US005352239A

United States Patent [19]

Pless

[11] Patent Number: 5,352,239

[45] Date of Patent: Oct. 4, 1994

[54] APPARATUS FOR PRODUCING CONFIGURABLE BIPHASTIC DEFIBRILLATION WAVEFORMS

[75] Inventor: **Benjamin Pless**, Menlo Park, Calif.

[73] Assignee: **Ventritex, Inc.**, Sunnyvale, Calif.

[21] Appl. No.: **37,482**

[22] Filed: **Mar. 24, 1993**

Related U.S. Application Data

[63] Continuation of Ser. No. 629,252, Dec. 18, 1990, abandoned.

[51] Int. Cl.^{5} A61N 1/39
[52] U.S. Cl. 607/5
[58] Field of Search 607/5

[56] **References Cited**

U.S. PATENT DOCUMENTS

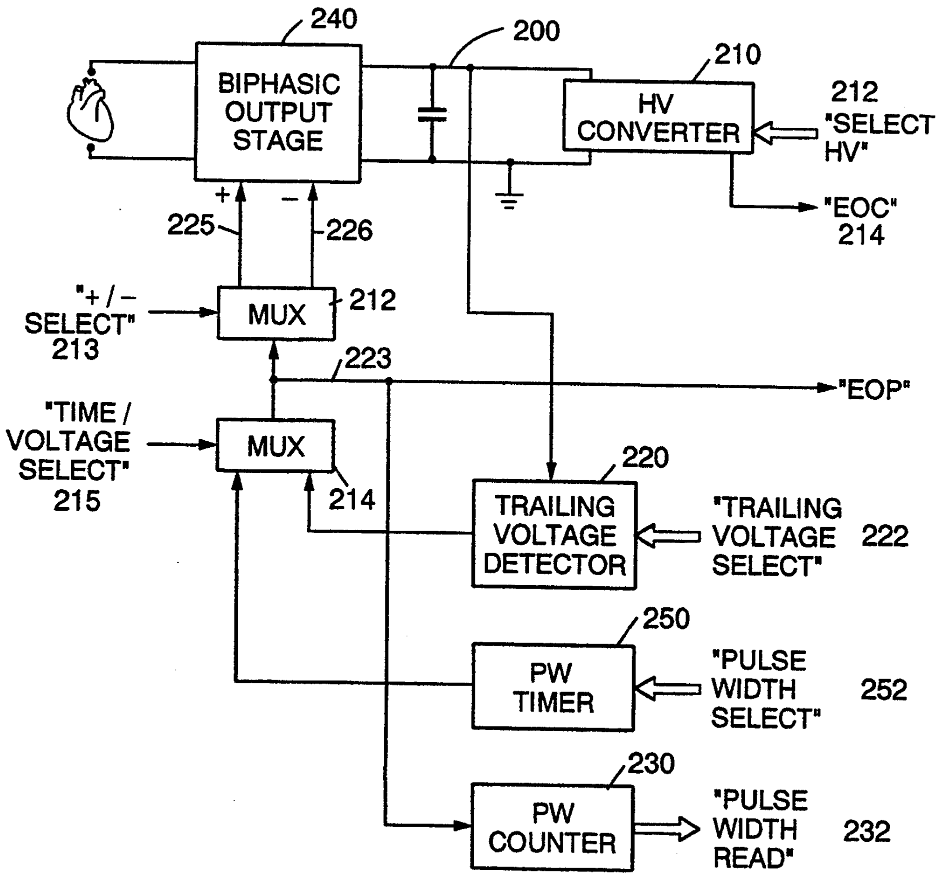
4,708,145 11/1987 Tacker, Jr. et al. .... 128/419 D
4,996,984 3/1991 Sweeney .... 128/419 D

Primary Examiner—William E. Kamm
Assistant Examiner—Scott M. Getzow
Attorney, Agent, or Firm—Steven M. Mitchell; Mark J. Meltzer

[57] **ABSTRACT**

A programmable implantable medical device utilizable for delivering a configurable defibrillation waveform to a heart. The device includes defibrillation electrode means adapted to be connected to the heart for delivering a multiphasic defibrillation waveform thereto. A programmable waveform generator connected to the heart generates the multiphasic waveform such that at least one phase of the defibrillation waveform has programmed constant tilt.

2 Claims, 3 Drawing Sheets



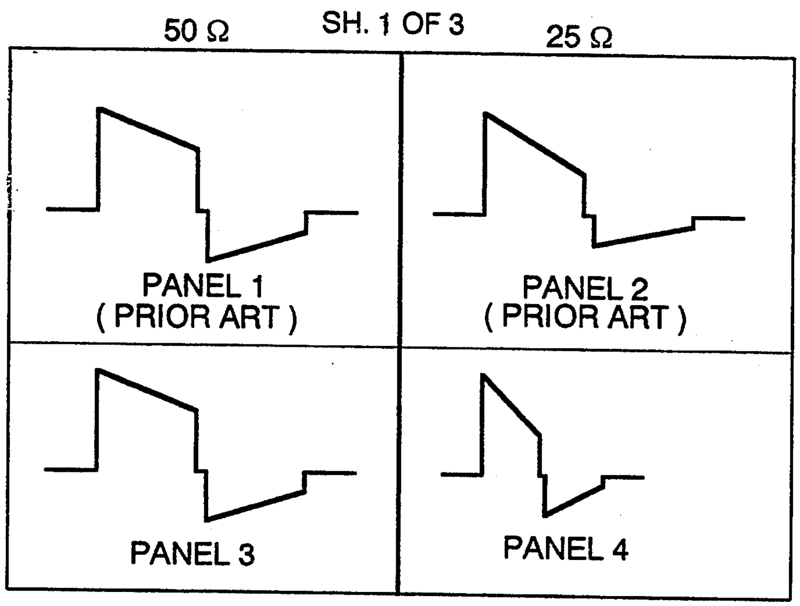

50 Ω
SH. 1 OF 3
25 Ω
PANEL 1
(PRIOR ART)
PANEL 2
(PRIOR ART)
PANEL 3
PANEL 4

FIG. 1

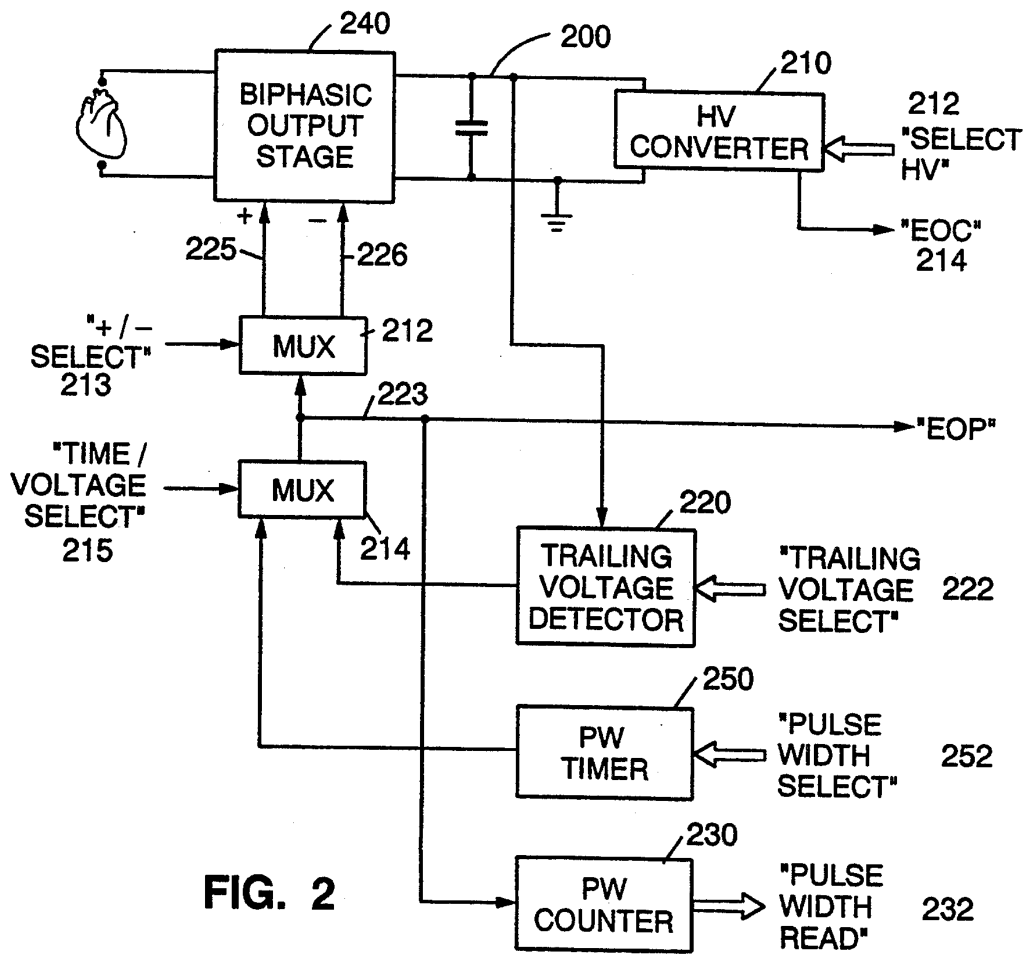

240
200
210
BIPHASIC OUTPUT STAGE
HV CONVERTER
212
"SELECT HV"
"EOC"
214
+
−
225
226
"+ / − SELECT"
213
MUX
212
223
"EOP"
"TIME / VOLTAGE SELECT"
215
MUX
214
220
TRAILING VOLTAGE DETECTOR
"TRAILING VOLTAGE SELECT"
222
250
PW TIMER
"PULSE WIDTH SELECT"
252
230
PW COUNTER
"PULSE WIDTH READ"
232

FIG. 2

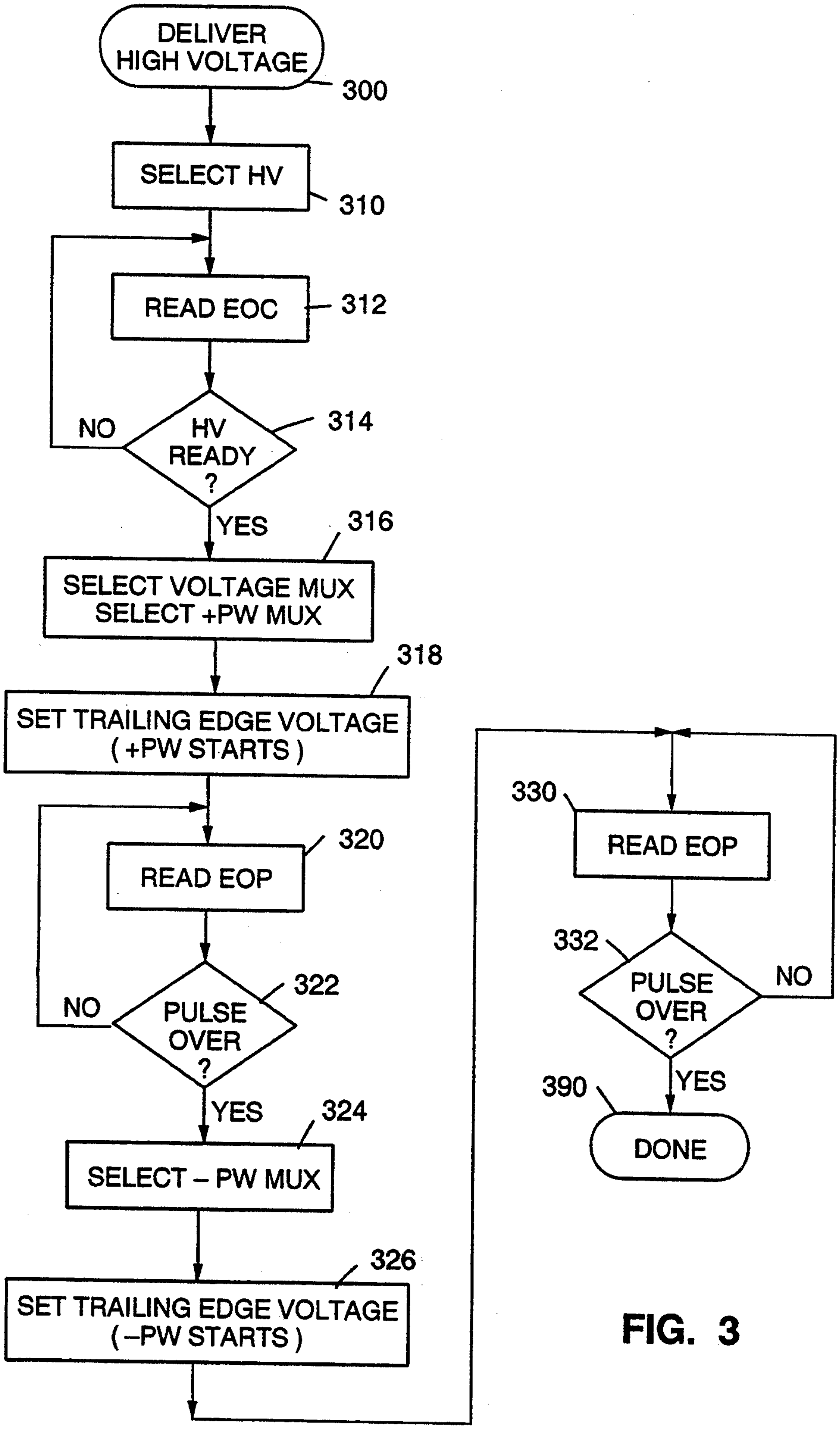

DELIVER HIGH VOLTAGE
300
SELECT HV
310
READ EOC
312
HV READY ?
314
NO
YES
316
SELECT VOLTAGE MUX
SELECT +PW MUX
318
SET TRAILING EDGE VOLTAGE
(+PW STARTS)
320
READ EOP
PULSE OVER ?
322
NO
YES
324
SELECT – PW MUX
326
SET TRAILING EDGE VOLTAGE
(–PW STARTS)
330
READ EOP
332
PULSE OVER ?
NO
YES
390
DONE

FIG. 3

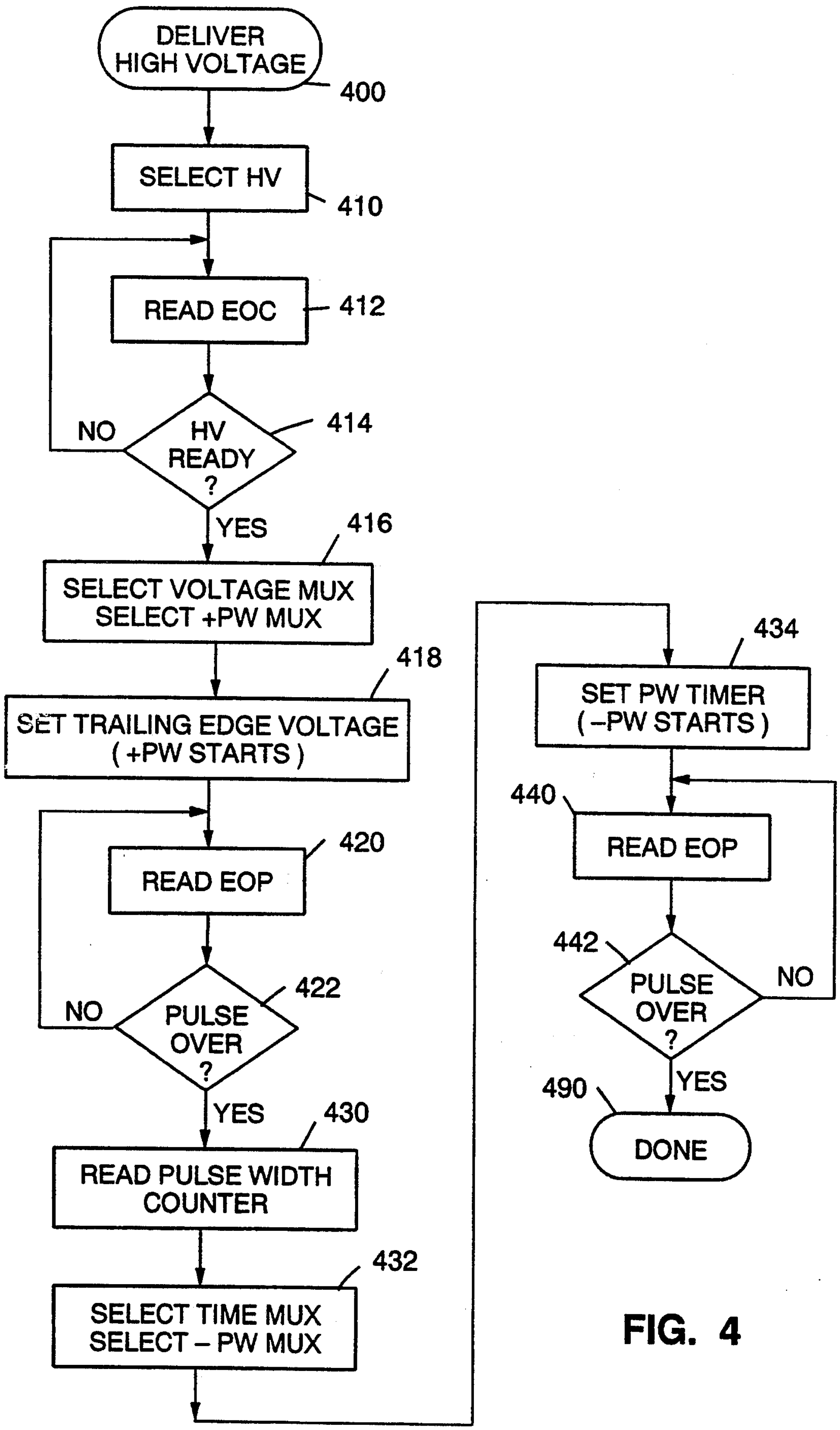

DELIVER HIGH VOLTAGE
400
SELECT HV
410
READ EOC
412
HV READY ?
414
NO
YES
416
SELECT VOLTAGE MUX
SELECT +PW MUX
418
SET TRAILING EDGE VOLTAGE
(+PW STARTS)
420
READ EOP
PULSE OVER ?
422
NO
YES
430
READ PULSE WIDTH COUNTER
432
SELECT TIME MUX
SELECT – PW MUX
434
SET PW TIMER
(–PW STARTS)
440
READ EOP
442
PULSE OVER ?
NO
YES
490
DONE

FIG. 4

APPARATUS FOR PRODUCING CONFIGURABLE BIPHASTIC DEFIBRILLATION WAVEFORMS

This is a continuation of application Ser. No. 07/629,252, filed on Dec. 18, 1990, now abandoned.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to implantable medical devices and, in particular, to a programmable defibrillator capable of delivering a configurable biphasic waveform.

2. Discussion of the Prior Art

Implantable defibrillators use truncated exponential waveforms to defibrillate the heart. The earliest devices used monophasic waveforms. More recent clinical investigations have evaluated the increased effectiveness of biphasic waveforms. See Troup, Implantable Cardioverters and Defibrillators, Current Problems in Cardiology, Volume XIV, Number 12, December 1989, pages 729–744. Some investigators have even recommended the use of triphasic waveforms as the most effective waveform for defibrillating a heart. See U.S. Pat. No. 4,637,397 issued to Jones and Jones on Jan. 20, 1987.

As described by Troup, monophasic waveforms are typically produced using silicon controlled rectifier (SCR) technology that truncates the pulse by "dumping" the energy on the defibrillator capacitor. This leaves no energy available on the capacitor for producing multiphasic waveforms.

As further described by Troup, there have been two methods available for truncation of a monophasic defibrillation waveform. According to one method, pulse truncation is accomplished by comparing the capacitor voltage to a reference voltage which is usually chosen as a function of the waveform leading edge voltage. The result is a defibrillation pulse with a constant ratio of trailing edge to leading edge voltage, or a "constant tilt" pulse.

Defibrillation pulse "tilt", described as percent tilt, is defined as follows:

$$\%\ Tilt = 100[1-(V_f/V_i)]_1$$

where V_f is the trailing edge voltage of the pulse and V_i is the leading edge voltage.

According to the second method, the defibrillation pulse is truncated by a timing circuit so that the pulse duration is constant.

Biphasic waveform generators have used MOS switches to produce the defibrillator output. The MOS switch technique is better suited to multiphasic waveforms since the defibrillator capacitor does not need to be "dumped" to truncate the pulse.

Prior art biphasic waveforms have been programmable in terms of pulse duration. The disadvantage of programming biphasic waveforms in terms of duration can be seen in FIG. 1. Panel 1 of FIG. 1 shows a conventional biphasic waveform with a 50 ohm load. Panel 2 shows a conventional biphasic waveform with the same duration of phases with a 25 ohm load. With a 50 ohm load, there is adequate residual voltage to produce an effective negative phase of the biphasic waveform. However, at the same pulse durations, with a 25 ohm load, the voltage during the positive phase has decayed to the point where very little is left for the negative phase.

While it is possible to select optimal pulse durations for a given patient impedance, the patient impedance may change. In particular, for higher defibrillation voltages, the patient impedance is lower. In addition, over time, the lead impedance may increase due to the build-up of scar tissue.

Due to their small size and battery operation, implantable defibrillators have limited output energy capability. It is not unusual for an implantable defibrillator to have only slightly more output capability than is required to defibrillate a patient. This lack of safety margin makes it all the more important that the output energy that is available is used in the most effective manner. While biphasic waveforms are a step in the right direction, the optimal settings for the positive and negative phase durations have not been addressed in the prior art.

U.S. Pat. No. 4,850,357 issued to Stanley M. Bach, Jr. on Jul. 25, 1989, discloses a circuit for generating a biphasic defibrillation waveform wherein both the positive and negative phases have constant tilt. However, the Bach, Jr. defibrillator generates a biphasic waveform having fixed characteristics. That is, only a single type of waveform can be delivered that has a first positive pulse having a specified constant tilt and a second negative pulse also having a specified constant tilt. Thus, the Back defibrillator circuit provides none of the therapeutic flexibility that is desirable in restoring rhythm to a fibrillating heart.

SUMMARY OF THE INVENTION

The present invention provides a microprocessor controlled output stage that allows for greater flexibility than has been available in defining a biphasic defibrillation waveform. In accordance with the invention, the biphasic waveform generator may be programmed to provide either positive and negative phases having selected constant tilt or a positive phase having a selected constant tilt and a negative phase having a duration that is related to the duration of the positive phase. The disclosed apparatus can also produce conventional multiphasic waveforms, if desired.

A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description and accompanying drawings which set forth an illustrative embodiment in which the principles of the invention are utilized.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 provides a comparison between prior art biphasic waveforms and configurable biphasic waveforms generated in accordance with the present invention.

FIG. 2 is a block diagram illustrating an embodiment of an apparatus for generating a configurable, biphasic waveform in accordance with the present invention.

FIG. 3 is a flow chart of a method for producing a biphasic waveform having selected constant positive and negative tilts.

FIG. 4 is a flow chart of a method for producing a biphasic waveform with a selected constant tilt positive phase and a negative phase the duration of which is related to the duration of the measured positive phase duration.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.

WHAT WILL YOU BUILD? | **sales@docketalarm.com** | **1-866-77-FASTCASE**

fastcase®
Smarter legal research.