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Wood

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(54) **DETECTION OF ABNORMAL AND INDUCTION OF NORMAL HEAT RATE VARIABILITY**

5,873,369 A 2/1999 Lanido et al.
5,891,044 A 4/1999 Golosarsky et al.

FOREIGN PATENT DOCUMENTS

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

SU 1607808 A1 11/1990
SU 1683679 A1 10/1991
SU 1769894 A1 10/1992
WO 8809146 12/1988
WO 9406350 3/1994
WO 9602185 A1 2/1996

OTHER PUBLICATIONS

“The Functional Model Regulation Homeokinesis of Heart Rhythm;” Golosarsky B., research worker, Odessa Research Institute of Medical Rehabilitation (1989).
Malik, Farrell, Cripps, Camm, Heart Rate Variability in Relation to Prognosis After Myocardial Infarction: Selection of Optimal Processing Techniques. *Eur. Heart J.* 1989;10:1060–1074.

(List continued on next page.)

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(51) **Int. Cl.**⁷ **A61B 5/0468**

(52) **U.S. Cl.** **600/515; 600/519**

(58) **Field of Search** 600/513, 515, 600/516, 517, 518, 519

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,018,219 A 4/1977 Hojaiban
4,312,356 A 1/1982 Sowton et al.
4,453,537 A 6/1984 Spitzer
D278,746 S 5/1985 Saynajakangas
4,531,527 A 7/1985 Reinhold, Jr. et al.
4,572,192 A 2/1986 Jackman et al.
D287,403 S 12/1986 Kiiski et al.
4,625,733 A 12/1986 Säynäjäkangas
4,827,943 A 5/1989 Bornn et al.
4,862,361 A 8/1989 Gordon et al.
4,883,063 A 11/1989 Bernard et al.
4,960,129 A 10/1990 dePaola et al.
5,042,497 A 8/1991 Shapland
5,058,597 A 10/1991 Onoda et al.
5,078,133 A 1/1992 Heinz et al.
5,226,425 A 7/1993 Righter
5,265,617 A 11/1993 Verrier et al.
5,419,338 A 5/1995 Sarma et al.
5,437,285 A 8/1995 Verrier et al.
5,462,060 A 10/1995 Jacobson et al.
5,522,854 A 6/1996 Ideker et al.
5,560,368 A 10/1996 Berger
5,560,370 A 10/1996 Verrier et al.
5,718,235 A 2/1998 Golosarsky et al.

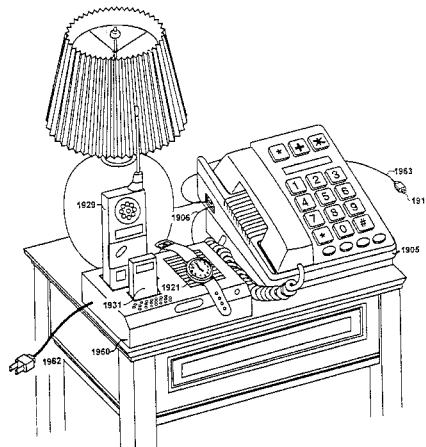
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(57) **ABSTRACT**

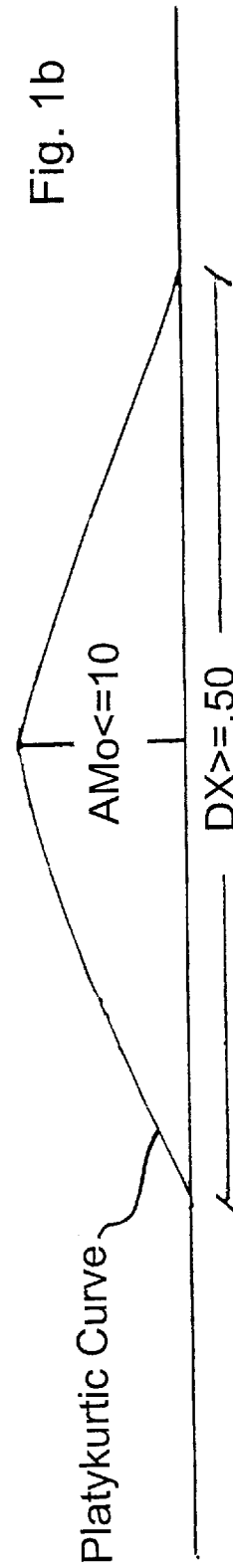
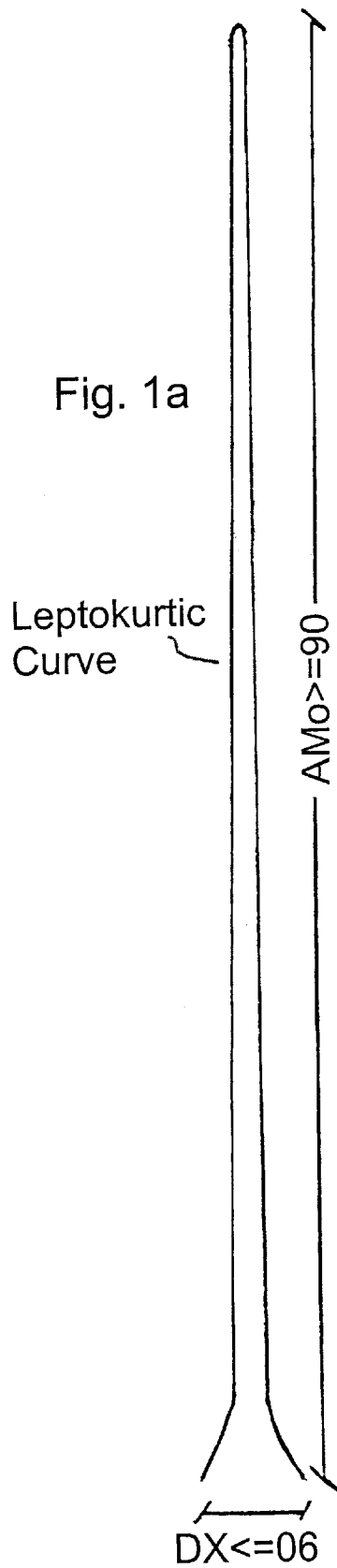
An apparatus and method for predicting potentially fatal arrhythmias up to twenty four hours in advance of the event by employing formulas indicating either too little or too much heart rate variability. A number of these formulas have both predetermined upper and lower limits, which if exceeded for a period of time are a predictor of a potentially fatal arrhythmia. When a patient's ALARM condition is predicted, whether the patient is indoors or outdoors, conscious or unconscious, a redundant protocol is utilized to relay that ALARM condition to a central monitoring station. The central monitoring station informs the patient's doctor, and then uses what ever means are available to transport the patient to the nearest emergency room for treatment. An apparatus and method for pacing the heart in a natural way, once a potentially fatal arrhythmia has been predicted is also disclosed.

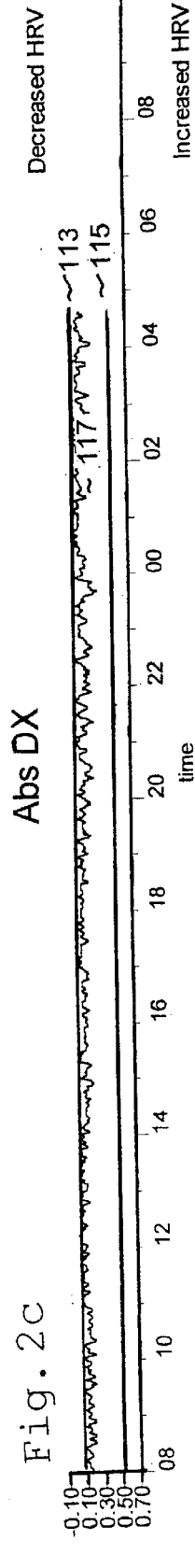
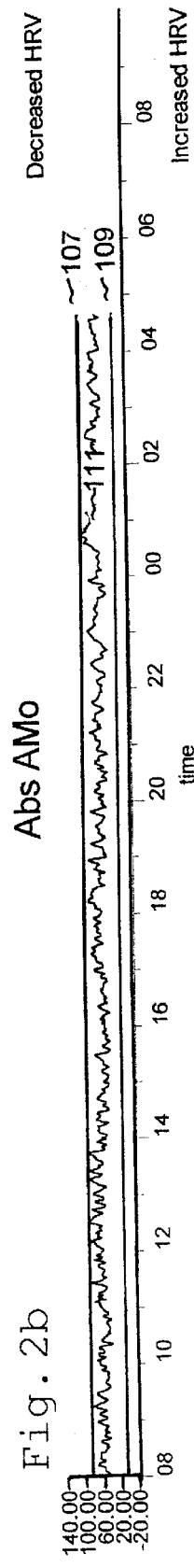
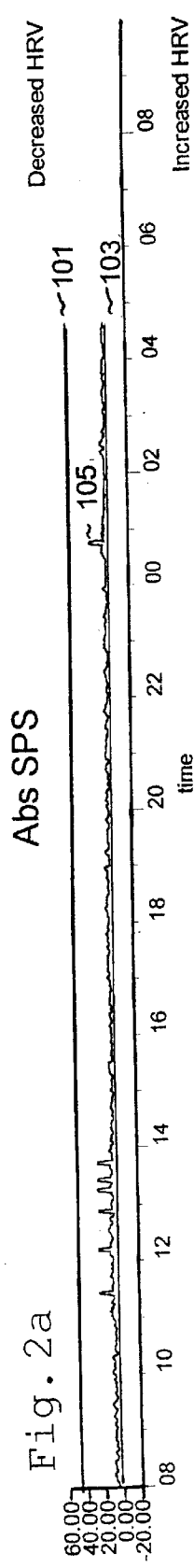
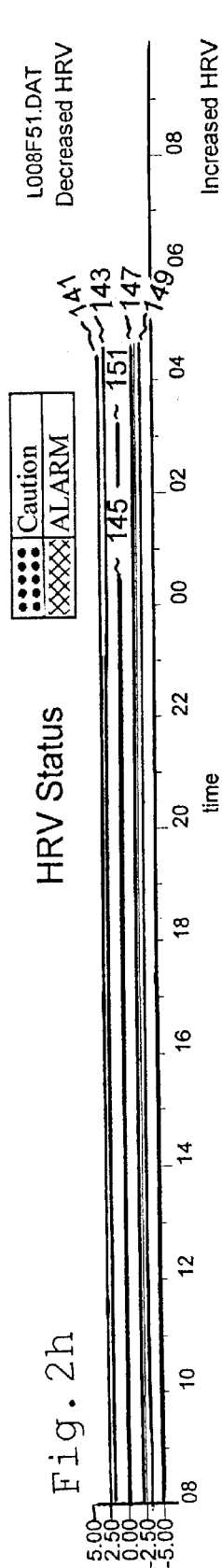
42 Claims, 22 Drawing Sheets

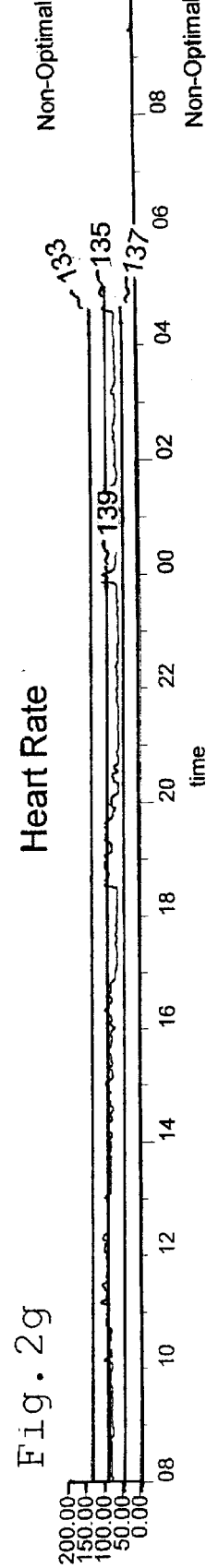
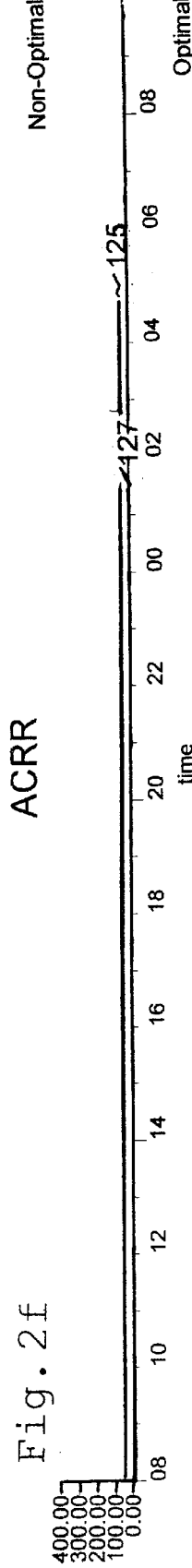
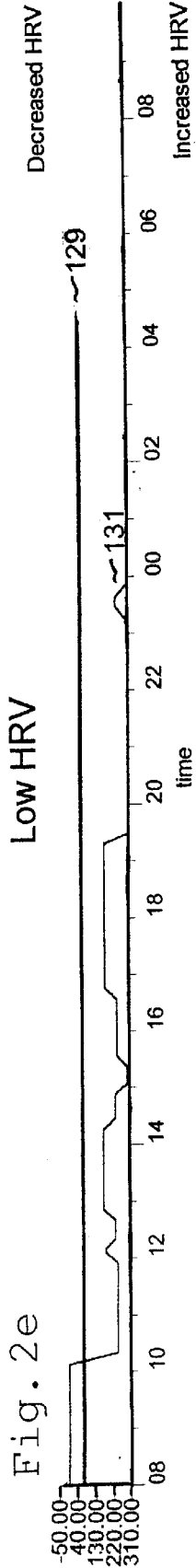
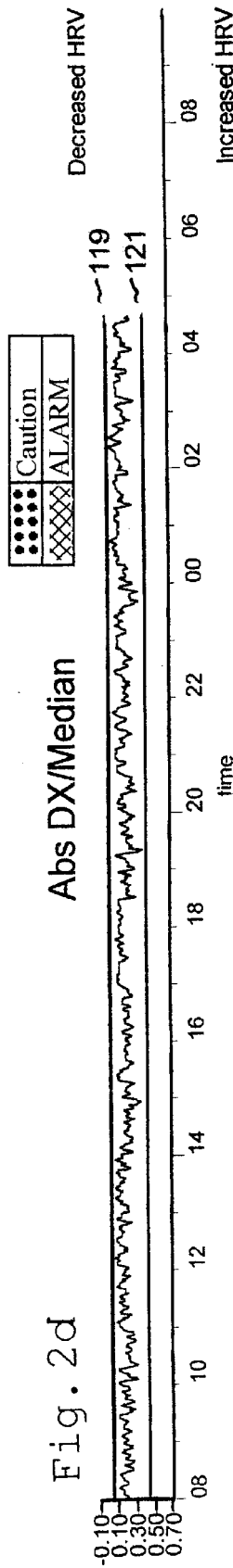


OTHER PUBLICATIONS

- Malik, Xia, Odemuyiwa, Staunton, Poloniecki, Camm, Influence of the Recognition Artefact in the Automatic Analysis of Long-term Electrocardiograms on Time-domain Measurement of Heart Rate Variability, *Med. Biol. Eng. Comput.* 1993;31:539-544.
- Malik, Camm, Components of Heart Rate Variability: What They Really Mean and What We Really Measure, *Am. J. Cardiol.* 1993; 72:821-822.
- Malik, Cripps, Farrell, Camm, Prognostic Value of Heart Rate Variability After Myocardial Infarction: A Comparison of Different Data Processing Methods, *Med. Biol. Eng. Comput.* 1989;27:603-611.
- Malik, Camm, Heart Rate Variability and Clinical Cardiology, *Br. Heart J.* 1994; 71:3-6.
- Malik, Camm. Significance of Long-term Components of Heart Rate Variability for the Further Prognosis After Acute Myocardial Infarction, *Cardiovasc. Res.* 1990;24:793-803.
- Fei, Malik, Short- and Long-term Assessment of Heart Rate Variability for Postinfarction Risk Stratification, In: Malik, Camm, eds, *Heart Rate Variability*, Armonk, NY: Futura; 1995: 341-346.
- Heart Rate Variability Standards of Measurement, Physiological Interpretation, and Clinical Use, *Circulation*, vol. 93, No. 5 (Mar. 1, 1996).
- Wood, N.B. "The Prediction of a Potentially Fatal Cardiac Event in the Next 2 to 24 Hours and the Prediction of a Myocardial Infarction Related Death or Sudden Death", Computers in Cardiology conference proceedings (Sep. 24-26, 2001).
- Schmidt, Georg, et al "Heart-Rate Turbulence after Ventricular Premature Beats as a Predictor of Mortality After Acute Myocardial Infarction", *The Lancet*, vol. 353, Issue 9162, p. 1390(1), (Apr. 24, 1999).
- de Bruyne, Martine C., et al "Both Decreased and Increased Heart Rate Variability on the Standard 10-Second Electrocardiogram Predict Cardiac Mortality in the Elderly: The Rotterdam Study", *American Journal of Epidemiology*, vol. 150, No. 12, pp. 1282-1288 (Dec. 15, 1999).
- Ziegler, D., et al "Normal Ranges and Reproducibility of Statistical, Geometric, Frequency Domain, and Non-Linear Measures of 24-Hour Heart Rate Variability", *Horm Metab Res* Issue 12, pp. 672-679 (Dec. 31, 1999).
- Pinar, Eduardo, et al "Effects of Verapamil on Indexes of Heart Rate Variability After Acute Myocardial Infarction", *The American Journal of Cardiology*, vol. 81, Issue 9, pp. 1085-1089 (May 1, 1998).
- Deligiannis, Asterios, et al "Effects of Physical Training on Heart Rate Variability in Patients on Hemodialysis", *The American Journal of Cardiology*, vol. 84, Issue 2, pp. 197-202 (Jul. 15, 1999).
- Hayano, Junichiro et al "Prognostic Value of Heart Rate Variability During Long-Term Follow-Up in Chronic Haemodialysis Patients with End-Stage Renal Disease", *Nephrology Dialysis Transplantation*, vol. 14, Issue 6, pp. 1480-1488 (Jun. 1999).
- Lotze, Ulrich, et al "Cardiac Sympathetic Activity as Measured by Myocardial 123-I-Metaiodobenzylguanidine Uptake and Heart Rate Variability in Idiopathic Dilated Cardiomyopathy", *The American Journal of Cardiology*, vol. 83, Issue 11, pp. 1548-1551 (Jun. 1, 1999).
- Ho, Kalon K.L. et al "Predicting Survival in Heart Failure Case and Control Subjects by Use of Fully Automated Methods for Deriving Nonlinear and Conventional Indices of Heart Rate Dynamics" *Circulation*, vol. 96, pp. 842-848 (1997).
- Mäkikallio, Timo H., et al "Heart Rate Dynamics Before Spontaneous Onset of Ventricular Fibrillation in Patients with Healed Myocardial Infarcts", *The American Journal of Cardiology*, vol. 83, pp. 880-884 (Mar. 15, 1999).
- Reardon, M., et al "Changes in Heart Rate Variability With Age", *Pacing Clin. Electrophysiol.*, vol. 11., Part 2, pp. 1863-1866 (Nov. 1996)(Abstract).
- Skinner, J.E., et al "New Non-Linear Algorithms for Analysis of Heart Rate Variability; Low Dimensional Chaos Predicts Lethal Arrhythmias", *Nonlinear Analysis of Physiological Data*, Springer, pp. 129-166 (1998).
- Fauchier, Laurent et al. "Prognostic Value of Heart Rate Variability for Sudden Death and Major Arrhythmic Events in Patients with Idiopathic Dilated Cardiomyopathy", *Journal of American College of Cardiology*, vol. 33, No. 5, pp. 1203-1207 (Apr. 1999).
- Cheng, T.O. "Decreased Heart Rate Variability as a Predictor for Sudden Death was Known in China in the Third Century A.D.", *European Heart Journal*, vol. 21, Issue 24, pp. 2081-2082 (Dec. 2000).
- Soejima, Kyoko et al. "Age-Adjusted Heart Rate Variability as an Index of the Severity and Prognosis of Heart Failure", *Japanese Circulation Journal*, vol. 64, pp. 32-38 (Jan. 2000).
- Reardon, Michael et al. "Changes in Heart Rate Variability with Age" *Pace*, vol. 19, pp. 1863-1866 (Nov. 1996).
- Makikallio, Timo H. et al. "Prediction of Sudden Cardiac Death by Fractal Analysis of Heart Rate Variability in Elderly Subjects", *Journal of the American College of Cardiology*, vol. 37, No. 5, pp. 1395-1402 (Apr. 2001).







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