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UTILITY SERIAL NUMBER	PATENT DATE	PATENT NUMBER
08/227553	MAR 04 1997	

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08/227,553	04/14/94	607		3305	

APPLICANTS

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CONTINUING DATA********
VERIFIED THIS APPLN IS A CIP OF 08/103,837 08/06/93

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VERIFIED none

CERTIFICATE

NOV 11 1997

OF CORRECTION

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TITLE

ELECTROTHERAPY METHOD AND APPARATUS

U.S. DEPT. of COMM./Pat. & TM Office — PTO-436L (rev. 10-78)

PARTS OF APPLICATION FILED SEPARATELY	Applications Examiner
6/17	

NOTICE OF ALLOWANCE MAILED		CLAIMS ALLOWED	
6-17-96	Kennedy J. Schaetzle, Assistant Examiner	Total Claims 58 59	Print Claim 36

ISSUE FEE		DRAWING		
Amount Due	Date Paid	Sheets Drwg.	Figs. Drwg.	Print Fig.
625.00	7-15-96	4	6	6

Marvin M. Lateef
MARVIN M. LATEEF
SUPERVISORY PATENT EXAMINER
GROUP 3300
Primary Examiner

ISSUE BATCH NUMBER B11

Label Area

PREPARED FOR ISSUE

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INITIALS

MAY 04 1994

GROUP 330 Date Received or Mailed

CONTENTS

		application & amdts papers.	
		Fwe-fee, signature	5/10/94
	3.	Dec Fee, Sm. Entity	5-31-94
	4.	Power of Att.	6-17-94
4-3	5.	Rej 3 mo	APR 11 1995
5-4	6.	Misc Letter	May 5 1995
7/25,	7.	Amdt A	7-21-95
10/2	8.	Rej 3 mo	OCT 13 95
	9.	Interview	1-17-96
	10.	Ext. 1 mo.	1-29-96 2/12
	11.	IDS	1-29-96
2, 3	12.	Amdt B	1-29-96
	13.	Supp. I.D.S.	1-11-96
4/15	14.	Final Rej 3 mo	4-19-96
	15.	Petition re IDS	5/8/96
	16.	Amdt C w/ Box AF	5/8/96
	17.	IDS Petition GRANTED	6/6/96
	18.	Exr Amdt D	6-17-96
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	20.	R.312 Amdt Due	7/3/96
	1.	Letter	10/22/96
	22.	Entry Notice	11/19/96
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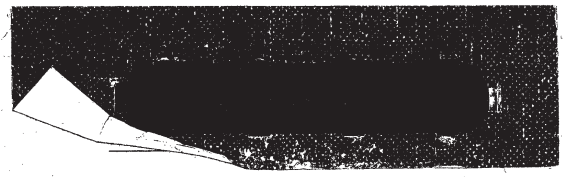

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SEARCH NOTES

	Date	Exmr.
Search update of 3-18-95 search	9-28-95	KA
Search update of 9-29-95 update	4-8-96	KA
Search update of 4-8-96 update	6-6-96	KA

INTERFERENCE SEARCHED

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INDEX OF CLAIMS

Claim Final	Claim Original	Date 3-9-95	9-29-95	4-1-96	6-10-96
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SYMBOLS

- ✓ ..... Rejected
- = ... Allowed
- - (Through numberal) Canceled
- + ... Restricted
- N ..... Non-elected
- I ..... Interference
- A ..... Appeal
- O ..... Objected

Claim Final	Claim Original	Date 3-9-95	9-29-95	4-1-96	6-10-96	10-22-96
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US005607454A

United States Patent [19]

Cameron et al.

[11] Patent Number: 5,607,454

[45] Date of Patent: Mar. 4, 1997

[54] **ELECTROTHERAPY METHOD AND APPARATUS**

[75] Inventors: **David Cameron**, Seattle; **Thomas D. Lyster**, Bothell; **Daniel J. Powers**, Bainbridge Island; **Bradford E. Gliner**, Bellevue; **Clinton S. Cole**, Seattle; **Carlton B. Morgan**, Bainbridge Island, all of Wash.

[73] Assignee: **Heartstream, Inc.**, Seattle, Wash.

[21] Appl. No.: **227,553**

[22] Filed: **Apr. 14, 1994**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 103,837, Aug. 6, 1993.

[51] **Int. Cl.**[6] **A61N 1/39**

[52] **U.S. Cl.** **607/5**; 607/7; 607/6; 607/74; 607/62

[58] **Field of Search** 607/2, 4, 5–7, 607/62, 74

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Primary Examiner—Marvin M. Lateef
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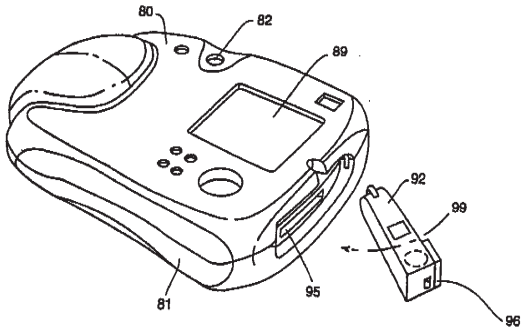
Attorney, Agent, or Firm—Morrison & Foerster

[57] **ABSTRACT**

An electrotherapy method and apparatus for delivering a multiphasic waveform from an energy source to a patient. The preferred embodiment of the method comprises the steps of charging the energy source to an initial level; discharging the energy source across the electrodes to deliver electrical energy to the patient in a multiphasic waveform; monitoring a patient-depehdent electrical parameter during the discharging step; shaping the waveform of the delivered electrical energy based on a value of the monitored electrical parameter, wherein the relative duration of the phases of the multiphasic waveform is dependent on the value of the monitored electrical parameter. The preferred apparatus comprises an energy source; two electrodes adapted to make electrical contact with a patient; a connecting mechanism forming an electrical circuit with the energy source and the electrodes when the electrodes are attached to a patient; and a controller operating the connecting mechanism to deliver electrical energy from the energy source to the electrodes in a multiphasic waveform the relative phase durations of which are based on an electrical parameter monitored during delivery of the electrical energy. The preferred defibrillator apparatus weighs less than 4 pounds and has a volume less than 150 cubic inches, and most preferably, weighs approximately three pounds or less and has a volume of approximately 141 cu. in.

59 Claims, 4 Drawing Sheets



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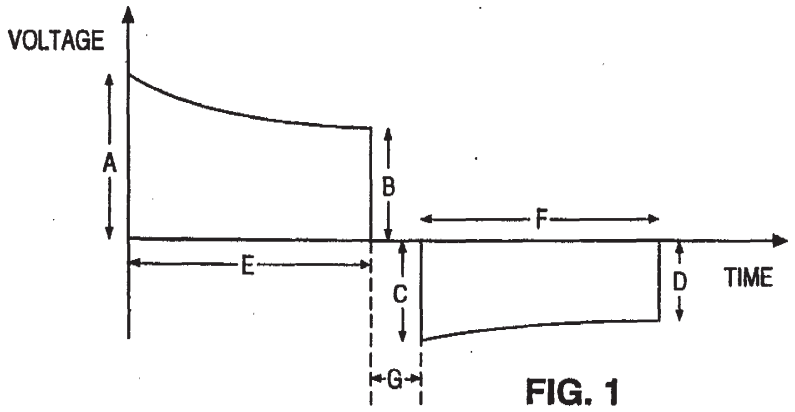

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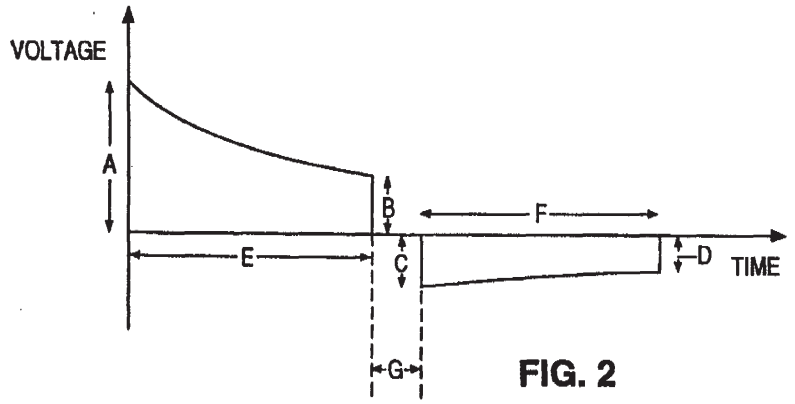

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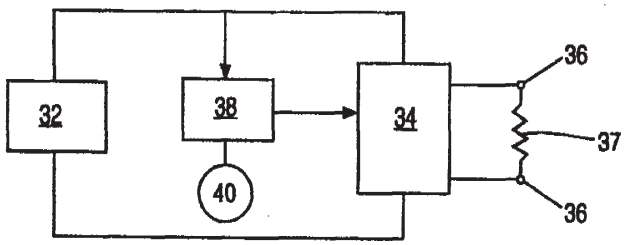

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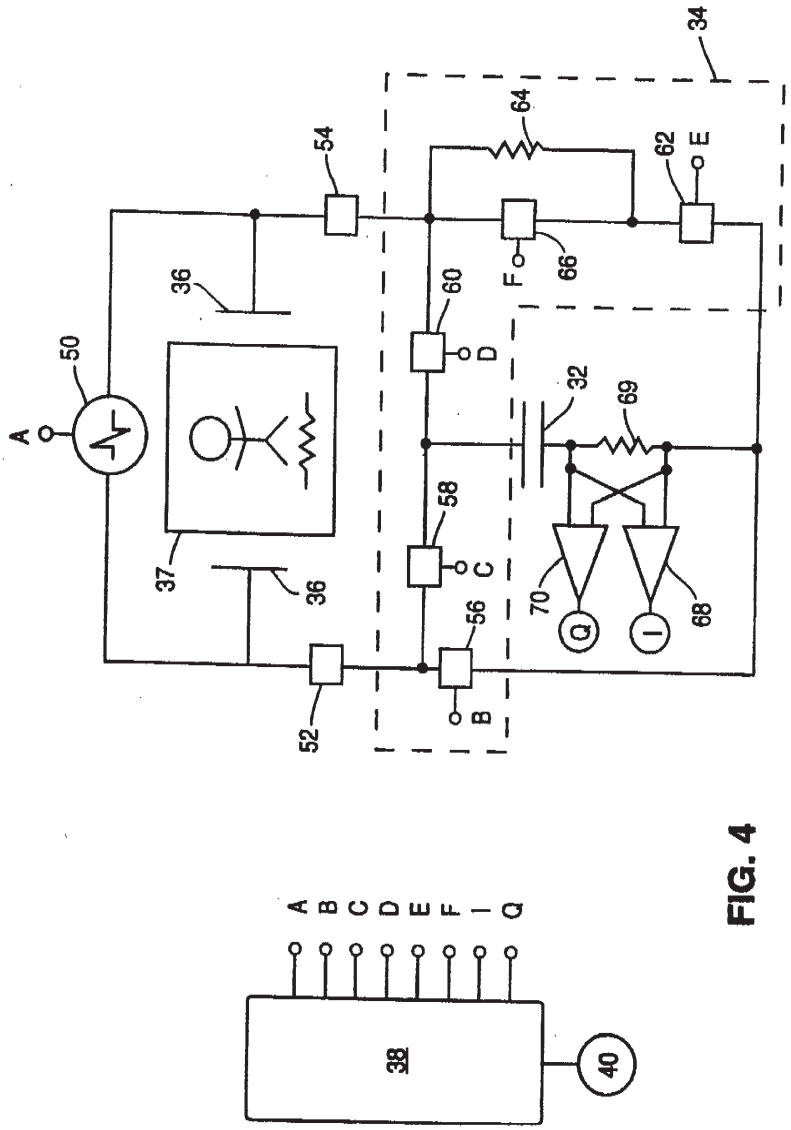
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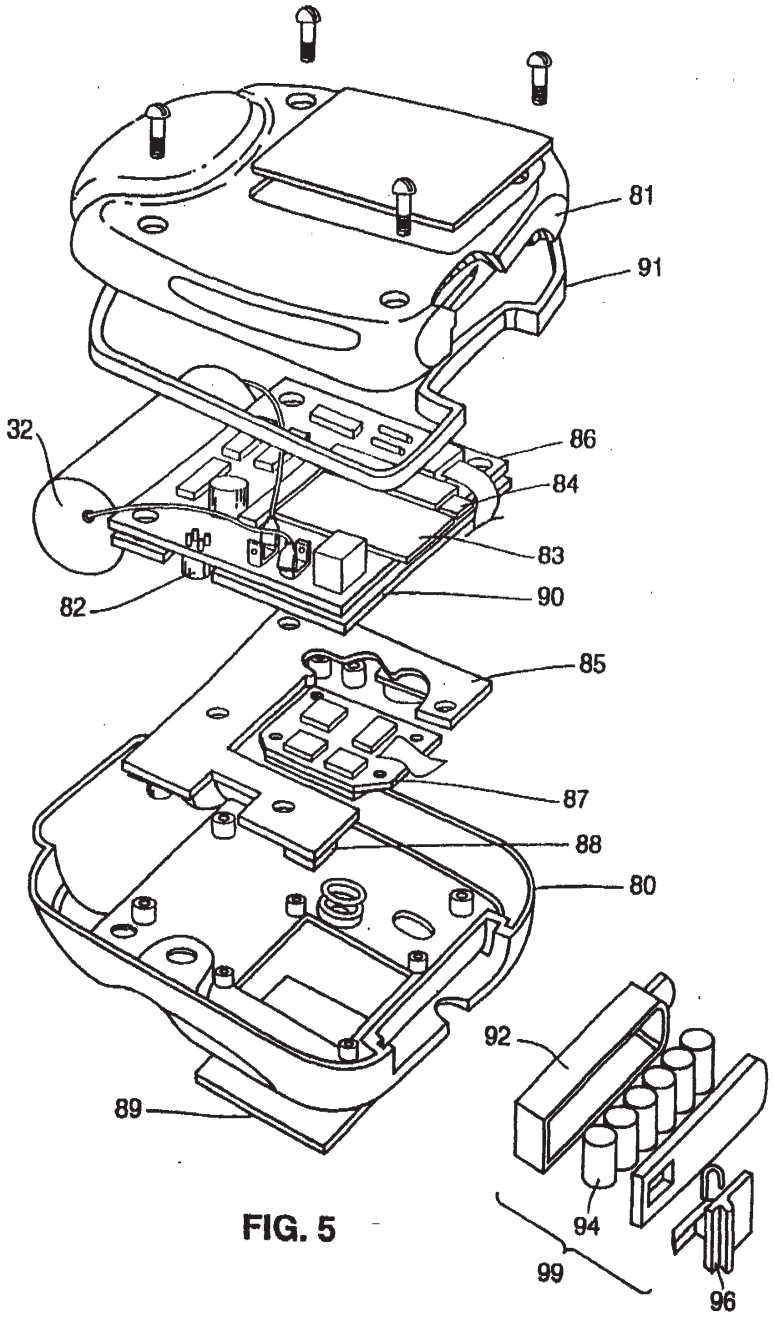

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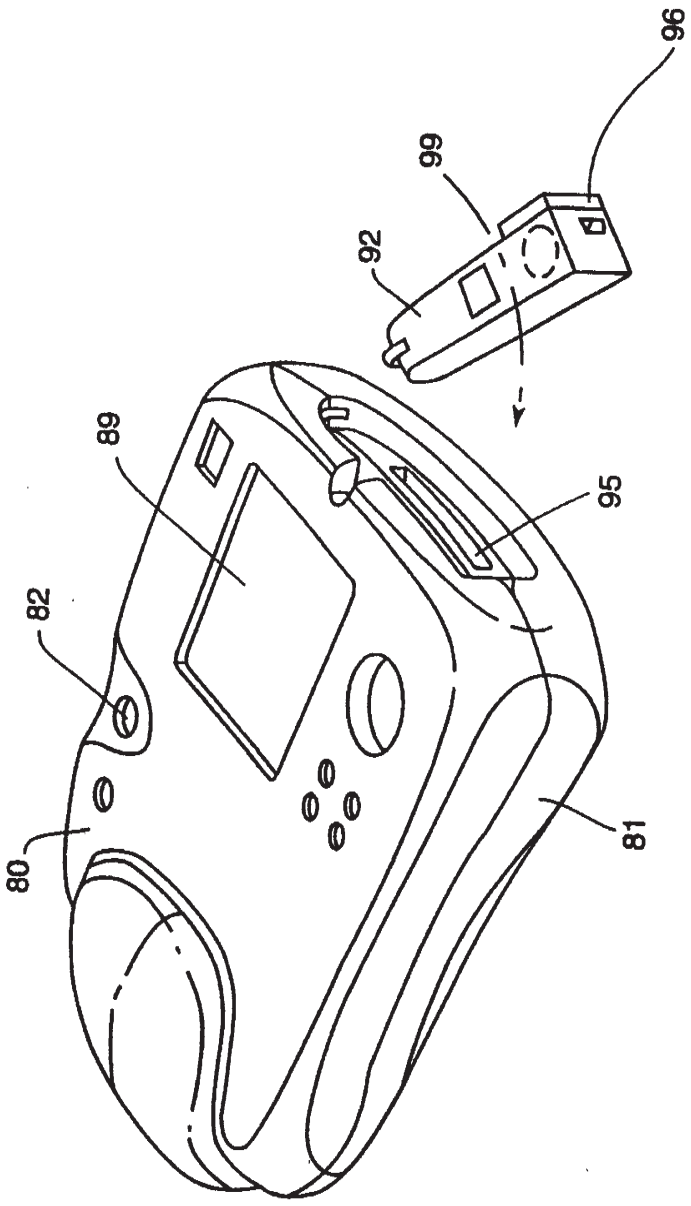

FIG. 6

ELECTROTHERAPY METHOD AND APPARATUS

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of U.S. patent application Ser. No. 08/103,837 filed Aug. 6, 1993, the disclosure of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

This invention relates generally to an electrotherapy method and apparatus for delivering an electrical pulse to a patient's heart. In particular, this invention relates to a method and apparatus for shaping the electrical waveform delivered by the defibrillator based on an electrical parameter measured during delivery of the waveform. The invention also relates to a defibrillator design meeting certain threshold size and weight requirements.

Sudden cardiac death is the leading cause of death in the United States. Most sudden cardiac death is caused by ventricular fibrillation, in which the heart's muscle fibers contract without coordination, thereby interrupting normal blood flow to the body. The only effective treatment for ventricular fibrillation is electrical defibrillation, which applies an electrical shock to the patient's heart.

To be effective, the defibrillation shock must be delivered to the patient within minutes of the onset of ventricular fibrillation. Studies have shown that defibrillation shocks delivered within one minute after ventricular fibrillation begins achieve up to 100% survival rate. The survival rate falls to approximately 30% if 6 minutes elapse before the shock is administered. Beyond 12 minutes, the survival rate approaches zero.

One way of delivering rapid defibrillation shocks is through the use of implantable defibrillators. 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. Implantable defibrillators are expensive, however, and are used on only a small fraction of the total population at risk for sudden cardiac death.

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. These high energy, voltage and current requirements have made existing 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 size and weight of prior art external defibrillators have limited their utility for rapid response by emergency medical response teams.

Defibrillator waveforms, i.e., time plots of the delivered current or voltage pulses, 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.; U.S. Pat. No. 4,953,551 to Mehra et al.; and U.S. Pat. No. 5,230,336 to Fain 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 a desired start and end voltage differential (i.e., a constant tilt). Even when an implanted defibrillator has the ability to change its operating parameters to compensate for changes in the impedance of the defibrillators leads and/or the patient's heart (as discussed in the Fain patent), the range of potential impedance changes for a single implantation in a single patient is relatively small.

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.

External defibrillators may be subjected to extreme load conditions which could potentially damage the waveform generator circuits. For example, improperly applied defibrillator electrodes may create a very low impedance current path during the shock delivery, which could result in excessively high current within the waveform circuit. Thus, an external defibrillator has an additional design requirement to limit the peak current to safe levels in the waveform circuit, which is not normally a concern for implanted defibrillators.

Prior art defibrillators have not fully addressed the patient variability problem. One prior art approach to this problem was to provide an 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.

Some prior art defibrillators measure the patient impedance, or a parameter related to patient impedance, and alter

the shape of a subsequent defibrillation shock based on the earlier measurement. For example, the implanted defibrillator described in the Fain patent delivers a defibrillation shock of predetermined shape to the patient's heart in response to a detected arrhythmia. The Fain device measures the system impedance during delivery of that shock and uses the measured impedance to alter the shape of a subsequently delivered shock.

Another example of the measurement and use of patient impedance information in prior art defibrillators is described in an article written by R. E. Kerber, et al., "Energy, current, and success in defibrillation and cardioversion," *Circulation* (May 1988). The authors describe an external defibrillator that administers a test pulse to the patient prior to administering the defibrillation shock. The test pulse is used to measure patient impedance; the defibrillator adjusts the amount of energy delivered by the shock in response to the measured patient impedance. The shape of the delivered waveform is a damped sinusoid.

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 the choice of switch and capacitor technologies. Total energy delivery requirements affect defibrillator battery and capacitor choices. Thus, even if an implantable defibrillator and an external defibrillator both deliver waveforms of similar shape, albeit with different waveform amplitudes, the actual designs of the two defibrillators would be radically different.

SUMMARY OF THE INVENTION

This invention provides a defibrillator and defibrillation method that automatically compensates for patient-to-patient differences in the delivery of electrotherapeutic pulses for defibrillation and cardioversion. The defibrillator has an energy source that may be discharged through electrodes to administer a truncated exponential biphasic voltage or current pulse to a patient.

The preferred embodiment of the method comprises the steps of charging the energy source to an initial level; 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; shaping the waveform of the delivered electrical energy based on a value of the monitored electrical parameter, wherein the relative duration of the phases of the multiphasic waveform is dependent on the value of the monitored electrical parameter.

The preferred apparatus comprises an energy source; two electrodes adapted to make electrical contact with a patient; a connecting mechanism forming an electrical circuit with the energy source and the electrodes when the electrodes are attached to a patient; and a controller operating the connecting mechanism to deliver electrical energy from the energy source to the electrodes in a multiphasic waveform the relative phase durations of which are based on an electrical parameter monitored during delivery of the electrical energy. The preferred defibrillator apparatus weighs less than 4 pounds and has a volume less than 150 cubic inches, and most preferably, weighs approximately three pounds or less and has a volume of approximately 141 cu. in.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic representation of a low-tilt biphasic electrotherapeutic waveform.

FIG. **2** is a schematic representation of a high-tilt biphasic electrotherapeutic waveform.

FIG. **3** is a block diagram of a defibrillator system according to a preferred embodiment of the invention.

FIG. **4** is a schematic circuit diagram of a defibrillator system according to a preferred embodiment of this invention.

FIG. **5** is an external view of a defibrillator according to a preferred embodiment of this invention.

FIG. **6** is a partial cutaway view of a defibrillator according to a preferred embodiment of this invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

For any given patient and for any given defibrillator system design, whether implantable or external, there is an optimal biphasic waveform for treating a particular kind of arrhythmia. This principle is used when implanting defibrillators; as noted above, implanted defibrillators are titrated to the patient at the time of implant. External defibrillators, on the other hand, must be designed to be effective in a wide population of patients.

For example, 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.

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 patient differences.

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 in the delivery of an effective cardioversion waveform. Thus, it is possible to design a defibrillator and defibrillation method that is effective not only for a single patient (as in most prior art implantable defibrillators) but is also effective for a broad

population of patients. In addition, it is also possible to meet external defibrillator design requirements regarding the size, weight and capacity of the defibrillator energy source while still meeting the needs of a wide patient population.

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 from an external defibrillator. 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. For example, the defibrillator may operate in an open loop, i.e., without any feedback regarding patient parameters and with preset pulse phase durations which will be effective for a certain range of patients. 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.

In order to ensure that the delivered shock will be within the optimum tilt range for an extended range of patients, this invention provides a defibrillator method and apparatus for adjusting the characteristics of the defibrillator waveform in response to a real-time measurement of a patient-dependent electrical parameter. FIG. **3** is a block diagram showing a preferred embodiment of the defibrillator system.

The defibrillator system **30** comprises an energy source **32** to provide a voltage or current pulse. 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 a pair of electrodes **36** electrically attached to a patient (represented here as a resistive load **37**) to and from the energy source. 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 discharge information (such as current, charge and/or voltage) from the discharge circuit. Controller **38** may also receive timing information from a timer **40**.

Controller **38** uses information from the discharge circuit and/or the timer to control the shape of the waveform delivered to the patient in real time (i.e., during delivery of the waveform), such as by selecting appropriate waveform parameters from a memory location associated with the controller or by otherwise adjusting the duration of the phases of the biphasic waveform. By controlling the waveform shape, the system controls the duration, tilt and total delivered energy of the waveform. For example, biphasic 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 increase the duration of the first phase of the biphasic waveform relative to the duration of the second phase to increase the overall efficacy of the electrotherapy by delivering a more efficacious waveform and to increase the total amount of energy delivered.

A preferred embodiment of a defibrillator system according to the invention is shown schematically in FIG. **4**. In this diagram, the energy source is a capacitor **32** preferably having a size between 60 and 150 microfarads, most preferably 100 microfarads. The system also includes a charging mechanism (not shown) for charging the capacitor to an initial voltage.

A controller **38** controls the operation of the defibrillator to deliver a shock to the patient **37** through electrodes **36** automatically in response to a detected arrhythmia or manually in response to a human operator. FIG. **4** shows an ECG system **50** attached to the electrodes to provide ECG monitoring and/or arrhythmia detection. FIG. **4** also shows a pair of switches **52** and **54** isolating the patient and the ECG system from the defibrillation circuitry. Switches **52** and **54** may be any suitable kind of isolators, such as mechanical relays, solid state devices, spark gaps, or other gas discharge devices. The ECG system and the isolation switches are not essential parts of this invention.

In this embodiment, the connecting mechanism **34** includes four switches **56**, **58**, **60** and **62** operated by the controller **38** to deliver a shock from the energy source **32** to the patient. The preferred embodiment also may include an optional current limiting circuit comprising a resistor **64** and switch **66** to provide additional protection to the defibrillator circuit components and to the defibrillator operator. The operation of the isolation switches and the connecting mechanism to deliver a waveform to the patient is described below.

For purposes of this description, it is assumed that all switches are open prior to discharge. It should be understood that this need not be the case. For example, switches **56**, **62** and **66** could start out in the closed position, with the operating sequence of the switches modified accordingly.

In response to a request for a shock, the controller first closes switches **52** and **54**, then switch **62**, then switch **58** to initiate delivery of a limited shock to the patient. A current sensor **68** monitors the current delivered by the capacitor. If

the peak current is below a circuit safety threshold, then switch **66** is closed to take safety resistor **64** out of the circuit. Peak current values above the threshold could indicate a short circuit condition.

In the preferred embodiment, the duration of the first and second phases of the biphasic waveform are determined by measuring a patient-dependent electrical parameter. As described in more detail below, the measured parameter in the preferred embodiment is the time it takes for a predetermined amount of charge to be delivered by the energy source to the patient. Charge control can provide better noise immunity than other waveform monitoring methods, such as voltage or current monitoring.

The system shown in FIG. **4** uses a current integrator **70** to provide charge information to the controller. The controller sets the duration of the first and second waveform phases (thereby controlling the waveform shape) based on charge information from current integrator **70**. Other means of determining phase durations may be used, of course, without departing from the scope of the invention.

At the end of the first phase of the waveform, the controller opens switch **62** to terminate delivery of the shock. Switch **66** may also be opened at any time from this point on. The controller opens switch **58** as well.

After the lapse of a brief interphase period, the controller closes switches **56** and **60** to initiate delivery of the second phase of the waveform. In the preferred embodiment the second phase duration is determined by the first phase duration. Other means of determining second phase duration are within the scope of the invention, however. At the end of the second phase, the controller opens switch **56** to terminate delivery of the shock. Switches **60**, **52** and **54** are opened thereafter.

The following example illustrates a specific implementation of the method and apparatus of this invention. The invention is not limited to the values and circuit elements discussed in this example.

In this example, switches **52** and **54** are implemented as a double pole, double throw mechanical relay. Switches **58** and **60** are each implemented as a pair of SCR's in series in order to meet required standoff voltages with currently available components. Switch **56** is implemented as two insulated gate bipolar transistors ("IGBT's") in series, again due to high voltage requirements.

The functions of switches **66** and **62** are shared among three IGBT's to meet voltage standoff requirements, with one IGBT being on at the same time as switch **66** and off at the same time as switch **62**. In this implementation resistor **64** is split into two resistors to equally divide the voltage across the IGBT's.

The current sensor **68** may be used to send current information to the controller for purposes of, e.g., short circuit protection, leads off detection, etc. The manner in which the short circuit or leads off conditions are detected are beyond the scope of this invention. The integrator **70** and current sensor **68** may each be an op-amp feeding a threshold comparator for detecting charge and Current limits, respectively. The integrator could be provided with a switch for resetting to initial conditions prior to a waveform delivery.

A comparator associated with the current integrator monitors the charge delivered to the patient and sends a signal to the waveform controller when the charge reaches 0.06182 Coulombs (referred to as "Qt"). The time required to reach that charge ("t(Qt)") is monitored by the controller using an up/down counter which counts a scaled down reference frequency. One element of the frequency scaler is a selectable 2:3 prescaler. The pre-scaler is set to 3 during the first phase. In this example, eleven time thresholds are stored in the controller, which determines the first phase duration ("t(Φ1)") based on the time required to reach Qt. At each time threshold, a new value of t(Φ1) is loaded until Qt is reached. If Qt is not reached within 6.35 mS, then t(Φ1) is set to 12 mS. The counter runs at the scaled down frequency during delivery of the entire first phase.

Some exemplary values for Qt thresholds and t(Φ1) are shown in Table I.

TABLE I

If t (Qt) < (mS)	Then t (ϕ1) is (mS)
1.13	2.3
1.60	2.85
2.07	3.79
2.56	4.02
3.07	4.83
3.58	6.76
4.10	7.73
4.64	8.69
5.20	9.66
5.77	10.62
6.35	11.59

In this example, the interphase delay is set at 300 μS. At 0 μS the first phase IGBT's are opened, terminating the first phase. At 250 μS, the second phase IGBT's are closed. At 300 μS the second phase SCR's are closed, initiating the second phase.

In this example, second phase timing is determined by first phase timing. Specifically, the count value accumulated during phase one (2.3 mS to 12 mS) is used to control the duration of the second phase. During the second phase, the counter that had been counted up during the first phase is counted down to 0, at which time the second phase is terminated. The actual duration of the second phase depends on the scaled down frequency used to run down the counter. If the first phase t(Qt) was less than 3.07 mS, then the reference clock prescaler is set to 3 to a give second phase duration equal to the first phase duration. If t(Qt) is greater than or equal to 3.07 mS, then the pre-scaler is set to 2, giving a second phase duration which is ⅔ of the first phase duration.

In an alternative embodiment, the measured patient-dependent electrical parameter is capacitor voltage. A comparator monitors the capacitor voltage and sends a signal to the waveform controller when the voltage decays to 1000 volts (Vt). As in the charge control embodiment, the time required to reach that voltage is monitored by the controller using an up/down counter which counts a scaled down reference frequency. The first phase duration (t(Φ1)) is based on the time required to reach Vt. The method of selecting the appropriate t(Φ1) is identical to the charge control embodiment. If Vt is not reached within 6.18 mS, then t(Φ1) is set to 12 mS. Table II shows the t(Vt) thresholds and their associated t(Φ1).

TABLE II

If t (Vt) < (mS)	Then t (ϕ1) is (mS)
1.24	2.3
1.73	2.85
2.23	3.79
2.72	4.02
3.22	4.83
3.71	6.76
4.20	7.73

TABLE II-continued

If t (Vt) < (mS)	Then t (ϕ1) is (mS)
4.70	8.69
5.19	9.66
5.69	10.62
6.18	11.59

Interphase delay and second phase timing is identical to the charge control method.

We have designed a new defibrillator meeting certain size, weight, efficacy and safety design goals. The size and weight are below the design thresholds of 150 cu. in. and four lbs. This new portable defibrillator may therefore be carried and stored in places such as drug kit boxes carried by early medical responders and in the glove boxes of cars.

The circuit design of the new defibrillator permits the use of a biphasic truncated exponential waveform, such as one of the waveforms described above. Use of the biphasic waveform permits the defibrillator to be operated with the same efficacy as prior art external defibrillators but with the storage and delivery of far less energy at lower voltages. For example, the new defibrillator effectively cardioverts patients by delivering shocks below 155 Joules of energy (167 Joules of energy stored), and most preferably on the order of 130 Joules of energy (**140** Joules stored), compared with the delivery of 200–360 Joules (240–439 Joules stored) by prior art external defibrillators.

A preferred embodiment of the new external defibrillator is shown in FIGS. **5** and **6**. This defibrillator is much smaller and lighter than prior art external defibrillators. The size of the preferred defibrillator (approx. 2.2 in. ×8 in. ×8 in., for a total volume of approx. 141 cu. in.) permits it to be carried and/or stored in places in which prior art external defibrillators could not fit. In addition, its lighter weight (approx. three pounds) enables the defibrillator to be moved more easily by the operator in an emergency.

As shown in FIGS. **5** and **6**, the preferred external defibrillator includes a molded two-part plastic housing with an upper case **80** and a lower case **81**. A main printed circuit board ("PCB") **86** supports the capacitor **32**, an electrode connector **82**, a PCMCIA memory card **83** and a PCMCIA memory card ejector mechanism **84**. The PCMCIA memory card **83** lies within a PCMCIA memory card slot **95** on PCB **86**.

A keyboard PCB **85** and a display PCB **87** is disposed between the main PCB **86** and the upper case **80**. Keyboard PCB **85** interfaces with the defibrillator's operator buttons, and display PCB **87** operates the defibrillator's LCD display **88**. A display window **89** in the upper case permits display **88** to be seen by an operator.

An insulator **90** is disposed between main PCB **86** and display PCB **87**. A sealing gasket **91** lines the edges between upper case **80** and lower case **81** when the housing is assembled.

A battery assembly **99** consisting of a battery housing **92** and six lithium-manganese dioxide primary cells **94** is disposed in upper case **80** so that the batteries are in electrical contact with the capacitor charge circuits and other circuits of main PCB **86**. The battery assembly has a latching mechanism **96** for attaching and detaching the battery assembly to and from the defibrillator.

The location of the battery assembly in front of the PCMCIA memory card slot prevents the defibrillator operator or others from accessing the PCMCIA card while the defibrillator is powered up and operating. This arrangement protects the operator and patient from accidental shocks and protects the defibrillator itself from damage caused by inadvertant removal of the PCMCIA card during operation.

The small size and light weight of our defibrillator is due to a combination of a variety of design features. Use of a truncated exponential biphasic waveform instead of the prior art damped sinusoid waveform permits operation without an inductor in the waveform circuit. In addition, the lower energy requirements permit the use of a smaller capacitor and smaller batteries than those used in prior art external defibrillators.

In an effort to reduce the battery size even further, the preferred embodiment is provided with a capacitor precharge circuit and controller that begins charging the capacitor soon after the defibrillator is activated, even before ventricular fibrillation (and therefore the need for defibrillation) has been detected. The precharge voltage level is kept below the level where damage to the defibrillator circuit, the patient or the operator could occur in the event of a single fault. Thus, for example, whereas in the preferred embodiment the full preshock capacitor voltage is 1650 V, the precharge level is 1100 V. This precharge procedure minimizes the amount of energy that needs to be transferred from the battery to the capacitor when a therapeutic shock is indicated, thereby reducing the required size of the battery and the defibrillator's transformer.

The preferred embodiment uses **6** lithium-manganese dioxide primary cells instead of rechargeable batteries. Primary cells have greater energy density than rechargeable batteries and are cheaper, lighter and, since they are disposable, they are easier to maintain. While primary cells also have lower power and energy characteristics, use of a truncated exponential biphasic waveform and a capacitor precharge circuit permits operation at lower power levels.

The preferred defibrillator shown in FIGS. **5** and **6** incorporates the solid state defibrillator circuit described above with reference to FIG. **4**. Use of this circuit along with the short-circuit protection feature described above also reduces the size and weight of the defibrillator by avoiding the use of the mechanical switches required by higher voltage devices.

Other smaller and lighter-weight features of the defibrillator shown in FIGS. **5** and **6** are the use of a flat panel LCD in place of the more conventional CRT display and the use of a PCMCIA memory card to record voice and instrument information instead of a magnetic tape recorder or a paper strip chart recorder. In addition, the preferred defibrillator includes a feature whereby part of the patient ECG information stored within the PCMCIA card can be displayed on the LCD for use by a medical professional. This feature takes the place of the strip chart recorders in prior art external defibrillators.

Lightweight defibrillator electrode designs may be used to reduce the weight of the overall device even further. For example, flexible patch electrodes may be used in place of the conventional paddle electrodes. In addition, because of the lower energy and voltage features of the defibrillator, relatively thin wires may be used to attach the electrodes to the defibrillator instead of thick cables.

Other component choices and other configurations of components are within the scope of this invention as long as the threshold size and weight requirements of 150 cu. in. and four pounds are met.

Any embodiment of this invention 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 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.

In addition, while the preferred embodiment of the invention has been discussed in the context of biphasic waveforms, monophasic, triphasic or other multiphasic waveforms may be used as well. Also, patient-dependent electrical parameters other than charge delivered may be monitored and used to shape the waveform during discharge.

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.

We claim:

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

charging the energy source to an initial level;

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;

shaping the waveform of the delivered electrical energy based on a value of the monitored electrical parameter, wherein the relative duration of the phases of the multiphasic waveform is dependent on the value of the monitored electrical parameter.

2. The method of claim **1** wherein the energy source is external to the patient.

3. The method of claim **1** wherein the shaping step further comprises controlling the duration of a waveform phase based on a value of the electrical parameter.

4. The method of claim **3** wherein the shaping step further comprises controlling the duration of another phase of the waveform based on the value.

5. The method of claim **4** further comprising the step of providing a plurality of phase duration values, the shaping step comprising the step of selecting phase duration values for each phase of the multiphasic waveform from the plurality of phase duration values.

6. The method of claim **3** wherein the electrical parameter is charge delivered by the energy source to one of the electrodes.

7. The method of claim **6** wherein the discharging step begins at a discharge start time, the method further comprising the step of monitoring elapsed time from the discharge start time, the shaping step further comprising the step of determining an elapsed time value at which the charge delivered has reached a predetermined threshold.

8. The method of claim **7** wherein the shaping step further comprises selecting a first phase duration based on the elapsed time value.

9. The method of claim **8** wherein the shaping step further comprises selecting a second phase duration based on the elapsed time value.

10. The method of claim **9** wherein the second phase duration is equal to the first phase duration for at least one possible elapsed time value.

11. The method of claim **9** wherein the second phase duration is less than the first phase duration for at least one possible elapsed time value.

12. The method of claim **1** wherein the duration of the monitoring step is shorter than the duration of the discharging step.

13. The method of claim **1** wherein the shaping step is performed without the use of an inductor.

14. The method of claim **1** wherein the initial level is an initial discharge level, the method further comprising the step of precharging the energy source to a level less than the initial discharge level prior to the step of charging the energy source to the initial discharge level.

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

charging the energy source to an initial level;

discharging the energy source across the electrodes to deliver electrical energy to the patient in a truncated exponential biphasic waveform;

monitoring an electrical parameter during the discharging step;

adjusting the tilt of the waveform based on the value of the monitored electrical parameter, the adjusting step comprising controlling the duration of a waveform phase based on a value of the electrical parameter wherein the relative duration of the phases of the waveform is dependent on the value of the monitored electrical parameter.

16. An apparatus for administering electrotherapy to a patient's heart through electrodes external to the patient comprising:

an energy source;

two electrodes adapted to make electrical contact with a patient;

a connecting mechanism forming an electrical circuit with the energy source and the electrodes when the electrodes are attached to a patient; an electrical parameter monitor; and

a controller operating the connecting mechanism to deliver electrical energy from the energy source to the electrodes in a truncated exponential multiphasic waveform the relative phase durations of which are based on an electrical parameter monitored during delivery of the electrical energy.

17. The apparatus of claim **16** wherein the connecting mechanism comprises a plurality of switches for selectively directing electrical energy from the energy source to the patient in one of two polarities.

18. The apparatus of claim **17** wherein the electrical parameter monitor comprises a charge sensor providing information to the controller related to charge delivered by the energy source to the electrodes.

19. The apparatus of claim **18** further comprising a timer associated with the charge sensor and the controller.

20. The apparatus of claim **19** wherein the controller comprises a counter with a controllable counting rate, the counter being adapted to count in one direction during delivery of a first phase of the multiphasic waveform and in another direction during delivery of a second phase of the multiphasic waveform.

21. The apparatus of claim **16** further comprising means for selectively limiting current flow through the electrodes and means for determining whether current flowing to the electrodes is below a predetermined threshold.

22. The apparatus of claim **21** wherein the means for selectively limiting current flow comprises an impedance

and a shunting switch in the circuit with the electrodes and the energy source.

23. The apparatus of claim 16 wherein the energy source comprises a battery disposed in a battery holder, the apparatus further comprising a solid state memory device disposed in a memory device holder, the battery blocking external access to the memory device when the battery is disposed in the battery holder.

24. An external defibrillator comprising:

an energy source;

two electrodes adapted to make electrical contact with the exterior of a patient;

a connecting mechanism forming an electrical circuit with the energy source and the electrodes when the electrodes are attached to a patient;

a controller operating the connecting mechanism to deliver electrical energy from the energy source to the electrodes; and

a housing containing at least the energy source, the connecting mechanism and the controller, the housing having a volume less than 150 cubic inches.

25. The defibrillator of claim 24 in which the housing has a first dimension not greater than 2.2 inches.

26. The defibrillator of claim 25 in which the housing has second and third dimensions not greater than 8 inches.

27. The defibrillator of claim 24 wherein the energy source comprises primary cell batteries.

28. The defibrillator of claim 27 wherein the primary cell batteries comprise lithium-manganese dioxide primary batteries.

29. The defibrillator of claim 24 wherein the connecting mechanism and the controller comprise means for delivering a multiphasic waveform without the use of an inductor.

30. The defibrillator of claim 24 wherein the energy source comprises a capacitor, the defibrillator further comprising a capacitor precharge circuit.

31. The defibrillator of claim 24 further comprising an ECG system.

32. The defibrillator of claim 31 further comprising an LCD display.

33. The defibrillator of claim 32 further comprising a PCMCIA memory card.

34. The defibrillator of claim 33 further comprising means for displaying ECG information stored in the PCMCIA card on the LCD display.

35. The defibrillator of claim 24 wherein the energy source comprises a capacitive energy source sized between 60 and 150 microfarads.

36. An external defibrillator comprising:

an energy source;

two electrodes adapted to make electrical contact with the exterior of a patient;

a connecting mechanism forming an electrical circuit with the energy source and the electrodes when the electrodes are attached to a patient;

a controller operating the connecting mechanism to deliver electrical energy from the energy source to the electrodes;

the defibrillator having a weight less than four pounds.

37. The defibrillator of claim 36 wherein the energy source comprises primary cell batteries.

38. The defibrillator of claim 37 wherein the primary cell batteries comprise lithium-manganese dioxide primary batteries.

39. The defibrillator of claim 36 wherein the connecting mechanism and the controller comprise means for delivering a multiphasic waveform without the use of an inductor.

40. The defibrillator of claim 36 wherein the energy source comprises a capacitor, the defibrillator further comprising a capacitor precharge circuit.

41. The defibrillator of claim 36 further comprising an ECG system.

42. The defibrillator of claim 41 further comprising an LCD display.

43. The defibrillator of claim 42 further comprising a PCMCIA memory card.

44. The defibrillator of claim 43 further comprising means for displaying ECG information stored in the PCMCIA card on the LCD display.

45. The defibrillator of claim 36 wherein the energy source comprises a capacitive energy source sized between 60 and 150 microfarads.

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

charging the energy source to an initial level;

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

determining the time during which a predetermined amount of charge is delivered to the patient;

shaping the waveform of the delivered electrical energy based on the value of the determined time, wherein the relative duration of the phases of the multiphasic waveform is dependent on the value of the determined time.

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

charging the energy source to an initial level;

maintaining the charge of the energy source at the initial level;

determining the need to apply a shock to a patient;

charging the energy source to a second level greater than the initial level;

discharging the energy source across the electrodes to deliver electrical energy to the patient.

48. The method of claim 47 wherein the initial level is below a charge level that could harm a patient.

49. The method of claim 47 wherein the first charging step is performed in response to activation of a defibrillator.

50. The method of claim 47 wherein the discharging step comprises the step of discharging the energy source across the electrodes to deliver electrical energy to the patient in a truncated exponential biphasic waveform.

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

charging the energy source to an initial level;

discharging the energy source across the electrodes to deliver electrical energy to the patient in a waveform, the patient and an additional impedance forming an electrical circuit with the energy source;

monitoring an electrical parameter during the discharging step;

removing the additional impedance from the electrical circuit if the electrical parameter is within a defined range prior to the end of the discharging step.

52. The method of claim 51 wherein the removing step comprises operating a switch associated with the additional impedance.

53. A method for applying electrotherapy to a patient comprising the following steps:

discharging an energy source across electrodes to deliver a waveform of electrical energy to the patient;

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

ceasing the monitoring step prior to the end of the discharge step;

adjusting a waveform discharge parameter based on a value of the monitored parameter.

54. The method of claim **53** wherein discharging step and the monitoring step begin substantially simultaneously.

55. The method of claim **53** wherein the monitored parameter is time for delivering a predetermined quantity of charge to the patient.

56. The method of claim **55** wherein the discharge parameter is waveform duration.

57. The method of claim **55** wherein the waveform is a biphasic waveform and the discharge parameter is duration of a waveform phase.

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

charging the energy source to an initial level prior to detecting a need to apply a shock to a patient;

determining the need to apply a shock to a patient;

charging the energy source to a second level greater than the initial level;

discharging the energy source across the electrodes to deliver electrical energy to the patient in a truncated exponential biphasic waveform.

59. The method of claim **58** wherein the first charging step is performed in response to activation of a defibrillator.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,607,454
DATED : March 4, 1997
INVENTOR(S) : David Cameron, Thomas D. Lyster, Daniel J. Powers, Bradford E. Gliner, Clinton S. Cole, Carlton B. Morgan

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

On the title page: Item [56]

add to U.S. documents the following:

—5,411,526	5/1995	Kroll et al.	607/5
5,334,430	9/1994	Berg et al.	607/7
5,097,833	3/1992	Campos	607/46 —

Signed and Sealed this

Eleventh Day of November, 1997

Attest:

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks

08/227553
Attorney Docket 241082000620
PATENT

APR 14 1994 PAT. & TRADEMARK OFF.

ABSTRACT

ELECTROTHERAPY METHOD AND APPARATUS

An electrotherapy method and apparatus for delivering a multiphasic waveform from an energy source to a patient. The preferred embodiment of the method comprises the steps of charging the energy source to an initial level; 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; shaping the waveform of the delivered electrical energy based on a value of the monitored electrical parameter, wherein the relative duration of the phases of the multiphasic waveform is dependent on the value of the monitored electrical parameter. The preferred apparatus comprises an energy source; two electrodes adapted to make electrical contact with a patient; a connecting mechanism forming an electrical circuit with the energy source and the electrodes when the electrodes are attached to a patient; and a controller operating the connecting mechanism to deliver electrical energy from the energy source to the electrodes in a multiphasic waveform the relative phase durations of which are based on an electrical parameter monitored during delivery of the electrical energy. The preferred defibrillator apparatus weighs less than 4 pounds and has a volume less than 150 cubic inches, and most preferably, weighs approximately three pounds or less and has a volume of approximately 141 cu.in.

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ELECTROTHERAPY METHOD AND APPARATUS

Cross Reference to Related Application

This application is a continuation-in-part of U.S. Patent Application S.N. 08/103,837 filed August 6, 1993, the disclosure of which is incorporated herein by reference.

Background of the Invention

This invention relates generally to an electrotherapy method and apparatus for delivering an electrical pulse to a patient's heart. In particular, this invention relates to a method and apparatus for shaping the electrical waveform delivered by the defibrillator based on an electrical parameter measured during delivery of the waveform. The invention also relates to a defibrillator design meeting certain threshold size and weight requirements.

Sudden cardiac death is the leading cause of death in the United States. Most sudden cardiac death is caused by ventricular fibrillation, in which the heart's muscle fibers contract without coordination, thereby interrupting normal blood flow to the body. The only effective treatment for ventricular fibrillation is electrical defibrillation, which applies an electrical shock to the patient's heart.

To be effective, the defibrillation shock must be delivered to the patient within minutes of the onset of ventricular fibrillation. Studies have shown that defibrillation shocks delivered within one minute after ventricular fibrillation begins achieve up to 100%

survival rate. The survival rate falls to approximately 30% if 6 minutes elapse before the shock is administered. Beyond 12 minutes, the survival rate approaches zero.

One way of delivering rapid defibrillation shocks is through the use of implantable defibrillators. 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. Implantable defibrillators are expensive, however, and are used on only a small fraction of the total population at risk for sudden cardiac death.

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. These high energy, voltage and current requirements have made existing 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 size and weight of prior art external defibrillators have limited their utility for rapid response by emergency medical response teams.

Defibrillator waveforms, i.e., time plots of the delivered current or voltage pulses, 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. Patent No. 4,821,723 to Baker, Jr., et al.; 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.; U.S. Patent No. 4,953,551 to Mehra et al.; and U.S. Patent No. 5,230,336 to Fain 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 a desired start and end voltage differential (i.e., a constant tilt). Even when an implanted defibrillator has the ability to change its operating parameters to compensate for changes in the impedance of the defibrillators leads and/or the patient's heart (as discussed in the Fain patent), the range of potential impedance changes for a single implantation in a single patient is relatively small.

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.

External defibrillators may be subjected to extreme load conditions which could potentially damage the waveform generator circuits. For example, improperly applied defibrillator electrodes may create a very low impedance current path during the shock delivery, which could result in excessively high current within the waveform circuit. Thus, an external defibrillator has an additional design requirement to limit the peak current to safe levels in the waveform circuit, which is not normally a concern for implanted defibrillators.

Prior art defibrillators have not fully addressed the patient variability problem. One prior art approach to this problem was to provide an 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.

Some prior art defibrillators measure the patient impedance, or a parameter related to patient impedance, and alter the shape of a subsequent defibrillation shock based on the earlier measurement. For example, the implanted defibrillator described in the Fain patent delivers a defibrillation shock of predetermined shape to the patient's heart in response to a detected arrhythmia. The Fain device measures the system impedance during delivery of that shock and uses the measured impedance to alter the shape of a subsequently delivered shock.

Another example of the measurement and use of patient impedance information in prior art defibrillators is described in an article written by R.E. Kerber, et al., "Energy, current, and success in defibrillation and cardioversion," Circulation (May 1988). The authors describe an external defibrillator that administers a test pulse to the patient prior to administering the defibrillation shock. The test pulse is used to measure patient impedance; the defibrillator adjusts the amount of energy delivered by the shock in response to the measured patient impedance. The shape of the delivered waveform is a damped sinusoid.

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 the choice of switch and capacitor technologies. Total energy delivery requirements affect defibrillator battery and capacitor choices. Thus, even if an implantable defibrillator and an external defibrillator both deliver waveforms of similar shape, albeit with different waveform amplitudes, the actual designs of the two defibrillators would be radically different.

Summary of the Invention

This invention provides a defibrillator and defibrillation method that automatically compensates for patient-to-patient differences in the delivery of electrotherapeutic pulses for defibrillation and cardioversion. The defibrillator has an energy source that may be discharged through electrodes to administer a truncated exponential biphasic voltage or current pulse to a patient.

The preferred embodiment of the method comprises the steps of charging the energy source to an initial level; 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; shaping the waveform of the delivered electrical energy based on a value of the monitored electrical parameter, wherein the relative duration of the phases of the multiphasic waveform is dependent on the value of the monitored electrical parameter.

The preferred apparatus comprises an energy source; two electrodes adapted to make electrical contact with a patient; a connecting mechanism forming an electrical circuit with the energy source and the electrodes when the electrodes are attached to a patient; and a controller operating the connecting mechanism to

deliver electrical energy from the energy source to the electrodes in a multiphasic waveform the relative phase durations of which are based on an electrical parameter monitored during delivery of the electrical energy. The preferred defibrillator apparatus weighs less than 4 pounds and has a volume less than 150 cubic inches, and most preferably, weighs approximately three pounds or less and has a volume of approximately 141 cu.in.

Brief Description of the Drawings

Figure 1 is a schematic representation of a low-tilt biphasic electrotherapeutic waveform.

Figure 2 is a schematic representation of a high-tilt biphasic electrotherapeutic waveform.

Figure 3 is a block diagram of a defibrillator system according to a preferred embodiment of the invention.

Figure 4 is a schematic circuit diagram of a defibrillator system according to a preferred embodiment of this invention.

Figure 5 is an external view of a defibrillator according to a preferred embodiment of this invention.

Figure 6 is a partial cutaway view of a defibrillator according to a preferred embodiment of this invention.

Detailed Description of the Preferred Embodiment

For any given patient and for any given defibrillator system design, whether implantable or external, there is an optimal biphasic waveform for treating a particular kind of arrhythmia. This principle is used when implanting defibrillators; as noted above, implanted defibrillators are titrated to the patient at the time of implant. External defibrillators, on the

other hand, must be designed to be effective in a wide population of patients.

For example, 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 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.

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:

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

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 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 patient differences.

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 in the delivery of an effective cardioversion waveform. Thus, it is possible to design a defibrillator and defibrillation method that is effective not only for a single patient (as in most prior art implantable defibrillators) but is also effective for a broad population of patients. In addition, it is also possible to meet external defibrillator design requirements regarding the size, weight and capacity of the defibrillator energy source while still meeting the needs of a wide patient population.

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 from an external

defibrillator. 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. For example, the defibrillator may operate in an open loop, i.e., without any feedback regarding patient parameters and with preset pulse phase durations which will be effective for a certain range of patients. 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.

In order to ensure that the delivered shock will be within the optimum tilt range for an extended range of patients, this invention provides a defibrillator method and apparatus for adjusting the

characteristics of the defibrillator waveform in response to a real-time measurement of a patient-dependent electrical parameter. Figure 3 is a block diagram showing a preferred embodiment of the defibrillator system.

The defibrillator system 30 comprises an energy source 32 to provide a voltage or current pulse. 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 a pair of electrodes 36 electrically attached to a patient (represented here as a resistive load 37) to and from the energy source. 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 discharge information (such as current, charge and/or voltage) from the discharge circuit. Controller 38 may also receive timing information from a timer 40.

Controller 38 uses information from the discharge circuit and/or the timer to control the shape of the waveform delivered to the patient in real time (i.e., during delivery of the waveform), such as by selecting appropriate waveform parameters from a memory location associated with the controller or by otherwise adjusting the duration of the phases of the biphasic waveform. By controlling the waveform shape, the system controls the duration, tilt and total delivered energy of

the waveform. For example, biphasic 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 increase the duration of the first phase of the biphasic waveform relative to the duration of the second phase to increase the overall efficacy of the electrotherapy by delivering a more efficacious waveform and to increase the total amount of energy delivered.

A preferred embodiment of a defibrillator system according to the invention is shown schematically in Figure 4. In this diagram, the energy source is a capacitor 32 preferably having a size between 60 and 150 microfarads, most preferably 100 microfarads. The system also includes a charging mechanism (not shown) for charging the capacitor to an initial voltage.

A controller 38 controls the operation of the defibrillator to deliver a shock to the patient 37 through electrodes 36 automatically in response to a detected arrhythmia or manually in response to a human operator. Figure 4 shows an ECG system 50 attached to the electrodes to provide ECG monitoring and/or arrhythmia detection. Figure 4 also shows a pair of switches 52 and 54 isolating the patient and the ECG system from the defibrillation circuitry. Switches 52 and 54 may be any suitable kind of isolators, such as mechanical relays, solid state devices, spark gaps, or other gas discharge devices. The ECG system and the isolation switches are not essential parts of this invention.

In this embodiment, the connecting mechanism 34 includes four switches 56, 58, 60 and 62 operated by the controller 38 to deliver a shock from the energy source

32 to the patient. The preferred embodiment also may include an optional current limiting circuit comprising a resistor 64 and switch 66 to provide additional protection to the defibrillator circuit components and to the defibrillator operator. The operation of the isolation switches and the connecting mechanism to deliver a waveform to the patient is described below.

For purposes of this description, it is assumed that all switches are open prior to discharge. It should be understood that this need not be the case. For example, switches 56, 62 and 66 could start out in the closed position, with the operating sequence of the switches modified accordingly.

In response to a request for a shock, the controller first closes switches 52 and 54, then switch 62, then switch 58 to initiate delivery of a limited shock to the patient. A current sensor 68 monitors the current delivered by the capacitor. If the peak current is below a circuit safety threshold, then switch 66 is closed to take safety resistor 64 out of the circuit. Peak current values above the threshold could indicate a short circuit condition.

In the preferred embodiment, the duration of the first and second phases of the biphasic waveform are determined by measuring a patient-dependent electrical parameter. As described in more detail below, the measured parameter in the preferred embodiment is the time it takes for a predetermined amount of charge to be delivered by the energy source to the patient. Charge control can provide better noise immunity than other waveform monitoring methods, such as voltage or current monitoring.

The system shown in Figure 4 uses a current integrator 70 to provide charge information to the controller. The controller sets the duration of the

first and second waveform phases (thereby controlling the waveform shape) based on charge information from current integrator 70. Other means of determining phase durations may be used, of course, without departing from the scope of the invention.

At the end of the first phase of the waveform, the controller opens switch 62 to terminate delivery of the shock. Switch 66 may also be opened at any time from this point on. The controller opens switch 58 as well.

After the lapse of a brief interphase period, the controller closes switches 56 and 60 to initiate delivery of the second phase of the waveform. In the preferred embodiment the second phase duration is determined by the first phase duration. Other means of determining second phase duration are within the scope of the invention, however. At the end of the second phase, the controller opens switch 56 to terminate delivery of the shock. Switches 60, 52 and 54 are opened thereafter.

The following example illustrates a specific implementation of the method and apparatus of this invention. The invention is not limited to the values and circuit elements discussed in this example.

In this example, switches 52 and 54 are implemented as a double pole, double throw mechanical relay. Switches 58 and 60 are each implemented as a pair of SCR's in series in order to meet required standoff voltages with currently available components. Switch 56 is implemented as two insulated gate bipolar transistors ("IGBT's") in series, again due to high voltage requirements.

The functions of switches 66 and 62 are shared among three IGBT's to meet voltage standoff requirements, with one IGBT being on at the same time as switch 66 and off at the same time as switch 62. In this

implementation resistor 64 is split into two resistors to equally divide the voltage across the IGBT's.

The current sensor 68 may be used to send current information to the controller for purposes of, e.g., short circuit protection, leads off detection, etc. The manner in which the short circuit or leads off conditions are detected are beyond the scope of this invention. The integrator 70 and current sensor 68 may each be an op-amp feeding a threshold comparator for detecting charge and current limits, respectively. The integrator could be provided with a switch for resetting to initial conditions prior to a waveform delivery.

A comparator associated with the current integrator monitors the charge delivered to the patient and sends a signal to the waveform controller when the charge reaches 0.06182 Coulombs (referred to as "Qt"). The time required to reach that charge ("t(Qt)") is monitored by the controller using an up/down counter which counts a scaled down reference frequency. One element of the frequency scaler is a selectable 2:3 pre-scaler. The pre-scaler is set to 3 during the first phase. In this example, eleven time thresholds are stored in the controller, which determines the first phase duration ("t(Φ1)") based on the time required to reach Qt. At each time threshold, a new value of t(Φ1) is loaded until Qt is reached. If Qt is not reached within 6.35 mS, then t(Φ1) is set to 12 mS. The counter runs at the scaled down frequency during delivery of the entire first phase.

Some exemplary values for Qt thresholds and t(Φ1) are shown in Table I.

TABLE I

If t(Qt)<(mS)	Then t(Φ1)is(mS)
1.13	2.3
1.60	2.85
2.07	3.79
2.56	4.02
3.07	4.83
3.58	6.76
4.10	7.73
4.64	8.69
5.20	9.66
5.77	10.62
6.35	11.59

In this example, the interphase delay is set at 300 μS. At 0 μS the first phase IGBT's are opened, terminating the first phase. At 250 μS, the second phase IGBT's are closed. At 300 μS the second phase SCR's are closed, initiating the second phase.

In this example, second phase timing is determined by first phase timing. Specifically, the count value accumulated during phase one (2.3 mS to 12 mS) is used to control the duration of the second phase. During the second phase, the counter that had been counted up during the first phase is counted down to 0, at which time the second phase is terminated. The actual duration of the second phase depends on the scaled down frequency used to run down the counter. If the first phase t(Qt) was less than 3.07 mS, then the reference clock prescaler is set to 3 to a give second phase duration equal to the first phase duration. If t(Qt) is greater than or equal to 3.07 mS, then the pre-scaler is set to 2, giving a second phase duration which is 2/3 of the first phase duration.

In an alternative embodiment, the measured patient-dependent electrical parameter is capacitor voltage. A comparator monitors the capacitor voltage and sends a signal to the waveform controller when the voltage decays to 1000 volts (Vt). As in the charge

control embodiment, the time required to reach that voltage is monitored by the controller using an up/down counter which counts a scaled down reference frequency. The first phase duration (t(Φ1)) is based on the time required to reach Vt. The method of selecting the appropriate t(Φ1) is identical to the charge control embodiment. If Vt is not reached within 6.18 mS, then t(Φ1) is set to 12 mS. Table II shows the t(Vt) thresholds and their associated t(Φ1).

TABLE II

If t(Vt)≤(mS)	Then t(Φ1)is(mS)
1.24	2.3
1.73	2.85
2.23	3.79
2.72	4.02
3.22	4.83
3.71	6.76
4.20	7.73
4.70	8.69
5.19	9.66
5.69	10.62
6.18	11.59

Interphase delay and second phase timing is identical to the charge control method.

We have designed a new defibrillator meeting certain size, weight, efficacy and safety design goals. The size and weight are below the design thresholds of 150 cu.in. and four lbs. This new portable defibrillator may therefore be carried and stored in places such as drug kit boxes carried by early medical responders and in the glove boxes of cars.

The circuit design of the new defibrillator permits the use of a biphasic truncated exponential waveform, such as one of the waveforms described above. Use of the biphasic waveform permits the defibrillator to be operated with the same efficacy as prior art external

defibrillators but with the storage and delivery of far less energy at lower voltages. For example, the new defibrillator effectively cardioverts patients by delivering shocks below 155 Joules of energy (167 Joules of energy stored), and most preferably on the order of 130 Joules of energy (140 Joules stored), compared with the delivery of 200-360 Joules (240-439 Joules stored) by prior art external defibrillators.

A preferred embodiment of the new external defibrillator is shown in Figures 5 and 6. This defibrillator is much smaller and lighter than prior art external defibrillators. The size of the preferred defibrillator (approx. 2.2 in. x 8 in. x 8 in., for a total volume of approx. 141 cu.in.) permits it to be carried and/or stored in places in which prior art external defibrillators could not fit. In addition, its lighter weight (approx. three pounds) enables the defibrillator to be moved more easily by the operator in an emergency.

As shown in Figures 5 and 6, the preferred external defibrillator includes a molded two-part plastic housing with an upper case 80 and a lower case 81. A main printed circuit board ("PCB") 86 supports the capacitor 32, an electrode connector 82, a PCMCIA memory card 83 and a PCMCIA memory card ejector mechanism 84. The PCMCIA memory card 83 lies within a PCMCIA memory card slot 95 on PCB 86.

A keyboard PCB 85 and a display PCB 87 is disposed between the main PCB 86 and the upper case 80. Keyboard PCB 85 interfaces with the defibrillator's operator buttons, and display PCB 87 operates the defibrillator's LCD display 88. A display window 89 in the upper case permits display 88 to be seen by an operator.

An insulator 90 is disposed between main PCB 86 and display PCB 87. A sealing gasket 91 lines the edges between upper case 80 and lower case 81 when the housing is assembled.

A battery assembly 99 consisting of a battery housing 92 and six lithium-manganese dioxide primary cells 94 is disposed in upper case 80 so that the batteries are in electrical contact with the capacitor charge circuits and other circuits of main PCB 86. The battery assembly has a latching mechanism 96 for attaching and detaching the battery assembly to and from the defibrillator.

The location of the battery assembly in front of the PCMCIA memory card slot prevents the defibrillator operator or others from accessing the PCMCIA card while the defibrillator is powered up and operating. This arrangement protects the operator and patient from accidental shocks and protects the defibrillator itself from damage caused by inadvertant removal of the PCMCIA card during operation.

The small size and light weight of our defibrillator is due to a combination of a variety of design features. Use of a truncated exponential biphasic waveform instead of the prior art damped sinusoid waveform permits operation without an inductor in the waveform circuit. In addition, the lower energy requirements permit the use of a smaller capacitor and smaller batteries than those used in prior art external defibrillators.

In an effort to reduce the battery size even further, the preferred embodiment is provided with a capacitor precharge circuit and controller that begins charging the capacitor soon after the defibrillator is activated, even before ventricular fibrillation (and therefore the need for defibrillation) has been detected.

The precharge voltage level is kept below the level where damage to the defibrillator circuit, the patient or the operator could occur in the event of a single fault. Thus, for example, whereas in the preferred embodiment the full preshock capacitor voltage is 1650 V, the precharge level is 1100 V. This precharge procedure minimizes the amount of energy that needs to be transferred from the battery to the capacitor when a therapeutic shock is indicated, thereby reducing the required size of the battery and the defibrillator's transformer.

The preferred embodiment uses 6 lithium-manganese dioxide primary cells instead of rechargeable batteries. Primary cells have greater energy density than rechargeable batteries and are cheaper, lighter and, since they are disposable, they are easier to maintain. While primary cells also have lower power and energy characteristics, use of a truncated exponential biphasic waveform and a capacitor precharge circuit permits operation at lower power levels.

The preferred defibrillator shown in Figures 5 and 6 incorporates the solid state defibrillator circuit described above with reference to Figure 4. Use of this circuit along with the short-circuit protection feature described above also reduces the size and weight of the defibrillator by avoiding the use of the mechanical switches required by higher voltage devices.

Other smaller and lighter-weight features of the defibrillator shown in Figures 5 and 6 are the use of a flat panel LCD in place of the more conventional CRT display and the use of a PCMCIA memory card to record voice and instrument information instead of a magnetic tape recorder or a paper strip chart recorder. In addition, the preferred defibrillator includes a feature whereby part of the patient ECG information stored within

the PCMCIA card can be displayed on the LCD for use by a medical professional. This feature takes the place of the strip chart recorders in prior art external defibrillators.

Lightweight defibrillator electrode designs may be used to reduce the weight of the overall device even further. For example, flexible patch electrodes may be used in place of the conventional paddle electrodes. In addition, because of the lower energy and voltage features of the defibrillator, relatively thin wires may be used to attach the electrodes to the defibrillator instead of thick cables.

Other component choices and other configurations of components are within the scope of this invention as long as the threshold size and weight requirements of 150 cu. in. and four pounds are met.

Any embodiment of this invention 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 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.

In addition, while the preferred embodiment of the invention has been discussed in the context of biphasic waveforms, monophasic, triphasic or other multiphasic waveforms may be used as well. Also, patient-dependent electrical parameters other than charge delivered may be monitored and used to shape the waveform during discharge.

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.

We claim:

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

charging the energy source to an initial level;

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;

shaping the waveform of the delivered electrical energy based on a value of the monitored electrical parameter, wherein the relative duration of the phases of the multiphasic waveform is dependent on the value of the monitored electrical parameter.

2. The method of claim 1 wherein the energy source is external to the patient.

3. The method of claim 1 wherein the shaping step further comprises controlling the duration of a waveform phase based on a value of the electrical parameter.

4. The method of claim 3 wherein the shaping step further comprises controlling the duration of another phase of the waveform based on the ~~measured~~ value.

5. The method of claim 4 further comprising the step of providing a plurality of phase duration values, the shaping step comprising the step of selecting phase duration values for each phase of the multiphasic waveform from the plurality of phase duration values.

6. The method of claim 3 wherein the electrical parameter is charge delivered by the energy source to one of the electrodes.

7. The method of claim 6 wherein the discharging step begins at a discharge start time, the method further comprising the step of monitoring elapsed time from the discharge start time, the shaping step further comprising the step of determining an elapsed time value at which the charge delivered has reached a predetermined threshold.

8. The method of claim 7 wherein the shaping step further comprises selecting a first phase duration based on the elapsed time value.

9. The method of claim 8 wherein the shaping step further comprises selecting a second phase duration based on the elapsed time value.

10. The method of claim 9 wherein the second phase duration is equal to the first phase duration for at least one possible elapsed time value.

11. The method of claim 9 wherein the second phase duration is less than the first phase duration for at least one possible elapsed time value.

12. The method of claim 1 wherein the duration of the monitoring step is shorter than the duration of the discharging step.

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

charging the energy source to an initial level;

discharging the energy source across the electrodes to deliver electrical energy to the patient in a waveform, the patient and an additional impedance forming an electrical circuit with the energy source and the electrodes;

monitoring an electrical parameter during the discharging step;

shaping the waveform of the delivered electrical energy based on the value of the monitored electrical parameter.

14. The method of claim 13 further comprising the step of removing the additional impedance from the electrical pathway if the electrical parameter is within a ~~second~~ defined range.

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

charging the energy source to an initial level;

discharging the energy source across the electrodes to deliver electrical energy to the patient in a truncated exponential biphasic waveform;

monitoring an electrical parameter during the discharging step;

adjusting the tilt of the waveform based on the value of the monitored electrical parameter.

16. The method of claim 15 wherein the adjusting step comprises controlling the duration of a waveform phase based on a value of the electrical parameter.

17. The method of claim 16 wherein the relative duration of the phases of the waveform is

dependent on the value of the monitored electrical parameter.

16. ~~18~~. An apparatus for administering electrotherapy to a patient's heart through electrodes external to the patient comprising:

an energy source;

two electrodes adapted to make electrical contact with a patient;

a connecting mechanism forming an electrical circuit with the energy source and the electrodes when the electrodes are attached to a patient; an electrical parameter monitor; and

a controller operating the connecting mechanism to deliver electrical energy from the energy source to the electrodes in a truncated exponential multiphasic waveform the relative phase durations of which are based on an electrical parameter monitored during delivery of the electrical energy.

17. ~~19~~. The apparatus of claim ~~18~~ 16 wherein the connecting mechanism comprises a plurality of switches for selectively directing electrical energy from the energy source to the patient in one of two polarities.

20. The apparatus of claim 19 further comprising a charge sensor providing information to the controller related to charge delivered by the energy source to the electrodes.

19. ~~21~~. The apparatus of claim ~~20~~ 18 further comprising a timer associated with the charge sensor and the controller.

20. ~~22~~. The apparatus of claim ~~21~~ 19 wherein the controller comprises a counter with a controllable

counting rate, the counter being adapted to count in one direction during delivery of a first phase of the multiphasic waveform and in another direction during delivery of a second phase of the multiphasic waveform.

21. ~~23~~. The apparatus of claim 16 ~~18~~ further comprising means for selectively limiting current flow through the electrodes and means for determining whether current flowing to the electrodes is below a predetermined threshold.

22. ~~24~~. The apparatus of claim 21 ~~23~~ wherein the means for selectively limiting current flow comprises an impedance and a shunting switch in the circuit with the electrodes and the energy source.

23. ~~25~~. The apparatus of claim 16 ~~18~~ wherein the energy source comprises a battery disposed in a battery holder, the apparatus further comprising a solid state memory device disposed in a memory device holder, the battery blocking external access to the memory device when the battery is disposed in the battery holder.

26. An external defibrillator comprising:

a capacitive energy source sized between 60 and 150 microfarads;

two electrodes adapted to make electrical contact with the exterior of a patient;

a connecting mechanism forming an electrical circuit with the energy source and the electrodes when the electrodes are attached to a patient; and

a controller operating the connecting mechanism to deliver electrical energy from the energy source to the electrodes

27. The defibrillator of claim 26 in which the connecting mechanism and the controller comprise means for delivering a truncated exponential biphasic waveform from the energy source to the electrodes.

24. 26. ~~28~~. An external defibrillator comprising:

an energy source;

two electrodes adapted to make electrical contact with the exterior of a patient;

a connecting mechanism forming an electrical circuit with the energy source and the electrodes when the electrodes are attached to a patient;

a controller operating the connecting mechanism to deliver electrical energy from the energy source to the electrodes; and

a housing containing at least the energy source, the connecting mechanism and the controller, the housing having a volume less than 150 cubic inches.

25. 27. ~~29~~. The defibrillator of claim ~~26~~ 24 in which the housing has a first dimension not greater than 2.2 inches.

26. 28. ~~30~~. The defibrillator of claim ~~29~~ 25 27 in which the housing has second and third dimensions not greater than 8 inches.

~~31~~. An external defibrillator comprising:

an energy source having a capacity less than 155 Joules;

two electrodes adapted to make electrical contact with the exterior of a patient;

a connecting mechanism forming an electrical circuit with the energy source and the electrodes when the electrodes are attached to a patient;

a controller operating the connecting mechanism to deliver electrical energy from the energy source to the electrodes in a truncated exponential multiphasic waveform.

36 32. An external defibrillator comprising:

an energy source;

two electrodes adapted to make electrical contact with the exterior of a patient;

a connecting mechanism forming an electrical circuit with the energy source and the electrodes when the electrodes are attached to a patient;

a controller operating the connecting mechanism to deliver electrical energy from the energy source to the electrodes;

the defibrillator having a weight less than four pounds.

Sub A 31

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

charging the energy source to an initial level;

determining the need to apply a shock to a patient;

charging the energy source to a second level greater than the initial level;

discharging the energy source across the electrodes to deliver electrical energy to the patient in a truncated exponential biphasic waveform.

46 47 34. A method for applying electrotherapy to a patient from an energy source external to the patient, the method comprising the following steps:

charging the energy source to an initial level;

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

determining the time during which a predetermined amount of charge is delivered to the patient;

shaping the waveform of the delivered electrical energy based on the value of the determined time, wherein the relative duration of the phases of the multiphasic waveform is dependent on the value of the determined time.

Add A'

Add B'

Add C'

Add D'

Attorney Docket No. 241082000620

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) X is attached hereto
__ was filed on

as application serial no. 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 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:

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Tyler Dylan - Reg. No. P-37,612
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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.

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08/227553

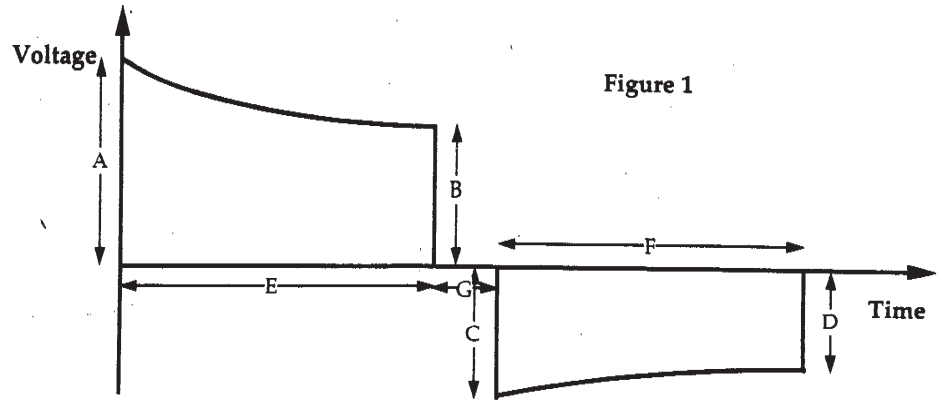

Figure 1

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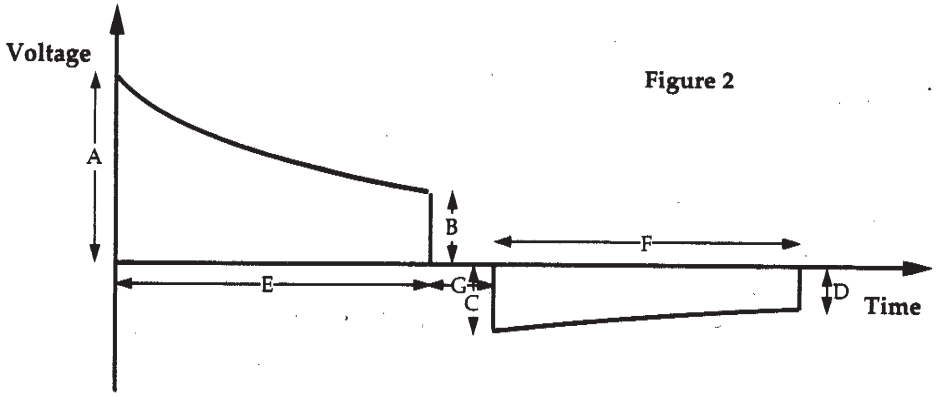

Figure 2

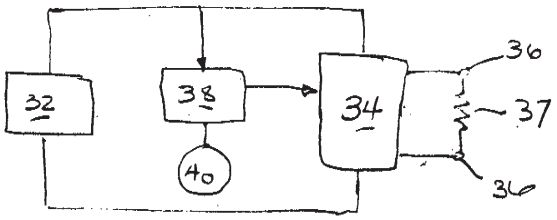

FIG. 3

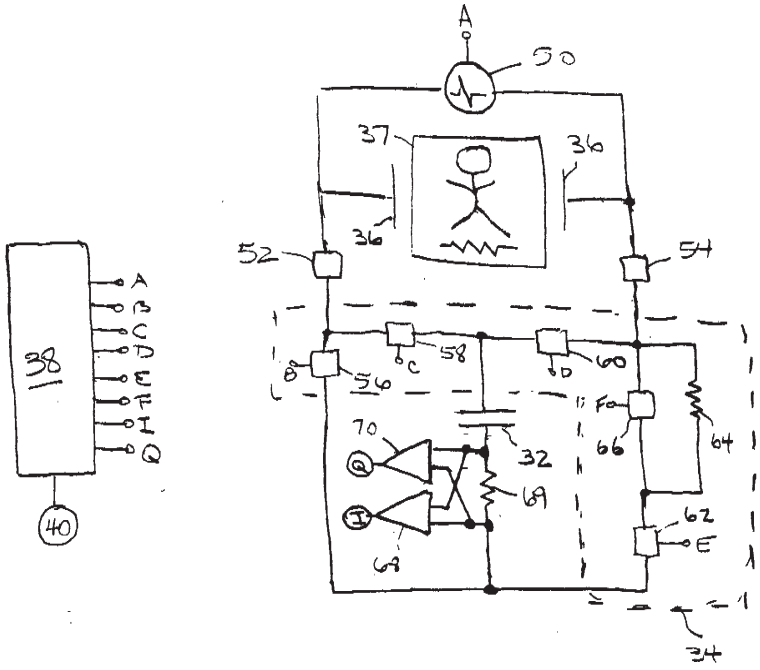
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FIG. 4

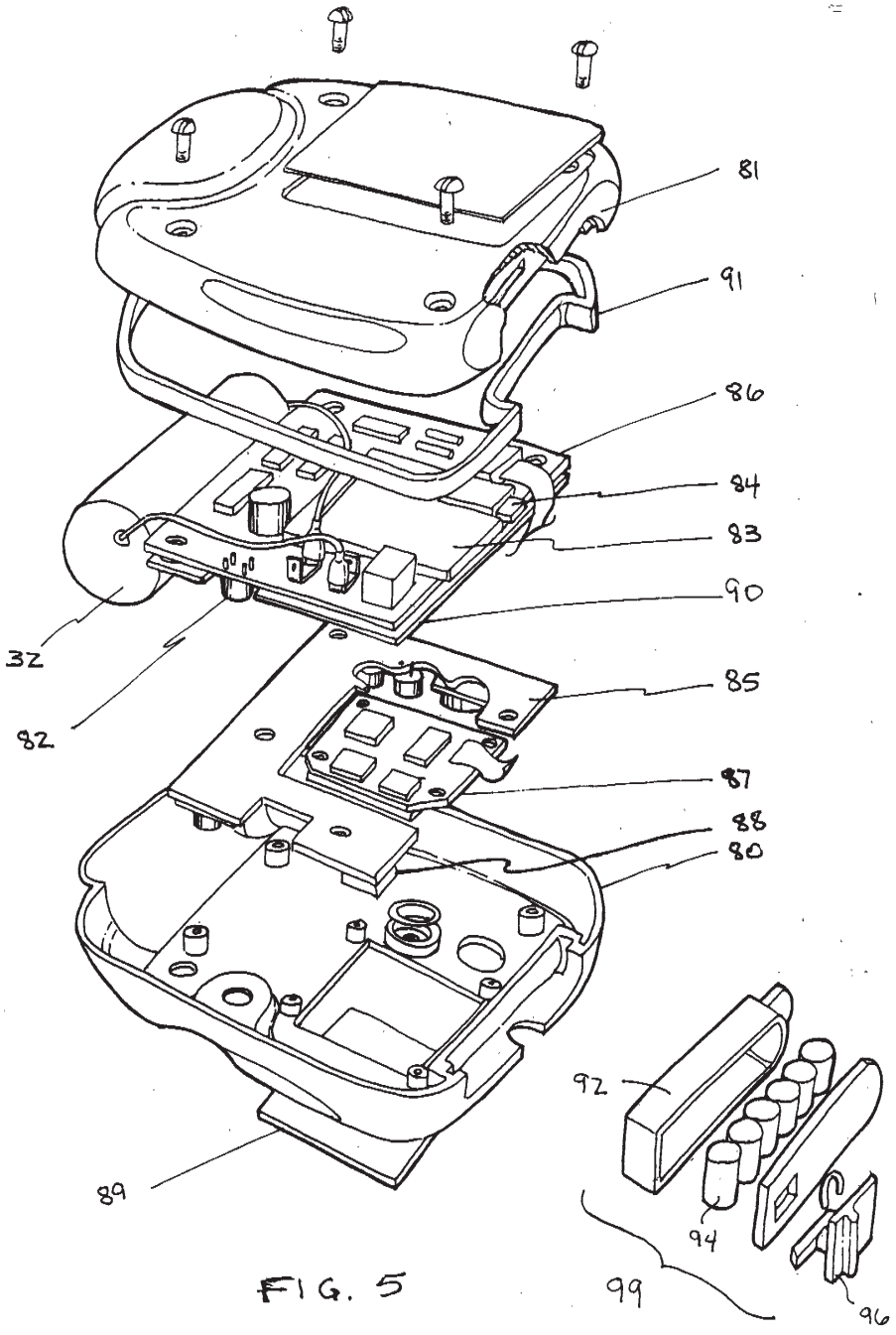

FIG. 5

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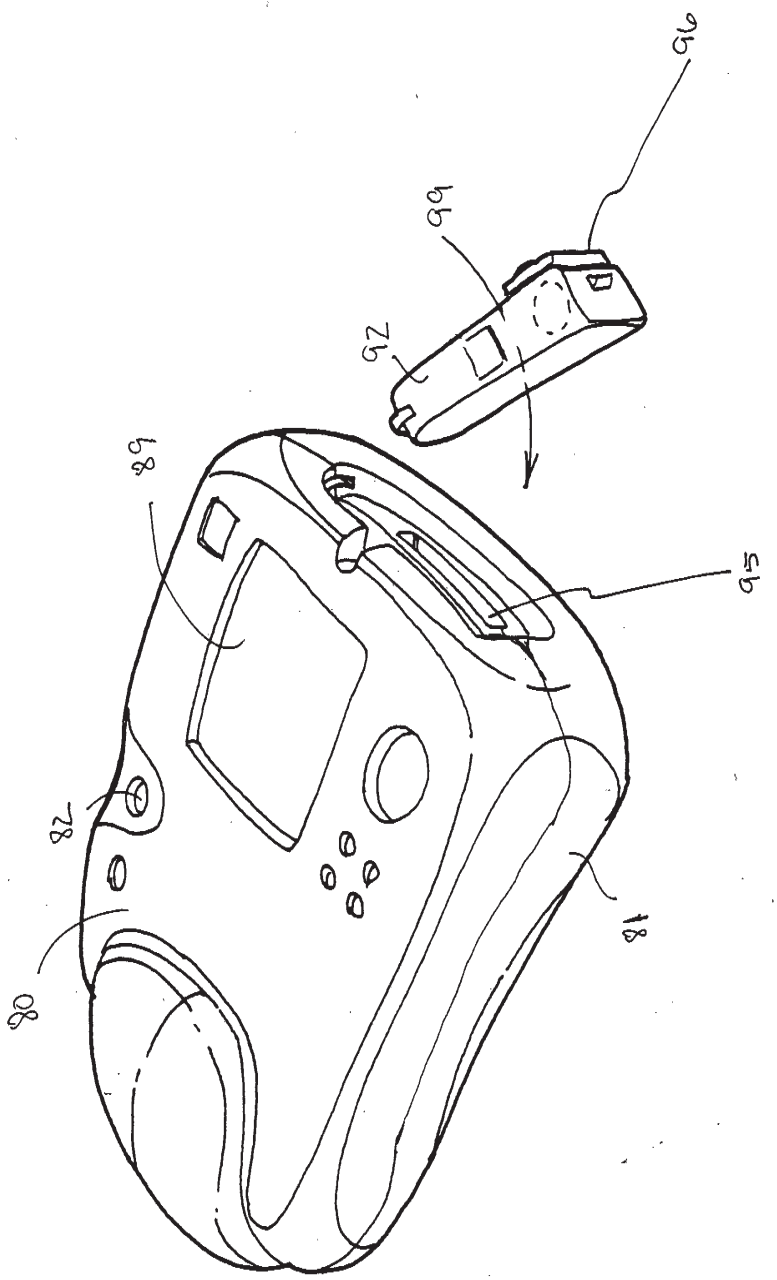

FIG. 6

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APPLICATION TRANSMITTAL LETTER

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G Bianchini
(Signature of Person Mailing Paper or Fee)

Transmitted herewith for filing is the patent application
of David Cameron, Too et al; Thomas Lyster; Daniel Powers; Bradford Gliner; Clinton Cole; Carlton Morgan
for ELECTROTHERAPY METHOD AND APPARATUS

Enclosed are:

4 sheet(s) of ___ formal X informal drawing(s).

___ A claim for foreign priority under 35 U.S.C. § 119/363 in
___ a separate document ___ the declaration.

___ A certified copy of the priority document.

___ verified statement(s) of small entity status.

___ Other:

The declaration of the inventor X is enclosed X unsigned.

The fee has been calculated as follows:

A. Basic Application Fee				$ 710.00
B. Total Claims 34 minus 20 = 14	x	$ 22.00		$ 308.00
C. Independent Claims 10 minus 3 = 7	x	$ 74.00		$ 518.00
D. If multiple dependent claims present, add		$ 230.00		$ 0
E. Total Application Fee (Total of A, B, C & D)			=	$1,536.00
F. If verified statement of small entity status is enclosed, fifty percent reduction of Total Application Fee (50% x E)			=	$ 0
G. Application Fee Due (E minus F)			=	$1,536.00
H. Assignment Recording Fee of $40.00 if assignment document is enclosed.			=	$ 0
I. TOTAL FEE (G plus H)			=	$1,536.00

By
James R. Shay
Registration No. 32,062

Phone No. (415) 677-63...

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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
08/227,553	04/14/94	CAMERON D	241082000620

03A1/0510

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PALO ALTO, CA 94304-1018

#2

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DATE MAILED: 05/10/94

NOTICE TO FILE MISSING PARTS OF APPLICATION
FILING DATE GRANTED

An Application Number and Filing Date have been assigned to this application. However, the items indicated below are missing. The required items and fees identified below must be timely submitted **ALONG WITH THE PAYMENT OF A SURCHARGE** for items 1 and 3-6 only of $ 130 for large entities or $ 65 for small entities who have filed a verified statement claiming such status. The surcharge is set forth in 37 CFR 1.16(e).

If all required items on this form are filed within the period set below, the total amount owed by applicant as a ~~large~~ entity, ☐ small entity (verified statement filed), is $ 1,666.

Applicant is given **ONE MONTH FROM THE DATE OF THIS LETTER, OR TWO MONTHS FROM THE FILING DATE** of this application, **WHICHEVER IS LATER,** within which to file all required items and pay any fees required above to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

1. ☒ ~~The~~ statutory basic filing fee is: ☒ ~~missing~~ ☐ insufficient. Applicant as a ☒ ~~large~~ entity ☐ small entity, must submit $ 710 to complete the basic filing fee.

2. ☒ ~~Additional~~ claim fees of $ 826 as a ☒ large entity, ☐ small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.

3. ☐ The oath or declaration:
   ☐ is missing.
   ☐ does not cover items omitted at time of execution.

   An oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date is required.

4. ☐ The oath or declaration does not identify the application to which it applies. An oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.

5. ☒ ~~The~~ signature to the oath or declaration is: ☒ missing; ☐ a reproduction; ☐ by a person other than the inventor or a person qualified under 37 CFR 1.42, 1.43, or 1.47. A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.

6. ☐ The signature of the following joint inventor(s) is missing from the oath or declaration:

   _____ An oath or declaration listing the names of all inventors and signed by the omitted inventor(s), identifying this application by the above Application Number and Filing Date, is required.

7. ☐ The application was filed in a language other than English. Applicant must file a verified English translation of the application and a fee of $_____ under 37 CFR 1.17(k), unless this fee has already been paid.

8. ☐ A $_____ processing fee is required for returned checks. (37 CFR 1.21(m)).

9. ☐ Your filing receipt was mailed in error because check was returned without payment.

10. ☐ The application does not comply with the Sequence Rules. See attached Notice to Comply with Sequence Rules 37 CFR 1.821-1.825.

11. ☐ Other.

Direct the response and any questions about this notice to B Douglas CRH, Application Processing Division, Special Processing and Correspondence Branch (703) 308-1202.

A copy of this notice MUST be returned with the response.

Attorney Docket 241082000620

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

MAIL ROOM MAY 31 1994 PAT. & TRADEMARK OFF.

In re Application of DAVID CAMERON et al.

Serial No.: 08/227,553

Filed: April 14, 1994

For: ELECTROTHERAPY METHOD AND APPARATUS

Group Art Unit: Unknown

Examiner: Unassigned

Attention: Application Division

RECEIVED JUN 1 6 1994 APPLICATION BRANCH

TRANSMITTAL LETTER FOR MISSING PARTS OF APPLICATION

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

In complete response to the Notice to File Missing Parts of Application Under 37 C.F.R. §1.53(d) dated 5/10/94, attached please find:

[XX] a combined Declaration and Power of Attorney signed by the inventor(s) and the surcharge of

[XX] $65.00 [ ] $130.00 as set forth in 37 C.F.R. §1.16(e);

[XX] a Declaration of Small Entity Status;

[ ] a Petition for Extension of Time;

[ ] a verified English translation of the application, and the $130 fee as set forth in 37 C.F.R. §1.17(k);

[ ] an Assignment document and the $40.00 Assignment recording fee;

[XX] other Blanket Petition; copy of Notice to File Missing Parts;

[XXX] a check in the amount of $ 833.00. ($768 application filing fee and $65 Missing Parts fee.)

[ ] Charge $_____ to Deposit Account No. 03-1952.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 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.

Respectfully submitted,

MORRISON & FOERSTER
755 Page Mill Road
Palo Alto, CA 94304-1018
Telephone: (415) 677-7012
Fax No.: (415) 677-6404

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

160 FS 06/08/94 08227553 1 205 65.00 CK
160 FS 06/08/94 08227553 1 201 355.00 CK
160 FS 06/08/94 08227553 1 202 413.00 CK

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, D.C. 20231, on 5/26/94 (Date)

_____ (Signature) 5/26/94 (Date)

Attorney Docket No. 241082000620

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
X was filed on April 14, 1994

as application serial no. 08/227,553 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 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 hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below, and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) and (b) set forth above which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.: 08/103,837
Filing Date: August 6, 1993
Status (patented, pending, abandoned): Pending

As to the subject matter of this application which is common to said earlier application, I do not know and do not believe that the same 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 earlier application, or in public use or on sale in the United States of America more than one year prior to said earlier application; that said common subject matter has not been patented or made the subject of an inventor's certificate issued before the date of said earlier application in any country foreign to the United States of America on an application filed by me or my legal representatives or assigns more than twelve months prior to said earlier application; and that the earliest application(s) for patent or inventor's certificate on said invention filed by me or my legal representatives or assigns in any country foreign to the United States of America is identified below, as well as all other such applications (if any) filed more than twelve months prior to the filing date of this application:

None

The priority of the earliest application(s) (if any) filed within a year prior to said pending prior application is hereby claimed under 35 U.S.C. § 119.

As to the subject matter of this application which is not common to said earlier application, I do not know and do not believe that the same 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 the date of this application, or in public use or on sale in the United States of America more than one year prior to the date of this application, and that said subject matter has not been patented or made the subject of an inventor's certificate issued in any country foreign to the United States of America on an application filed by me or my legal representatives or assigns more than twelve months prior to the date of this application, and that the earliest application(s) for patent or inventor's certificate on said subject matter filed by me or my legal representatives or assigns in any country foreign to the United States of America is identified below, as well as all other such application(s) (if any) filed more than twelve months prior to the filing date of this application:

The priority of the earliest application(s) (if any) filed within a year to this application is hereby claimed under 35 U.S.C. § 119.

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:

Reid G. Adler - Reg. No. 30,988
William H. Benz - Reg. No. 25,952
Felissa H. Cagan - Reg. No. 35,089
Thomas E. Ciotti - Reg. No. 21,013
Patricia M. Drost - Reg. No. 29,790
Edward G. Durney - Reg. No. P37,611
Tyler Dylan - Reg. No. P-37,612
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
Shmuel Livnat - Reg. No. 33,949
Michelle M. McSpadden - Reg. No. 32,048
Gladys H. Monroy - Reg. No. 32,430
Kate H. Murashige - Reg. No. 29,959
Jackie N. Nakamura - Reg. No. 35,966
Freddie K. Park - Reg. No. 35,636
Paul F. Schenck - Reg. No. 27,253
Lynn E. Schwenning - Reg. No. 37,233
James R. Shay - Reg. No. 32,062
Debra A. Shetka - Reg. No. 33,309
Cecily Anne Snyder - Reg. No. 37,448
E. Thomas Wheelock - Reg. No. 28,825
Anna Lewak Wight - Reg. No. 33,006

24

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, Esq. 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.

1-00

Full Name Inventor: DAVID CAMERON

Signature: _____ Date 5/20/94

Residence: Seattle, Washington 98109 WA

Citizenship: U.S.A.

Post Office Address: 911 First Avenue North, Seattle, Washington 98109

Full Name Inventor: THOMAS D. LYSTER 2-00

Signature: _____ Date 5-20-94

Residence: Bothell, Washington WA

Citizenship: U.S.A.

Post Office Address: 23309 - 21st Avenue S.E., Bothell, Washington 98021

Full Name Inventor: DANIEL J. POWERS 3-00

Signature: _____ Date 5-20-94

Residence: Bainbridge Island, Washington WA

Citizenship: U.S.A.

Post Office Address: 10797 Bill Point View, Bainbridge Island, Washington 98110

Full Name Inventor: BRADFORD E. GLINER 4-00

Signature: _____ Date 5-20-94

Residence: Bellevue, Washington WA

Citizenship: U.S.A.

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

Full Name Inventor: CLINTON S. COLE 3-CC

Signature: Clinton S Cole Date 5/23/94
Residence: Seattle, Washington WA
Citizenship: U.S.A.
Post Office Address: 911 First Avenue North, Seattle, Washington 98109

Full Name Inventor: CARLTON B. MORGAN 6-CC

Signature: Carlton B Morgan Date 5/20/94
Residence: Bainbridge Island, Washington WA
Citizenship: U.S.A.
Post Office Address: 4143 Palomino Drive N.E., Bainbridge Island, Washington 98110

Applicant or Patentee: DAVID CAMERON et al.
Serial or Patent No.: 08/227,553
Filed or Issued: April 14, 1994
For: ELECTROTHERAPY METHOD AND APPARATUS

Attorney Docket No.: 241082000620

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:
[XX] 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, Washington 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) DAVID CAMERON; THOMAS LYSTER; DANIEL POWERS; BRADFORD GLINER; CLINTON COLE; and CARLTON MORGAN
described in

[ ] the specification filed herewith
[XX] application serial no. 08/227,553, filed April 14, 1994.
[ ] 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 verified statement is directed.

NAME OF PERSON SIGNING: Carlton B. Morgan
TITLE OF PERSON OTHER THAN OWNER: Vice President, Research & Development
ADDRESS OF PERSON SIGNING: Market Place Tower, Suite 610, 2025 First Avenue
Seattle, Washington 98121
SIGNATURE: _____ DATE: 5/20/94

#7

*torney Docket 241082000620

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

DAVID CAMERON et al.

Serial No.: 08/227,553

Filed: April 14, 1994

For: ELECTROTHERAPY METHOD AND APPARATUS

Group Art Unit: Unknown

Examiner: Unassigned

BLANKET PETITION FOR EXTENSION OF TIME AND AUTHORIZATION TO CHARGE OR CREDIT DEPOSIT ACCOUNT

Honorable Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

It a paper is untimely filed in the subject application by applicant(s) or her/his/their representative, the Commissioner is hereby petitioned under 37 C.F.R. § 1.136(a) for the minimum extension of time required to make said paper timely. In the event a petition for extension of time is made under the provisions of this paragraph, the Commissioner is hereby requested to charge any fee required under 37 C.F.R. § 1.17(a)-(d) to Deposit Account No. 03-1952.

If a paper is subsequently filed in the subject application by applicant(s) or her/his/their representative and a fee under 37 C.F.R. §§ 1.16-1.17 is required to effect any amendment, petition or other action requested in said paper, the Commissioner is hereby authorized to charge any deficiency in said fee, or credit any overpayment to Deposit Account No. 03-1952.

Respectfully submitted,

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

MORRISON & FOERSTER
755 Page Mill Road
Palo Alto, CA 94304-1018
(415) 813-5600
Fax: (415) 494-0792

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, D.C. 20231 on 5/26/94.

5/26/94 _____

#23

MAY 31 1994 PATENT AND TRADEMARK OFF.

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

TC

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
08/227,553	04/14/94	CAMERON	2410/2000620

RECEIVED
JUN 10 1994
APPLICATION BRANCH

03A1/0510

MORRISON & FOERSTER
755 PAGE MILL ROAD
PALO ALTO, CA 94304-1018

0000

DATE MAILED: 05/10/94

NOTICE TO FILE MISSING PARTS OF APPLICATION
FILING DATE GRANTED

An Application Number and Filing Date have been assigned to this application. However, the items indicated below are missing. The required items and fees identified below must be timely submitted **ALONG WITH THE PAYMENT OF A SURCHARGE** for items 1 and 3-6 only of $ 130 for large entities or $ 65 for small entities who have filed a verified statement claiming such status. The surcharge is set forth in 37 CFR 1.16(e).

If all required items on this form are filed within the period set below, the total amount owed by applicant as a ~~☒~~ large entity, ☐ small entity (verified statement filed), is $ 1,666.

Applicant is given **ONE MONTH FROM THE DATE OF THIS LETTER, OR TWO MONTHS FROM THE FILING DATE** of this application, **WHICHEVER IS LATER,** within which to file all required items and pay any fees required above to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

1. ~~☒~~ The statutory basic filing fee is: ☒ missing ☐ insufficient. Applicant as a ☒ large entity ☐ small entity, must submit $ 710 to complete the basic filing fee.

2. ~~☒~~ Additional claim fees of $ 826 as a ☒ large entity, ☐ small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.

3. ☐ The oath or declaration: 4/5
   ☐ is missing.
   ☐ does not cover items omitted at time of execution.

   An oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date is required.

4. ☐ The oath or declaration does not identify the application to which it applies. An oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.

5. ~~☒~~ The signature to the oath or declaration is: ☒ missing; ☐ a reproduction; ☐ by a person other than the inventor or a person qualified under 37 CFR 1.42, 1.43, or 1.47. A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.

6. ☐ The signature of the following joint inventor(s) is missing from the oath or declaration:

   _____ An oath or declaration listing the names of all inventors and signed by the omitted inventor(s), identifying this application by the above Application Number and Filing Date, is required.

7. ☐ The application was filed in a language other than English. Applicant must file a verified English translation of the application and a fee of $_____ under 37 CFR 1.17(k), unless this fee has already been paid.

8. ☐ A $_____ processing fee is required for returned checks. (37 CFR 1.21(m)).

9. ☐ Your filing receipt was mailed in error because check was returned without payment.

10. ☐ The application does not comply with the Sequence Rules. See attached Notice to Comply with Sequence Rules 37 CFR 1.821-1.825.

11. ☐ Other.

Direct the response and any questions about this notice to Douglas, Application Processing Division, Special Processing and Correspondence Branch (703) 308-1202. Cru

A copy of this notice MUST be returned with the response.

MAIL ROOM
55 JUN 17 1994
PAT. & TRADEMARK OFF.

PATENT
Atty Dkt: 241082000620

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, D.C. 20231 on

6/14/94
Date

Signature

RECEIVED
JUL 27 1994
APPLICATION BRANCH

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:
DAVID CAMERON et al.

Serial No.: 08/227,553 Group Art Unit: Unknown

Filing Date: 14 April 1994 Examiner: Unassigned

Title: ELECTROTHERAPY METHOD AND APPARATUS

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94 JUN 23 PM 4:59
GROUP 130

INFORMATION DISCLOSURE
STATEMENT UNDER 37 CFR § 1.97

The Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Dear Sir:

The information listed below may be material to the above-identified patent application and is thus submitted herewith in compliance with the applicant's duty of disclosure as set forth under 37 CFR § 1.56. Copies of the information and completed PTO-1449 forms are submitted herewith. The Examiner is respectfully requested to make this information of official record in the application. The information includes:

U.S. Patent Numbers:

4,328,808 to Charbonnier et al., (05/11/82).
4,504,773 to Suzuki et al., (03/12/85).
4,574,810 to Lerman (03/11/86).

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SEP 16 94
GROUP 330

153014.1

U.S. Patent Numbers (continued):
4,595,009 to Leinders (06/17/86).
4,610,254 to Morgan et al., (09/09/86).
4,745,923 to Winstrom (05/24/88).
4,840,177 to Charbonnier et al., (06/20/89).
5,107,834 to Ideker et al., (04/28/92).
5,111,813 to Charbonnier et al., (05/12/92).
5,215,081 to Ostroff (06/01/93).
5,222,480 to Couche et al., (06/29/93).
5,237,989 to Morgan et al., (08/24/93).
5,275,157 to Morgan et al., (01/04/94).
5,306,291 to Kroll et al., (04/26/94).

Foreign Patent Publications:
European Patent No. 0315368 (05/10/89).

This Information Disclosure Statement is submitted less than three months from the application filing date. Therefore, the applicants believe that no fee is due. However, the Commissioner is hereby authorized to charge any fees which may be required by this paper to Deposit Account Number 03-1952.

Applicants would appreciate the Examiner's initialling and returning the Form PTO-1449, indicating that the references have indeed been considered and made of record herein.

This Information Disclosure Statement under 37 CFR § 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.

Respectfully submitted,

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

MORRISON & FOERSTER
755 Page Mill Road
Palo Alto, CA 94304-1018
(415) 813-5600
Fax: (415) 494-0792

COM SSIONER OF PATENTS AND TRADEMA S
Washington, D.C. 20231

Docket No. 241082000620
PATENT

FORM PTO-1449 (Modified)
LIST OF PATENTS AND PUBLICATIONS
FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT
(Use several sheets if necessary)
Sheet 1 of 2

In the Application of

DAVID CAMERON et al.

Serial No. 08/227,553

Filed: 14 April 1994

Art Unit: 3305 ~~Unknown~~

Examiner: Unassigned

U.S. PATENT DOCUMENTS

Ref. Desig.	Examiner's Initials	Document Number	Date	Name	Class/Subclass	(If appropriate) Filing Date
1.	[illegible]	4,328,808	05/11/82	Charbonnier et al.		
2.		4,504,773	03/12/85	Suzuki et al.		
3.		4,574,810	03/11/86	Lerman		
4.		4,595,009	06/17/86	Leinders		
5.		4,610,254	09/09/86	Morgan et al.,		
6.		4,745,923	05/24/88	Winstrom		
7.		4,840,177	06/20/89	Charbonnier et al.		
8.		5,107,834	04/28/92	Ideker et al.		
9.		5,111,813	05/12/92	Charbonnier et al.		
10.		5,215,081	06/01/93	Ostroff		
11.		5,222,480	06/29/93	Couche et al.		
12.		5,237,989	08/24/93	Morgan et al.		
13.		5,275,157	01/04/94	Morgan et al.		
14.	[illegible]	5,306,291	04/26/94	Kroll et al.		

Examiner: K. Schaetzle Date Considered: 3-20-95

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.

153014.1

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

Docket No. 241082000620
PATENT

FORM PTO-1449 (Modified)
LIST OF PATENTS AND PUBLICATIONS
FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT
(Use several sheets if necessary)
Sheet 2 of 2

In the Application of

DAVID CAMERON et al.

Serial No. 08/227,553

Filed: 14 April 1994

Art Unit: Unknown

Examiner: Unassigned

FOREIGN PATENT PUBLICATIONS

Ref. Desig.	Examiner's Initials	Document Number	Date	Country
15.	KS	0315368	05/10/89	EPO

Examiner: K Schaetzle Date Considered: 3-20-95

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.

153014.1

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/227,553	04/14/94	CAMERON	D 241082000620

EXAMINER	
SCHAETZLE,K	
ART UNIT	**PAPER NUMBER**
3305	5

33M1/0411

JAMES R. SHAY
MORRISON & FOERSTER
755 PAGE MILL ROAD
PALO ALTO, CA 94304-1018

DATE MAILED: 04/11/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☒ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 1-34 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.
3. ☒ Claims 1-12 & 26-32 are allowed.
4. ☒ Claims 13-25, 33 & 34 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Part III DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 14, 16-25 and 34 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 14, the reference to a *second* defined range is vague as a first defined range has not been recited.

In claim 16, it would appear necessary to insert the word *further* after the word *step* on line 2 since this seems to be a recitation of an additional step over that of adjusting tilt.

Claim 18 appears to be incomplete. It would appear necessary to include a means for monitoring an electrical parameter in order for the controller to operate as recited.

In claim 34 the reference to the electrodes lacks antecedence.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 13 and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Bell et al.

Regarding claim 13, the examiner considers the impedance of the leads to constitute an additional impedance.

Concerning claim 14, the leads of Bell et al. are effectively removed from the electrical pathway when the measured energy equals the pre-selected value for this parameter, or more practically, when the measured energy falls within a range of significant digits close enough to the pre-selected value to be considered statistically equivalent by the energy computer.

4. Claims 15 and 16 are rejected under 35 U.S.C. § 102(e) as being clearly anticipated by Lang et al.

The applicants should note that the examiner does not have access to parent case 08/103,837, of which the present application is a CIP thereof, in order to adequately make a determination as to the effective filing date of the subject matter contained in claims 15 and 16.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

6. Claim 33 is rejected under 35 U.S.C. § 103 as being unpatentable over Angel in view of Kroll ('219).

Angel does not explicitly discuss the use of truncated exponential biphasic waveforms. Kroll, however, teaches that such pulses (note Fig. 4) have been used extensively in defibrillators due to their proven effectiveness (col. 2, lines 17-19). Any ordinarily skilled artisan desiring to maximize the efficiency and effectiveness of defibrillation, would have seen the obviousness of employing such a ubiquitous waveform in the system of Angel as taught by Kroll.

Regarding the charging steps, applicants should note col. 3, lines 37-54 and col. 10, lines 50-59 of Angel.

Allowable Subject Matter

7. Claims 1-12 and 26-32 are allowable over the prior art of record.

8. Claims 17 and 19-25 would be allowable if rewritten to overcome the rejection under 35 U.S.C. § 112 and to include all of the limitations of the base claim and any intervening claims.

9. Claim 34 would be allowable if rewritten or amended to overcome the rejection under 35 U.S.C. § 112.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ken Schaetzle whose telephone number is (703) 308-2211.

Ken Schaetzle
AU 3305
April 3, 1995

TO SEPARATE, HOLD TOP AND BOTTOM EDGES, SNAP–APART AND REMOVE CARBON

FORM PTO-892 (REV. 2-92) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	SERIAL NO.	GROUP ART UNIT	ATTACHMENT TO PAPER NUMBER
NOTICE OF REFERENCES CITED	08/227 553	3305	5
	APPLICANT(S) Cameron et al.		

U.S. PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
	A	5230336	7-1993	Fain et al.	607	007	
	B	5372606	12-1994	Lang et al.	607	008	
	C	3862636	1-1975	Bell et al.	607	005	
	D	3782389	1-1974	Bell	607	008	
	E	3860009	1-1975	Bell et al.	607	008	
	F	4023573	5-1977	Pantridge et al.	607	005	
	G	3886950	6-1975	Ukkestad et al.	607	005	
	H	5249573	10-1993	Fincke et al.	607	006	
	I						
	J						
	K						

FOREIGN PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUB-CLASS	PERTINENT SHTS. DWG	PERTINENT PP. SPEC.
	L								
	M								
	N								
	O								
	P								
	Q								

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	R	
	S	
	T	
	U	

EXAMINER	DATE
K. Schaetzle	3-20-95

* A copy of this reference is not being furnished with this office action.
(See Manual of Patent Examining Procedure, section 707.05 (a).)

Form PTO 948 (Rev. 10-93) U.S. DEPARTMENT OF COMMERCE - Patent and Trademark Office Application No. 227 583

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) 4/4/94, are
A. ___ not objected to by the Draftsperson under 37 CFR 1.84 or 1.152.
B. X 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.

2. PHOTOGRAPHS. 37 CFR 1.84(b)
   ___ Photographs are not acceptable until petition is granted.

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(e)
   ___ Paper not flexible, strong, white, smooth, nonshiny, and durable. Sheet(s)___
   ___ Erasures, alterations, overwritings, interlineations, cracks, creases, and folds not allowed. Sheet(s)___

5. SIZE OF PAPER. 37 CFR 1.84(f): Acceptable paper 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 cm. X 29.7 cm. (DIN Size A4)
T	5.1 cm. (2")	2.5 cm. (1")	2.5 cm. (1")	2.5cm.
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)___
   ___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. Fig(s)___
   ___ Views contain center lines. Fig(s)___

Partial views. 37 CFR 1.84(h)(2)
   ___ Separate sheets not linked edge to edge. Fig(s)___
   ___ View and enlarged view not labeled separately. Fig(s)___
   ___ Long view relationship between different parts not clear and unambiguous. 37 CFR 1.84(h)(2)(ii). Fig(s)___

Sectional views. 37 CFR 1.84(h)(3)
   ___ Hatching not indicated for sectional portions of an object. Fig(s)___
   ___ Hatching of regularly spaced oblique parallel lines not spaced sufficiently. Fig(s)___
   ___ Hatching not at substantial angle to surrounding axes or principal lines. Fig(s)___
   ___ Cross section not drawn same as view with parts in cross section with regularly spaced parallel oblique strokes. Fig(s)___
   ___ Hatching of juxtaposed different elements not angled in a different way. Fig(s)___

Alternate position. 37 CFR 1.84(h)(4)
   ___ A separate view required for a moved position. Fig(s)

Modified forms. 37 CFR 1.84(h)(5)
   ___ Modified forms of construction must be shown in separate views. Fig(s)___

8. ARRANGEMENT OF VIEWS. 37 CFR 1.84(i)
   ___ View placed upon another view or within outline of another. Fig(s)___
   ___ Words do not appear in 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 without 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)___
   ___ Elements of same view not in proportion to each other. Fig(s)___

10. CHARACTER OF LINES, NUMBERS, & LETTERS. 37 CFR 1.84(l)
   X Lines, numbers & letters not uniformly thick and well defined, clean, durable, and black (except for color drawings). Fig(s) 1 — 6

11. SHADING. 37 CFR 1.84(m)
   ___ Shading used for other than shape of spherical, cylindrical, and conical elements of an object, or for flat parts. Fig(s)___
   ___ Solid black shading areas not permitted. 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)(l) Fig(s)___
   ___ Numbers and reference characters used in conjuction with brackets, inverted commas, or enclosed within outlines. 37 CFR 1.84(p)(l) Fig(s)___
   ___ Numbers and reference characters not oriented in same direction as the view. 37 CFR 1.84(p)(l) 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)___

13. LEAD LINES. 37 CFR 1.84(q)
   ___ Lead lines cross each other. Fig(s)___
   ___ Lead lines missing. Fig(s)___
   ___ Lead lines not as short as possible. Fig(s)___

14. NUMBERING OF SHEETS OF DRAWINGS. 37 CFR 1.84(t)
   ___ Number appears in top margin. Fig(s)___
   ___ Number not larger than reference characters. Fig(s)___
   ___ 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)___
   ___ Single view contains a view number and the abbreviation Fig.
   ___ Numbers not larger than reference characters. Fig(s)___

16. CORRECTIONS. 37 CFR 1.84(w)
   ___ Corrections not durable and permanent. 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)___

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address : COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/227,553	04/14/94	CAMERON D	241082000620

33M1/0505

JAMES R. SHAY
MORRISON & FOERSTER
755 PAGE MILL ROAD
PALO ALTO, CA 94304-1018

EXAMINER	
SCHAETZLE K.	
ART UNIT	PAPER NUMBER
3305	6

DATE MAILED: 05/05/95

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents.

As per your request of May 2, 1995, please find enclosed a copy of the recited Angel reference and its corresponding citation on the supplemental PTO-892 form.

KA
5-2-95

TO SEPARATE, HOLD TOP AND BOTTOM EDGES, SNAP–APART AND REMOVE CARBON

FORM PTO-892 (REV. 2-92)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	SERIAL NO.	GROUP ART UNIT	ATTACHMENT TO PAPER NUMBER	
NOTICE OF REFERENCES CITED		08/227 553	3305		6
		APPLICANT(S) Cameron et al.			

U.S. PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
	A	4473078	9-1984	Angel	607	6	
	B						
	C						
	D						
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	K						

FOREIGN PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUB-CLASS	PERTINENT SHTS. DWG	PERTINENT PP. SPEC.
	L								
	M								
	N								
	O								
	P								
	Q								

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	R	
	S	
	T	
	U	

EXAMINER	DATE	
K. Schaetzle	5-2-95	

* A copy of this reference is not being furnished with this office action.
(See Manual of Patent Examining Procedure, section 707.05 (a).)

PATENT
Atty Dkt 241082000620

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 June 23, 1995

6/23/95
Date

Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

David Cameron, et al.

Serial No.: 08/227,553 Group Art Unit: 3305

Filing Date: April 14, 1994 Examiner: K. Schaetzle

Title: ELECTROTHERAPY METHOD AND APPARATUS

7/6 DJ 7/25

AMENDMENT UNDER 37 CFR § 1.111

RECEIVED
JUL 2 1 1995
GROUP 3300

Assistant Commissioner
for Patents
Washington, D.C. 20231

Dear Sir:

AMENDMENT

In response to the Office Action mailed April 11, 1995, please amend this application as follows:

IN THE CLAIMS:

In claim 13, line 8, please insert --and the electrodes-- after "energy source".

In claim 14, line 4, delete "second".

Please rewrite claim 17 as follows:

-1-

15. ~~17~~. (Amended) A method for applying electrotherapy to a patient through electrodes connected to an energy source, the method comprising the following steps:

charging the energy source to an initial level;

discharging the energy source across the electrodes to deliver electrical energy to the patient in a truncated exponential biphasic waveform;

monitoring an electrical parameter during the discharging step;

adjusting the tilt of the waveform based on the value of the monitored electrical parameter, the adjusting step comprising controlling the duration of a waveform phase based on a value of the electrical parameter [The method of claim 16] wherein the relative duration of the phases of the waveform is dependent on the value of the monitored electrical parameter.

Please rewrite claim 20 as follows:

18. ~~20~~. (Amended) The apparatus of claim ~~19~~ 17 [further comprising] wherein the electrical parameter monitor comprises a charge sensor providing information to the controller related to charge delivered by the energy source to the electrodes.

Please rewrite claim 33 as follows:

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

charging the energy source to an initial level prior to detecting a need to apply a shock to a patient;

determining the need to apply a shock to a patient;

charging the energy source to a second level greater than the initial level;

discharging the energy source across the electrodes to deliver electrical energy to the patient in a truncated exponential biphasic waveform.

In claim 34, lines 5-6, delete "across the electrodes".

Please add the following new claims:

-- 27. ~~29.~~ ~~35.~~ The defibrillator of claim ~~26~~ 24 wherein the energy source comprises primary cell batteries.

28. ~~30.~~ ~~36.~~ The defibrillator of claim ~~29~~ 27 wherein the primary cell batteries comprise lithium-manganese dioxide primary batteries.

29. ~~31.~~ ~~37.~~ The defibrillator of claim ~~26~~ 24 wherein the connecting mechanism and the controller comprise means for delivering a multiphasic waveform without the use of an inductor.

30. ~~32.~~ ~~38.~~ The defibrillator of claim ~~26~~ 24 wherein the energy source comprises a capacitor, the defibrillator further comprising a capacitor precharge circuit.

31. ~~33.~~ ~~39.~~ The defibrillator of claim ~~26~~ 24 further comprising an ECG system.

32. 34. 40. The defibrillator of claim 33 31 further comprising an LCD display.

33. 35. 41. The defibrillator of claim 34 32 further comprising a PCMCIA memory card.

34. 36. 42. The defibrillator of claim 35 33 further comprising means for displaying ECG information stored in the PCMCIA card on the LCD display.

37. 38. 43. The defibrillator of claim 37 36 wherein the energy source comprises primary cell batteries.

Q4

38. 39. 44. The defibrillator of claim 38 37 wherein the primary cell batteries comprise lithium-manganese dioxide primary batteries.

39. 40. 45. The defibrillator of claim 37 36 wherein the connecting mechanism and the controller comprise means for delivering a multiphasic waveform without the use of an inductor.

40. 41. 46. The defibrillator of claim 37 36 wherein the energy source comprises a capacitor, the defibrillator further comprising a capacitor precharge circuit.

41. 42. 47. The defibrillator of claim 37 36 further comprising an ECG system.

42. 43. 48. The defibrillator of claim 42 41 further comprising an LCD display.

43. 44. 43 42

~~49~~. The defibrillator of claim ~~48~~ further comprising a PCMCIA memory card.

44. 45. 44 43

~~50~~. The defibrillator of claim ~~49~~ further comprising means for displaying ECG information stored in the PCMCIA card on the LCD display.

13.

~~51~~. The method of claim 1 wherein the shaping step is performed without the use of an inductor.

14.

~~52~~. The method of claim 1 wherein the initial level is an initial discharge level, the method further comprising the step of precharging the energy source to a level less than the initial discharge level prior to the step of charging the energy source to the initial discharge level.

53. The method of claim 14 wherein the step of removing the additional impedance from the electrical pathway is performed prior to the end of the discharging step.

54. The method of claim 33 wherein the first charging step is performed in response to activation of a defibrillator.

47. 48.

~~55~~. A method for applying electrotherapy to a patient through electrodes connected to an energy source, the method comprising the following steps:

charging the energy source to an initial level;

maintaining the charge of the energy source at the initial level;

determining the need to apply a shock to a patient;

charging the energy source to a second level greater than the initial level;

discharging the energy source across the electrodes to deliver electrical energy to the patient.

48. 49. ~~56~~. The method of claim ~~55~~ 48 47 wherein the initial level is below a charge level that could harm a patient.

G4

49. 50. ~~57~~. The method of claim ~~58~~ 48 47 wherein the first charging step is performed in response to activation of a defibrillator.

50. 51. ~~58~~. The method of claim ~~55~~ 48 47 wherein the discharging step comprises the step of discharging the energy source across the electrodes to deliver electrical energy to the patient in a truncated exponential biphasic waveform. --

REMARKS

This Amendment responds to the Office Action dated April 11, 1995. Claims 1-58 are pending after entry of the Amendment.

Claim Rejections Under 35 U.S.C. § 112

The Examiner rejected claims 14, 16-25 and 34 under 35 U.S.C. § 112 as being indefinite. With respect to claim 14, the Examiner pointed out that the recited "second defined range" was vague since no first defined range had been recited. Applicants have deleted "second" from claim 14 so that the claim now refers only to a defined range

without ranking it first or second. Claim 14 meets the requirements of 35 U.S.C. § 112.

With respect to claim 16, the Examiner suggested insertion of "further" after the word "step" on line 2 of the claim. Controlling the duration of a waveform phase, however, is one way to adjust the tilt of the waveform. Claim 16 therefore properly recites this method step. The rejection of claims 16 and 17 under § 112 should therefore be withdrawn.

The Examiner suggested that claim 18's recitation of an apparatus for administering electrotherapy is incomplete. Applicants have amended claim 18 to include an electrical parameter monitor. A conforming amendment has also been made to claim 20. Claim 18 and the claims depending from it meet the requirements of § 112.

Finally, the Examiner correctly noted that Applicants recitation of "the electrodes" in claim 34 lacked antecedent basis. Applicants have therefore deleted this recitation from the claim. Claim 34 meets the requirements of § 112.

Rejection Under 35 U.S.C. § 102(b) Over Bell et al.

The Examiner rejected claims 13 and 14 under 35 U.S.C. § 102(b) as being anticipated by Bell et al. The Examiner listed two Bell et al. references on the accompanying form PTO-892: Bell et al. U.S. Patent No. 3,862,636 and Bell et al. U.S. Patent No. 3,860,009. Applicants assume the Examiner's rejection is based on either reference.

Bell et al. '636 describes an external defibrillator which can be set to deliver a fixed amount of energy to a patient. The defibrillator uses current and

voltage monitors to compute energy delivered to the patient and halts energy delivery when the preset energy level has been reached. Bell et al. '009 adds a resistance monitor (in the form of a high impedance oscillator) to determine the patient resistance so that the current delivered to the patient can be adjusted automatically. Neither of these references anticipates claims 13 and 14.

Claim 13 recites a step of discharging the energy source across electrodes to deliver electrical energy to the patient through a circuit comprising the energy source, the patient and an additional impedance. The Examiner asserts that the Bell et al. electrodes are the recited "additional impedance." It is clear from claim 13's recitation of an impedance that this element is not the electrodes, which were recited earlier in the claim. Nonetheless, in an effort to make this point even more clearly, Applicants have amended claim 13 to point out that the recited impedance is an element separate from the electrodes and that the impedance forms a circuit with the patient, the energy source and the electrodes. The Bell et al. references lack this additional impedance. Claim 13, as amended, therefore defines over either Bell et al. reference, and claims 13, 14 and 53 are therefore allowable over the prior art of record under § 102(b).

Claim 14, as amended, further limits claim 13 by requiring the additional impedance to be removed if the monitored electrical parameter is within a predetermined range. Neither Bell et al. reference discloses an additional impedance that is used in this way. Claim 14 therefore defines over both Bell et al. references for this reason as well.

New claim 53 depends from claim 14 and requires that the impedance removal step be performed prior to the end of the discharging step. Nothing in either Bell et al. reference teaches or suggests this additional limitation. Claim 53 is therefore allowable over the Bell et al. references.

Rejection Under 35 U.S.C. § 102(e) Over Lang et al.

The Examiner rejected claims 15 and 16 under 35 U.S.C. § 102(e) as being anticipated by Lang et al. In doing so, the Examiner noted that he did not have access to the parent case, S.N. 08/103,837, to determine the effective filing date of the claims. In a recent telephone conversation with the undersigned attorney, Examiner Schaetzle confirmed that the parent case has now been found. Applicants respectfully suggest that the Examiner will find that these claims are fully supported by the disclosure of the parent case, which has a filing date prior to the filing date of the Lang et al. reference. The rejection of claims 15 and 16 over Lang et al. is therefore improper and should be withdrawn.

Rejection Under 35 U.S.C. § 103

The Examiner rejected claim 33 under 35 U.S.C. § 103 over "Angel" in view of "Kroll '219". While Applicants were able to determine that "Kroll '219" must be Kroll U.S. Patent No. 5,334,219, Applicants were unable to determine what "Angel" referred to. At Applicants' request, the Examiner sent a copy of Angel U.S. Patent No. 4,473,078 and an accompanying form PTO-892 citing this reference. Applicants now request the Examiner to confirm that U.S. Patent No. 5,334,219 is the reference relied upon by the

Examiner in his rejection and to cite this reference on a form PTO-892.

Angel describes a defibrillator which supplies a shock to a patient when the patient has stopped breathing for 12 seconds and the identification of three occurrences of tachycardia and/or ventricular fibrillation during the 12 second period. Time between identification of the need for defibrillation and application of therapy is minimized in Angel's device by beginning the capacitor charging process at the time of the second indication of tachycardia or ventricular fibrillation.

Kroll describes an implantable defibrillator employing a truncated exponential biphasic waveform. Kroll does not describe any precharge step in using his device.

Claim 33, as amended, requires that the precharging step occur prior to detecting a need to apply a shock to a patient. Angel, on the other hand, does not begin precharging until tachycardia and/or ventricular fibrillation has been detected. Since Kroll '219 does not even suggest precharging, claim 33, as amended, is allowable over Angel and Kroll '219 under § 103.

New claim 54 depends from and further limits claim 33 by requiring the first charging step to be performed in response to activation of a defibrillator. This limitation is neither disclosed nor suggested by Angel or Kroll '219. New claim 54 is allowable over the prior art of record.

New independent claim 55 recites a method for applying electrotherapy to a patient through electrodes connected to an energy source comprising the steps of charging the energy source to an initial level; maintaining the charge of the energy source at the initial level; determining the need to apply a shock to a patient; charging

the energy source to a second level greater than the initial level; and discharging the energy source across the electrodes to deliver electrical energy to the patient. Neither Angel nor Kroll '219 suggest that there be any precharging to an initial level which is maintained prior to determining the need to apply a shock. New claim 55 is allowable over these references and the other prior art of record.

Claim 56 depends from claim 55 and limits the initial charge level to one that could not harm a patient. Claim 57 depends from claim 55 and requires the first charging step to be performed in response to activation of a defibrillator. Claim 58 depends from claim 55 and requires that the discharging step deliver a truncated exponential biphasic waveform. These claims are allowable over the prior art for the reasons stated above.

Allowable Subject Matter

The Examiner indicated that claims 1-12 and 26-32 are allowable over the prior art of record. Applicants have added new claims 35-42 depending from allowed claim 28, new claims 43-50 depending from allowed claim 32, and new claims 51-52 depending from allowed claim 1. Applicants respectfully suggest that these new claims are allowable as well.

The Examiner also indicated that claim 17 would be allowable if rewritten in independent form. Applicants have therefore amended claim 17 to incorporate the limitations of claims 15 and 16. Claim 17 is now therefore allowable over the prior art of record.

Finally, the Examiner indicated that claim 34 would be allowable if amended to overcome the § 112 rejection.

Applicants have done so, as discussed above. Claim 34 is therefore now allowable over the prior art of record.

CONCLUSION

For the reasons stated above, claims 1-58 meet the formal requirements of 35 U.S.C. § 112 are allowable over the prior art of record. Applicants respectfully request the Examiner to allow the claims and to pass this case to issue.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to our Deposit Account No. 03-1952. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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

Date: 6/23/95

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UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
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Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/227,553	04/14/94	CAMERON D	241082000620

EXAMINER
SCHAEFER

33M1/1013

JAMES R. SHAY
MORRISON & FOERSTER
755 PAGE MILL ROAD
PALO ALTO, CA 94304-1018

ART UNIT	PAPER NUMBER
3305	8

DATE MAILED: 10/13/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 7-21-95 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 1-58 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.
3. ☒ Claims 1-12, 17, 26-58 are allowed.
4. ☒ Claims 13-16 & 18-25 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Part III DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 18-25 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The correction to claim 18 discussed by the attorney in the Remarks associated with the rejection of April 11, 1995 was not included in the amendment. The correction discussed on page 7 of the Remarks would be approved by the examiner if submitted with the next response.

Double Patenting

2. 35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

3. Claim 15 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 43 of copending application Serial No. 08/103,837 in view of Bach, Jr.

This is a *provisional* obviousness-type double patenting rejection.

The use of truncated exponential biphasic waveforms in the defibrillator art is well-known and commonly employed to effectively revert cardiac arrhythmias (note Bach, Jr.). Furthermore, any artisan desiring to adjust the discharge waveform based on a monitored electrical parameter, would have seen the obviousness of utilizing a patient-dependent electrical parameter as such utilization allows one to tailor the discharge to the individual charge recipient. The monitorization of exponential discharge decay voltage --known to be a patient-dependent electrical parameter-- is old in the art as evidenced by Bach, Jr.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 13 and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Bell et al. ('009).

Regarding claim 13, the examiner considers the impedance of the leads to constitute an additional impedance.

Concerning claim 14, the leads of Bell et al. are effectively removed from the electrical pathway when the measured

energy equals the pre-selected value for this parameter, or more practically, when the measured energy falls within a range of significant digits close enough to the pre-selected value to be considered statistically equivalent by the energy computer.

6. Claims 15 and 16 are rejected under 35 U.S.C. § 102(b) as being anticipated by Bach, Jr.

The adjustment of tilt is enacted via the control of pulse duration as a function of capacitor voltage exponential decay as monitored during discharge.

Response to Amendment

Concerning claims 13 and 14, the examiner considers an electrode to be distinct from a lead. Such a distinction means that the examiner can still consider the leads to be representative of the additional impedance. As claimed, one could also consider the additional impedance limitation of claim 13 to be met by any inherent internal defibrillator device impedance (attention is invited to the circuit modeling of Lerman ('810) col. 5, lines 16-19).

Allowable Subject Matter

7. Claims 1-12, 17, 26-58 are allowable over the prior art of record.

8. Claims 18-25 would be allowable if rewritten or amended to overcome the rejection under 35 U.S.C. § 112.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ken Schaetzle whose telephone number is (703) 308-2211.

K.S.
October 2, 1995

WILLIAM E. KAMM
PRIMARY EXAMINER
ART UNIT 335

FORM PTO-892 (rev daw 7-94)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	SERIAL NUMBER 08/ 227,553	GROUP ART UNIT 3305	Attachment to Paper Number	8
NOTICE OF REFERENCES CITED		APPLICANT(S) Cameron et al.			

U.S. PATENT DOCUMENTS

*		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	Filing date
	A	5,411,526	5/1995	Kroll et al.	607	5	3/1992
	B	5,334,430	9/1994	Berg et al.	607	7	4/1993
	C	5,097,833	3/1992	Campos	607	46	
	D						
	E						
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	G						
	H						
	I						
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FOREIGN PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUBCLASS
	L						
	M						
	N						
	O						
	P						
	Q						
	R						
	S						

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	T	
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	V	
	W	

EXAMINER	DATE	
K. Schaetzle	10/2/95	

* A copy of this reference is not being furnished with this Office Action.
(See Manual of Patent Examining Procedure, section 707.05 (a).)

HEARTSTREAM

Facsimile Cover Sheet

To: Mrs. Watson
Company: USPTO
Phone: 703.305.8140
Facsimile: 703.308.6672

From: Cecily Anne Snyder
Phone: 206-834-7630
Facsimile: 206-834-9694

Date: 29 Sep 97
Pages including this cover page: 2

Comments:

Attached is a copy of the 892 prepared by Examiner Schaetzle, which was attached to Paper No. 8.

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#9

Interview Summary	Application No. 08/227,553	Applicant(s) Cameron et al.
	Examiner Ken Schaetzle	Group Art Unit 3305

All participants (applicant, applicant's representative, PTO personnel):

(1) *Ken Schaetzle* (3) _____

(2) *James Shay* (4) _____

Date of Interview *Jan 17, 1996*

Type: ☒ Telephonic ☐ Personal (copy is given to ☐ applicant ☐ applicant's representative).

Exhibit shown or demonstration conducted: ☐ Yes ☒ No. If yes, brief description:

Agreement ☐ was reached. ☒ was not reached.

Claim(s) discussed: *15 and 16*

Identification of prior art discussed:
Bach, Jr.

Description of the general nature of what was agreed to if an agreement was reached, or any other comments:
Attorney stated that, according to the definition of tilt as disclosed in the specification, Bach, Jr. shows a fixed tilt discharge. Examiner agreed that if such a definition were used to define the Bach, Jr. discharge, it would appear that the reference shows a fixed tilt waveform. Double patenting rejection also briefly discussed. Attorney will consolidate subject matter in one application.

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendents which would render the claims allowable is available, a summary thereof must be attached.)

1. ☐ It is not necessary for applicant to provide a separate record of the substance of the interview.

Unless the paragraph above has been checked to indicate to the contrary, A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a response to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW.

2. ☐ Since the Examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections and requirements that may be present in the last Office action, and since the claims are now allowable, this completed form is considered to fulfill the response requirements of the last Office action. Applicant is not relieved from providing a separate record of the interview unless box 1 above is also checked.

Examiner Note: You must sign and stamp this form unless it is an attachment to a signed Office action.

U. S. Patent and Trademark Office

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PATENT
Docket No. 241082000620

CERTIFICATE OF MAILING BY "FIRST CLASS MAIL"

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 January 24, 1996.

Christian Neville

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

David Cameron et al.

Serial No.: 08/227,553

Filing Date: April 14, 1994

For: ELECTROTHERAPY METHOD AND APPARATUS

Examiner: K. Schaetzle

Group Art Unit: 3305

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GROUP 330

#10

PETITION FOR EXTENSION OF TIME

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

The following extension of time is requested in response to the Office Action dated October 13, 1995.

☒ One month from January 13, 1996 to February 13, 1996. The extension fee is $55.00.

☒ A check in the amount of $88.00 ($55.00 + $33.00) is attached to transmittal.

00 03 02/06/96 08227553
01 FC 55.00 CH

sf-75589

The Assistant Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 that 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.

Dated: January 24, 1996

Respectfully submitted,

By: Stuart P. Kaler

Stuart P. Kaler
Registration No. 35,913

Morrison & Foerster LLP
345 California Street
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PATENT
Docket No. 241082000620

CERTIFICATE OF MAILING BY "FIRST CLASS MAIL"

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Christian Neville

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#11

In the application of:

DAVID CAMERON et al.

Serial No.: 08/227,553

Filing Date: April 14, 1994

For: ELECTROTHERAPY METHOD AND APPARATUS

Examiner: K. Schaetzle

Group Art Unit: 3305

TC/

2-9

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GROUP 300

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

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

In addition to the information cited in the Information Disclosure Statement dated June 14, 1994 and the Supplemental Information Disclosure Statement dated January 3, 1996, the citations listed below are submitted in connection with the examination of the above-identified application. Copies of the information and completed PTO-1449 forms are submitted herewith. The Examiner is requested to make this information of record in the application. The information includes: dans subclass

02/06/96 08227553
210.00 CR

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. 4,419,998 to Heath (12/13/83).

U.S. Patent No. 4,494,552 to Heath (01/22/85).

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. 4,800,883 to Winstrom (01/31/89).

U.S. Patent No. 4,821,723 to Baker, Jr. et al. (04/18/89).

U.S. Patent No. 4,848,345 to Zenkich (07/18/89).

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).

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U.S. Patent No. 5,207,219 to Adams et al. (05/04/93).

U.S. Patent No. 5,222,492 to Morgan et al. (06/29/93).

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U.S. Patent No. 5,370,664 to Morgan et al. (12/06/94).

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).

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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).

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Tang et al., "Ventricular defibrillation using biphasic waveforms of different phasic duration," PACE, 10: abstract no. 47 (March-April 1987).

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

Walcott et al., "Comparison of monophasic, biphasic, and the edmark waveform for external defibrillation," PACE, 15:563, abstract 218 (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., 72:384, 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).

This Information Disclosure Statement is submitted before receipt of the final Office Action and the Notice of Allowance, but after three months of the filing date and the mailing date of the first office Action in this application. Therefore, applicant is enclosing the $210.00 filing fee that is due. However, the Assistant Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16, 1.17, and 1.21 which may be required by this paper, or to credit any overpayment, to **Deposit Account No. 03-1952**.

Applicant would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the references have been considered and made of record herein.

This Supplemental 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: January 24, 1996

Respectfully submitted,

By: Stuart P. Kaler

Stuart P. Kaler
Registration No. 35,913
Filed under § 1.34(a)

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Form PTO-1449

INFORMATION DISCLOSURE CITATION IN AN APPLICATION
(Use several sheets if necessary)

Docket Number 241082000620	Application Number 08/227,553
Applicant: DAVID CAMERON	
Filing Date April 14, 1994	Group Art Unit 3305

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U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
KS	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.	12/13/83	4,419,998	Heath			
	5.	01/22/85	4,494,552	Heath			
	6.	10/28/86	4,619,265	Morgan et al.			
	7.	01/20/87	4,637,397	Jones et al.			
	8.	01/31/89	4,800,883	Winstrom			
	9.	04/18/89	4,821,723	Baker, Jr. et al.			
	10.	07/18/89	4,848,345	Zenkich			
	11.	09/04/90	4,953,551	Mehra et al.			
	12.	03/12/91	4,998,531	Bocchi et al.			
	13.	01/07/92	5,078,134	Heilman et al.			
	14.	01/28/92	5,083,562	de Coriolis et al.			
	15.	05/12/92	5,111,816	Pless et al.			
	16.	05/04/93	5,207,219	Adams et al.			
	17.	06/29/93	5,222,492	Morgan et al.			
	18.	08/02/94	5,334,219	Kroll			
KS	19.	12/06/94	5,370,664	Morgan et al.			

EXAMINER: K. Schaetzle DATE CONSIDERED: 4-12-96

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 241082000620	Application Number 08/227,553
INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Applicant	DAVID CAMERON
(Use several sheets if necessary)	Filing Date April 14, 1994	Group Art Unit 3305

FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES	Translation NO
KS	20.	10/13/94	94/22530	WO				
	21.	09/29/94	94/21327	WO				
	22.	09/02/93	93/16759	WO				
	23.	09/07/88	0,281,219	EP				
	24.	02/07/90	0,353,341	EP				
	25.	07/17/91	0,437,104	EP				
	26.	10/07/92	0,507,504	EP				
	27.	09/09/81	2,070,435	GB				
	28.	03/24/82	2,083,363	GB				

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Form PTO-1449	Docket Number 241082000620	Application Number 08/227,553
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(Use several sheets if necessary)	Filing Date April 14, 1994	Group Art Unit 3305

OTHER DOCUMENTS *(including author, title, Date, Pertinent Pages, Etc.)*

Examiner Initials	Ref. No.	Title
	29	Alferness et al., "The influence of shock waveforms on defibrillation efficacy," IEEE Engineering in Medicine and Biology, pp. 25-27 (June 1990).
	30	Anderson et al., "The efficacy of trapezoidal wave forms for ventricular defibrillation," Chest, 70(2):298-300 (1976).
	31	Blilie et al., "Predicting and validating cardiothoracic current flow using finite element modeling," PACE, 15:563, abstract 219 (April 1992).
	32	Chapman et al., "Non-thoracotomy internal defibrillation: Improved efficacy with biphasic shocks," Circulation, 76:312, abstract no. 1239 (1987).
	33	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).
	34	Cooper et al., "The effect of phase separation on biphasic waveform defibrillation," PACE, 16:471-482 (March 1993).
	35	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).
	36	Crampton et al., "Low-energy ventricular defibrillation and miniature defibrillators," JAMA, 235(21):2284 (1976).
	37	Dahlbäck et al., "Ventricular defibrillation with square-waves," The Lancet (July 2, 1966).
	38	Echt et al., "Biphasic waveform is more efficacious than monophasic waveform for transthoracic cardioversion," PACE, 16:914, abstract no. 256 (April 1993).
	39	Feeser et al., "Strength-duration and probability of success curves for defibrillation with biphasic waveforms," Circulation, 82(6):2128-2141 (1990).
	40	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).
	41	Jones et al., "Decreased defibrillator-induced dysfunction with biphasic rectangular waveforms," Am. J. Physiol., 247:H792-796 (1984).

EXAMINER: K. Schaetzle	DATE CONSIDERED: 4-12-96

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Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION *(Use several sheets if necessary)*	Docket Number 241082000620	Application Number 08/227,553
	Applicant DAVID CAMERON	
	Filing Date April 14, 1994	Group Art Unit 3305

OTHER DOCUMENTS *(including author, title, Date, Pertinent Pages, Etc.)*

Examiner Initials	Ref. No.	Title
	42	Jones et al., "Defibrillator waveshape optimization," Devices and Tech. Meeting, NIH (1982).
	43	Jones et al., "Improved defibrillator waveform safety factor with biphasic waveforms," Am. J. Physiol., 245:H60-65 (1983).
	44	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).
	45	Jude et al., "Fundamentals of Cardiopulmonary Resuscitation," F.A. Davis Company, Philadelphia PA, pp. 98-104 (1965).
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	51	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).
	52	Mirowski et al., "Clinical treatment of life threatening ventricular tachyarrhythmias with the automatic implantable defibrillator," American Heart Journal, 102(2):265-270 (1981).
	53	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).

EXAMINER: K. Schaefle	DATE CONSIDERED: 4-12-96

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Form PTO-1449	Docket Number 241082000620	Application Number 08/227,553
INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Applicant DAVID CAMERON	
(Use several sheets if necessary)	Filing Date April 14, 1994	Group Art Unit 3305

OTHER DOCUMENTS *(including author, title, Date, Pertinent Pages, Etc.)*

Examiner Initials	Ref. No.	Title
	54	Podolsky, "Keeping the beat alive," U.S. News & World Report (July 22, 1991).
	55	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.
	56	Product Brochure for the Shock Advisory System (1987), Physio-Control, 11811 Willows Road Northeast, P.O. Box 97006, Redmond, WA 98073-9706.
	57	Redd (editor), "Defibrillation with biphasic waveform may increase safety, improve survival," Medlines, pp. 1-2 (June-July 1984).
	58	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).
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	60	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).
	61	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).
	62	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).
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Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION *(Use several sheets if necessary)*	Docket Number 241082000620	Application Number 08/227,553
	Applicant DAVID CAMERON	
	Filing Date April 14, 1994	Group Art Unit 3305

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	69	Schuder et al., "Waveform dependency in defibrillating 100 kg Calves," Devices & Tech. Meeting NIH (1982).
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	72	Tang et al., "Strength duration curve for ventricular defibrillation using biphasic waveforms," PACE, 10: abstract no. 49 (August 1987).
	73	Tang et al., "Ventricular defibrillation using biphasic waveforms of different phasic duration," PACE, 10: abstract no. 47 (March-April 1987).
	74	Tang et al., "Ventricular defibrillation using biphasic waveforms: The importance of phasic duration," JACC, 13(1):207-214 (1989).
	75	Walcott et al., "Comparison of monophasic, biphasic, and the edmark waveform for external defibrillation," PACE, 15:563, abstract 218 (April 1992).
	76	Wathen et al., "Improved defibrillation efficacy using four nonthoracotomy leads for sequential pulse defibrillation," PACE, 15:563, abstract 220 (April 1992).
	77	Wetherbee et al., "Subcutaneous patch electrode - A means to obviate thoracotomy for implantation of the automatic implantable cardioverter defibrillation system?" Circ., 72:384, abstract no. 1536 (1985).
	78	Winkle "The implantable defibrillator in ventricular arrhythmias," Hospital Practice, pp. 149-165 (March 1983).

EXAMINER: K. Schaetzle	DATE CONSIDERED: 4-12-96

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Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION *(Use several sheets if necessary)*	Docket Number 241082000620	Application Number 08/227,553
	Applicant DAVID CAMERON	
	Filing Date April 14, 1994	Group Art Unit 3305

OTHER DOCUMENTS *(including author, title, Date, Pertinent Pages, Etc.)*

Examiner Initials	Ref. No.	Title
	79	Winkle et al., "Improved low energy defibrillation efficacy in man using a biphasic truncated exponential waveform," JACC, 9(2):142A (1987).
	80	Zipes, "Sudden cardiac death," Circulation, 85(1):160-166 (1992).

EXAMINER: K Schaetzle	DATE CONSIDERED: 4-12-96

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GP 3305

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1/24/96
Date

Christian Ne
Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#12 B.D. 2/9

In Re Application of: David Cameron, et al.

Serial No.: 08/227,553 Group Art Unit: 3305

Filing Date: April 14, 1994 Examiner: K. Schaetzle

Title: ELECTROTHERAPY METHOD AND APPARATUS

RECEIVED
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GROUP 3300

AMENDMENT

Assistant Commissioner for Patents
Washington, DC 20231

Dear Sir:

In response to the Office Action mailed October 13, 1995, please amend this application as follows:

IN THE CLAIMS:

Please cancel claims 13-16.

In claim 18, line 9, please insert --an electrical parameter monitor;-- after ";".

Please add the following new claims:

-- 51. 52. 59. A method for applying electrotherapy to a patient through electrodes connected to an energy source, the method comprising the following steps:

charging the energy source to an initial level;

discharging the energy source across the electrodes to deliver electrical energy to the patient in a waveform, the patient and an additional impedance forming an electrical circuit with the energy source;

monitoring an electrical parameter during the discharging step;

removing the additional impedance from the electrical circuit if the electrical parameter is within a defined range prior to the end of the discharging step.

~~52.~~ 53. ~~60.~~ The method of claim ~~59~~ 61 wherein the removing step comprises operating a switch associated with the additional impedance.

53. ~~54.~~ ~~61.~~ A method for applying electrotherapy to a patient comprising the following steps:

discharging an energy source across electrodes to deliver a waveform of electrical energy to the patient;

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

ceasing the monitoring step prior to the end of the discharge step;

adjusting a waveform discharge parameter based on a value of the monitored parameter.

54. ~~55.~~ ~~62.~~ The method of claim ~~61~~ 53 wherein discharging step and the monitoring step begin substantially simultaneously.

55. ~~63.~~ The method of claim ~~61~~ 53 wherein the monitored parameter is time for delivering a predetermined quantity of charge to the patient.

~~56. 57.~~ ~~64.~~ The method of claim ~~63~~ 55 wherein the discharge parameter is waveform duration.

57. ~~58.~~ ~~65.~~ 56 55 The method of claim ~~63~~ wherein the waveform is a biphasic waveform and the discharge parameter is duration of a waveform phase. --

B1

REMARKS

This Amendment responds to the Office Action dated October 13, 1996. Claims 1-12 and 17-65 are pending after entry of the Amendment.

The Rejection

The Examiner rejected claims 18-25 under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants have amended claim 18 to include the recitation of an electrical parameter monitor. These claims now meet the requirements of § 112.

The Examiner provisionally rejected claim 15 under the judicially-created doctrine of obviousness double patenting in view of claim 43 of copending application S.N. 08/103,837. This claim has been canceled.

The Examiner rejected claims 13 and 14 over Bell '009. These claims have been canceled.

The Examiner rejected claims 15 and 16 under 35 U.S.C. § 102 as being anticipated by Bach, Jr. These claims have been canceled.

The New Claims

Applicants have added new claims 59-65. Claim 59 recites a method for applying electrotherapy to a patient including the step of removing the additional impedance from an electrical circuit formed with the patient and the energy source if the monitored electrical parameter is within a defined range prior to the end of the discharging step. Even if, for the sake of argument, the Bell '009 device's leads could be read as the recited "additional impedance" and even if the completion of waveform delivery could be interpreted as removing the leads from the circuit, new claim 59 still defines over Bell '009 by requiring that the monitored electrical parameter be within the defined range--the triggering event for removal of the additional impedance--prior to the end of the

discharging step. Claim 59, and claim 60 which depends from it, are allowable over Bell and the other prior art of record.

New claim 61 recites a method for applying electrotherapy to a patient including the steps of monitoring a patient-dependent electrical parameter during discharge and ceasing the monitoring prior to the end of discharge. New claim 62 depends from claim 61 and requires the discharging step and the monitoring step to begin substantially simultaneously. New claim 63 depends from claim 61 and limits the monitored parameter to time for delivering a predetermined quantity of charge to the patient. New claim 64 depends from claim 63 and limits the discharge parameter to waveform duration. Finally, new claim 65 also depends from claim 63 and limits the waveform to a biphasic waveform (such as, for example, the truncated exponential biphasic waveform disclosed as the preferred embodiment of Applicants' invention), with the discharge parameter being limited to duration of a waveform phase. Support for each of these claims may be found on pages 15-17 of Applicants' specification.

New claims 61-65 define over the prior art of record in this application. For example, while the Bach, Jr., reference describes a device that monitors voltage during discharge, the monitoring does not cease prior to the end of the discharge step. Rather, Bach monitors voltage throughout the entire discharge of each waveform phase. Thus, Bach neither anticipates nor renders obvious the subject matter of claims 61-65.

Prior Art Citations

Applicants submitted on January 3, 1996, a Supplemental Information Disclosure Statement citing the Bach, Jr., reference which had not yet been made of record in this case on either a PTO-892 form or a PTO-1449 form. In addition, Applicants are submitting herewith another Supplemental Information Disclosure Statement citing the Kroll '219 reference on which the Examiner relied in the office action dated April 11, 1995, as well as other references which have not yet been made of record in this case. Applicants respectfully request the Examiner to review the references cited in these Statements and to make them of record in this application.

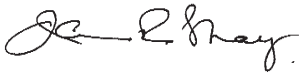
CONCLUSION

For the reasons stated above, claims 1-12 and 17-65 meet the requirements of 35 U.S.C. § 112 and are allowable over the prior art of record. Applicants respectfully request the Examiner to allow the claims and to pass this case to issue.

In the unlikely event that the transmittal letter is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to our Deposit Account No. 03-1952. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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

Respectfully submitted,



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PATENT
Docket No. 241082000620

CERTIFICATE OF MAILING BY "FIRST CLASS MAIL"

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Christian Neville

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

David Cameron et al.

Serial No.: 08/227,553

Filing Date: April 14, 1994

For: ELECTROTHERAPY METHOD AND APPARATUS

Examiner: K. Schaetzle

Group Art Unit: 3305

AMENDMENT TRANSMITTAL

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Transmitted herewith is an Amendment in response to the Office Action dated October 13, 1995 in the above-referenced patent application:

- ☒ A verified Statement of Small Entity Status was previously submitted.
- ☒ A petition for Extension of Time (and $55.00 fee) is enclosed.
- ☐ No additional fee is required.
- ☒ Other enclosures: postcard.

sf-75573

The fee (if any) has been calculated as follows:

FOR	CLAIMS ON FILE AFTER THIS AMENDMENT MINUS HIGHEST NUMBER PREVIOUSLY PAID FOR	NUMBER EXTRA	RATE	CALCULATIONS
TOTAL CLAIMS	61-58	3	x $22.00	$66.00
INDEPENDENT CLAIMS	12-12	0	x $78.00	$0
MULTIPLE DEPENDENT CLAIM(S) (if not previously paid for and presented for the first time)			$250.00	$0
			EXTENSION FEE	$110.00
		TOTAL OF ABOVE CALCULATIONS =		$176.00
Reduction by ½ for filing by small entity (Note 37 C.F.R. §§ 1.9, 1.27, 1.28).				$88.00
			TOTAL =	$88.00

☒ A check in the amount of $88.00 (extension fee included) is attached.

☒ The Assistant Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 and 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.

Dated: January 24, 1996

Respectfully submitted,

By: Stuart P. Kaler

Stuart P. Kaler
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INITIAL REVIEW
JAN 1 1996
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PATENT
Docket No. 241082000620

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Christian Neville

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

DAVID CAMERON et al.

Serial No.: 08/227,553

Filing Date: April 14, 1994

For: ELECTROTHERAPY METHOD AND APPARATUS

Examiner: K. Schaetzle

Group Art Unit: 3305

Supp. I.D.S.
K. Turner
4-4-96
P.# 13

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

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

In addition to the Information Disclosure Statement Under 37 C.F.R. § 1.97 mailed to the PTO on June 14, 1994, the citation listed below is submitted in conjunction with the examination of the above-identified application in compliance with the duty of disclosure as defined in 37 C.F.R. § 1.56. The Examiner is requested to make the following citation of record in the application.

U.S. Patent No. 4,850,357 to Bach, Jr. (07/25/89).

sf-65427

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

Applicant would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the references have 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.

CERTIFICATE OF PROMPT FILING

I hereby certify that to the best of my knowledge, no item of information contained in the Information Disclosure Statement submitted herewith was cited in a communication from a foreign patent office in a counterpart foreign application or was known by any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the enclosed Information Disclosure Statement.

Dated: January 3, 1996

Respectfully submitted,

By: Stuart P. Kaler

Stuart P. Kaler
Registration No. 35,913

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

Form PTO-1449	Docket Number 241082000620	Application Number 08/227,553
INFORMATION DISCLOSURE CITATION IN AN APPLICATION *(Use several sheets if necessary)*	Applicant DAVID CAMERON et al.	
	Filing Date April 14, 1994	Group Art Unit 3305

U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
MB	1.	07/25/89	4,850,357	Bach, Jr.			

FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES	Translation NO
	1.							

OTHER DOCUMENTS *(including author, title, Date, Pertinent Pages, Etc.)*

Examiner Initials	Ref. No.	Title
	1.	

EXAMINER: K Schaetzle	DATE CONSIDERED: 4-8-96

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.

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/227,553	04/14/94	CAMERON D	241082000620

33M1/0419

JAMES R. SHAY
MORRISON & FOERSTER
755 PAGE MILL ROAD
PALO ALTO, CA 94304-1018

EXAMINER	
SCHAETZLE,K	

ART UNIT	PAPER NUMBER
3305	14

DATE MAILED: 04/19/96

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/227,553	Cameron et al.
Examiner	**Group Art Unit**
Ken Schaetzle	3305

☒ Responsive to communication(s) filed on *Jan 29, 1996 and the interview of April 11, 1996*.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-12, 17-30, and 32-65* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) *1-3, 6-12, 17-25, 28-30, and 32-65* is/are allowed.

☒ Claim(s) *4, 5, 26, and 27* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ 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).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *11, 13*

☒ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 4 and 5 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 4, the word "measured" lacks antecedence. As discussed in the interview of April 11, 1996, deletion of the word "measured" would eliminate this error.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 26 is rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Schuder et al. (the article entitled "Comparison of Effectiveness of Relay-Switched, One-Cycle Quasisinusoidal Waveform with Critically Damped Sinusoid Waveform in Transthoracic Defibrillation of 100-Kilogram Calves"). Note in particular Fig. 1.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section

> 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

5. Claim 27 is rejected under 35 U.S.C. § 103 as being unpatentable over Schuder et al. in view of Walcott et al. (the abstract entitled "Comparison of Monophasic, Biphasic, and the Edmark Waveform for External Defibrillation").

Schuder et al. do not discuss the employment of a means for delivering a truncated exponential biphasic waveform from the energy source to the electrodes. Walcott et al., on the other hand, suggest that such a waveform may be superior in certain areas over the damped sinusoidal waveform traditionally used in external defibrillators, and thus may make a good replacement therefor. Clearly the choice of waveform type, and concomitantly the type of means necessary to produce such a waveform, would have been considered an obvious designer's prerogative in view of the teachings of Walcott et al.

Allowable Subject Matter

6. Claims 1-3, 6-12, 17-25, 28-30 and 32-65 are allowable over the prior art of record.

Regarding newly submitted claim 59, the prior art of record fails to teach the step of removing the recited additional impedance from the electrical circuit if the electrical parameter is within a defined range prior to the end of the discharging step.

Concerning newly submitted claim 61, the prior art of record fails to teach the step of adjusting a waveform discharge parameter based on a value of a monitored patient-dependent *electrical* parameter. Note also the attached interview summary in regards to this matter.

7. Claims 4 and 5 would be allowable if rewritten to overcome the rejection under 35 U.S.C. 112 and to include all of the limitations of the base claim and any intervening claims.

Conclusion

8. Regarding claim 31, since the cancellation of said claim was agreed upon in the interview of April 11, 1996 in view of the Kouwenhoven article, for expediency purposes the examiner is treating this claim as cancelled. Any response to the final rejection should include cancellation of claim 31.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ken Schaetzle whose telephone number is (703) 308-2211.

K.S.
April 14, 1996

WILLIAM E. KAMM
PRIMARY EXAMINER
ART UNIT 335

Interview Summary

Application No.	Applicant(s)	
08/227,553	Cameron et al.	
Examiner	Group Art Unit	
Ken Schaetzle	3305	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Ken Schaetzle* (3) _____

(2) *James Shay* (4) _____

Date of Interview *Apr 11, 1996*

Type: ☐ Telephonic ☒ Personal (copy is given to ☐ applicant ☒ applicant's representative).

Exhibit shown or demonstration conducted: ☒ Yes ☐ No. If yes, brief description:
Demonstration of the defibrillator was given showing its size and weight along with the system monitoring feature.

Agreement ☐ was reached. ☒ was not reached.

Claim(s) discussed: *4, 26, 31, and 61-65*

Identification of prior art discussed:
Pless (5,352,239) and the Kouwenhoven article entitled "The Developement of the Defibrillator."

Description of the general nature of what was agreed to if an agreement was reached, or any other comments:
Attorney stated that while the Pless reference measures a patient-dependent parameter, it does not measure a patient-dependent electrical parameter (i.e., charge). Examiner concurred. Examiner referred attorney to the Kouwenhoven article in regards to claim 31 and its reference to an external defibrillator employing an energy of 100J. Attorney agreed to cancel claim 31 in light of Kouwenhoven. Claim 4 also discussed to correct an antecedent basis problem. If the case is subsequently deemed to be allowable, the examiner will make these changes by Examiner's Amendment.

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendents which would render the claims allowable is available, a summary thereof must be attached.)

1. ☐ It is not necessary for applicant to provide a separate record of the substance of the interview.

Unless the paragraph above has been checked to indicate to the contrary, A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a response to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW.

2. ☐ Since the Examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections and requirements that may be present in the last Office action, and since the claims are now allowable, this completed form is considered to fulfill the response requirements of the last Office action. Applicant is not relieved from providing a separate record of the interview unless box 1 above is also checked.

Examiner Note: You must sign and stamp this form unless it is an attachment to a signed Office action.

U.S. Patent and Trademark Office

Notice of References Cited

Application No.	Applicant(s)		
08/227,553	Cameron et al.		
Examiner		Group Art Unit	Page 1 of 1
Ken Schaetzle		3305	

U.S. PATENT DOCUMENTS

	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS
A	5,352,239	10/1994	Pless	607	5
B					
C					
D					
E					
F					
G					
H					
I					
J					
K					
L					
M					

FOREIGN PATENT DOCUMENTS

	DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUBCLASS
N						
O						
P						
Q						
R						
S						
T						

NON-PATENT DOCUMENTS

	DOCUMENT (Including Author, Title, Source, and Pertinent Pages)	DATE
U		
V		
W		
X		

130-122

PATENT
Atty Dkt 241082000620

#15
5/29

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, BOX AF, Washington, D.C. 20231 on May 6, 1996.

Reg No 37448
Cecily Anne Snyder, Reg. No. 37,448

RECEIVED
MAY 10 1996
GROUP 3300

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: David Cameron, et al.

Serial No.: 08/227,553 Group Art Unit: 3305

Filing Date: April 14, 1994 Examiner: K. Schaetzle

Title: ELECTROTHERAPY METHOD AND APPARATUS

EXPEDITED PROCEDURE — GROUP 3305

PETITION TO CONSIDER AN INFORMATION DISCLOSURE STATEMENT
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
AND
CERTIFICATE OF PROMPT FILING

Assistant Commissioner for Patents
BOX AF
Washington, DC 20231

Dear Sir:

Applicants hereby petition, pursuant to 37 C.F.R. § 1.97(d)(2), that the Patent Office consider the Supplemental Information Disclosure Statement incorporated herein. The petition fee of $130.00 is attached hereto.

In addition to the information cited in the Information Disclosure Statement dated June 14, 1994 and the Supplemental Information Disclosure Statements dated January 3, 1996 and January 24, 1996, the citations listed below are submitted in connection with the examination of the above-identified application. Copies of the information and completed PTO-1449 forms are submitted herewith. The Examiner is requested to make this information of record in the application. The information includes:

010 WJ 05/09/96 08227553
130.00 OP

1. Product information for Model H MSA Portable Defibrillator (Bulletin No. 1108-2); 4 pp.
2. Product information for MSA Portable Defibrillator (Bulletin No. 1108-1); 4 pp.

Applicants would appreciate the Examiner initialing and returning the Form PTO-1449 indicating that the references have been considered and made of record.

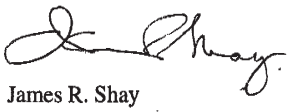
CERTIFICATE OF PROMPT FILING

37 C.F.R. § 1.97(e)(2)

This Information Disclosure Statement is submitted after receipt of the final Office action but before the Notice of Allowance. No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in § 1.56(c) more than three months prior to the filing of this statement.

Please direct all future telephone calls and correspondence 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 LLP
345 California Street
San Francisco, CA 94104
Telephone: (415) 677-6159
Facsimile: (415) 677-7522

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1996
PAT. & TRADEMARK OFF.

Form PTO—1449	Docket Number (Optional)	Application Number
INFORMATION DISCLOSURE CITATION IN AN APPLICATION	24108-20006.20	08/227,553
	Applicant: David Cameron, et al.	
(Use several sheets if necessary)	Filing Date: 14 April 1994	Group Art Unit: 3305

U.S. PATENT DOCUMENTS

Reference No.	Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate

FOREIGN PATENT DOCUMENTS

Reference No.	Examiner Initial	Document Number	Date	Country	Class	Subclass	Translation YES	Translation NO

OTHER DOCUMENTS

Reference No.	Examiner Initial	Title, Date, Pages, etc.
1.	KS	Product information for Model H MSA Portable Defibrillator (Bulletin No. 1108-2); 4 pp.
2.	KS	Product information for MSA Portable Defibrillator (Bulletin No. 1108-1); 4 pp.

Examiner	Date Considered
K. Schaetzle	6-7-96

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

Approved for entry
6-7-96

PATENT
Atty Dkt 241082000620

Initial Review
BOX AF

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, BOX AF, Washington, D.C. 20231 on May 1996.

REG NO 37445
Cecily Anne Snyder, Reg. No. 37,448

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#16/C
5/24

In Re Application of: David Cameron, et al.

Serial No.: 08/227,553 — Group Art Unit: 3305

Filing Date: April 14, 1994 — Examiner: K. Schaetzle

Title: ELECTROTHERAPY METHOD AND APPARATUS — **EXPEDITED PROCEDURE — GROUP 3305**

AMENDMENT UNDER 37 C.F.R. § 1.116

Assistant Commissioner for Patents
BOX AF
Washington, DC 20231

Dear Sir:

In response to the Office Action mailed April 19, 1996, please amend this application as follows:

IN THE CLAIMS:

In claim 4, line 3, delete "measured".

Please cancel claims 26, 27 and 33.

Please add the following new claims:

C

-- 35~~27~~. ~~26~~ 24 ~~66~~. The defibrillator of claim ~~28~~ wherein the energy source comprises a capacitive energy source sized between 60 and 150 microfarads.

C1

45~~47~~. ~~67~~. 3736 The defibrillator of claim ~~32~~ wherein the energy source comprises a capacitive energy source sized between 60 and 150 microfarads. --

REMARKS

This Amendment responds to the Office Action dated April 19, 1996. Claims 1-12, 17-25, 28-30 and 32-67 are pending after entry of the Amendment.

The Interview

Applicants thank the Examiner for the courteous and informative interview conducted with the undersigned attorney on April 11, 1996.

Claims 4 and 5

The Examiner rejected claims 4 and 5 under 35 U.S.C. § 112, second paragraph, as being indefinite. As agreed in the interview, Applicants have amended claim 4 to delete the reference to a "measured" value in order to conform "value" with its antecedent. Claims 4 and 5 now meet the definiteness requirements of § 112.

Claims 26 and 27

The Examiner rejected claim 26 under 35 U.S.C. § 102(b) as being anticipated by Schuder et al.. The Examiner rejected claim 27 under 35 U.S.C. § 103 as being obvious in view of Schuder et al. and Walcott et al. Applicants have canceled these claims.

The New Claims

Applicants have added new claims 66 and 67 depending from independent claims 28 and 32, respectively. Claims 28 and 32 have been allowed by the Examiner. Claims 66 and 67 are therefore allowable as well.

The Finality of the Rejection

Claims 4, 5, 26 and 27 were each in the form originally presented with the application as filed. Since the new basis of rejection of these claims was not necessitated by an amendment of these claims by Applicants, the rejection should not have been made final. See MPEP 706.07(a). Applicants respectfully request the Examiner to withdraw the finality of the rejection should further prosecution on the merits be necessary in this application.

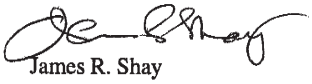
CONCLUSION

For the reasons stated above, claims 1-12, 17-25, 28-30 and 32-67 meet the requirements of 35 U.S.C. § 112 and are allowable over the prior art of record. Applicants respectfully request the Examiner to allow the claims and to pass this case to issue.

In the unlikely event that the transmittal letter is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to our Deposit Account No. 03-1952. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Please direct all future telephone calls and correspondence 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 LLP
345 California Street
San Francisco, CA 94104
(415) 677-6159
Fax: (415) 677-7522

MAIL ROOM
MAY 8 1996
10
PAT. & TRADEMARK OFF.

M 4-19

PATENT
Docket No. 241082000620

Initial Review
BOX AF

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, BOX AF, Washington, D.C. 20231 on May 6 1996.

Reg No 37448
Cecily Anne Snyder, Reg. No. 37,448

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: David Cameron, et al.

Serial No.: 08/227,553 — Group Art Unit: 3305

Filing Date: April 14, 1994 — Examiner: K. Schaetzle

Title: ELECTROTHERAPY METHOD AND APPARATUS — **EXPEDITED PROCEDURE — GROUP 3305**

AMENDMENT TRANSMITTAL

RECEIVED
MAY 1 0 1996
GROUP 3300

Box AF
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Transmitted herewith is an Amendment in response to the Office Action **FINAL** dated **19 April 1996** in the above-referenced patent application:

- ☒ A verified Statement of Small Entity Status was previously submitted on May 26, 1994.
- ☐ A petition for Extension of Time is enclosed.
- ☒ No additional fee is required for the Amendment.
- ☒ Other enclosures:
  1. Petition to Consider an Information Disclosure Statement, Supplemental Information Disclosure Statement and Certificate of Prompt Filing
  2. PTO Form 1449, 2 references
  3. Check in payment of the Petition fee

4. Postcard

The fee (if any) *for the amendment* has been calculated as follows:

FOR	CLAIMS ON FILE AFTER THIS AMENDMENT MINUS HIGHEST NUMBER PREVIOUSLY PAID FOR	NUMBER EXTRA	RATE	CALCULATIONS
TOTAL CLAIMS	61 - 61	0	x $22.00	$ 0.00
INDEPENDENT CLAIMS	12 - 12	0	x $78.00	$ 0.00
MULTIPLE DEPENDENT CLAIM(S) (if not previously paid for and presented for the first time) *			+ $250.00	$ 0.00
			EXTENSION FEE	$ 0.00
		TOTAL OF ABOVE CALCULATIONS =		$ 0.00
Reduction by ½ for filing by small entity (Note 37 C.F.R. §§ 1.9, 1.27, 1.28).				$ 0.00
			TOTAL =	**$ 0.00**

Dated: May 2, 1996

Respectfully submitted,

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

Stuart P. Kaler
Morrison & Foerster LLP
345 California Street
San Francisco, CA 94104
Telephone: (415) 677-7159
Facsimile: (415) 677-7522

MAILED

JUN 6 1996

GROUP 3300

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

#17

In re Application:	:	DECISION ON PETITION
David Cameron et al.	:	UNDER 37 CFR 1.97 FOR
Serial No.: 08/227,553	:	CONSIDERATION OF
Filed: 04/14/94	:	INFORMATION DISCLOSURE
For: Electrotherapy Method And Apparatus	:	STATEMENT AFTER FINAL

The petition under 37 CFR 1.97(d)(2)(ii) for consideration of an information disclosure statement filed after final rejection has been:

[X] GRANTED

[ ] DENIED

The petition lacks:

[ ] The required fee under 37 CFR1.97(d)(2)(ii) and 1.17(i)(1).

[ ] A proper certification as specified in 37 CFR 1.97(d)(2)(i) and 1.97(e).

The Information Disclosure Statement has been placed of record in the file and will not be considered by the examiner.

Marvin M. Lateef
Supervisory Patent Examiner
Art Unit 3305

MML:jfb

James R. Shay
Morrison & Foerster
755 Page Mill Road
Palo, Alto, CA 94304-1018

Notice of Allowability	Application No. 08/227,553	Applicant(s) Cameron 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 telephonic interview of June 10, 1996*.

☒ The allowed claim(s) is/are *1-12, 17-25, 28-30, 32, 34-52, and 55-67*.

☐ 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 lettter 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). 15

☐ 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

MARVIN M. LATEEF
SUPERVISORY PATENT EXAMINER
GROUP 3300

U.S. Patent and Trademark Office

EXAMINER'S AMENDMENT

1. An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Mr. James Shay on June 10, 1996.

2. The application has been amended as follows:

****

Claims

Claims 53 and 54 were cancelled.

In claim 60, line 1, the number "13" was replaced by the number --59--.

****

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ken Schaetzle whose telephone number is (703) 308-2211, and whose SPE is Marvin Lateef. Official communications may be sent by FAX to (703) 305-3590.

K.S.
June 10, 1996

MARVIN M. LATEEF
SUPERVISORY PATENT EXAMINER
GROUP 3300

Interview Summary

Application No.	Applicant(s)
08/227,553	Cameron et al.
Examiner	**Group Art Unit**
Ken Schaetzle	3305

All participants (applicant, applicant's representative, PTO personnel):

(1) *Ken Schaetzle* (3) _____

(2) *James Shay* (4) _____

Date of Interview *Jun 10, 1996*

Type: ☒ Telephonic ☐ Personal (copy is given to ☐ applicant ☐ applicant's representative).

Exhibit shown or demonstration conducted: ☐ Yes ☒ No. If yes, brief description:

Agreement ☒ was reached. ☐ was not reached.

Claim(s) discussed: *53, 54, and 60*

Identification of prior art discussed:
N/A

Description of the general nature of what was agreed to if an agreement was reached, or any other comments:
Proposed corrections to account for 35 U.S.C. § 112 errors agreed to. See Examiner's Amendment.

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendents which would render the claims allowable is available, a summary thereof must be attached.)

1. ☒ It is not necessary for applicant to provide a separate record of the substance of the interview.

Unless the paragraph above has been checked to indicate to the contrary, A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a response to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW.

2. ☒ Since the Examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections and requirements that may be present in the last Office action, and since the claims are now allowable, this completed form is considered to fulfill the response requirements of the last Office action. Applicant is not relieved from providing a separate record of the interview unless box 1 above is also checked.

Examiner Note: You must sign and stamp this form unless it is an attachment to a signed Office action.

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: Box ISSUE FEE
COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

33M1/0617

JAMES R. SHAY
MORRISON & FOERSTER
755 PAGE MILL ROAD
PALO ALTO, CA 94304-1018

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

☐ Note attached communication from the Examiner
☐ This notice is issued in view of applicant's communication filed _____

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
08/227,553	04/14/94	058	SCHAETZLE, K 3305	06/17/96

First Named Applicant: CAMERON, DAVID

TITLE OF INVENTION: ELECTROTHERAPY METHOD AND APPARATUS

	ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
3	241082000620	607-105,000	811	UTILITY	YES	$625.00	09/17/96

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:

A. 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
B. If the Status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:
A. Pay FEE DUE shown above, or
B. File verified statement of Small Entity Status before, or with, pay 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, Part C of this notice should also be completed and returned.

III. All communications regarding this application must give series code (or filing date), serial number and batch number. Please direct all communication prior to issuance to Box ISSUE FEE unless advised to 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.

PATENT AND TRADEMARK OFFICE COPY

PART B—ISSUE FEE TRANSMITTAL

MAILING INSTRUCTIONS: This form should be used for 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.**

1. CORRESPONDENCE ADDRESS	2. INVENTOR(S) ADDRESS CHANGE (Complete only if there is a change)
33M1/0617 JAMES R. SHAY MORRISON & FOERSTER 755 PAGE MILL ROAD PALO ALTO, CA 94304-1018	INVENTOR'S NAME Street Address City, State and ZIP Code CO-INVENTOR'S NAME Street Address City, State and ZIP Code ☐ Check if additional changes are on reverse side

Publishing Division
JUL 15 1996

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
08/227,553	04/14/94	058	SCHAETZLE, K 3305	06/17/95

First Named Applicant: CAMERON, DAVID

TITLE OF INVENTION: ELECTROTHERAPY METHOD AND APPARATUS

	ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
3	24108200620	607-005.000	B11	UTILITY	YES	$625.00	09/17/95

3. Correspondence address change (Complete only if there is a change)

James R. Shay
Heartstream, Inc.
2401 Fourth Avenue, Suite 300
Seattle Washington 98121

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

DO NOT USE THIS SPACE

820 TD 08-1515 07/24/96 08227553
82225 242 625.00CH
82226 561 30.00CH

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, Washington

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 PART C)
☒ Issue Fee ☒ Advance Order - # of Copies 10
☐ 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) Reg. No. 37448 (Date) 10JUL96

NOTE: The Issue Fee will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the Patent and Trademark Office.

TRANSMIT THIS FORM WITH FEE-CERTIFICATE OF MAILING ON REVERSE

6/28/96 3301 4101

#19 JT

PATENT
Heartstream Ref. 93-003-us2

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 onJuly 10, 1996

Cecily Anne Snyder, Reg. No. 37,448

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED
Publishing Division
JUL 15 1996

In the application of:

David Cameron

Serial No.: 08/227,553

Filing Date: 14 April 1994

For: **ELECTROTHERAPY METHOD AND APPARATUS**

Examiner: K. Schaetzle

Group Art Unit: 3305

BATCH NO. B11
NOTICE OF ALLOWANCE
6/17/96

DT

SUBMISSION OF FORMAL DRAWINGS

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

Dear Sir:

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

Dated: July 10, 1996

Respectfully submitted,

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

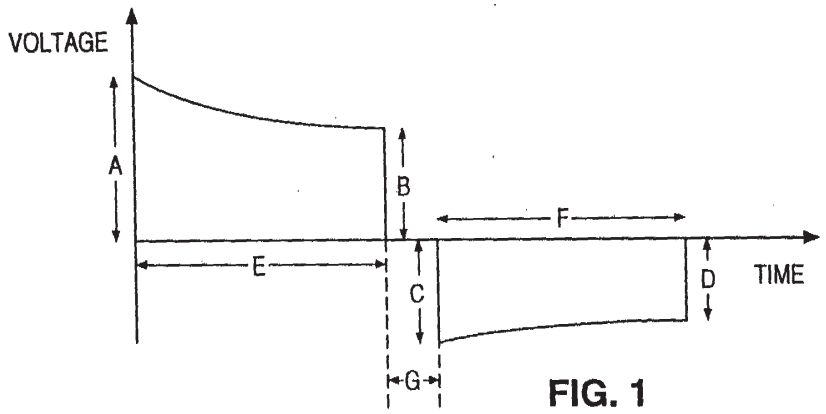


FIG. 1

APPROVED BY GRAFTSMAN
O.G. FIG. 6
CLASS 602
SUBCLASS 005

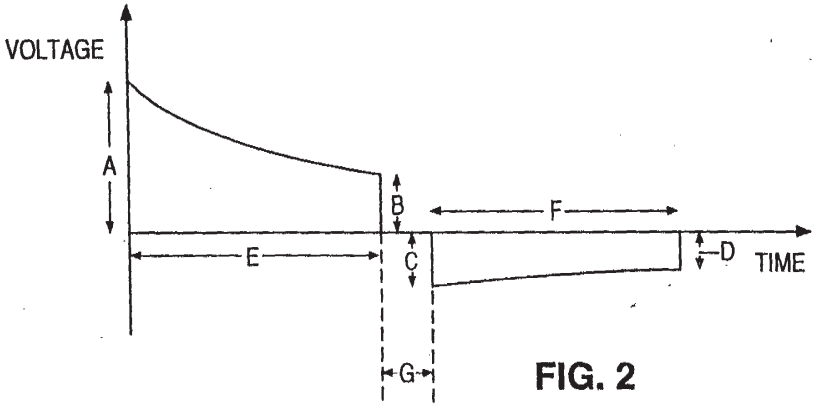


FIG. 2

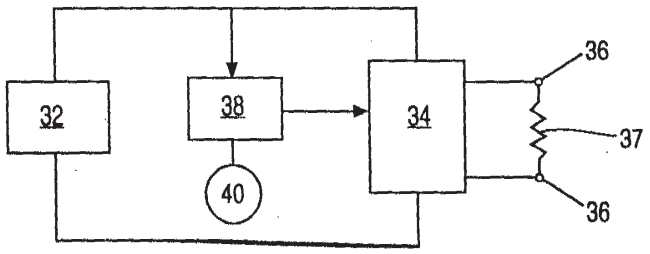


FIG. 3

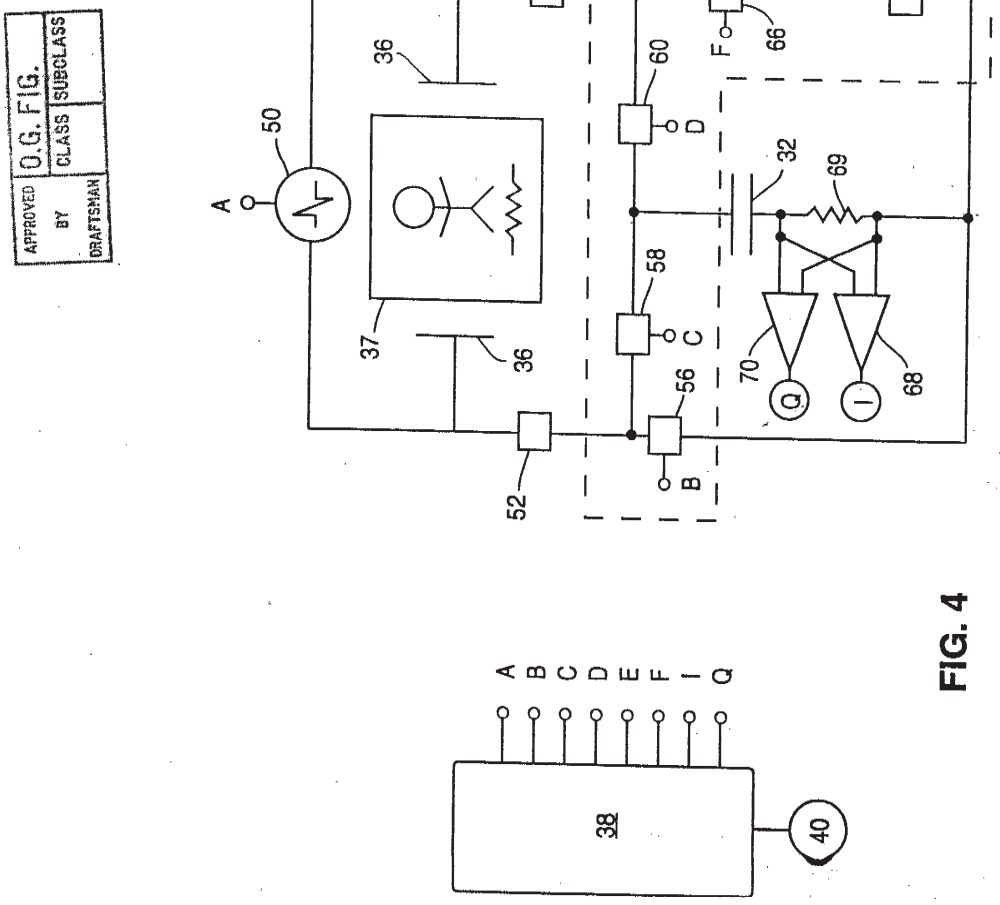


FIG. 4

APPROVED BY DRAFTSMAN | O.G. FIG. | CLASS | SUBCLASS

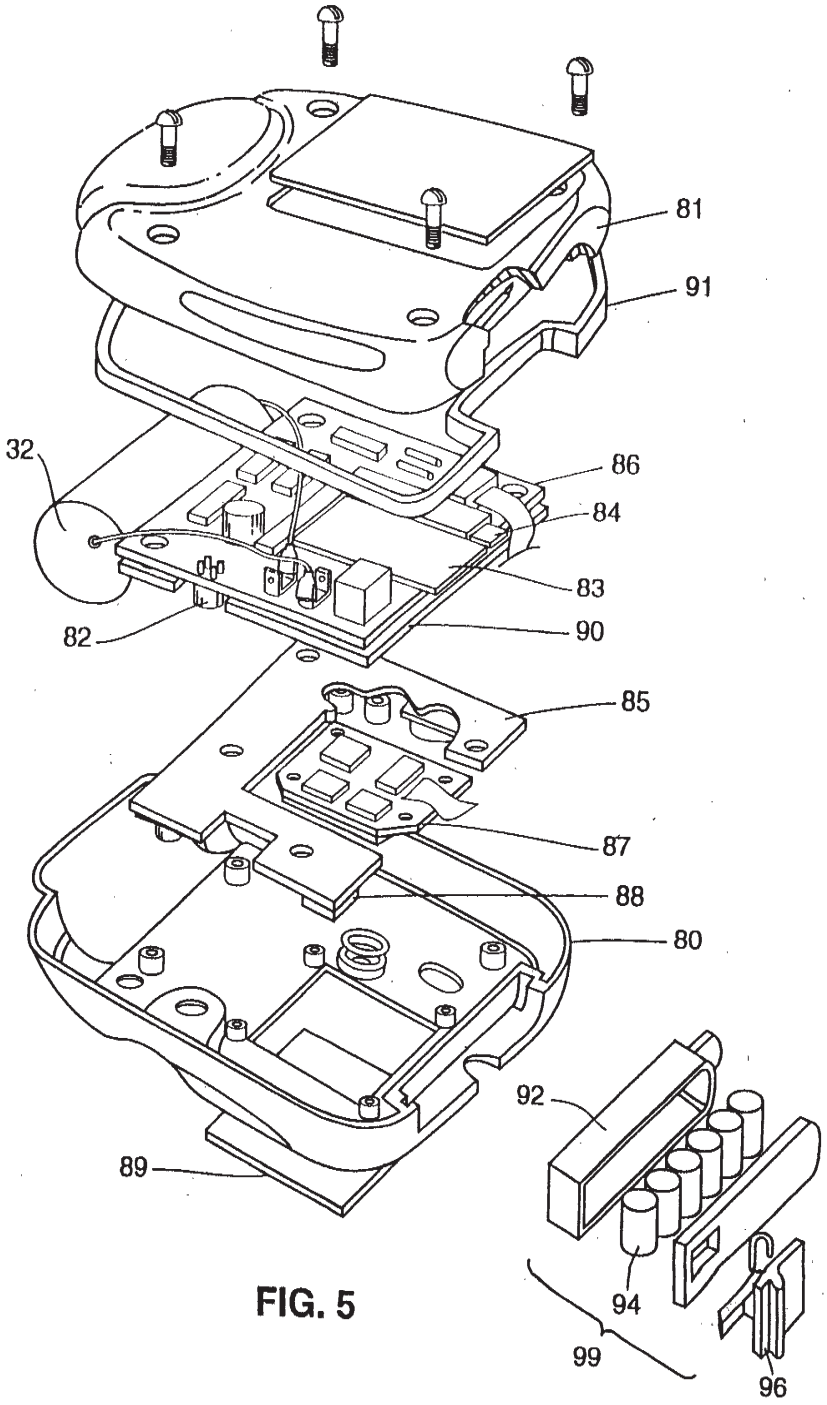


FIG. 5

APPROVED BY DRAFTSMAN | O.G. FIG. | CLASS | SUBCLASS

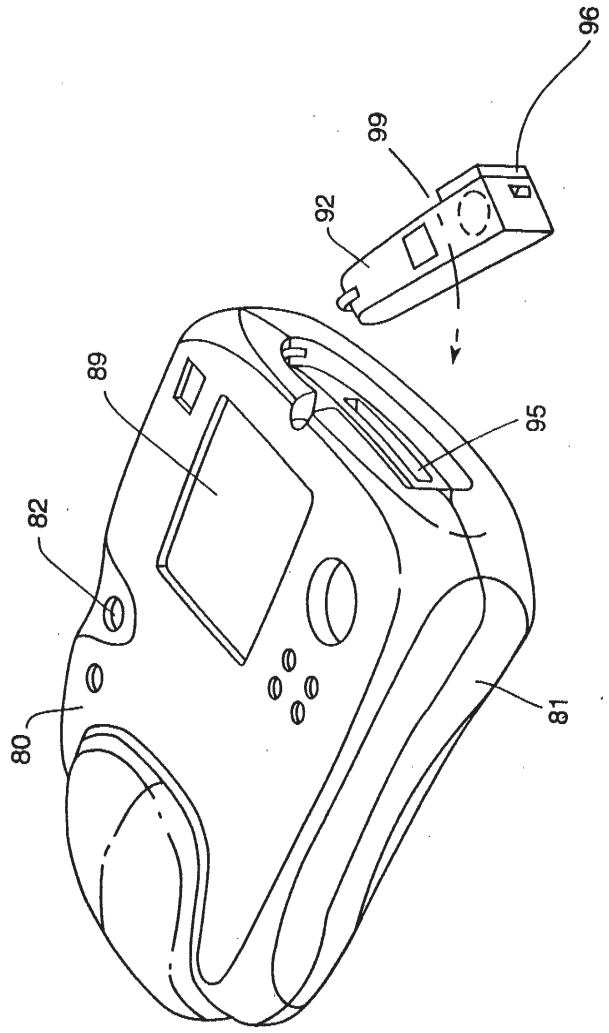


FIG. 6

APPROVED BY DRAFTSMAN
O.G. FIG. 6
CLASS 600
SUBCLASS 225

PATENT
Atty Dkt 241082000620
Heartstream Ref. 93-003-US2

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 28 JUN 96.

CECILY ANNE SNYDER
Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

20/D

11/15

In Re Application of:
DAVID CAMERON et al.

Serial No.:	08/227,553	Group Art Unit:	3305
Filing Date:	April 14, 1994	Examiner:	K. Schaetzle
Title:	Electrotherapy Method and Apparatus	**BATCH NO. B 11 NOTICE OF ALLOWANCE 6/17/96**	

AMENDMENT UNDER 37 C.F.R. § 1.312

Assistant Commissioner for Patents
BOX 312
Washington, DC 20231

Dear Sir:

Please amend this application by adding the following new claims:

58
~~68.~~ A method for applying electrotherapy to a patient through electrodes attached to an energy source, the method comprising the following steps:

D1

charging the energy source to an initial level prior to detecting a need to apply a shock to a patient;

determining the need to apply a shock to a patient;

charging the energy source to a second level greater than the initial level;

discharging the energy source across the electrodes to deliver electrical energy to the patient in a truncated exponential biphasic waveform.

59 58
~~69.~~ The method of claim ~~68~~ wherein the first charging step is performed in response to activation of a defibrillator. —

1

REMARKS

Applicants are filing this Amendment to replace two previously-allowed claims that were inadvertently canceled from this application. Specifically, new claim 68 is identical to canceled claim 33, and new claim 69 is identical to canceled claim 54. The Examiner had allowed claims 33 and 54 in the Office Action dated October 13, 1995.

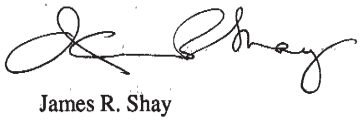
In the Amendment mailed May 6, 1996, Applicants had intended to cancel claim 53. Instead, Applicants canceled claim 33. The Examiner called Applicants' attorney on June 10, 1996, to suggest cancellation of claim 53, and Applicants' attorney agreed, since that was Applicants' intention all along. The Examiner also noted that claim 54 depended from canceled claim 33 and therefore suggested cancellation of claim 54 as well. Applicants' attorney recently discovered the typographical error, and the errors based on the original typographical error, after receiving the Notice of Allowance.

This Amendment is needed to give Applicants coverage for the subject matter to which claims 68 and 69 pertain. Since these claims have already been examined and allowed, entry of this Amendment will not require any additional search or examination.

Claim 68 is allowable for the reasons stated with respect to claim 33 in the Amendment dated June 23, 1995, and claim 69 is allowable for the reasons stated with respect to claim 54 in that Amendment. Applicants respectfully request entry of this Amendment and allowance of claims 68 and 69.

Applicants' attorney may be reached by telephone at (206) 441-5207. Applicants' attorney's mailing address is listed below.

Respectfully submitted,



James R. Shay
Reg. No. 32,062

Morrison & Foerster LLP
345 California Street
San Francisco, CA 94104
Fax: (415)677-7522

Response to Rule 312 Communication	Application No. 08/227,553	Applicant(s) Cameron et al.
	Examiner Ken Schaetzle	Group Art Unit 3305

☐ The petition filed on _____ under 37 CFR 1.312(b) is granted. The paper has been forwarded to the examiner for consideration on the merits.

☒ The amendment filed on *Jul 3, 1996* under 37 CFR 1.312 has been considered, and has been:

- ☒ entered.
- ☐ entered as directed to matters of form not affecting the scope of the invention (Order 3311).
- ☐ disapproved. See explanation below.
- ☐ entered in part. See explanation below.

MARVIN M. LATEEF
SUPERVISORY PATENT EXAMINER
GROUP 3300

11-12-96

PATENT
Heartstream Ref. 93-003-US2

5607454
3/04/97

Certificate of Mailing Under 37 C.F.R. § 1.10
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 and is addressed to: Assistant Commissioner for Patents, Washington, DC 20231 on 19 Feb 97 using Express Mail Label EM301 628 490 US

Cecily Anne Snyder, Reg. No. 37,448

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: David Cameron et al.

Serial No.: 08/227,553 Group Art Unit: 3305

Filing Date: 14 April 1994 Examiner: K. Schaetzle

Title: ELECTROTHERAPY METHOD AND APPARATYS

BATCH B11
NOTICE OF ALLOWANCE 6/17/96

PETITION TO WITHDRAW APPLICATION FROM ISSUE PURSUANT TO 37 C.F.R. § 1.313.(b)(5)

Assistant Commissioner for Patents
BOX 313(b)
Washington, DC 20231

Dear Sir:

Applicants hereby petition the Commissioner to withdraw the above-identified application from issue. The issue fee in this application was timely paid on July 10, 1996. The Office has assigned Patent No. 5,607,454 with an issue date of March 4, 1997 to this application.

Applicants respectfully petition that the above-identified application be withdrawn from issue and abandoned, in order to permit consideration of an Information Disclosure Statement under 37 C.F.R. § 1.97 in a continuation application being simultaneously filed herewith.

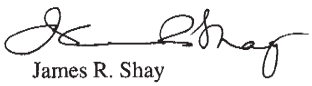
Applicant respectfully requests that this petition be granted and the above-referenced application be withdrawn from issue and abandoned pursuant to 37 C.F.R. § 1.313(b)(5) in favor of the continuation application.

PAYMENT OF FEES

The Assistant Commissioner is hereby authorized to charge the Petition fee of **$130.00** for consideration of this Petition to Deposit Account **08-1515.** Please also charge any additional fees under 37 C.F.R. § 1.17 that may be required by this communication, or to credit any overpayment, to **Deposit Account No. 08-1515.**

Dated: February 19, 1997

Respectfully submitted,



James R. Shay
Registration No. 32,062

Heartstream, Inc.
2401 Fourth Avenue, Suite 300
Seattle WA 98121.1436
Tele: 206.443.7630
Facsimile: 206.443.9694

DOCKET NUMBER	ANTICIPATED CLASSIFICATION OF THIS APPLICATION:		PRIOR APPLICATION:	
	CLASS	SUBCLASS	EXAMINER	ART UNIT
93003US2.1	**607**	**005.00**	**K. Schaetzle**	**3305**

HEARTSTREAM, INC.
2401 Fourth Avenue, Suite 300
Seattle, WA 98121.1436
Telephone: 206.443.7630
Facsimile: 204.443.9694

Certificate of Mailing Under 37 C.F.R. § 1.10

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 and is addressed to: Assistant Commissioner for Patents, Washington, DC 20231 on 19 Feb 97 using Express Mail Label EM 501628 498 US.

Cecily Anne Snyder, Reg. No. 37,448

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

REQUEST FOR FILING A CONTINUATIONAPPLICATION UNDER 37 C.F.R. § 1.62

Box 313(b)
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

This is a Request for filing a CONTINUATION application under 37 C.F.R. § 1.62 of prior application Serial No. 08/227,553, filed on 14 Apr 1994 entitled **ELECTROTHERAPY METHOD AND APPARATUS** by the following inventor:

	FULL NAME OF INVENTOR	FAMILY NAME **CAMERON**	FIRST GIVEN NAME David	SECOND GIVEN NAME
	RESIDENCE & CITIZENSHIP	CITY Seattle	STATE OR FOREIGN COUNTRY Washington	COUNTRY OF CITIZENSHIP USA
	POST OFFICE ADDRESS	POST OFFICE ADDRESS 1522 2nd Ave W	CITY Seattle	STATE & ZIP CODE/COUNTRY WA 98119

	FULL NAME OF INVENTOR	FAMILY NAME **LYSTER**	FIRST GIVEN NAME Thomas	SECOND GIVEN NAME D.
	RESIDENCE & CITIZENSHIP	CITY Seattle	STATE OR FOREIGN COUNTRY Washington	COUNTRY OF CITIZENSHIP USA
	POST OFFICE ADDRESS	POST OFFICE ADDRESS 23309 21st Ave SE	CITY Bothell	STATE & ZIP CODE/COUNTRY WA 98021
	FULL NAME OF INVENTOR	FAMILY NAME POWERS	FIRST GIVEN NAME Daniel	SECOND GIVEN NAME J.
	RESIDENCE & CITIZENSHIP	CITY Issaquah	STATE OR FOREIGN COUNTRY Washington	COUNTRY OF CITIZENSHIP USA
	POST OFFICE ADDRESS	POST OFFICE ADDRESS 2145 Squak Mountain Loop Drive	CITY Issaquah	STATE & ZIP CODE/COUNTRY WA 98027
	FULL NAME OF INVENTOR	FAMILY NAME GLYNER	FIRST GIVEN NAME Bradford	SECOND GIVEN NAME E.
	RESIDENCE & CITIZENSHIP	CITY Bellevue	STATE OR FOREIGN COUNTRY Washington	COUNTRY OF CITIZENSHIP USA
	POST OFFICE ADDRESS	POST OFFICE ADDRESS 3020-128th Ave. NE	CITY Bellevue	STATE & ZIP CODE/COUNTRY WA 98005
	FULL NAME OF INVENTOR	FAMILY NAME COLE	FIRST GIVEN NAME Clinton	SECOND GIVEN NAME S.
	RESIDENCE & CITIZENSHIP	CITY Issaquah	STATE OR FOREIGN COUNTRY Washington	COUNTRY OF CITIZENSHIP USA
	POST OFFICE ADDRESS	POST OFFICE ADDRESS 15435 263rd Ave SE	CITY Issaquah	STATE & ZIP CODE/COUNTRY WA 98027
	FULL NAME OF INVENTOR	FAMILY NAME MORGAN	FIRST GIVEN NAME Carlton	SECOND GIVEN NAME B.
	RESIDENCE & CITIZENSHIP	CITY Bainbridge Isl	STATE OR FOREIGN COUNTRY Washington	COUNTRY OF CITIZENSHIP USA
	POST OFFICE ADDRESS	POST OFFICE ADDRESS 4143 Palomino Dr. NE	CITY Bainbridge Isl	STATE & ZIP CODE/COUNTRY WA

The above-identified prior application in which no payment of the issue fee, abandonment of, or termination of proceedings has occurred, is hereby expressly abandoned under 37 C.F.R. § 1.62(g) as of the filing date of this new application. Please use all the contents of the prior application file wrapper, including the drawings, as the basic papers for the new application (No new specification is required, 37 C.F.R. § 1.62(e)).

☐ Enter the unentered amendment previously filed on under 37 C.F.R. § 1.116 in the prior application.

☐ A preliminary amendment is enclosed.

☐ This application is being filed by less than all the inventors named in the application. The Assistant Commissioner is requested under 37 C.F.R. § 1.62(a) to delete the names of the

following person or persons from the prior application who are not inventors of the invention being claimed in this application:

☒ The filing fee is calculated on the basis of the claims existing in the prior application as amended above.

FOR	NUMBER FILED	NUMBER EXTRA	RATE	CALCULATIONS
TOTAL CLAIMS	**59** - 20 =	39	x $22	$858
INDEPENDENT CLAIMS	**10** - 3 =	7	x $80	$560
MULTIPLE DEPENDENT CLAIM(S) (if applicable) (37 C.F.R. § 1.16(d))			+ $260	$0
			BASIC FEE	$770
		TOTAL OF ABOVE CALCULATIONS =		$2188
Reduction by 1/2 for filing by small entity (Note 37 C.F.R. §§ 1.9, 1.27, 1.28).				$1094
			TOTAL =	$1094

☒ ***Verified statement to establish small entity status under 37 C.F.R. §§ 1.9 and 1.27:***

☐ is enclosed.

☒ ***dated May 20, 1994 was filed in the prior application serial no 08/227,553 on May 26, 1994 and such status is still proper and desired (37 C.F.R. § 1.28 (a)).***

☐ A check in the amount of $_____ is enclosed.

☒ The Assistant Commissioner is hereby authorized to charge **$1094.00** to **Deposit Account No. 08-1515**. A duplicate copy of this request is enclosed for that purpose.

☒ The Assistant Commissioner is hereby authorized to charge any additional fees under 37 C.F.R. §§ 1.16 and 1.17 that may be required, or credit any overpayment to **Deposit Account No. 08-1515**. A duplicate copy of this request is enclosed for that purpose.

☐ A new oath or declaration in compliance with 37 C.F.R. § 1.63 is included since this application is a continuation-in-part which discloses and claims additional matter.

☒ Amend the specification at page 1, the beginning of line 4, after "This application" by inserting :

—is a CONTINUATION of application Serial No. 08/227,553, filed 14 Apr 1994, now abandoned; which —

☐ Priority of foreign application Serial No. _____, filed on _____ in _____ is claimed under 35 U.S.C. § 119(a) through (d).

☐ The certified copy of the priority application is enclosed.

☐ The certified copy of the priority application was 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. (Reel/Frame 7009/0318).

☒ The power of attorney in the prior application is to:

James R. Shay, Registration No. 32,062
Cecily Anne Snyder, Registration No. 37,448

☐ Recognize as Associate Attorney(s):

☒ Address all future communications (may only be completed by applicant, or attorney or agent of record) to:

James R. Shay

at the address for **Customer No. 020067**

☒ Also enclosed: Postcard; Information Disclosure Statement

It is understood that secrecy under 35 U.S.C. § 122 is hereby waived to the extent that if information or access is available to any one of the applications in the file wrapper of a 37 C.F.R. § 1.62 application, be it either this application or a prior application in the same file wrapper, the Patent and Trademark Office may provide similar information or access to all the other applications in the same file wrapper.

Dated: 2/19/97

Respectfully submitted,

By: _____
James R. Shay
Reg. No. 32,062

Address of signator:

☐ Inventor
☐ Assignee of complete interest
☒ Attorney or Agent of record
☐ Filed under 37 C.F.R. § 1.34(a)
(no associate Power of Attorney given)

PATENT
Heartstream Ref. 93-003-US2.1

Certificate of Mailing Under 37 C.F.R. § 1.10
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 and is addressed to: Assistant Commissioner for Patents, Washington, DC 20231 on 19Febr97 using Express Mail Label EM 501 028 498 US

Cecily Anne Snyder, Reg. No. 37,448

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

David Cameron et al.

Serial No.: *to be assigned* Group Art Unit: 3305

Filing Date: 19 Feb 1997 Examiner: K. Schaetzle

Title: ELECTROTHERAPY METHOD AND APPARATUS

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

BOX 313(b)
Assistant Commissioner for Patents
Washington, DC 20231

Dear Sir:

The information listed below is submitted in conjunction with the examination of the above-identified application. Copies of the information and completed PTO-1449 forms are submitted herewith. The Examiner is respectfully requested to make this information of official record in the application. The information includes:

Patent No.	Author	Issued	Filed
US 5,431,686	Kroll et al.	07/1995	2/18/92
US 5,413,591	Kroll	05/1995	7/22/93

This information is in addition, to the information previously disclosed in the Information Disclosure Statements filed in the parent application 08/227,553, for which this application is a File Wrapper.

This Information Disclosure Statement is submitted within three months of filing the application. Therefore, the applicants believe that no fee is due. However, the

Assistant Commissioner is hereby authorized to charge any fees which may be required by this paper to **Deposit Account 08-1515**.

Applicants would appreciate the Examiner's initialling and returning the Form PTO-1449, indicating that the references have indeed 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 a complete search has been made, additional information material to the examination of this application does not exist, the information, protocols, results and the like reported by third parties are accurate or enabling, or that the above information constitutes prior art to the subject invention.

Dated: February 18, 1997

Respectfully submitted,

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

Heartstream, Inc.
2401 Fourth Avenue, Suite 300
Seattle Washington 98121
Telephone: 206.441.5207
Facsimile: 206.443.9694

PTO UTILITY GRANT

Paper Number 23

The United States of America

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.

Bruce Lehman

Commissioner of Patents and Trademarks

Marcie V. Turner

Attest

Form PTO-1584 (Rev. 5/96)

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/227,553	04/14/94	CAMERON	D 2410820006

33M1/1119

JAMES R. SHAY
MORRISON & FOERSTER
755 PAGE MILL ROAD
PALO ALTO CA 94304-1018

EXAMINER	
SCHAETZLE,K	
ART UNIT	PAPER NUMBER
3305	24

DATE MAILED: 11/19/96

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Supplemental

Notice of Allowability

Application No.	Applicant(s)
08/227,553	Cameron et al.
Examiner	**Group Art Unit**
Ken Schaetzle	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 entry of the 312 Amendment received July 3, 1996*.

☒ The allowed claim(s) is/are *1-12, 17-25, 28-30, 32, 34-52, and 55-69*.

☒ The drawings filed on *Jul 17, 1996* 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. _____.

☐ 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 lettter 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). _____

☐ 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

Marvin M. Lateef

MARVIN M. LATEEF
SUPERVISORY PATENT EXAMINER
GROUP 3300

KS

11-12-96

MAIL ROOM MAY 14 1997 PATENT & TRADEMARK OFFICE

PATENT
Heartstream Ref. 93-003-US2

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 22 May 97.

Cecily Anne Snyder, Reg. No. 37,448

#24
1/23

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

David Cameron et al.

Serial No.: 08/227,553
Group Art Unit: 3305

Filing Date: 14 Apr 1994
Examiner: K. Schaetzle

Patent No.: 5,607,454

Issue Date: 4 Mar 1997

Title: **ELECTROTHERAPY METHOD AND APPARATUS**

MAY 27 1997 PATENT & TRADEMARK OFFICE

RECEIVED
JUN 10 1997
GROUP 3300

WITHDRAWAL OF PETITION

Assistant Commissioner for Patents
Washington, DC 20231

Dear Sir:

Applicants filed a Petition to Withdraw the underlying application from issue on February 19, 1997. The application issued into U.S. Patent 5,607,454 on March 4, 1997. Accordingly, Applicants' February 19, 1997 petition is moot. Applicants therefore request that the Petition to Withdraw the application from issue be withdrawn.

Dated: 22 May 97

Respectfully submitted,

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

Direct Dial 206.441.5188

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

OIPE JC58 JUL 13 1998 PATENT & TRADEMARK OFFICE

PATENT
Attorney's Ref. No. 90980062-1 DSD

RECEIVED
1998 JUL 16 AM 3:47
DSD/PTCS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: David Cameron, et al.
Serial No.: 08/227,553
Filing Date: 14 Apr 1994
Group Art Unit: 3305
Examiner: K. Schaetzle
Title: ELECTROTHERAPY METHOD AND APPARATUS
Patent No.: 5,607,454
Issued: 4 Mar 1997

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: 7/7/98

Typed Name: Michelle Ogland

Signature: Michelle Ogland

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 filed on 26 May 1994, is hereby withdrawn.

Date: July 7, 1998

Heartstream, Inc.
c/o Hewlett-Packard Company
IP Administration
Legal Department, 20BN
PO Box 10301
Palo Alto, CA 94303-0890

Douglas J. Barker
Douglas J Barker
Practitioner of record
Reg. No.: 40,423
Telephone No.: 360/212-8369
Customer No.: 020067

EXPEDITE NOTICE RE: CERTIFICATES OF CORRECTION EXPEDITE

DATE : 9.29.97

TO : Supervisor, Art Unit 3305

SUBJECT: Certificate of Correction Request in Patent No. 5,607,454

A response to the following question(s) is requested with respect to the accompanying request for a certificate of correction.

☐ 1. Would the change(s) requested under 37 CFR 1.323 constitute new matter or require reexamination of the application?

☐ 2. Would the change(s) requested under 37 CFR 1.323 Materially affect the scope or meaning of the claims allowed by the examiner in the patent?

☐ 3. Applicant disagrees with change(s) initialed and dated by Examiner in lieu of an Examiner's Amendment. Should the change request be granted?

☒ 4. With respect to the change(s) requested, correcting Office errors, should the patent read as shown in the certificate of correction? Should U.S. Documents be approved? (Comment)

☐ 5. If the amendment filed _____ had been considered by the Examiner, would the amendment have been entered?

PLEASE RESPOND WITHIN 7 DAYS AND RETURN THE FILE TO ROOM 918, PK III

Linda Watson

Legal Instrument Examiner

Return to

EXPEDITE EXPEDITE EXPEDITE

TO: CERTIFICATE OF CORRECTION BRANCH DATE: 10/10/97

The decision regarding the change(s) requested in the certificate of correction is shown below.

☐ 1.YES	☐ NO	☐ Comments below
☐ 2.YES	☐ NO	☐ Comments below
☐ 3.YES	☐ NO	☐ Comments below
☒ 4.YES	☐ NO	☐ Comments below
☐ 5.YES	☐ NO	☐ Comments below

☐ Comments _____

K. Schaetzle — Supervisor

3305 — Art Unit

PTOL-306 (REV. 10/87) U.S. DEPARTMENT OF COMMERCE Patent and Trademark Office

PATENT APPLICATION FEE DETERMINATION RECORD

Effective October 1, 1992

Application or Docket Number: 227553

CLAIMS AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE	SMALL ENTITY FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY FEE
BASIC FEE				$355.00	OR		$710.00
TOTAL CLAIMS	34 minus 20 =	* 14	x$11=	154	OR	x$22=	308
INDEPENDENT CLAIMS	10 minus 3 =	* 7	x 37=	259	OR	x 74=	518
MULTIPLE DEPENDENT CLAIM PRESENT			+115=		OR	+230=	
			TOTAL	768	OR	TOTAL	1536

* If the difference in column 1 is less then zero, enter "0" in column 2

CLAIMS AS AMENDED - PART II

A

AMENDMENT A		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE	SMALL ENTITY ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY ADDITIONAL FEE
	Total	* 58	Minus	** 34	= 24	x$11=	264	OR	x$22=	
	Independent	* 12	Minus	*** 10	= 2	~~x 37=~~ 38	76	OR	x 74=	
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM					+ 115=		OR	+230=	
						TOTAL ADDIT. FEE	Pd.	OR	TOTAL ADDIT. FEE	

B

AMENDMENT B		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE	ADDITIONAL FEE	OR	RATE	ADDITIONAL FEE
	Total	* 61	Minus	** 58	= 3	x$11=	33	OR	x$22=	
	Independent	* 12	Minus	*** 12	= 0	x 37=	0	OR	x 74=	
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM					+ 115=		OR	+ 230=	
						TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

C

AMENDMENT C		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE	ADDITIONAL FEE	OR	RATE	ADDITIONAL FEE
	Total	* 59	Minus	** 61	= 0	x$11=		OR	x$22=	
	Independent	* 9	Minus	*** 12	= 0	x 37=		OR	x 74=	
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM					+115=		OR	+230=	
						TOTAL ADDIT. FEE		OR	TOTAL 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.

FORM PTO-875
(Rev.10-92)

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

PTO 1130 U.S. DEPARTMENT OF COMMERCE- PATENT & TRADEMARK OFFICE

(REV 11/91) PACE DATA ENTRY CODING SHEET

1ST EXAMINER B. Douglas DATE 5/6/94

2ND EXAMINER Jay DATE 8-15-94

APPLICATION NUMBER	TYPE APPL	FILING DATE MONTH	DAY	YEAR	SPECIAL HANDLING	GROUP ART UNIT	CLASS	SHEETS OF DRAWING
08/227553	1	04	14	94	0	3305	607	4

TOTAL CLAIMS	INDEPENDENT CLAIMS	SMALL ENTITY?	FILING FEE	FOREIGN LICENSE	ATTORNEY DOCKET NUMBER
34	10	~~0~~	833	Y	24108200062ϕ

CONTINUITY DATA

CONTINUITY CODE	STATUS CODE	PARENT APPPLICATION SERIAL NUMBER	PARENT PATENT NUMBER	PARENT FILING DATE MONTH	DAY	YEAR
03	2	08103837		08	06	93
		0				
		0				
		0				
		0				

PCT/FOREIGN APPLICATION DATA

FOREIGN PRIORITY CLAIMED	COUNTRY CODE	PCT/FOREIGN APPLICATION SERIAL NUMBER	FOREIGN FILING DATE MONTH	DAY	YEAR