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(54) **SLEEP DETECTION USING AN ADJUSTABLE THRESHOLD**

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(56) **References Cited**

U.S. PATENT DOCUMENTS

3,309,924 A 3/1967 Kolin et al.
3,522,811 A 8/1970 Schwartz et al.
3,650,277 A 3/1972 Sjostrand et al.
3,835,864 A 9/1974 Rasor et al.
3,870,051 A 3/1975 Brindley

(Continued)

FOREIGN PATENT DOCUMENTS

EP 0940155 8/1999
EP 1151718 11/2001

(Continued)

OTHER PUBLICATIONS

U.S. Appl. No. 10/269,611, filed Oct. 11, 2002, Hatlestad.

(Continued)

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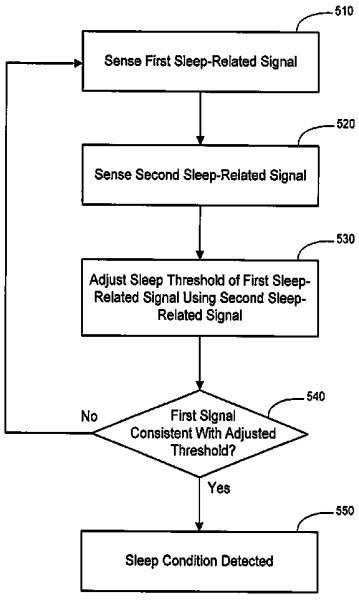
(57) **ABSTRACT**

Devices and methods for sleep detection involve the use of an adjustable threshold for detecting sleep onset and termination. A method for detecting sleep includes adjusting a sleep threshold associated with a first sleep-related signal using a second sleep-related signal. The first sleep-related signal is compared to the adjusted threshold and sleep is detected based on the comparison. The sleep-related signals may be derived from implantable or external sensors. Additional sleep-related signals may be used to confirm the sleep condition. A sleep detector device implementing a sleep detection method may be a component of an implantable pulse generator such as a pacemaker or defibrillator.

**19 Claims, 10 Drawing Sheets**



(56) **References Cited**

U.S. PATENT DOCUMENTS

3,943,936 A 3/1976 Rasor et al.
4,312,734 A 1/1982 Nichols
4,323,073 A 4/1982 Ferris
4,365,636 A 12/1982 Barker
4,390,405 A 6/1983 Hahn et al.
4,573,481 A 3/1986 Bullara
4,590,946 A 5/1986 Loeb
4,702,253 A 10/1987 Nappholz et al.
4,719,921 A 1/1988 Chirife
4,721,110 A 1/1988 Lampadius
4,777,962 A 10/1988 Watson et al.
4,784,162 A 11/1988 Ricks et al.
4,791,931 A 12/1988 Slate
4,802,485 A 2/1989 Bowers et al.
4,807,629 A 2/1989 Baudino et al.
4,819,662 A 4/1989 Heil, Jr. et al.
4,827,943 A 5/1989 Bornn et al.
4,836,219 A 6/1989 Hobson et al.
4,846,195 A 7/1989 Alt
4,856,524 A 8/1989 Baker, Jr.
4,875,477 A 10/1989 Waschke et al.
4,886,064 A 12/1989 Strandberg
4,940,065 A 7/1990 Tanagho et al.
4,953,551 A 9/1990 Mehra et al.
4,958,632 A 9/1990 Duggan
4,960,129 A 10/1990 dePaola et al.
4,961,423 A 10/1990 Canducci
4,967,159 A 10/1990 Manes
4,972,842 A 11/1990 Korten et al.
4,972,848 A 11/1990 DiDomenico
4,982,738 A 1/1991 Griebel
5,010,888 A 4/1991 Jadvar et al.
5,024,222 A 6/1991 Thacker
5,040,533 A 8/1991 Fearnot
5,047,930 A 9/1991 Martens et al.
5,063,927 A 11/1991 Webb et al.
5,105,354 A 4/1992 Nishimura
5,111,815 A 5/1992 Mower
5,133,353 A 7/1992 Hauser
5,144,960 A 9/1992 Mehra et al.
5,156,157 A 10/1992 Valenta, Jr. et al.
5,170,784 A 12/1992 Ramon et al.
5,174,287 A 12/1992 Kallok et al.
5,179,945 A 1/1993 Van Hofwegen et al.
5,183,038 A 2/1993 Hoffman et al.
5,187,657 A 2/1993 Forbes
5,188,106 A 2/1993 Nappholz et al.
5,190,035 A 3/1993 Salo et al.
5,199,424 A 4/1993 Sullivan et al.
5,199,428 A 4/1993 Obel et al.
5,203,326 A 4/1993 Collins
5,209,229 A 5/1993 Gilli
5,215,089 A 6/1993 Baker, Jr.
5,233,983 A 8/1993 Markowitz
5,243,979 A 9/1993 Stein et al.
5,243,980 A 9/1993 Mehra
5,245,995 A 9/1993 Sullivan et al.
5,259,373 A 11/1993 Gruenke et al.
5,261,400 A 11/1993 Bardy
5,275,159 A 1/1994 Griebel
5,280,791 A 1/1994 Lavie
5,282,468 A 2/1994 Klepinski
5,292,338 A 3/1994 Bardy
5,299,118 A 3/1994 Martens et al.
5,300,106 A 4/1994 Dahl et al.
5,314,430 A 5/1994 Bardy
5,314,459 A 5/1994 Swanson et al.
5,318,592 A 6/1994 Schaldach
5,318,597 A 6/1994 Hauck et al.
5,330,505 A 7/1994 Cohen
5,330,507 A 7/1994 Schwartz
5,330,515 A 7/1994 Rutecki et al.
5,331,966 A 7/1994 Bennett et al.
5,334,221 A 8/1994 Bardy
5,335,647 A 8/1994 Brustad
5,335,657 A 8/1994 Terry, Jr. et al.
5,351,394 A 10/1994 Weinberg
5,356,425 A 10/1994 Bardy et al.
5,363,842 A 11/1994 Mishelevich et al.
5,372,606 A 12/1994 Lang et al.
5,376,106 A 12/1994 Stahmann et al.
5,398,682 A 3/1995 Lynn
5,404,877 A 4/1995 Nolan et al.
5,411,525 A 5/1995 Swanson et al.
5,411,531 A 5/1995 Hill et al.
5,411,539 A 5/1995 Neisz
5,411,540 A 5/1995 Edell et al.
5,437,285 A 8/1995 Verrier et al.
5,439,482 A 8/1995 Adams et al.
5,441,518 A 8/1995 Adams et al.
5,466,245 A 11/1995 Spinelli et al.
5,468,254 A 11/1995 Hahn et al.
5,483,969 A 1/1996 Testerman et al.
5,485,851 A 1/1996 Erickson
5,487,755 A 1/1996 Snell et al.
5,507,784 A 4/1996 Hill et al.
5,520,176 A 5/1996 Cohen
5,522,382 A 6/1996 Sullivan et al.
5,522,854 A 6/1996 Ideker et al.
5,522,862 A 6/1996 Testerman et al.
5,531,779 A 7/1996 Dahl et al.
5,540,734 A 7/1996 Zabara
5,540,735 A 7/1996 Wingrove
5,549,655 A 8/1996 Erickson
5,571,150 A 11/1996 Wernicke et al.
5,578,061 A 11/1996 Stroetmann et al.
5,590,648 A 1/1997 Mitchell et al.
5,591,216 A 1/1997 Testerman et al.
5,593,431 A 1/1997 Sheldon
5,605,151 A 2/1997 Lynn
5,606,969 A 3/1997 Butler et al.
5,620,466 A 4/1997 Haefner et al.
5,622,178 A 4/1997 Gilham
5,632,281 A 5/1997 Rayburn
5,634,938 A 6/1997 Swanson et al.
5,641,326 A 6/1997 Adams
5,643,330 A 7/1997 Holsheimer et al.
5,658,318 A 8/1997 Stroetmann et al.
5,662,688 A 9/1997 Haefner et al.
5,683,430 A 11/1997 Markowitz et al.
5,690,681 A 11/1997 Geddes et al.
5,693,000 A 12/1997 Crosby et al.
5,697,951 A 12/1997 Harpstead et al.
5,697,953 A 12/1997 Kroll et al.
5,700,282 A 12/1997 Zabara
5,701,894 A 12/1997 Cherry et al.
5,704,345 A 1/1998 Berthon-Jones
5,704,365 A 1/1998 Albrecht et al.
5,707,400 A 1/1998 Terry, Jr. et al.
5,713,933 A 2/1998 Condie et al.
5,716,377 A 2/1998 Rise et al.
5,720,771 A 2/1998 Snell
5,724,984 A 3/1998 Arnold et al.
5,727,558 A 3/1998 Hakki et al.
5,738,102 A 4/1998 Lemelson
5,766,236 A 6/1998 Detty et al.
5,792,188 A 8/1998 Starkweather et al.
5,794,615 A 8/1998 Estes
5,800,464 A 9/1998 Kieval
5,800,470 A 9/1998 Stein et al.
5,802,188 A 9/1998 McDonough
5,814,087 A 9/1998 Renirie
5,826,579 A 10/1998 Remmers et al.
5,827,326 A 10/1998 Kroll et al.
5,839,430 A 11/1998 Cama
5,861,011 A * 1/1999 Stoop ..... 607/25
5,861,015 A 1/1999 Benja-Athon
5,871,011 A 2/1999 Howell et al.
5,895,414 A 4/1999 Sanchez-Zambrano
5,902,250 A 5/1999 Verrier et al.
5,916,239 A 6/1999 Geddes et al.
5,919,141 A 7/1999 Money et al.
5,919,220 A 7/1999 Stieglitz et al.
5,928,272 A 7/1999 Adkins et al.

5,938,596 A 8/1999 Woloszko et al.
5,944,680 A 8/1999 Christopherson et al.
5,957,861 A 9/1999 Combs et al.
5,957,956 A 9/1999 Kroll et al.
5,961,446 A 10/1999 Beller et al.
5,961,450 A 10/1999 Merchant et al.
5,964,788 A 10/1999 Greenhut
5,970,975 A 10/1999 Estes et al.
5,974,349 A 10/1999 Levine
5,981,011 A 11/1999 Overcash et al.
5,989,230 A 11/1999 Frassica
6,006,134 A 12/1999 Hill et al.
6,015,388 A 1/2000 Sackner et al.
6,016,449 A 1/2000 Fischell et al.
6,021,351 A 2/2000 Kadhiresan et al.
6,044,297 A 3/2000 Sheldon et al.
6,047,203 A 4/2000 Sackner et al.
6,050,940 A 4/2000 Braun et al.
6,050,952 A 4/2000 Hakki et al.
6,058,331 A 5/2000 King
6,059,725 A 5/2000 Steinschneider
6,073,048 A 6/2000 Kieval et al.
6,091,973 A 7/2000 Colla et al.
6,091,986 A 7/2000 Keimel
6,099,479 A 8/2000 Christopherson et al.
6,105,575 A 8/2000 Estes et al.
6,110,098 A 8/2000 Renirie 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.
6,132,384 A 10/2000 Christopherson et al.
6,134,470 A 10/2000 Hartlaub
6,144,866 A 11/2000 Miesel et al.
6,148,230 A 11/2000 KenKnight
6,148,814 A 11/2000 Clemmer et al.
6,155,976 A 12/2000 Sackner et al.
6,161,042 A 12/2000 Hartley et al.
6,161,047 A 12/2000 King et al.
6,168,568 B1 1/2001 Gavriely
6,178,349 B1 1/2001 Kieval
6,181,961 B1 1/2001 Prass
6,181,966 B1 1/2001 Nigam
6,190,326 B1 2/2001 McKinnon et al.
6,200,265 B1 3/2001 Walsh et al.
6,206,914 B1 3/2001 Soykan et al.
6,208,894 B1 3/2001 Schulman et al.
6,212,435 B1 4/2001 Lattner et al.
6,221,011 B1 4/2001 Bardy
6,236,873 B1 5/2001 Holmstrom
6,240,314 B1 5/2001 Plicchi et al.
6,251,126 B1 6/2001 Ottenhoff et al.
6,258,039 B1 7/2001 Okamoto et al.
6,261,238 B1 7/2001 Gavriely
6,263,244 B1 7/2001 Mann et al.
6,264,606 B1 7/2001 Ekwall et al.
6,269,269 B1 7/2001 Ottenhoff et al.
6,272,377 B1 8/2001 Sweeney et al.
6,280,462 B1 8/2001 Hauser et al.
6,286,508 B1 9/2001 Remmers et al.
6,287,264 B1 9/2001 Hoffman
6,292,695 B1 9/2001 Webster et al.
6,292,703 B1 9/2001 Meier et al.
6,303,270 B1 10/2001 Flaim et al.
6,306,088 B1 10/2001 Krausman
6,310,085 B1 10/2001 Willis
6,317,627 B1 11/2001 Ennen
6,331,536 B1 12/2001 Radulovacki et al.
6,351,670 B1 2/2002 Kroll
6,356,788 B2 3/2002 Boveja
6,357,444 B1 3/2002 Parker
6,360,127 B1 3/2002 Ding et al.
6,361,494 B1 3/2002 Lindenthaler
6,361,522 B1 3/2002 Scheiner et al.
6,363,270 B1 3/2002 Colla et al.
6,366,813 B1 4/2002 DiLorenzo
6,368,287 B1 4/2002 Hadas
6,375,614 B1 4/2002 Braun et al.
6,375,621 B1 4/2002 Sullivan
6,375,623 B1 4/2002 Gavriely
6,387,907 B1 5/2002 Hendricks et al.
6,397,109 B1 5/2002 Cammilli et al.
6,397,845 B1 6/2002 Burton
6,398,739 B1 6/2002 Sullivan et al.
6,400,982 B2 6/2002 Sweeney et al.
6,401,129 B1 6/2002 Lenander
6,409,675 B1 6/2002 Turcott
6,409,676 B2 6/2002 Ruton et al.
6,411,845 B1 6/2002 Mower et al.
6,411,850 B1 6/2002 Kay et al.
6,415,174 B1 7/2002 Bebehani et al.
6,415,183 B1 7/2002 Scheiner et al.
6,421,557 B1 7/2002 Meyer
6,431,171 B1 8/2002 Burton
6,438,407 B1 8/2002 Ousdigian et al.
6,438,428 B1 8/2002 Axelgaard et al.
6,442,413 B1 8/2002 Silver
6,442,435 B2 8/2002 King et al.
6,447,459 B1 9/2002 Larom
6,449,507 B1 9/2002 Hill et al.
6,450,957 B1 9/2002 Yoshimi
6,454,708 B1 9/2002 Ferguson et al.
6,454,719 B1 9/2002 Greenhut
6,463,326 B1 10/2002 Hartley et al.
6,463,327 B1 10/2002 Lurie et al.
6,467,333 B2 10/2002 Lewis et al.
6,468,219 B1 10/2002 Njemanze
6,473,644 B1 10/2002 Terry, Jr. et al.
6,487,450 B1 11/2002 Chen et al.
6,491,639 B1 12/2002 Turcott
6,493,585 B2 12/2002 Plicchi et al.
6,497,658 B2 12/2002 Roizen et al.
6,511,500 B1 1/2003 Rahme
6,512,940 B1 1/2003 Brabec et al.
6,514,218 B2 2/2003 Yamamoto
6,517,497 B2 2/2003 Rymut et al.
6,522,915 B1 2/2003 Ceballos et al.
6,522,926 B1 2/2003 Kieval et al.
6,527,729 B1 3/2003 Turcott
6,532,388 B1 3/2003 Hill et al.
6,542,774 B2 4/2003 Hill et al.
6,547,743 B2 4/2003 Brydon
6,564,096 B2 5/2003 Mest
6,564,101 B1 5/2003 Zikria
6,564,106 B2 5/2003 Guck et al.
6,572,543 B1 6/2003 Christopherson et al.
6,572,557 B2 6/2003 Tchou et al.
6,574,507 B1 6/2003 Bonnet
6,580,944 B1 6/2003 Katz et al.
6,589,188 B1 7/2003 Street et al.
6,595,928 B2 7/2003 Mansy et al.
6,600,956 B2 7/2003 Maschino
6,606,993 B1 8/2003 Wiesmann et al.
6,607,509 B2 8/2003 Bobroff et al.
6,611,713 B2 8/2003 Schauerte
6,615,083 B2 9/2003 Kupper
6,622,041 B2 9/2003 Terry, Jr. et al.
6,622,046 B2 9/2003 Fraley et al.
6,628,986 B1 9/2003 Mouchawar et al.
6,628,987 B1 9/2003 Hill et al.
6,641,542 B2 11/2003 Cho et al.
6,658,292 B2 12/2003 Kroll et al.
6,662,032 B1 12/2003 Gavish et al.
6,679,250 B2 1/2004 Walker et al.
6,694,186 B2 2/2004 Bardy
6,704,590 B2 3/2004 Haldeman
6,708,058 B2 3/2004 Kim et al.
6,708,063 B2 3/2004 Czygan et al.
6,723,055 B2 4/2004 Hoffman
6,731,984 B2 5/2004 Cho et al.
6,741,885 B1 5/2004 Park et al.
6,748,252 B2 6/2004 Lynn et al.
6,752,765 B1 * 6/2004 Jensen et al. ..... 600/536
6,752,766 B2 6/2004 Kowallik et al.
6,765,062 B2 7/2004 Chin et al.
6,770,022 B2 8/2004 Mechlenburg et al.
6,770,029 B2 8/2004 Iliff
6,773,404 B2 8/2004 Poezevera et al.
6,786,866 B2 9/2004 Odagiri et al.

6,810,287 B2 10/2004 Zhu et al.
6,832,609 B2 12/2004 Wright et al.
6,881,192 B1 4/2005 Park
6,892,095 B2 5/2005 Salo
6,894,204 B2 5/2005 Dunshee
6,895,275 B2 5/2005 Markowitz et al.
6,904,320 B2 6/2005 Park et al.
6,907,288 B2 6/2005 Daum
6,910,481 B2 6/2005 Kimmel et al.
6,928,324 B2 8/2005 Park et al.
6,932,084 B2 8/2005 Estes et al.
6,934,583 B2 8/2005 Weinberg et al.
6,942,686 B1 9/2005 Barbut et al.
6,951,539 B2 10/2005 Bardy
6,964,641 B2 11/2005 Cho et al.
6,988,498 B2 1/2006 Berthon-Jones et al.
6,999,817 B2 2/2006 Park et al.
7,010,337 B2 3/2006 Furnary et al.
7,025,729 B2 4/2006 De Chazal et al.
7,039,468 B2 5/2006 Freed et al.
7,062,308 B1 6/2006 Jackson
7,065,409 B2 6/2006 Mazar
7,089,936 B2 8/2006 Madaus et al.
7,092,755 B2 8/2006 Florio
7,101,341 B2 9/2006 Tsukashima et al.
7,117,036 B2 10/2006 Florio
7,127,300 B2 10/2006 Mazar et al.
7,130,687 B2 10/2006 Cho et al.
7,136,704 B2 11/2006 Schulman
7,155,278 B2 12/2006 King et al.
7,155,284 B1 12/2006 Whitehurst et al.
7,168,429 B2 1/2007 Matthews et al.
7,184,817 B2 2/2007 Zhu et al.
7,189,204 B2 3/2007 Ni et al.
7,194,313 B2 3/2007 Libbus
7,204,805 B2 4/2007 Dean
7,206,635 B2 4/2007 Cho et al.
7,207,945 B2 4/2007 Bardy
7,212,862 B2 5/2007 Park et al
7,218,964 B2 5/2007 Hill et al.
7,225,013 B2 5/2007 Geva et al.
7,225,809 B1 6/2007 Bowen et al.
7,231,250 B2 6/2007 Band et al.
7,245,971 B2 7/2007 Park et al.
7,252,640 B2 8/2007 Ni et al.
7,258,670 B2 8/2007 Bardy
7,269,459 B1 9/2007 Koh
7,277,757 B2 10/2007 Casavant et al.
7,277,761 B2 10/2007 Shelchuk
7,302,295 B2 11/2007 Stahmann et al.
7,314,046 B2 1/2008 Schroeder et al.
7,366,572 B2 4/2008 Heruth et al.
7,376,463 B2 5/2008 Salo et al.
7,396,333 B2 7/2008 Stahmann et al.
7,400,928 B2 7/2008 Hatlestsad
7,413,549 B1 8/2008 Koh
7,425,200 B2 9/2008 Brockway et al.
7,428,468 B2 9/2008 Takemura et al.
7,435,221 B1 10/2008 Bharmi et al.
7,440,795 B2 10/2008 Poezevara
7,460,906 B2 12/2008 Libbus
7,469,697 B2 12/2008 Lee et al.
7,486,991 B2 2/2009 Libbus et al.
7,499,742 B2 3/2009 Bolea
7,509,164 B2 * 3/2009 Jensen et al. ..... 600/547
7,509,166 B2 3/2009 Libbus
7,680,537 B2 3/2010 Stahmann et al.
7,720,541 B2 5/2010 Stahmann et al.
7,766,842 B2 8/2010 Ni et al.
8,192,376 B2 6/2012 Lovett et al.
2001/0031930 A1 10/2001 Roizen et al.
2002/0005982 A1 1/2002 Borlinghaus
2002/0026222 A1 2/2002 Schauerte et al.
2002/0035376 A1 3/2002 Bardy 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.
2002/0035380 A1 3/2002 Rissmann et al.
2002/0035381 A1 3/2002 Bardy et al.
2002/0042629 A1 4/2002 Bardy et al.
2002/0042630 A1 4/2002 Bardy et al.
2002/0042634 A1 4/2002 Bardy et al.
2002/0049475 A1 4/2002 Bardy et al.
2002/0049476 A1 4/2002 Bardy et al.
2002/0052636 A1 5/2002 Bardy et al.
2002/0058877 A1 5/2002 Baumann et al.
2002/0068897 A1 6/2002 Jenkins et al.
2002/0068958 A1 6/2002 Bardy et al.
2002/0072773 A1 6/2002 Bardy et al.
2002/0072776 A1 6/2002 Osorio et al.
2002/0082652 A1 6/2002 Wentkowski et al.
2002/0082658 A1 6/2002 Heinrich et al.
2002/0091414 A1 7/2002 Bardy et al.
2002/0095184 A1 7/2002 Bardy et al.
2002/0103510 A1 8/2002 Bardy et al.
2002/0103516 A1 8/2002 Patwardhan et al.
2002/0107544 A1 8/2002 Ostroff et al.
2002/0107545 A1 8/2002 Rissmann et al.
2002/0107546 A1 8/2002 Ostroff et al.
2002/0107547 A1 8/2002 Erlinger et al.
2002/0107548 A1 8/2002 Bardy et al.
2002/0107549 A1 8/2002 Bardy et al.
2002/0107553 A1 8/2002 Hill et al.
2002/0107559 A1 8/2002 Sanders et al.
2002/0120299 A1 8/2002 Ostroff et al.
2002/0128700 A1 9/2002 Cross, Jr.
2002/0143264 A1 10/2002 Ding et al.
2002/0143369 A1 10/2002 Hill et al.
2002/0151051 A1 10/2002 Li
2002/0161410 A1 10/2002 Kramer et al.
2002/0165462 A1 11/2002 Westbrook et al.
2002/0169384 A1 11/2002 Kowallik et al.
2002/0169485 A1 11/2002 Pless et al.
2002/0183237 A1 12/2002 Puskas
2002/0193685 A1 12/2002 Mate et al.
2002/0193839 A1 12/2002 Cho et al.
2002/0198570 A1 12/2002 Puskas
2003/0003052 A1 1/2003 Hampton
2003/0004546 A1 1/2003 Casey
2003/0004549 A1 1/2003 Hill et al.
2003/0004552 A1 1/2003 Plombon et al.
2003/0023175 A1 1/2003 Arzbaecher et al.
2003/0023279 A1 1/2003 Spinelli et al.
2003/0036773 A1 2/2003 Whitehurst et al.
2003/0036778 A1 2/2003 Ostroff et al.
2003/0045904 A1 3/2003 Bardy et al.
2003/0045909 A1 3/2003 Gross et al.
2003/0045914 A1 3/2003 Cohen et al.
2003/0050538 A1 3/2003 Naghavi et al.
2003/0055461 A1 3/2003 Girouard et al.
2003/0060848 A1 3/2003 Kieval et al.
2003/0060857 A1 3/2003 Perrson et al.
2003/0060858 A1 3/2003 Kieval et al.
2003/0069609 A1 4/2003 Thompson
2003/0073919 A1 4/2003 Hampton et al.
2003/0074039 A1 4/2003 Puskas
2003/0078629 A1 4/2003 Chen
2003/0083241 A1 5/2003 Young
2003/0088278 A1 5/2003 Bardy et al.
2003/0088279 A1 5/2003 Rissmann et al.
2003/0088280 A1 5/2003 Ostroff
2003/0088281 A1 5/2003 Ostroff et al.
2003/0088282 A1 5/2003 Ostroff
2003/0088283 A1 5/2003 Ostroff
2003/0088286 A1 5/2003 Ostroff et al.
2003/0097153 A1 5/2003 Bardy et al.
2003/0100924 A1 5/2003 Foreman et al.
2003/0105493 A1 6/2003 Salo et al.
2003/0111079 A1 6/2003 Matthews et al.
2003/0149450 A1 8/2003 Mayberg
2003/0153955 A1 8/2003 Park et al.
2003/0153956 A1 8/2003 Park et al.
2003/0171687 A1 9/2003 Irie et al.
2003/0171791 A1 9/2003 KenKnight et al.
2003/0178031 A1 9/2003 Du Pen et al.
2003/0181951 A1 9/2003 Cates
2003/0187336 A1 10/2003 Odagiri et al.
2003/0195571 A1 10/2003 Burnes et al.

2003/0195578 A1 10/2003 Perron et al.
2003/0199945 A1 10/2003 Ciulla
2003/0204213 A1 10/2003 Jensen et al.
2003/0212436 A1 11/2003 Brown
2003/0212440 A1 11/2003 Boveja
2003/0216789 A1 11/2003 Deem et al.
2003/0216792 A1 11/2003 Levin et al.
2003/0229380 A1 12/2003 Adams et al.
2003/0236558 A1 12/2003 Whitehurst
2004/0002742 A1 1/2004 Florio
2004/0019364 A1 1/2004 Kieval et al.
2004/0059240 A1 3/2004 Cho et al.
2004/0073093 A1 4/2004 Hatlestad
2004/0102814 A1 5/2004 Sorensen et al.
2004/0116981 A1 6/2004 Mazar
2004/0122487 A1 6/2004 Hatlestad et al.
2004/0122488 A1 6/2004 Mazar et al.
2004/0128161 A1 7/2004 Mazar et al.
2004/0133079 A1 7/2004 Mazar et al.
2004/0138719 A1 7/2004 Cho et al.
2004/0163648 A1 8/2004 Burton
2004/0172074 A1 9/2004 Yoshihito
2004/0176809 A1 9/2004 Cho et al.
2004/0193231 A1 9/2004 David et al.
2004/0210154 A1 10/2004 Kline
2004/0210155 A1 10/2004 Takemura et al.
2004/0210261 A1 10/2004 King et al.
2004/0215240 A1 10/2004 Lovett et al.
2004/0215289 A1 10/2004 Fukui
2004/0230229 A1 11/2004 Lovett et al.
2004/0230230 A1 11/2004 Lindstrom
2004/0249299 A1 12/2004 Cobb
2004/0249416 A1 12/2004 Yun et al.
2004/0254616 A1 12/2004 Rossing et al.
2005/0004615 A1 1/2005 Sanders
2005/0021092 A1 1/2005 Yun et al.
2005/0039745 A1 2/2005 Stahmann et al.
2005/0042589 A1 2/2005 Hatlestad et al.
2005/0043772 A1 2/2005 Stahmann et al.
2005/0065447 A1 3/2005 Lee et al.
2005/0065567 A1 3/2005 Lee et al.
2005/0065572 A1 3/2005 Hartley et al.
2005/0065575 A1 3/2005 Dobak
2005/0076908 A1 4/2005 Lee
2005/0085864 A1 4/2005 Schulman et al.
2005/0093581 A1 5/2005 Libbus et al.
2005/0096705 A1 5/2005 Pastore et al.
2005/0101841 A9 5/2005 Kaylor et al.
2005/0107838 A1 5/2005 Lovett et al.
2005/0119711 A1 6/2005 Cho et al.
2005/0131467 A1 6/2005 Boveja
2005/0137645 A1 6/2005 Voipio et al.
2005/0142070 A1 6/2005 Hartley et al.
2005/0143779 A1 6/2005 Libbus
2005/0143787 A1 6/2005 Boveja et al.
2005/0145246 A1 7/2005 Hartley et al.
2005/0149128 A1 7/2005 Heil, Jr. et al.
2005/0149129 A1 7/2005 Libbus et al.
2005/0149130 A1 7/2005 Libbus
2005/0149131 A1 7/2005 Libbus et al.
2005/0149132 A1 7/2005 Libbus
2005/0149133 A1 7/2005 Libbus et al.
2005/0149143 A1 7/2005 Libbus
2005/0149155 A1 7/2005 Scheiner et al.
2005/0149156 A1 7/2005 Libbus et al.
2005/0159784 A1 7/2005 Arceta
2005/0197675 A1 9/2005 David et al.
2005/0288728 A1 12/2005 Libbus et al.
2006/0047333 A1 3/2006 Tockman et al.
2006/0079802 A1* 4/2006 Jensen et al. ..... 600/547
2006/0079945 A1 4/2006 Libbus
2006/0106428 A1 5/2006 Libbus et al.
2006/0106429 A1 5/2006 Libbus et al.
2006/0116737 A1 6/2006 Libbus
2006/0122675 A1 6/2006 Libbus et al.
2006/0195041 A1 8/2006 Lynn et al.
2006/0206153 A1 9/2006 Libbus
2006/0206154 A1 9/2006 Moffitt
2006/0217772 A1 9/2006 Libbus
2006/0224188 A1 10/2006 Libbus et al.
2006/0293714 A1 12/2006 Salo et al.
2007/0038278 A1 2/2007 Zarembo
2007/0055115 A1 3/2007 Kwok et al.
2007/0093875 A1 4/2007 Chavan et al.
2007/0112388 A1 5/2007 Salo
2007/0142871 A1 6/2007 Libbus
2007/0149860 A1 6/2007 Lynn et al.
2007/0150014 A1 6/2007 Kramer et al.
2007/0161873 A1 7/2007 Ni et al.
2007/0185542 A1 8/2007 Bolea et al.
2007/0282215 A1 12/2007 Ni et al.
2008/0045813 A1 2/2008 Phuah et al.
2009/0007918 A1 1/2009 Darkin et al.

## FOREIGN PATENT DOCUMENTS

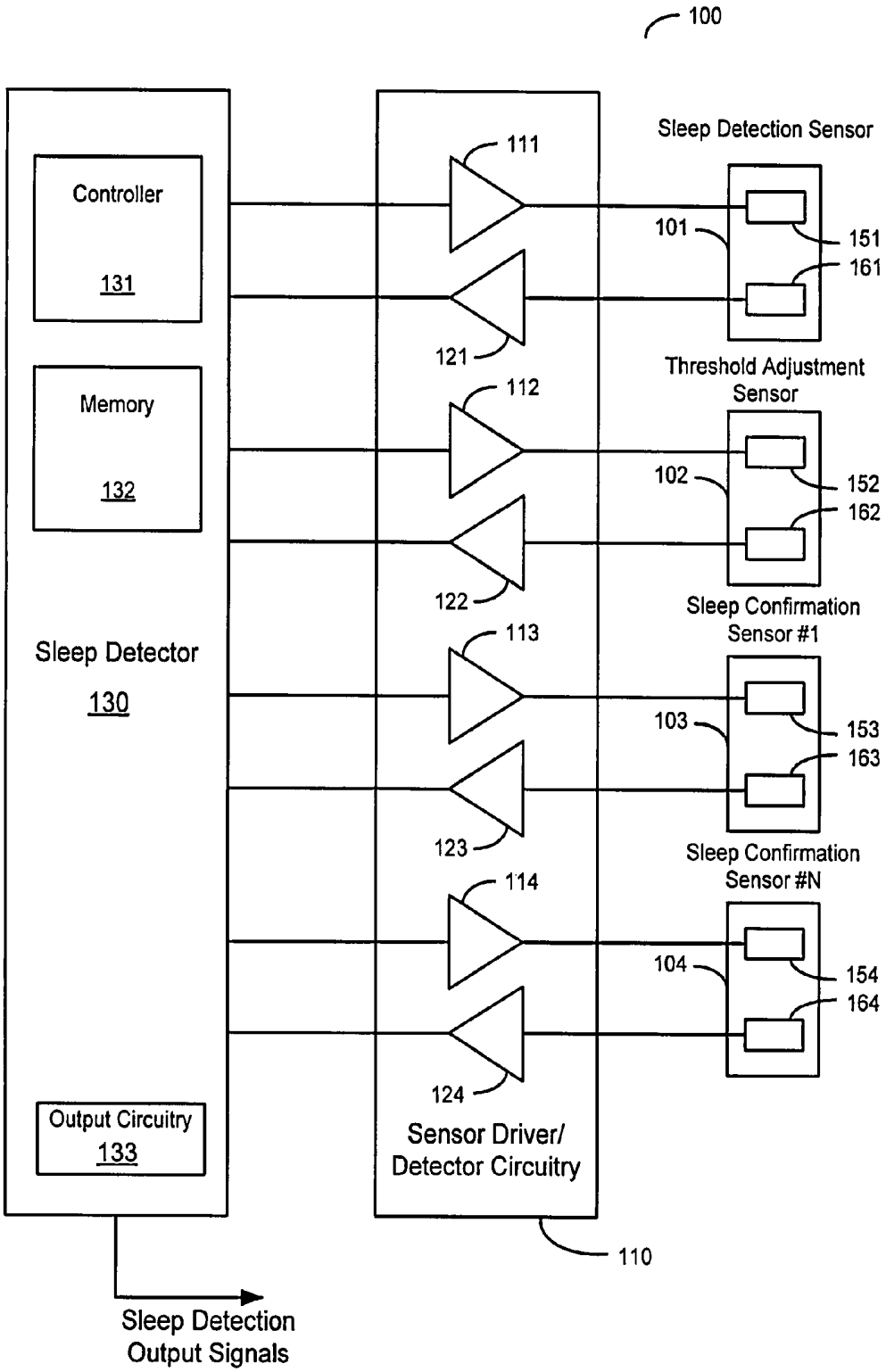
| | | |
|---|---|---|
| EP | 1 317 943 A | 6/2003 |
| JP | 2002519161 | 7/2002 |
| WO | WO0001438 | 1/2000 |
| WO | WO 00/17615 | 3/2000 |
| WO | WO0240096 | 5/2002 |
| WO | WO02087433 | 11/2002 |
| WO | WO00363954 | 8/2003 |
| WO | WO2004062485 | 7/2004 |
| WO | WO2005028029 | 3/2005 |

## OTHER PUBLICATIONS

U.S. Appl. No. 10/309,771, filed Dec. 4, 2002, Ni et al.
U.S. Appl. No. 10/643,154, filed Aug. 18, 2003, Stahmann et al.
U.S. Appl. No. 10/643,203, filed Aug. 18, 2003, Stahmann et al.
U.S. Appl. No. 11/890,404, filed Aug. 6, 2007, Ni et al.
2001, Balaban et al., *Feasibility of Screening for Sleep Apnea Using Pacemaker Impedance Sensor*, NASPE 22nd Annual Scientific Sessions, Apr. 2001, vol. 24, No. 4, Part II, #313, 1 page, Abstract Only.
Garrigue et al., *Night Atrial Overdrive with DDD Pacing Results in a Significant Reduction of Sleep Apnea Episodes and QOL Improvement in Heart Failure Patients*, NASPE, 2001, 1 page, #145, Abstract Only.
2000, Garrigue et al., *Night Atrial Overdrive with DDD Pacing: A New Therapy for Sleep Apnea Syndrome*, NASPE 21st Annual Scientific Sessions, Apr. 2000, vol. 23, No. 4, Part II, #591, 1 page, Abstract Only.
Ajilore et al., *Nightcap: Laboratory and home-based evaluation of a portable sleep monitor*, 32 Psychophysiology, 32-98 (1995). Abstract only.
Garrigue et al., *Benefit of Atrial Pacing in Sleep Apnea Syndrome*, 346 N. Engl. J. Med. 404-412, 2002.
Japanese Office Action dated Aug. 2, 2010 from Japanese patent application No. 2004557545, 2 pages, transl.
Japanese Office Action dated Dec. 13, 2010 from Japanese patent application No. 2006-524027, 4 pages, transl.
Notice of Allowance dated Feb. 14, 2007 from U.S. Appl. No. 10/309,770, 7 pages.
Office Action Response dated Nov. 27, 2006 from U.S. Appl. No. 10/309,770, 16 pages.
Office Action dated Aug. 25, 2006 from U.S. Appl. No. 10/309,770, 8 pages.
Office Action Response dated Jun. 5, 2006 from U.S. Appl. No. 10/309,770, 10 pages.
Office Action dated Apr. 3, 2006 from U.S. Appl. No. 10/309,770, 5 pages.
Office Action Response dated Jan. 12, 2006 from U.S. Appl. No. /309,770, 10 pages.
Office Action dated Dec. 15, 2005 from U.S. Appl. No. 10/309,770, 5 pages.
Notice of Allowance dated Aug. 22, 2006 from U.S. Appl. No. 10/309,771, 4 pages.
Office Action Response dated Aug. 4, 2006 from U.S. Appl. No. 10/309,771, 15 pages.
Office Action dated Apr. 4, 2006 from U.S. Appl. No. 10/309,771, 5 pages.
Office Action Response dated Jan. 12, 2006 from U.S. Appl. No. 10/309,771, 10 pages.

Office Action dated Dec. 15, 2005 from U.S. Appl. No. 10/309,771, 5 pages.
Office Action dated Jan. 6, 2010 from U.S. Appl. No. 11/890,404, 6 pages.
Office Action Response dated Sep. 29, 2009 from U.S. Appl. No. 11/890,404, 8 pages.
Office Action dated Sep. 1, 2009 from U.S. Appl. No. 11/890,404, 6 pages.
Examiner's Answer dated Mar. 4, 2009 from U.S. Appl. No. 10/920,675, 6 pages.
Appeal Brief dated Dec. 9, 2008 from U.S. Appl. No. 10/920,675, 36 pages.
Pre-Appeal Brief dated Sep. 8, 2008 from U.S. Appl. No. 10/920,675, 5 pages.
Office Action Response dated Jun. 16, 2008 from U.S. Appl. No. 10/920,675, 12 pages.
Office Action dated Apr. 14, 2008 from U.S. Appl. No. 10/920,675, 6 pages.
Office Action Response dated Jan. 27, 2007 from U.S. Appl. No. 10/920,675, 15 pages.
Office Action dated Oct. 27, 2006 from U.S. Appl. No. 10/920,675, 6 pages.
Office Action dated Jul. 14, 2006 from European Application No. 04781543.6, 3 pages.
Office Action Response dated Nov. 16, 2006 from European Application No. 04781543.6, 6 pages.
Office Action dated Feb. 8, 2007 from European Application No. 04781543.6, 3 pages.
Office Action Response dated Aug. 6, 2007 from European Application No. 04781543.6, 12 pages.
Office Action dated May 9, 2007 from European Application No. 04784602.7, 3 pages.
Office Action Response dated Apr. 17, 2008 from European Application No. 04784602.7, 10 pages.
Office Action dated Mar. 12, 2007 from European Application No. 03790294.7, 9 pages.
Office Action Response dated Sep. 21, 2007 from European Application No. 03790294.7, 13 pages.
Office Action dated Mar. 12, 2010 from European Application No. 03790294.7, 4 pages.
Office Action dated Feb. 22, 2006 from European Application No. 03790304.4, 3 pages.
Office Action Response dated Sep. 4, 2006 from European Application No. 03790304.4, 9 pages.
International Search Report and Written Opinion dated Dec. 4, 2003 from International Application No. PCT/US03/38438, 10 pages.
International Search Report and Written Opinion dated Dec. 6, 2004 from International Application No. PCT/US2004/026883, 15 pages.
International Preliminary Report on Patentability dated Mar. 2, 2006 from International Application No. PCT/US2004/026883, 9 pages.
File History for EP Application No. 03790294.7 as retrieved from the European Patent Office Electronic File System on May 26, 2011, 250 pages.
International Search Report dated Dec. 22, 2004 from PCT Application No. PCT/US2004/030787, 8 pages.
International Search Report dated Jul. 26, 2004 from PCT Application No. PCT/US2003/038438, 10 pages.
Office Action Response dated Apr. 27, 2010 from European Application No. 03790294.7, 8 pages.
Office Action dated Aug. 6, 2007 from European Application No. 03790304.4, 6 pages.
File History for U.S. Appl. No. 10/643,006 as retrieved from U.S. Patent and Trademark Office on Jul. 28, 2011, 447 pages.
File History for U.S. Appl. No. 10/643,006 as retrieved from U.S. Patent and Trademark Office on Jan. 12, 2012, 499 pages.
Hilton et al., "Evaluation of Frequency and Time-frequency Spectral Analysis of Heart Rate Variability as a Diagnostic Marker of the Sleep Apnea Syndrome." Med Biol Eng Comput Nov. 1999, 37(6), 760-9.
File History for EP Application No. 03790304.4 as retrieved from the European Patent Office Electronic File System on Jun. 5, 2012, 105 pages.
File History for U.S. Appl. No. 10/309,771.
File History for U.S. Appl. No. 10/643,006.
File History for U.S. Appl. No. 10/920,675.
File History for U.S. Appl. No. 12/847,711.
Office action translation dated Mar. 5, 2010 from JP Application No. 2004-557558, 3 pages.
Office action translation dated Jul. 14, 2010 from JP Application No. 2004-557558, 2 pages.

* cited by examiner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Controller
131
Memory
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Sleep Detector
130
Output Circuitry
133
Sleep Detection
Output Signals
111
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112
122
113
123
114
124
Sensor Driver/
Detector Circuitry
110
Sleep Detection Sensor
101
151
161
Threshold Adjustment
Sensor
102
152
162
Sleep Confirmation
Sensor #1
103
153
163
Sleep Confirmation
Sensor #N
104
154
164

Figure 1

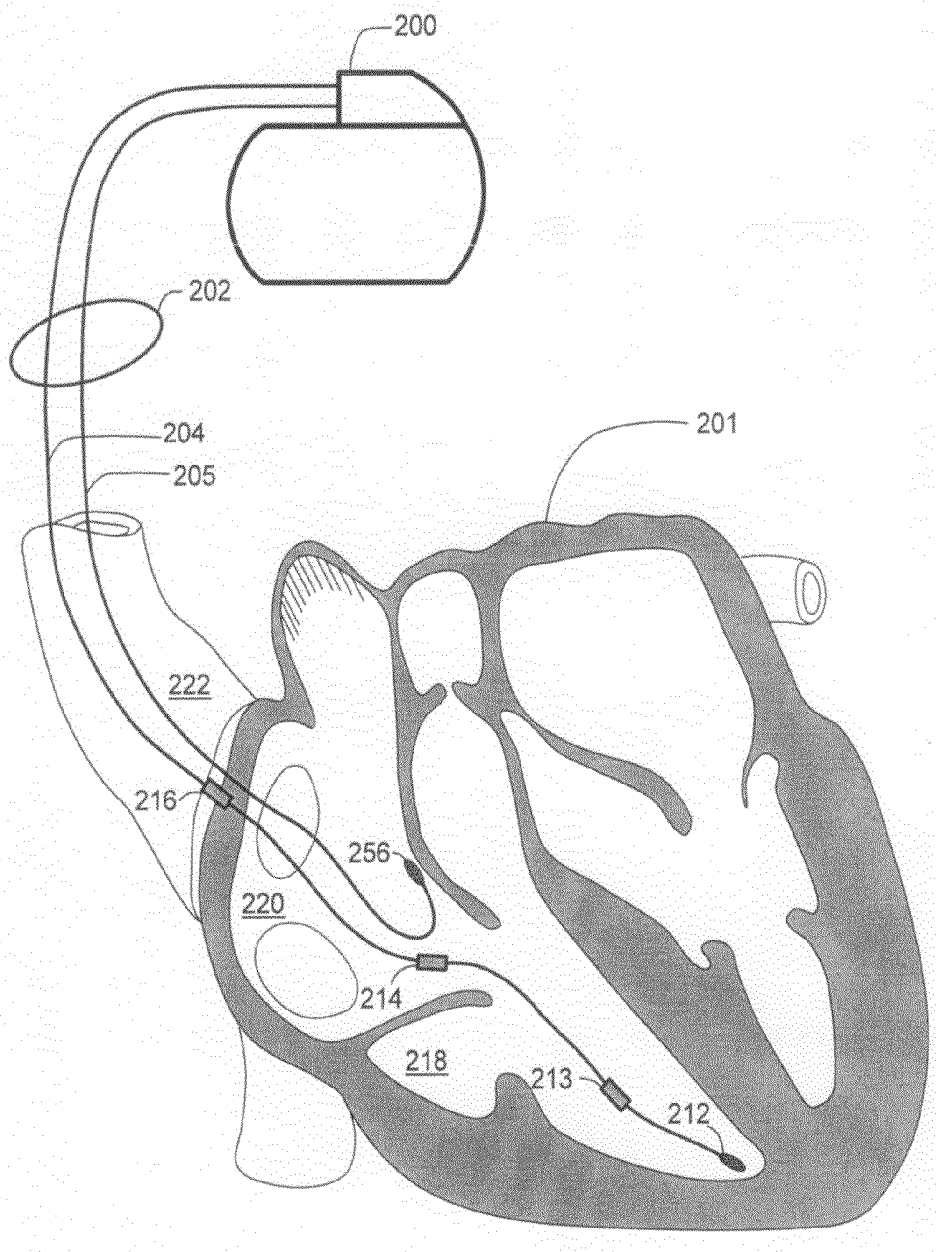
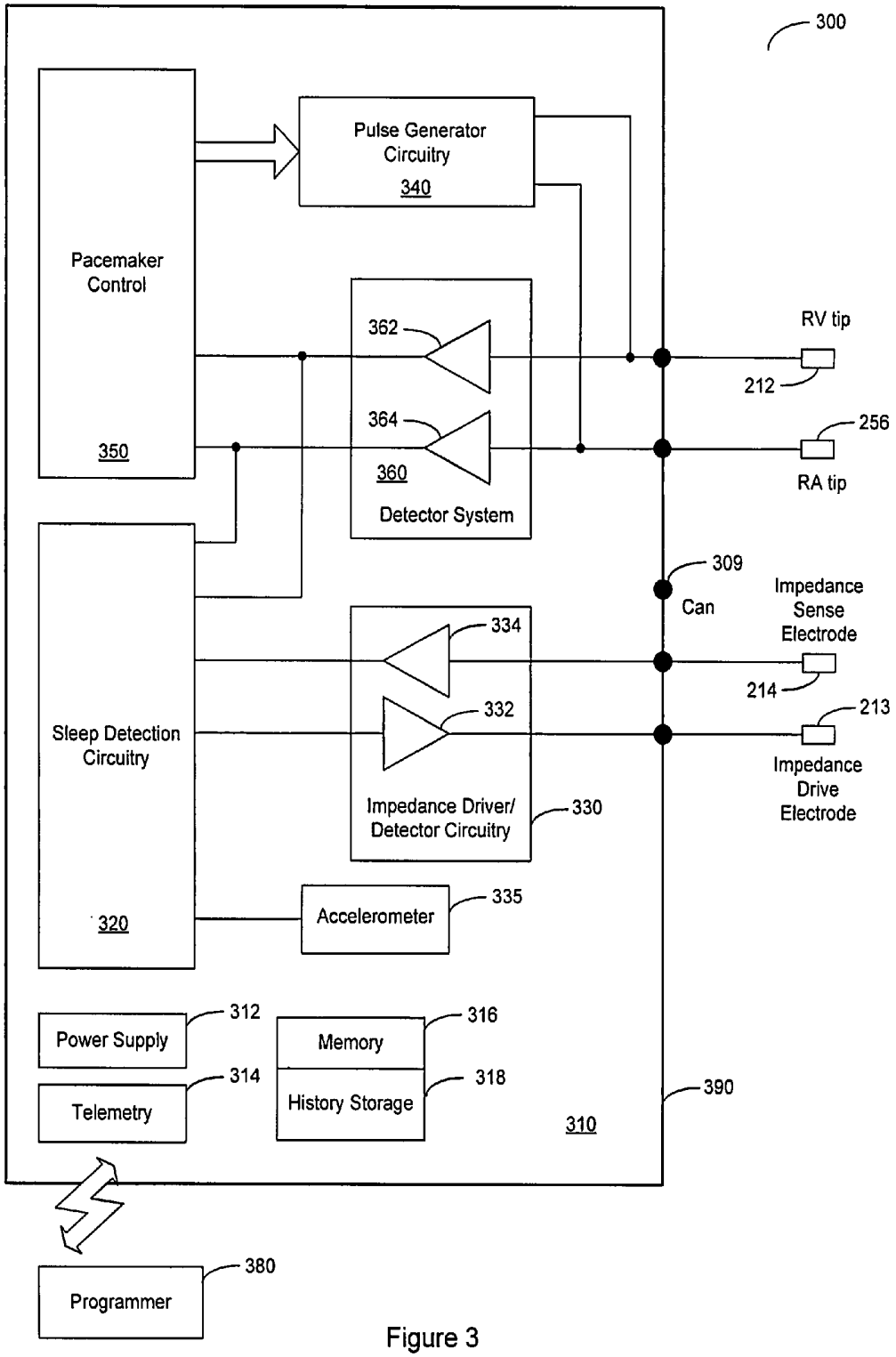



Figure 2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Pacemaker Control
350
Pulse Generator Circuitry
340
362
364
360
Detector System
RV tip
212
256
RA tip
309
Can
Impedance Sense Electrode
214
213
Impedance Drive Electrode
334
332
Impedance Driver/ Detector Circuitry
330
Sleep Detection Circuitry
320
Accelerometer
335
Power Supply
312
Telemetry
314
Memory
316
History Storage
318
310
390
Programmer
380

Figure 3

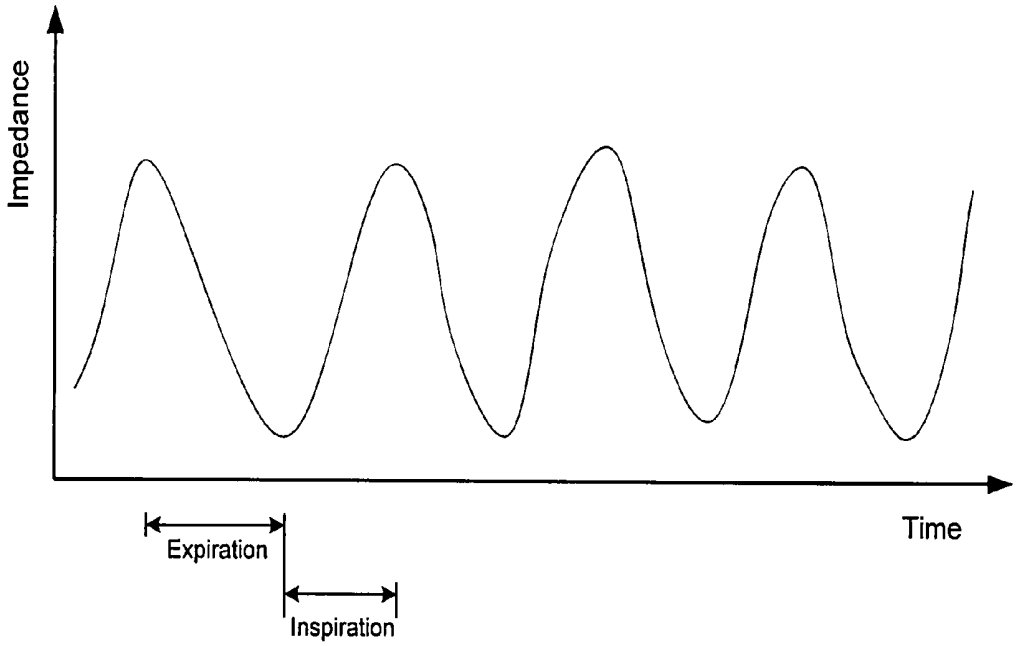



Figure 4

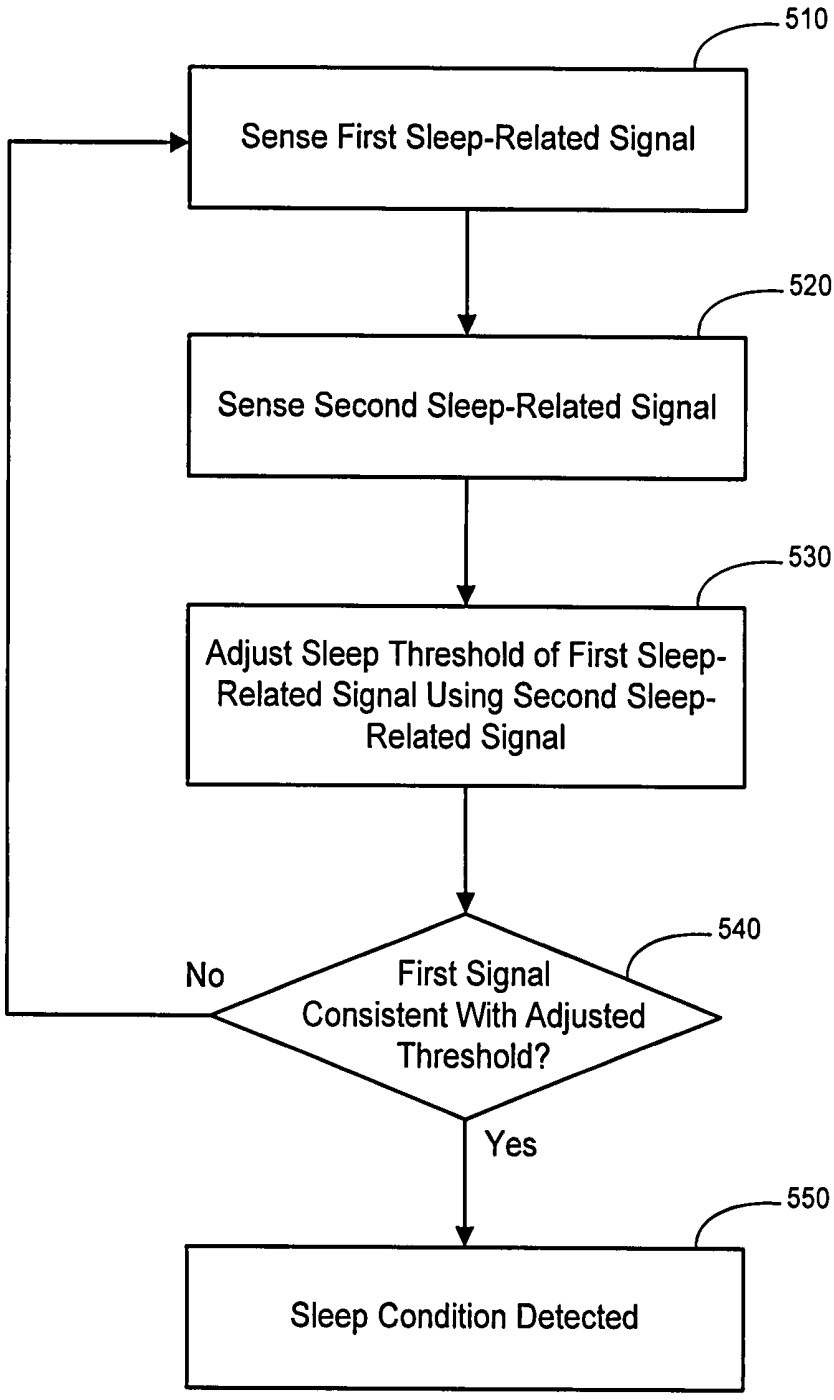

510
Sense First Sleep-Related Signal
520
Sense Second Sleep-Related Signal
530
Adjust Sleep Threshold of First Sleep-Related Signal Using Second Sleep-Related Signal
540
First Signal Consistent With Adjusted Threshold?
No
Yes
550
Sleep Condition Detected

Figure 5

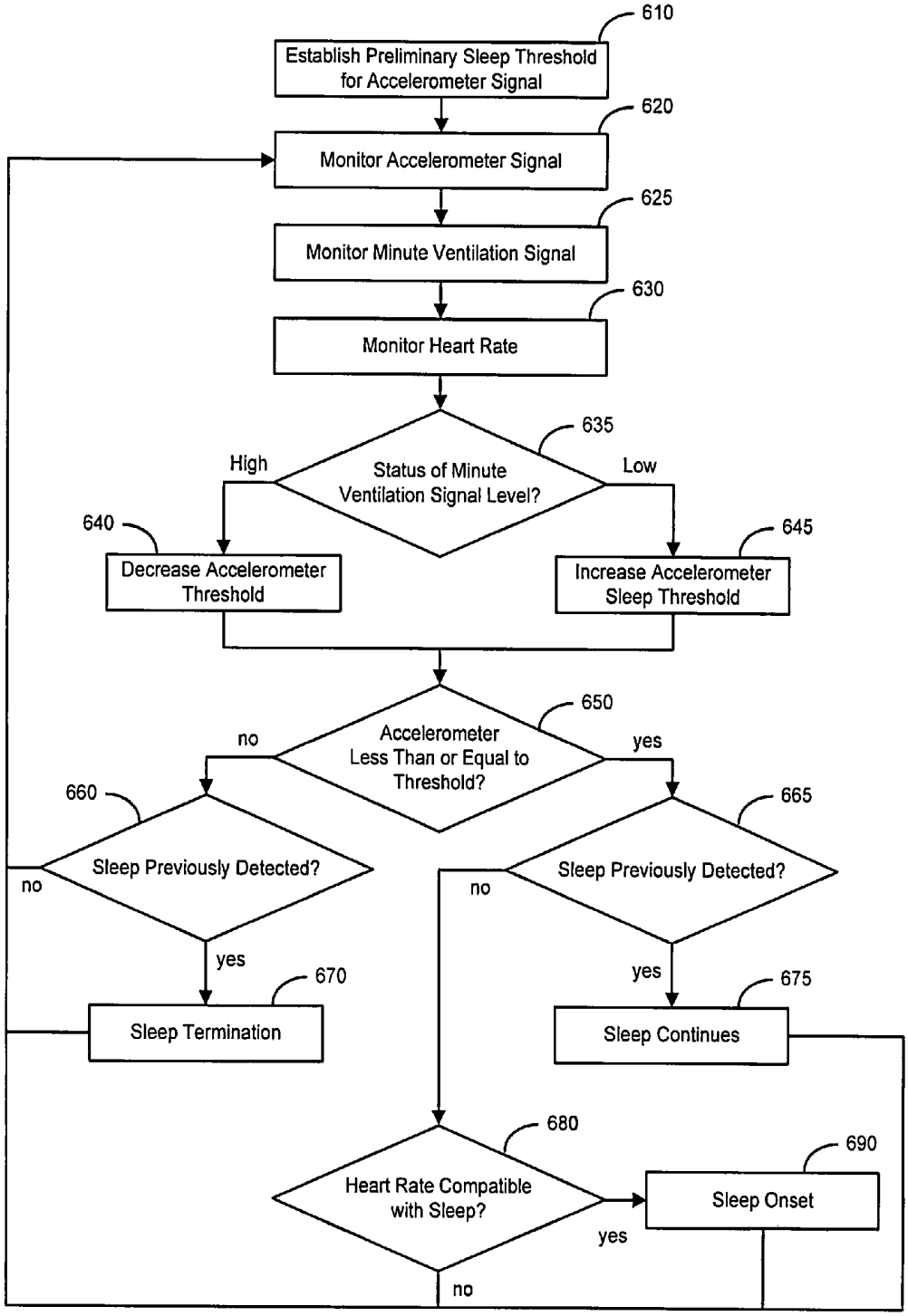

610
Establish Preliminary Sleep Threshold for Accelerometer Signal
620
Monitor Accelerometer Signal
625
Monitor Minute Ventilation Signal
630
Monitor Heart Rate
635
Status of Minute Ventilation Signal Level?
High
Low
640
Decrease Accelerometer Threshold
645
Increase Accelerometer Sleep Threshold
650
Accelerometer Less Than or Equal to Threshold?
no
yes
660
Sleep Previously Detected?
no
yes
665
Sleep Previously Detected?
no
yes
670
Sleep Termination
675
Sleep Continues
680
Heart Rate Compatible with Sleep?
yes
690
Sleep Onset
no

Figure 6

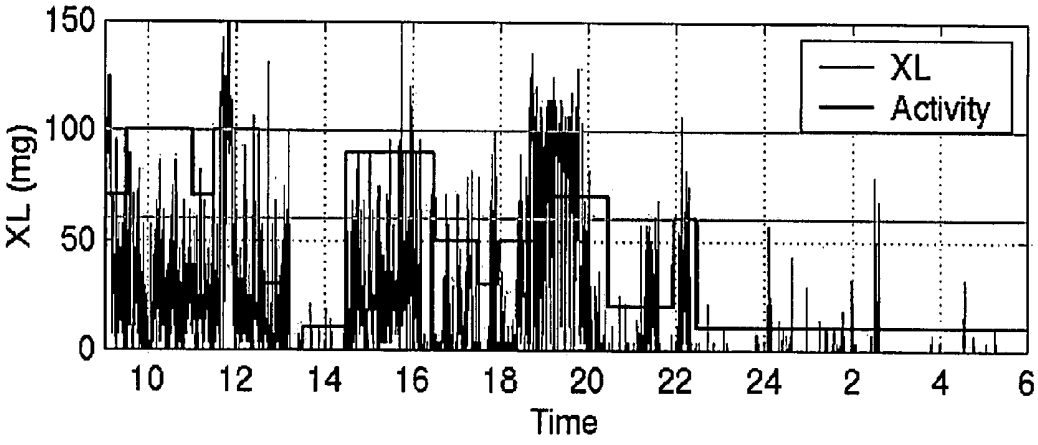



Figure 7A

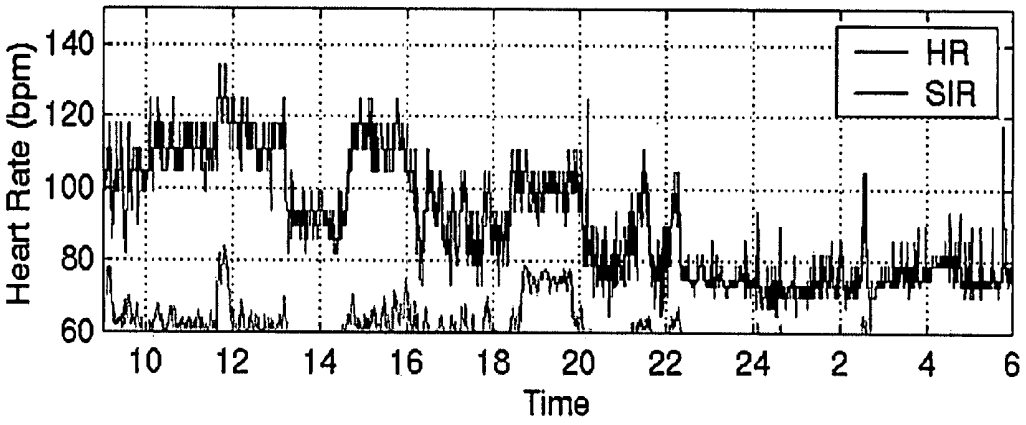
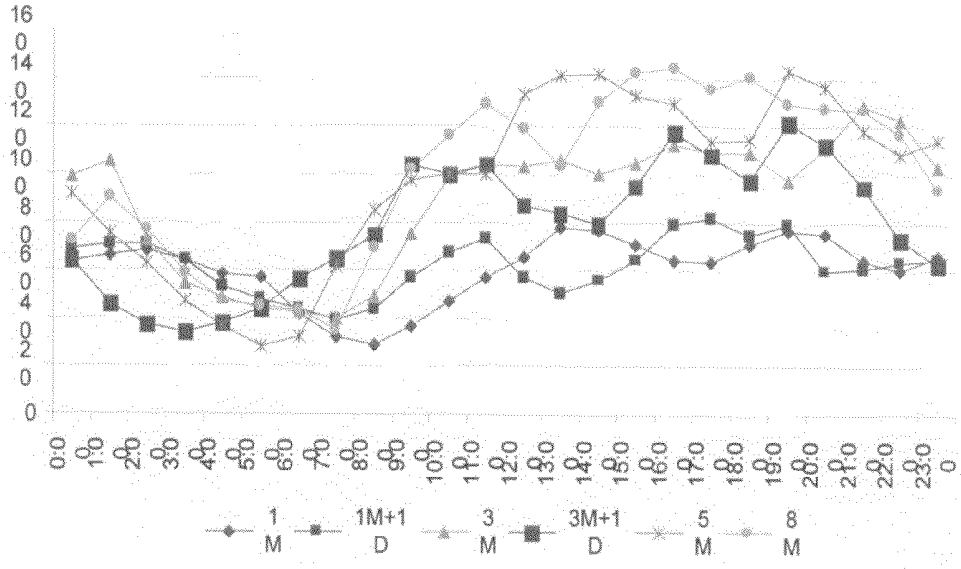

Heart Rate (bpm)
140
120
100
80
60
10
12
14
16
18
20
22
24
2
4
6
Time
HR
SIR

Figure 7B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12
10
8
6
4
2
0
0:0
1:0
2:0
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5:0
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7:0
8:0
9:0
10:0
11:0
12:0
13:0
14:0
15:0
16:0
17:0
18:0
19:0
20:0
21:0
22:0
23:0
0
1 M
1M+1 D
3 M
3M+1 D
5 M
8 M

Figure 8

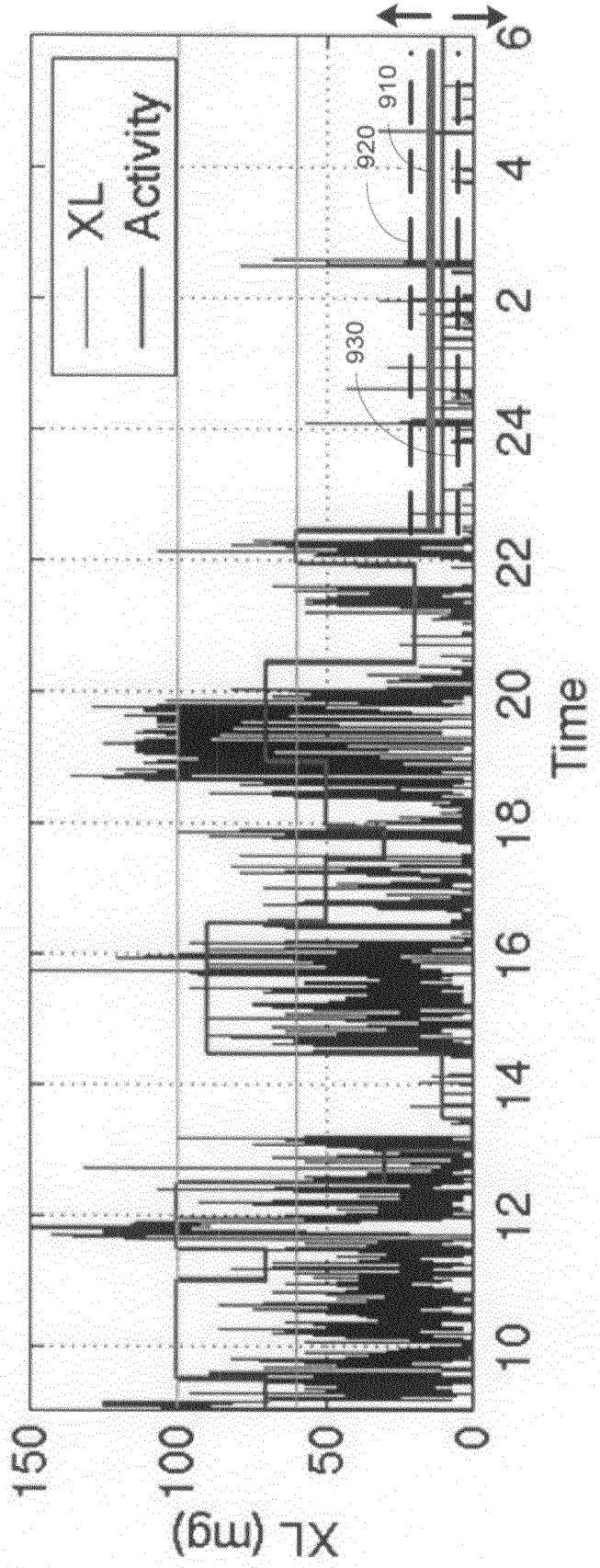
XL
Activity
910
920
930
XL (mg)
150
100
50
0
10
12
14
16
18
20
22
24
2
4
6
Time

Figure 9

# SLEEP DETECTION USING AN ADJUSTABLE THRESHOLD

## RELATED PATENT DOCUMENTS

This is a division of patent application Ser. No. 10/309,771, filed on Dec. 4, 2002, now U.S. Pat. No. 7,189,204, to which Applicant claims priority under 35 U.S.C. §120, and which is incorporated herein by reference.

## FIELD OF THE INVENTION

The present invention relates generally to sleep detection and, more particularly, to detecting sleep by adjusting a sleep threshold associated with a first sleep-related signal using a second sleep-related signal.

## BACKGROUND OF THE INVENTION

Sleep is generally beneficial and restorative to a patient, exerting great influence on the quality of life. A typical night's sleep for a normal person begins with a sleep stage known as slow wave sleep (SWS) characterized by low frequency electroencephalogram (EEG) activity. As the person falls asleep, brain activity declines and there is a progressive increase in the depth of sleep. At approximately ninety minute intervals, sleep lightens and a sleep stage known as rapid eye movement (REM) sleep is initiated. REM sleep is characterized by high frequency EEG activity, bursts of rapid eye movements, skeletal muscle atonia, and heightened autonomic activity.

There are typically 4-6 REM periods per night, with increasing duration and intensity toward morning. While dreams can occur during either REM or SWS sleep, the nature of the dreams varies depending on the type of sleep. REM sleep dreams tend to be more vivid and emotionally intense than SWS sleep dreams. Furthermore, autonomic nervous system activity is dramatically altered when REM sleep is initiated.

In patients with respiratory or heart disease, the brain during sleep can precipitate breathing disturbances, myocardial ischemia, or arrhythmia. Although REM sleep is a necessary component of normal sleep, serious consequences may be associated with both the increase in autonomic activity and the intense emotional responses that accompany dreaming in patients with cardiovascular disease or respiratory disorders, for example.

Disruptions of the respiratory system during sleep may include the conditions of sleep apnea or sleep hypopnea. Sleep apnea is a serious breathing disorder caused by airway obstruction, denoted obstructive sleep apnea, or derangement in central nervous system control of respiration, denoted central sleep apnea. Regardless of the type of apnea, people with sleep apnea stop breathing repeatedly during their sleep, sometimes hundreds of times a night and often for a minute or longer. Whereas sleep apnea refers to cessation of breathing, hypopnea is associated with periods of abnormally slow or shallow breathing. With each apnea or hypopnea event, the person generally briefly arouses to resume normal breathing. As a result, people with sleep apnea or hypopnea may experience sleep fragmented by frequent arousals.

An adequate quality and quantity of sleep is required to maintain physiological homeostasis. Prolonged sleep deprivation or periods of highly fragmented sleep ultimately will have serious health consequences. Chronic lack of sleep may be associated with various cardiac or respiratory disorders affecting a patient's health and quality of life.



## SUMMARY OF THE INVENTION

The present invention is directed to detecting sleep. In one embodiment of the invention, a device for detecting sleep includes a first sensor for sensing a first sleep-related signal and a second sensor for sensing a second sleep-related signal, wherein the first and the second sleep-related signals are indicative of sleep. A sleep detector coupled to the first and the second sensors is configured to adjust a sleep threshold associated with the first sleep-related signal using the second sleep-related signal. The sleep detector detects a sleep condition by comparing the first sleep-related signal with the adjusted threshold. A component of one or more of the sleep detector, first sensor, and second sensor is implantable.

In accordance with another embodiment of the present invention, a method for sleep detection involves adjusting a sleep threshold associated with a first sleep-related signal using a second sleep-related signal. The first sleep-related signal is compared to the adjusted threshold and sleep is detected based on the comparison.

Yet another embodiment of the invention includes means for adjusting a sleep threshold of a first sleep-related signal using a second sleep-related signal, means for comparing the first sleep-related signal to the adjusted threshold, and means for detecting sleep based on the comparison.

In a further embodiment of the invention, a method for detecting sleep includes sensing a plurality of sleep-related signals. A relationship is defined between at least two of the sleep-related signals, the relationship associated with sleep detection. Sleep is detected using the sleep-related signal relationship. At least one of the sensing and detecting is performed at least in part implantably.

The above summary of the 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 block diagram of a sleep detection device in accordance with an embodiment of the invention;

FIG. **2** is a partial view of one embodiment of an implantable medical device that may be used for sleep detection in accordance with an embodiment of the invention;

FIG. **3** is a system block diagram of an implantable medical device with which sleep detection may be implemented in accordance with an embodiment of the invention;

FIG. **4** is a graph of blood impedance used in connection with sleep detection according to an embodiment of the invention;

FIG. **5** is a flow graph illustrating a method of detecting sleep according to an embodiment of the invention;

FIG. **6** is a flow graph illustrating a method of detecting sleep using an accelerometer and a minute ventilation sensor according to an embodiment of the invention;

FIG. **7**A is a graph of an accelerometer signal indicating patient activity over time that may be used to implement a sleep detection method in accordance with an embodiment of the present invention;

FIG. **7**B is a graph of a heart rate signal indicating patient activity over time that may be used to implement a sleep detection method in accordance with an embodiment of the present invention;

FIG. **8** is a graph of a minute ventilation signal indicating patient respiration that may be used to implement a sleep detection method in accordance with an embodiment of the present invention; and

FIG. **9** is a graph illustrating adjustment of an accelerometer sleep threshold using an MV signal in accordance with an embodiment 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 which form 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.

An adequate duration and quality of sleep is required to maintain sleep-related homeostasis. Prolonged sleep deprivation or periods of poor quality sleep ultimately will have serious health consequences. To diagnose the reasons for sleep disturbances, people suffering from sleep disorders may spend one or more nights in a sleep laboratory. In a sleep laboratory, a patient is typically instrumented for data acquisition and observed by trained personnel. Sleep assessment in a laboratory setting presents a number of obstacles in acquiring an accurate picture of a patient's typical sleep patterns. For example, spending a night in a sleep laboratory typically causes a patient to experience a condition known as "first night syndrome," involving disrupted sleep during the first few nights in an unfamiliar location. Furthermore, sleeping while instrumented and observed may not result in a realistic perspective of the patient's normal sleep patterns.

Sleep quality assessments depend upon acquiring data regarding a patient's typical sleep patterns. An initial step to sleep quality assessment is an accurate and reliable method for recognizing that a patient is asleep. Detecting the onset, termination, duration, stages, and quality of sleep experienced by a patient may be used in connection with the treatment of various conditions. For example, detection of disordered breathing during sleep may be helpful in delivering appropriate therapy for patients suffering from sleep disorders ranging from snoring to sleep apnea. Furthermore, trending sleep data over a long term, including number and severity of disordered breathing episodes, arousal episodes or periods of disturbed sleep, may provide insight into the emotional and physical health of a patient. For example, knowledge of sleep patterns may influence a number of aspects of patient therapy including cardiac or respiratory therapy.

In the context of cardiac rhythm management (CRM) therapy, for example, it may be advantageous to regulate the lower rate limit of a pacemaker based on recognition of sleep or non-sleep states. Adjustment of the lower rate limit to accommodate periods of sleep may improve the quality of the patient's sleep in addition to lengthening battery life of the CRM device. Furthermore, arrhythmia therapy may be improved with sleep recognition. The periods of arousal from REM sleep have been associated with an increased likelihood of arrhythmia for patients with heart disease. Therefore, the ability to recognize sleep may enhance the ability to predict and detect arrhythmias associated with sleep and to provide anti-arrhythmia therapy during sleep.

Respiratory therapy may also be enhanced by a method for accurately recognizing a sleep state. Sleep apnea treatments may include positive airway pressure devices that supply a steady or adjustable flow of air to the patient during sleep, periodic electrical stimulation of the hypoglossal nerve to open the upper airways, and cardiac atrial overdrive pacing to suppress sleep apnea events or awaken the patient to terminate an apneic event. Each of these methods, as well as methods for treating respiratory disorders, may be improved by reliable detection that the patient is sleeping.

Various embodiments of the invention involve detecting sleep using signals associated with a condition of sleep. One embodiment of the invention involves adjusting a sleep threshold associated with a first sleep-related signal using a second sleep-related signal. The first sleep-related signal is compared to the adjusted threshold and sleep is detected based on the comparison. At least one of sensing the sleep-related signals, comparing the first sleep-related signal to the sleep threshold, and detecting sleep is performed at least in part implantably.

Another embodiment of the invention involves defining a relationship between two or more sleep-related signals. The relationship is associated with sleep detection. Sleep is detected using the relationship. Sensing the sleep-related signals and/or detecting sleep is performed at least in part implantably.

Defining a relationship includes, for example, establishing a sleep criterion associated with at least one of the sleep-related signals. The criterion may be, for example, a threshold or other index related to the condition of sleep. Detection of sleep involves comparing the sleep criterion to the state of one or more of the sleep-related signals.

According to one embodiment of the invention, the sleep-related signals may be derived from external or implantable sensors and analyzed by an external sleep detector. Some or all of the sensors may have remote communication capabilities, such as a wireless Bluetooth communications transmitter or transceiver, to link them to the sleep detector.

According to another embodiment of the invention, the sleep-related signals may be derived from external or implantable sensors and analyzed by an implantable device. The sleep detector may be a component of a device that also performs other functions, such as cardiac pacemaker or defibrillation functions. Some or all of the sensors may be wirelessly coupled to the implantable device by telemetry, for example.

According to an embodiment of the present system, methods of sleep detection may be implemented in an implantable cardiac rhythm management (CRM) system configured as a dual chamber pacemaker device which may operate in numerous pacing modes known in the art. The systems and methods of the present invention may also be implemented in various types of implantable or external diagnostic medical devices including, for example, polysomnography devices, respiratory monitors, and cardiac monitors. In addition, the systems and methods of the present invention may be implemented in a number of implantable or external therapeutic medical devices such as continuous positive airway pressure (CPAP) devices or hypoglossal nerve stimulators.

FIG. **1** is a block diagram of a sleep detection device **100** that may be used to detect sleep in accordance with an embodiment of the invention. The sleep detection device

includes a number of sensors **101**, **102**, **103**, **104**, including electrodes **151**, **152**, **161**, **162**, **153**, **163**, **154**, and **164**, that sense sleep-related signals associated with sleep. A representative set of sensed sleep-related signals associated with sleep include body movement, heart rate, QT interval, eye movement, respiration rate, transthoracic impedance, tidal volume, minute ventilation, body posture, electroencephalogram (EEG), electrocardiogram (ECG), electrooculogram (EOG), electromyogram (EMG), muscle tone, body temperature, time of day, historical sleep times, blood pressure, and pulse oximetry.

A first sleep-related signal derived from a sleep detection sensor **101** is a signal associated with sleep that is compared to a sleep threshold for detecting the onset and termination of sleep. A second sleep-related signal derived from a threshold adjustment sensor **102** is used to adjust the sleep threshold. Although one sleep detection sensor and one threshold adjustment sensor are shown in FIG. **1**, any number of thresholds or other indices corresponding to a number of sleep detection sensors may be used. Furthermore, signals from any number of adjustment sensors may be used to adjust the thresholds or indices of a plurality of sleep detection signals. Additional sleep-related signals derived from confirmation sensors **103**, **104** may optionally be used to confirm the onset or termination of the sleep condition.

The sleep-related signals derived from the sensors **101**, **102**, **103**, **104** are received by a sensor driver/detector system **110** which includes detection circuitry **121**, **122**, **123**, **124**. The detection circuitry **121**, **122**, **123**, **124** may include, for example, amplifiers, signal processing circuitry, and/or A/D conversion circuitry for each sensor signal. The sensor driver/detector system **110** may further include sensor drive circuitry **111**, **112**, **113**, **114** required to activate the sensors **101**, **102**, **103**, **104**.

A sleep detector **130**, according to certain embodiments, transmits control signals to the drive circuitry **111**, **112**, **113**, **114** and receives signals from the detection circuitry **121**, **122**, **123**, **124**. The sleep detector **130** may include a microprocessor controller **131** which cooperates with memory circuitry **132** for implementing sleep detection methods of the present invention. The memory circuitry **132** may be used to store program data to implement sleep detection, to store parameters associated with sleep detection, such as a sleep threshold, or to store historical data regarding sleep onset and termination over a selected period.

The sleep detector **130** is configured to compare the level of a first sleep-related signal to a sleep threshold adjusted by a second sleep-related signal and determine sleep onset or termination based on the comparison. The sleep detector **130** may use one or more thresholds or indices associated with one or more sleep-related signals. In addition, the sleep detector **130** may use one or more sleep-related signals to adjust the sleep thresholds or indices. Furthermore, the sleep detector **130** may confirm the onset or termination of sleep using an additional number of sleep-related signals.

The sleep detector **130** may include output circuitry **133** for communicating various signals associated with sleep to another device, to other components of a sleep detection device, a data storage device and/or a display device. The signals associated with sleep may include, for example, a sleep detection signal, parameters associated with sleep detection, such as a sleep threshold, and/or historical data relevant to sleep (e.g., historical sleep time data or an average of same which can be used to establish a sleep threshold). The sleep detector may communicate with another device over a wired or wireless communication channel, for example.

The sensors **101**, **102**, **103**, **104** may comprise implantable sensors or external sensors. In one embodiment, the sensors **101**, **102**, **103**, **104** are coupled to the sensor driver/detector circuitry **110** and thus to the sleep detector **130** through a wired connection. In another embodiment, the sensors **101**, **102**, **103**, **104** and sensor driver/detector circuitry **110** are incorporated into sensing devices that include wireless communication capabilities, e.g., a Bluetooth transmitter or transceiver, and may be coupled to the sleep detector **130** through a wireless link. The sleep detector **130** and/or sensor driver/detector circuitry **110** may be incorporated into an implantable or external device.

FIG. **2** is a partial view of one embodiment of an implantable medical device that may be used for sleep detection in accordance with the principles of the invention. The implantable device illustrated in FIG. **2** is a cardiac rhythm management (CRM) system that includes an implantable pacemaker **200** electrically and physically coupled to an intracardiac lead system **202**. The intracardiac lead system **202** is implanted in a human body with portions of the intracardiac lead system **202** inserted into a heart **201**. The intracardiac lead system **202** is used to detect and analyze electric cardiac signals produced by the heart **201** and to provide electrical energy to the heart **201** under predetermined conditions to treat cardiac arrhythmias of the heart **201**.

The CRM **200** depicted in FIG. **2** is a dual chamber device, capable of sensing signals from the right atrium and right ventricle and providing pacing pulses to the right atrium and the right ventricle. Low energy pacing pulses may be delivered to the heart to regulate the heart beat or maintain a lower rate heart beat, for example. In a configuration that includes cardioversion/defibrillation capabilities, high energy pulses may also be delivered to the heart if an arrhythmia is detected that requires cardioversion or defibrillation.

The intracardiac lead system **202** includes a right ventricular lead system **204** and a right atrial lead system **205**. The right ventricular lead system **204** includes an RV-tip pace/sense electrode **212** and one or more electrodes **213**, **214**, **216** suitable for measuring transthoracic impedance. In one arrangement, impedance sense and drive electrodes **216**, **214**, **213** are configured as ring electrodes. The impedance drive electrode **213** may be located, for example, in the right ventricle **218**. The impedance sense electrode **214** may be located in the right atrium **220**. Alternatively or additionally, an impedance sense electrode **216** may be located in the superior right atrium **220** or near the right atrium **220** within the superior vena cava **222**.

A two-electrode impedance sensing configuration is also possible, wherein the right ventricular lead system includes an impedance drive electrode **213** and a tip electrode **212**. In this configuration, the tip electrode **212** may be used as the impedance sense electrode as well as a cardiac sense/pace electrode. Other locations and combinations of impedance sense and drive electrodes are also possible.

The atrial lead system **205** includes an A-tip cardiac pace/sense electrode **256**.

In the configuration of FIG. **2**, the intracardiac lead system **202** is positioned within the heart **201**, with a portion of the atrial lead system **205** extending into the right atrium **220** and portions of the right ventricular lead system **204** extending through the right atrium **220** into the right ventricle **218**. The A-tip electrode **256** is positioned at an appropriate location within the right atrium **220** for pacing the right atrium **220** and sensing cardiac activity in the right atrium **220**. The RV-tip electrode **212** is positioned at appropriate locations within the right ventricle **218** for pacing the right ventricle **218** and sensing cardiac activity in the right ventricle **218**.

Additional configurations of sensing, pacing and defibrillation electrodes can be included in the intracardiac lead system to allow for various sensing, pacing, and defibrillation capabilities of multiple heart chambers. In one configuration, the right ventricular and right atrial leads may include additional electrodes for bipolar sensing and/or pacing, for example. Further, the right ventricular and right atrial leads may also include additional electrodes for cardioversion or defibrillation.

In other configurations, the intracardiac lead system may have only a single lead with electrodes positioned in the right atrium or the right ventricle to implement sleep detection and single chamber cardiac pacing. In yet other embodiments, the intracardiac lead system may include endocardial leads that are advanced into the coronary sinus and coronary veins to locate the distal electrode(s) adjacent to the left ventricle or the left atrium.

Other intracardiac lead and electrode arrangements and configurations known in the art are also possible and considered to be within the scope of the present system.

Referring now to FIG. **3**, there is shown a block diagram of an embodiment of a CRM system **300** configured as a pacemaker and suitable for implementing a sleep detection methodology of the present invention. FIG. **3** shows the CRM **300** divided into functional blocks. It will be understood by those skilled in the art that there exist many possible configurations in which these functional blocks can be arranged and implemented. The example depicted in FIG. **3** is one possible functional arrangement. The CRM **300** includes sleep detection circuitry **320** for receiving sleep-related signals and detecting sleep in accordance with an embodiment of the invention.

In one embodiment, sleep detection circuitry **320** is incorporated as part of the CRM circuitry **310** encased and hermetically sealed in a housing **390** suitable for implanting in a human body. Power to the CRM **300** is supplied by an electrochemical battery power supply **312** housed within the CRM **300**. A connector block (not shown) is additionally attached to the CRM housing **390** to allow for the physical and electrical attachment of the intracardiac lead system conductors to the CRM circuitry **310**.

The CRM circuitry **310** may be configured as a programmable microprocessor-based system, with circuitry for detecting sleep in addition to providing pacing therapy to the heart. Cardiac signals may be detected by the detector circuitry **360** and delivered to the pacemaker control system **350**. Pace pulses controlled by the pacemaker control **350** and generated by the pulse generator **340** are delivered to the heart to treat various arrhythmias of the heart.

The memory circuit **316** may store parameters for various device operations involved in sleep detection and/or cardiac pacing and sensing. The memory circuit **316** may also store data indicative of sleep-related signals received by components of the CRM circuitry **310**, such as the impedance drive/sense circuitry **330**, the cardiac signal detector system **360**, and the accelerometer **335**.

The sleep detection circuitry **320** receives signals derived from the cardiac signal detector system **360**, the impedance driver/detector circuitry **330** and the accelerometer **335** to perform operations involving detecting sleep onset and termination according to the principles of the present invention. Historical data storage **318** may be coupled to the sleep detection circuitry **320** for storing historical sleep related data. Such data may be transmitted to an external programmer unit **380** and used for various diagnostic purposes and as needed or desired.

Telemetry circuitry **314** is coupled to the CRM circuitry **310** to allow the CRM **300** to communicate with an external programmer unit **380**. In one embodiment, the telemetry circuitry **314** and the programmer unit **380** use a wire loop antenna and a radio frequency telemetric link to receive and transmit signals and data between the programmer unit **380** and telemetry circuitry **314**. In this manner, programming commands and data are transferred between the CRM circuitry **310** and the programmer unit **380** during and after implant.

The programming commands allow a physician to set or modify various parameters used by the CRM. These parameters may include setting sleep detection parameters for use during sleep detection, such as which sleep-related signals are to be used for sleep detection and threshold adjustment, and the initial sleep detection thresholds. In addition, the CRM system **300** may download to the programmer unit **380** stored data pertaining to sensed sleep periods, including the amount of time spent sleeping, the time of day sleep periods occurred, historical data on sleep times, and the number of arousals during the sleep periods, for example.

Signals associated with patient activity and posture may be detected through the use of an accelerometer **335** positioned within the housing **390** of the CRM **300**. The accelerometer responds to patient activity and the accelerometer signal may be correlated with activity level, workload and/or posture. Signals derived from the accelerometer **335** are coupled to the sleep detection circuitry **320** and may also be used by the pacemaker circuitry for implementing a rate adaptive pacing regimen, for example.

The impedance sense electrode **214**, the impedance drive electrode **213**, and the impedance driver/detector circuitry **330** are used to detect a voltage signal related to transthoracic impedance. The transthoracic impedance measurement may be used to calculate various parameters associated with respiration. Under the control of the sleep detection circuitry **320**, the impedance driver circuitry **332** produces a current that flows through the blood between the impedance drive electrode **213** and the can electrode **309**. The voltage at the impedance sense electrode **214** relative to the can electrode **309** changes as the transthoracic impedance changes. The voltage signal developed between the impedance sense electrode **214** and the can electrode **309** is detected by the impedance sense amplifier **334** located within the impedance driver/detector circuitry **330** and is delivered to the sleep detection circuitry **320** for further processing.

The voltage signal developed at the impedance sense electrode **214**, illustrated in FIG. **4**, is proportional to the transthoracic impedance, with the impedance increasing during respiratory inspiration and decreasing during respiratory expiration. The peak-to-peak transition of the impedance measurement, illustrated in FIG. **4**, is proportional to the amount of air inhaled in one breath, denoted the tidal volume. The impedance measurement may be further processed to determine the tidal volume, corresponding to the volume of air moved in a breath, or minute ventilation corresponding to the amount of air moved per minute.

In addition to impedance and accelerometer measurements, cardiac signals indicative of heart rate or other cardiac functions may also be used in connection with sleep detection. Turning back to FIG. **3**, cardiac signals are sensed through use of the RV-tip and RA-tip sense electrodes **212**, **256**. More particularly, the right ventricle signal may be detected as a voltage developed between the RV-tip electrode **212** and the can electrode **309**. Right ventricle cardiac signals are sensed and amplified by a right ventricle V-sense amplifier **362** located in the detector system **360**. The output of the right

ventricle V-sense amplifier **362** may be coupled, for example, to a signal processor and A/D converter within the detector system **360**. The processed right ventricle signals may be delivered to the pacemaker control **350** and the sleep detection circuitry **320**.

Right atrium cardiac signals are sensed and amplified by a right atrial A-sense amplifier **364** located in the detector system **360**. The output of the right atrium A-sense amplifier **364** may be processed by signal processing circuitry and received by the pacemaker control **350** and the sleep detection circuitry **320**.

The pacemaker control **350** communicates pacing control signals to the pulse generator circuitry **340** for delivering pacing stimulation pulses to the RV-tip and RA-tip electrodes **212** and **256**, respectively, according to a preestablished pacing regimen under appropriate conditions.

FIG. **5** illustrates a method of detecting sleep according to principles of the invention. A sleep threshold associated with a first sleep-related signal is established. The sleep threshold may be determined from clinical data of a sleep threshold associated with sleep acquired using a group of subjects, for example. The sleep threshold may also be determined using historical data taken from the particular patient for whom the sleep condition is to be detected. For example, a history of a given patient's sleep times can be stored, and a sleep threshold can be developed using data associated with the patient's sleep time history.

The first sleep-related signal is sensed **510**. A second sleep-related signal associated with sleep is sensed **520**. The first and the second sleep-related signals may be sensed from sensors implanted in the patient, attached externally to the patient or located nearby the patient, for example. The first and the second sleep-related signals may be any signal associated with the condition of sleep, such as the representative sleep-related signals associated with sleep listed above.

The sleep threshold established for the first sleep-related signal is adjusted using the second sleep-related signal **530**. For example, if the second sleep-related signal indicates a high level of activity that is incompatible with a sleep state, the sleep threshold of the first sleep-related signal may be adjusted downward to require sensing a decreased level of the first sleep-related signal before a sleep condition is detected.

If the first sleep-related signal is consistent with sleep according to the adjusted sleep threshold **540**, a sleep condition is detected **550**. If the first sleep-related signal is not consistent with sleep using the adjusted sleep threshold, the first and the second sleep-related signals continue to be sensed **510**, **520** and the threshold adjusted **530** until a condition of sleep is detected **550**.

In another embodiment of the invention, illustrated in FIG. **6**, an accelerometer and a minute ventilation sensor are used as first and second signals associated with sleep. A preliminary accelerometer signal sleep threshold is determined **610**. For example, the preliminary sleep threshold may be determined from clinical data taken from a group of subjects or historical data taken from the patient over a period of time.

The activity level of the patient is monitored using an accelerometer **620** that may be incorporated into an implantable cardiac pacemaker as described above. Alternatively, the accelerometer may be attached externally to the patient. The patient's minute ventilation (MV) signal is monitored **625**. The MV signal may be acquired, for example, using the transthoracic impedance method described above using an implantable cardiac device. Other methods of determining the MV signal are also possible and are considered to be within the scope of this invention.

In this example, the accelerometer signal represents the sleep detection signal associated with the sleep threshold. The MV signal is the threshold adjustment signal used to adjust the sleep threshold. Heart rate is monitored **630** in this example to provide a sleep confirmation signal.

Threshold adjustment may be accomplished by using the patient's MV signal to moderate the accelerometer sleep threshold. If the patient's MV signal is low relative to an expected MV level associated with sleep, the accelerometer sleep threshold is increased. Similarly, if the patient's MV signal level is high relative to an expected MV level associated with sleep, the accelerometer sleep threshold is decreased. Thus, when the patient's MV level is high, less activity is required to make the determination that the patient is sleeping. Conversely when the patient's MV level is relatively low, a higher activity level may result in detection of sleep. The use of two sleep-related signals to determine a sleep condition enhances the accuracy of sleep detection over previous methods using only one sleep-related signal to determine that a patient is sleeping.

Various signal processing techniques may be employed to process the raw sensor signals. For example, a moving average of a plurality of samples of each sleep-related signal may be calculated and used as the sleep-related signal. Furthermore, the sleep-related signals may be filtered and/or digitized. If the MV signal is high **635** relative to an expected MV level associated with sleep, the accelerometer sleep threshold is decreased **640**. If the MV signal is low **635** relative to an expected MV level associated with sleep, the accelerometer sleep threshold is increased **645**.

If the sensed accelerometer signal is less than or equal to the adjusted sleep threshold **650**, and if the patient is not currently in a sleep state **665**, then the patient's heart rate is checked **680** to confirm the sleep condition. If the patient's heart rate is compatible with sleep **680**, then sleep onset is determined **690**. If the patient's heart rate is incompatible with sleep, then the patient's sleep-related signals continue to be monitored.

If the accelerometer signal is less than or equal to the adjusted sleep threshold **650** and if the patient is currently in a sleep state **665**, then a continuing sleep state is determined and the patient's sleep-related signals continue to be monitored for sleep termination to occur.

If the accelerometer signal is greater than the adjusted sleep threshold **650** and the patient is not currently in a sleep state **660**, then the patient's sleep-related signals continue to be monitored until sleep onset is detected **690**. If the accelerometer signal is greater than the adjusted sleep threshold **650** and the patient is currently in a sleep state **660**, then sleep termination is detected **670**.

The graphs of FIGS. **7-9** illustrate the adjustment of the accelerometer sleep threshold using the MV signal. The relationship between patient activity and the accelerometer and MV signals is trended over a period of time to determine relative signal levels associated with a sleep condition. FIG. **7**A illustrates activity as indicated by the accelerometer signal. The patient's heart rate for the same period is graphed in FIG. **7**B. The accelerometer signal indicates a period of sleep associated with a relatively low level of activity beginning at slightly before 23:00 and continuing through 6:00. Heart rate appropriately tracks the activity level indicated by the accelerometer indicating a similar period of low heart rate corresponding to sleep. The accelerometer trends are used to establish a threshold for sleep detection.

FIG. **8** is a graph of baseline trending for an MV signal. Historical data of minute ventilation of a patient is graphed over an 8 month period. The MV signal trending data is used

to determine the MV signal level associated with sleep. In this example, a composite MV signal using the historical data indicates a roughly sinusoidal shape with the relatively low MV levels occurring approximately during the period from hours 21:00 through 8:00. The low MV levels are associated with periods of sleep. The MV signal level associated with sleep is used to implement sleep threshold adjustment.

FIG. **9** illustrates adjustment of the accelerometer sleep threshold using the MV signal. The initial sleep threshold **910** is established using the baseline accelerometer signal data acquired as discussed above. If the patient's MV signal is low relative to an expected MV level associated with sleep, the accelerometer sleep threshold is increased **920**. If the patient's MV signal level is high relative to an expected MV level associated with sleep, the accelerometer sleep threshold is decreased **930**. When the patient's MV level is high, less activity detected by the accelerometer is required to make the determination that the patient is sleeping. However, if the patient's MV level is relatively low, a higher activity level may result in detection of sleep. The use of two sleep-related signals to adjust a sleep threshold for determining a sleep condition enhances the accuracy of sleep detection over previous methods.

Additional sleep-related signals may be sensed and used to improve the sleep detection mechanism described above. For example, a posture sensor may be used to detect the posture of the patient and used to confirm sleep. If the posture sensor indicates a vertical posture, then the posture sensor signal may be used to override a determination of sleep using the sleep detection and threshold adjustment signals. Other signals may also be used in connection with sleep determination or confirmation, including the representative set of sleep-related signals associated with sleep indicated above.

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 detecting sleep, comprising:

sensing a plurality of sleep-related signals, the sleep-related signals comprising at least two of a cardiac signal, a respiratory signal, and a patient activity signal;

adjusting a sleep criterion associated with a specified sleep-related signal of the plurality of sleep-related signals using one of the sleep-related signals other than the specified signal;

comparing the specified signal to the adjusted sleep criterion;

detecting sleep based on the comparison;

generating an output signal indicative of an outcome of the sleep detection; and

transmitting the output signal to another device capable of operating responsively to the output signal;

wherein at least one of sensing, adjusting, comparing, and detecting is performed at least in part implantably and effectuated at least in part by a processor.

**2**. The method of claim **1**, further comprising establishing the sleep criterion.

**3**. The method of claim **2**, wherein the sleep criterion is established based on clinical data.

**4**. The method of claim **2**, wherein establishing the sleep criterion comprises establishing a sleep threshold associated with the specified one of the sleep-related signals.

**5**. The method of claim **2**, wherein establishing the sleep criterion further comprises modifying the sleep criterion.

**6**. The method of claim **2**, wherein establishing the sleep criterion further comprises adjusting a sensitivity of the sleep criterion.

**7**. The method of claim **2**, further comprising adjusting the sleep criterion associated with the activity signal using another one of the cardiac signal and the respiratory signal.

**8**. The method of claim **1**, wherein at least one of the sleep-related signals is a non-physiological signal.

**9**. A sleep detection device, comprising:

sensors, including cardiac electrodes configured to sense cardiac electrical signals, configured to sense a plurality of sleep-related signals; and

an implantable sleep processor coupled to the sensors, the sleep processor configured to adjust a sleep criterion associated with a first sleep-related signal using a second sleep-related signal of the plurality of sleep-related signals, compare the first sleep-related signal to the adjusted sleep criterion; detect sleep based on the comparison, generate an output signal indicative of an outcome of the sleep detection, and transmit the output signal to another device capable of receiving the output signal.

**10**. The device of claim **9**, wherein the sleep processor is configured to determine a relationship between at least two of the sleep-related signals based on patient data.

**11**. The device of claim **9**, wherein the sleep processor is configured to determine a relationship between at least two of the sleep-related signals based on clinical data.

**12**. The device of claim **9**, wherein the sensors include an accelerometer configured to sense patient activity and transthoracic impedance sensor configured to sense respiration.

**13**. The device of claim **9**, wherein at least one of the sensors is external of the patient.

**14**. The device of claim **9**, wherein the sleep processor is a component of an implantable cardiac therapy device.

**15**. A sleep detection system, comprising:

sensors, including cardiac electrodes configured to sense cardiac electrical signals, configured to detect a plurality of sleep-related signals;

means for adjusting a sleep criterion associated with a first sleep-related signal using a second sleep-related signal of the plurality of sleep-related signals;

means for comparing the first sleep-related signal to the adjusted sleep criterion;

means for implantably detecting sleep based on the comparison; and

means for transmitting an output signal to another device capable of receiving the output signal, the output signal indicative of an outcome of the sleep detection.

**16**. The system of claim **15**, further comprising means for determining a relationship between at least two of the sleep-related signals to establish the sleep criterion.

**17**. The system of claim **15**, further comprising means for establishing the sleep criterion based on at least one of the sleep-related signals.

**18**. The system of claim **17**, further comprising means for adjusting a sensitivity of the sleep criterion.

**19**. The system of claim **15**, further comprising means for modifying the sleep criterion.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

# CERTIFICATE OF CORRECTION



PATENT NO. : 8,535,222 B2
APPLICATION NO. : 11/717561
DATED : September 17, 2013
INVENTOR(S) : Quan Ni

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Claims

Column 12
Line 11: before "one of the cardiac", delete "another".

Signed and Sealed this
Twenty-seventh Day of May, 2014

Michelle K. Lee

Michelle K. Lee
*Deputy Director of the United States Patent and Trademark Office*

| | | | |
|---|---|---|---|
| 专利名称(译) | 使用可调阈值进行睡眠检测 | | |
| 公开(公告)号 | US8535222 | 公开(公告)日 | 2013-09-17 |
| 申请号 | US11/717561 | 申请日 | 2007-03-13 |
| [标]申请(专利权)人(译) | 心脏起搏器股份公司 | | |
| 申请(专利权)人(译) | 心脏起搏器，INC. | | |
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| IPC分类号 | A61B5/00 A61B5/0205 | | |
| CPC分类号 | A61B5/0205 A61N1/365 A61B5/686 A61B5/1116 A61B5/0031 A61B5/4815 G06F19/345 A61B5/7271 G06F19/3406 A61B5/7282 A61B5/085 A61B5/021 A61N1/362 A61N1/36542 A61B5/4809 G16H40/63 G16H50/20 | | |
| 助理审查员(译) | ARCHER，MARIE | | |
| 其他公开文献 | US20070161873A1 | | |
| 外部链接 | Espacenet USPTO | | |


摘要(译)

用于睡眠检测的装置和方法涉及使用可调节阈值来检测睡眠开始和终止。用于检测睡眠的方法包括使用第二睡眠相关信号调整与第一睡眠相关信号相关联的睡眠阈值。将第一睡眠相关信号与调整后的阈值进行比较，并基于该比较检测睡眠。睡眠相关信号可以从可植入或外部传感器导出。额外的睡眠相关信号可用于确认睡眠状况。实现睡眠检测方法的睡眠检测器设备可以是可植入脉冲发生器的组件，例如起搏器或除颤器。