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[54] ELECTROTHERAPY METHOD FOR EXTERNAL DEFIBRILLATORS

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United States Patent [19]

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Gliner et al.

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#### **Related U.S. Application Data**

- [63] Continuation of Ser. No. 103,837, Aug. 6, 1993, abandoned.
- [51] Int. Cl.<sup>6</sup> ..... A61N 1/39
- [52] U.S. Cl. ..... 607/7; 607/74; 607/5;

#### [56] **References Cited**

#### **U.S. PATENT DOCUMENTS**

| 3,211,154 | 10/1965 | Becker et al   |
|-----------|---------|----------------|
| 3,241,555 | 3/1966  | Caywood et al  |
| 3,782,389 | 1/1974  | Bell .         |
| 3,862,636 | 1/1975  | Bell et al     |
| 3,886,950 | 6/1975  | Ukkestad et al |

#### (List continued on next page.)

#### FOREIGN PATENT DOCUMENTS

| 0353341     | 2/1990  | European Pat. Off |
|-------------|---------|-------------------|
| 0437104     | 7/1991  | European Pat. Off |
| 0457604 A   | 11/1991 | European Pat. Off |
| 0491649 A   | 6/1992  | European Pat. Off |
| 0507504     | 10/1992 | European Pat. Off |
| 2070435     | 9/1981  | United Kingdom    |
| 2083363     | 3/1982  | United Kingdom .  |
| 93/16759    | 9/1993  | WIPO .            |
| 94/21327    | 9/1994  | WIPO .            |
| 94/22530    | 10/1994 | WIPO .            |
| VO 95/05215 | 2/1995  | WIPO .            |

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| vo | 95/09673 | 4/1995  | WIPO |
|----|----------|---------|------|
| vo | 95/32020 | 11/1995 | WIPO |

#### OTHER PUBLICATIONS

Saksena et al., "Developments for future implantable cardioverters and defibrillators," *PACE*, 10:1342–1358 (Nov.– Dec. 1987).

Schuder "The role of an engineering oriented medical research group in developing improved methods and devices for achieving ventricular defibrillation: The University of Missouri experience," *PACE*, 16:95–124 (Jan. 1993).

(List continued on next page.)

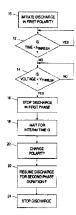
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#### [57] ABSTRACT

This invention provides an external defibrillator and defibrillation method that automatically compensates for patientto-patient impedance differences in the delivery of electrotherapeutic pulses for defibrillation and cardioversion. In a preferred embodiment, the defibrillator has an energy source that may be discharged through electrodes on the patient to provide a biphasic voltage or current pulse. In one aspect of the invention, the first and second phase duration and initial first phase amplitude are predetermined values. In a second aspect of the invention, the duration of the first phase of the pulse may be extended if the amplitude of the first phase of the pulse fails to fall to a threshold value by the end of the predetermined first phase duration, as might occur with a high impedance patient. In a third aspect of the invention, the first phase ends when the first phase amplitude drops below a threshold value or when the first phase duration reaches a threshold time value, whichever comes first, as might occur with a low to average impedance patient. This method and apparatus of altering the delivered biphasic pulse thereby compensates for patient impedance differences by changing the nature of the delivered electrotherapeutic pulse, resulting in a smaller, more efficient and less expensive defibrillator.

#### 18 Claims, 7 Drawing Sheets



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#### U.S. PATENT DOCUMENTS

| 4,595,009 6/1986 Leinders.   4,619,265 10/1986 Morgan et al.   4,745,923 5/1988 Winstrom.   4,848,345 7/1989 Zenkich.   5,078,134 1/1992 Heilman et al.   5,097,833 3/1992 Campos   5,222,492 6/1993 Morgan et al. | 46  |
|--|-----|
| 5,249,573 10/1993 Fincke et al<br>5,34,219 8/1994 Kroll .<br>5,334,430 8/1994 Berg et al   | 7/5 |

#### OTHER PUBLICATIONS

Schuder et al. "Comparison of effectiveness of relayswitched, one-cycle quasisinusoidal waveform with critically damped sinusoid waveform in transthoracic defibrillation of 100-kilogram calves," *Medical Instrumentation*, 22(6):281-285(1988).

Schuder et al., "A multielectrode-time sequential laboratory defibrillator for the study of implanted electrode systems," *Amer.Soc.Artif.Int.Organs, XVIII*:514-519 (1972).

Schuder et al., "Development of automatic implanted defibrillator," Devices & Tech. Meeting NIH (1981).

Stanton et al., "Relationship between defibrillation threshold and upper limit of vulnerability in humans," *PACE*, 15:563, abstract 221 (Apr. 1992).

Tang et al., "Ventricular defibrillation using biphasic waveforms: The importance of phasic duration," *JACC*, 13(1):207-214 (1989).

Walcott et al., "Comparison of monophasic, biphasic, and the edmark waveform for external defibrillation," PACE, 15:563, abstract 218 (Apr. 1992).

Wathen et al., "Improved defibrillation efficacy using four nonthoracotomy leads for sequential pulse defibrillation," *PACE*, 15:563, abstract 220 (Apr. 1992).

Winkle "The implantable defibrillator in ventricular arrhythmias," Hospital Practice, pp. 149-165 (Mar. 1983).

Zipes, "Sudden cardiac death," Circulation, 85(1):160-166 (1992).

Jones et al., "Reduced excitation threshold in potassium depolarized myocardial cells with symmetrical biphasic waveforms," *J. Mol. Cell. Cardiol.*, 17(39):XXVII, abstract No. 39 (1985).

Jude et al., "Fundamentals of Cardiopulmonary Resuscitation," F.A. Davis Company, Philadelphia PA, pp. 98-104 (1965).

Knickerbocker et al., "A portable defibrillator," *IEEE Trans.* on Power and Apparatus Systems, 69:1089-1093 (1963). Kouwenhoven, "The development of the defibrillator,"

Annals of Internal Medicine, 71(3):449–458 (1969).

Langer et al., "Considerations in the development of the automatic implantable defibrillator," *Medical Instrumentation*, 10(3):163-167 (1976).

Lindsay et al., "Prospective evaluation of a sequential pacing and high-energy bi-directional shock algorithm for transvenous cardioversion in patients with ventricular tachycardia," *Circulation*, 76(3):601-609 (1987).

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Mirowski et al., "Clinical treatment of life threatening ventricular tachyarrhythmias with the automatic implantable defibrillator," *American Heart Journal*, 102(2):265–270 (1981).

Mirowski et al., "Termination of malignant ventricular arrhythmias with an implanted automatic defibrillator in human beings," *The New England Journal of Medicine*, 303(6):322-324 (1980).

Podolsky, "Keeping the beat alive," U.S. News & World Report (Jul. 22, 1991).

Product Brochure for the Shock Advisory System (1987), Physio-Control, 11811 Willows Road Northeast, P.O. Box 97006, Redmond, WA 98073-9706.

Redd (editor), "Defibrillation with biphasic waveform may increase safety, improve survival," *Medlines*, pp. 1–2 (Jun.– Jul. 1984).

Saksena et al., "A prospective evaluation of single and dual current pathways for transvenous cardioversion in rapid ventricular tachycardia," *PACE*, 10:1130–1140 (Sep.–Oct. 1987).

Alferness et al., "The influence of shock waveforms on defibrillation efficacy," *IEEE Engineering in Medicine and Biology*, pp. 25–27 (Jun. 1990).

Blilie et al., "Predicting and validating cardiothoracic current flow using finite element modeling," *PACE*, 15:563, abstract 219 (Apr. 1992).

Chapman et al., "Non-thoracotomy internal defibrillation: Improved efficacy with biphasic shocks," *Circulation*, 76:312, abstract No. 1239 (1987).

Cooper et al., "Temporal separation of the two pulses of single capacitor biphasic and dual monophasic waveforms." *Circulation*, 84(4):612, abstract No. 2433 (1991).

Cooper et al., "The effect of phase separation on biphasic waveform defibrillation." PACE, 16:471-482 (Mar. 1993).

Cooper et al., "The effect of temporal separation of phases on biphasic waveform defibrillation efficacy," *The Annual International Conference of the IEEE Engineering in Medicine and Biology Society*, 13(2):0766–0767 (1991).

Crampton et al., "Low-energy ventricular defibrillation and miniature defibrillators," JAMA, 235(21):2284 (1976).

Dahlbäck et al., "Ventricular defrillation with square-waves," The Lancet (Jul. 2, 1966).

Echt et al., "Biphasic waveform is more efficacious than monophasic waveform for transthoracic cardioversion," *PACE*, 16:914, abstract No. 256 (Apr. 1993).

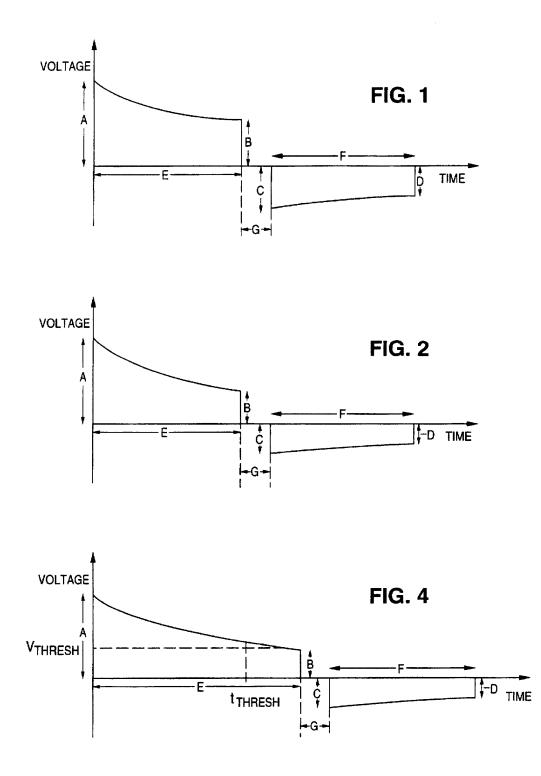
Feeser et al., "Strength-duration and probability of success curves for defibrillation with biphasic waveforms," *Circulation*, 82(6):2128-2141 (1990).

Guse et al., "Defibrillation with low voltage using a left ventricular catheter and four cutaneous patch electrodes in dogs," *PACE*, 14:443–451 (Mar. 1991).

Jones et al., "Defibrillator waveshape optimization," Devices and Tech. Meeting, NIH (1982).

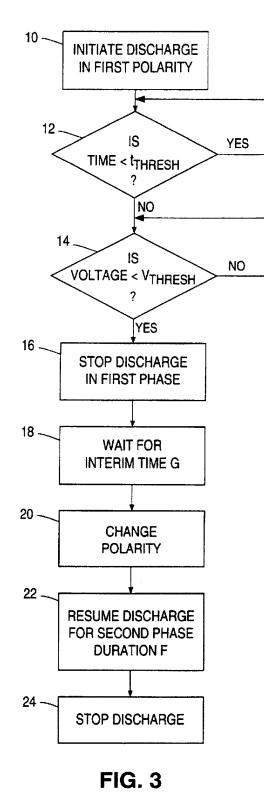
Kerber, et al., "Energy, current, and success in defibrillation and cardioversion: clinical studies using an automated impedance-based method of energy adjustment," *Circulation*, 77(5):1038-1046 (1988); and.

Lerman, et al., "Current-Based Versus Energy-Based Ventricular Defibrillation: A Prospective Study," *JACC*, 12(5):1259-1264 (1988).



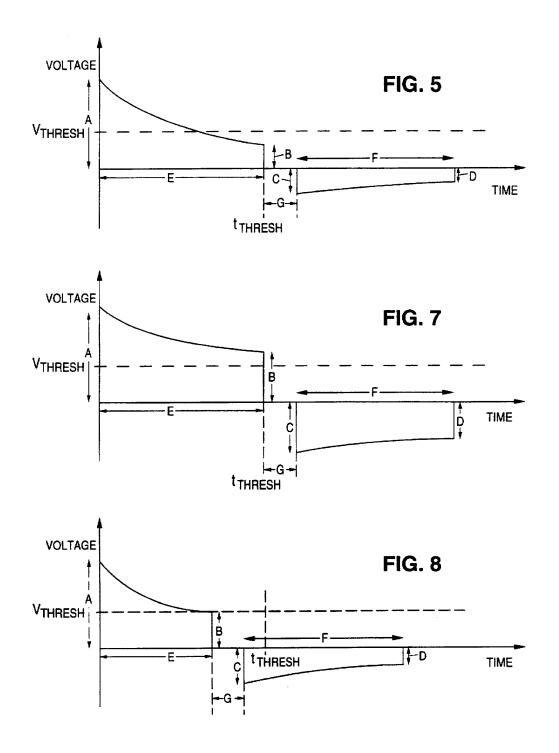
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