

| | | | |
|---------------|------------|-------|----------|
| SERIAL NUMBER | FILED DATE | CLASS | SUBCLASS |
| 08/601.617 | 02/14/96 | 607 | 000 |
| RULE 60 | | | |

BRADFORD F. GLINER, BELLEVUE, WA; THOMAS D. LING
 CLINTON S. COLE, KIRKLAND, WA; DANIEL J. POWERS
 CARLTON D. MORGAN, RAINBOW ISLAND, WA

CONTINUING DATA*****
 VERIFIED THIS APPLN IS A DIV OF 08/103,837 08/03/96

FOREIGN/PCT APPLICATIONS*****
 VERIFIED none

BEST COPY

FOREIGN FILING LICENSE GRANTED 04/15/96 ***** SMALL ENTITY *****

| | | | | | | | | |
|---------------------------|---------------------------------------------------------------------|-------------|---------------------|------------------|-----------------|-----------------|------------------------|---------------------------|
| Priority claimed | <input type="checkbox"/> yes <input checked="" type="checkbox"/> no | AS FILED | STATE OR COUNTRY | SHEETS DRWGS. | TOTAL CLAIMS | INDER CLAIMS | FILING FEE RECEIVED | ATTORNEY'S BOOKLET NO. |
| 35 USC 119 conditions met | <input type="checkbox"/> yes <input checked="" type="checkbox"/> no | | | | | | | |
| Filed and Acknowledged | Examiner's Initials | WA | 7 | 8 | 1 | \$375.00 | 241082000610 | |

STUART P. KALER
 MURRISON & FOERSTER
 345 CALIFORNIA STREET
 SAN FRANCISCO CA 94104-2675

ISSUE FEE IN FILE

ELECTROTHERAPY METHOD AND APPARATUS

9-9-96

CERTIFICATE DEPT. OF COMM./PAT. & TM - FTS-430L (Rev. 5-89)

08/601517

Class
Subclass
ISSUE CLASSIFICATION



5593427
5593427

UTILITY SERIAL NUMBER 08/601517

PATENT DATE JAN 14 1997

PATENT NUMBER

SERIAL NUMBER FILING DATE CLASS SUBCLASS GROUP ART UNIT EXAMINER
007 Schaeetzle

APPLICANTS

RA

RA

none

BEST COPY

Foreign priority claimed 35 USC 119 conditions met ☐ yes ☒ no ☐ yes ☒ no AS FILED STATE OR COUNTRY SHEETS DRWGS. TOTAL CLAIMS INDEP. CLAIMS FILING FEE RECEIVED ATTORNEY'S DOCKET NO.
Verified and Acknowledged Examiner's initials

ADDRESS

ISSUE FEE IN FILE

RA 9-9-96

TITLE

CERTIFICATE DEPT. OF COMM. / PAT. & TM PTO-436L (Rev. 12-94)

SEP 30 1997

| | | | | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|---------------------------------------------|--|-----------------------------------------|-------------|
| PARTS OF APPLICATION FILED SEPARATELY | | OF CORRECTION | | R Johnson Applications Examiner 9/17 | |
| NOTICE OF ALLOWANCE MAILED | | Kennedy J. Schaeetzle Assistant Examiner | | CLAIMS ALLOWED | |
| 9-12-96 | | | | Total Claims | Print Claim |
| | | | | 18 | 1 |
| ISSUE FEE | | | | DRAWING | |
| Amount Due | Date Paid | | | Sheets Drwg. | Figs. Drwg. |
| \$625.00 | 9-30-96 | | | 7 | 11 |
| | | | | Print Fig. | 6 |
| Label Area | | Primary Examiner | | ISSUE BATCH NUMBER | |
| | | PREPARED FOR ISSUE | | E19 | |
| WARNING: The information disclosed herein may be restricted. Unauthorized disclosure may be prohibited by the United States Code Title 35, Sections 122, 181 and 368. Possession outside the U.S. Patent & Trademark Office is restricted to authorized employees and contractors only. | | | | | |

Form PTO-436A (Rev. 8/92)

40

(FACE)

08/501517

Date
Entered
or
Counted

PATENT APPLICATION



08601617

CONTENTS

APPROVED FOR LICENSE ☒

INITIALS _____

Date
Received
or
Mailed

| | | |
|----------------|--------------------------------------------|----------------|
| <u>D</u> | 1. Application <u>PRINTS & papers.</u> | |
| | 2. <u>PRE AMEND / A</u> | <u>2-14-96</u> |
| | 3. <u>AMEND / B</u> | <u>2-14-96</u> |
| | 4. <u>I. D. S.</u> | <u>5-20-96</u> |
| | 5. <u>allowance</u> | <u>9-12-96</u> |
| <u>10/8/96</u> | 6. <u>Final Office Action 7-1-96</u> | <u>9/30/96</u> |
| | 7. _____ | |
| | 8. <u>CYC</u> | <u>7-29-97</u> |
| | 9. _____ | |
| | 10. _____ | |
| | 11. _____ | |
| | 12. _____ | |
| | 13. _____ | |
| | 14. _____ | |
| | 15. _____ | |
| | 16. _____ | |
| | 17. _____ | |
| | 18. _____ | |
| | 19. _____ | |
| | 20. _____ | |
| | 21. _____ | |
| | 22. _____ | |
| | 23. _____ | |
| | 24. _____ | |
| | 25. _____ | |
| | 26. _____ | |
| | 27. _____ | |
| | 28. _____ | |
| | 29. _____ | |
| | 30. _____ | |
| | 31. _____ | |
| | 32. _____ | |

(FRONT)

SEARCHED

| Class | Sub. | Date | Exmr. |
|-------|------------------------|--------|--------------------|
| 607 | 7 5 6 4 74 | 9-4-96 | <i>[Signature]</i> |

INTERFERENCE SEARCHED

| Class | Sub. | Date | Exmr. |
|-------|-----------|--------|--------------------|
| 607 | 4-7 74 | 9-9-96 | <i>[Signature]</i> |

SEARCH NOTES

| | Date | Exmr. |
|--|------|-------|
| | | |

(RIGHT OUTSIDE)

Staple Issue Slip Here

| POSITION | ID NO. | DATE |
|-------------|--------|----------|
| CLASSIFIER | | 8 3-5-96 |
| EXAMINER | 249 | |
| TYPIST | mg | 4/13/96 |
| VERIFIER | mg | 4/25/96 |
| CORPS CORR. | | |
| SPEC. HAND | | |
| FILE MAINT. | | |
| DRAFTING | | |

INDEX OF CLAIMS

| Claim | Date |
|----------|------|
| Final | |
| Original | |
| 1 | |
| 2 | |
| 3 | |
| 4 | |
| 5 | |
| 6 | |
| 7 | |
| 8 | |
| 9 | |
| 10 | |
| 11 | |
| 12 | |
| 13 | |
| 14 | |
| 15 | |
| 16 | |
| 17 | |
| 18 | |
| 19 | |
| 20 | |
| 21 | |
| 22 | |
| 23 | |
| 24 | |
| 25 | |
| 26 | |
| 27 | |
| 28 | |
| 29 | |
| 30 | |
| 31 | |
| 32 | |
| 33 | |
| 34 | |
| 35 | |
| 36 | |
| 37 | |
| 38 | |
| 39 | |
| 40 | |
| 41 | |
| 42 | |
| 43 | |
| 44 | |
| 45 | |
| 46 | |
| 47 | |
| 48 | |
| 49 | |
| 50 | |

SYMBOLS

- ✓ Rejected
- Allowed
- (Through numeral) Canceled
- N Restricted
- I Non-elected
- A Interference
- O Appeal
- O Objected

| Claim | Date |
|----------|------|
| Final | |
| Original | |
| 51 | |
| 52 | |
| 53 | |
| 54 | |
| 55 | |
| 56 | |
| 57 | |
| 58 | |
| 59 | |
| 60 | |
| 61 | |
| 62 | |
| 63 | |
| 64 | |
| 65 | |
| 66 | |
| 67 | |
| 68 | |
| 69 | |
| 70 | |
| 71 | |
| 72 | |
| 73 | |
| 74 | |
| 75 | |
| 76 | |
| 77 | |
| 78 | |
| 79 | |
| 80 | |
| 81 | |
| 82 | |
| 83 | |
| 84 | |
| 85 | |
| 86 | |
| 87 | |
| 88 | |
| 89 | |
| 90 | |
| 91 | |
| 92 | |
| 93 | |
| 94 | |
| 95 | |
| 96 | |
| 97 | |
| 98 | |
| 99 | |
| 100 | |

(LEFT INSIDE)

STAPLE

AREA

★ U.S. GOVERNMENT PRINTING OFFICE: 1979-347-700

| | | | |
|------------------------------------|--|-------------------------|------------------------------------------------------|
| PATENT NUMBER | | ORIGINAL CLASSIFICATION | |
| | | CLASS | SUBCLASS |
| | | 607 | 007 |
| APPLICATION SERIAL NUMBER | | CROSS REFERENCE(S) | |
| 08/601 617 | | | |
| APPLICANT'S NAME (PLEASE PRINT) | | CLASS | SUBCLASS (ONE SUBCLASS PER BLOCK) |
| Gliner et al. | | 607 | 005 074 |
| IF REISSUE, ORIGINAL PATENT NUMBER | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| INTERNATIONAL CLASSIFICATION | | GROUP | ASSISTANT EXAMINER (PLEASE STAMP OR PRINT FULL NAME) |
| A 21 N | | ART UNIT | Kennedy J. Schaetzle |
| 1/39 | | 3305 | PRIMARY EXAMINER (PLEASE STAMP OR PRINT FULL NAME) |
| | | | WILLIAM E. KAMM |

PTO 270
(REV. 5-91)

ISSUE CLASSIFICATION SLIP

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE



US005593427A

United States Patent [19]
Gliner et al.

[11] **Patent Number:** **5,593,427**
 [45] **Date of Patent:** **Jan. 14, 1997**

- [54] **ELECTROTHERAPY METHOD**
- [75] Inventors: **Bradford E. Gliner**, Bellevue; **Thomas D. Lyster**, Bothell; **Clinton S. Cole**, Kirkland; **Daniel J. Powers**, Bainbridge Island; **Carlton B. Morgan**, Bainbridge Island, all of Wash.
- [73] Assignee: **Heartstream, Inc.**, Seattle, Wash.
- [21] Appl. No.: **601,617**
- [22] Filed: **Feb. 14, 1996**

94/21327 9/1994 WIPO .
 94/22530 10/1994 WIPO .

OTHER PUBLICATIONS

Alfeness et al., "The influence of shock waveforms on defibrillation efficacy," *IEEE Engineering in Medicine and Biology*, pp. 25-27 (Jun. 1990).
 Anderson, et al., "The Efficacy of Trapezoidal Wave Forms for Ventricular Defibrillation," *Chest* 70(2):298-300.
 Billie et al., "Predicting and validating cardiothoracic current flow using finite element modeling," *PACE*, 15:563, abstract 219 (Apr. 1992).

(List continued on next page.)

Related U.S. Application Data

- [62] Division of Ser. No. 103,837, Aug. 6, 1993.
- [51] Int. Cl.⁶ **A61N 1/39**
- [52] U.S. Cl. **607/7; 607/5; 607/74**
- [58] Field of Search **607/7, 5, 6, 4, 607/74**

Primary Examiner—William E. Kamm
Assistant Examiner—Kennedy J. Schaetzle
Attorney, Agent, or Firm—Morrison & Foerster

[57] ABSTRACT

This invention provides an external defibrillator and defibrillation method that automatically compensates for patient-to-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.

[56] References Cited

U.S. PATENT DOCUMENTS

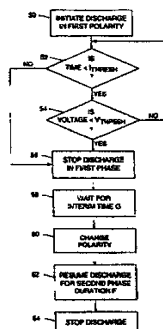
3,211,154 10/1965 Becker et al. .
 3,241,553 3/1966 Caywood et al. .
 3,706,313 12/1972 Milani et al. .
 3,782,389 1/1974 Bell .
 3,860,009 1/1975 Bell et al. .
 3,862,636 1/1975 Bell et al. .
 3,886,950 6/1975 Ukkestad et al. .
 4,023,573 5/1977 Pantridge et al. .
 4,328,808 5/1982 Charbonnier et al. .
 4,419,998 12/1983 Heath .

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

0281219 9/1988 European Pat. Off. .
 0315368 5/1989 European Pat. Off. .
 0353341 2/1990 European Pat. Off. .
 0437104 7/1991 European Pat. Off. .
 0507504 10/1992 European Pat. Off. .
 2070435 9/1981 United Kingdom .
 2083363 3/1982 United Kingdom .
 93/16759 9/1993 WIPO .

18 Claims, 7 Drawing Sheets



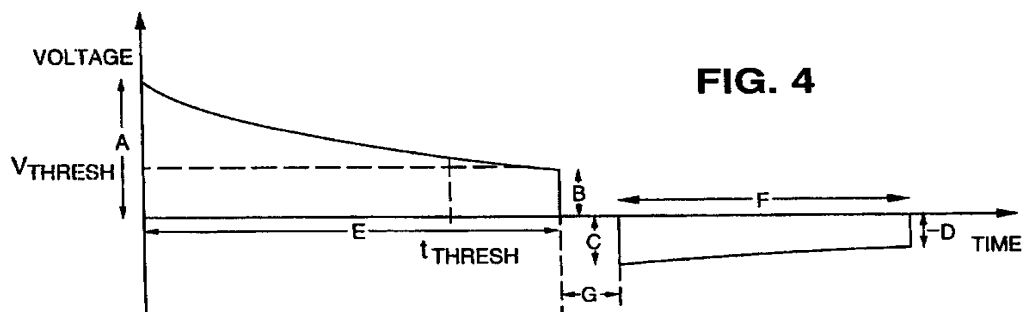
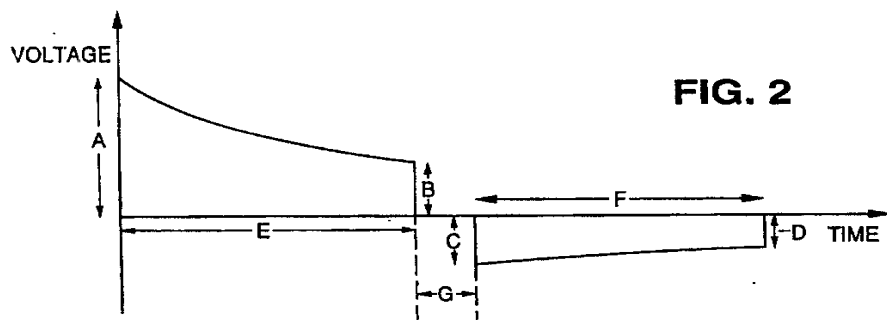
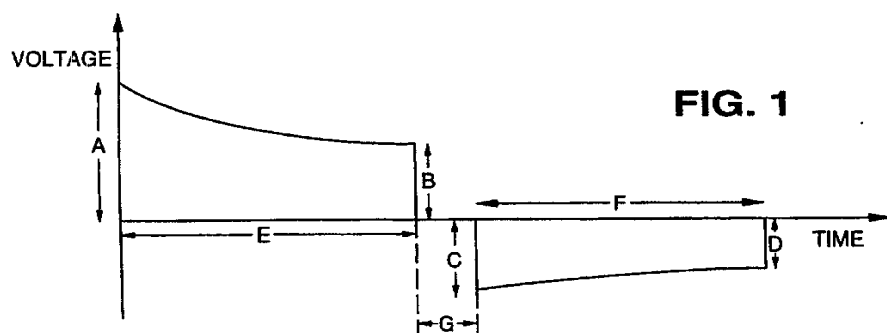
U.S. PATENT DOCUMENTS

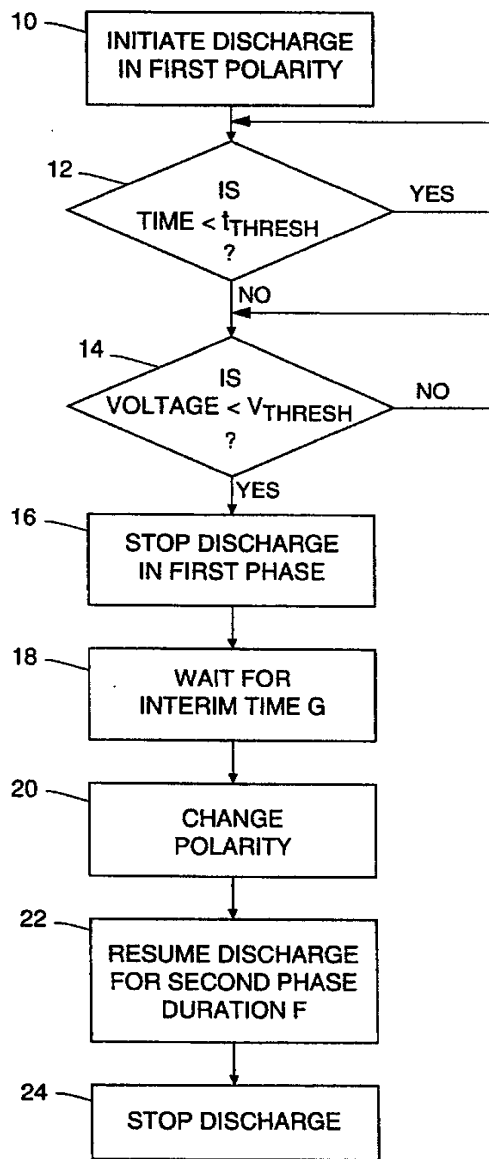
4,473,078 9/1984 Angel .
 4,494,552 1/1985 Heath .
 4,504,773 3/1985 Suzuki et al. .
 4,574,810 3/1986 Lerman .
 4,595,009 6/1986 Leinders .
 4,610,254 9/1986 Morgan et al. .
 4,619,265 10/1986 Morgan et al. .
 4,637,397 1/1987 Jones et al. .
 4,745,923 5/1988 Winstrom .
 4,800,883 1/1989 Winstrom .
 4,821,723 4/1989 Baker et al. .
 4,840,177 6/1989 Charbonnier et al. .
 4,848,345 7/1989 Zenklich .
 4,850,357 7/1989 Bach, Jr. .
 4,953,551 9/1990 Mehra et al. .
 4,998,531 3/1991 Bocchi et al. .
 5,078,134 1/1992 Heitman et al. .
 5,083,562 1/1992 de Coriolis et al. .
 5,097,833 3/1992 Campos .
 5,107,834 4/1992 Ideker et al. .
 5,111,813 5/1992 Charbonnier et al. .
 5,111,816 5/1992 Pless et al. .
 5,207,219 5/1993 Adams et al. .
 5,215,081 6/1993 Ostroff .
 5,222,480 6/1993 Couche et al. .
 5,222,492 6/1993 Morgan et al. .
 5,230,336 7/1993 Fain et al. .
 5,237,989 8/1993 Morgan et al. .
 5,249,573 10/1993 Fincke et al. .
 5,272,157 1/1994 Morgan et al. .
 5,306,291 4/1994 Kroll et al. .
 5,334,219 8/1994 Kroll .
 5,334,430 9/1994 Berg et al. .
 5,352,239 10/1994 Pless .
 5,370,664 12/1994 Morgan et al. .
 5,372,606 12/1994 Lang et al. .
 5,411,526 5/1995 Kroll et al. .

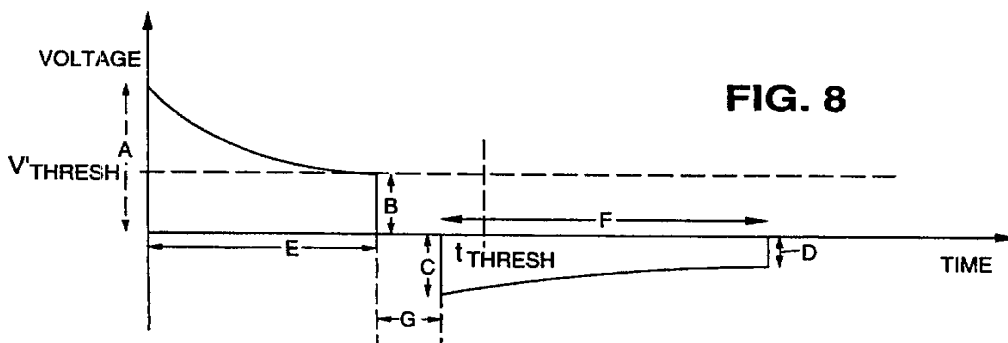
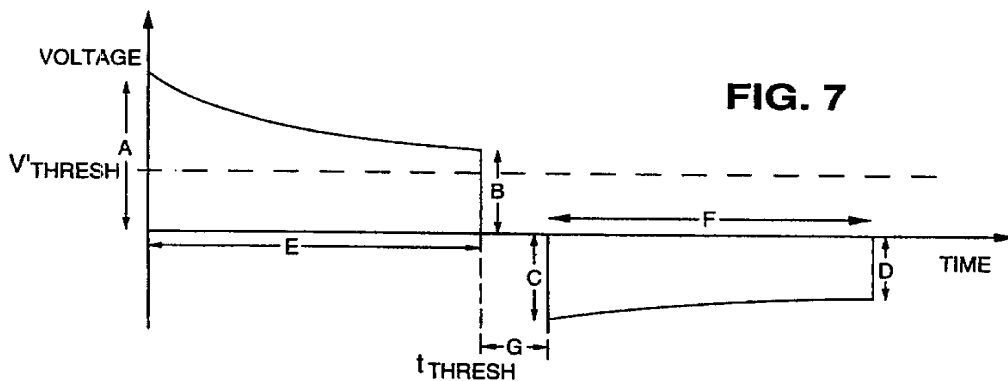
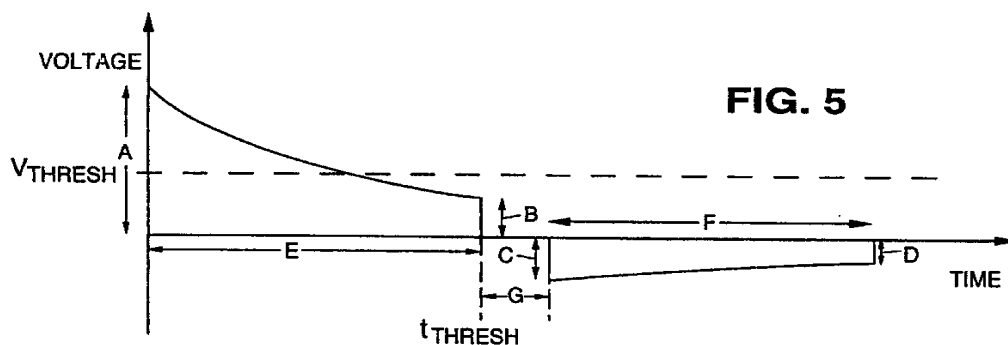
OTHER PUBLICATIONS

- 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 defibrillation 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).
 Feaser 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).
 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).
 Jones, et al., "Decreased defibrillator-induced dysfunction with biphasic rectangular waveforms," *Am. J. Physiol.* 247:H792-796 (1984).
 Jones, et al., "Improved defibrillator waveform safety factor with biphasic waveforms," *Am. J. Physiol.*, 245:H60-65 (1983).
 Jude et al., "Fundamentals of Cardiopulmonary Resuscitation," F. A. Davis Company, Philadelphia PA, pp. 98-104 (1965).
 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).
 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).
 Lerman, et al., "Currency-Based Versus Energy-Based Ventricular Defibrillation: A Prospective Study," *JACC* 12(5):1259-1264 (1988).
 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).
 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 First Medic Semi-Automatic Defibrillators (1994), Spacelabs Medical Products, 15220 N.E. 40th Street, P.O. Box 97013, Redmond, WA 98073-9713.
 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*, 10:1130-1141 (Sep.-Oct. 1987).
 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).

- Schuder et al., "Comparison of effectiveness of relay-switched, 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).
- Schuder, et al., "One-Cycle Bidirectional Rectangular Wave Shocks for Open Chest Defibrillation in the Calf," *Abstr. Am. Soc. Artif. Intern. Organs*, 9: 16.
- Schuder, et al., "Transthoracic Ventricular Defibrillation with Square-wave Stimuli: One half Cycle," *Circ. Res.*, XV:258-264 (1964).
- Schuder, et al., "Defibrillation of 100 kg calves with asymmetrical, bidirectional, rectangular pulses," *Card. Res.*, 18:419-426 (1984).
- Schuder, et al., "Transthoracic Ventricular Defibrillation in the 100 kg Calf with Symmetrical One-Cycle Bidirectional Rectangular Wave Stimuli," *IEEE Trans. BME*, 30(7):415-422 (1983).
- Schuder, et al., "Ultrahigh-energy hydrogen thyron/SCR Bidirectional waveform defibrillator," *Med. & Biol. Eng. & Comput.*, 20:419-424 (1982).
- Schuder, et al., "Wave form Dependency in Defibrillating 100 kg Calves," *Devices & Tech. Meeting, NIH* (1981).
- Schuder, et al., "Waveform dependency in defibrillation," *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).
- Tang, et al., "Strength Duration Curve for Ventricular Defibrillation Using Biphasic Waveforms," *PACE*, abstract no. 49 (1987).
- Tang, et al., "Ventricular Defibrillation Using Biphasic Waveforms of Different Phasic Duration," *PACE*, abstract no. 47 (1987).
- 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).
- Wetherbec, et al., "Subcutaneous Patch Electrode-A Means to Obviate Thoracotomy for Implantation of the Automatic Implantable cardioverter Defibrillation System?," *Circ.* 72:III-384, abstract no. 1536 (1985).
- Winkle "The implantable defibrillator in ventricular arrhythmias," *Hospital Practice*, pp. 149-165 (Mar. 1983).
- Winkle et al., "Improved Low Energy Defibrillation Efficacy in Man Using a Biphasic Truncated Exponential Waveform," *JACC*, 9(2): 142A (1987).
- Zipes, "Sudden cardiac death," *Circulation*, 85(1):160-166 (1992).



**FIG. 3**



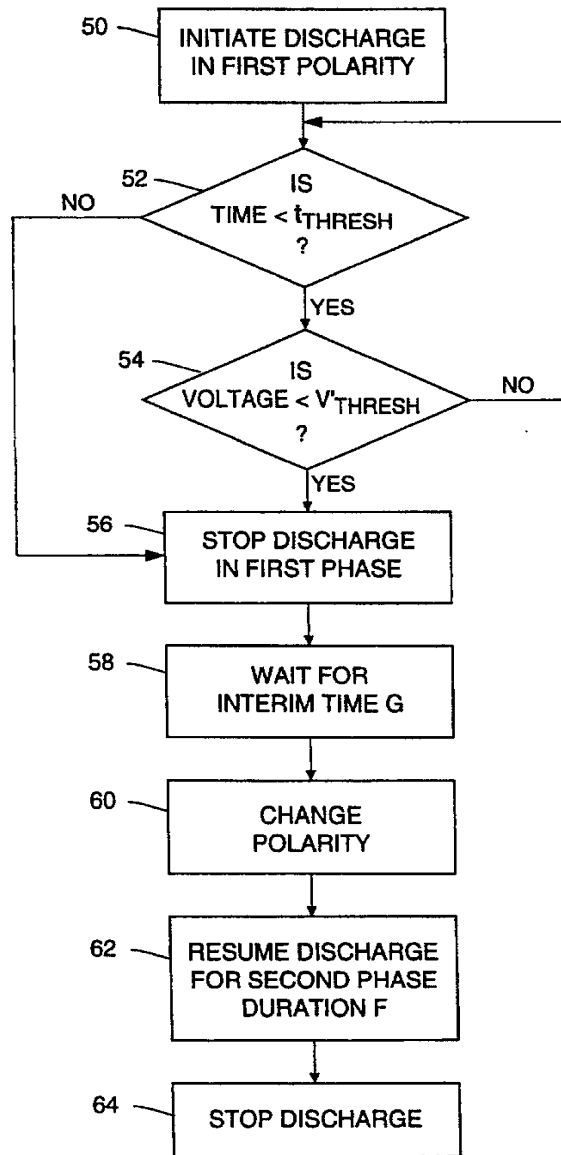


FIG. 6

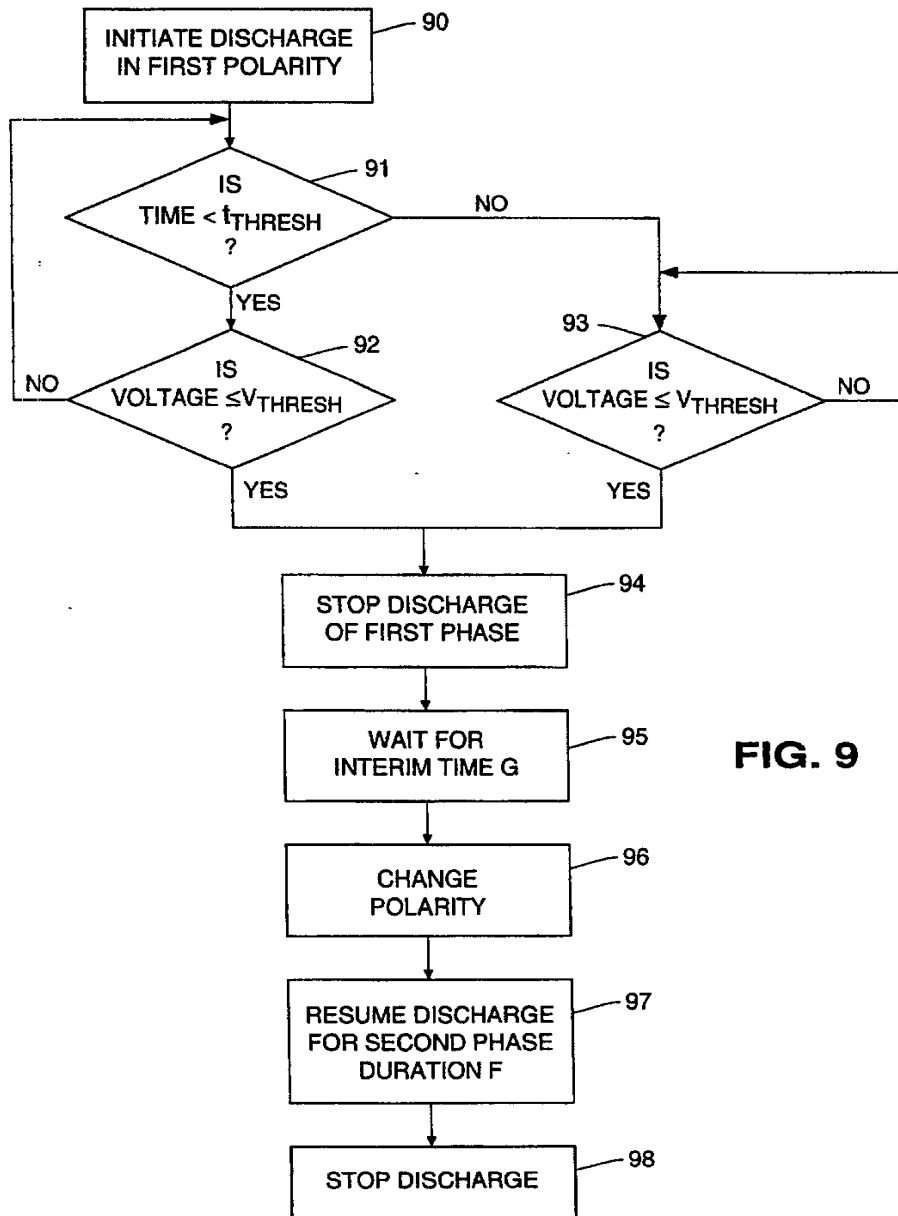


FIG. 9

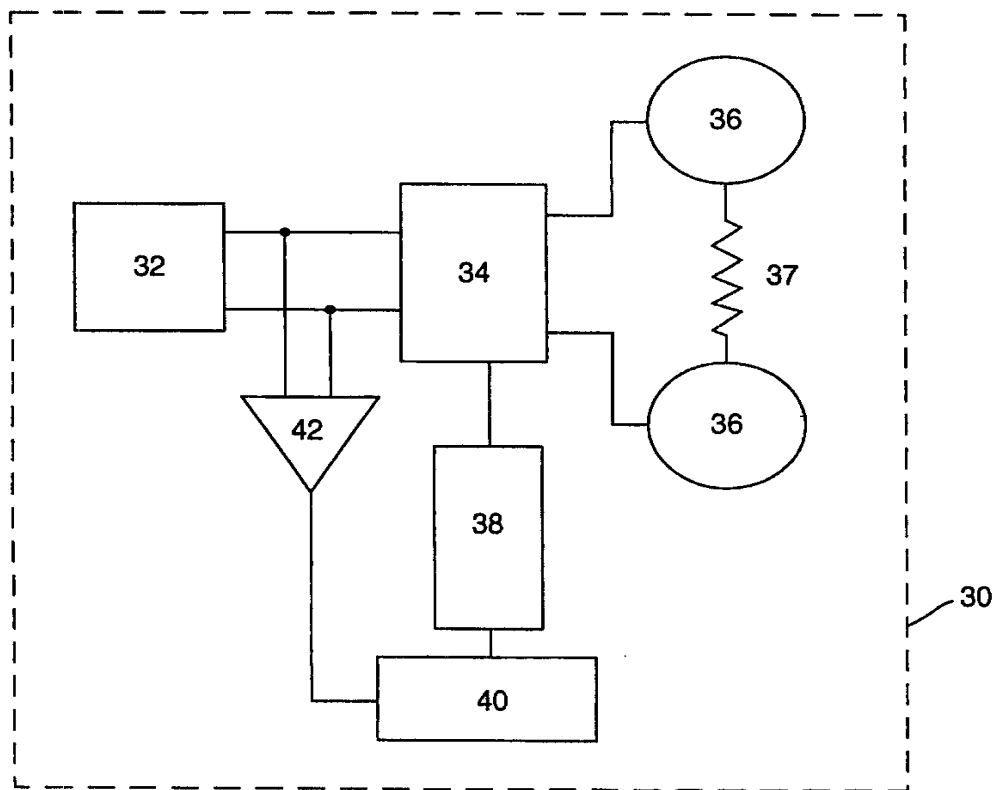


FIG. 10

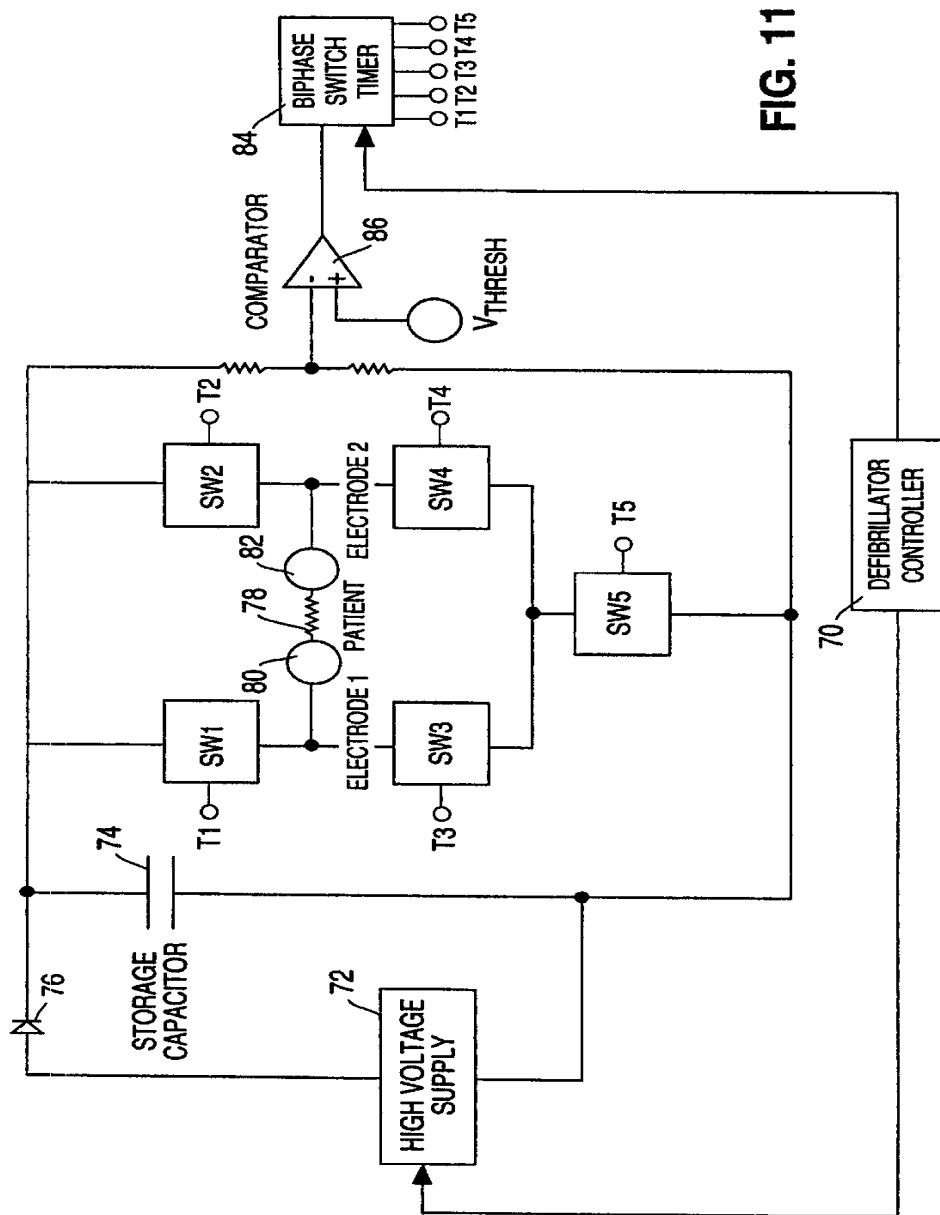


FIG. 11

1

ELECTROTHERAPY METHOD

This application is a divisional of application Ser. No. 08/103,837 filed Aug. 6, 1993.

BACKGROUND OF THE INVENTION

This invention relates generally to an electrotherapy method and apparatus for delivering a shock to a patient's heart. In particular, this invention relates to a method and apparatus for using an external defibrillator to deliver a biphasic defibrillation shock to a patient's heart through electrodes attached to the patient.

Defibrillators apply pulses of electricity to a patient's heart to convert ventricular arrhythmias, such as ventricular fibrillation and ventricular tachycardia, to normal heart rhythms through the processes of defibrillation and cardioversion, respectively. There are two main classifications of defibrillators: external and implanted. Implantable defibrillators are surgically implanted in patients who have a high likelihood of needing electrotherapy in the future. Implanted defibrillators typically monitor the patient's heart activity and automatically supply electrotherapeutic pulses directly to the patient's heart when indicated. Thus, implanted defibrillators permit the patient to function in a somewhat normal fashion away from the watchful eye of medical personnel.

External defibrillators send electrical pulses to the patient's heart through electrodes applied to the patient's torso. External defibrillators are useful in the emergency room, the operating room, emergency medical vehicles or other situations where there may be an unanticipated need to provide electrotherapy to a patient on short notice. The advantage of external defibrillators is that they may be used on a patient as needed, then subsequently moved to be used with another patient. However, because external defibrillators deliver their electrotherapeutic pulses to the patient's heart indirectly (i.e., from the surface of the patient's skin rather than directly to the heart), they must operate at higher energies, voltages and/or currents than implanted defibrillators. The high energy, voltage and current requirements have made current external defibrillators large, heavy and expensive, particularly due to the large size of the capacitors or other energy storage media required by these prior art devices.

The time plot of the current or voltage pulse delivered by a defibrillator shows the defibrillator's characteristic waveform. Waveforms are characterized according to the shape, polarity, duration and number of pulse phases. Most current external defibrillators deliver monophasic current or voltage electrotherapeutic pulses, although some deliver biphasic sinusoidal pulses. Some prior art implantable defibrillators, on the other hand, use truncated exponential, biphasic waveforms. Examples of biphasic implantable defibrillators may be found in U.S. Pat. No. 4,821,723 to Baker, Jr., et al.; U.S. Pat. No. 5,083,562 to de Coriolis et al.; U.S. Pat. No. 4,800,883 to Winstrom; U.S. Pat. No. 4,850,357 to Bach, Jr.; and U.S. Pat. No. 4,953,551 to Mehra et al.

Because each implanted defibrillator is dedicated to a single patient, its operating parameters, such as electrical pulse amplitudes and total energy delivered, may be effectively titrated to the physiology of the patient to optimize the defibrillator's effectiveness. Thus, for example, the initial voltage, first phase duration and total pulse duration may be set when the device is implanted to deliver the desired amount of energy or to achieve that desired start and end voltage differential (i.e., a constant tilt).

2

In contrast, because external defibrillator electrodes are not in direct contact with the patient's heart, and because external defibrillators must be able to be used on a variety of patients having a variety of physiological differences, external defibrillators must operate according to pulse amplitude and duration parameters that will be effective in most patients, no matter what the patient's physiology. For example, the impedance presented by the tissue between external defibrillator electrodes and the patient's heart varies from patient to patient, thereby varying the intensity and waveform shape of the shock actually delivered to the patient's heart for a given initial pulse amplitude and duration. Pulse amplitudes and durations effective to treat low impedance patients do not necessarily deliver effective and energy efficient treatments to high impedance patients.

Prior art external defibrillators have not fully addressed the patient variability problem. One prior art approach to this problem was to provide the external defibrillator with multiple energy settings that could be selected by the user. A common protocol for using such a defibrillator was to attempt defibrillation at an initial energy setting suitable for defibrillating a patient of average impedance, then raise the energy setting for subsequent defibrillation attempts in the event that the initial setting failed. The repeated defibrillation attempts require additional energy and add to patient risk. What is needed, therefore, is an external defibrillation method and apparatus that maximizes energy efficiency (to minimize the size of the required energy storage medium) and maximizes therapeutic efficacy across an entire population of patients.

SUMMARY OF THE INVENTION

This invention provides an external defibrillator and defibrillation method that automatically compensates for patient-to-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.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic representation of a low-tilt biphasic electrotherapeutic waveform according to a first aspect of this invention.

FIG. 2 is a schematic representation of a high-tilt biphasic electrotherapeutic waveform according to the first aspect of this invention.

3

FIG. 3 is a flow chart demonstrating part of an electrotherapy method according to a second aspect of this invention.

FIG. 4 is a schematic representation of a biphasic waveform delivered according to the second aspect of this invention.

FIG. 5 is a schematic representation of a biphasic waveform delivered according to the second aspect of this invention.

FIG. 6 is a flow chart demonstrating part of an electrotherapy method according to a third aspect of this invention.

FIG. 7 is a schematic representation of a biphasic waveform delivered according to the third aspect of this invention.

FIG. 8 is a schematic representation of a biphasic waveform delivered according to the third aspect of this invention.

FIG. 9 is a flow chart demonstrating part of an electrotherapy method according to a combination of the second and third aspects of this invention.

FIG. 10 is a block diagram of a defibrillator system according to a preferred embodiment of this invention.

FIG. 11 is a schematic circuit diagram of a defibrillator system according to a preferred embodiment of this invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIGS. 1 and 2 illustrate the patient-to-patient differences that an external defibrillator design must take into account. These figures are schematic representations of truncated exponential biphasic waveforms delivered to two different patients from an external defibrillator according to the electrotherapy method of this invention for defibrillation or cardioversion. In these drawings, the vertical axis is voltage, and the horizontal axis is time. The principles discussed here are applicable to waveforms described in terms of current versus time as well, however.

The waveform shown in FIG. 1 is called a low-tilt waveform, and the waveform shown in FIG. 2 is called a high-tilt waveform, where tilt H is defined as a percent as follows:

$$H = \frac{|A| - |D|}{|A|} \times 100$$

As shown in FIGS. 1 and 2, A is the initial first phase voltage and D is the second phase terminal voltage. The first phase terminal voltage B results from the exponential decay over time of the initial voltage A through the patient, and the second phase terminal voltage D results from the exponential decay of the second phase initial voltage C in the same manner. The starting voltages and first and second phase durations of the FIG. 1 and FIG. 2 waveforms are the same; the differences in end voltages B and D reflect differences in patient impedance.

Prior art disclosures of the use of truncated exponential biphasic waveforms in implantable defibrillators have provided little guidance for the design of an external defibrillator that will achieve acceptable defibrillation or cardioversion rates across a wide population of patients. The defibrillator operating voltages and energy delivery requirements affect the size, cost, weight and availability of components. In particular, operating voltage requirements affect

4

the choice of switch and capacitor technologies. Total energy delivery requirements affect defibrillator battery and capacitor choices.

We have determined that, for a given patient, externally-applied truncated exponential biphasic waveforms defibrillate at lower voltages and at lower total delivered energies than externally-applied monophasic waveforms. In addition, we have determined that there is a complex relationship between total pulse duration, first to second phase duration ratio, initial voltage, total energy and total tilt.

Up to a point, the more energy delivered to a patient in an electrotherapeutic pulse, the more likely the defibrillation attempt will succeed. Low-tilt biphasic waveforms achieve effective defibrillation rates with less delivered energy than high-tilt waveforms. However, low-tilt waveforms are energy inefficient, since much of the stored energy is not delivered to the patient. On the other hand, defibrillators delivering high-tilt biphasic waveforms deliver more of the stored energy to the patient than defibrillators delivering low-tilt waveforms while maintaining high efficacy up to a certain critical tilt value. Thus, for a given capacitor, a given initial voltage and fixed phase durations, high impedance patients receive a waveform with less total energy and lower peak currents but better conversion properties per unit of energy delivered, and low impedance patients receive a waveform with more delivered energy and higher peak currents. There appears to be an optimum tilt range in which high and low impedance patients will receive effective and efficient therapy. An optimum capacitor charged to a predetermined voltage can be chosen to deliver an effective and efficient waveform across a population of patients having a variety of physiological differences.

This invention is a defibrillator and defibrillation method that takes advantage of this relationship between waveform tilt and total energy delivered in high and low impedance patients. In one aspect of the invention, the defibrillator operates in an open loop, i.e., without any feedback regarding patient impedance parameters and with preset pulse phase durations. The preset parameters of the waveforms shown in FIG. 1 and 2 are therefore the initial voltage A of the first phase of the pulse, the duration E of the first phase, the interphase duration G, and the duration F of the second phase. The terminal voltage B of the first phase, the initial voltage C of the second phase, and the terminal voltage D of the second phase are dependent upon the physiological parameters of the patient and the physical connection between the electrodes and the patient.

For example, if the patient impedance (i.e., the total impedance between the two electrodes) is high, the amount of voltage drop (exponential decay) from the initial voltage A to the terminal voltage B during time E will be lower (FIG. 1) than if the patient impedance is low (FIG. 2). The same is true for the initial and terminal voltages of the second phase during time F. The values of A, E, G and F are set to optimize defibrillation and/or cardioversion efficacy across a population of patients. Thus, high impedance patients receive a low-tilt waveform that is more effective per unit of delivered energy, and low impedance patients receive a high-tilt waveform that delivers more of the stored energy and is therefore more energy efficient.

Another feature of biphasic waveforms is that waveforms with relatively longer first phases have better conversion properties than waveforms with equal or shorter first phases, provided the total duration exceeds a critical minimum. Therefore, in the case of high impedance patients, it may be desirable to extend the first phase of the biphasic waveform (while the second phase duration is kept constant) to

increase the overall efficacy of the electrotherapy by delivering a more efficacious waveform and to increase the total amount of energy delivered. FIGS. 3-5 demonstrate a defibrillation method according to this second aspect of the invention in which information related to patient impedance is fed back to the defibrillator to change the parameters of the delivered electrotherapeutic pulse.

FIG. 3 is a flow chart showing the method steps following the decision (by an operator or by the defibrillator itself) to apply an electrotherapeutic shock to the patient through electrodes attached to the patient and charging of the energy source, e.g., the defibrillator's capacitor or capacitor bank, to the initial first phase voltage A. Block 10 represents initiation of the first phase of the pulse in a first polarity. Discharge may be initiated manually by the user or automatically in response to patient heart activity measurements (e.g., ECG signals) received by the defibrillator through the electrodes and analyzed by the defibrillator controller in a manner known in the art.

Discharge of the first phase continues for at least a threshold time t_{THRESH} as shown by block 12 of FIG. 3. If, at the end of time t_{THRESH} , the voltage measured across the energy source has not dropped below the minimum first phase terminal voltage threshold V_{THRESH} , first phase discharge continues, as shown in block 14 of FIG. 3. For high impedance patients, this situation results in an extension of the first phase duration beyond t_{THRESH} , as shown in FIG. 4, until the measured voltage drops below the threshold V_{THRESH} . Discharge then ends to complete the first phase, as represented by block 16 of FIG. 3. If, on the other hand, the patient has low impedance, the voltage will have dropped below V_{THRESH} when the time threshold is reached, resulting in a waveform like the one shown in FIG. 5.

At the end of the first phase, and after a predetermined interim period G, the polarity of the energy source connection to the electrodes is switched, as represented by blocks 18 and 20 of FIG. 3. Discharge of the second phase of the biphasic pulse then commences and continues for a predetermined second phase duration F, as represented by block 26 of FIG. 3, then ceases. This compensating electrotherapy method ensures that the energy is delivered by the defibrillator in the most efficacious manner by providing for a minimum waveform tilt and by extending the first phase duration to meet the requirements of a particular patient.

Because this method increases the waveform tilt for high impedance patients and delivers more of the energy from the energy source than a method without compensation, the defibrillator's energy source can be smaller than in prior art external defibrillators, thereby minimizing defibrillator size, weight and expense. It should be noted that the waveforms shown in FIGS. 4 and 5 could be expressed in terms of current versus time using a predetermined current threshold value without departing from the scope of the invention.

FIGS. 6-8 illustrate a third aspect of this invention that prevents the delivered waveform from exceeding a maximum tilt (i.e., maximum delivered energy) in low impedance patients. As shown by blocks 52 and 54 in FIG. 6, the first phase discharge stops either at the end of a predetermined time t_{THRESH} or when the first phase voltage drops below V_{THRESH} . The second phase begins after an interim period G and continues for a preset period F as in the second aspect of the invention. Thus, in high impedance patients, the first phase ends at time t_{THRESH} , even if the voltage has not yet fallen below V_{THRESH} , as shown in FIG. 7. In low impedance patients, on the other hand, the first phase of the delivered waveform could be shorter in duration than the time t_{THRESH} , as shown in FIG. 8.

Once again, the waveforms shown in FIGS. 7 and 8 could be expressed in terms of current versus time using a predetermined current threshold value without departing from the scope of the invention.

FIG. 9 is a flow chart illustrating a combination of the defibrillation methods illustrated in FIGS. 3 and 6. In this combination method, the first phase of the biphasic waveform will end if the voltage reaches a first voltage threshold V_{THRESH} prior to the first phase duration threshold t_{THRESH} , as shown by blocks 91 and 92. This defibrillator decision path delivers a waveform like that shown in FIG. 8 for low impedance patients. For high impedance patients, on the other hand, if at the expiration of t_{THRESH} the voltage has not fallen below V_{THRESH} , the duration of the first phase is extended beyond t_{THRESH} until the voltage measured across the electrodes reaches a second voltage threshold V_{THRESH} , as shown in decision blocks 91 and 93. This defibrillator method path will deliver a waveform like that shown in FIG. 4.

In alternative embodiments of this invention, the second phase pulse could be a function of the first phase voltage, current or time instead of having a fixed time duration. In addition, any of the above embodiments could provide for alternating initial polarities in successive monophasic or biphasic pulses. In other words, if in the first biphasic waveform delivered by the system the first phase is a positive voltage or current pulse followed by a second phase negative voltage or current pulse, the second biphasic waveform delivered by the system would be a negative first phase voltage or current pulse followed by a positive second phase voltage or current pulse. This arrangement would minimize electrode polarization, i.e., build-up of charge on the electrodes.

For each defibrillator method discussed above, the initial first phase voltage A may be the same for all patients or it may be selected automatically or by the defibrillator user. For example, the defibrillator may have a selection of initial voltage settings, one for an infant, a second for an adult, and a third for use in open heart surgery.

FIG. 10 is a schematic block diagram of a defibrillator system according to a preferred embodiment of this invention. The defibrillator system 30 comprises an energy source 32 to provide the voltage or current pulses described above. In one preferred embodiment, energy source 32 is a single capacitor or a capacitor bank arranged to act as a single capacitor. A connecting mechanism 34 selectively connects and disconnects energy source 32 to and from a pair of electrodes 36 electrically attached to a patient, represented here as a resistive load 37. The connections between the electrodes and the energy source may be in either of two polarities with respect to positive and negative terminals on the energy source.

The defibrillator system is controlled by a controller 38. Specifically, controller 38 operates the connecting mechanism 34 to connect energy source 32 with electrodes 36 in one of the two polarities or to disconnect energy source 32 from electrodes 36. Controller 38 receives timing information from a timer 40, and timer 40 receives electrical information from electrical sensor 42 connected across energy source 32. In some preferred embodiments, sensor 42 is a voltage sensor; in other preferred embodiments, sensor 42 is a current sensor.

FIG. 11 is a schematic circuit diagram illustrating a device according to the preferred embodiments discussed above. Defibrillator controller 70 activates a high voltage power supply 72 to charge storage capacitor 74 via diode 76 to a predetermined voltage. During this period, switches SW1,

SW2, SW3 and SW4 are turned off so that no voltage is applied to the patient (represented here as resistor 78) connected between electrodes 80 and 82. SW5 is turned on during this time.

After charging the capacitor, controller 70 deactivates supply 72 and activates biphasic switch timer 84. Timer 84 initiates discharge of the first phase of the biphasic waveform through the patient in a first polarity by simultaneously turning on switches SW1 and SW4 via control signals T1 and T4, while switch SW5 remains on to deliver the initial voltage A through electrodes 80 and 82 to the patient 78.

Depending on the operating mode, delivery of the first phase of the biphasic pulse may be terminated by the timer 84 after the end of a predetermined period or when the voltage across the electrodes has dropped below a predetermined value as measured by comparator 86. Timer 84 terminates pulse delivery by turning off switch SW5 via control signal T5, followed by turning off switches SW1 and SW4. The voltage across electrodes 80 and 82 then returns to zero.

During the interim period G, SW5 is turned on to prepare for the second phase. After the end of interim period G, timer 84 initiates delivery of the second phase by simultaneously turning on switches SW2 and SW3 via control signals T2 and T3 while switch SW5 remains on. This configuration applies voltage from the capacitor to the electrodes at an initial second phase voltage C and in a polarity opposite to the first polarity. Timer 84 terminates delivery of the second phase by turning off switch SW5 via control signal T5, followed by turning off switches SW2 and SW3. The second phase may be terminated at the end of a predetermined period or when the voltage measured by comparator 86 drops below a second phase termination voltage threshold.

In a preferred embodiment, switch SW5 is an insulated gate bipolar transistor (IGBT) and switches SW1-SW4 are silicon-controlled rectifiers (SCRs). The SCRs are avalanche-type switches which can be turned on to a conductive state by the application of a control signal, but cannot be turned off until the current through the switch falls to zero or near zero. Thus, the five switches can be configured so that any of the switches SW1-SW4 will close when SW5 is closed and will reopen only upon application of a specific control signal to SW5.

This design has the further advantage that switch SW5 does not need to withstand the maximum capacitor voltage. The maximum voltage that will be applied across switch SW5 will occur when the first phase is terminated by turning SW5 off, at which time the capacitor voltage has decayed to some fraction of its initial value.

Other switches and switch configurations may be used, of course without departing from the scope of the invention. In addition, the defibrillator configurations of FIGS. 10 and 11 may be used to deliver electric pulses of any polarity, amplitude, and duration singly and in any combination.

While the invention has been discussed with reference to external defibrillators, one or more aspects of the invention would be applicable to implantable defibrillators as well. Other modifications will be apparent to those skilled in the art.

What is claimed is:

1. A method for applying electrotherapy to a patient through electrodes external to a patient, the electrodes being electrically connected in a predetermined polarity to an energy source charged to an initial level, the method comprising the following step:

discharging the energy source across the electrodes in the predetermined polarity until the end of a predetermined time period or until an electrical unit measured across the electrodes decays to a predetermined terminal level, whichever occurs first.

2. The method of claim 1 further comprising the following steps after the first discharging step:

reversing the polarity of connection of the energy source to the electrodes; and

discharging the energy source across the electrodes in the reversed polarity.

3. The method of claim 2 wherein the discharging step in the reversed polarity continues for a second predetermined time period.

4. The method of claim 2 wherein the discharging step in the reversed polarity continues until an electrical unit measured across the electrodes decays to a second predetermined terminal level.

5. The method of claim 2 wherein the duration of the discharging step in the reversed polarity is a function of the duration of the first discharging step.

6. The method of claim 2 wherein the measured electrical unit decays to a first phase end value at the end of the first discharging step, the duration of the discharging step in the reversed polarity being a function of the first phase end value.

7. The method of claim 1 wherein the energy source is a voltage source and the measured electrical unit is voltage.

8. The method of claim 7 wherein the voltage source comprises a capacitor.

9. A method for applying electrotherapy to a patient through electrodes connected to an energy source, the method comprising the following steps:

discharging the energy source across the electrodes to deliver electrical energy to the patient in a multiphasic waveform;

monitoring a patient-dependent electrical parameter during the discharging step;

adjusting a discharge parameter based on a value of the monitored electrical parameter,

the adjusting step comprising discharging the energy source across the electrodes in a phase of the multiphasic waveform until the end of a predetermined time period or until the monitored electrical parameter reaches a predetermined value, whichever occurs first.

10. The method of claim 9 wherein the electrical parameter is energy source voltage.

11. The method of claim 9 wherein the electrical parameter is energy source current.

12. The method of claim 9 wherein the adjusting step further comprises adjusting a discharge parameter of a later phase of the multiphasic waveform as a function of a value of the electrical parameter during an earlier phase.

13. The method of claim 12 wherein the discharge parameter of the later phase is phase duration.

14. The method of claim 9 wherein the adjusting step further comprises adjusting a discharge parameter of a later phase of the multiphasic waveform as a function of duration of an earlier phase.

15. The method of claim 14 wherein the discharge parameter of the later phase is phase duration.

16. The method of claim 7 wherein a phase of the multiphasic waveform has a fixed duration.

17. The method of claim 9 wherein the multiphasic waveform has an earlier phase and a later phase, the later phase having a fixed duration.

18. The method of claim 9 wherein the multiphasic waveform comprises a truncated exponential biphasic waveform.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 5,593,427

DATED : January 14, 1997

INVENTOR(S) : Bradford E. Gliner, Thomas D. Lyster, Clinton S. Cole,
Daniel J. Powers, and Carlton B. Morgan

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

Item [56] "5,272,157" should be — 5,275,157 —.

Item [56] "Alfeness" should be — Alferness —.

Column 8, line 58, (claim 16) "claim 7" should be — claim 9 —.

Signed and Sealed this
Thirtieth Day of September, 1997

Attest:



BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks

PATENT APPLICATION SERIAL NO. 08/801617

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

280 FC 03/11/96 08/801617
1.00 31.00 34105.000010

PTO-1556
(5/87)

Abstract

08/001417

ELECTROTHERAPY METHOD AND APPARATUS

This invention provides an external
5 defibrillator and defibrillation method that
automatically compensates for patient-to-patient
impedance differences in the delivery of
electrotherapeutic pulses for defibrillation and
cardioversion. In a preferred embodiment, the
10 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..
15 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
20 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
25 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.

30

CERTIFICATE OF MAILING BY "EXPRESS MAIL"
"Express Mail" Mailing Label No. T8418694B47US
Date of Deposit August 6, 1993

I hereby certify that this paper or fee is being deposited
with the United States Postal Service "Express Mail Post
Office to Addressee" service under 37 CFR 1.10 on the date
indicated above and is addressed to the Commissioner of
Patents and Trademarks, Washington, D.C. 20231.

GRU BIANCHINI

(Typed or Printed Name of Person Mailing Paper or Fee)

(Signature of Person Mailing Paper or Fee)

ELECTROTHERAPY METHOD AND APPARATUS

A¹ Dkt 241082000600
PATENT

08/601617

-1-

Background of the Invention

This invention relates generally to an electrotherapy method and apparatus for delivering a shock to a patient's heart. In particular, this invention relates to a method and apparatus for using an external defibrillator to deliver a biphasic defibrillation shock to a patient's heart through electrodes attached to the patient.

Defibrillators apply pulses of electricity to a patient's heart to convert ventricular arrhythmias, such as ventricular fibrillation and ventricular tachycardia, to normal heart rhythms through the processes of defibrillation and cardioversion, respectively. There are two main classifications of defibrillators: external and implanted. Implantable defibrillators are surgically implanted in patients who have a high likelihood of needing electrotherapy in the future. Implanted defibrillators typically monitor the patient's heart activity and automatically supply electrotherapeutic pulses directly to the patient's heart when indicated. Thus, implanted defibrillators permit the patient to function in a somewhat normal fashion away from the watchful eye of medical personnel.

External defibrillators send electrical pulses to the patient's heart through electrodes applied to the patient's torso. External defibrillators are useful in the emergency room, the operating room, emergency medical vehicles or other situations where there may be an unanticipated need to provide electrotherapy to a patient

-2-

on short notice. The advantage of external
defibrillators is that they may be used on a patient as
needed, then subsequently moved to be used with another
patient. However, because external defibrillators
5 deliver their electrotherapeutic pulses to the patient's
heart indirectly (i.e., from the surface of the patient's
skin rather than directly to the heart), they must
operate at higher energies, voltages and/or currents than
implanted defibrillators. The high energy, voltage and
10 current requirements have made current external
defibrillators large, heavy and expensive, particularly
due to the large size of the capacitors or other energy
storage media required by these prior art devices.

The time plot of the current or voltage pulse
15 delivered by a defibrillator shows the defibrillator's
characteristic waveform. Waveforms are characterized
according to the shape, polarity, duration and number of
pulse phases. Most current external defibrillators
deliver monophasic current or voltage electrotherapeutic
20 pulses, although some deliver biphasic sinusoidal pulses.
Some prior art implantable defibrillators, on the other
hand, use truncated exponential, biphasic waveforms.
Examples of biphasic implantable defibrillators may be
found in U.S. Patent No. 4,821,723 to Baker, Jr., et al.;
25 U.S. Patent No. 5,083,562 to de Coriolis et al.; U.S.
Patent No. 4,800,883 to Winstrom; U.S. Patent No.
4,850,357 to Bach, Jr.; and U.S. Patent No. 4,953,551 to
Mehra et al.

Because each implanted defibrillator is
30 dedicated to a single patient, its operating parameters,
such as electrical pulse amplitudes and total energy
delivered, may be effectively titrated to the physiology
of the patient to optimize the defibrillator's
effectiveness. Thus, for example, the initial voltage,
35 first phase duration and total pulse duration may be set
when the device is implanted to deliver the desired

-3-

amount of energy or to achieve that desired start and end voltage differential (i.e, a constant tilt).

5 In contrast, because external defibrillator electrodes are not in direct contact with the patient's heart, and because external defibrillators must be able to be used on a variety of patients having a variety of physiological differences, external defibrillators must operate according to pulse amplitude and duration parameters that will be effective in most patients, no
10 matter what the patient's physiology. For example, the impedance presented by the tissue between external defibrillator electrodes and the patient's heart varies from patient to patient, thereby varying the intensity and waveform shape of the shock actually delivered to the
15 patient's heart for a given initial pulse amplitude and duration. Pulse amplitudes and durations effective to treat low impedance patients do not necessarily deliver effective and energy efficient treatments to high impedance patients.

20 Prior art external defibrillators have not fully addressed the patient variability problem. One prior art approach to this problem was to provide the external defibrillator with multiple energy settings that could be selected by the user. A common protocol for
25 using such a defibrillator was to attempt defibrillation at an initial energy setting suitable for defibrillating a patient of average impedance, then raise the energy setting for subsequent defibrillation attempts in the event that the initial setting failed. The repeated
30 defibrillation attempts require additional energy and add to patient risk. What is needed, therefore, is an external defibrillation method and apparatus that maximizes energy efficiency (to minimize the size of the required energy storage medium) and maximizes therapeutic efficacy across an entire population of patients.
35

-4-

Summary of the Invention

This invention provides an external defibrillator and defibrillation method that automatically compensates for patient-to-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.

Brief Description of the Drawings

Figure 1 is a schematic representation of a low-tilt biphasic electrotherapeutic waveform according to a first aspect of this invention.

Figure 2 is a schematic representation of a high-tilt biphasic electrotherapeutic waveform according to the first aspect of this invention.

-5-

Figure 3 is a flow chart demonstrating part of an electrotherapy method according to a second aspect of this invention.

5 Figure 4 is a schematic representation of a biphasic waveform delivered according to the second aspect of this invention.

Figure 5 is a schematic representation of a biphasic waveform delivered according to the second aspect of this invention.

10 Figure 6 is a flow chart demonstrating part of an electrotherapy method according to a third aspect of this invention.

Figure 7 is a schematic representation of a biphasic waveform delivered according to the third aspect of this invention.

15 Figure 8 is a schematic representation of a biphasic waveform delivered according to the third aspect of this invention.

20 Figure 9 is a flow chart demonstrating part of an electrotherapy method according to a combination of the second and third aspects of this invention.

Figure 10 is a block diagram of a defibrillator system according to a preferred embodiment of this invention.

25 Figure 11 is a schematic circuit diagram of a defibrillator system according to a preferred embodiment of this invention.

Detailed Description of the Preferred Embodiment

30 Figures 1 and 2 illustrate the patient-to-patient differences that an external defibrillator design must take into account. These figures are schematic representations of truncated exponential biphasic waveforms delivered to two different patients from an external defibrillator according to the electrotherapy method of this invention for defibrillation or

35

-6-

cardioversion. In these drawings, the vertical axis is voltage, and the horizontal axis is time. The principles discussed here are applicable to waveforms described in terms of current versus time as well, however.

5 The waveform shown in Figure 1 is called a low-tilt waveform, and the waveform shown in Figure 2 is called a high-tilt waveform, where tilt H is defined as a percent as follows:

T7CX

$$H = \frac{|A| - |D|}{|A|} \times 100$$

10 As shown in Figures 1 and 2, A is the initial first phase voltage and D is the second phase terminal voltage. The first phase terminal voltage B results from the exponential decay over time of the initial voltage A through the patient, and the second phase terminal voltage D results from the exponential decay of the
15 second phase initial voltage C in the same manner. The starting voltages and first and second phase durations of the Figure 1 and Figure 2 waveforms are the same; the differences in end voltages B and D reflect differences in patient impedance.

20 Prior art disclosures of the use of truncated exponential biphasic waveforms in implantable defibrillators have provided little guidance for the design of an external defibrillator that will achieve acceptable defibrillation or cardioversion rates across a
25 wide population of patients. The defibrillator operating voltages and energy delivery requirements affect the size, cost, weight and availability of components. In particular, operating voltage requirements affect the choice of switch and capacitor technologies. Total
30 energy delivery requirements affect defibrillator battery and capacitor choices.

We have determined that, for a given patient, externally-applied truncated exponential biphasic

-7-

5 waveforms defibrillate at lower voltages and at lower
total delivered energies than externally-applied
monophasic waveforms. In addition, we have determined
that there is a complex relationship between total pulse
duration, first to second phase duration ratio, initial
voltage, total energy and total tilt.

10 Up to a point, the more energy delivered to a
patient in an electrotherapeutic pulse, the more likely
the defibrillation attempt will succeed. Low-tilt
biphasic waveforms achieve effective defibrillation rates
with less delivered energy than high-tilt waveforms.
However, low-tilt waveforms are energy inefficient, since
much of the stored energy is not delivered to the
patient. On the other hand, defibrillators delivering
15 high-tilt biphasic waveforms deliver more of the stored
energy to the patient than defibrillators delivering low-
tilt waveforms while maintaining high efficacy up to a
certain critical tilt value. Thus, for a given
capacitor, a given initial voltage and fixed phase
20 durations, high impedance patients receive a waveform
with less total energy and lower peak currents but better
conversion properties per unit of energy delivered, and
low impedance patients receive a waveform with more
delivered energy and higher peak currents. There appears
25 to be an optimum tilt range in which high and low
impedance patients will receive effective and efficient
therapy. An optimum capacitor charged to a predetermined
voltage can be chosen to deliver an effective and
efficient waveform across a population of patients having
30 a variety of physiological differences.

This invention is a defibrillator and
defibrillation method that takes advantage of this
relationship between waveform tilt and total energy
delivered in high and low impedance patients. In one
35 aspect of the invention, the defibrillator operates in an
open loop, i.e., without any feedback regarding patient

-8-

impedance parameters and with preset pulse phase durations. The preset parameters of the waveforms shown in Figure 1 and 2 are therefore the initial voltage A of the first phase of the pulse, the duration E of the first phase, the interphase duration G, and the duration F of the second phase. The terminal voltage B of the first phase, the initial voltage C of the second phase, and the terminal voltage D of the second phase are dependent upon the physiological parameters of the patient and the physical connection between the electrodes and the patient.

For example, if the patient impedance (i.e., the total impedance between the two electrodes) is high, the amount of voltage drop (exponential decay) from the initial voltage A to the terminal voltage B during time E will be lower (Figure 1) than if the patient impedance is low (Figure 2). The same is true for the initial and terminal voltages of the second phase during time F. The values of A, E, G and F are set to optimize defibrillation and/or cardioversion efficacy across a population of patients. Thus, high impedance patients receive a low-tilt waveform that is more effective per unit of delivered energy, and low impedance patients receive a high-tilt waveform that delivers more of the stored energy and is therefore more energy efficient.

Another feature of biphasic waveforms is that waveforms with relatively longer first phases have better conversion properties than waveforms with equal or shorter first phases, provided the total duration exceeds a critical minimum. Therefore, in the case of high impedance patients, it may be desirable to extend the first phase of the biphasic waveform (while the second phase duration is kept constant) to increase the overall efficacy of the electrotherapy by delivering a more efficacious waveform and to increase the total amount of energy delivered. Figures 3-5 demonstrate a

-9-

defibrillation method according to this second aspect of the invention in which information related to patient impedance is fed back to the defibrillator to change the parameters of the delivered electrotherapeutic pulse.

5 Figure 3 is a flow chart showing the method steps following the decision (by an operator or by the defibrillator itself) to apply an electrotherapeutic shock to the patient through electrodes attached to the patient and charging of the energy source, e.g., the
10 defibrillator's capacitor or capacitor bank, to the initial first phase voltage A. Block 10 represents initiation of the first phase of the pulse in a first polarity. Discharge may be initiated manually by the user or automatically in response to patient heart
15 activity measurements (e.g., ECG signals) received by the defibrillator through the electrodes and analyzed by the defibrillator controller in a manner known in the art.

 Discharge of the first phase continues for at least a threshold time t_{THRESH} , as shown by block 12 of
20 Figure 3. If, at the end of time t_{THRESH} , the voltage measured across the energy source has not dropped below the minimum first phase terminal voltage threshold V_{THRESH} , first phase discharge continues, as shown in block 14 of Figure 3. For high impedance patients, this situation
25 results in an extension of the first phase duration beyond t_{THRESH} , as shown in Figure 4, until the measured voltage drops below the threshold V_{THRESH} . Discharge then ends to complete the first phase, as represented by block
30 16 of Figure 3. If, on the other hand, the patient has low impedance, the voltage will have dropped below V_{THRESH} when the time threshold is reached, resulting in a waveform like the one shown in Figure 5.

 At the end of the first phase, and after a predetermined interim period G, the polarity of the
35 energy source connection to the electrodes is switched, as represented by blocks 18 and 20 of Figure 3.

10
101065.1

-10-

Discharge of the second phase of the biphasic pulse then commences and continues for a predetermined second phase duration F, as represented by block 26 of Figure 3, then ceases. This compensating electrotherapy method ensures that the energy is delivered by the defibrillator in the most efficacious manner by providing for a minimum waveform tilt and by extending the first phase duration to meet the requirements of a particular patient.

Because this method increases the waveform tilt for high impedance patients and delivers more of the energy from the energy source than a method without compensation, the defibrillator's energy source can be smaller than in prior art external defibrillators, thereby minimizing defibrillator size, weight and expense. It should be noted that the waveforms shown in Figures 4 and 5 could be expressed in terms of current versus time using a predetermined current threshold value without departing from the scope of the invention.

Figures 6-8 illustrate a third aspect of this invention that prevents the delivered waveform from exceeding a maximum tilt (i.e., maximum delivered energy) in low impedance patients. As shown by blocks 52 and 54 in Figure 6, the first phase discharge stops either at the end of a predetermined time t_{THRESH} or when the first phase voltage drops below V'_{THRESH} . The second phase begins after an interim period G and continues for a preset period F as in the second aspect of the invention. Thus, in high impedance patients, the first phase ends at time t_{THRESH} , even if the voltage has not yet fallen below V'_{THRESH} , as shown in Figure 7. In low impedance patients, on the other hand, the first phase of the delivered waveform could be shorter in duration than the time t_{THRESH} , as shown in Figure 8.

Once again, the waveforms shown in Figures 7 and 8 could be expressed in terms of current versus time

-11-

using a predetermined current threshold value without departing from the scope of the invention.

Figure 9 is a flow chart illustrating a combination of the defibrillation methods illustrated in Figures 3 and 6. In this combination method, the first phase of the biphasic waveform will end if the voltage reaches a first voltage threshold V'_{THRESH} prior to the first phase duration threshold t_{THRESH} , as shown by blocks 91 and 92. This defibrillator decision path delivers a waveform like that shown in Figure 8 for low impedance patients. For high impedance patients, on the other hand, if at the expiration of t_{THRESH} the voltage has not fallen below V'_{THRESH} , the duration of the first phase is extended beyond t_{THRESH} until the voltage measured across the electrodes reaches a second voltage threshold V_{THRESH} , as shown in decision blocks 91 and 93. This defibrillator method path will deliver a waveform like that shown in Figure 4.

In alternative embodiments of this invention, the second phase pulse could be a function of the first phase voltage, current or time instead of having a fixed time duration. In addition, any of the above embodiments could provide for alternating initial polarities in successive monophasic or biphasic pulses. In other words, if in the first biphasic waveform delivered by the system the first phase is a positive voltage or current pulse followed by a second phase negative voltage or current pulse, the second biphasic waveform delivered by the system would be a negative first phase voltage or current pulse followed by a positive second phase voltage or current pulse. This arrangement would minimize electrode polarization, i.e., build-up of charge on the electrodes.

For each defibrillator method discussed above, the initial first phase voltage A may be the same for all patients or it may be selected automatically or by the

-12-

defibrillator user. For example, the defibrillator may have a selection of initial voltage settings, one for an infant, a second for an adult, and a third for use in open heart surgery.

5 Figure 10 is a schematic block diagram of a defibrillator system according to a preferred embodiment of this invention. The defibrillator system 30 comprises an energy source 32 to provide the voltage or current pulses described above. In one preferred embodiment, 10 energy source 32 is a single capacitor or a capacitor bank arranged to act as a single capacitor. A connecting mechanism 34 selectively connects and disconnects energy source 32 to and from a pair of electrodes 36 electrically attached to a patient, represented here as a 15 resistive load 37. The connections between the electrodes and the energy source may be in either of two polarities with respect to positive and negative terminals on the energy source.

The defibrillator system is controlled by a 20 controller 38. Specifically, controller 38 operates the connecting mechanism 34 to connect energy source 32 with electrodes 36 in one of the two polarities or to disconnect energy source 32 from electrodes 36. Controller 38 receives timing information from a timer 25 40, and timer 40 receives electrical information from electrical sensor 42 connected across energy source 32. In some preferred embodiments, sensor 42 is a voltage sensor; in other preferred embodiments, sensor 42 is a current sensor.

30 Figure 11 is a schematic circuit diagram illustrating a device according to the preferred embodiments discussed above. Defibrillator controller 70 activates a high voltage power supply 72 to charge storage capacitor 74 via diode 76 to a predetermined 35 voltage. During this period, switches SW1, SW2, SW3 and SW4 are turned off so that no voltage is applied to the

-13-

patient (represented here as resistor 78) connected between electrodes 80 and 82. SW5 is turned on during this time.

5 After charging the capacitor, controller 70 de-
activates supply 72 and activates biphasic switch timer
84. Timer 84 initiates discharge of the first phase of
the biphasic waveform through the patient in a first
polarity by simultaneously turning on switches SW1 and
10 SW4 via control signals T1 and T4, while switch SW5
remains on to deliver the initial voltage A through
electrodes 80 and 82 to the patient 78.

Depending on the operating mode, delivery of
the first phase of the biphasic pulse may be terminated
by the timer 84 after the end of a predetermined period.
15 or when the voltage across the electrodes has dropped
below a predetermined value as measured by comparator 86.
Timer 84 terminates pulse delivery by turning off switch
SW5 via control signal T5, followed by turning off
switches SW1 and SW4. The voltage across electrodes 80
20 and 82 then returns to zero.

During the interim period G, SW5 is turned on
to prepare for the second phase. After the end of
interim period G, timer 84 initiates delivery of the
second phase by simultaneously turning on switches SW2
25 and SW3 via control signals T2 and T3 while switch SW5
remains on. This configuration applies voltage from the
capacitor to the electrodes at an initial second phase
voltage C and in a polarity opposite to the first
polarity. Timer 84 terminates delivery of the second
30 phase by turning off switch SW5 via control signal T5,
followed by turning off switches SW2 and SW3. The second
phase may be terminated at the end of a predetermined
period or when the voltage measured by comparator 86
drops below a second phase termination voltage threshold.

35 In a preferred embodiment, switch SW5 is an
insulated gate bipolar transistor (IGBT) and switches

101065.1

14

-14-

SW1-SW4 are silicon-controlled rectifiers (SCRs). The SCRs are avalanche-type switches which can be turned on to a conductive state by the application of a control signal, but cannot be turned off until the current
5 through the switch falls to zero or near zero. Thus, the five switches can be configured so that any of the switches SW1-SW4 will close when SW5 is closed and will reopen only upon application of a specific control signal to SW5.

10 This design has the further advantage that switch SW5 does not need to withstand the maximum capacitor voltage. The maximum voltage that will be applied across switch SW5 will occur when the first phase is terminated by turning SW5 off, at which time the
15 capacitor voltage has decayed to some fraction of its initial value.

Other switches and switch configurations may be used, of course without departing from the scope of the invention. In addition, the defibrillator configurations
20 of Figures 10 and 11 may be used to deliver electric pulses of any polarity, amplitude, and duration singly and in any combination.

While the invention has been discussed with reference to external defibrillators, one or more aspects
25 of the invention would be applicable to implantable defibrillators as well. Other modifications will be apparent to those skilled in the art.

-15-

What is claimed is:

1. A method for applying electrotherapy to a patient from a source external to the patient, the method comprising the following steps:
 - placing two electrodes on a patient, the electrodes being electrically connected in a first polarity to an energy source external to the patient;
 - charging the energy source to an energy level corresponding to a first start amplitude;
 - discharging the energy source across the electrodes, the discharging step automatically compensating for the patient impedance of the patient on whom the electrodes are placed;
 - reversing the polarity of connection of the energy source to the electrodes to a second polarity; and
 - discharging the energy source across the electrodes.
2. The method of claim 1 wherein the discharging step automatically compensates for patient impedance by adjusting the discharge duration.
3. The method of claim 1 wherein the discharging step automatically compensates for patient impedance by adjusting the first end amplitude.
4. A method for applying electrotherapy to a patient through electrodes external to a patient, the electrodes being electrically connected in a first predetermined polarity to an energy source charged to an initial level, the method comprising the following step:
 - discharging the energy source across the electrodes until the end of a predetermined time period and until an electrical unit measured across the electrodes decays to a predetermined terminal level.

-16-

5. The method of claim 4 further comprising the following steps after the first discharging step: reversing the polarity of connection of the energy source to the electrodes to a second polarity; and discharging the energy source across the electrodes.

6. The method of claim 5 wherein the discharging step in the reversed polarity continues for a second predetermined time period.

7. The method of claim 5 wherein the discharging step in the reversed polarity continues until an electrical unit measured across the electrodes decays to a second predetermined terminal level.

8. The method of claim 5 wherein the duration of the discharging step in the reversed polarity is a function of the duration of the first discharging step.

9. The method of claim 4 wherein the energy source is a voltage source and the measured electrical unit is voltage.

10. The method of claim 9 wherein the voltage source comprises a capacitor.

11. A method for applying electrotherapy to a patient through electrodes external to a patient, the electrodes being electrically connected in a first predetermined polarity to an energy source, the method comprising the following steps:

- (1) charging the energy source to an initial level;
- (2) discharging the energy source across the electrodes;

-17-

(3) reversing the polarity of connection of the energy source to the electrodes to a second polarity and repeating steps (1) and (2) for successive electrotherapy applications to the same patient.

5

12. A method for applying electrotherapy to a patient through electrodes external to a patient, the electrodes being connected in a polarity to an energy source, the method comprising the following steps:

10

(1) charging the energy source to an initial level;

(2) discharging the energy source across the electrodes;

15

(3) reversing the polarity of connection of the energy source to the electrodes;

(4) discharging the energy source across the electrodes; and

20

(5) repeating steps (1) - (4) for successive electrotherapy applications to the same patient, thereby alternating the initial polarity of successive waveforms.

13. A method for applying electrotherapy to a patient from a source external to the patient, the method comprising the following steps:

25

placing two electrodes on a patient, the electrodes being electrically connected in a first polarity to an energy source external to the patient;

charging the energy source to an energy level corresponding to a first start amplitude;

30

discharging the energy source across the electrodes at a first phase start time;

measuring the time elapsed from the first phase start time;

35

stopping the energy source discharge when the time elapsed reaches a first predetermined time period;

-18-

reversing the polarity of connection of the
energy source to the electrodes; and
discharging the energy source for a second
predetermined time period.

14. The method of claim 13 wherein the energy
source is a capacitor.

15. A method for applying electrotherapy to a
patient through electrodes external to a patient, the
electrodes being electrically connected in a
predetermined polarity to an energy source charged to an
initial level, the method comprising the following steps:
discharging the energy source across the
electrodes in the predetermined polarity until the end of
a predetermined time period or until an electrical unit
measured across the electrodes decays to a predetermined
terminal level, whichever occurs first.

16. The method of claim 15 further comprising
the following steps after the first discharging step:
reversing the polarity of connection of the
energy source to the electrodes; and
discharging the energy source across the
electrodes in the reversed polarity.

17. The method of claim 16 wherein the
discharging step in the reversed polarity continues for a
second predetermined time period.

18. The method of claim 16 wherein the
discharging step in the reversed polarity continues until
an electrical unit measured across the electrodes decays
to a second predetermined terminal level.

-19-

⁵/₁₉. The method of claim ⁵/₁₆ wherein the duration of the discharging step in the reversed polarity is a function of the duration of the first discharging step.

5 ⁶/₂₀. The method of claim ²/₁₆ wherein the measured electrical unit decays to a first phase end value at the end of the first discharging step, the duration of the discharging step in the reversed polarity
10 being a function of the first phase end value.

⁷/₂₁. The method of claim ¹/₁₆ wherein the energy source is a voltage source and the measured electrical unit is voltage.

15 ⁸/₂₂. The method of claim ⁷/₂₁ wherein the voltage source comprises a capacitor.

~~23. An apparatus for administering~~
20 ~~electrotherapy to a patient's heart through electrodes external to the patient comprising:~~
~~an energy source;~~
~~first and second electrodes adapted to make~~
~~electrical contact with a patient,~~
25 ~~a controller controlling application of~~
~~electrical energy from the energy source to the~~
~~electrodes, the controller comprising~~
~~a timer for generating a timing signal~~
~~corresponding to the application of electrical~~
30 ~~energy from the energy source to the~~
~~electrodes, and~~
~~means for selectively connecting the~~
~~energy source to the electrodes in a first~~
~~polarity and in a second polarity.~~

-20-

24. The apparatus of claim 23 wherein the controller further comprises means for measuring an electrical unit of the energy source applied across the electrodes and for generating a signal corresponding to the measured electrical unit.

25. The apparatus of claim 24 wherein the energy source is a voltage source and the measured electrical unit is voltage.

26. The apparatus of claim 25 wherein the voltage source comprises a capacitor.

27. The apparatus of claim 24 wherein the energy source is a current source and the measured electrical unit is current.

28. The apparatus of claim 24 wherein the controller further comprises threshold means for determining whether the measured electrical unit signal is less than a predetermined threshold value.

29. The apparatus of claim 28 wherein the means for selectively connecting comprises a first switch for connecting a first terminal of the energy source with the first electrode; a second switch for connecting the first terminal of the energy source with the second electrode; a third switch for connecting the first electrode with a junction; a fourth switch for connecting the second electrode with the junction; and a fifth switch for connecting the junction with the second terminal of the energy source.

30. An apparatus for administering electrotherapy to a patient's heart comprising:

-21-

a voltage source having first and second terminals;

first and second electrodes adapted to make electrical contact with a patient; and

5 a controller controlling application of voltage from the voltage source to the electrodes, the controller comprising means for selectively connecting the voltage source to the electrodes in a first polarity and in a second polarity, the means for selectively connecting
10 comprising

a first switch for connecting the first terminal of the voltage source with the first electrode;

15 a second switch for connecting the first terminal of the voltage source with the second electrode;

a third switch for connecting the first electrode with a junction;

20 a fourth switch for connecting the second electrode with the junction; and

a fifth switch for connecting the junction with the second terminal of the voltage source.

25 31. The apparatus of claim 30 wherein the fifth switch is an insulated gate bipolar transistor.

32. The apparatus of claim 31 wherein the first, second, third and fourth switches are silicon controlled rectifiers.

30 33. An external defibrillator comprising:
an energy source;
first and second electrodes adapted to make electrical contact with external sites on a patient;

-22-

a controller controlling application of
electrical energy from the energy source to the
electrodes, the controller comprising

5 a timer for generating a timing signal
corresponding to the application of electrical
energy from the energy source to the
electrodes, and

10 means for selectively connecting the
energy source to the electrodes in a first
polarity for a first predetermined time period
and in a second polarity for a second
predetermined time period.

15 34. The apparatus of claim 33 wherein the
energy source comprises a capacitor.

COMBINED DECLARATION AND POWER OF ATTORNEY
FOR UTILITY PATENT APPLICATION

AS A BELOW-NAMED INVENTOR, I HEREBY DECLARE THAT:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if more than one name is listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

ELECTROTHERAPY METHOD AND APPARATUS, the specification of which

(check one) ☐ is attached hereto
☒ was filed on August 6, 1993

as application serial no. 08/103,837 and was amended on _____ (if applicable).

I HAVE REVIEWED AND UNDERSTAND THE CONTENTS OF THE ABOVE-IDENTIFIED SPECIFICATION, INCLUDING THE CLAIMS, AS AMENDED BY ANY AMENDMENT REFERRED TO ABOVE.

I acknowledge and understand that I am an individual who has a duty to disclose information which is material to the patentability of the claims of this application in accordance with Title 37, Code of Federal Regulations, §§ 1.56(a) and (b) which state:

"(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or

67104

attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) prior art cited in search reports of a foreign patent office in a counterpart application, and

(2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability."

I do not know and do not believe this invention was ever known or used in the United States of America before my or our invention thereof, or patented or described in any printed publication in any country before my or our invention thereof or more than one year prior to said application. This invention was not in public use or on sale in the United States of America more than one year prior to this application. This invention has not been patented or made the subject of an inventor's certificate issued before the date of this application in any country foreign to the United States of America on any application filed by me or my legal representatives or assigns more than six months prior to this application.

I hereby appoint the following attorneys and agents to prosecute that application and to transact all business in the Patent and Trademark Office connected therewith and to file, to prosecute and to transact all business in connection with all patent applications directed to the invention:

William H. Benz - Reg. No. 25,952
Karl Bozicevic - Reg. No. 28,807
Felissa H. Cagan - Reg. No. 35,089
Thomas E. Ciotti - Reg. No. 21,013
Alan E. Dow - Reg. No. 35,123
Patricia M. Drost - Reg. No. 29,790
Nancy Joyce Gracey - Reg. No. 28,216
Bill Kennedy - Reg. No. 33,407
Paul C. Kimball - Reg. No. 34,641
Susan K. Lehnhardt - Reg. No. 33,943
Timothy J. Lithgow - Reg. No. 36,856
Shmuel Livnat - Reg. No. 33,949

Barbara J. Luther - Reg. No. 33,954
Michelle M. McSpadden - Reg. No. 32,048
Kate H. Murashige - Reg. No. 29,959
Gladys H. Monroy - Reg. No. 32,430
Jackie N. Nakamura - Reg. No. 35,966
Freddie K. Park - Reg. No. 35,656
Paul F. Schenck - Reg. No. 27,253
Lynne E. Schwenning - Reg. No. P37,233
James R. Shay - Reg. No. 32,062
Debra A. Shetka - Reg. No. 33,309
Cecily Anne Snyder - Reg. No. P37,448
E. Thomas Wheelock - Reg. No. 28,825

Address all correspondence to: James R. Shay, Esq.

MORRISON & FOERSTER
755 Page Mill Road
Palo Alto, CA 94304-1018

Address all telephone calls to: James R. Shay at (415) 677-6394.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

¹⁻⁸⁰
Full Name Inventor: BRADFORD E. GLINER

Signature: Bradford E. Gliner

Date 9/7/93

Residence: Bellevue, Washington WA
Citizenship: U.S.A.

Post Office Address: 3020 128th Avenue N.E., Bellevue, WA 98005

2-0
Full Name Inventor: THOMAS D. LYSTER

Signature: Thomas D. Lyster Date 9-7-93
Residence: Bothell, Washington WA
Citizenship: U.S.A.
Post Office Address: 23309 21st Avenue S.E., Bothell, WA 98021

3-0
Full Name Inventor: CLINTON S. COLE

Signature: Clinton S. Cole Date 9/7/93
Residence: Kirkland, Washington WA
Citizenship: U.S.A.
Post Office Address: 11417 N.E. 100th, Kirkland, WA 98033

4-0
Full Name Inventor: DANIEL J. POWERS

Signature: Daniel J. Powers Date 9/7/93
Residence: Bainbridge Island, Washington WA
Citizenship: U.S.A.
Post Office Address: 10797 Bill Point View N.E., Bainbridge Island, WA 98110

5-0
Full Name Inventor: CARLTON B. MORGAN

Signature: Carlton B. Morgan Date 9/7/93
Residence: Bainbridge Island, Washington WA
Citizenship: U.S.A.
Post Office Address: 4143 Palomino Drive N.E., Bainbridge Island, WA 981180

Applicant or Patentee: BRADFORD E. GLINER et al. Attorney 241082000600
Serial or Patent No.: 08/103,837 Docket No.
Filed or Issued: August 6, 1993
For: ELECTROTHERAPY METHOD AND APPARATUS

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
37 CFR 1.9(f) and 1.27(c) - SMALL BUSINESS CONCERN**

I hereby declare that I am

- ☐ the owner of the small business concern identified below:
☒ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN HEARTSTREAM, INC.
ADDRESS OF CONCERN Market Place Tower, Suite 610, 2025 First Avenue,
Seattle, WA 98121

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the person employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled ELECTROTHERAPY METHOD AND APPARATUS by inventor(s)
Bradford E. Gliner, Thomas D. Lyster, Clinton S. Cole, Daniel J. Powers and
Carlton B. Morgan
described in

- ☐ the specification filed herewith
☒ application serial no. 08/103,837, filed August 6, 1993
☐ patent no. _____, issued _____

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor if that person made the invention under 37 CFR 1.9(c) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or by a nonprofit organization under 37 CFR 1.9(e).
*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

NAME _____
ADDRESS _____
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

NAME _____
ADDRESS _____
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. [37 CFR 1.28(b)]

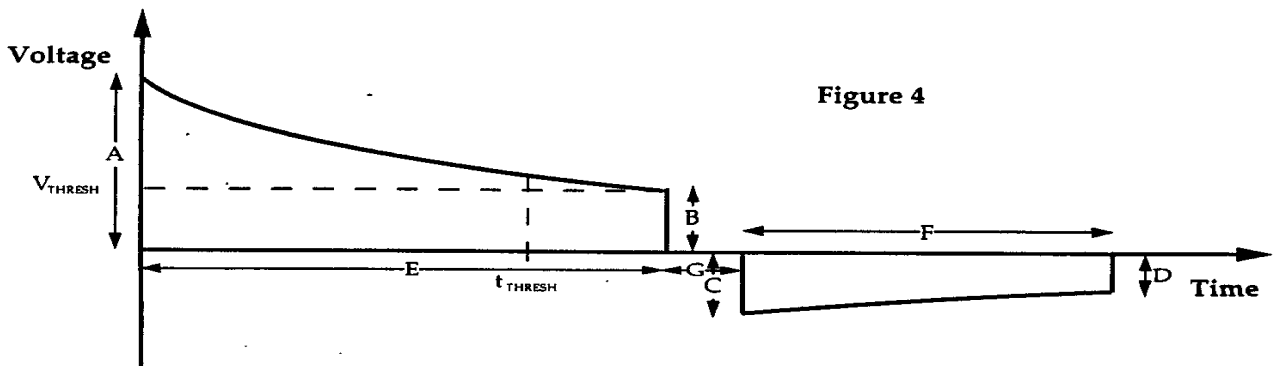
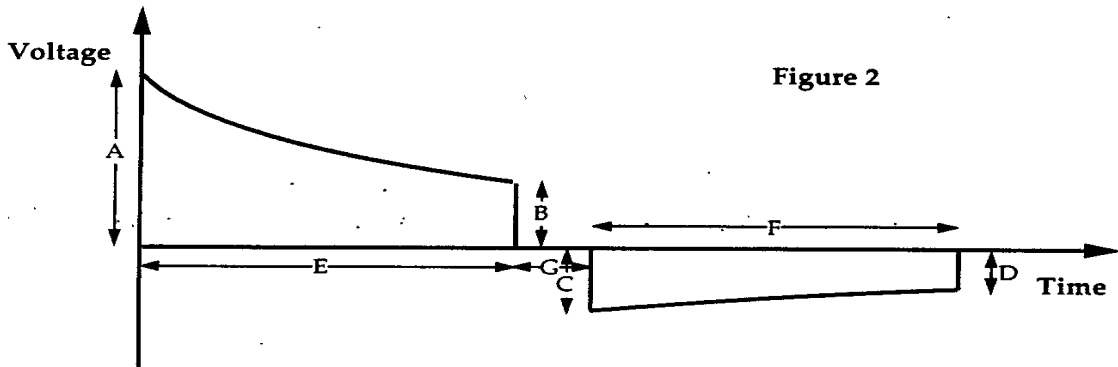
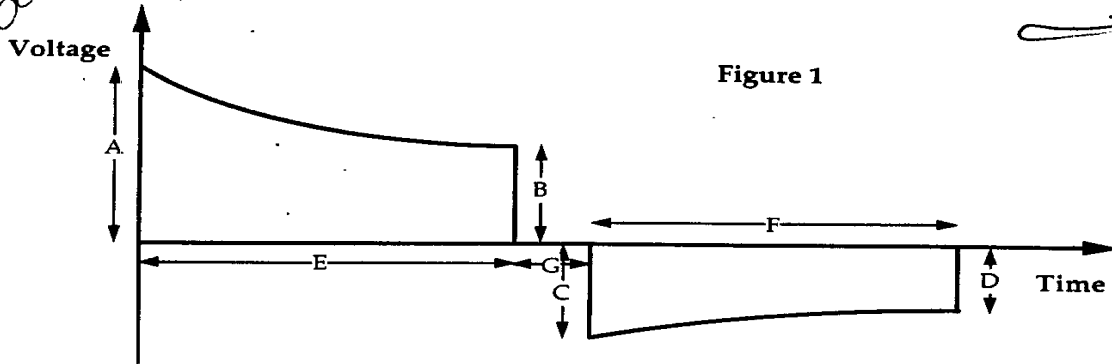
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verification statement is directed.

NAME OF PERSON SIGNING BRADFORD E. GLINER
TITLE OF PERSON OTHER THAN OWNER DIRECTOR OF RESEARCH
ADDRESS OF PERSON SIGNING Market Place Tower, Suite 610, 2025 First
Avenue, Seattle, Washington 98121
SIGNATURE Bradford E. Gliner DATE 9/7/93

607
005

08/501517

330
7-1



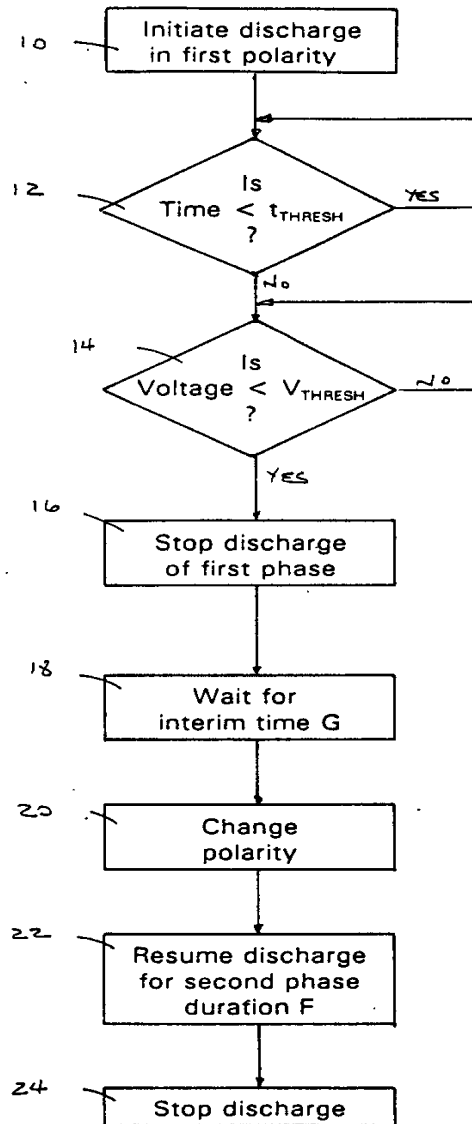
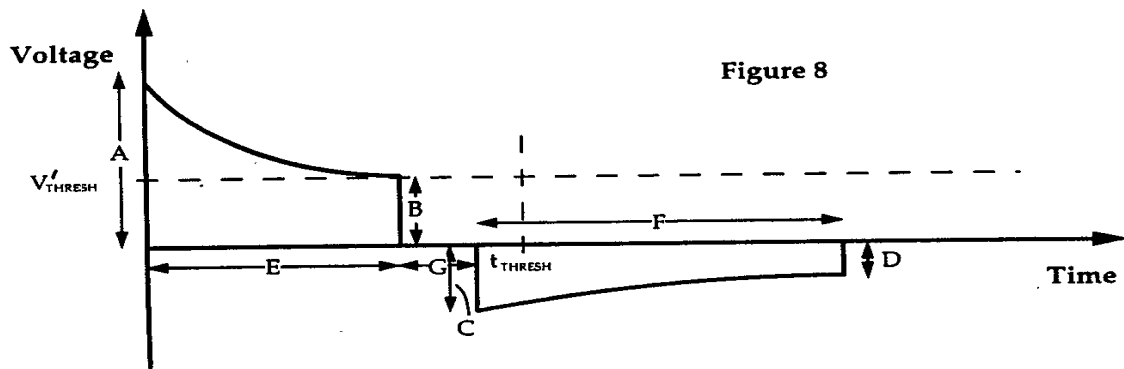
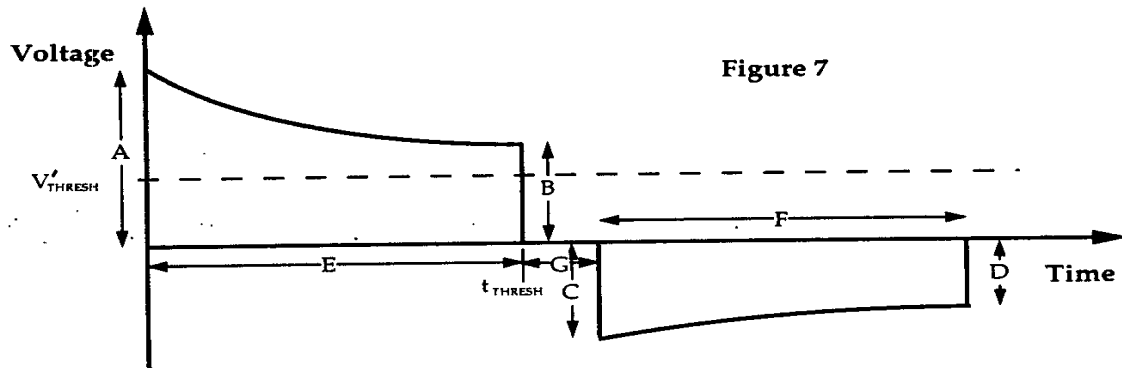
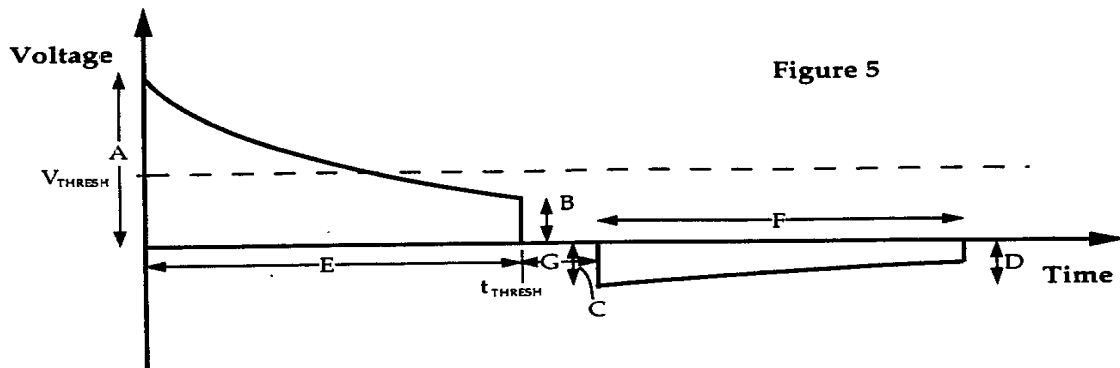


FIG. 3



08/501517

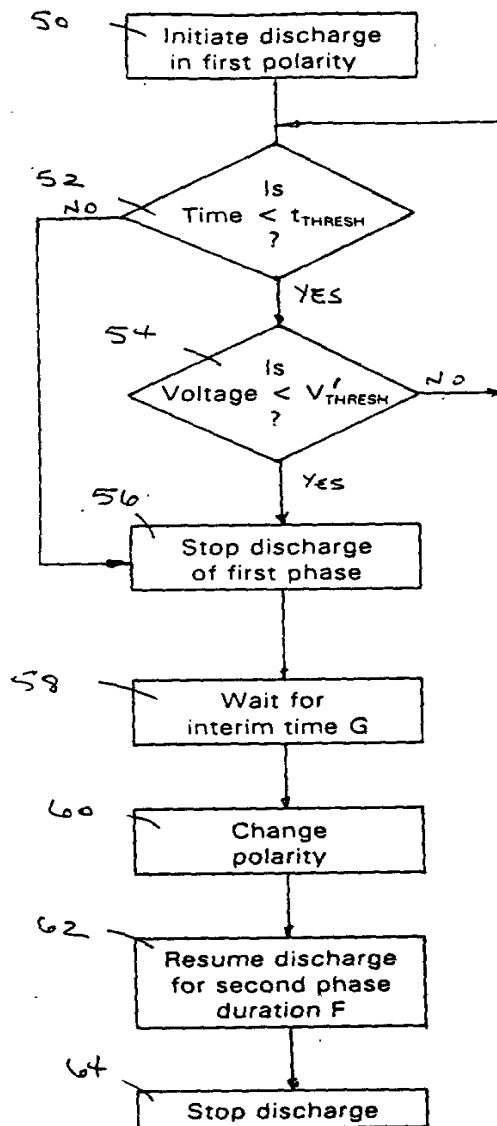


FIG. 6

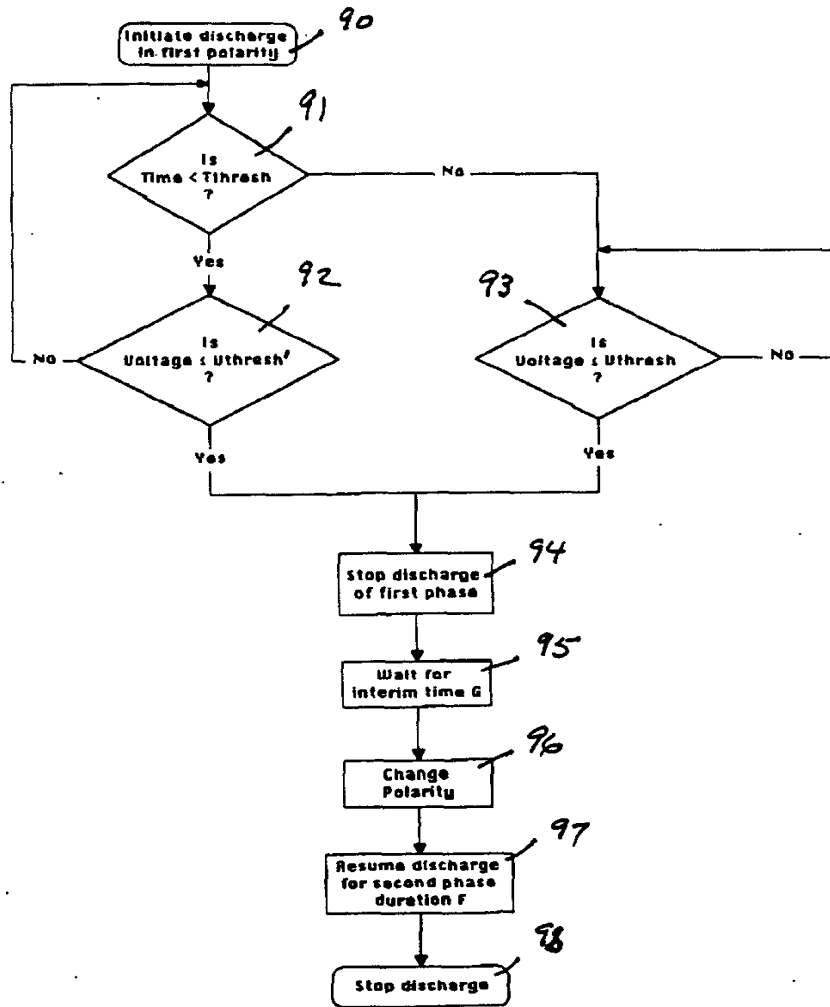


FIGURE 9

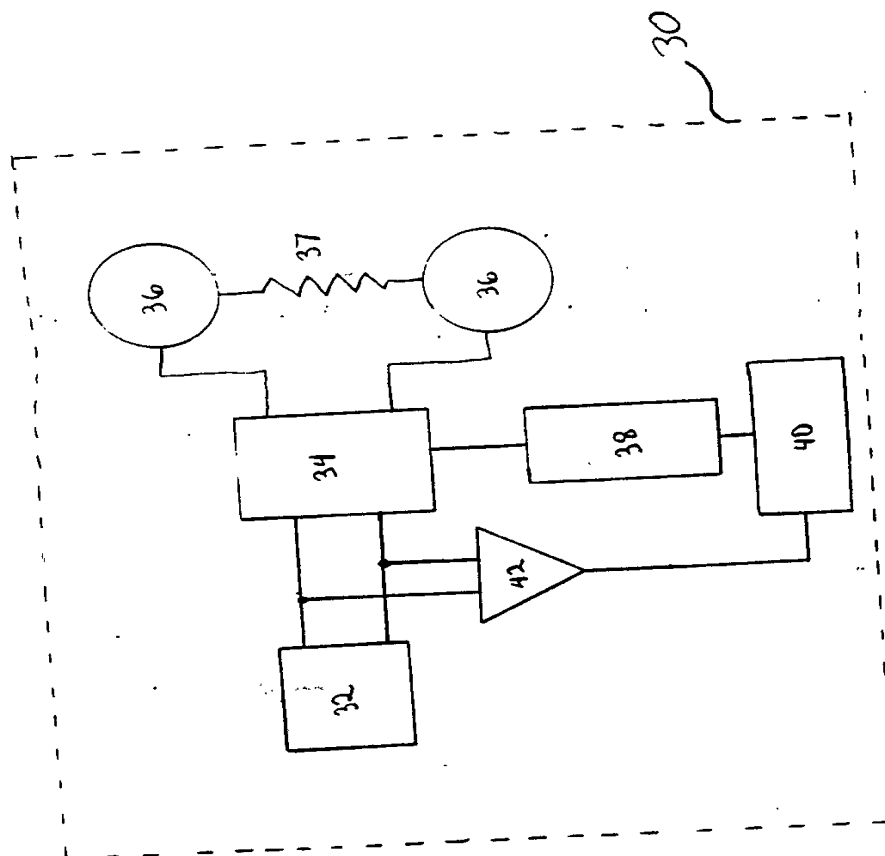
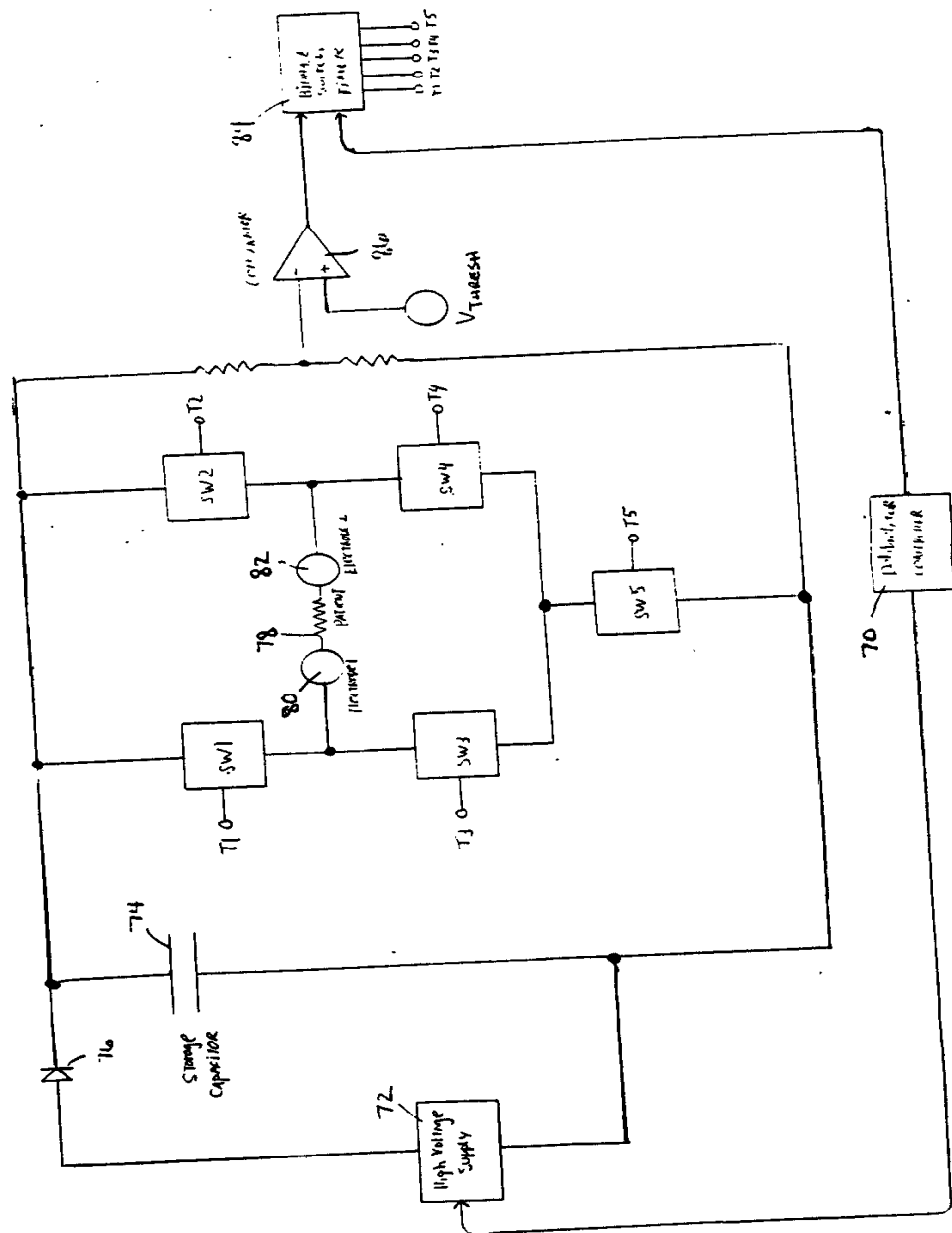


FIG 10



08/501517

330
7-1

607
005

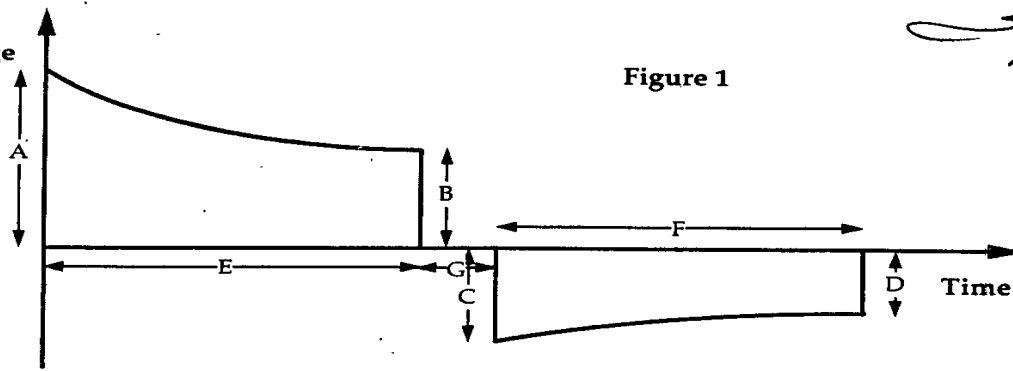


Figure 1

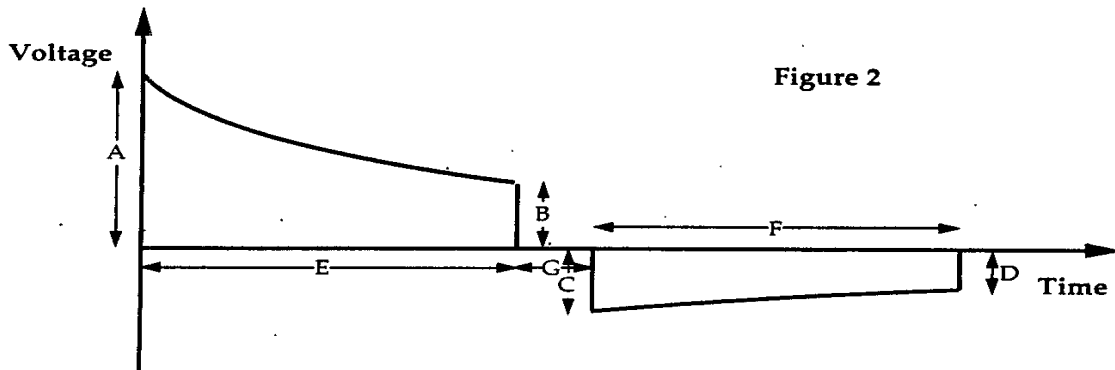


Figure 2

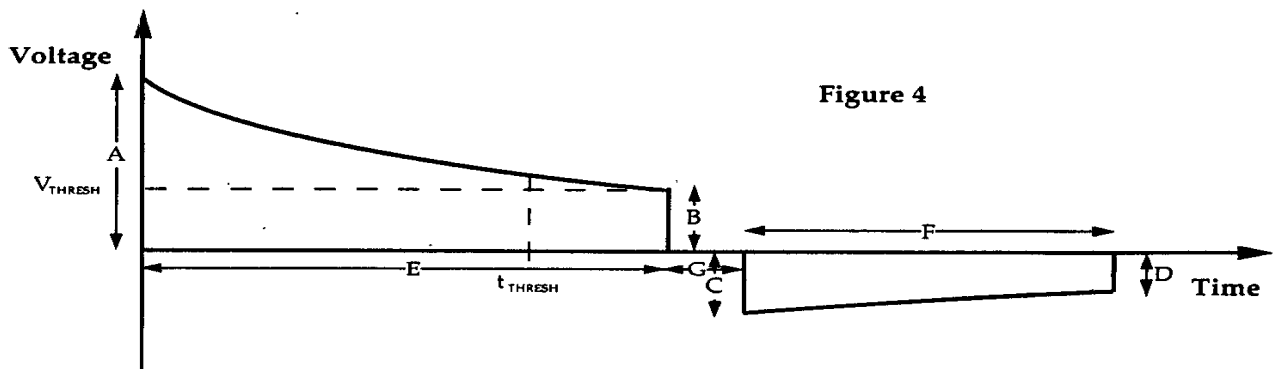


Figure 4

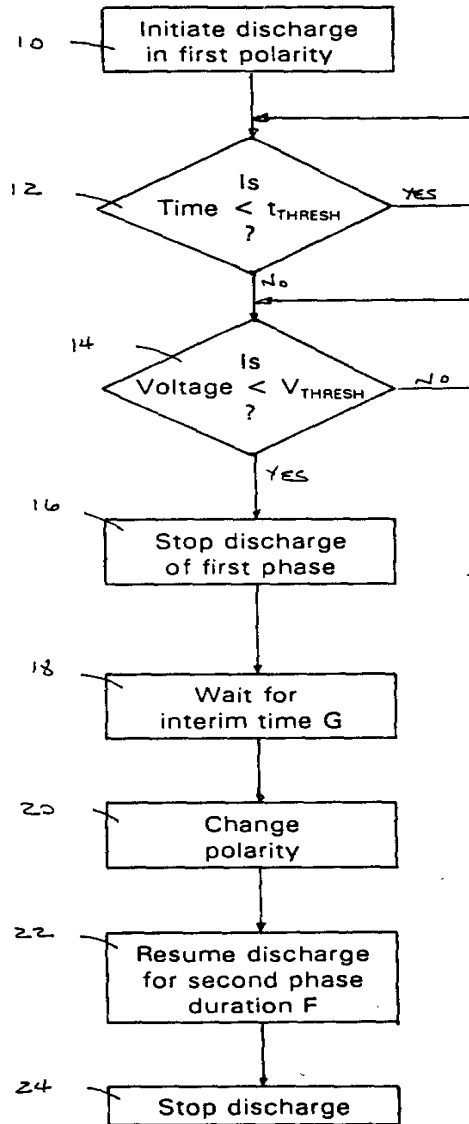
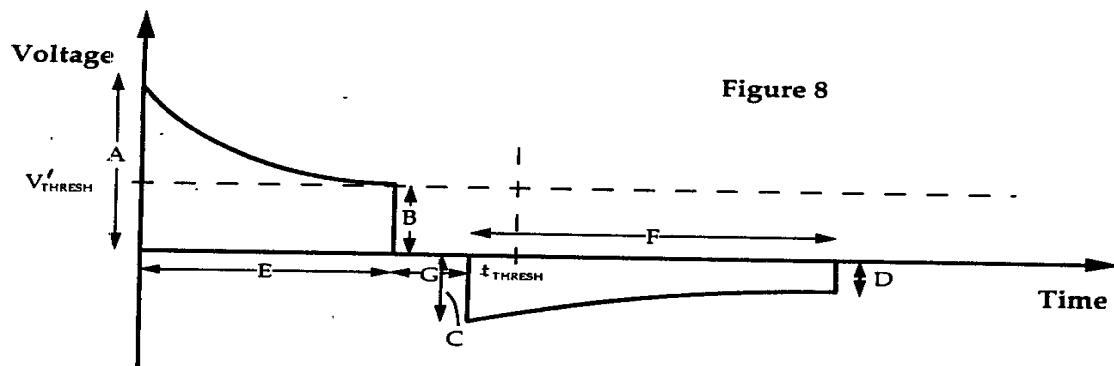
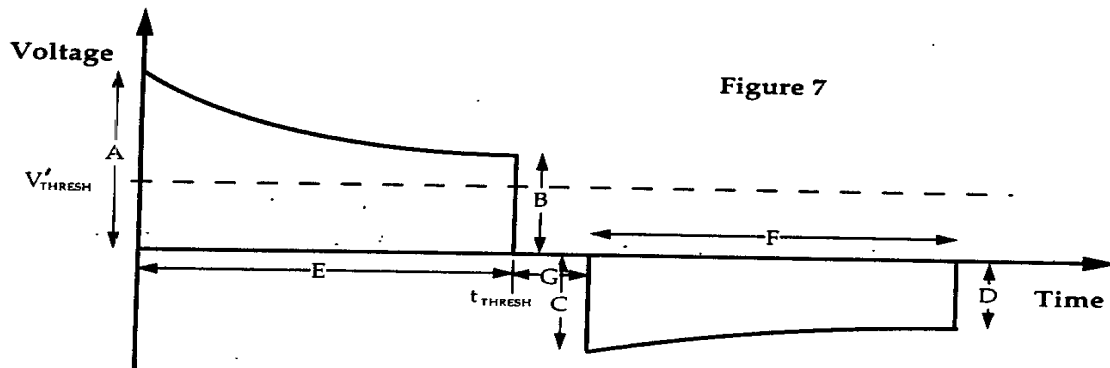
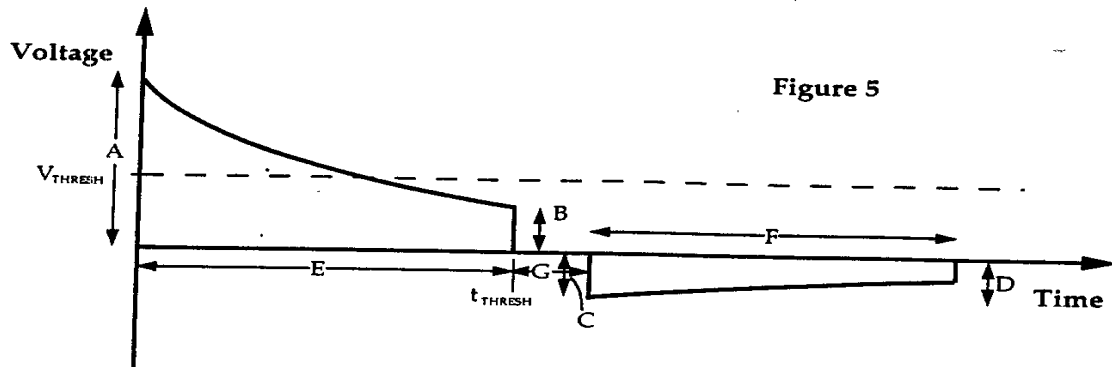


FIG. 3



08/501517

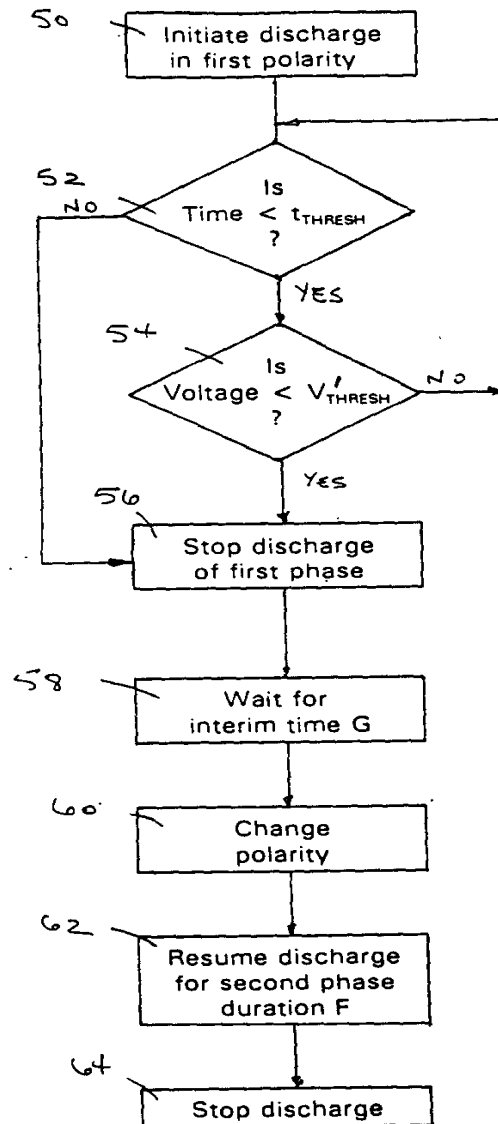


FIG. 6

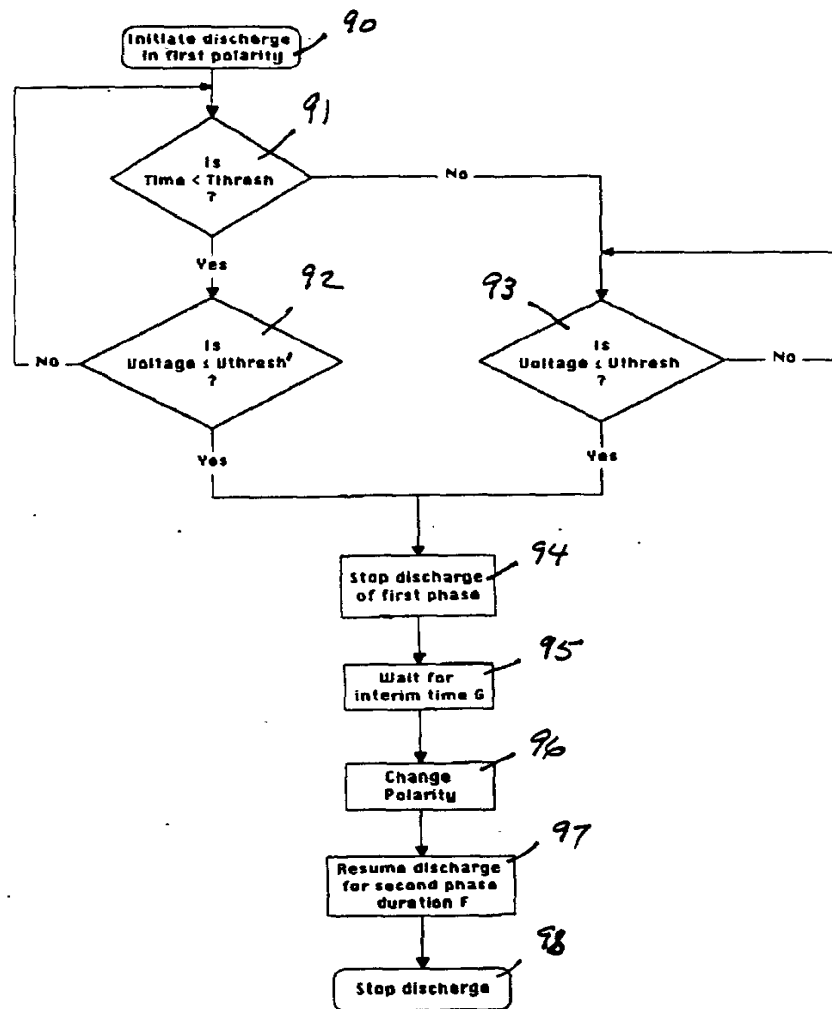


FIGURE 9

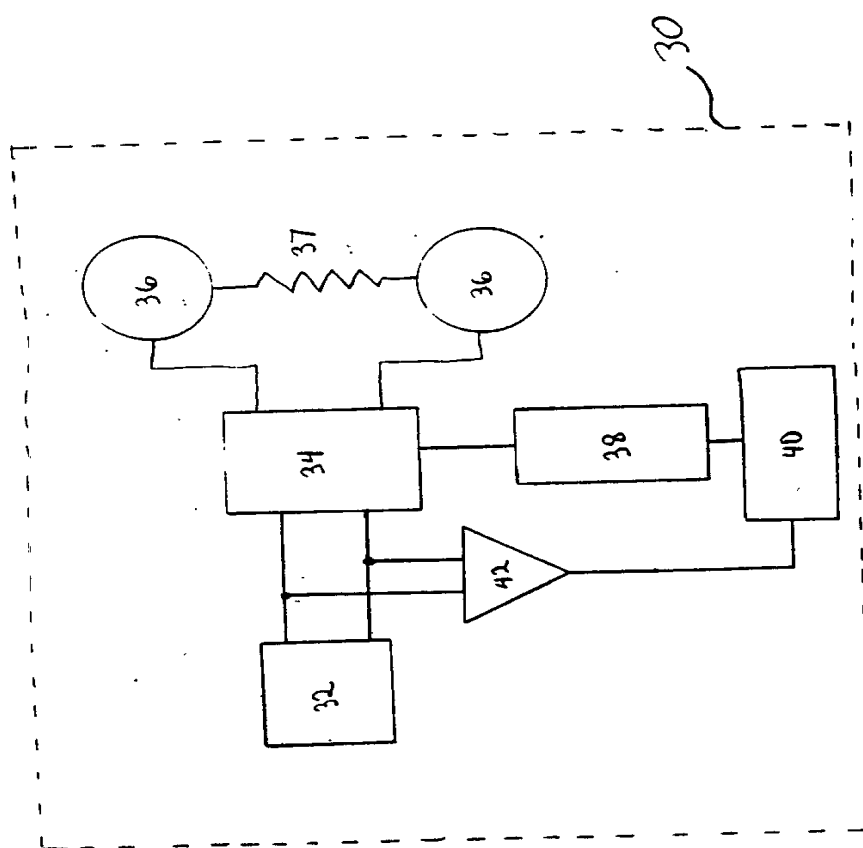
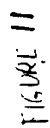
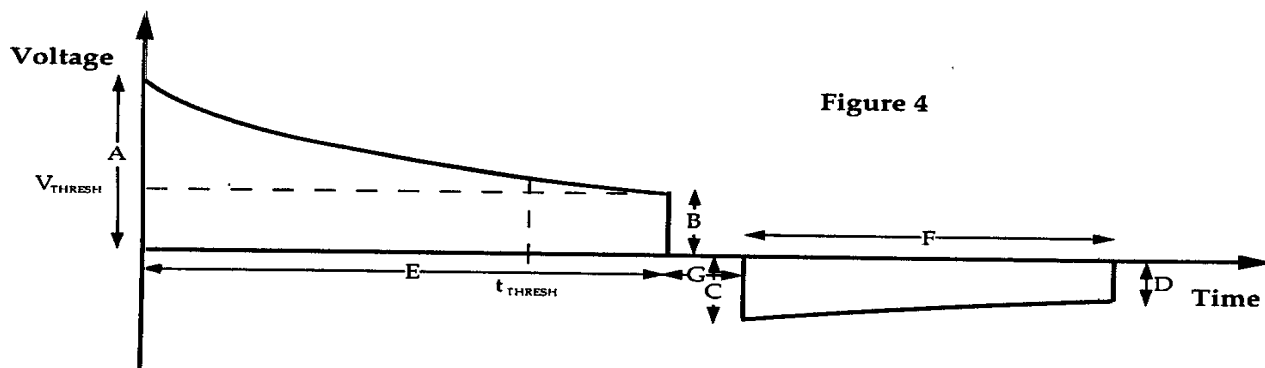
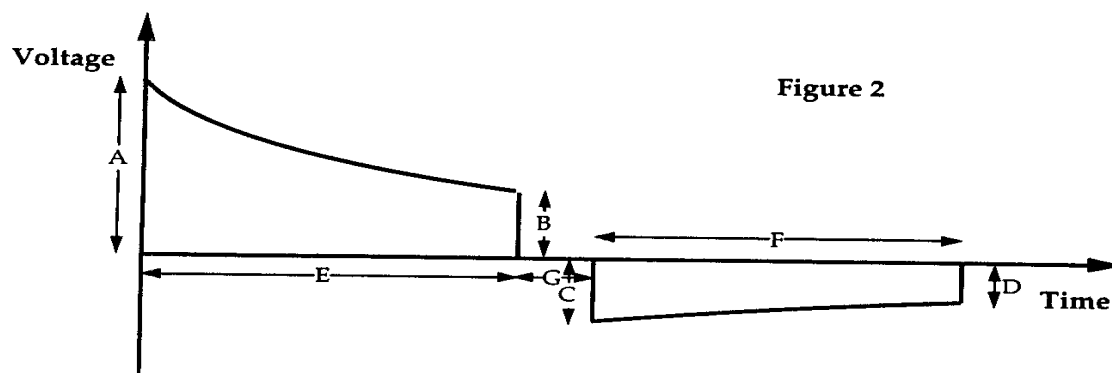
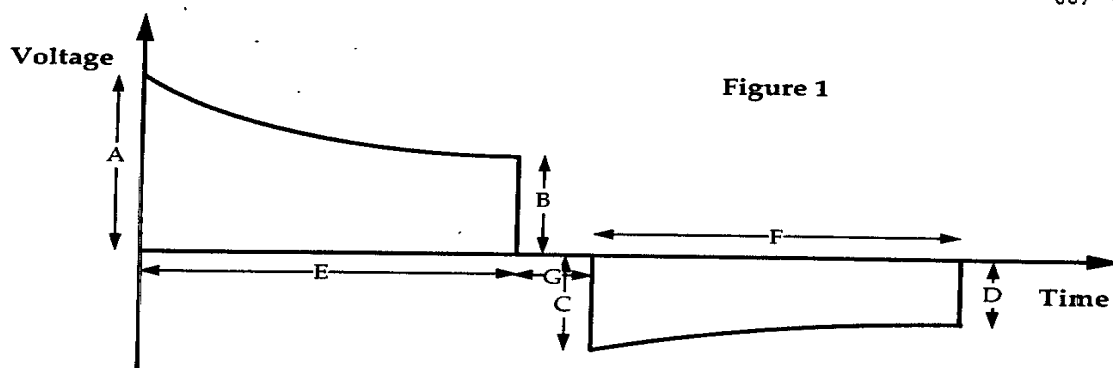


FIG. 10



08/501517



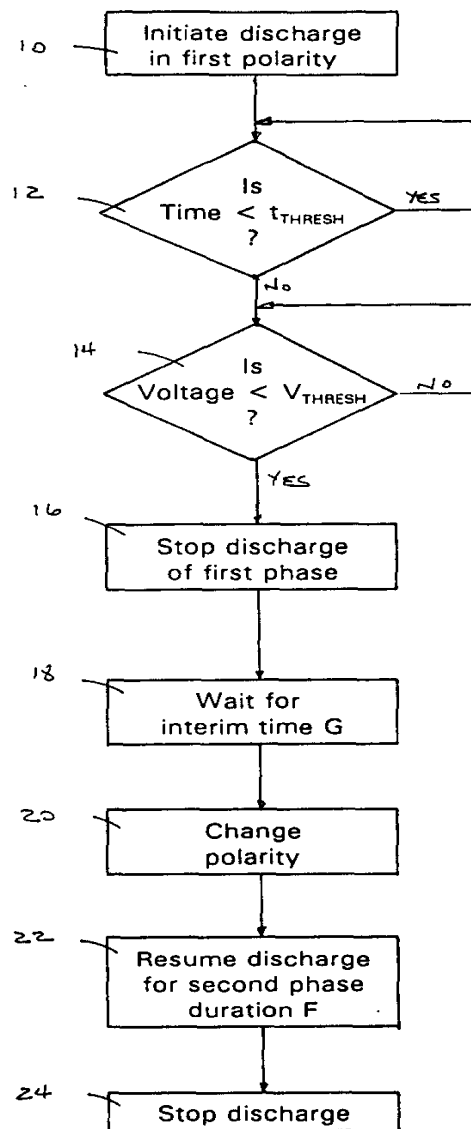
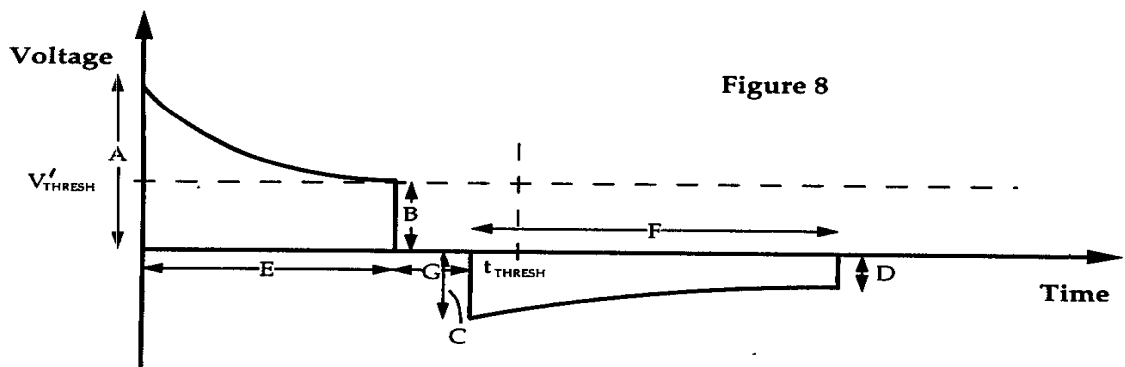
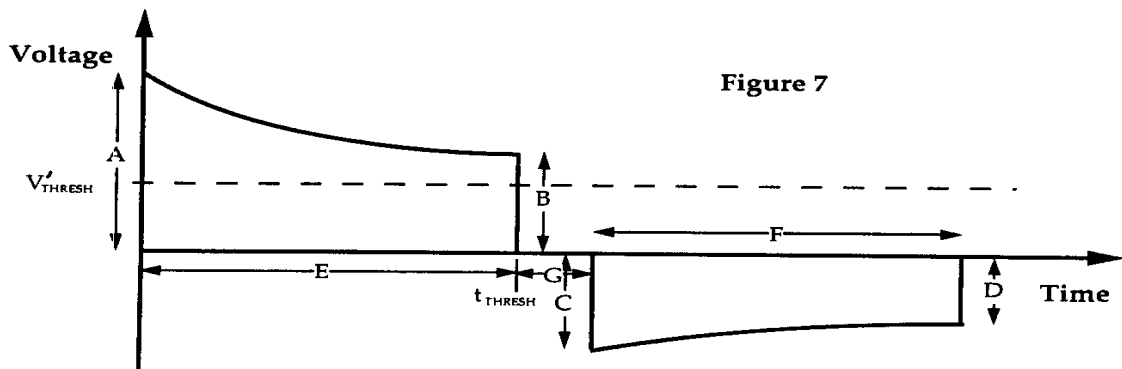
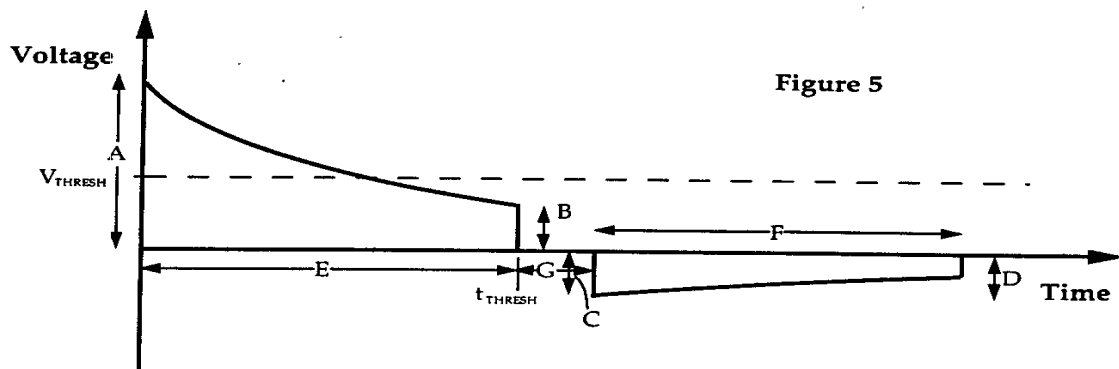


FIG. 3

After



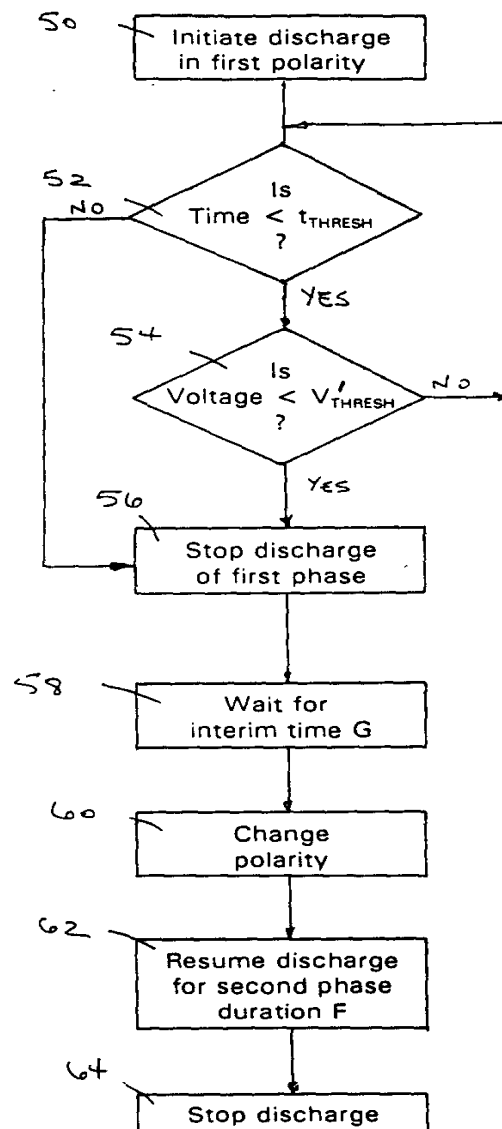


FIG. 6

6101

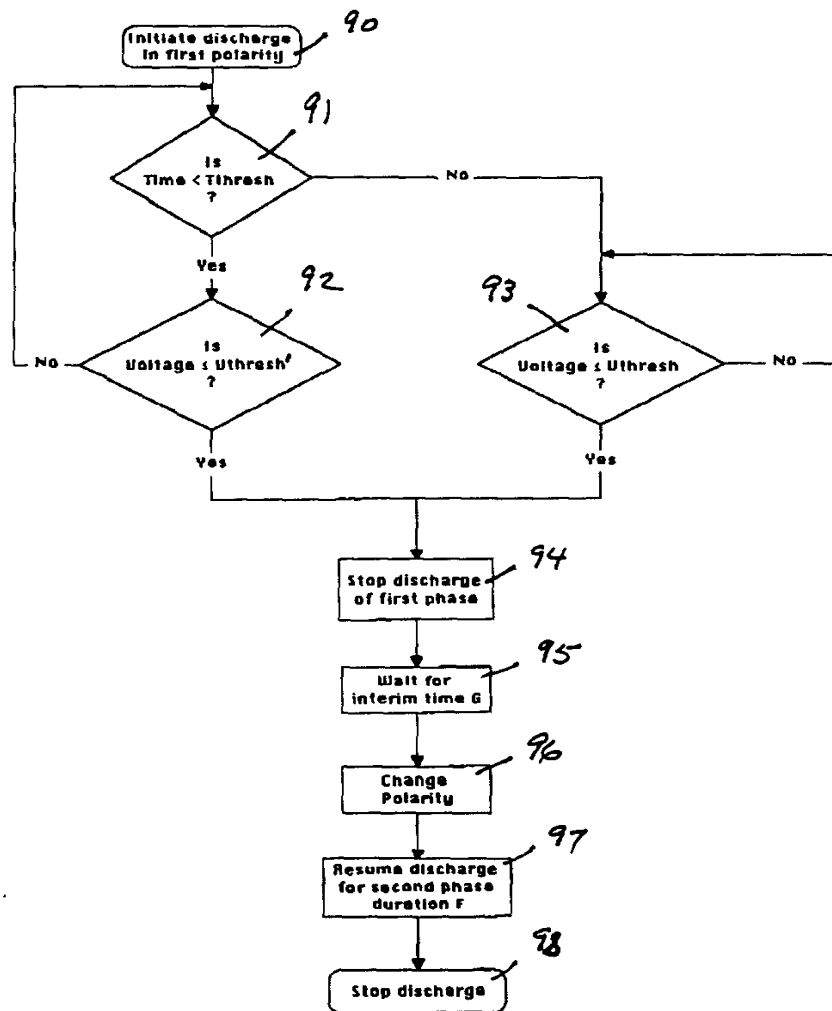


FIGURE 9

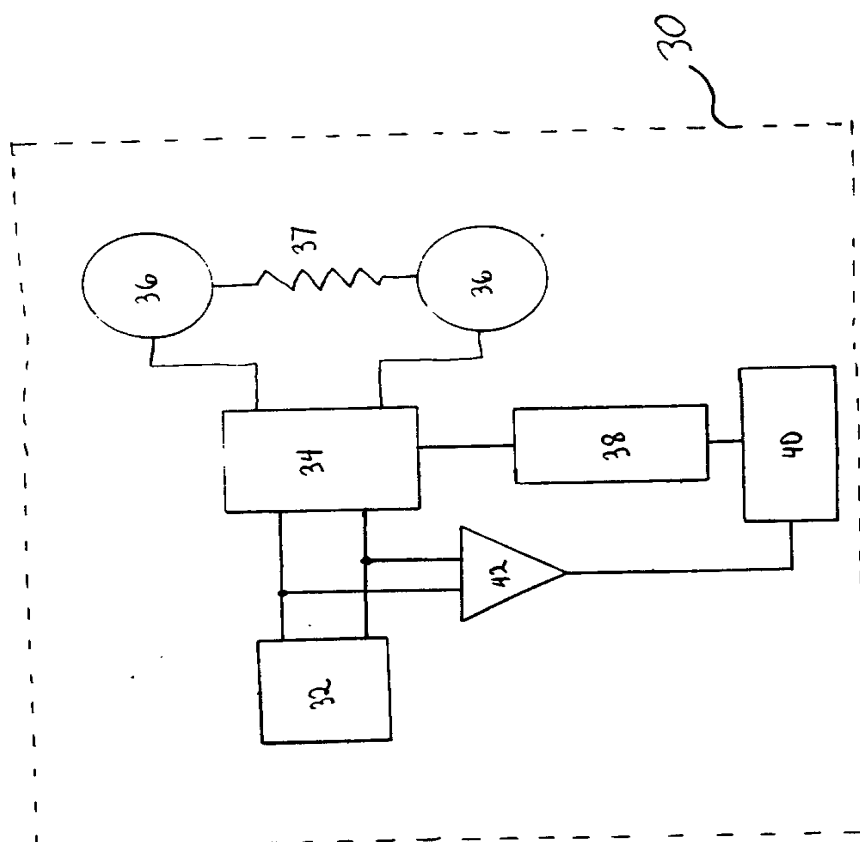


FIG. 10

08/601617

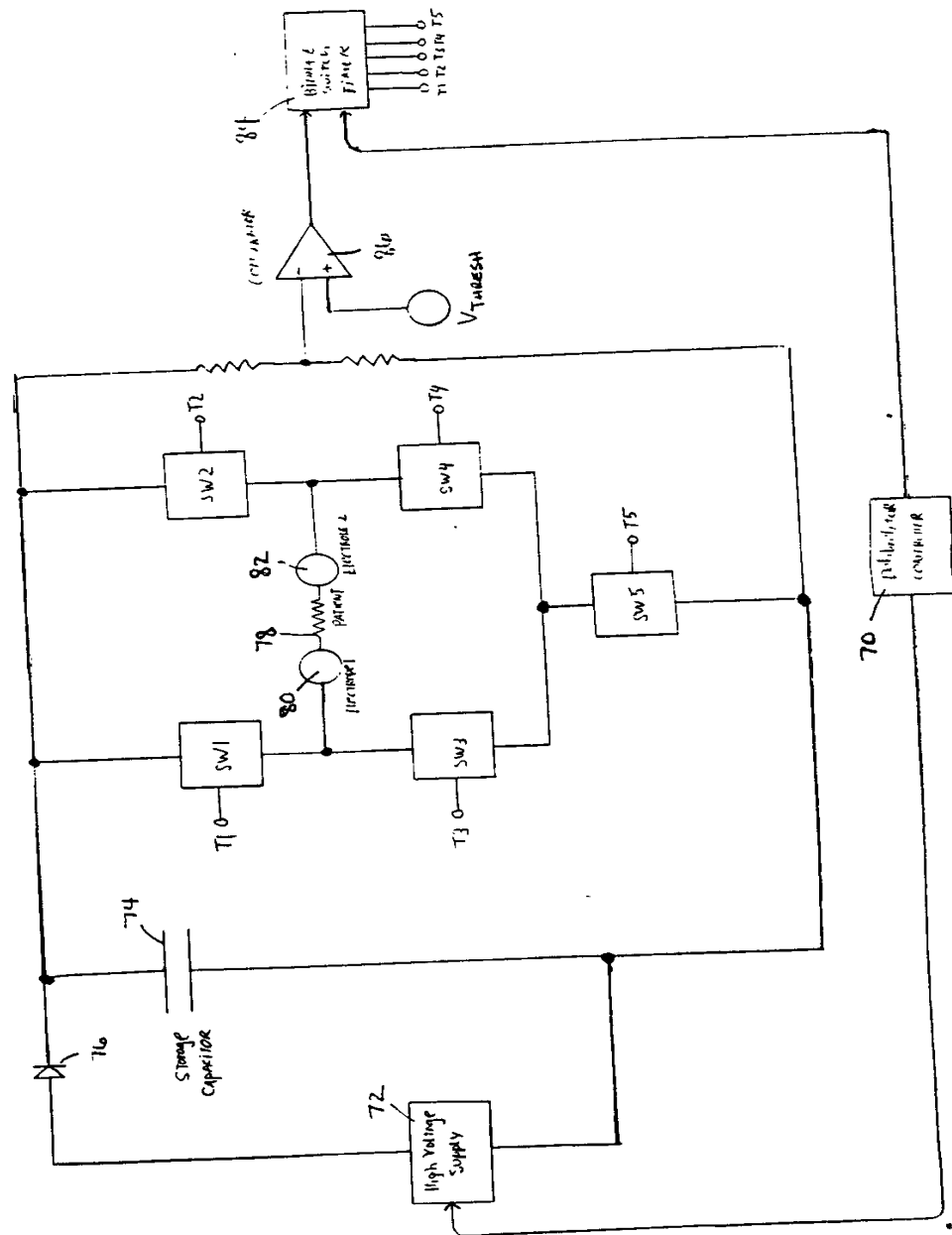
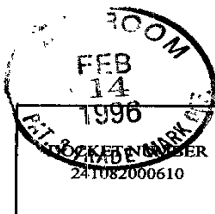


FIGURE 11



2000

375 00 201 A
08/601617

| | | | |
|--------------------------------------|----------|------------------------------------------------|------------------|
| ANTICIPATED CLASSIFICATION: CLASS | SUBCLASS | PRIOR APPLICATION: EXAMINER K. Schaetzle | ART UNIT 3305 |
|--------------------------------------|----------|------------------------------------------------|------------------|

Morrison & Foerster LLP
345 California Street
San Francisco, California 94104-2675

| | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| CERTIFICATE OF MAILING BY "EXPRESS MAIL" | |
| Express Mail Label No.: EM221308163US | Date of Deposit: February 14, 1996 |
| I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231. | |
| <i>Andrew R. Schmidt</i> Andrew R. Schmidt | |

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

37 C.F.R. § 1.60
REQUEST FOR FILING
DIVISIONAL APPLICATION

PRE AMEND/A
K. TURNER
5-22-96
P. # 2

Box PATENT APPLICATION
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

This is a Request for filing a Divisional application under 37 C.F.R. § 1.60 of prior application Serial No. 08/103,837, filed on August 06, 1993, entitled ELECTROTHERAPY METHOD AND APPARATUS by the following inventor:

| | | | |
|-----------------------|-------------|------------------|-------------------|
| FULL NAME OF INVENTOR | FAMILY NAME | FIRST GIVEN NAME | SECOND GIVEN NAME |
| | Gliner | Bradford | E. |
| FULL NAME OF INVENTOR | FAMILY NAME | FIRST GIVEN NAME | SECOND GIVEN NAME |
| | Lyster | Thomas | D. |
| FULL NAME OF INVENTOR | FAMILY NAME | FIRST GIVEN NAME | SECOND GIVEN NAME |
| | Cole | Clinton | S. |
| FULL NAME OF INVENTOR | FAMILY NAME | FIRST GIVEN NAME | SECOND GIVEN NAME |
| | Powers | Daniel | J. |

sf-85370

A

| | | | |
|--------------------------|-----------------------|-----------------------------|-------------------------|
| FULL NAME OF INVENTOR | FAMILY NAME Morgan | FIRST GIVEN NAME Carlton | SECOND GIVEN NAME B. |
|--------------------------|-----------------------|-----------------------------|-------------------------|

☒ Enclosed is a true copy of the prior complete application as filed including the specification (with claims), drawings and inventor signed oath or declaration (including any amendments referenced therein). I hereby verify that the attached papers are a true copy of the latest inventor signed prior application serial no. 08/103,837 as originally filed on August 6, 1993, and that any amendments referred to in the declaration and oath did not introduce new matter. Further I hereby verify that all statements made herein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

☒ A verified statement(s) of small entity status was filed in prior application serial no. 08/103,837, filed on August 6, 1993 (copy enclosed).

☒ The filing fee is calculated below:

| FOR | NUMBER FILED | NUMBER EXTRA | RATE | CALCULATIONS |
|-----------------------------------------------------------------------------------------------------------------------------------------|--------------|--------------|-----------|--------------|
| TOTAL CLAIMS | 18 - 20 = | 0 | x \$22.00 | \$0 |
| INDEPENDENT CLAIMS | 2 - 3 = | 0 | x \$78.00 | \$0 |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable) | | | \$250.00 | \$0 |
| | | | BASIC FEE | \$750.00 |
| TOTAL OF ABOVE CALCULATIONS = | | | | \$750.00 |
| Reduction by 1/2 for filing by small entity (Note 37 C.F.R. §§ 1.9, 1.27, 1.28). If applicable, verified statement must be attached. | | | | \$375.00 |
| | | | TOTAL = | \$375.00 |

☒ A check in the amount of \$375.00 is enclosed.

- ☒ The Assistant Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 which may be required by this paper, or to credit any overpayment to **Deposit Account No. 03-1952**. A duplicate copy of this sheet is enclosed.
- ☒ Cancel in this application original claims ~~1-14~~ and ~~23-34~~ of the prior application before calculating the filing fee.

- ☒ Amend the specification by inserting before the first line the sentence:

A' -- This application is a divisional of application serial no. 08/103,837 filed August 06, 1993.--

- ☐ Transfer the drawings from the pending prior application to this application and abandon said prior application as of the filing date accorded this application. A duplicate copy of this sheet is enclosed for filing in the prior application file.
- ☐ New formal drawings are enclosed.
- ☐ Priority of foreign application serial no. *, filed on * in * is claimed under 35 U.S.C. § 119.
- ☐ The certified copy of the priority application *[is enclosed/has been filed in prior application serial no. *, filed on *].
- ☐ A certified copy has NOT yet been filed.
- ☒ The prior application is assigned of record to Heartstream, Inc.
- ☒ A preliminary amendment is enclosed.
- ☒ The power of attorney in the prior application is to:

Thomas E. Ciotti (Reg No 21,013)
Gladys H. Monroy (Reg No 32,430)
Paul Schenck (Reg No 27,253)
Freddie K. Park (Reg No 35,636)
Paul C. Kimball (Reg No 34,641)
Shmuel Livnat (Reg No 33,949)
James R. Shay (Reg No 32,062)

Kate H. Murashige (Reg No 29,959)
Debra Shetka (Reg No 33,309)
E. Thomas Wheelock (Reg No 28,825)
Susan K. Lehnhardt (Reg No 33,943)
Patricia M. Drost (Reg No 29,790)
Cecily Anne Snyder (Reg No 37,448)

- ☒ The power appears in the original papers in the prior application.

☒ Recognize as Associate Attorney(s):

Tyler Dylan (Reg No 37,612)
Reid G. Adler (Reg No 30,988)
Antoinette F. Konski (Reg No 34,202)
Stuart P. Kaler (Reg No 35,913)
Robert Saltzberg (Reg No 36,910)
Mani Adei (Reg No P39,585)
Sean Brennan (Reg No P39,917)
J. Michael Schiff (Reg No P40,253)
Robert K. Cerpa (Reg No P39,933)

Carol M. LaSalle (Reg No P39,740)
Gary A. Green (Reg No 38,474)
Harry J. Macey (Reg No 32,818)
David L. Bradfute (Reg No 39,117)
Laurie Axford (Reg No 35,053)
Catherine M. Polizzi (Reg No P40,130)
James C. Peacock III (Reg No P40,124)
Robert A. Millman (Reg No 36,217)
Ronald D. Devore (Reg No P39,958)


☒ Address all future communications to:

Stuart P. Kaler
Morrison & Foerster LLP
345 California Street
San Francisco, California 94104-2675

Dated: February 14, 1996

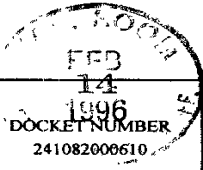
Respectfully submitted,

By:

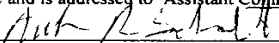

Stuart P. Kaler
Registration No. 35,913

Morrison & Foerster LLP
345 California Street
San Francisco, California 94104-2675
Telephone: (415) 677-6159
Facsimile: (415) 677-7522

601517
COPY

| | | | |
|--------------------------------------------------------------------------------------------------------------------|-----------------------------|----------|--------------------------|
|  DOCKET NUMBER 241082000610 | ANTICIPATED CLASSIFICATION: | | PRIOR APPLICATION: |
| | CLASS | SUBCLASS | EXAMINER K. Schaetzle |
| | | | ART UNIT 3305 |

Morrison & Foerster LLP
 345 California Street
 San Francisco, California 94104-2675

| CERTIFICATE OF MAILING BY "EXPRESS MAIL" | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| Express Mail Label No. EM221308163US | Date of Deposit. February 14, 1996 |
| I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231. | |
|  Andrew R. Schmidt | |

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**37 C.F.R. § 1.60
 REQUEST FOR FILING
 DIVISIONAL APPLICATION**

Box PATENT APPLICATION
 Assistant Commissioner for Patents
 Washington, D.C. 20231

Dear Sir:

This is a Request for filing a Divisional application under 37 C.F.R. § 1.60 of prior application Serial No. 08/103,837, filed on August 06, 1993, entitled ELECTROTHERAPY METHOD AND APPARATUS by the following inventor:

| FULL NAME OF INVENTOR | FAMILY NAME | FIRST GIVEN NAME | SECOND GIVEN NAME |
|-----------------------|-------------|------------------|-------------------|
| | Gliner | Bradford | E. |
| | Lyster | Thomas | D. |
| | Cole | Clinton | S. |
| | Powers | Daniel | J. |

sf-85370

| | | | |
|--------------------------|-----------------------|-----------------------------|-------------------------|
| FULL NAME OF INVENTOR | FAMILY NAME Morgan | FIRST GIVEN NAME Carlton | SECOND GIVEN NAME B. |
|--------------------------|-----------------------|-----------------------------|-------------------------|

- ☒ Enclosed is a true copy of the prior complete application as filed including the specification (with claims), drawings and inventor signed oath or declaration (including any amendments referenced therein). I hereby verify that the attached papers are a true copy of the latest inventor signed prior application serial no. 08/103,837 as originally filed on August 6, 1993, and that any amendments referred to in the declaration and oath did not introduce new matter. Further I hereby verify that all statements made herein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.
- ☒ A verified statement(s) of small entity status was filed in prior application serial no. 08/103,837, filed on August 6, 1993 (copy enclosed).
- ☒ The filing fee is calculated below:

| FOR | NUMBER FILED | NUMBER EXTRA | RATE | CALCULATIONS |
|-----------------------------------------------------------------------------------------------------------------------------------------|--------------|--------------|-----------|--------------|
| TOTAL CLAIMS | 18 - 20 = | 0 | x \$22.00 | \$0 |
| INDEPENDENT CLAIMS | 2 - 3 = | 0 | x \$78.00 | \$0 |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable) | | | \$250.00 | \$0 |
| | | | BASIC FEE | \$750.00 |
| TOTAL OF ABOVE CALCULATIONS = | | | | \$750.00 |
| Reduction by 1/2 for filing by small entity (Note 37 C.F.R. §§ 1.9, 1.27, 1.28). If applicable, verified statement must be attached. | | | | \$375.00 |
| | | | TOTAL = | \$375.00 |

- ☒ A check in the amount of \$375.00 is enclosed.

- ☒ The Assistant Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 which may be required by this paper, or to credit any overpayment to **Deposit Account No. 03-1952**. A duplicate copy of this sheet is enclosed.
- ☒ Cancel in this application original claims 1-14 and 23-34 of the prior application before calculating the filing fee.
- ☒ Amend the specification by inserting before the first line the sentence:
-- This application is a divisional of application serial no. 08/103,837 filed August 06, 1993.--
- ☐ Transfer the drawings from the pending prior application to this application and abandon said prior application as of the filing date accorded this application. A duplicate copy of this sheet is enclosed for filing in the prior application file.
- ☐ New formal drawings are enclosed.
- ☐ Priority of foreign application serial no. *, filed on * in * is claimed under 35 U.S.C. § 119.
 - ☐ The certified copy of the priority application *[is enclosed/has been filed in prior application serial no. *, filed on *].
 - ☐ A certified copy has NOT yet been filed.
- ☒ The prior application is assigned of record to Heartstream, Inc.
- ☒ A preliminary amendment is enclosed.
- ☒ The power of attorney in the prior application is to:

| | |
|----------------------------------|------------------------------------|
| Thomas E. Ciotti (Reg No 21,013) | Kate H. Murashige (Reg No 29,959) |
| Gladys H. Monroy (Reg No 32,430) | Debra Shetka (Reg No 33,309) |
| Paul Schenck (Reg No 27,253) | E. Thomas Wheelock (Reg No 28,825) |
| Freddie K. Park (Reg No 35,636) | Susan K. Lehnhardt (Reg No 33,943) |
| Paul C. Kimball (Reg No 34,641) | Patricia M. Drost (Reg No 29,790) |
| Shmuel Livnat (Reg No 33,949) | Cecily Anne Snyder (Reg No 37,448) |
| James R. Shay (Reg No 32,062) | |
- ☒ The power appears in the original papers in the prior application.

☒ Recognize as Associate Attorney(s):

Tyler Dylan (Reg No 37,612)
Reid G. Adler (Reg No 30,988)
Antoinette F. Konski (Reg No 34,202)
Stuart P. Kaler (Reg No 35,913)
Robert Saltzberg (Reg No 36,910)
Mani Adeli (Reg No P39,585)
Sean Brennan (Reg No P39,917)
J. Michael Schiff (Reg No P40,253)
Robert K. Cerpa (Reg No P39,933)

Carol M. LaSalle (Reg No P39,740)
Gary A. Green (Reg No 38,474)
Harry J. Macey (Reg No 32,818)
David L. Bradfute (Reg No 39,117)
Laurie Axford (Reg No 35,053)
Catherine M. Polizzi (Reg No P40,130)
James C. Peacock III (Reg No P40,124)
Robert A. Millman (Reg No 36,217)
Ronald D. Devore (Reg No P39,958)

☒ Address all future communications to:

Stuart P. Kaler
Morrison & Foerster LLP
345 California Street
San Francisco, California 94104-2675

Dated: February 14, 1996

Respectfully submitted,

By: Stuart P. Kaler
Stuart P. Kaler
Registration No. 35,913

Morrison & Foerster LLP
345 California Street
San Francisco, California 94104-2675
Telephone: (415) 677-6159
Facsimile: (415) 677-7522



08/501617

PATE.
Atty Dkt 241082000610

"Express Mail" Filing Label No. EM221308163US Date of Deposit 2/14/96
I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Andrew R. Schmidt
Name (print)

Andrew R. Schmidt
Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: Bradford E. Gliner et al.

Serial No.: Division of 08/103,837

Group Art Unit: unknown

Filing Date: Concurrent herewith

Examiner: unknown

Title: Electrotherapy Method and Apparatus

PRELIMINARY AMENDMENT

Amend 1/B
K. MILLER
5-22-96
p. #3

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

Prior to examination on the merits, please amend this application as follows:

IN THE CLAIMS:

Please add the following new claims:

B
1. ~~9~~ A method for applying electrotherapy to a patient through electrodes connected to an energy source, the method comprising the following steps:
discharging the energy source across the electrodes to deliver electrical energy to the patient in a multiphasic waveform;
monitoring a patient-dependent electrical parameter during the discharging step;
adjusting a discharge parameter based on a value of the monitored electrical parameter,
the adjusting step comprising discharging the energy source across the electrodes in a phase of the multiphasic waveform until the end of a predetermined time period or

20

until the monitored electrical parameter reaches a predetermined value, whichever occurs first.

¹⁰
~~36.~~ The method of claim ~~35~~⁹ wherein the electrical parameter is energy source voltage.

¹¹
~~37.~~ The method of claim ~~35~~⁹ wherein the electrical parameter is energy source current.

¹²
~~38.~~ The method of claim ~~35~~⁹ wherein the adjusting step further comprises adjusting a discharge parameter of a later phase of the multiphasic waveform as a function of a value of the electrical parameter during an earlier phase.

¹³
~~39.~~ The method of claim ~~38~~¹² wherein the discharge parameter of the later phase is phase duration.

¹⁴
~~40.~~ The method of claim ~~35~~⁹ wherein the adjusting step further comprises adjusting a discharge parameter of a later phase of the multiphasic waveform as a function of duration of an earlier phase.

¹⁵
~~41.~~ The method of claim ~~40~~¹⁴ wherein the discharge parameter of the later phase is phase duration.

¹⁶
~~42.~~ The method of claim ~~35~~⁹ wherein a phase of the multiphasic waveform has a fixed duration.

¹⁷
~~43.~~ The method of claim ~~35~~⁹ wherein the multiphasic waveform has an earlier phase and a later phase, the later phase having a fixed duration.

B' (cont.)

18
44.

9

PATE'
Atty Dkt 24108200061 0

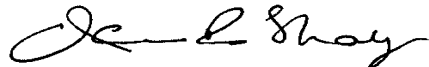
The method of claim *35* wherein the multiphasic waveform comprises a truncated exponential biphasic waveform. --

REMARKS

This preliminary amendment is being submitted concurrently with a divisional application of the parent case described in the caption above in order to claim one of the non-elected inventions from the parent case.

Please direct all correspondence in this application to Applicants' attorney Stuart P. Kaler at the address and telephone number listed below.

Respectfully submitted,



James R. Shay
Registration No. 32,062

MORRISON & FOERSTER
345 California Street
San Francisco, CA 94104
(415) 677-6159
Fax: (415) 677-7522

22



[Handwritten signature]

RECEIVED

MAY 21 1996

PATENT
Docket No. 241082000610

CERTIFICATE OF MAILING BY "FIRST CLASS MAIL"

I hereby certify that this correspondence is being deposited with the United States Postal Service in first class mail in an envelope addressed to:
Assistant Commissioner for Patents, Washington, D.C. 20231, on May 15, 1996.

[Handwritten signature: Christian Neville]
Christian Neville

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Gliner et al.

Serial No.: 08/601,617

Filing Date: February 14, 1996

For: ELECTROTHERAPY METHOD AND
APPARATUS

Examiner: K. Schaetzle

Group Art Unit: 3305

*I. D. S.
A. TURNER
6-27-96
P. #4*

INFORMATION DISCLOSURE
STATEMENT UNDER 37 C.F.R. § 1.97

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

The information listed below was previously disclosed in Information Disclosure Statements in connection with the parent application Serial Number 08/103,837 (filed August 6, 1993). Copies of the publications were also previously submitted; therefore, copies are not included herewith. This protocol conforms with 37 CFR § 1.98(d) and MPEP 609(A)(2). The Examiner is respectfully requested to make this information of official record in the above-identified application. The information includes:

U.S. Patent No. 3,211,154 to Becker et al. (10/12/65).

U.S. Patent No. 3,241,555 to Caywood et al. (03/22/66).

U.S. Patent No. 3,706,313 to Milani et al. (12/19/72).

U.S. Patent No. 3,782,389 to Bell (01/01/74).
U.S. Patent No. 3,860,009 to Bell et al. (01/14/75).
U.S. Patent No. 3,862,636 to Bell et al. (01/28/75).
U.S. Patent No. 3,886,950 to Ukkestad et al. (06/03/75).
U.S. Patent No. 4,023,573 to Pantridge et al. (05/17/77).
U.S. Patent No. 4,328,808 to Charbonnier et al. (05/11/82).
U.S. Patent No. 4,419,998 to Heath (12/13/83).
U.S. Patent No. 4,473,078 to Angel (09/25/84).
U.S. Patent No. 4,494,552 to Heath (01/22/85).
U.S. Patent No. 4,504,773 to Suzuki et al. (03/12/85).
U.S. Patent No. 4,574,810 to Lerman (03/11/86).
U.S. Patent No. 4,595,009 to Leinders (06/17/86).
U.S. Patent No. 4,610,254 to Morgan et al. (09/09/86).
U.S. Patent No. 4,619,265 to Morgan et al. 10/28/86).
U.S. Patent No. 4,637,397 to Jones et al. (01/20/87).
U.S. Patent No. 4,745,923 to Winstrom (05/24/88).
U.S. Patent No. 4,800,883 to Winstrom (01/31/89).
U.S. Patent No. 4,821,723 to Baker, Jr., et al. (04/18/89).
U.S. Patent No. 4,840,177 to Charbonnier et al. (06/20/89).
U.S. Patent No. 4,848,345 to Zenkich (07/18/89).
U.S. Patent No. 4,850,357 to Bach, Jr. (07/25/89).
U.S. Patent No. 4,953,551 to Mehra et al. (09/04/90).
U.S. Patent No. 4,998,531 to Bocchi et al. (03/12/91).
U.S. Patent No. 5,078,134 to Heilman et al. (01/07/92).
U.S. Patent No. 5,083,562 to de Coriolis et al. (01/28/92).
U.S. Patent No. 5,107,834 to Ideker et al. (04/28/92).
U.S. Patent No. 5,111,813 to Charbonnier et al. (05/12/92).
U.S. Patent No. 5,111,816 to Pless et al. (06/12/92).
U.S. Patent No. 5,207,219 to Adams et al. (05/04/93).

U.S. Patent No. 5,215,081 to Ostroff (06/01/93).
 U.S. Patent No. 5,222,480 to Couche et al. (06/29/93).
 U.S. Patent No. 5,222,492 to Morgan et al. (06/29/93).
 U.S. Patent No. 5,230,336 to Fain et al. (07/27/93).
 U.S. Patent No. 5,237,989 to Morgan et al. (08/24/93).
 U.S. Patent No. 5,249,573 to Fincke et al. (10/05/93).
 U.S. Patent No. 5,275,157 to Morgan (01/04/94).
 U.S. Patent No. 5,306,291 to Kroll et al. (04/26/94).
 U.S. Patent No. 5,334,219 to Kroll (08/02/94).
 U.S. Patent No. 5,370,664 to Morgan et al. (12/06/94).
 U.S. Patent No. 5,372,606 to Lang et al. (12/13/94).
 PCT Patent Publication No. WO 93/16759 (09/02/93).
 PCT Patent Publication No. WO 94/21327 (09/29/94).
 PCT Patent Publication No. WO 94/22530 (10/13/94).
 European Patent Publication No. EP 0,281,219 (09/07/88).
 European Patent Publication No. EP 0,353,341 (02/07/90).
 European Patent Publication No. EP 0,437,104 (07/17/91).
 European Patent Publication No. EP 0,507,504 (10/07/92).
 U.K. Patent Application No. GB 2,070,435 (09/09/81).
 U.K. Patent Application No. GB 2,083,363 (03/24/82).
 Alferness et al., "The influence of shock waveforms on defibrillation efficacy," IEEE Engineering in Medicine and Biology, pp. 25-27 (June 1990).
 Anderson, et al., "The Efficacy of Trapezoidal Wave Forms for Ventricular Defibrillation," Chest 70(2) : 298-300
 Blilie et al., "Predicting and validating cardiothoracic current flow using finite element modeling," PACE, 15:563, abstract 219 (April 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 (March 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 defibrillation with square-waves," The Lancet (July 2, 1966).
- Echt et al., "Biphasic waveform is more efficacious than monophasic waveform for transthoracic cardioversion," PACE, 16:914, abstract no. 256 (April 1993).
- Feese 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 (March 1991).
- Jones et al., "Defibrillator waveshape optimization," Devices and Tech. Meeting, NIH (1982).
- 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).
- Jones, et al., "Decreased defibrillator-induced dysfunction with biphasic rectangular waveforms," Am. J. Physiol., 247:H792-796 (1984)
- Jones, et al., "Improved defibrillator waveform safety factor with biphasic waveforms," Am. J. Physiol., 245:H60-65 (1983)
- Jude et al., "Fundamentals of Cardiopulmonary Resuscitation," F.A. Davis Company, Philadelphia PA, pp. 98-104 (1965).
- 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)
- 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).
- Lerman, et al., "Currency-Based Versus Energy-Based Ventricular Defibrillation: A Prospective Study," JACC 12(5) : 1259-1264 (1988)

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).

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 (July 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 (June-July 1984).

Saksena et al., "A prospective evaluation of single and dual current pathways for transvenous cardioversion in rapid ventricular tachycardia," PACE, 10:1130-1141 (September-October 1987).

Saksena et al., "Developments for future implantable cardioverters and defibrillators," PACE, 10:1342-1358 (November-December 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 (January 1993).

Schuder et al. "Comparison of effectiveness of relay-switched, 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).

Schuder, et al., "One-Cycle Bidirectional Rectangular Wave Shocks for Open Chest Defibrillation in the Calf," Abs. Am. Soc. Artif. Intern. Organs, 9 : 16

Schuder, et al., "Transthoracic Ventricular Defibrillation with Square-wave Stimuli: One half Cycle," Circ. Res., XV: 258-264 (1964)

Schuder, et al., "Defibrillation of 100 kg calves with asymmetrical, bidirectional, rectangular pulses," Card. Res., 18:419-426 (1984)

Schuder, et al., "Transthoracic Ventricular Defibrillation in the 100 kg Calf with Symmetrical One-Cycle Bidirectional Rectangular Wave Stimuli," IEEE Trans. BME, 30(7) : 415-422 (1983)

Schuder, et al., "Ultrahigh-energy hydrogen thyatron/SCR Bidirectional waveform defibrillator," Med. & Biol. Eng. & Comput., 20 : 419-424 (1982)

Schuder, et al., "Wave form Dependency in Defibrillating 100 kg Calves," Devices & Tech. Meeting, NIH (1981)

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

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

Tang, et al., "Strength Duration Curve for Ventricular Defibrillation Using Biphasic Waveforms," PACE, abstract no. 49 (1987)

Tang, et al., "Ventricular Defibrillation Using Biphasic Waveforms of Different Phasic Duration," PACE, abstract no. 47 (1987)

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

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

Wetherbee, et al. , "Subcutaneous Patch Electrode - A Means to Obviate Thoracotomy for Implantation of the Automatic Implantable cardioverter Defibrillation System?," Circ., 72 : III-384, abstract no. 1536 (1985)

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

Winkle et al., "Improved Low Energy Defibrillation Efficacy in Man Using a Biphasic Truncated Exponential Waveform," JACC, 9(2) : 142A (1987)

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

In addition to the references disclosed above, the information listed below was previously cited in an Office Action dated October 13, 1995 directed to the parent application Serial Number 08/103,837 (filed August 6, 1993). Copies of the publications are included in the parent prosecution application; therefore, copies are not included herewith. The Examiner is respectfully requested to make this information of official record in the above-identified application. The information includes:

U.S. Patent No. 5,097,833 to Campos (03/19/92)
U.S. Patent No. 5,334,430 to Berg et al. (09/19/94)
U.S. Patent No. 5,411,526 to Kroll et al. (05/19/95)

In addition to the references disclosed above, the information listed below was previously disclosed in Information Disclosure Statements in connection with patent application Serial No. 08/227,553 (filed April 14, 1994) a continuation-in-part of the parent patent application Serial Number 08/103,837 (filed August 6, 1993). Copies of the references are submitted herewith. The Examiner is requested to make these references of record in the application. The references include:

European Patent Publication No. EP 0,315,368 (05/10/89).
Product Brochure for First Medic Semi-Automatic Defibrillators (1994),
Spacelabs Medical Products, 15220 N.E. 40th Street, P.O. Box 97013,
Redmond, WA 98073-9713.
Schuder et al., "Waveform dependency in defibrillation," Devices & Tech.
Meeting NIH (1981).

Finally, in addition to the references disclosed above, the information listed below was previously disclosed in the first action dated May 3, 1996, in connection with patent application Serial No. 08/601,234 (filed February 14, 1996) a divisional of the parent patent application Serial Number 08/103,837 (filed August 6, 1993). A copy of the reference is submitted herewith. The Examiner is requested to make this reference of record in the application. The reference is:

U.S. Patent No. 5,352,239 to Pless (10/04/94)

CERTIFICATE OF PROMPT FILING

This Information Disclosure Statement is submitted before receipt of the first Office Action on the merits. Therefore, applicant believes that no fee is due. However, the Assistant Commissioner is hereby authorized to charge any fees which may be required by this statement to Deposit Account Number 03-1952.

The completed PTO-1449 form is submitted herewith. Applicant would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

This Information Disclosure Statement under 37 C.F.R. § 1.97 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

Dated: May 15, 1996

Respectfully submitted,

By: Stuart P. Kaler
Stuart P. Kaler
Registration No. 35,913
Morrison & Foerster LLP
345 California Street
San Francisco, California 94104-2675
Telephone: (415) 677-6159
Facsimile: (415) 677-7522

| Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION <i>(Use several sheets if necessary)</i> | | | | Docket Number 241082000610 Applicant <u>Gliner et al.</u> Filing Date February 14, 1996 Group Art Unit 3305 | | Application Number 08/601,617 | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|----------|--------------|----------------------------------------------------------------------------------------------------------------------|-------|-------------------------------|----------------------------|
| U.S. PATENT DOCUMENTS GROUP 3300 | | | | | | | |
| Examiner Initials | Ref. No. | Date | Document No. | Name | Class | Subclass | Filing Date If Appropriate |
| <div style="font-size: 2em; font-weight: bold;">2A</div> | 1. | 10/12/65 | 3,211,154 | Becker et al. | | | |
| | 2. | 03/22/66 | 3,241,555 | Caywood et al. | | | |
| | 3. | 12/19/72 | 3,706,313 | Milani, et al. | | | |
| | 4. | 01/01/74 | 3,782,389 | Bell | | | |
| | 5. | 01/14/75 | 3,860,009 | Bell, et al. | | | |
| | 6. | 01/28/75 | 3,862,636 | Bell et al. | | | |
| | 7. | 06/03/75 | 3,886,950 | Ukkestad et al. | | | |
| | 8. | 05/17/77 | 4,023,573 | Pantridge et al. | | | |
| | 9. | 05/11/82 | 4,328,808 | Charbonnier, et al. | | | |
| | 10. | 12/13/83 | 4,419,998 | Heath | | | |
| | 11. | 09/25/84 | 4,473,078 | Angel | | | |
| | 12. | 01/22/85 | 4,494,552 | Heath | | | |
| | 13. | 03/12/85 | 4,504,773 | Suzuki, et al. | | | |
| | 14. | 03/11/86 | 4,574,810 | Lerman | | | |
| | 15. | 06/17/86 | 4,595,009 | Leinders | | | |
| | 16. | 09/09/86 | 4,610,254 | Morgan, et al. | | | |
| | 17. | 10/28/86 | 4,619,265 | Morgan et al. | | | |
| | 18. | 01/20/87 | 4,637,397 | Jones, et al. | | | |
| | 19. | 05/24/88 | 4,745,923 | Winstrom | | | |
| | 20. | 01/31/89 | 4,800,883 | Winstrom | | | |
| | 21. | 04/18/89 | 4,821,723 | Baker, et al. | | | |
| | 22. | 06/20/89 | 4,840,177 | Charbonnier, et al. | | | |
| | 23. | 07/18/89 | 4,848,345 | Zenkich | | | |
| | 24. | 07/25/89 | 4,850,357 | Bach, Jr. | | | |
| | 25. | 09/04/90 | 4,953,551 | Mehra, et al. | | | |
| | 26. | 03/12/91 | 4,998,531 | Bocchi, et al. | | | |
| | 27. | 01/07/92 | 5,078,134 | Heilman et al. | | | |
| | 28. | 01/28/92 | 5,083,562 | de Coriolis, et al. | | | |
| | 29. | 03/19/92 | 5,097,833 | Campos | | | |
| EXAMINER: <u>K. Schaetzle</u> | | | | DATE CONSIDERED: <u>9-5-96</u> | | | |
| EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant. | | | | | | | |

| Form PTO-1449 | | | | Docket Number 241082000610 | | Application Number 08/601,617 | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|-----------|--------------|-----------------------------------------------------------------|--------------------------------|-------------------------------|----------------------------|
| INFORMATION DISCLOSURE CITATION IN AN APPLICATION <small>(Use several sheets if necessary)</small> | | | | Applicant Gliner et al. Filing Date February 14, 1996 | | | |
| <div style="border: 2px solid black; border-radius: 50%; padding: 10px; display: inline-block;"> MAIL ROOM MAY 20 1996 U.S. PATENT OFFICE </div> | | | | RECEIVED MAY 21 1996 GROUP 3300 | | | |
| PATENT DOCUMENTS | | | | | | | |
| Examiner Initials | Ref. No. | Date | Document No. | Name | Class | Subclass | Filing Date If Appropriate |
| <i>KA</i> <div style="border-left: 1px solid black; height: 100px; margin-left: 10px;"></div> | 30. | 04/28/92 | 5,107,834 | Ideker, et al. | | | |
| | 31. | 05/12/92 | 5,111,813 | Charbonnier, et al. | | | |
| | 32. | 05/12/92 | 5,111,816 | Pless, et al. | | | |
| | 33. | 05/04/93 | 5,207,219 | Adams, et al. | | | |
| | 34. | 06/01/93 | 5,215,081 | Ostroff | | | |
| | 35. | 06/29/93 | 5,222,480 | Couche, et al. | | | |
| | 36. | 06/29/93 | 5,222,492 | Morgan et al. | | | |
| | 37. | 07/27/93 | 5,230,336 | Fain, et al. | | | |
| | 38. | 08/24/93 | 5,237,989 | Morgan, et al. | | | |
| | 39. | 10/05/93 | 5,249,573 | Fincke et al. | | | |
| | 40. | 01/04/94 | 5,275,157 | Morgan, et al. | | | |
| | 41. | 04/26/94 | 5,306,291 | Kroll, et al. | | | |
| | 42. | 08/02/94 | 5,334,219 | Kroll | | | |
| | 43. | 09/19/94 | 5,334,430 | Berg, et al. | | | |
| | 44. | 12/06/94 | 5,370,664 | Morgan et al. | | | |
| | 45. | 12/13/94 | 5,372,606 | Lang, et al. | | | |
| | 46. | 05/19/95 | 5,411,526 | Kroll, et al. | | | |
| 47. | 10/04/94 | 5,352,239 | Pless | | | | |
| FOREIGN PATENT DOCUMENTS | | | | | | | |
| Examiner Initials | Ref. No. | Date | Document No. | Country | Class | Subclass | Translation YES NO |
| <i>KA</i> <div style="border-left: 1px solid black; height: 100px; margin-left: 10px;"></div> | 48. | 10/13/94 | 94/22530 | WO | | | |
| | 49. | 09/29/94 | 94/21327 | WO | | | |
| | 50. | 09/02/93 | 93/16759 | WO | | | |
| | 51. | 02/07/90 | 0,353,341 | EP | | | |
| | 52. | 07/17/91 | 0,437,104 | EP | | | |
| | 53. | 10/07/92 | 0,507,504 | EP | | | |
| | 54. | 09/09/81 | 2,070,435 | GB | | | |
| | EXAMINER: <i>K Schaefer</i> | | | | DATE CONSIDERED: <i>9-5-96</i> | | |
| EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant. | | | | | | | |



PTO/SB/08 (2-92)
Sheet 3 of 7

| | | | | | | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|-------------------------------|-------|-------------------------------|--------------------|
| Form PTO-1449 | | | | Docket Number 24108200610 | | Application Number 08/601,617 | |
| INFORMATION DISCLOSURE IN AN APPLICATION <i>(Use several sheets if necessary)</i> | | | | Applicant Gliner et al. | | | |
| | | | | Filing Date February 14, 1996 | | Group Art Unit 3305 | |
| FOREIGN PATENT DOCUMENTS | | | | | | | |
| Examiner Initials | Ref. No. | Date | Document No. | Country | Class | Subclass | Translation YES NO |
| RA | 55. | 03/24/82 | 2,083,363 | GB | | | |
| | 56. | 05/10/89 | 0,315,368 | EP | | | |
| | 57. | 09/07/88 | 0,281,219 | EP | | | |
| OTHER DOCUMENTS <i>(including author, title, Date, Pertinent Pages, Etc.)</i> | | | | | | | |
| Examiner Initials | Ref. No. | Title | | | | | |
| RA | 58. | Alferness et al., "The influence of shock waveforms on defibrillation efficacy," <u>IEEE Engineering in Medicine and Biology</u> , pp. 25-27 (June 1990). | | | | | |
| | 59. | Anderson, et al., "The Efficacy of Trapezoidal Wave Forms for Ventricular Defibrillation," <u>Chest</u> 70(2) : 298-300 | | | | | |
| | 60. | Blilie et al., "Predicting and validating cardiothoracic current flow using finite element modeling," <u>PACE</u> , 15:563, abstract 219 (April 1992). | | | | | |
| | 61. | Chapman et al., "Non-thoracotomy internal defibrillation: Improved efficacy with biphasic shocks," <u>Circulation</u> , 76:312, abstract no. 1239 (1987). | | | | | |
| | 62. | Cooper et al., "Temporal separation of the two pulses of single capacitor biphasic and dual monophasic waveforms," <u>Circulation</u> , 84(4):612, abstract no. 2433 (1991). | | | | | |
| | 63. | Cooper et al., "The effect of phase separation on biphasic waveform defibrillation," <u>PACE</u> , 16:471-482 (March 1993). | | | | | |
| | 64. | Cooper et al., "The effect of temporal separation of phases on biphasic waveform defibrillation efficacy," <u>The Annual International Conference of the IEEE Engineering in Medicine and Biology Society</u> , 13(2):0766-0767 (1991). | | | | | |
| | 65. | Crampton et al., "Low-energy ventricular defibrillation and miniature defibrillators," <u>JAMA</u> , 235(21):2284 (1976). | | | | | |
| | 66. | Dahlbäck et al., "Ventricular defibrillation with square-waves," <u>The Lancet</u> (July 2, 1966). | | | | | |
| | 67. | Echt et al., "Biphasic waveform is more efficacious than monophasic waveform for transthoracic cardioversion," <u>PACE</u> , 16:914, abstract no. 256 (April 1993). | | | | | |
| EXAMINER: K. Schaefer | | | | DATE CONSIDERED: 9-5-96 | | | |
| EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant. | | | | | | | |

| Form PTO-1449 | | Docket Number 241882006170 | | Application Number 08/601,617 | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|-------------------------------|--|
| INFORMATION DISCLOSURE CITATION IN AN APPLICATION (Use several sheets if necessary) | | Applicant Gliner et al. | | Filing Date February 14, 1996 | |
| | | GROUP 3300 | | Group Art Unit 3305 | |
| OTHER DOCUMENTS (including author, title, Date, Pertinent Pages, Etc.) | | | | | |
| Examiner Initials | Ref. No. | Title | | | |
| ZA | 68. | Feeser et al., "Strength-duration and probability of success curves for defibrillation with biphasic waveforms," <u>Circulation</u> , 82(6):2128-2141 (1990). | | | |
| | 69. | Guse et al., "Defibrillation with low voltage using a left ventricular catheter and four cutaneous patch electrodes in dogs," <u>PACE</u> , 14:443-451 (March 1991). | | | |
| | 70. | Jones et al., "Defibrillator waveshape optimization," Devices and Tech. Meeting, NIH (1982). | | | |
| | 71. | Jones et al., "Reduced excitation threshold in potassium depolarized myocardial cells with symmetrical biphasic waveforms," <u>J. Mol. Cell. Cardiol.</u> , 17(39):XXVII, abstract no. 39 (1985). | | | |
| | 72. | Jones, et al., "Decreased defibrillator-induced dysfunction with biphasic rectangular waveforms," <u>Am. J. Physiol.</u> , 247:H792-796 (1984) | | | |
| | 73. | Jones, et al., "Improved defibrillator waveform safety factor with biphasic waveforms," <u>Am. J. Physiol.</u> , 245:H60-65 (1983) | | | |
| | 74. | Jude et al., "Fundamentals of Cardiopulmonary Resuscitation," F.A. Davis Company, Philadelphia PA, pp. 98-104 (1965). | | | |
| | 75. | Kerber, et al., "Energy, current, and success in defibrillation and cardioversion: clinical studies using an automated impedance-based method of energy adjustment," <u>Circulation</u> , 77(5): 1038-1046 (1988) | | | |
| | 76. | Knickerbocker et al., "A portable defibrillator," <u>IEEE Trans. on Power and Apparatus Systems</u> , 69:1089-1093 (1963). | | | |
| | 77. | Kouwenhoven, "The development of the defibrillator," <u>Annals of Internal Medicine</u> , 71(3):449-458 (1969). | | | |
| | 78. | Langer et al., "Considerations in the development of the automatic implantable defibrillator," <u>Medical Instrumentation</u> , 10(3):163-167 (1976). | | | |
| | 79. | Lerman, et al., "Currency-Based Versus Energy-Based Ventricular Defibrillation: A Prospective Study," <u>JACC</u> 12(5): 1259-1264 (1988) | | | |
| N | 80. | Lindsay et al., "Prospective evaluation of a sequential pacing and high-energy bi-directional shock algorithm for transvenous cardioversion in patients with ventricular tachycardia," | | | |
| | EXAMINER: K. Schaefer | | DATE CONSIDERED: 9-5-90 | | |
| EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant. | | | | | |


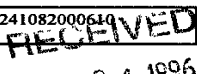
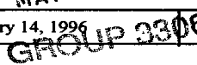

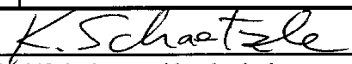



PTO/SB/08 (2-92)
Sheet 5 of 7


| | | | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|-------------------------------|
| Form PTO-1449 | | | Docket Number 241082000610 | Application Number 08/601,617 |
| INFORMATION DISCLOSURE IN AN APPLICATION (Use several sheets if necessary) | | | Applicant Gliner et al. | |
| | | | Filing Date February 14, 1998 | Group Art Unit 3305 |
| OTHER DOCUMENTS (including author, title, Date, Pertinent Pages, Etc.) | | | | |
| Examiner Initials | Ref. No. | Title | | |
| 2A | | Circulation, 76(3):601-609 (1987). | | |
| | 81. | Mirowski et al., "Clinical treatment of life threatening ventricular tachyarrhythmias with the automatic implantable defibrillator," <u>American Heart Journal</u> , 102(2):265-270 (1981). | | |
| | 82. | Mirowski et al., "Termination of malignant ventricular arrhythmias with an implanted automatic defibrillator in human beings," <u>The New England Journal of Medicine</u> , 303(6):322-324 (1980). | | |
| | 83. | Podolsky, "Keeping the beat alive," <u>U.S. News & World Report</u> (July 22, 1991). | | |
| | 84. | Product Brochure for First Medic Semi-Automatic Defibrillators (1994), Spacelabs Medical Products, 15220 N.E. 40th Street, P.O. Box 97013, Redmond, WA 98073-9713. | | |
| | 85. | Product Brochure for the Shock Advisory System (1987), Physio-Control, 11811 Willows Road Northeast, P.O. Box 97006, Redmond, WA 98073-9706. | | |
| | 86. | Redd (editor), "Defibrillation with biphasic waveform may increase safety, improve survival," <u>Medlines</u> , pp. 1-2 (June-July 1984). | | |
| | 87. | Saksena et al., "A prospective evaluation of single and dual current pathways for transvenous cardioversion in rapid ventricular tachycardia," <u>PACE</u> , 10:1130-1141 (September-October 1987). | | |
| | 88. | Saksena et al., "Developments for future implantable cardioverters and defibrillators," <u>PACE</u> , 10:1342-1358 (November-December 1987). | | |
| | 89. | 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," <u>PACE</u> , 16:95-124 (January 1993). | | |
| | 90. | Schuder et al. "Comparison of effectiveness of relay-switched, one-cycle quasisinusoidal waveform with critically damped sinusoid waveform in transthoracic defibrillation of 100-kilogram calves," <u>Medical Instrumentation</u> , 22(6):281-285 (1988). | | |
| | 91. | Schuder et al., "A multielectrode-time sequential laboratory defibrillator for the study of implanted electrode systems," <u>Amer. Soc. Artif. Int. Organs</u> , XVIII:514-519 (1972). | | |
| N | 92. | Schuder et al., "Development of automatic implanted defibrillator," <u>Devices & Tech.</u> | | |
| EXAMINER: | | DATE CONSIDERED: | | |
| K. Schaetzel | | 9-5-96 | | |
| EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant. | | | | |

PTO/SB/08 (2-92)

Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

| Form PTO-1449 | |  | Docket Number 241082000610 | Application Number 08/601,617 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------|
| INFORMATION DISCLOSURE CITATION IN AN APPLICATION (Use several sheets if necessary) | | Applicant |  | |
| | | Filing Date February 14, 1996 |  | |
| OTHER DOCUMENTS (including author, title, Date, Pertinent Pages, Etc.) | | | | |
| Examiner Initials | Ref. No. | Title | | |
|  | | Meeting NIH (1981). | | |
| | 93. | Schuder, et al., "One-Cycle Bidirectional Rectangular Wave Shocks for Open Chest Defibrillation in the Calf," <u>Abs. Am. Soc. Artif. Intern. Organs</u> , 9 : 16 | | |
| | 94. | Schuder, et al., "Transthoracic Ventricular Defibrillation with Square-wave Stimuli: One half Cycle," <u>Circ. Res.</u> , XV: 258-264 (1964) | | |
| | 95. | Schuder, et al., "Defibrillation of 100 kg calves with assymetrical, bidirectional, retangular pulses," <u>Card. Res.</u> , 18:419-426 (1984) | | |
| | 96. | Schuder, et al., "Transthoracic Ventricular Defibrillation in the 100 kg Calf with Symetrical One-Cycle Bidirectional Rectangular Wave Stimuli," <u>IEEE Trans. BME</u> , 30(7) : 415-422 (1983) | | |
| | 97. | Schuder, et al., "Ultrahigh-energy hydrogen thyatron/SCR Bidirectional waveform defibrillator," <u>Med. & Biol. Eng. & Comput.</u> , 20 : 419-424 (1982) | | |
| | 98. | Schuder, et al., "Wave form Dependency in Defibrillating 100 kg Calves," <u>Devices & Tech. Meeting, NIH</u> (1981) | | |
| | 99. | Schuder et al., "Waveform dependency in defibrillation," <u>Devices & Tech. Meeting NIH</u> (1981). | | |
| | 100. | Stanton et al., "Relationship between defibrillation threshold and upper limit of vulnerability in humans," <u>PACE</u> , 15:563, abstract 221 (April 1992). | | |
| | 101. | Tang et al., "Ventricular defibrillation using biphasic waveforms: The importance of phasic duration," <u>JACC</u> , 13(1):207-214 (1989). | | |
| | 102. | Tang, et al., "Strength Duration Curve for Ventricular Defibrillation Using Biphasic Waveforms," <u>PACE</u> , abstract no. 49 (1987) | | |
| | 103. | Tang, et al., "Ventricular Defibrillation Using Biphasic Waveforms of Different Phasic Duration," <u>PACE</u> , abstract no. 47 (1987) | | |
| | 104. | Walcott et al., "Comparison of monophasic, biphasic, and the edmark waveform for external defibrillation," <u>PACE</u> , 15:563, abstract 218 (April 1992). | | |
| | 105. | Wathen et al., "Improved defibrillation efficacy using four nonthoracotomy leads for | | |
| | EXAMINER: | |  | |
| | | DATE CONSIDERED: 9-5-96 | | |
| EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant. | | | | |

| Form PTO-1449 | |  | | Docket Number 08/601,617 | Application Number 08/601,617 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|-------------------------------------------------------------|-------------------------------|
| INFORMATION DISCLOSURE CITATION | | IN AN APPLICATION | | Applicant Gliner et al. Filing Date February 1996 | |
| (Use several sheets if necessary) | | | | Group Art Unit 3305 | |
| OTHER DOCUMENTS <small>(including author, title, Date, Pertinent Pages, Etc.)</small> | | | | | |
| Examiner Initials | Ref. No. | Title | | | |
| <i>[Signature]</i> | | sequential pulse defibrillation," <u>PACE</u> , 15:563, abstract 220 (April 1992). | | | |
| <i>[Signature]</i> | 106. | Wetherbee, et al. , "Subcutaneous Patch Electrode - A Means to Obviate Thoracotomy for Implantation of the Automatic Implantable cardioverter Defibrillation System?," <u>Circ.</u> , 72 : III-384, abstract no. 1536 (1985) | | | |
| <i>[Signature]</i> | 107. | Winkle "The implantable defibrillator in ventricular arrhythmias," <u>Hospital Practice</u> , pp. 149-165 (March 1983). | | | |
| <i>[Signature]</i> | 108. | Winkle et al., "Improved Low Energy Defibrillation Efficacy in Man Using a Biphasic Truncated Exponential Waveform," <u>JACC</u> , 9(2) : 142A (1987) | | | |
| <i>[Signature]</i> | 109. | Zipes, "Sudden cardiac death," <u>Circulation</u> , 85(1):160-166 (1992). | | | |
| | | | | | |
| EXAMINER: <i>K. Schaefer</i> | | DATE CONSIDERED: <i>9-5-96</i> | | | |
| EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant. | | | | | |

| | | | |
|-------------------------------|--------------------------------------|--------------------------------------|-------------------------------------------------------------------------------------|
| Notice of Allowability | Application No. 08/601,617 | Applicant(s) Gliner et al. | |
| | Examiner Ken Schaetzle | Group Art Unit 3305 |  |

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

☒ This communication is responsive to the amendment received Feb 14, 1996

☒ The allowed claim(s) is/are 15-22 and 35-44

☐ The drawings filed on _____ are acceptable.

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE **THREE MONTHS** FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.

☒ Applicant MUST submit NEW FORMAL DRAWINGS

☐ because the originally filed drawings were declared by applicant to be informal.
☒ including changes required by the Notice of Draftsperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. 5.
☐ including changes required by the proposed drawing correction filed on _____, which has been approved by the examiner.
☐ including changes required by the attached Examiner's Amendment/Comment.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

Attachment(s)

☐ Notice of References Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4
☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152
☐ Interview Summary, PTO-413
☐ Examiner's Amendment/Comment
☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
☒ Examiner's Statement of Reasons for Allowance

Serial Number: 08/601,617

Page 2

Art Unit: 3305

REASONS FOR ALLOWANCE

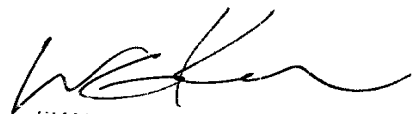
1. The following is an examiner's statement of reasons for allowance: the prior art of record fails to teach the discharging step (claim 15) and the adjusting step (claim 35). In other words, there is no teaching to discharge until the end of a predetermined time period or until an electrical unit measured across the electrodes decays to a predetermined terminal level, whichever occurs first.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

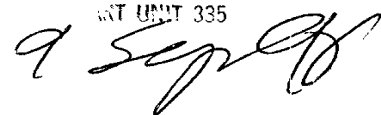
2. Any inquiry concerning this communication should be directed to Ken Schaetzle at telephone number (703) 308-2211.



K.S.
September 9, 1996



WILLIAM E. KAMM
PRIMARY EXAMINER
ART UNIT 335



NOTICE OF DRAFTSPERSON'S PATENT DRAWING REVIEW

PTO Draftpersons review all originally filed drawings regardless of whether they are designated as formal or informal. Additionally, patent Examiners will review the drawings for compliance with the regulations. Direct telephone inquiries concerning this review to the Drawing Review Branch, 703-305-8404.

The drawings filed (insert date) 02/14/96, are
 A. ☐ not objected to by the Draftsperson under 37 CFR 1.84 or 1.152.
 B. ☒ objected to by the Draftsperson under 37 CFR 1.84 or 1.152 as indicated below. The Examiner will require submission of new, corrected drawings when necessary. Corrected drawings must be submitted according to the instructions on the back of this Notice.

1. DRAWINGS. 37 CFR 1.84(a): Acceptable categories of drawings:
 Black ink. Color.
☐ Not black solid lines. Fig(s) _____
☐ Color drawings are not acceptable until petition is granted. Fig(s) _____
2. PHOTOGRAPHS. 37 CFR 1.84(b)
☐ Photographs are not acceptable until petition is granted. Fig(s) _____
☐ Photographs not properly mounted (must use bristol board or photographic double-weight paper). Fig(s) _____
☐ Poor quality (half-tone). Fig(s) _____
3. GRAPHIC FORMS. 37 CFR 1.84 (d)
☐ Chemical or mathematical formula not labeled as separate figure. Fig(s) _____
☐ Group of waveforms not presented as a single figure, using common vertical axis with time extending along horizontal axis. Fig(s) _____
☐ Individuals waveform not identified with a separate letter designation adjacent to the vertical axis. Fig(s) _____
4. TYPE OF PAPER. 37 CFR 1.84(c)
☐ Paper not flexible, strong, white, smooth, nonshiny, and durable. Sheet(s) _____
☐ Erasures, alterations, overwritings, interlineations, cracks, creases, and folds copy machine marks not accepted. Fig(s) _____
☐ Mylar, velum paper is not acceptable (too thin). Fig(s) _____
5. SIZE OF PAPER. 37 CFR 1.84(f): Acceptable sizes:
 21.6 cm. by 35.6 cm. (8 1/2 by 14 inches)
 21.6 cm. by 33.1 cm. (8 1/2 by 13 inches)
 21.6 cm. by 27.9 cm. (8 1/2 by 11 inches)
 21.0 cm. by 29.7 cm. (DIN size A4)
☐ All drawing sheets not the same size. Sheet(s) _____
☐ Drawing sheet not an acceptable size. Sheet(s) _____
6. MARGINS. 37 CFR 1.84(g): Acceptable margins:

Paper size

| | | | |
|-----------------------------------------|-----------------------------------------|-----------------------------------------|-----------------------------------|
| 21.6 cm. X 35.6 cm. (8 1/2 X 14 inches) | 21.6 cm. X 33.1 cm. (8 1/2 X 13 inches) | 21.6 cm. X 27.9 cm. (8 1/2 X 11 inches) | 21.0 cm. X 29.7 cm. (DIN Size A4) |
| T 5.1 cm. (2") | 2.5 cm. (1") | 2.5 cm. (1") | 2.5 cm. |
| L .64 cm. (1/4") | .64 cm. (1/4") | .64 cm. (1/4") | 2.5 cm. |
| R .64 cm. (1/4") | .64 cm. (1/4") | .64 cm. (1/4") | 1.5 cm. |
| B .64 cm. (1/4") | .64 cm. (1/4") | .64 cm. (1/4") | 1.0 cm. |

Margins do not conform to chart above.

Sheet(s) FIG. 1, 3, 5
☒ Top (T) ☐ Left (L) ☐ Right (R) ☐ Bottom (B)

7. VIEWS. 37 CFR 1.84(h)
 REMINDER: Specification may require revision to correspond to drawing changes.
☐ All views not grouped together. Fig(s) _____
☐ Views connected by projection lines or lead lines. Fig(s) _____
 Partial views. 37 CFR 1.84(h) 2

- ☐ View and enlarged view not labeled separately or properly. Fig(s) _____
 Sectional views. 37 CFR 1.84 (h) 3
☐ Hatching not indicated for sectional portions of an object. Fig(s) _____
☐ Cross section not drawn same as view with parts in cross section with regularly spaced parallel oblique strokes. Fig(s) _____
8. ARRANGEMENT OF VIEWS. 37 CFR 1.84(i)
☐ Words do not appear on a horizontal, left-to-right fashion when page is either upright or turned so that the top becomes the right side, except for graphs. Fig(s) _____
9. SCALE. 37 CFR 1.84(k)
☐ Scale not large enough to show mechanism with crowding when drawing is reduced in size to two-thirds in reproduction. Fig(s) _____
☐ Indication such as "actual size" or scale 1/2" not permitted. Fig(s) _____
10. CHARACTER OF LINES, NUMBERS, & LETTERS. 37 CFR 1.84(l)
☒ Lines, numbers & letters not uniformly thick and well defined, clean, durable, and black (except for color drawings). Fig(s) ALL
11. SHADING. 37 CFR 1.84(m)
☐ Solid black shading areas not permitted. Fig(s) _____
☐ Shade lines, pale, rough and blurred. Fig(s) _____
12. NUMBERS, LETTERS, & REFERENCE CHARACTERS. 37 CFR 1.84(p)
☒ Numbers and reference characters not plain and legible. 37 CFR 1.84(p)(1) Fig(s) 10, 11
☐ Numbers and reference characters not oriented in same direction as the view. 37 CFR 1.84(p)(1) Fig(s) _____
☐ English alphabet not used. 37 CFR 1.84(p)(2) Fig(s) _____
☒ Numbers, letters, and reference characters do not measure at least .32 cm. (1/8 inch) in height. 37 CFR(p)(3) Fig(s) ALL
13. LEAD LINES. 37 CFR 1.84(q)
☐ Lead lines cross each other. Fig(s) _____
☐ Lead lines missing. Fig(s) _____
14. NUMBERING OF SHEETS OF DRAWINGS. 37 CFR 1.84(t)
☐ Sheets not numbered consecutively, and in Arabic numerals, beginning with number 1. Sheet(s) _____
15. NUMBER OF VIEWS. 37 CFR 1.84(u)
☐ Views not numbered consecutively, and in Arabic numerals, beginning with number 1. Fig(s) _____
☐ View numbers not preceded by the abbreviation Fig Fig(s) _____
16. CORRECTIONS. 37 CFR 1.84(w)
☐ Corrections not made from prior PTO-948. Fig(s) _____
17. DESIGN DRAWING. 37 CFR 1.152
☐ Surface shading shown not appropriate. Fig(s) _____
☐ Solid black shading not used for color contrast. Fig(s) _____

COMMENTS:

ATTACHMENT TO PAPER NO. 5REVIEWER LAMDATE 02/14/96



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: Box ISSUE FEE
ASSISTANT COMMISSIONER FOR PATENTS
Washington, D.C. 20231

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

STUART P KALER
MORRISON & FOERSTER
345 CALIFORNIA STREET
SAN FRANCISCO CA 94104-2675

| APPLICATION NO. | FILING DATE | TOTAL CLAIMS | EXAMINER AND GROUP ART UNIT | DATE MAILED |
|-----------------------|---------------------|--------------|-----------------------------|---------------|
| 08/601,617 | 02/14/96 | 018 | SCHAETZLE, K | 3305 09/13/96 |
| First Named Applicant | GLINER, BRADFORD E. | | | |

TITLE OF INVENTION ELECTROTHERAPY METHOD

| ATTY'S DOCKET NO. | CLASS-SUBCLASS | BATCH NO. | APPLN. TYPE | SMALL ENTITY | FEE DUE | DATE DUE |
|-------------------|----------------|-------------|-------------|--------------|----------|----------|
| 3 | 241082000610 | 607-007.000 | E19 UTILITY | YES | \$625.00 | 12/13/96 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.
If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
- If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- Pay FEE DUE shown above, or
- File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B of this notice should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "6b" of Part B should be completed.

III. All communications regarding this application must give application number and batch number. Please direct all communication prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

3. PATENT AND TRADEMARK OFFICE COPY

PART B—ISSUE FEE TRANSMITTAL

MAILING INSTRUCTIONS: This form should be used ☒ transmitting the ISSUE FEE. Blocks 2 through 6 should be completed where appropriate. All further correspondence including the Issue Fee Receipt, the Patent, advance orders and notification of maintenance fees will be mailed to addressee entered in Block 1 unless you direct otherwise, by: (a) specifying a new correspondence address in Block 3 below; or (b) providing the PTO with a separate "FEE ADDRESS" for maintenance fee notifications with the payment of Issue Fee or thereafter. See reverse for Certificate of Mailing, below.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending on the needs of the individual case. Any comments on the amount of time required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, D.C. 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Issue Fee, Assistant Commissioner for Patents, Washington D.C. 20231

| | | | |
|-----------------------------------------------------------------------------------------------|--|--------------------------------------------------------------------|--|
| 1. CORRESPONDENCE ADDRESS | | 2. INVENTOR(S) ADDRESS CHANGE (Complete only if there is a change) | |
| STUART P KALER MORRISON & FOERSTER 345 CALIFORNIA STREET SAN FRANCISCO CA 94104-2675 | | INVENTOR'S NAME Street Address City, State and ZIP Code | |
| 33M1/0913 | | CO-INVENTOR'S NAME Street Address City, State and ZIP Code | |
| | | SEP 30 1996 DT | |
| | | <input type="checkbox"/> Check if additional changes are enclosed | |

| APPLICATION NO. | FILING DATE | TOTAL CLAIMS | EXAMINER AND GROUP ART UNIT | DATE MAILED |
|-----------------------|-------------|--------------|-----------------------------|---------------|
| 08/601,617 | 02/14/96 | 018 | SCHAETZLE, K | 3305 09/13/96 |
| First Named Applicant | GLINER | BRADFORD E. | | |

TITLE OF INVENTION
ELECTROTHERAPY METHOD

| ATTY'S DOCKET NO. | CLASS-SUBCLASS | BATCH NO. | APPLN. TYPE | SMALL ENTITY | FEE DUE | DATE DUE |
|-------------------|----------------|-------------|-------------|--------------|--------------|----------|
| 3 | 241082000610 | 607-007.000 | E19 | UTILITY | YES \$625.00 | 12/13/96 |

3. Correspondence address change (Complete only if there is a change)
Heartstream, Inc.
Legal Department
2401 Fourth Avenue, Suite 300
Seattle, WA 98121.1436

4. For printing on the patent front page, list the names of not more than 3 registered patent attorneys or agents OR, alternatively, the name of a firm having as a member a registered attorney or agent. If no name is listed, no name will be printed.
1 Morrison & Foerster
2
3

5. ASSIGNMENT DATA TO BE PRINTED ON THE PATENT (print or type)

(1) NAME OF ASSIGNEE: HEARTSTREAM, INC.

(2) ADDRESS: (CITY & STATE OR COUNTRY) Seattle WA

A. ☐ This application is NOT assigned.
☒ Assignment previously submitted to the Patent and Trademark Office.
☐ Assignment is being submitted under separate cover. Assignments should be directed to Box ASSIGNMENTS.

PLEASE NOTE: Unless an assignee is identified in Block 5, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the PTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

6a. The following fees are enclosed:
☐ Issue Fee ☐ Advance Order - # of Copies
 6b. The following fees should be charged to: DEPOSIT ACCOUNT NUMBER 08-1515
 (ENCLOSE A COPY OF THIS FORM)
☒ Issue Fee ☒ Advance Order - # of Copies 12
☒ Any Deficiencies in Enclosed Fees

The COMMISSIONER OF PATENTS AND TRADEMARKS is requested to apply the Issue Fee to the application identified above.

(Authorized Signature) (Date) 9-24-96

Certificate of Mailing

Note: If this certificate of mailing is used, it can only be used to transmit the Issue Fee. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

Box ISSUE FEE
Assistant Commissioner for Patents
Washington, D.C. 20231

810 BL 08-1515 10/10/96 08401417
81137 242 625.00CN
81138 561 36.00CN

on: 24 Sep 96 (Date)
Cecily Anne Snyder (Name of person making deposit)
(Signature)
24 Sep 96 (Date)

1. TRANSMIT THIS FORM WITH FEE

PTOL-85B (REV.05-96) Approved for use through 05/31/96. OMB 0851-0033

Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

4150
Dny

#62

PATENT
Heartstream Ref. 93-003-us1.d1
Morrison & Foerster Ref. 24108-20006.10

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on September 24, 1996
Cecily Anne Snyder, Reg. No. 37,448

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Bradford E. Gliner

Serial No.: 08/601,617

Filing Date: 14 February 1996

For: ELECTROTHERAPY METHOD

Examiner: K. Schaetzle

Group Art Unit: 3305

BATCH NO. E19
NOTICE OF ALLOWANCE
9/13/96

SUBMISSION OF FORMAL DRAWINGS

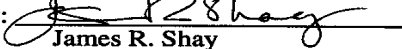
Box ISSUE FEE
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

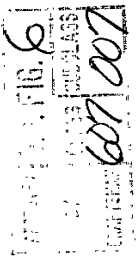
Enclosed are seven sheet(s) of formal drawings in connection with the above-identified application.

Dated: September 24, 1996

Respectfully submitted,

By: 
James R. Shay
Registration No. 32,062

1/7



2/7

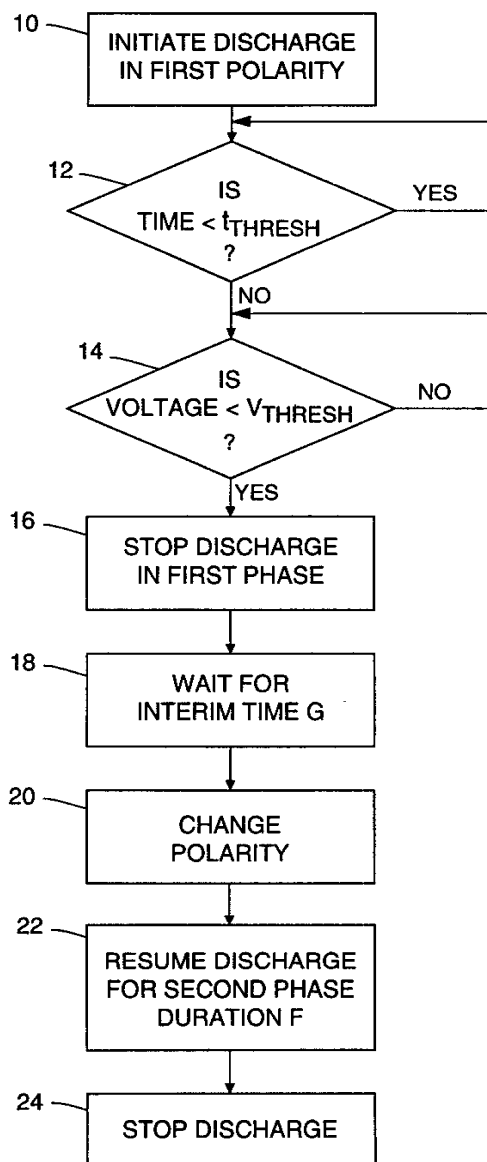
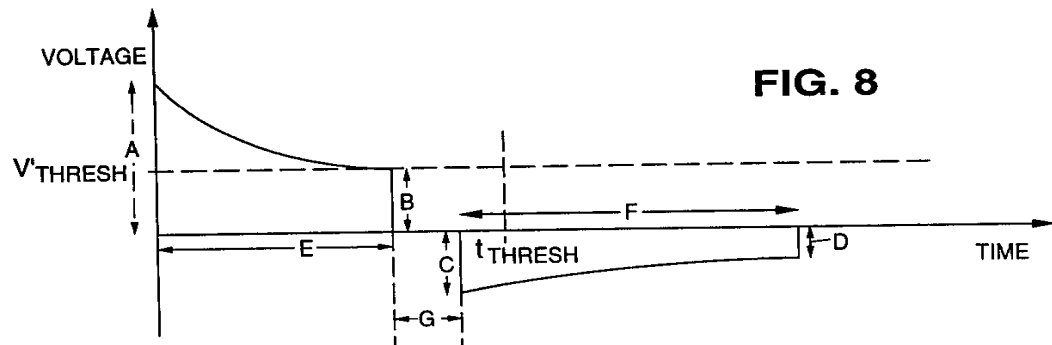
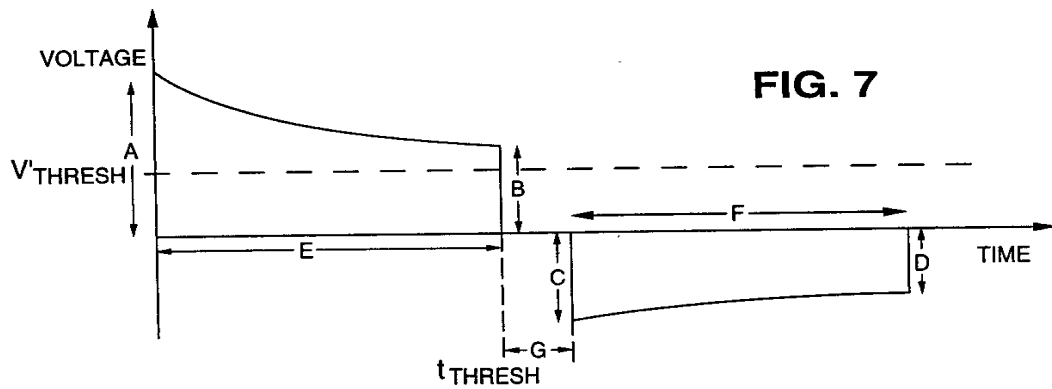
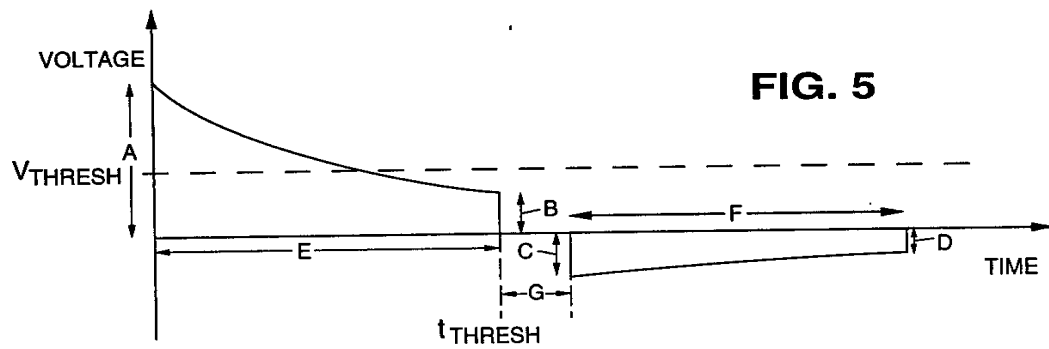
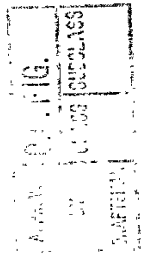


FIG. 3



4/7

FIG. 6
100/007

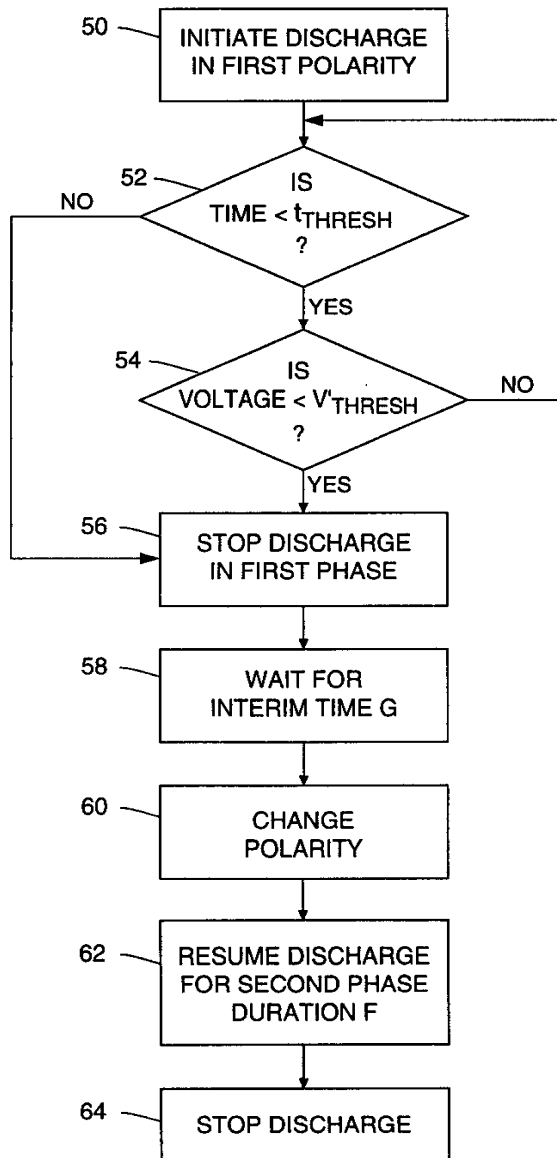


FIG. 6

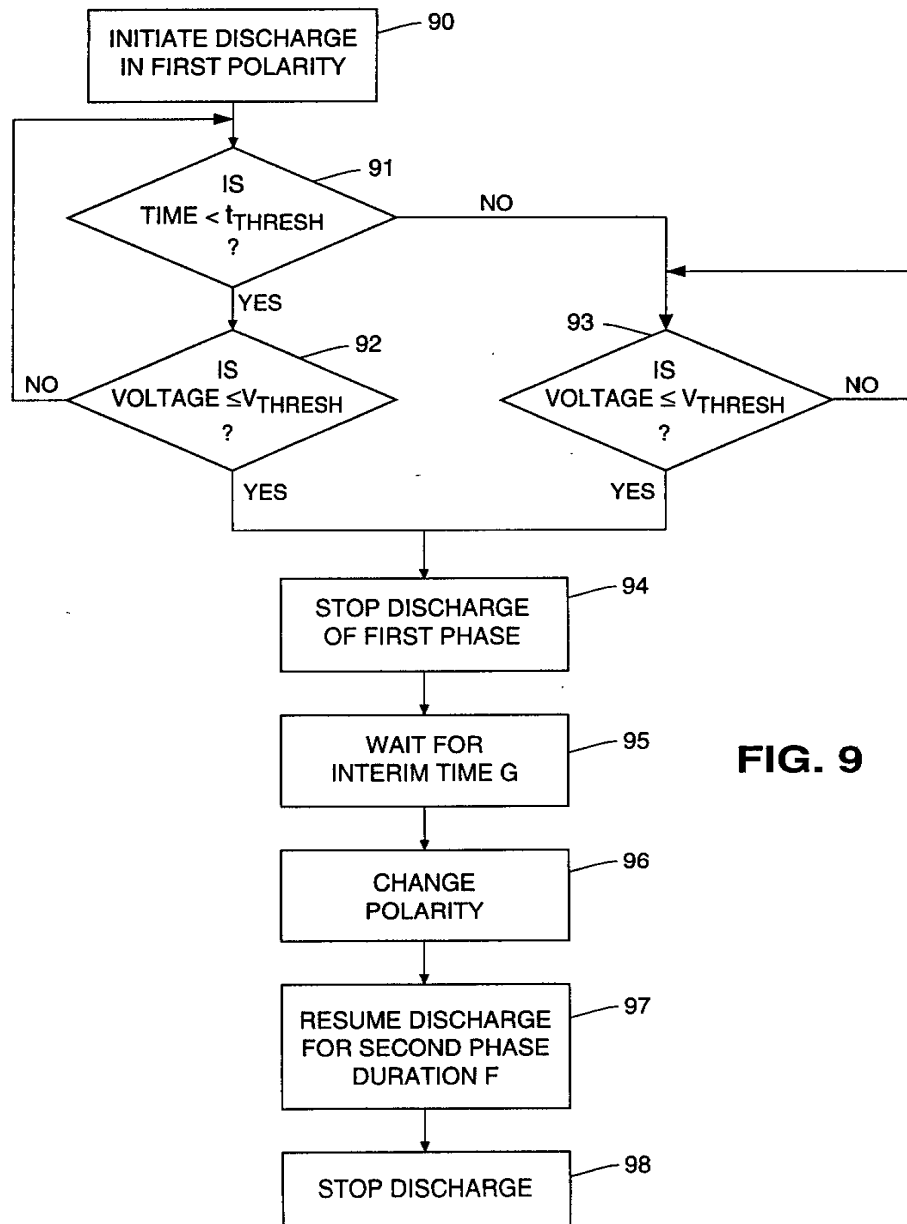


FIG. 9

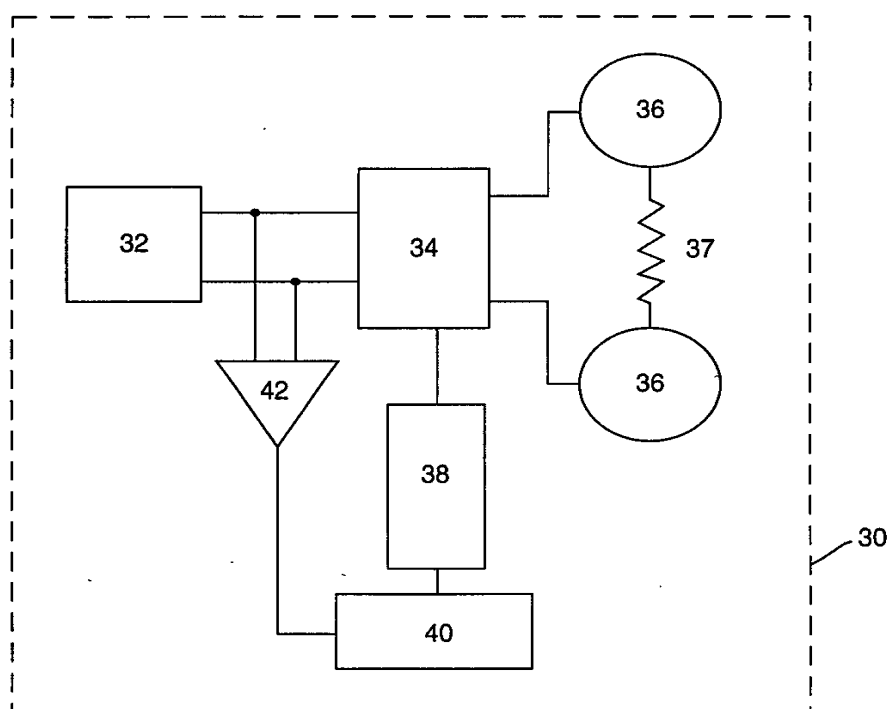
**FIG. 10**

FIG. 11

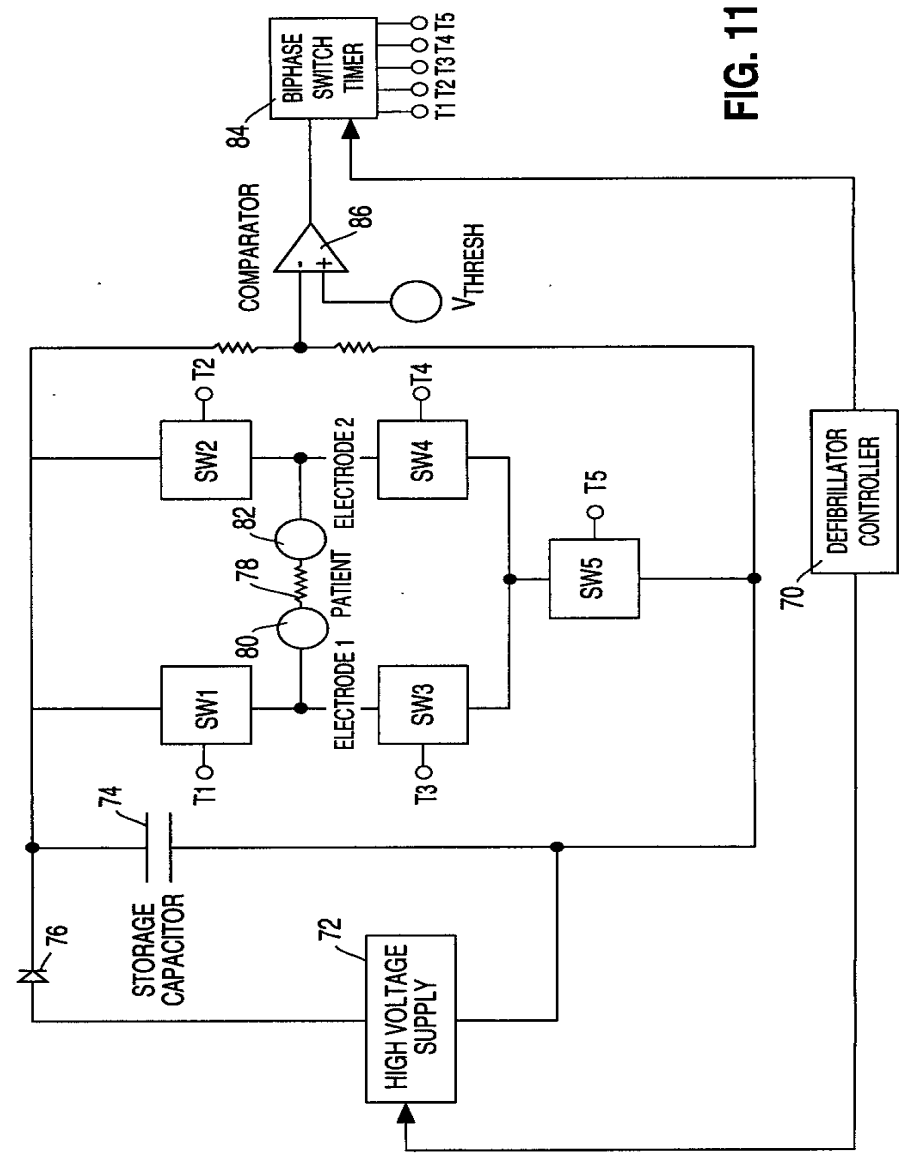


FIG. 11

The
United
States
of
America



PTO UTILITY GRANT

Paper Number 7

The Commissioner of Patents
and Trademarks

Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

Therefore, this

United States Patent

Grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States of America for the term set forth below, subject to the payment of maintenance fees as provided by law.

If this application was filed prior to June 8, 1995, the term of this patent is the longer of seventeen years from the date of grant of this patent or twenty years from the earliest effective U.S. filing date of the application, subject to any statutory extension.

If this application was filed on or after June 8, 1995, the term of this patent is twenty years from the earliest effective U.S. filing date of the application, subject to any statutory extension.

Bence Lehman

Commissioner of Patents and Trademarks

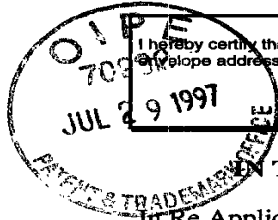
Melvinia Gary


Attest

Form PTO-1584 (Rev. 5/96)

(RIGHT INSIDE)

C O C
PATENT
Heartstream Ref. 93-003-US1.D1



CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on 21 Jan 97.

Cecily Anne Snyder, Reg. No. 37,448

PS
#8

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Bradford E. Gliner, et al.

Serial No.: 08/601,617

Group Art Unit: 3305

Filing Date: 14 Feb 1996

Examiner: K. Schaetzle

Patent No.: 5,593,427

Issue Date: 14 Jan 1997

Title: **ELECTROTHERAPY METHOD**

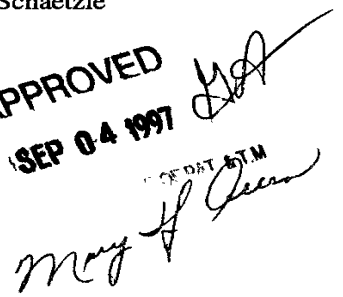
**REQUEST FOR CERTIFICATE OF CORRECTION
UNDER 37 C.F.R. § 1.322**

Assistant Commissioner for Patents
Washington, DC 20231

CERTIFICATE

AUG 22 1997

APPROVED
SEP 04 1997


Mary H. Green
OFFICE OF PAT. & T.M.

Dear Sir:

OF CORRECTION

Applicants request that the above-referenced patent be corrected. Along with this request, Applicants enclose a Certificate of Correction for the patent. Applicants respectfully request acceptance and issuance of this Certificate of Correction.

Pursuant to 37 C.F.R. § 1.322, Applicants request that the following typographical errors that occurred during the printing of the patent be corrected:

In the References Cited section, field [56]:

U.S. PATENT DOCUMENTS

"5,272,157" should be — 5,275,157 —. Support for this correction can be found in the Information Disclosure Citation (PTO-1449) considered May 20, 1996; Reference Number 40.

PATENT

OTHER PUBLICATIONS

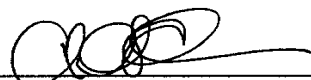
"Alfeness" should be — Alferness —. Support for this correction can be found in the Information Disclosure Citation (PTO-1449) considered May 20, 1996; Reference Number 58.

In the Text of the Patent

Column 8, line 58, (Claim 16) "claim 7" should be — claim 9 —. Claim 16 of the issued patent corresponds to Claim 42 presented by Applicants in the Preliminary Amendment filed February 14, 1996. As originally presented, Claim 42 depended from Claim 35. Claim 35 became Claim 9 in the issued patent, and Claim 42 should have been modified to depend from issued Claim 9 when the Office renumbered the allowed claims.

Dated: 24 Jul 97

Respectfully submitted,

By: 
Cecily Anne Snyder, Patent Agent
Reg. No. 37,448


Heartstream, Inc.
Legal Department
2401 Fourth Avenue, Suite 300
Seattle Washington 98121
Telephone: 206.443.7630
Facsimile: 206.443.9694

g:...cert-cor.doc


UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : **5,593,427**
DATED : 14 Jan 1997
INVENTOR(S): Bradford E. Gliner, Thomas D. Lyster, Clinton S. Cole,
Daniel J. Powers, and Carlton B. Morgan

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

In field [56] "5,272,157" should be — 5,275,157 —. 

In field [56] "Alfeness" should be — Alferness —. 

Column 8, line 58, (claim 16) "claim 7" should be — claim 9 —. 

MAILING ADDRESS OF SENDER

Cecily Anne Snyder, Patent Agent
Heartstream, Inc.
Legal Department
2401 Fourth Avenue, Suite 300
Seattle, Washington 98121

FORM PTO 1050 (Rev. 2-93)

PATENT NO. **5,593,427**

No. of add'l copies

@ 50¢ per page

⇒ _____

Page 1 of 1 •

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 5,593,427

DATED : January 14, 1997

INVENTOR(S) : Bradford E. Gliner, Thomas D. Lyster, Clinton S. Cole,
Daniel J. Powers, and Carlton B. Morgan

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

Item [56] "5,272,157" should be — 5,275,157 —.

Item [56] "Alfeness" should be — Alferness —.

Column 8, line 58, (claim 16) "claim 7" should be — claim 9 —.

Signed and Sealed this
Thirtieth Day of September, 1997

Attest:



BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks

ENTERED BY DSD

PATENT
HP PD NO. 90980060-5
Heartstream 93-003-US1.D1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Bradford E. Gliner et al.

Patent No.:

Issue Date: 01/14/97

Title: **Electrotherapy Method**

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to Commissioner of Patents and Trademarks, Washington DC 20231.

Date of Deposit: 4/20/98

Typed Name: Michelle L. Ogland

Signature: *Michelle Ogland*

BOX M FEE
Assistant Commissioner for Patents
Washington, D.C. 20231

NOTIFICATION OF LOSS OF ENTITLEMENT TO SMALL ENTITY STATUS

Applicant hereby notifies the Patent and Trademark Office that it is no longer entitled to status as a small entity, and that the claim for small entity status, set forth in the verified statement executed on September 7, 1993, is hereby withdrawn.

Correspondence Address:
Hewlett-Packard Company
Legal Department, 20BN
PO Box 10301
Palo Alto, CA 94303-0890

Respectfully submitted,

By: *Douglas J. Barker*
Douglas J. Barker
Registration No. 40,423
Direct Dial Telephone: 360/212-8369
Customer No.: 020067



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

CHANGE OF ADDRESS/POWER OF ATTORNEY

LOCATION 9200 SERIAL NUMBER 08601617 PATENT NUMBER 5593427

THE CORRESPONDENCE ADDRESS HAS BEEN CHANGED TO CUSTOMER # 20067

THE PRACTITIONERS OF RECORD HAVE BEEN CHANGED TO CUSTOMER # 20067

THE FEE ADDRESS HAS BEEN CHANGED TO CUSTOMER # 20067

ON 02/17/00 THE ADDRESS OF RECORD FOR CUSTOMER NUMBER 20067 IS:

HEARTSTREAM INC
AGILENT TECHNOLOGIES LEGAL DEPT
5301 STEVENS CREEK BLVD MS 51UPD
P O BOX 58043
SANTA CLARA CA 95052-8043

AND THE PRACTITIONERS OF RECORD FOR CUSTOMER NUMBER 20067 ARE:

24288 27586 29992 30275 33272 36184 37448

PTO INSTRUCTIONS: PLEASE TAKE THE FOLLOWING ACTION WHEN THE
CORRESPONDENCE ADDRESS HAS BEEN CHANGED TO CUSTOMER NUMBER:
RECORD, ON THE NEXT AVAILABLE CONTENTS LINE OF THE FILE JACKET,
'ADDRESS CHANGE TO CUSTOMER NUMBER'. LINE THROUGH THE OLD
ADDRESS ON THE FILE JACKET LABEL AND ENTER ONLY THE 'CUSTOMER
NUMBER' AS THE NEW ADDRESS. FILE THIS LETTER IN THE FILE JACKET.
WHEN ABOVE CHANGES ARE ONLY TO FEE ADDRESS AND/OR PRACTITIONERS
OF RECORD, FILE LETTER IN THE FILE JACKET.



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

CHANGE OF ADDRESS/POWER OF ATTORNEY

FILE LOCATION 9200 SERIAL NUMBER 08601617 PATENT NUMBER 5593427

THE CORRESPONDENCE ADDRESS HAS BEEN CHANGED TO CUSTOMER # 22878

THE PRACTITIONERS OF RECORD HAVE BEEN CHANGED TO CUSTOMER # 22878

ON 06/05/01 THE ADDRESS OF RECORD FOR CUSTOMER NUMBER 22878 IS:

AGILENT TECHNOLOGIES, INC.
INTELLECTUAL PROPERTY ADMINISTRATION, LE
P.O. BOX 7599
M/S DL429
LOVELAND CO 80537-0599

AND THE PRACTITIONERS OF RECORD FOR CUSTOMER NUMBER 22878 ARE:

| | | | | | | | | | |
|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| 24288 | 26252 | 27586 | 29331 | 29992 | 30275 | 30528 | 30682 | 32426 | 33272 |
| 33381 | 34075 | 34886 | 36081 | 36184 | 36211 | 36771 | 37265 | 37448 | 37648 |
| 38197 | 38345 | 40026 | 40907 | | | | | | |

PTO INSTRUCTIONS: PLEASE TAKE THE FOLLOWING ACTION WHEN THE
CORRESPONDENCE ADDRESS HAS BEEN CHANGED TO CUSTOMER NUMBER:
RECORD, ON THE NEXT AVAILABLE CONTENTS LINE OF THE FILE JACKET,
ADDRESS CHANGE TO CUSTOMER NUMBER. LINE THROUGH THE OLD
ADDRESS ON THE FILE JACKET LABEL AND ENTER ONLY THE CUSTOMER
NUMBER AS THE NEW ADDRESS. FILE THIS LETTER IN THE FILE JACKET.
WHEN ABOVE CHANGES ARE ONLY TO FEE ADDRESS AND/OR PRACTITIONERS
OF RECORD, FILE LETTER IN THE FILE JACKET.
THIS FILE IS ASSIGNED TO GAU 3305.



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

CHANGE OF ADDRESS/POWER OF ATTORNEY

FILE LOCATION 9200 SERIAL NUMBER 08601617 PATENT NUMBER 5593427

THE CORRESPONDENCE ADDRESS HAS BEEN CHANGED TO CUSTOMER # 29139

THE PRACTITIONERS OF RECORD HAVE BEEN CHANGED TO CUSTOMER # 29139

THE FEE ADDRESS HAS BEEN CHANGED TO CUSTOMER # 29139

ON 08/10/01 THE ADDRESS OF RECORD FOR CUSTOMER NUMBER 29139 IS:

AGILENT TECHNOLOGIES, INC.
LEGAL DEPARTMENT, M/S 51UPB
5301 STEVENS CREEK BLVD.
SANTA CLARA CA 95052

AND THE PRACTITIONERS OF RECORD FOR CUSTOMER NUMBER 29139 ARE:

| | | | | | | | | | |
|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| 24288 | 26252 | 27586 | 29331 | 29992 | 30275 | 30528 | 30682 | 32426 | 33272 |
| 33381 | 33825 | 34075 | 36081 | 36184 | 36211 | 37648 | 38197 | 38345 | 40026 |
| 40907 | 45549 | | | | | | | | |

PTO INSTRUCTIONS: PLEASE TAKE THE FOLLOWING ACTION WHEN THE
CORRESPONDENCE ADDRESS HAS BEEN CHANGED TO CUSTOMER NUMBER:
RECORD, ON THE NEXT AVAILABLE CONTENTS LINE OF THE FILE JACKET,
'ADDRESS CHANGE TO CUSTOMER NUMBER'. LINE THROUGH THE OLD
ADDRESS ON THE FILE JACKET LABEL AND ENTER ONLY THE 'CUSTOMER
NUMBER' AS THE NEW ADDRESS. FILE THIS LETTER IN THE FILE JACKET.
WHEN ABOVE CHANGES ARE ONLY TO FEE ADDRESS AND/OR PRACTITIONERS
OF RECORD, FILE LETTER IN THE FILE JACKET.
THIS FILE IS ASSIGNED TO GAU 3305.



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

CHANGE OF ADDRESS/POWER OF ATTORNEY

FILE LOCATION 9200 SERIAL NUMBER 08601617 PATENT NUMBER 5593427

THE CORRESPONDENCE ADDRESS HAS BEEN CHANGED TO CUSTOMER # 24737

THE PRACTITIONERS OF RECORD HAVE BEEN CHANGED TO CUSTOMER # 24737

THE FEE ADDRESS HAS BEEN CHANGED TO CUSTOMER # 24737

ON 05/13/03 THE ADDRESS OF RECORD FOR CUSTOMER NUMBER 24737 IS:

PHILIPS ELECTRONICS NORTH AMERICAN CORP
580 WHITE PLAINS RD
TARRYTOWN NY 10591

AND THE PRACTITIONERS OF RECORD FOR CUSTOMER NUMBER 24737 ARE:

| | | | | | | | | | |
|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| 22861 | 26236 | 26358 | 26531 | 26902 | 27677 | 28613 | 30245 | 32266 | 32603 |
| 33357 | 35721 | 36921 | 37520 | 39398 | 39703 | 40007 | 42079 | 42080 | 43305 |

PTO INSTRUCTIONS: PLEASE TAKE THE FOLLOWING ACTION WHEN THE
CORRESPONDENCE ADDRESS HAS BEEN CHANGED TO CUSTOMER NUMBER:
RECORD, ON THE NEXT AVAILABLE CONTENTS LINE OF THE FILE JACKET,
'ADDRESS CHANGE TO CUSTOMER NUMBER'. LINE THROUGH THE OLD
ADDRESS ON THE FILE JACKET LABEL AND ENTER ONLY THE 'CUSTOMER
NUMBER' AS THE NEW ADDRESS. FILE THIS LETTER IN THE FILE JACKET.
WHEN ABOVE CHANGES ARE ONLY TO FEE ADDRESS AND/OR PRACTITIONERS
OF RECORD, FILE LETTER IN THE FILE JACKET.
THIS FILE IS ASSIGNED TO GAU 0000.

| PATENT APPLICATION FEE DETERMINATION RECORD Effective October 1, 1995 | | | | | | Application or Docket Number <div style="font-size: 1.2em; margin-top: 5px;">08/601617</div> | |
|---------------------------------------------------------------------------------|------------------------------------------------|----------------------------------|-----------------|------------------------------------|---------------|-------------------------------------------------------------------------------------------------|-------------------------|
| CLAIMS AS FILED - PART I | | | | | | | |
| | | (Column 1) | (Column 2) | | | | |
| FOR | | NUMBER FILED | | NUMBER EXTRA | | | |
| BASIC FEE | | | | | | | |
| TOTAL CLAIMS | | 8 | minus 20 = | * | | | |
| INDEPENDENT CLAIMS | | 1 | minus 3 = | * | | | |
| MULTIPLE DEPENDENT CLAIM PRESENT | | | | | | | |
| * If the difference in column 1 is less than zero, enter "0" in column 2 | | | | | | | |
| CLAIMS AS AMENDED - PART II | | | | | | | |
| | | (Column 1) | (Column 2) | (Column 3) | | | |
| AMENDMENT A | | CLAIMS REMAINING AFTER AMENDMENT | | HIGHEST NUMBER PREVIOUSLY PAID FOR | PRESENT EXTRA | | |
| | Total | * | Minus | ** | = | | |
| | Independent | * | Minus | *** | = | | |
| | FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM | | | | | | |
| | | | | | | | |
| AMENDMENT B | | CLAIMS REMAINING AFTER AMENDMENT | | HIGHEST NUMBER PREVIOUSLY PAID FOR | PRESENT EXTRA | | |
| | Total | * | Minus | ** | = | | |
| | Independent | * | Minus | *** | = | | |
| | FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM | | | | | | |
| | | | | | | | |
| AMENDMENT C | | CLAIMS REMAINING AFTER AMENDMENT | | HIGHEST NUMBER PREVIOUSLY PAID FOR | PRESENT EXTRA | | |
| | Total | * | Minus | ** | = | | |
| | Independent | * | Minus | *** | = | | |
| | FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM | | | | | | |
| | | | | | | | |
| | | | | SMALL ENTITY | | OR | OTHER THAN SMALL ENTITY |
| | | RATE | FEE | | | | |
| | | | 375.00 | | | | 750.00 |
| | | x\$11= | | | | | x\$22= |
| | | x39= | | | | | x78= |
| | | +125= | | | | | +250= |
| | | TOTAL | 375 | | | | TOTAL |
| | | | | SMALL ENTITY | | OR | OTHER THAN SMALL ENTITY |
| | | RATE | ADDI-TIONAL FEE | | | | |
| | | x\$11= | | | | | x\$22= |
| | | x39= | | | | | x78= |
| | | +125= | | | | | +250= |
| | | TOTAL | | | | | TOTAL |
| | | ADDIT. FEE | | | | | ADDIT. FEE |

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

