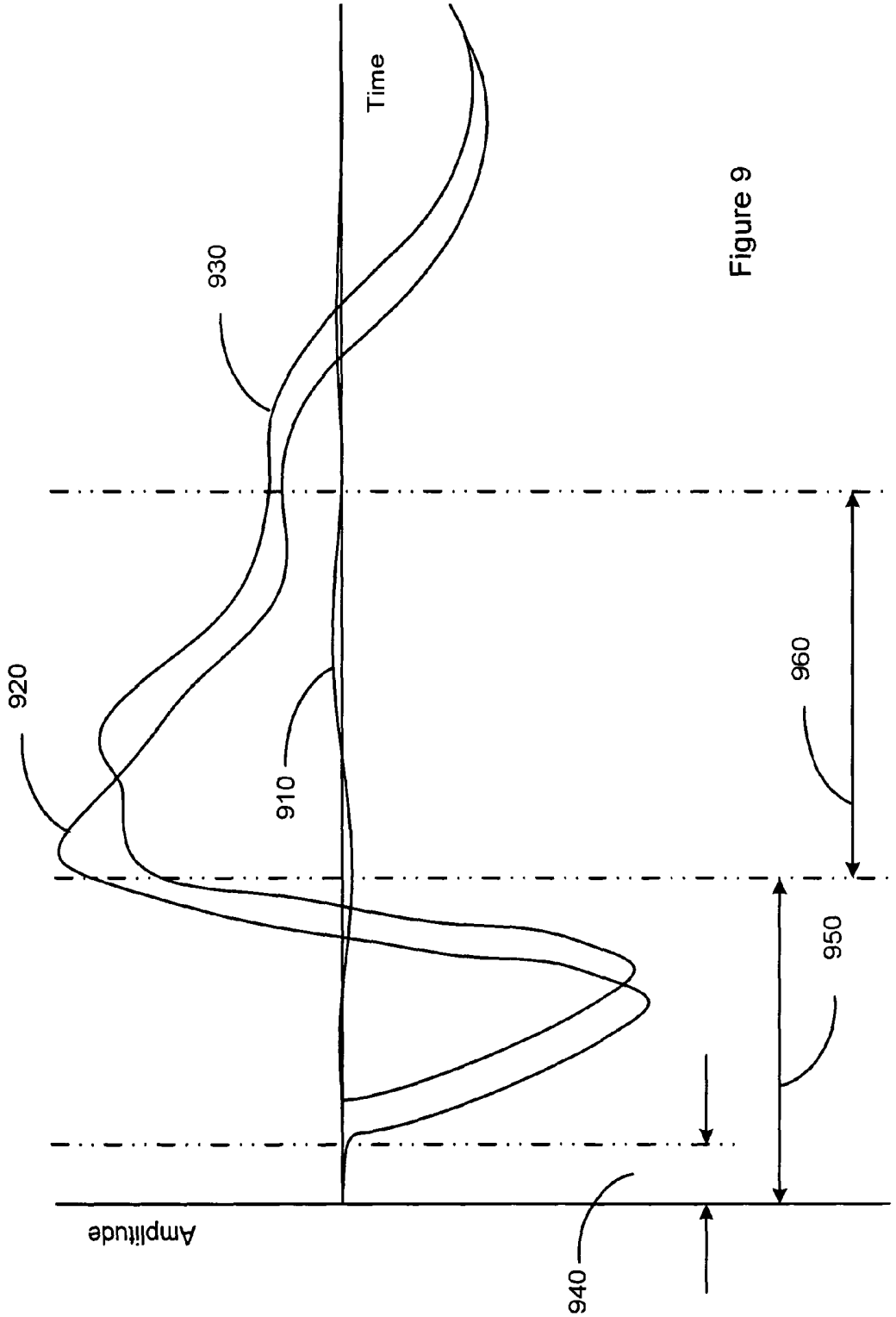


Figure 9

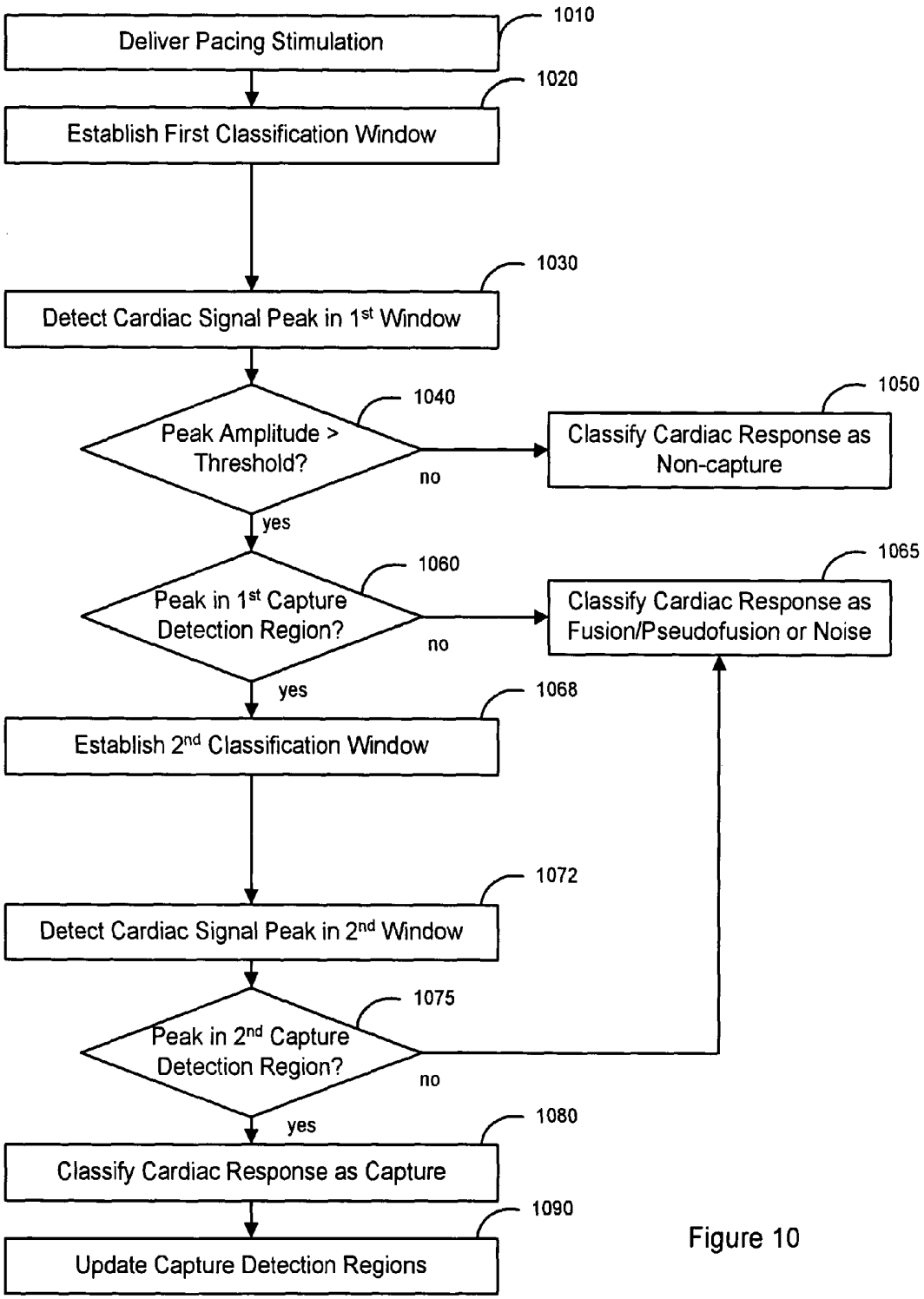

Deliver Pacing Stimulation
1010
Establish First Classification Window
1020
Detect Cardiac Signal Peak in 1st Window
1030
Peak Amplitude > Threshold?
1040
no
Classify Cardiac Response as Non-capture
1050
yes
Peak in 1st Capture Detection Region?
1060
no
Classify Cardiac Response as Fusion/Pseudofusion or Noise
1065
yes
Establish 2nd Classification Window
1068
Detect Cardiac Signal Peak in 2nd Window
1072
Peak in 2nd Capture Detection Region?
1075
no
yes
Classify Cardiac Response as Capture
1080
Update Capture Detection Regions
1090

Figure 10

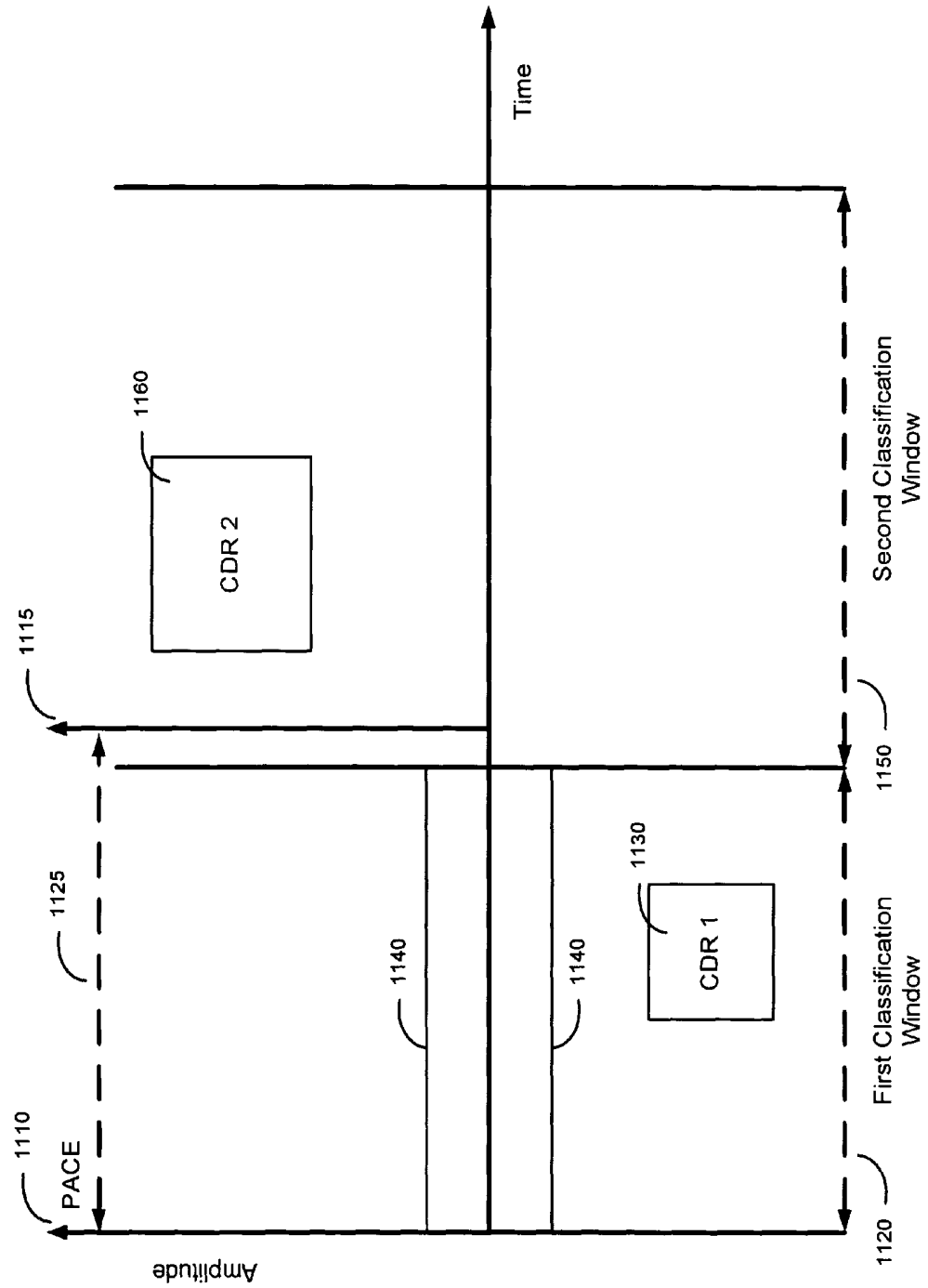

Time
Amplitude
1110
PACE
1115
1120
1125
1130
CDR 1
1140
1140
1150
1160
CDR 2
First Classification Window
Second Classification Window

Figure 11

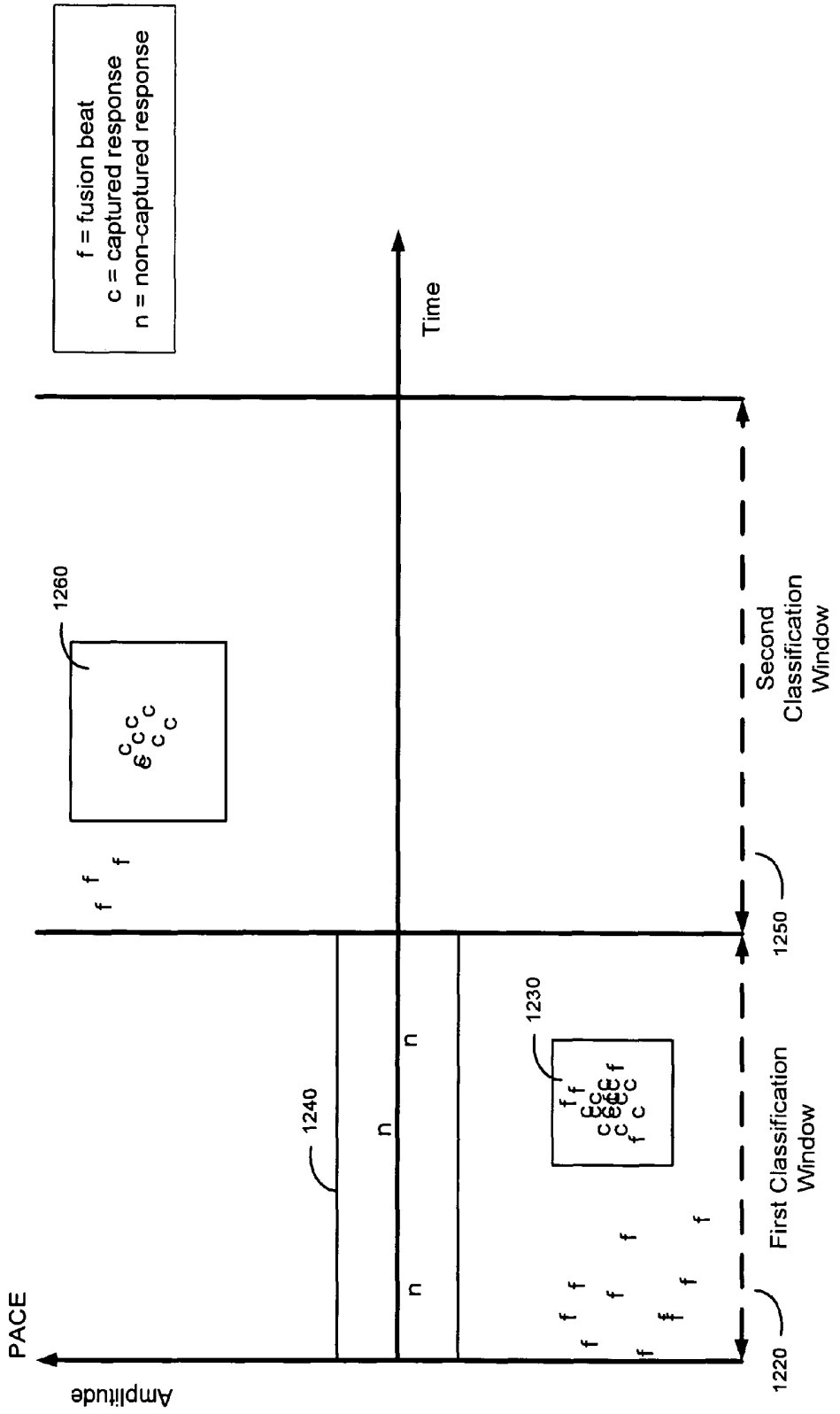
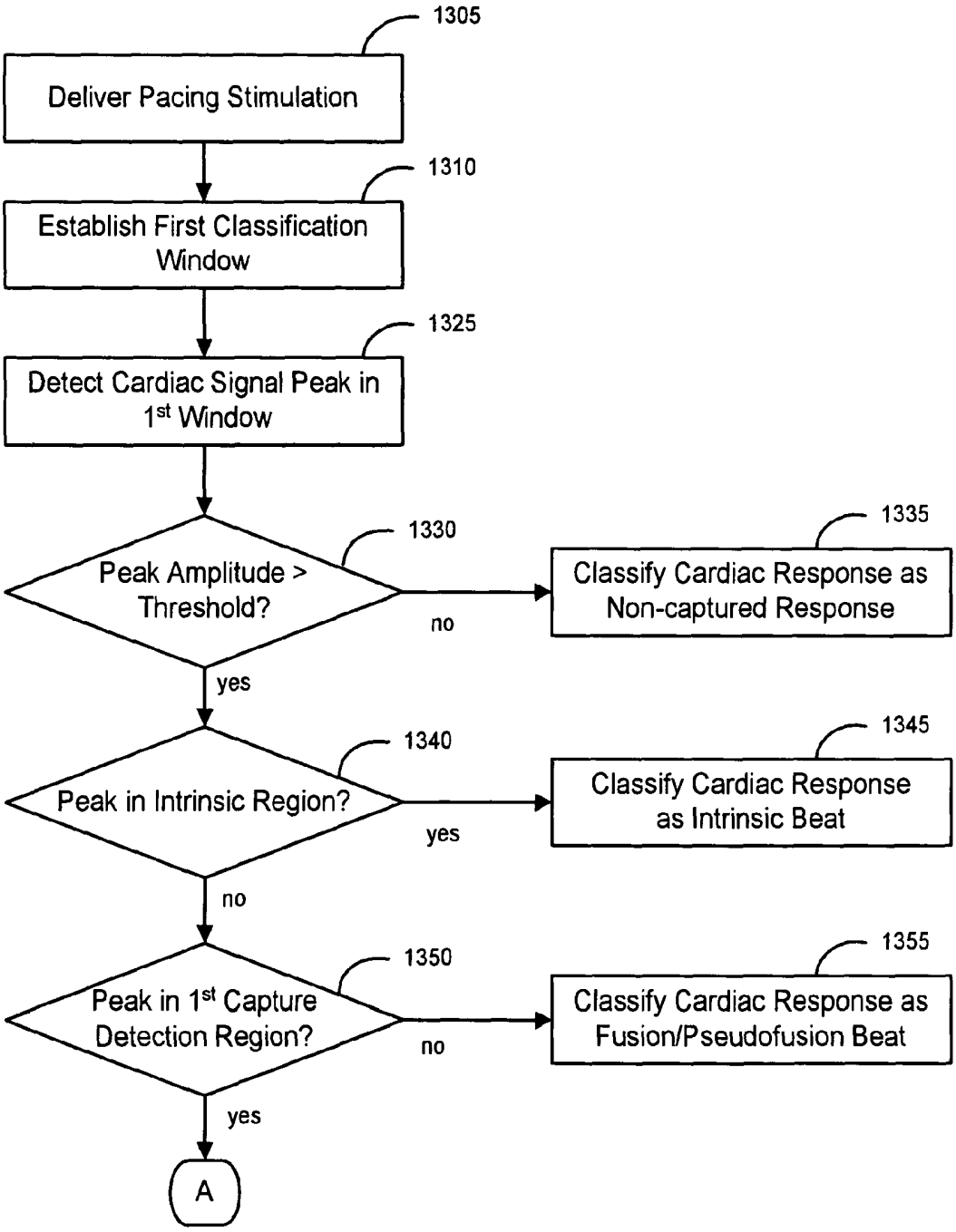

f = fusion beat
c = captured response
n = non-captured response
Time
Amplitude
PACE
1220
1230
1240
1250
1260
First Classification Window
Second Classification Window

Figure 12

Figure 13A


1305
Deliver Pacing Stimulation
1310
Establish First Classification Window
1325
Detect Cardiac Signal Peak in 1st Window
1330
Peak Amplitude > Threshold?
no
1335
Classify Cardiac Response as Non-captured Response
yes
1340
Peak in Intrinsic Region?
yes
1345
Classify Cardiac Response as Intrinsic Beat
no
1350
Peak in 1st Capture Detection Region?
no
1355
Classify Cardiac Response as Fusion/Pseudofusion Beat
yes
A

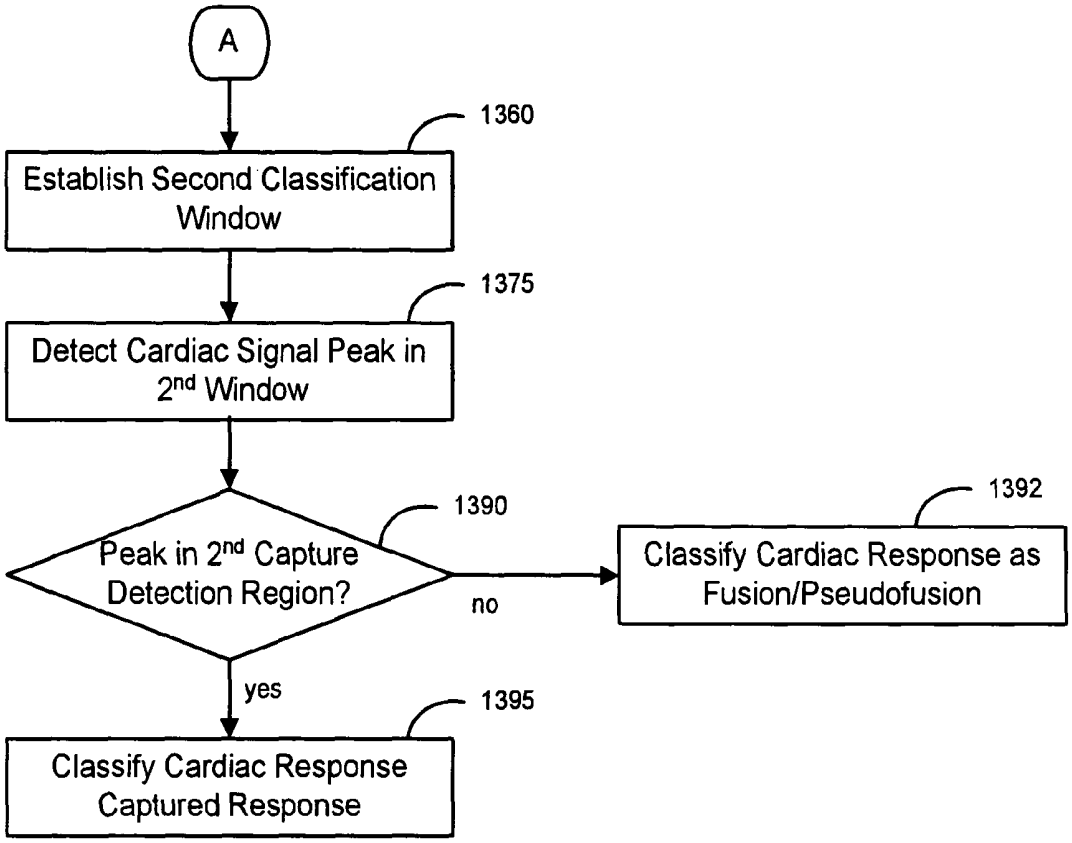

A
1360
Establish Second Classification Window
1375
Detect Cardiac Signal Peak in 2nd Window
1390
Peak in 2nd Capture Detection Region?
no
1392
Classify Cardiac Response as Fusion/Pseudofusion
yes
1395
Classify Cardiac Response Captured Response

Figure 13B

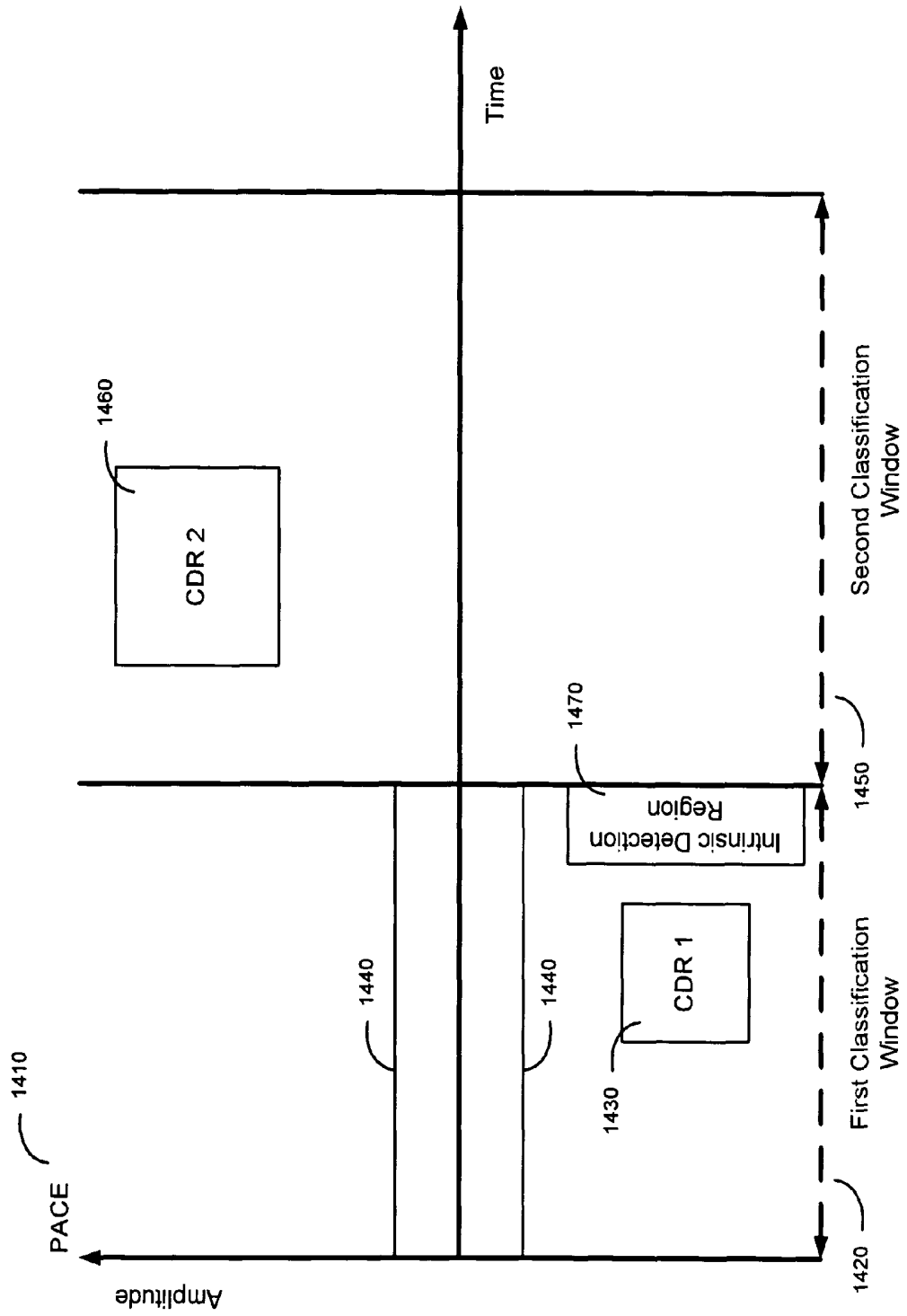

Time
Amplitude
PACE
1410
1420
1430
1440
1440
1450
1460
1470
CDR 1
CDR 2
First Classification Window
Second Classification Window
Intrinsic Detection Region

Figure 14

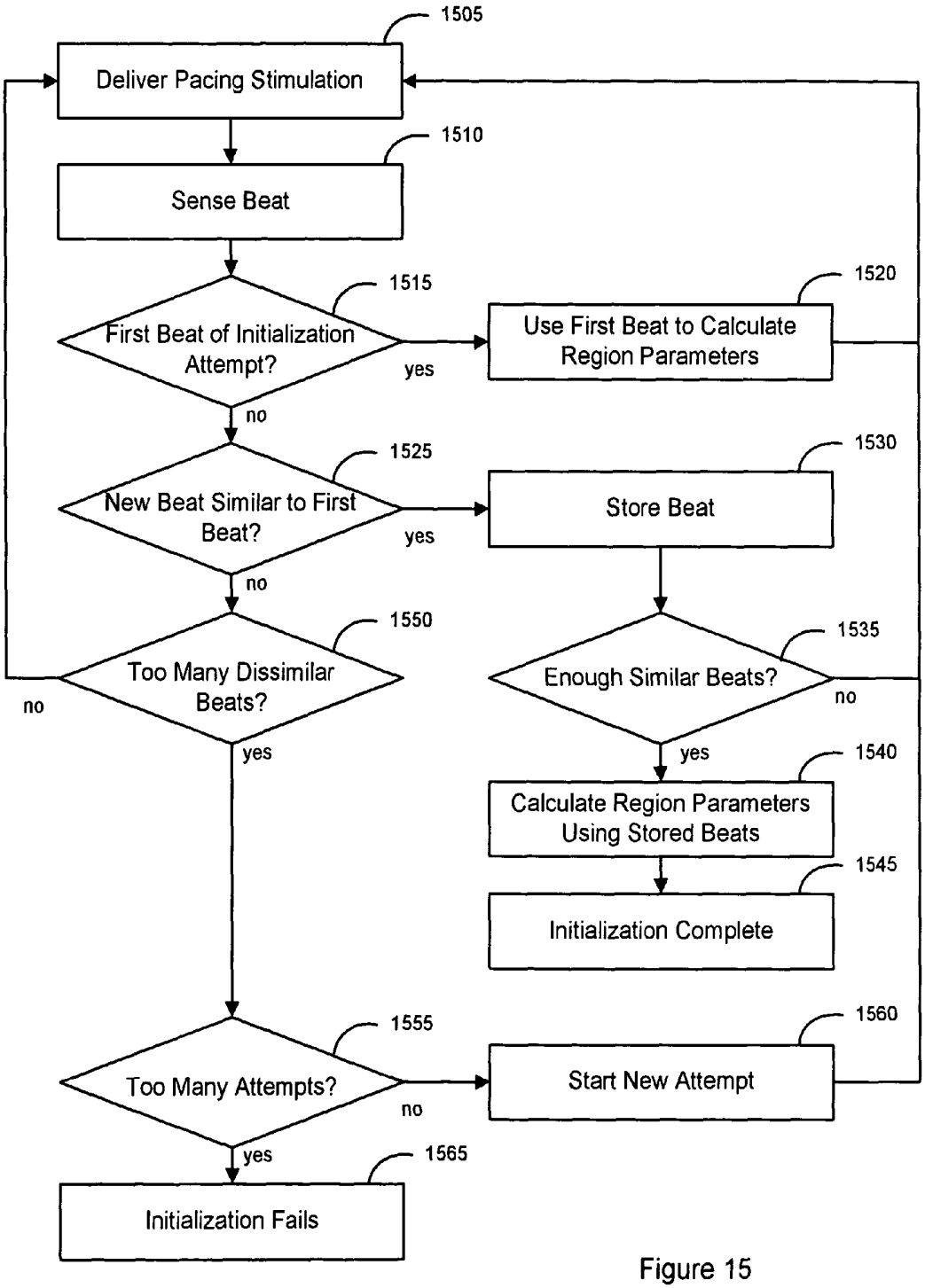

1505
Deliver Pacing Stimulation
1510
Sense Beat
1515
First Beat of Initialization Attempt?
yes
no
1520
Use First Beat to Calculate Region Parameters
1525
New Beat Similar to First Beat?
yes
no
1530
Store Beat
1535
Enough Similar Beats?
no
yes
1540
Calculate Region Parameters Using Stored Beats
1545
Initialization Complete
1550
Too Many Dissimilar Beats?
no
yes
1555
Too Many Attempts?
no
yes
1560
Start New Attempt
1565
Initialization Fails

Figure 15

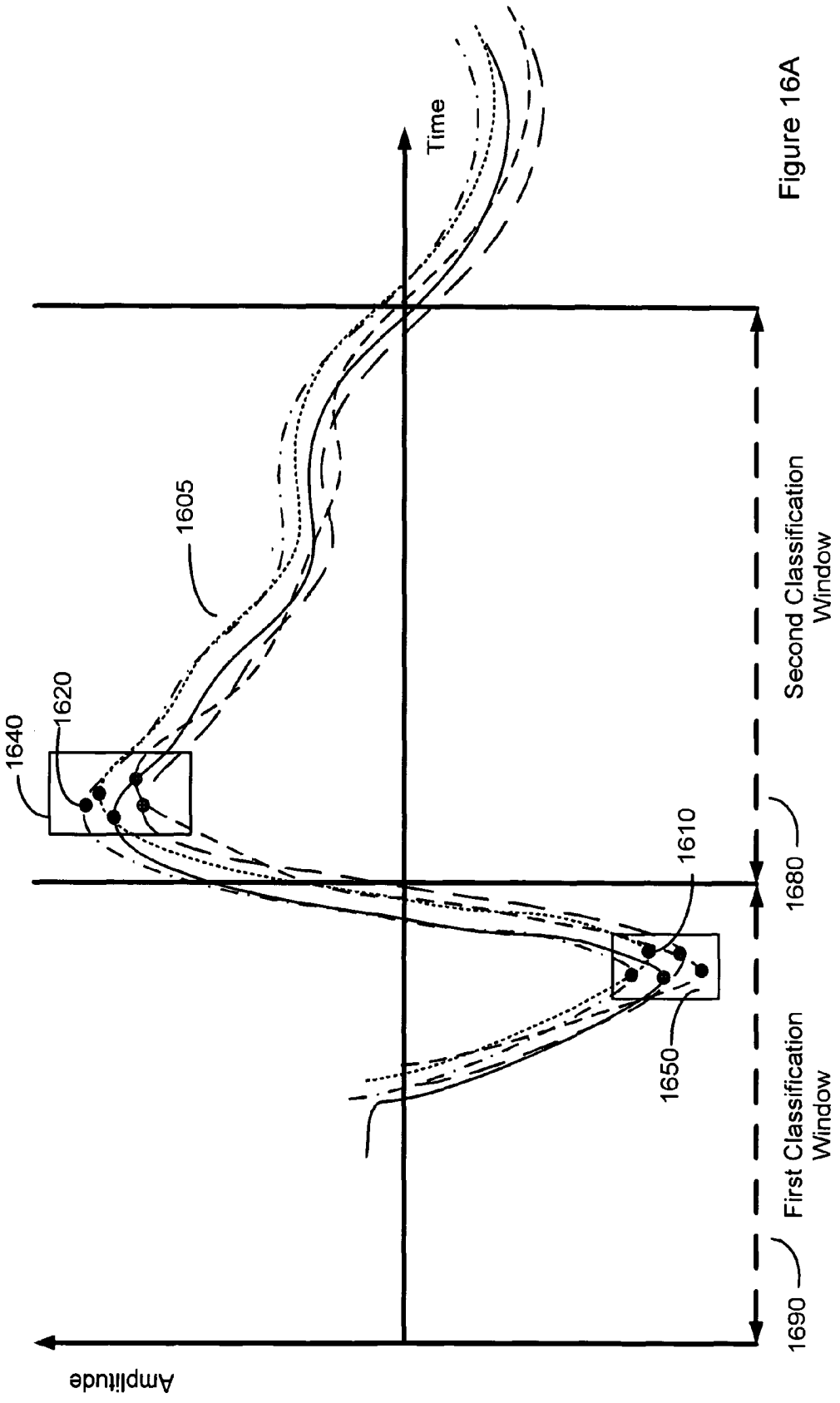

Time
Amplitude
1605
1620
1640
1610
1650
1680
1690
Second Classification Window
First Classification Window

Figure 16A

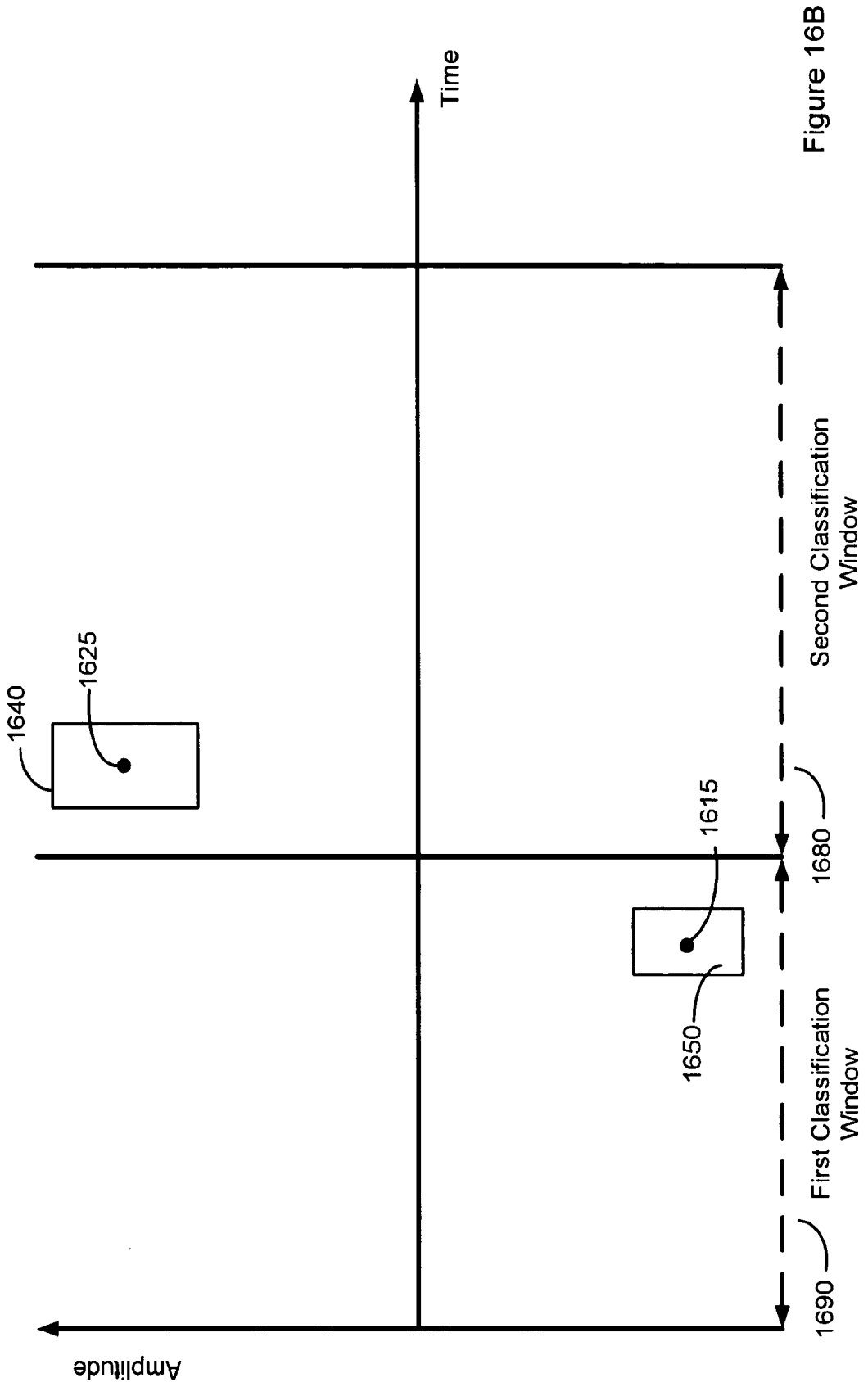

Time
Amplitude
1640
1625
1615
1650
1680
1690
Second Classification Window
First Classification Window

Figure 16B

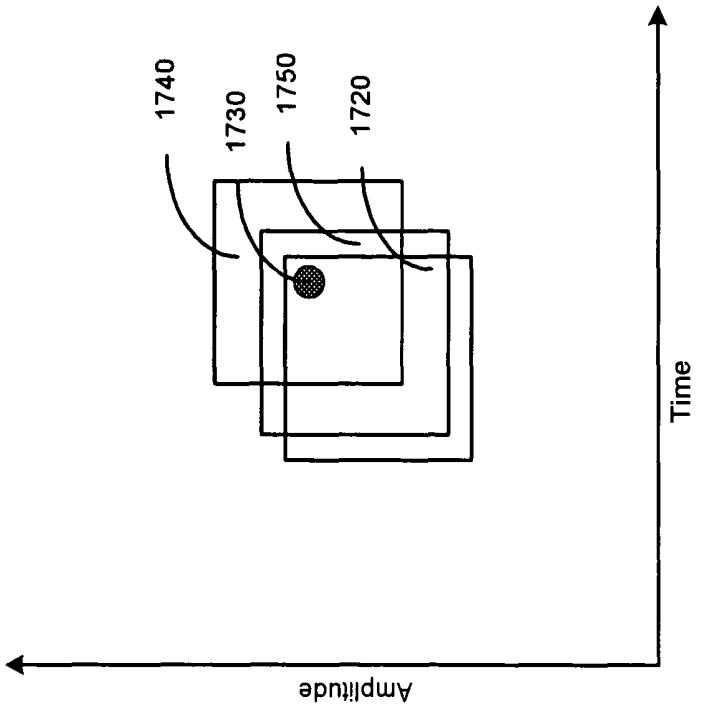


Figure 17B

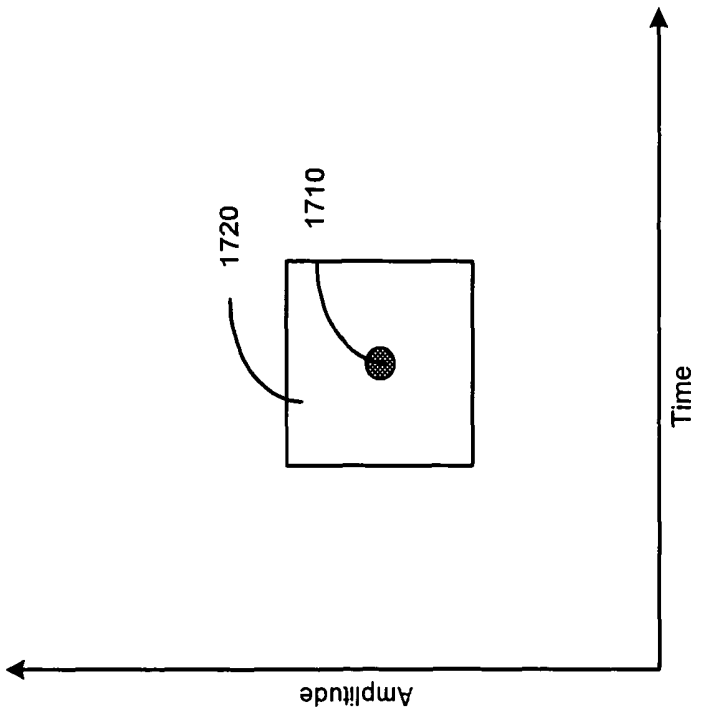


Figure 17A

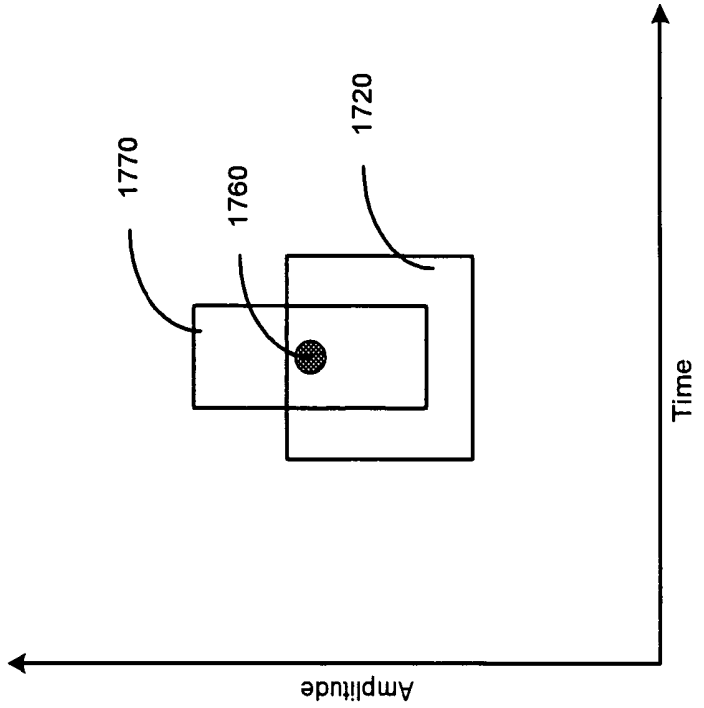


Figure 17D

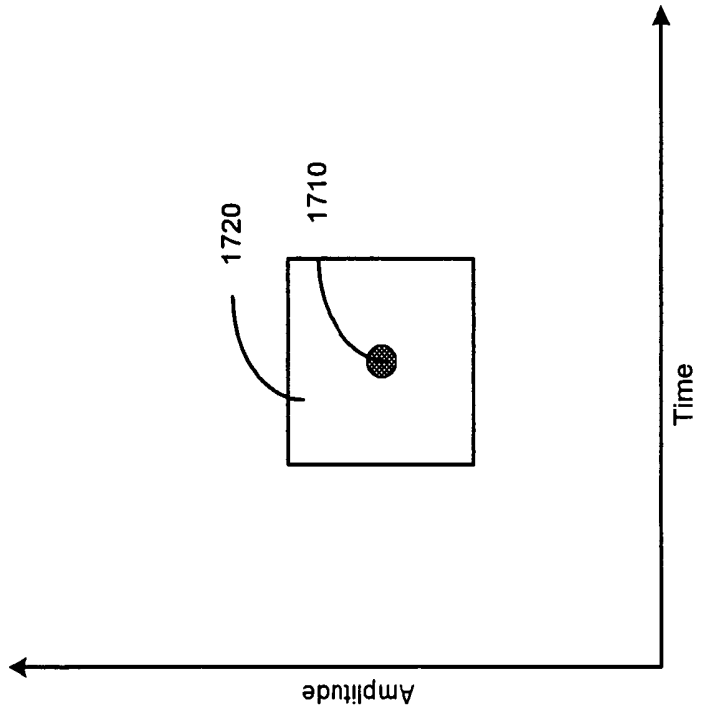


Figure 17C

CARDIAC RESPONSE CLASSIFICATION USING RETRIGGERABLE CLASSIFICATION WINDOWS

RELATED PATENT DOCUMENTS

This patent application is a continuation of U.S. patent application Ser. No. 10/734,599 filed on Dec. 12, 2003, to which priority is claimed under 35 U.S.C. §120, and which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

The present invention relates generally to implantable medical devices and, more particularly, to classifying a cardiac response following delivery of a pace pulse.

BACKGROUND OF THE INVENTION

When functioning normally, the heart produces rhythmic contractions and is capable of pumping blood throughout the body. However, due to disease or injury, the heart rhythm may become irregular resulting in diminished pumping efficiency. Arrhythmia is a general term used to describe heart rhythm irregularities arising from a variety of physical conditions and disease processes. Cardiac rhythm management systems, such as implantable pacemakers and cardiac defibrillators, have been used as an effective treatment for patients with serious arrhythmias. These systems typically comprise circuitry to sense electrical signals from the heart and a pulse generator for delivering electrical stimulation pulses to the heart. Leads extending into the patient's heart are connected to electrodes that contact the myocardium for sensing the heart's electrical signals and for delivering stimulation pulses to the heart in accordance with various therapies for treating the arrhythmias.

Cardiac rhythm management systems operate to stimulate the heart tissue adjacent to the electrodes to produce a contraction of the tissue. Pacemakers are cardiac rhythm management systems that deliver a series of low energy pace pulses timed to assist the heart in producing a contractile rhythm that maintains cardiac pumping efficiency. Pace pulses may be intermittent or continuous, depending on the needs of the patient. There exist a number of categories of pacemaker devices, with various modes for sensing and pacing one or more heart chambers.

When a pace pulse produces a contraction in the heart tissue, the electrical cardiac signal preceding the contraction is denoted the captured response (CR). The captured response may include an electrical signal, denoted the evoked response signal, associated with the heart contraction, along with a superimposed signal associated with residual post pace polarization at the electrode-tissue interface. The magnitude of the residual post pace polarization signal, or pacing artifact, may be affected by a variety of factors including lead polarization, after-potential from the pace pulse, lead impedance, patient impedance, pace pulse width, and pace pulse amplitude, for example.

A pace pulse must exceed a minimum energy value, or capture threshold, to produce a contraction. It is desirable for a pace pulse to have sufficient energy to stimulate capture of the heart without expending energy significantly in excess of the capture threshold. Thus, accurate determination of the capture threshold is required for efficient pace energy management. If the pace pulse energy is too low, the pace pulses may not reliably produce a contractile response in the heart and may result in ineffective pacing. If the pace pulse energy is too high, the patient may experience discomfort and the battery life of the device will be shorter.

Capture detection allows the cardiac rhythm management system to adjust the energy level of pace pulses to correspond to the optimum energy expenditure that reliably produces a contraction. Further, capture detection allows the cardiac rhythm management system to initiate a back-up pulse at a higher energy level whenever a pace pulse does not produce a contraction.

At times, a pacing pulse may merge with an intrinsic beat, producing a fusion beat. A fusion beat is a cardiac contraction that occurs when two cardiac depolarizations of a particular chamber, but from separate initiation sites, merge. When the heart is being paced, a fusion beat occurs when two cardiac depolarizations of a particular chamber, but from separate sites, merge. Fusion beats, as seen on electrocardiographic recordings, exhibit various morphologies. The merging depolarizations of a fusion beat do not contribute evenly to the total depolarization.

Pseudofusion occurs when a pacing stimulus is delivered on a spontaneous P wave during atrial pacing or on a spontaneous QRS complex during ventricular pacing. In pseudofusion, the pacing stimulus may be ineffective because the tissue around the electrode has already spontaneously depolarized and is in its refractory period.

During normal pacing, fusion/pseudofusion beats may be of little consequence except for wasted energy due to the generation of unnecessary pace pulses. However, discrimination between a fusion/pseudofusion beat and a captured response may be required during an automatic capture or threshold determination procedures. Fusion/pseudofusion beats may cause false detection of capture and may lead to erroneous capture threshold values and/or erroneous automatic capture verification information.

SUMMARY OF THE INVENTION

The present invention involves various methods and devices for classifying cardiac responses to pacing stimulation. In accordance with one embodiment of the invention, a method of classifying a cardiac response to a pacing stimulation involves delivering a pacing stimulation to a heart and establishing a first classification window subsequent to delivery of the pacing stimulation. A cardiac signal is sensed in the first classification window. A second classification window is established if a trigger characteristic of the cardiac signal is detected in the first classification window. The cardiac signal is sensed in the second classification window if the second classification window is triggered. The cardiac response to the pacing stimulation is classified based on one or more characteristics of the cardiac signal.

In accordance with another embodiment of the invention, a medical device includes a pulse delivery system and a sensing system. The pulse delivery system is configured to deliver a pacing stimulation to a heart. The sensing system is configured to a sense cardiac signal following delivery of the pacing stimulation. The medical device further includes a control system, coupled to the sensing system. The control system is configured to establish a first classification window subsequent to delivery of the pacing stimulation. The control system establishes a second classification window if a trigger characteristic of the cardiac signal is detected in the first classification window. The cardiac response to the pacing stimulation is classified by the control system based on one or more characteristics of the sensed cardiac signal.

The above summary of the present invention is not intended to describe each embodiment or every implementation of the present invention. Advantages and attainments, together with a more complete understanding of the invention, will become apparent and appreciated by referring to the following detailed description and claims taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a partial view of one embodiment of an implantable medical device in accordance with embodiments of the invention;

FIG. **2**A is a block diagram of an implantable medical device that may be used to classify a cardiac response to pacing in accordance with embodiments of the invention;

FIG. **2**B is a schematic diagram of a circuit that may be used to generate pacing stimulations in accordance with embodiments of the invention;

FIG. **2**C is a schematic diagram of a circuit that may be used to sense a cardiac signal following the delivery of a pacing stimulation and to classify the cardiac response to the pacing stimulation according to embodiments of the invention;

FIG. **3** is a graph of a cardiac signal that indicates consistent capture;

FIG. **4**A depicts superimposed graphs of captured responses, non-captured responses, and fusion/pseudofusion beats in accordance with embodiments of the invention;

FIG. **4**B depicts superimposed graphs comparing an early intrinsic beat and a captured response in accordance with embodiments of the invention;

FIG. **4**C illustrates superimposed graphs of a captured response and a non-captured response in accordance with embodiments of the invention;

FIG. **5** is a graph illustrating a cardiac signal sensed on a right ventricular (RV) shock channel vector following a pacing pulse delivered on a rate channel in accordance with embodiments of the invention;

FIG. **6** is a flowchart illustrating a method of classifying a cardiac response to pacing using retriggerable classification windows in accordance with embodiments of the invention;

FIG. **7** is a flowchart illustrating a method of triggering multiple cardiac response classification windows in accordance with embodiments of the invention;

FIG. **8** is a diagram illustrating a retriggerable cardiac response classification window in accordance with embodiments of the invention;

FIG. **9** illustrates cardiac signals indicative of a variety of cardiac pacing responses and their relation to the cardiac response classification windows in accordance with embodiments of the invention;

FIG. **10** is a flowchart illustrating a method of classifying a cardiac response to pacing using capture detection regions defined in accordance with embodiments of the invention;

FIG. **11** is a diagram illustrating cardiac response classification windows and capture detection regions in accordance with embodiments of the invention;

FIG. **12** is a diagram illustrating positions of cardiac signal peaks in relation to the first and second capture detection regions for various cardiac responses in accordance with embodiments of the invention;

FIGS. **13**A and **13**B illustrate a flowchart of a method of cardiac response classification including intrinsic response classification in accordance with embodiments of the invention;

FIG. **14** is a diagram illustrating cardiac response classification windows, capture detection windows, and an intrinsic detection window used to classify a cardiac response to pacing in accordance with embodiments of the invention;

FIG. **15** illustrates a flowchart of a method of initializing detection regions in accordance with embodiments of the invention;

FIG. **16**A shows peak locations of five cardiac signal waveforms representing a captured response in accordance with embodiments of the invention;

FIG. **16**B illustrates an averaged coordinate location of the cardiac signal peaks detected in the first cardiac response classification window in accordance with embodiments of the invention; and

FIGS. **17**A-**17**D are diagrams illustrating adjustment of a detection region in accordance with embodiments of the invention.

While the invention is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail below. It is to be understood, however, that the intention is not to limit the invention to the particular embodiments described. On the contrary, the invention is intended to cover all modifications, equivalents, and alternatives falling within the scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION OF VARIOUS EMBODIMENTS

In the following description of the illustrated embodiments, references are made to the accompanying drawings forming a part hereof, and in which are shown by way of illustration, various embodiments by which the invention may be practiced. It is to be understood that other embodiments may be utilized, and structural and functional changes may be made without departing from the scope of the present invention.

Embodiments of the invention are directed methods and systems for classifying the cardiac response following the delivery of pacing stimulation to the heart. In accordance with various aspects of the invention, cardiac response classification may be implemented by defining one or more retriggerable classification windows relative to and following a pacing stimulation.

In one approach, a first cardiac response classification window is established subsequent to a pacing pulse. A cardiac signal following the pacing stimulation is sensed in the first classification window. A second cardiac response classification is triggered if a trigger characteristic is detected in the first classification window. The cardiac response to the pacing stimulation is determined based on the one or more detected characteristics and the particular classification windows in which the one or more characteristics are detected. The cardiac response may be determined to be one of a captured response, a non-captured response, a non-captured response added to an intrinsic beat, and a fusion/pseudofusion beat, for example.

In another approach, multiple cardiac response classification windows may be triggered by characteristics of the cardiac signal. In one implementation, multiple classification windows may be triggered to allow the system to acquire additional information before classifying the cardiac response. In another implementation, additional classification windows may be triggered if non-capture is detected and a back up pace is delivered. In this situation, additional

classification windows may be triggered to classify the cardiac response to the back up pace.

Various embodiments of the invention involve using the same electrode combination for pacing and sensing. Other embodiments involve using an electrode combination for pacing that is different from the electrode combination used for sensing the cardiac response to pacing. Employing different electrode combinations for pacing and sensing reduces the effect of the pacing artifact in the captured response signal.

By way of example, the processes of the present invention may be used to enhance capture threshold testing to determine the optimal energy for pacing. Determination of the optimal pacing energy may be implemented, for example, by an automatic capture threshold testing procedure executed by an implantable cardiac rhythm management system. Additionally, automatic capture verification may be used to monitor pacing on a beat-by-beat basis. Automatic capture verification may be used to control back up pacing when a pace pulse delivered to the heart fails to evoke a captured response (CR). These and other applications may be enhanced by employment of the systems and methods of the present invention.

Those skilled in the art will appreciate that reference to a capture threshold procedure indicates a method of determining the capture threshold in one of the left atrium, the right atrium, the left ventricle, and the right ventricle. In such a procedure, the pacemaker, automatically or upon command, initiates a search for the capture threshold of the selected heart chamber or chambers. The capture threshold is defined as the lowest pacing energy that consistently produces a contraction of the heart chamber.

In one example of an automatic capture threshold procedure, the pacemaker delivers a sequence of pacing pulses to the heart and detects the cardiac responses to the pace pulses. The energy of the pacing pulses may be decreased in discrete steps until a predetermined number of loss-of-capture events occur. After the predetermined number of loss-of-capture events occur, the pacemaker may increase the stimulation energy in discrete steps until a predetermined number of capture events occur to confirm the capture threshold. A capture threshold test may be performed using cardiac response classification methods of the present invention.

Other procedures for implementing capture threshold testing may be utilized. In one example, the pacing energy may be increased in discrete steps until capture is detected. In another example, the pacing energy may be adjusted according to a binomial search pattern.

Automatic capture threshold determination is distinguishable from automatic capture detection, a procedure that may occur on a beat-by-beat basis during pacing. Automatic capture detection verifies that a delivered pace pulse results in a captured response. When a captured response is not detected following a pace pulse, the pacemaker may deliver a back up safety pace to ensure consistent pacing. The back up pace may be delivered, for example, about 90-110 ms after the initial pace pulse. If a predetermined number of pace pulses delivered during normal pacing do not produce a captured response, the pacemaker may initiate a capture threshold test to determine the capture threshold. Automatic capture detection and back up pacing may be implemented using the cardiac response classification processes of the present invention.

The embodiments of the present system illustrated herein are generally described as being implemented in an implantable cardiac defibrillator (ICD) that may operate in numerous pacing modes known in the art. Various types of single and multiple chamber implantable cardiac defibrillators are known in the art and may be used in connection with the cardiac response classification methods of the present invention. The methods of the present invention may also be implemented a variety of implantable or patient-external cardiac rhythm management devices, including single and multi chamber pacemakers, defibrillators, cardioverters, biventricular pacemakers, cardiac resynchronizers, and cardiac monitoring systems, for example.

Although the present system is described in conjunction with an implantable cardiac defibrillator having a microprocessor-based architecture, it will be understood that the implantable cardiac defibrillator (or other device) may be implemented in any logic-based integrated circuit architecture, if desired.

Referring now to FIG. **1** of the drawings, there is shown a cardiac rhythm management system that may be used to implement cardiac response classification methods of the present invention. The cardiac rhythm management system in FIG. **1** includes an ICD **100** electrically and physically coupled to a lead system **102**. The housing and/or header of the ICD **100** may incorporate one or more electrodes **208**, **209** used to provide electrical stimulation energy to the heart and to sense cardiac electrical activity. The ICD **100** may utilize all or a portion of the ICD housing as a can electrode **209**. The ICD **100** may include an indifferent electrode positioned, for example, on the header or the housing of the ICD **100**. If the ICD **100** includes both a can electrode **209** and an indifferent electrode **208**, the electrodes **208**, **209** typically are electrically isolated from each other.

The lead system **102** is used to detect electric cardiac signals produced by the heart **101** and to provide electrical energy to the heart **101** under certain predetermined conditions to treat cardiac arrhythmias. The lead system **102** may include one or more electrodes used for pacing, sensing, and/or defibrillation. In the embodiment shown in FIG. **1**, the lead system **102** includes an intracardiac right ventricular (RV) lead system **104**, an intracardiac right atrial (RA) lead system **105**, an intracardiac left ventricular (LV) lead system **106**, and an extracardiac left atrial (LA) lead system **108**. The lead system **102** of FIG. **1** illustrates one embodiment that may be used in connection with the cardiac response classification methodologies described herein. Other leads and/or electrodes may additionally or alternatively be used.

The lead system **102** may include intracardiac leads **104**, **105**, **106** implanted in a human body with portions of the intracardiac leads **104**, **105**, **106** inserted into a heart **101**. The intracardiac leads **104**, **105**, **106** include various electrodes positionable within the heart for sensing electrical activity of the heart and for delivering electrical stimulation energy to the heart, for example, pacing pulses and/or defibrillation shocks to treat various arrhythmias of the heart.

As illustrated in FIG. **1**, the lead system **102** may include one or more extracardiac leads **108** having electrodes, e.g., epicardial electrodes, positioned at locations outside the heart for sensing and pacing one or more heart chambers.

The right ventricular lead system **104** illustrated in FIG. **1** includes an SVC-coil **116**, an RV-coil **114**, an RV-ring electrode **111**, and an RV-tip electrode **112**. The right ventricular lead system **104** extends through the right atrium **120** and into the right ventricle **119**. In particular, the RV-tip electrode **112**, RV-ring electrode **111**, and RV-coil electrode **114** are positioned at appropriate locations within the right ventricle **119** for sensing and delivering electrical stimulation pulses to the heart. The SVC-coil **116** is positioned at an

appropriate location within the right atrium chamber **120** of the heart **101** or a major vein leading to the right atrial chamber **120** of the heart **101**.

In one configuration, the RV-tip electrode **112** referenced to the can electrode **209** may be used to implement unipolar pacing and/or sensing in the right ventricle **119**. Bipolar pacing and/or sensing in the right ventricle may be implemented using the RV-tip **112** and RV-ring **111** electrodes. In yet another configuration, the RV-ring **111** electrode may optionally be omitted, and bipolar pacing and/or sensing may be accomplished using the RV-tip electrode **112** and the RV-coil **114**, for example. The right ventricular lead system **104** may be configured as an integrated bipolar pace/shock lead. The RV-coil **114** and the SVC-coil **116** are defibrillation electrodes.

The left ventricular lead **106** includes an LV distal electrode **113** and an LV proximal electrode **117** located at appropriate locations in or about the left ventricle **124** for pacing and/or sensing the left ventricle **124**. The left ventricular lead **106** may be guided into the right atrium **120** of the heart via the superior vena cava. From the right atrium **120**, the left ventricular lead **106** may be deployed into the coronary sinus ostium, the opening of the coronary sinus **150**. The lead **106** may be guided through the coronary sinus **150** to a coronary vein of the left ventricle **124**. This vein is used as an access pathway for leads to reach the surfaces of the left ventricle **124** which are not directly accessible from the right side of the heart. Lead placement for the left ventricular lead **106** may be achieved via subclavian vein access and a preformed guiding catheter for insertion of the LV electrodes **113**, **117** adjacent to the left ventricle.

Unipolar pacing and/or sensing in the left ventricle may be implemented, for example, using the LV distal electrode referenced to the can electrode **209**. The LV distal electrode **113** and the LV proximal electrode **117** may be used together as bipolar sense and/or pace electrodes for the left ventricle. The left ventricular lead **106** and the right ventricular lead **104**, in conjunction with the ICD **100**, may be used to provide cardiac resynchronization therapy such that the ventricles of the heart are paced substantially simultaneously, or in phased sequence, to provide enhanced cardiac pumping efficiency for patients suffering from chronic heart failure.

The right atrial lead **105** includes a RA-tip electrode **156** and an RA-ring electrode **154** positioned at appropriate locations in the right atrium **120** for sensing and pacing the right atrium **120**. In one configuration, the RA-tip **156** referenced to the can electrode **209**, for example, may be used to provide unipolar pacing and/or sensing in the right atrium **120**. In another configuration, the RA-tip electrode **156** and the RA-ring electrode **154** may be used to effect bipolar pacing and/or sensing.

FIG. **1** illustrates one embodiment of a left atrial lead system **108**. In this example, the left atrial lead **108** is implemented as an extracardiac lead with LA distal **118** and LA proximal **115** electrodes positioned at appropriate locations outside the heart **101** for sensing and pacing the left atrium **122**. Unipolar pacing and/or sensing of the left atrium may be accomplished, for example, using the LA distal electrode **118** to the can **209** pacing vector. The LA proximal **115** and LA distal **118** electrodes may be used together to implement bipolar pacing and/or sensing of the left atrium **122**.

Referring now to FIG. **2**A, there is shown an embodiment of a cardiac defibrillator **200** suitable for implementing a cardiac response classification methodology of the present invention. FIG. **2**A shows a cardiac defibrillator divided into functional blocks. It is understood by those skilled in the art that there exist many possible configurations in which these functional blocks can be arranged. The example depicted in FIG. **2**A is one possible functional arrangement. Other arrangements are also possible. For example, more, fewer or different functional blocks may be used to describe a cardiac defibrillator suitable for implementing the cardiac response classification methodology of the present invention. In addition, although the cardiac defibrillator **200** depicted in FIG. **2** contemplates the use of a programmable microprocessor-based logic circuit, other circuit implementations may be utilized.

The cardiac defibrillator **200** depicted in FIG. **2** includes circuitry for receiving cardiac signals from a heart and delivering electrical stimulation energy to the heart in the form of pacing pulses or defibrillation shocks. In one embodiment, the circuitry of the cardiac defibrillator **200** is encased and hermetically sealed in a housing **201** suitable for implanting in a human body. Power to the cardiac defibrillator **200** is supplied by an electrochemical battery **280**. A connector block (not shown) is attached to the housing **201** of the cardiac defibrillator **200** to allow for the physical and electrical attachment of the lead system conductors to the circuitry of the cardiac defibrillator **200**.

The cardiac defibrillator **200** may be a programmable microprocessor-based system, including a control system **220** and a memory **270**. The memory **270** may store parameters for various pacing, defibrillation, and sensing modes, along with other parameters. Further, the memory **270** may store data indicative of cardiac signals received by other components of the cardiac defibrillator **200**. The memory **270** may be used, for example, for storing historical EGM and therapy data. The historical data storage may include, for example, data obtained from long term patient monitoring used for trending or other diagnostic purposes. Historical data, as well as other information, may be transmitted to an external programmer unit **290** as needed or desired.

The control system **220** and memory **270** may cooperate with other components of the cardiac defibrillator **200** to control the operations of the cardiac defibrillator **200**. The control system depicted in FIG. **2** incorporates a cardiac response classification processor **225** for classifying cardiac responses to pacing stimulation in accordance with various embodiments of the present invention. The control system **220** may include additional functional components including a pacemaker control circuit **222**, an arrhythmia detector **221**, and a template processor **224** for cardiac signal morphology analysis, along with other components for controlling the operations of the cardiac defibrillator **200**.

Telemetry circuitry **260** may be implemented to provide communications between the cardiac defibrillator **200** and an external programmer unit **290**. In one embodiment, the telemetry circuitry **260** and the programmer unit **290** communicate using a wire loop antenna and a radio frequency telemetric link, as is known in the art, to receive and transmit signals and data between the programmer unit **290** and the telemetry circuitry **260**. In this manner, programming commands and other information may be transferred to the control system **220** of the cardiac defibrillator **200** from the programmer unit **290** during and after implant. In addition, stored cardiac data pertaining to capture threshold, capture detection and/or cardiac response classification, for example, along with other data, may be transferred to the programmer unit **290** from the cardiac defibrillator **200**.

In the embodiment of the cardiac defibrillator **200** illustrated in FIG. **2**, electrodes RA-tip **156**, RA-ring **154**, RV-tip **112**, RV-ring **111**, RV-coil **114**, SVC-coil **116**, LV distal

electrode **113**, LV proximal electrode **117**, LA distal electrode **118**, LA proximal electrode **115**, indifferent electrode **208**, and can electrode **209** are coupled through a switch matrix **210** to sensing circuits **231-237**.

A right atrial sensing circuit **231** serves to detect and amplify electrical signals from the right atrium of the heart. Bipolar sensing in the right atrium may be implemented, for example, by sensing voltages developed between the RA-tip **156** and the RA-ring **154**. Unipolar sensing may be implemented, for example, by sensing voltages developed between the RA-tip **156** and the can electrode **209**. Outputs from the right atrial sensing circuit are coupled to the control system **220**.

A right ventricular sensing circuit **232** serves to detect and amplify electrical signals from the right ventricle of the heart. The right ventricular sensing circuit **232** may include, for example, a right ventricular rate channel **233** and a right ventricular shock channel **234**. Right ventricular cardiac signals sensed through use of the RV-tip **112** electrode are right ventricular near-field signals and are denoted RV rate channel signals. A bipolar RV rate channel signal may be sensed as a voltage developed between the RV-tip **112** and the RV-ring **111**. Alternatively, bipolar sensing in the right ventricle may be implemented using the RV-tip electrode **112** and the RV-coil **114**. Unipolar rate channel sensing in the right ventricle may be implemented, for example, by sensing voltages developed between the RV-tip **112** and the can electrode **209**.

Right ventricular cardiac signals sensed through use of the RV-coil electrode **114** are far-field signals, also referred to as RV morphology or RV shock channel signals. More particularly, a right ventricular shock channel signal may be detected as a voltage developed between the RV-coil **114** and the SVC-coil **116**. A right ventricular shock channel signal may also be detected as a voltage developed between the RV-coil **114** and the can electrode **209**. In another configuration the can electrode **209** and the SVC-coil electrode **116** may be electrically shorted and a RV shock channel signal may be detected as the voltage developed between the RV-coil **114** and the can electrode **209**/SVC-coil **116** combination.

Outputs from the right ventricular sensing circuit **232** are coupled to the control system **220**. In one embodiment of the invention, rate channel signals and shock channel signals may be used to develop morphology templates for analyzing cardiac signals. In this embodiment, rate channel signals and shock channel signals may be transferred from the right ventricular sensing circuit **232** to the control system **220** and to a template processor **224** where the morphological characteristics of a cardiac signal are analyzed. The template processor **224** works in combination with the control system **220** and the memory **270** to generate and maintain various types of templates, including, for example, templates used for arrhythmia discrimination as well as cardiac response classification as described in more detail below.

Left atrial cardiac signals may be sensed through the use of one or more left atrial electrodes **115**, **118**, which may be configured as epicardial electrodes. A left atrial sensing circuit **235** serves to detect and amplify electrical signals from the left atrium of the heart. Bipolar sensing and/or pacing in the left atrium may be implemented, for example, using the LA distal electrode **118** and the LA proximal electrode **115**. Unipolar sensing and/or pacing of the left atrium may be accomplished, for example, using the LA distal electrode **118** to can vector **209** or the LA proximal electrode **115** to can vector **209**.

A left ventricular sensing circuit **236** serves to detect and amplify electrical signals from the left ventricle of the heart. Bipolar sensing in the left ventricle may be implemented, for example, by sensing voltages developed between the LV distal electrode **113** and the LV proximal electrode **117**. Unipolar sensing may be implemented, for example, by sensing voltages developed between the LV distal electrode **113** or the LV proximal electrode **117** to the can electrode **209**.

Optionally, an LV coil electrode (not shown) may be inserted into the patient's cardiac vasculature, e.g., the coronary sinus, adjacent the left heart. Signals detected using combinations of the LV electrodes, **113**, **117**, LV coil electrode (not shown), and/or can electrodes **209** may be sensed and amplified by the left ventricular sensing circuitry **236**. The output of the left ventricular sensing circuit **236** is coupled to the control system **220**.

The outputs of the switching matrix **210** may be operated to couple selected combinations of electrodes **111**, **112**, **113**, **114**, **115**, **116**, **117**, **118**, **156**, **154** to an evoked response sensing circuit **237**. The evoked response sensing circuit **237** serves to sense and amplify voltages developed using various combinations of electrodes for cardiac response classification in accordance with embodiments of the invention.

In the embodiments described below, various combinations of pacing and sensing electrodes may be utilized in connection with pacing and sensing the cardiac signal following the pace pulse to classify the cardiac response to the pacing pulse. For example, in some embodiments, a first electrode combination is used for pacing a heart chamber and a second electrode combination is used to sense the cardiac signal following pacing. In other embodiments, the same electrode combination is used for pacing and sensing.

Sensing the cardiac signal following a pacing pulse using the same electrode combination for both pacing and sensing may yield a sensed cardiac signal including a pacing artifact component associated with residual post pace polarization at the electrode-tissue interface. The pacing artifact component may be superimposed on a smaller signal indicative of the cardiac response to the pacing pulse, i.e., the evoked response. The pacing output circuitry may include a coupling capacitor to block DC components from the heart and to condition the pacing stimulus pulse. A relatively large coupling capacitor may cause a larger pacing artifact that decays exponentially over a relatively large period of time.

The presence of a large pacing artifact signal may complicate the classification of the cardiac response to pacing. Various embodiments of the invention are directed to methods involving detection of a cardiac signal following pacing and canceling the pacing artifact from the detected signal. Classification of the cardiac response to pacing may be implemented using the pacing artifact cancelled signal. Cancellation of the pacing artifact in cardiac response classification is particularly important when the same or similar electrode combinations are used both for delivering pacing pulses and for sensing the cardiac signals following the delivery of the pacing pulses. Cancellation of the pacing artifact may also be used when a first electrode combination is used for pacing the heart chamber and a different electrode combination is used to sense the subsequent cardiac response. Methods and systems for pacing artifact cancellation are described in commonly owned U.S. patent application Ser. No. 10/335,534, filed Dec. 31, 2002, which is incorporated by reference herein in its entirety.

In various embodiments described herein a first electrode combination may be used for pacing the heart chamber and a second electrode combination used for sensing the cardiac

signals following the pace for cardiac response classification. If different electrode combinations are used for pacing and sensing, a temporal separation between the cardiac response signal, e.g., the evoked response, and the pacing artifact may facilitate classification of the cardiac response to pacing. The temporal separation occurs due to the propagation delay of the depolarization wavefront initiated at the pacing electrode and traveling to a sensing electrode that is physically spaced apart from the pacing electrode. The temporal separation of the cardiac response signal and the pacing artifact may be sufficient to obviate cancellation of the pacing artifact. Use of different electrodes for pacing and sensing in connection with capture verification is described in commonly owned U.S. Pat. No. 6,128,535 which is incorporated herein by reference.

The pacemaker control circuit **222**, in combination with pacing circuitry for the left atrium, right atrium, left ventricle, and right ventricle **241**, **242**, **243**, **244**, may be implemented to selectively generate and deliver pacing pulses to the heart using various electrode combinations. The pacing electrode combinations may be used to effect bipolar or unipolar pacing of the heart chambers as described above

As described above, bipolar or unipolar pacing pulses may be delivered to a heart chamber using one of the pacing vectors as described above. The electrical signal following the delivery of the pacing pulses may be sensed through various sensing vectors coupled through the switch matrix **210** to the evoked response sensing circuit **237** and used to classify the cardiac response to pacing.

In one example, the cardiac signal following the pacing pulse may be sensed using the same vector as was used for delivery of the pacing pulse. In this scenario, the pacing artifact may be canceled from the sensed cardiac signal using the pacing artifact cancellation techniques described below. Following cancellation of the pacing artifact, retriggerable classification windows may be defined following the pacing pulse and used to classify the cardiac response to pacing. The cardiac response may be classified as one of a captured response, a non-captured response, a non-captured response and an intrinsic beat, and a fusion/pseudofusion beat, for example.

In another example, the vector used to sense the cardiac signal following the pacing pulse may be different from the vector that was used to deliver the pacing pulse. The sensing vector may be selected to minimize the pacing artifact. Cancellation of the pacing artifact may not be necessary if the pacing artifact is sufficiently minimized using this technique.

In various embodiments, the pacing vector may be a near-field vector and the sensing vector may be a far-field vector. In an example of right ventricular pacing and cardiac response sensing, the pacing vector may be the rate channel vector and the sensing vector may be the shock channel vector. Cardiac response classification may be accomplished, for example, using retriggerable classification windows defined following delivery of the pacing pulse as described in greater detail below.

Possible sensing vectors for effecting cardiac response classification may include, for example, RV-tip **112** and RV-coil **114**, RV-coil **114** and LV distal electrode **113**, RV coil **114** and LV proximal electrode **117**, RV-coil **114** and can **209**, RV-coil **114** and SVC coil **116**, RV-coil **114** and SVC coil **116** tied and the can **209**, RV-coil **114** and A-ring **154**, RV-coil **114** and A-tip **156**, LV distal electrode **113** and LV proximal electrode **117**, LV distal electrode **113** and can **209**, LV distal electrode **113** and SVC coil **116**, LV distal electrode **113** and A-ring **154**, LV distal electrode **113** and A-tip **156**, LV proximal electrode **117** and can **209**, LV proximal electrode **117** and SVC coil **116**, LV proximal electrode **117** and A-ring **154**, LV proximal electrode **117** and RA-tip **156**, SVC coil **116** and can **209**, RA-ring **154** and can **209**, RA-tip **156** and can **209**, SVC coil **116** and A-ring **154**, SVC coil **116** and A-tip **156**, RA-ring **154** and RA-tip **156**, RA-ring **154** and can **209**, RA-tip **156** and RV-coil **114**, RA-ring **154** and RV-coil **114**, RA-tip **156** and RV-tip **112**, RA-ring **154** and RV-tip **112**, RV-tip **112** and can **209**, RV-ring **111** and can **209**, LV distal electrode **113** and RV-coil **114**, LV proximal electrode **117** and RV-coil **114**, LV distal electrode **113** and RV-ring **111**, and LV distal electrode **113** and RV-ring **111**. This list is not exhaustive and other sensing vector combinations may be developed to implement cardiac response classification in accordance with embodiments of the invention. For example, other combinations may include a coronary sinus electrode, an indifferent electrode, a leadless ECG electrode, cardiac epicardial electrodes, subcutaneous electrodes, and/or other electrodes.

Approaches for using leadless ECG electrodes for capture detection are described in U.S. Pat. No. 5,222,493, which is incorporated by reference in its entirety.

Subcutaneous electrodes may provide additional sensing vectors useable for cardiac response classification. In one implementation, cardiac rhythm management system may involve a hybrid system including an intracardiac device configured to pace the heart and an extracardiac device, e.g., a subcutaneous defibrillator, configured to perform functions other than pacing. The extracardiac device may be employed to detect and classify cardiac response to pacing based on signals sensed using subcutaneous electrode arrays. The extracardiac and intracardiac devices may operate cooperatively with communication between the devices occurring over a wireless link, for example. Examples of subcutaneous electrode systems and devices are described in commonly owned U.S. patent application Ser. Nos. 10/462,001, filed Jun. 13, 2003 and 10/465,520, filed Jun. 19, 2003, which are incorporated herein by reference in their respective entireties.

For right ventricular pacing, bipolar pacing may be delivered using the RV-tip electrode **112** and the RV-ring electrode **111**. Unipolar pacing may be delivered using the RV-tip **112** to can **209** vector. The preferred sensing electrode combinations for cardiac response classification following RV pacing include RV-coil **114** to SVC-coil **116** tied to the can electrode **209**, RV-coil **114** to can electrode **209**, and, if the system includes an left ventricular lead, LV distal electrode **113** to LV proximal electrode **117**.

In an example of left ventricular pacing, bipolar pacing pulses may be delivered to the left ventricle between the LV distal electrode **113** and the LV proximal electrode **117**. In another example, unipolar pacing pulses may be delivered to the left ventricle, for example, between the LV distal electrode **113** and the can **209**. The cardiac signal following the delivery of the pacing pulses may preferably be sensed using the LV proximal electrode **117** and the can **209**.

In an example of right atrial pacing, bipolar pacing pulses may be delivered to the right atrium between the RA-tip electrode **156** and the RA-ring electrode **154**. In another example, unipolar pacing pulses may be delivered to the right atrium, for example, between the RA-tip electrode **156** and the can electrode **209**. For unipolar right atrial pacing, the preferred electrode combination for sensing cardiac signals following pacing for cardiac response classification comprises the RA-ring **154** to indifferent electrode.

In an example of left atrial pacing, bipolar pacing pulses may be delivered to the left atrium between the LA distal electrode **118** and the LA proximal electrode **115**. In another example, unipolar pacing pulses may be delivered to the left atrium, for example, between the LA distal electrode **118** and the can electrode **209**. The cardiac signal following the delivery of the pacing pulses and used for cardiac response classification may preferably be sensed using the RA-tip **156** to RA-ring **154** vector.

In one embodiment of the invention, a switching matrix **210** is coupled to the RA-tip **156**, RA-ring **154**, RV-tip **112**, RV-coil **114**, LV distal electrode **113**, LV proximal electrode **117**, SVC coil **116**, LA distal electrode **118**, LA proximal electrode **115**, indifferent, and can **209** electrodes. The switching matrix **210** may be arranged to provide connections to various configurations of pacing and defibrillation electrodes. The outputs of the switching matrix **210** are coupled to an evoked response (ER) sensing circuit **237** that serves to sense and amplify cardiac signals detected between the selected combinations of electrodes. The detected signals are coupled through the ER amplifier **237** to a cardiac response classification processor **225**. The cardiac response classification processor **225** includes circuitry configured to classify a cardiac response to a pacing stimulation, including, for example, classifying a captured response, a non-captured response, an intrinsic beat added to a non-captured response, and a fusion/pseudofusion response, in accordance with the invention.

FIGS. **2**B and **2**C illustrate more detailed examples of pacing and sensing circuitry, respectively, that may be used for cardiac pace/sense channels of a pacemaker in accordance with embodiments of the invention. It will be appreciated that the example pacing and sensing circuits illustrated in FIGS. **2**B and **2**C may be arranged to achieve the pacing and sensing vectors described above.

In example embodiments of the invention, the pacing circuit of FIG. **2**B includes a power supply or battery **261**, a first switch **262**, a second switch **264**, a pacing charge storage capacitor **263**, coupling capacitor **265**, and a pacer capacitor charging circuit **269** all of which are cooperatively operable under the direction of a controller of known suitable construction. The power supply or battery **261** is preferably the battery provided to power the pacemaker and may comprise any number of commercially available batteries suitable for pacing applications. The switches **262**, **264** may be implemented using any number of conventionally available switches. The pacing capacitor charging circuit **269** includes circuitry to regulate the voltage across the pacing charge storage capacitor **263**.

The pacing charge storage capacitor **263** may also comprise any number of conventional storage capacitors that can be used to develop a sufficient pacing charge for stimulating the heart. The primary function of the coupling capacitor **265** is to attenuate the polarization voltage or "afterpotential" which results from pacing and additionally block any DC signals from reaching the heart **268** during pacing. The coupling capacitor **265** may have a capacitance, for example, in the range of about 2 microfarads to about 22 microfarads. Energy stored in the pacing charge storage capacitor **263** may be delivered to the heart **268** using various combinations of cardiac electrodes **266**, **267**, as described above.

FIG. **2**C illustrates a block diagram of circuit **295** that may be used to sense cardiac signals following the delivery of a pacing stimulation and classify the cardiac response to the pacing stimulation according to embodiments of the invention. A switch matrix **284** is used to couple the cardiac electrodes **271**, **272** in various combinations discussed above to the sensing portion **270** of the cardiac response classification circuit **295**. The sensing portion **270** includes filtering and blanking circuitry **275**, **277**, sense amplifier **285**, band pass filter **281**, and window generation and signal characteristic detector **282**. The window generation and signal characteristic detector **282** is coupled to a cardiac response classification processor **283**.

A control system, e.g., the control system **220** depicted in FIG. **2**A, is operatively coupled to components of the cardiac response classification circuit **295** and controls the operation of the cardiac response classification circuit **295**, including the filtering and blanking circuits **275**, **277**. Following a blanking period of sufficient duration following delivery of the pacing stimulation, the blanking circuitry **275**, **277** operates to allow detection of a cardiac signal responsive to the pacing stimulation. The cardiac signal is filtered, amplified, and converted from analog to digital form. The digitized signal is communicated to the cardiac response classification processor **283** which operates in cooperation with other components of the control system **220**, FIG. **2**A to classify cardiac responses to pacing according to embodiments of the invention.

When pacing pulses delivered to the heart produce a depolarization wave in cardiac tissue resulting in a cardiac contraction, a captured response may be detected by examining the cardiac signal following the delivery of the pacing pulse. FIG. **3** is a graph illustrating the output of the sensing portion **270** of the cardiac response classification circuit **295** of FIG. **2**C in which the cardiac signal consistently indicates capture following a sequence of pacing pulses. In this example, a pacing pulse is delivered to the heart using the RV-tip and RV-coil electrodes, also referred to herein as a right ventricular rate channel. The cardiac signal following a right ventricular pace is sensed using a RV-coil to SVC-coil+can sensing vector, also referred to herein as the shock channel.

FIG. **4**A depicts superimposed graphs of captured responses **410**, non-captured responses **420**, and fusion/pseudofusion beats **430**. FIG. **4**B depicts superimposed graphs comparing an early intrinsic beat **440** and a captured response **450**. The graphs of FIGS. **4**A and **4**B represent the cardiac signal following the pacing stimulation if the pacing pulse is delivered on the RV rate channel and the cardiac signal following pacing is sensed on the RV shock channel. The captured response exhibits a consistent morphology when detected on this vector, as illustrated in the graphs of FIGS. **4**A and **4**B.

In another example, the same vector may be used to pace the heart chamber and sense the cardiac signal following the pace to classify the cardiac response. Pacing in the right ventricle may be accomplished using the pacing vector RV-tip to RV-ring, for example. FIG. **4**C illustrates superimposed graphs of a captured response **460** and a non-captured response **470** sensed using the same sensing vector, e.g., RA-tip to RA-ring.

As previously discussed, if a first vector, e.g., rate channel vector RV-tip to RV-coil, is used to deliver a pacing pulse and a second vector, e.g., shock channel vector RV-coil to SVC-coil or RV-coil to SVC-coil+can, is used to sense the cardiac signal responsive to the pacing pulse, the pacing artifact is separated from the evoked response due to a propagation delay from RV-tip to RV-coil. FIG. **5** is a graph illustrating a cardiac signal **520** sensed on a right ventricular (RV) shock channel vector following a pacing pulse **510** delivered on a rate channel. The cardiac signal **520** exhibits a propagation delay **530**, for example, a propagation delay of

about 55 ms, between the pacing pulse **510** and the portion of the cardiac signal indicating a captured response **540**.

FIG. **6** is a flowchart illustrating a method of classifying a cardiac response to a pacing stimulation in accordance with embodiments of the invention. In this method the same electrode combination may be used for pacing and sensing, or a first electrode combination may be used for pacing and a second electrode combination may be used for sensing. If the same electrode combination is used for pacing and sensing, then pacing artifact cancellation may facilitate cardiac response classification. In accordance with this method, a pacing stimulation is delivered **610** to a heart and a first cardiac response classification window is established **620** subsequent to delivery of the pacing stimulation.

The pacing stimulation may be delivered to any heart chamber. For example, the pacing stimulation may be delivered to the right ventricle, the left ventricle, the right atrium, and the left atrium.

The cardiac signal is sensed **630** in the first cardiac response classification window. If a trigger feature of the cardiac signal is detected **640** in the first classification window, a second cardiac response classification window is established **650**. The cardiac signal is sensed **660** in the second cardiac response classification window. The cardiac response to the pacing stimulation delivered to the chamber or combination of chambers is classified **670** based on one or more characteristics of the cardiac signal. Although in various examples provided herein, the cardiac response classification windows are represented as contiguous and non-overlapping, the classification windows may be overlapping and/or may involve a delay interval defined between classification windows.

The process of establishing cardiac response classification windows if trigger characteristics are detected in previous cardiac response classification windows may continue until a sufficient amount of information is acquired for classifying the cardiac response. The flowchart of FIG. **7** illustrates a method of triggering multiple cardiac response classification windows in accordance with embodiments of the invention. A pacing stimulation is delivered to the heart **710** and a cardiac response classification window is established **720** subsequent to the delivery of the pacing stimulation. A cardiac signal following the pacing stimulation is sensed in the classification window. If a trigger characteristic is detected **740**, more information is needed **750** to classify the cardiac response. The next classification window is established **720**. Additional classification windows are established to facilitate the acquisition of additional cardiac signal information as indicated in process blocks **720-740**. If enough information is acquired, then the cardiac response is classified **760**.

In the example process illustrated in FIG. **7**, the trigger characteristic may comprise the absence of sufficient information to classify the cardiac response. This situation may arise, for example, if a cardiac signal feature indicative of a particular cardiac response type is not detected, but additional information is desired before eliminating the particular cardiac response type as the cardiac response. Further, this situation may arise if a cardiac signal feature indicative of a particular cardiac response type is detected, but additional information is required to classify the cardiac response. Additional information may also be required to classify the cardiac response if the cardiac signal is detected as noisy.

FIG. **8** is a diagram illustrating a retriggerable cardiac response classification window in accordance with embodiments of the invention. A pacing stimulation **810** is delivered to the heart, for example, to the right ventricle. The cardiac signal is blanked for a period of time **820**, for example, about 0 ms to about 40 ms, following the delivery of the pacing stimulation **810**. After the blanking period **820**, a first cardiac response classification window **830** is established. The length of the first cardiac response classification window may be a programmable length, for example, less than about 325 ms. The cardiac signal following the pacing pulse is sensed during the first cardiac response classification window **830**. If a trigger characteristic is detected within the first cardiac response classification window, then a second cardiac response classification window **840** is triggered. The length of the second cardiac response classification window may be programmable, and may have a length less than about 325 ms. The length of the second classification window may be different from the length of the first classification window. Alternatively, the lengths of the first and the second classification windows may be the same.

A delay period **850** may be established between the end of the first cardiac response classification window **830** and the beginning of the second cardiac response classification window **840**. The length of the delay may be in a range of about 0 ms (no delay) to about 40 ms, for example. The cardiac signal is sensed in the second cardiac response classification window **840** if the second cardiac response classification window **840** is triggered. The cardiac response to the pacing stimulation **810** is classified based on characteristics of the sensed cardiac signal.

FIG. **9** illustrates cardiac signals indicative of a variety of cardiac pacing responses and their relation to the cardiac response classification windows in accordance with embodiments of the invention. In the depiction of FIG. **9**, cardiac signals indicative of a non-captured response **910**, a captured response **930** and a fusion/pseudofusion beat **920** are illustrated. A blanking period **940** follows delivery of the pacing pulse. A first classification window **950** begins after the pacing pulse. If a trigger characteristic of the cardiac signal is detected in the first classification window, a second classification window **960** is established.

The flowchart of FIG. **10** illustrates a method of classifying the cardiac response to pacing in accordance with embodiments of the invention. The process illustrated in FIG. **10** involves first and second capture detection regions respectively defined in the first and the second cardiac response classification windows. The first and second capture detection regions may be defined as functions of time and amplitude. The capture detection regions may be any shape, including, for example, a circle, square, rectangle, or other shape. The first capture detection region may have a shape that is different from the second capture detection region. In this example, a cardiac signal peak detected in the first capture detection region comprises a trigger characteristic for the first cardiac response classification window. The peak of the cardiac signal within a cardiac response classification window may comprise, for example, a signal maximum or signal minimum detected within the cardiac response classification window.

Turning now to FIG. **10**, subsequent to the delivery **1010** of a pacing stimulation, a first classification window is established **1020**. The cardiac signal is sensed following the pacing stimulation and a peak of the cardiac signal is determined **1030** in the first classification window. If the absolute value of the peak amplitude is less or equal to **1040** a threshold value, then the cardiac response is classified **1050** as a non-captured response. If the absolute value of the peak amplitude is beyond **1040** the threshold value and is detected **1060** in the first capture detection region, then a

second classification window is established **1068**. In this example, detection **1060** of a peak of the cardiac signal within the first capture detection region comprises a trigger characteristic of the cardiac signal. If the trigger characteristic is detected **1060**, then the second classification window is established **1068**.

If the peak of the cardiac signal exceeds **1040** the threshold value, but is not detected **1060** in the first capture detection region, then the cardiac response may be classified **1065** as fusion/pseudofusion.

If the second cardiac response classification window is established **1068**, the cardiac signal is sensed in the second cardiac response classification window. A peak of the cardiac signal is detected **1072** in the second classification window. If the peak is not detected **1075** in the second capture detection region, then the cardiac response may be classified **1065** as a fusion/pseudofusion. If the peak is detected **1075** in the second capture detection region, then the cardiac response is classified **1080** as a captured response.

The first and/or the second capture detection windows may be updated **1090** based on the characteristics of the sensed cardiac signal. In one implementation, the location of the cardiac signal peaks in the first and the second capture detection windows are combined with previously acquired cardiac signal peaks, for example, by averaging. The new average peak locations may be used to define the locations of subsequent capture detection regions. Various methods and systems for initializing and updating target regions including capture detection regions are described in commonly owned U.S. patent application identified by Ser. No. 10/448,260, filed May 28, 2003, which is incorporated herein by reference in its entirety.

FIG. **11** is a diagram illustrating the cardiac response classification windows and the capture detection regions described in connection with FIG. **10** and used in the classifying the cardiac response to pacing in accordance with embodiments of the invention. A pacing stimulation **1110** is delivered to the heart and a first cardiac response classification window **1120** is established subsequent to the delivery of the pacing stimulation **1110**. A first capture detection region (CDR) **1130** is defined within the first cardiac response classification window. The cardiac signal following the pacing stimulation is sensed and the peak amplitude is detected. If the peak is less than or equal to a threshold **1140**, then the cardiac response is classified as a non-captured response. If the cardiac response is classified as a non-captured response, then a back up pace **1115** may be delivered upon expiration of a back up pace interval **1125**. The back up pace interval **1125** may comprise an interval of about 100 ms, for example. If a back up pace is delivered, one or more additional cardiac response classification windows may be established to assess the effectiveness of the back up pace.

If the cardiac signal peak falls within the first capture detection region **1130**, then a second cardiac response classification window is established **1150**. The cardiac signal is sensed in the second cardiac response classification window and a peak of the cardiac signal is detected. If the peak of the cardiac signal falls within the second capture detection region **1160**, then the cardiac response is classified as a captured response. The cardiac response may be classified as fusion/pseudofusion if the peak of the cardiac signal falls beyond the boundary of the first capture detection region **1130** in the first classification window **1120** and/or beyond the boundary of the second capture detection region **1160** in the second classification window **1150**.

FIG. **12** is a diagram illustrating the positions of cardiac signal peaks detected in the first and the second classification windows **1220**, **1250** for various cardiac responses in relation to the first and second capture detection regions **1230**, **1260**. Cardiac responses associated with signal peaks less than or equal to a non-capture threshold **1240** are classified as non-captured responses.

FIGS. **13**A and **13**B illustrate a flowchart of a method of cardiac response classification including intrinsic response classification in accordance with embodiments of the invention. A pacing stimulation is delivered to the heart **1305**. A first classification window is established **1310** subsequent to the pacing stimulation. A cardiac signal peak is detected in the first classification window. If the magnitude of the cardiac signal peak amplitude is less than or equal to **1330** a threshold value, then the cardiac response is classified **1335** as a non-captured response.

If the magnitude of the peak amplitude is greater than **1330** the threshold and the peak is detected **1340** in an intrinsic detection region, then the cardiac response is classified **1345** as a non-captured response combined with an intrinsic beat. If the peak amplitude is greater than **1330** the threshold and the peak is not detected **1350** in a first capture detection region, then the cardiac response is classified as fusion/pseudofusion.

If the peak is detected **1350** in the first capture detection region, then a second cardiac response classification window is established **1360**. A peak of the cardiac signal is detected **1375** in the second cardiac response classification window. If the peak of the cardiac signal is not detected **1390** in a second capture detection region, then the cardiac response is classified **1392** as a fusion/pseudofusion. If the peak is detected **1390** in second capture detection region, then the cardiac response is classified as a captured response **1395**.

FIG. **14** is a diagram illustrating the cardiac response classification windows, capture detection windows, and the intrinsic detection window described in connection with FIGS. **13**A and **13**B and used to classify the cardiac response to pacing in accordance with embodiments of the invention. A pacing stimulation **1410** is delivered to the heart and a first cardiac response classification window **1420** is established subsequent to the delivery of the pacing stimulation **1410**. A first capture detection region (CDR) **1430** is defined within the first cardiac response classification window. An intrinsic detection region **1470** is defined. The cardiac signal following the pacing stimulation is sensed and the peak amplitude is detected. If the magnitude of the peak is less than or equal to a threshold **1440**, then the cardiac response is classified as a non-captured response.

If the peak of the cardiac signal detected in the first cardiac response classification window **1420** is detected in the intrinsic detection region **1470**, then the cardiac response is classified as a non-captured response combined with an intrinsic beat.

If the cardiac signal peak falls within the first capture detection region **1430**, then a second cardiac response classification window is established **1450**. The cardiac signal is sensed in the second cardiac response classification window **1450** and a peak of the cardiac signal is detected. If the peak of the cardiac signal falls within the second capture detection region **1460**, then the cardiac response is classified as a captured response.

The cardiac response may be classified as a fusion/pseudofusion beat if the peak of the cardiac signal falls beyond the boundaries of the first capture detection region **1430** and/or beyond the boundaries of the second capture detection region **1460**.

Before using the capture detection regions described above, the capture detection regions may be initialized for use. In accordance with various embodiments, an initialization process may involve determining that the morphology of the cardiac signals includes consistent peak information. A number of cardiac signals may be used to determine the boundaries of the capture detection regions.

FIG. **15** illustrates a flowchart of a method of initializing detection regions, e.g., capture detection regions and/or intrinsic detection regions, in accordance with embodiments of the invention. The method involves sensing a number of cardiac signals representative of a particular response. If a sufficient number of similar cardiac beats representative of a particular type of pacing response are acquired, then the capture detection region boundaries may be calculated based on the acquired beats.

The detection regions boundaries may be calculated, for example, based on coordinates of characteristic features of the sensed cardiac signals. In one implementation, the average of the characteristic feature coordinates may be defined as a point, such as a center, or other location, within a detection region. In this example, the boundaries of a detection region may be established according to a predetermined shape, for example, a circle, square, rectangle, rhombus, or other quadrilateral. Additionally or alternatively, the detection region may be created to enclose a predetermined area.

After a detection region is initialized, it may be adapted using additional cardiac signal representative of a particular type of cardiac response. Initialization of capture detection regions preferably involves pacing at an energy level sufficient to ensure an adequate number of cardiac signals representative of a captured response. Adaptation of the capture detection regions may involve modification of capture detection region parameters using subsequently acquired cardiac signals representative of a captured response.

Turning now to the initialization process illustrated in FIG. **15**, a pacing stimulation is delivered **1505** to the heart and a cardiac beat signal following delivery of the pacing stimulation is sensed **1510**. One or more characteristic features of the first beat of the initialization attempt **1515** may be used to calculate **1520** an initial morphology template representative of the type of cardiac response.

If the cardiac beat is not **1515** the first beat in the initialization attempt, then one or more characteristic features of the cardiac beat are compared **1525** to the previously determined template. The comparison may be implemented, for example, by calculating a degree of similarity or correlation between the sensed cardiac beat and the template. If the sensed cardiac beat is similar **1525** to the template, then the sensed cardiac beat is saved **1530**.

If enough similar beats are saved **1535**, for example, about 7 similar beats out of about 12 beats, then the detection region parameters are calculated **1540** using the stored beats. The initialization attempt is complete **1545**.

If the sensed cardiac beat is not similar **1525** to the first beat, and if too many dissimilar beats have been sensed **1550** in the initialization attempt, then another attempt may be initiated **1560**. However, if too many previous attempts have been made **1555**, then the initialization effort fails **1565**.

FIGS. **16**A and **16**B illustrate a process of initializing the capture detection regions in accordance with an embodiment of the invention. FIG. **16**A shows five cardiac signal waveforms **1605** each representing a captured response. Peaks **1610** of the cardiac signal waveforms **1605** are detected in the first cardiac response classification window **1690**. The peaks **1610** detected in the first classification window **1690** are used to form the first capture detection region **1650**. Peaks **1620** of the cardiac signal waveforms **1605** detected in the second cardiac response classification window **1680** are used to form the second capture detection region **1640**.

In accordance with one implementation, the coordinate locations of the peaks detected in a particular classification window may be averaged, and the averaged coordinate location used as a center for the capture detection region. As illustrated in FIG. **16**B, the averaged coordinate location **1625** of the coordinate locations of the cardiac signal peaks **1620** detected in the first cardiac response classification window **1690** is used as the center of the first capture detection region **1640**. The averaged location **1615** of the coordinate locations of the cardiac signal peaks **1620** detected in the second cardiac response classification window **1680** are used as the center of the second capture detection region **1650**.

After initialization of the detection regions, the detection regions may be adapted to accommodate gradual morphological changes in the cardiac signal. A cardiac signal waveform, e.g., a cardiac signal waveform representative of a captured response, may exhibit natural variations in its morphology over time. Unless the detection regions are adjusted, the cardiac waveform morphology may gradually drift away from the originally established detection regions. It may be desirable to adjust the detection regions to track changes in the captured response waveform.

In accordance with embodiments of the invention, one or more of the detection regions may be adapted to changes in cardiac waveform morphology by adjusting the one or more detection regions. A particular detection region may be adjusted according to a relationship, e.g., a spatial relationship, between the particular detection region and its associated waveform feature, for example a peak of the cardiac signal. Adjustment of the detection regions may involve, for example changing the size, shape, or location of the detection region.

A cardiac feature location, such as a peak, may be identified by a timing coordinate (usually represented as an x-axis coordinate) and an amplitude coordinate (y-axis coordinate). A detection region may be adjusted based on a relationship between a detected feature's amplitude coordinate and the associated detection region's amplitude range. A detection region may also be adjusted based on a relationship between an associated detected feature's timing coordinate and the detection region's amplitude range. In other examples, the detection region may be adjusted based on a variability of an associated detected feature's timing and/or amplitude coordinates.

According to embodiments of the invention, the adjustment of a detection region involves modifying the detection region in the direction of an associated cardiac feature location. In various examples, a detected cardiac feature may fall within a particular detection region, but be offset from the center of the detection region. The location, size, and/or shape of the detection region may be modified in the direction of re-centering or otherwise re-orienting the detection region with respect to an associated detected cardiac feature point falling within the detection region. The detection region may be adjusted, for example, using a function-based or rules-based technique.

According to one implementation, adjustment of the detection regions may be accomplished using a function that is based on present and past locations of an associated detected cardiac waveform feature, e.g., a peak. According to one example, the detection region may be adjusted using

an exponential average based on the present location of the waveform feature and the previous locations of the detection region. Adjustment of the detection region may be implemented based on Equation 1 below.

$$\text{Adjusted Location}=\forall*\text{Past Location}+(1-\forall)*\text{Current Location} \quad [1]$$

By selecting the values of $\forall$, more emphasis may be placed on the past location of the detection region, corresponding to $\forall>0.5$, or more emphasis may be placed on the current location, corresponding to $\forall<0.5$. The value of $\forall$ may vary for different features or characteristics. The location of the detection region may be determined by re-centering or otherwise re-orienting the detection region using the adjusted location.

In other implementations, a detection region may be adjusted using a rules-based technique. For example, the detection region may be adjusted in the direction of a detected associated feature point based on one or more re-centering rules.

A cardiac beat may be required to meet certain qualifications before it is used to adjust the detection regions. A cardiac beat qualified to adjust a detection region may be required to meet certain timing, rate, amplitude, regularity, or other criteria. The cardiac beat may be compared, for example, to a template representing a captured response. If the cardiac beat is consistent with the template, then the cardiac beat may be used to adjust the capture detection regions.

Adjustment of a detection region is illustrated in the diagrams of FIGS. **17**A-B. FIG. **17**A illustrates a detection region **1720** having a center **1710** based on locations of the previously detected cardiac waveform features associated with the detection region. FIG. **17**B illustrates the situation after the next cardiac signal is sensed. The current cardiac waveform feature point **1730** is detected. The location of the current feature point **1730** has drifted above and to the right of the original center **1710** illustrated in FIG. **17**A. A current detection region **1740** centered on the new cardiac waveform feature **1730** would represent a significant change from the original detection region **1720**. In one example embodiment, adjustment of the detection region is performed so that modifications exhibit a relatively smooth transition. The adjusted detection region **1750** may be determined, for example using Equation 1 or other method, to smoothly accommodate the waveform feature drift based on both the past detection region location **1720** and the current detection region location **1740**. The adjustment of the detection region may be limited to predetermined upper and lower boundaries with respect to the amplitude and time coordinates.

Although Equation 1 mathematically describes adjusting the detection region location using an exponential average, other methods of adjusting the detection region locations are also possible. For example, in other embodiments, each of the one or more detection regions may be adjusted according to a moving window average, or another function representing the change in distance between the original detection region and the waveform feature. In a further embodiment, the detection regions may be adjusted according to a rules-based process. A rules-based adjustment process may involve adjusting the detection region location by an amount based on the locations of subsequently detected cardiac waveform features. For example, the detection region location may be moved an incremental amount to the right if a predetermined number, e.g., five, consecutive cardiac signals exhibit cardiac waveform features located within the detection region, but to the right of center of the original detection region. Adjustments in other directions, i.e., left, up, and down, may be made using similar criteria.

In yet other embodiments, adjustment of a detection region may include adjusting the shape and/or size of the detection region. FIGS. **17**C-D are diagrams illustrating adjusting a detection region by modifying the shape of the detection region. FIG. **17**C illustrates a detection region **1720** having a center **1710**. FIG. **17**D illustrates the situation after the next cardiac signal is sensed. The cardiac waveform feature **1760** associated with the detection region **1720** is detected. The location of the current feature point **1760** has drifted above the original center **1710** of the detection region **1720**. An adjusted detection region **1770**, having a different shape from the original detection region **1720**, is defined. The adjustment of the detection region may be limited to a predetermined range with respect to the amplitude and time coordinates.

Embodiments of the invention are directed to methods and systems employing one or more retriggerable cardiac response classification windows. Various embodiments describe discriminating between cardiac response types based on one or more characteristics of the cardiac signal detected the cardiac response classification windows. The use of multiple classification windows for cardiac response classification is described in commonly owned U.S. patent application, identified under Attorney Docket Number GUID.045PA, filed Dec. 11, 2003, and incorporated herein by reference in its entirety. Methods and systems for cardiac response classification involving using different pacing and sensing electrode combinations are described in commonly owned U.S. patent application, identified under Attorney Docket Number GUID.160PA, filed concurrently with this patent application and incorporated herein by reference in its entirety.

Various modifications and additions can be made to the preferred embodiments discussed hereinabove without departing from the scope of the present invention. Accordingly, the scope of the present invention should not be limited by the particular embodiments described above, but should be defined only by the claims set forth below and equivalents thereof.

What is claimed is:

1. A method of classifying a cardiac response to a pacing stimulation, comprising:

delivering the pacing stimulation to a heart chamber;

sensing a cardiac signal of the heart chamber following delivery of the pacing stimulation;

detecting a first trigger feature of the cardiac signal within a first predetermined capture detection region;

in response to detecting the first trigger feature of the cardiac signal within the first predetermined capture detection region, continuing to evaluate at least a portion of a QRS waveform of the cardiac signal that occurs after the first trigger feature;

classifying the cardiac response as fusion or capture of the heart chamber based on at least a portion of the QRS waveform of the cardiac signal that occurs after the first trigger feature; and

delivering pacing therapy based on the classification of the cardiac response as fusion or capture.

2. The method of claim **1**, wherein classifying the cardiac response as fusion or capture comprises:

determining if a second feature of the cardiac signal, which is part of the QRS waveform of the cardiac signal, falls within a second predetermined capture

detection region triggered by detection of the first trigger feature within the first predetermined capture region;

classifying the cardiac response as capture if the first trigger feature of the cardiac signal falls within the first capture detection region and the second feature of the cardiac signal falls within the second predetermined capture detection region; and

classifying the cardiac response as fusion if the second feature of the cardiac signal does not fall within the second predetermined capture detection region triggered by detection of the first trigger feature within the first predetermined capture region.

3. The method of claim **1**, wherein the first predetermined capture detection region is bounded by upper and lower time boundaries and upper and lower amplitude boundaries.

4. The method of claim **1**, wherein:

the first predetermined capture detection region occurs within a first classification window; and

wherein continuing to evaluate the portion of the QRS waveform of the cardiac signal that occurs after the first trigger feature comprises continuing to evaluate the portion of the QRS waveform of the cardiac signal in one or more additional classification windows.

5. The method of claim **1**, wherein discriminating between fusion and capture comprises discriminating between fusion and capture of the left ventricle.

6. The method of claim **1**, wherein discriminating between fusion and capture comprises discriminating between fusion and capture of the right ventricle.

7. The method of claim **1**, wherein discriminating between fusion and capture comprises discriminating between fusion and capture of an atrial chamber.

8. The method of claim **1**, further comprising classifying the cardiac response as an intrinsic beat if the first trigger feature of the cardiac signal falls within an intrinsic detection region.

9. The method of claim **8**, wherein the intrinsic detection region is bounded by upper and lower time boundaries and upper and lower amplitude boundaries.

10. A cardiac device, comprising:

a pacing pulse generator configured to generate cardiac pacing pulses;

a sensing system configured to sense a cardiac pacing response signal of a heart chamber following delivery of a pacing pulse to the heart chamber; and

a cardiac response classification system configured to detect a first trigger feature of the cardiac signal within a first classification window, and, in response to detecting the first trigger feature of the cardiac signal, to continue to evaluate at least a portion of a QRS waveform of the cardiac signal that occurs after the first trigger feature, the cardiac response classification system further configured to discriminate between fusion and capture of the heart chamber based on the portion of the QRS waveform of the cardiac signal that occurs after the first trigger feature.

11. The device of claim **10**, further comprising one or more left ventricular electrodes coupled to the sensing system, wherein the heart chamber is the left ventricle and the cardiac pacing response signal is sensed via the left ventricular electrodes.

12. The device of claim **11**, wherein the pacing pulse generator is configured to deliver a back up pace if noncapture of the heart chamber is detected by the cardiac response classification system.

13. The device of claim **10**, wherein the pacing pulse is delivered using a first electrode vector and the cardiac pacing response signal is sensed using a second electrode vector.

14. The device of claim **10**, wherein the cardiac response classification system is configured to determine if the first trigger feature occurs within a first capture detection region, the first capture detection region bounded by upper and lower time boundaries and upper and lower amplitude boundaries.

15. The device of claim **10**, wherein:

the cardiac response classification system is configured to continue to evaluate the cardiac signal in one or more additional classification windows that extend after the first classification window.

16. The device of claim **15**, wherein the cardiac response classification system is configured to adapt one or both of an amplitude coordinate and a timing coordinate of the first classification window based on previous captured responses.

17. A cardiac device, comprising:

a pacing pulse generator configured to generate cardiac pacing pulses;

a sensing system configured to sense a cardiac pacing response signal of a heart chamber following delivery of a pacing pulse to the heart chamber; and

a cardiac response classification system configured to sense for a trigger feature of the cardiac signal within a first classification window, and, in response to detecting the trigger feature of the cardiac signal within the first classification window to continue to evaluate at least a portion of a QRS waveform of the cardiac signal that occurs after the first classification window in one or more additional classification windows, the cardiac response classification system further configured to discriminate between fusion and capture of the heart chamber based at least in part on the portion of the QRS waveform of the cardiac signal that occurs in the one or more additional classification windows.

18. The device of claim **17**, wherein the cardiac response classification system is configured to determine if the trigger feature occurs within a capture detection region of the first classification window.

19. The device of claim **17**, wherein the cardiac response classification system is configured to discriminate between fusion and capture of the heart chamber based on a timing of a feature that occurs within one of the one or more additional classification windows.

20. The device of claim **17**, wherein the cardiac response classification system is configured to discriminate between fusion and capture of the left ventricle.

21. A method of operating a cardiac device, comprising:

delivering the pacing stimulation to a heart chamber during a cardiac cycle;

sensing a cardiac signal of the heart chamber during the cardiac cycle and following delivery of the pacing stimulation;

determining if a trigger feature of the cardiac signal occurs within one or more detection regions, the detection regions having upper and lower timing boundaries and upper and lower amplitude boundaries;

in response to determining that a cardiac signal trigger feature falls within one of the detection regions, continuing to evaluate at least a portion of a QRS waveform of the cardiac signal that occurs after the determined trigger feature;

classifying the cardiac signal based on one or more of detection of the trigger feature within the one or more

detection regions and at least a portion of the QRS waveform of the cardiac signal that occurs after the determined trigger feature; and

delivering pacing therapy based on classification of the cardiac signal.

22. A cardiac device configured to implement the method of claim **21**.

23. A method of classifying a cardiac response to a pacing stimulation, comprising:

delivering the pacing stimulation to a heart chamber;

sensing a cardiac signal of the heart chamber following delivery of the pacing stimulation;

searching for a first feature of a QRS waveform associated with the cardiac signal within a first capture detection region;

if the first feature is detected within the first capture detection region, searching for a second feature of the QRS waveform within a second capture detection region;

classifying the cardiac response as fusion or capture of the heart chamber based, at least in part, on whether the first feature of the QRS waveform was detected in the first capture detection region and/or whether the second feature of the QRS waveform was detected in the second capture detection region; and

delivering pacing therapy based on the classification of the cardiac response as fusion or capture.

* * * * *

专利名称(译)	使用可重新触发的分类窗口进行心脏反应分类		
公开(公告)号	US9993205	公开(公告)日	2018-06-12
申请号	US12/818066	申请日	2010-06-17
[标]申请(专利权)人(译)	MEYER斯科特 MANIAK JEREMY BIRHOLZ DOUG VOEGELE JOHN		
申请(专利权)人(译)	MEYER斯科特 盐亭董 MANIAK JEREMY BIRHOLZ DOUG VOEGELE JOHN		
当前申请(专利权)人(译)	心脏起搏器，INC.		
[标]发明人	MEYER SCOTT A DONG YANTING MANIAK JEREMY BIRHOLZ DOUG VOEGELE JOHN		
发明人	MEYER, SCOTT A. DONG, YANTING MANIAK, JEREMY BIRHOLZ, DOUG VOEGELE, JOHN		
IPC分类号	A61N1/08 A61B5/00 A61N1/37 A61B5/0452 A61B5/04		
CPC分类号	A61B5/7264 A61N1/371 A61B5/7217 A61B5/04525 G16H50/20		
代理机构(译)	SCHWEGMAN和Lundberg & 沃斯纳，P.A.		
其他公开文献	US20100256703A1		
外部链接	Espacenet USPTO		

摘要(译)

用于将心脏响应分类为起搏的方法和设备涉及建立可重新触发的心脏响应分类窗口。在递送起搏脉冲之后建立第一心脏响应分类窗口。在起搏刺激之后的心脏信号在第一分类窗口中被感测。如果在第一分类窗口中检测到触发特性，则可以触发第二心脏响应分类。如果建立了第二分类窗口，则在第二分类窗口中感测心脏信号。基于心脏信号的特征来确定对起搏刺激的心脏响应。例如，心脏响应可以被确定为捕获的响应，非捕获的响应，添加到固有节拍的未捕获的响应以及融合/伪融合节拍中的一个。